The neutral zone for mandibular complete dentures: a clinical trial

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DECLARATION

I declare that *The neutral zone for mandibular complete dentures: a clinical trial* is my own work, that it has not been submitted for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged by complete references.

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ABSTRACT

Rehabilitation of edentulous jaws without the option of osseointegrating implants will remain the only treatment option within reach of many older patients for the foreseeable future. Many routine prosthodontic procedures are based on dogmas, because no high-level scientific evidence exists to either accept or reject them, among these is the "neutral zone" (NZ) concept. In spite of paucity of evidence using approved patient-based outcome instruments, it is generally agreed that the NZ should be respected when constructing complete dentures.

The purpose of this research project was to determine how shapes of conventional and NZ mandibular dentures differ, and if the two different types of dentures impact differently on oral health–related quality of life by using an accepted oral health-related quality of life instrument as a patient-based outcome.

Thirty nine edentulous patients were selected for his prospective, randomised, cross-over, single-blinded clinical trial. Two sets of complete dentures were made for each patient. One denture set was made following conventional biometric guidelines for determining the position of the mandibular posterior denture teeth in relation to the ridge; another set was made following a functional impression of the potential denture space. Each set of dentures was worn for at least two months. A similar number of types of dentures were delivered first. Widths of residual ridges and mandibular denture arches were measured using digital measuring software. Position of denture teeth was related to the ridge. Denture dimensions were compared by means of analysis of variance using the mixed procedure. Using formula of parabola, arch-widths were compared using paired *t*-tests. Pre- and post-treatment patient feedback was obtained by means of the 20-item Oral Health Impact Profile (OHIP-20) and a preference score. Treatment effect size (ES) was established based on the OHIP-20 scores. Relevant associations among denture dimensions, OHIP-20 scores, preference, age, gender, marital status, education, income, period of edentulousness, and quality of denture-bearing tissue were done using the generalised linear model and correlation analysis. For all statistical analysis, level of significance was determined at $p<0.05$.

The mean age of the sample was 62.3 years. Twenty four patients were female. Mean period of edentulousness was 31 years and mean number of denture sets worn prior to the trial was 2.5. Except for the canine region, NZ dentures were statistically wider than anatomic dentures. The difference in mean widths between the two types of dentures was larger for female patients. Older patients had smaller differences in denture dimensions. More unfavourable denture-bearing tissue was associated with a larger difference in the two types of dentures. Both types of mandibular dentures significantly improved the OHRQoL of patients. Both types of dentures had a high treatment ES. The OHIP-20 instrument could not distinguish a statistical difference in impact on OHRQoL between the two treatment options. There was a minute difference in treatment ES between the two types of treatment. The only domain representing a small clinical benefit between NZ and anatomic dentures was "physical pain", with the NZ dentures scoring better. There was no correlation between pre- and post-treatment scores for both types of dentures. No significant associations were found between post-treatment OHIP-20 scores on the one hand and tissue scores, gender, age, education, marital status, period of edentulousness and denture dimension differences on the other hand. Based on OHIP-20 scores, there was a significant association between denture preference and NZ dentures, but not for the other preferences. No significant associations were found between denture preferences on the one hand and tissue scores, gender, age, period of edentulousness and denture dimension differences on the other hand. Even though no significant relationship was found between preference and gender, the majority of female patients preferred the NZ denture and the majority of male patients did not express a preference.

Providing new complete dentures improved OHRQoL of edentulous patients. The majority of female patients preferred the NZ compared over the ANA denture. The NZ technique appeared to have a higher positive impact on OHRQoL of female patients compared to male patients.

KEYWORDS

Edentulousness

Mandibular denture

Neutral zone

Oral health-related quality of life

Denture preference

Cross-over trial

DEFINITIONS AND ABBREVIATIONS

Anatomic - ANA

Denture stability: The quality of a removable dental prosthesis to be firm, steady, or constant, to resist displacement by functional horizontal or rotational stresses. Resistance to horizontal displacement of a prosthesis (The Glossary of Prosthodontic Terms, 2005).

Denture retention: That quality inherent in the dental prosthesis acting to resist the forces of dislodgment along the path of placement (The Glossary of Prosthodontic Terms, 2005).

Disability: Being prevented from partaking in everyday activities such as chewing and speaking (WHO, 1980).

Edentulousness: The state of being edentulous; without natural teeth (The Glossary of Prosthodontic Terms, 2005).

Effect size – ES: A means of recognizing change that may be clinically meaningful (Allen *et al*., 2009).

Health-related quality of life – HRQoL: General health-related quality of life and oral health related quality of life refer to an individual's subjective assessment of general and oral health and functional and emotional well-being (Sischo & Broder, 2011).

Interalveolar distance - IAD

Neutral zone – NZ: The potential space between the lips and cheeks on one side and the tongue on the other; that area or position where the forces between the tongue and cheeks or lips are equal" (The Glossary of Prosthodontic Terms, 2005).

Oral health: Oral health is a state of being free from chronic mouth and facial pain, oral and throat cancer, oral sores, birth defects such as cleft lip and palate, periodontal (gum) disease, tooth decay and tooth loss, and other diseases and disorders that affect the oral cavity (WHO, www.who.oralhealth/ accessed 6 September 2014).

Oral health-related quality of life – OHRQoL: Considered to be a subset of HRQoL – see HRQoL.

Occlusal vertical dimension - OVD

Patient based outcomes – PBO

Patient reported outcome – PRO

Piezography: From Greek: a shape formed by pressure (Klein, 1974).

Quality of life: An individual's perception of his or her position in life, in the context of the culture and value systems in which they live, and in relation to their goals, expectations, and concerns (Calman, 1984). QoL involves the physical, functional, social and emotional well-being of persons (Fallowfield, 2009).

Residual bone: That component of maxillary or mandibular bone that remains after the teeth are lost (The Glossary of Prosthodontic Terms, 2005).

Residual ridge: The portion of the residual bone and its soft tissue covering that remains after the removal of teeth (The Glossary of Prosthodontic Terms, 2005).

Residual ridge crest: The most coronal portion of the residual ridge (The Glossary of Prosthodontic Terms, 2005).

Residual ridge resorption - RRR: A term used for the diminishing quantity and quality of the residual ridge after teeth are removed (The Glossary of Prosthodontic Terms, 2005).

Visual analogue scale - VAS

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CHAPTER 1: INTRODUCTION

Edentulousness can be regarded as a personal plight afflicting humanity over centuries. It has been associated with adverse psycho-social and health consequences (Locker *et al.,* 2000). Until the late 1900’s, conventional complete dentures have been the exclusive method of restoring form and function for edentulous people. It was in 1982 that the Toronto Conference on Tissue-Integrated Prostheses launched the treatment option of a fixed implant-restored edentulous mandible (Henry, 1998). This opened the gates for a vast variety of treatment options for tooth loss, implant-retained mandibular overdentures being one of them.

The positive effect on patient satisfaction following rehabilitation with implant-retained mandibular overdentures has been confirmed by several clinical trials (Emami *et al.,* 2009b). However, the importance of respecting patients’ preferences when deciding on a treatment option was illustrated in a study by Walton & McEntee (2005) who reported that when patients were offered free implants for mandibular overdentures, more than a third declined. The reasons for refusal were a fear of surgical risks and satisfaction with the function of complete dentures. This suggests that part of the edentulous community is satisfied with a conventional complete denture option and even prefers it. And yet, successful management of the edentulous patient can never be guaranteed.

In 2002, consensus was reached among experts, globally, that the restoration of the edentulous mandible with an implant-supported overdenture should be the standard of care (Feine *et al.,* 2002; McGill, 2002). This created a moral dilemma for clinicians: should treatment with conventional complete dentures now be regarded as a second-rated treatment option for numerous patients who have no access to implant-treatment in developing, and even first-world countries?

Other potential consequences of such a consensus statement are that implant treatment may be regarded as a blanket solution for problems associated with poorly constructed complete dentures and a decreased interest in training and research into the rehabilitation of the edentulous patient by means of conventional complete denture construction. This is illustrated by continuously diminishing 'journal space' dedicated to research publications on complete denture prosthodontics (Carlsson, 2005).

With improved life expectancy and multi-morbidity of an ageing population, it is expected that the rehabilitation of edentulous jaws without the option of osseointegrating implants will remain with the dental profession for the foreseeable future (Carlsson & Omar, 2010). Therefore, researchers, educators and clinicians will have to remain focused in an effort to improve rehabilitation of edentulousness by means of conventional complete denture therapy. This philosophy is in line with the World Health Organization (WHO) (2014a) who identified older persons as an important target group for reducing its oral disease burden and improving oral health and quality of life (OHRQoL).

Many common prosthodontic practices are still based on dogmas, because no high-level scientific evidence exists to either accept or reject them (Carlsson, 2009). This may sound true for several complete denture practices, among them the neutral zone (NZ) concept. Even though it is generally agreed that the NZ should be respected when constructing complete dentures (Owen, 2006), little high level scientific evidence exists to support this idea. This status quo is highlighted in the literature review on the NZ in the next chapter of this dissertation. In this era of evidence-based dentistry, ineffective treatment options should be eliminated from clinical practice and decision-making should be based on highest level of available evidence. The results of the trial described in this dissertation provide information that may be included in systematic reviews or meta-analyses to take the scientific evidence on the topic to a higher level of significance. It is within this conceptual framework that the following research questions were raised: how do shapes of "conventional" and "NZ" mandibular dentures differ, and to what extent do the two different types of dentures influence patient-based outcomes by assessing OHRQoL and preference?

The research described in this dissertation aims to answer these questions by analysing the data collected by means of a prospective, randomised, cross-over, single-blinded clinical trial. This research was unique because it is the largest cross-over trial studying features of NZ and conventional dentures together with patient-based feedback using an approved OHRQoL instrument, the 20-item oral health impact profile (OHIP-20).

This trial involved the rehabilitation of a population of edentulous patients by means of two types of complete dentures. One set of dentures was made following conventional biometric parameters for determining the position of the posterior denture teeth in relation to the ridge; the second set of dentures was made following a functional impression of the potential denture space. The width of the arches of the dentures was analysed with the aid of digital measuring software. Patient feedback was analysed by using the OHIP-20 instrument.

In the next chapter of this thesis, a literature review on general aspects related to edentulousness, treatment of edentulousness, the NZ and OHRQoL is presented.

The third chapter describes the study design, sampling, clinical and laboratory procedures involved in constructing the two types of dentures, data collection and data analysis methods.

The fourth chapter presents the results in terms of the demographic profile of the study sample, the descriptive and analytical results of the denture dimensions and the OHIP-20 data related to the two types of intervention.

The final chapter discusses the findings. Where possible, findings are compared with previously published papers. Strengths and limitations are given, as well as clinical significance and recommendations for future research are made. The work is illustrated by appropriate tables and figures.

A list of references is provided at the end of the thesis and background information is provided in the appendices.

CHAPTER 2: LITERATURE REVIEW

2.1. INTRODUCTION: SCOPE OF THE LITERATURE REVIEW

The literature review that introduces and supports this research project included the following fields: edentulousness, its prevalence, consequences and rehabilitation; the neutral zone (NZ), its methodology and scientific evidence; denture satisfaction and OHRQoL.

PubMed was used as the main resource for literature. Initial searches were performed using single or combinations of keywords. Publications were filtered according to journal category (Dental Journals) and language (English). No other filters were activated. Titles were reviewed and selected for suitability and abstracts of all selected articles were read. References related and linked to these abstracts were also screened. If abstracts proved applicable, full articles were acquired and read. References from full articles were also screened for possible relevant publications not revealed in the PubMed searches. Full articles were retrieved from the University Library electronic databases which include most large international journal databases.

As mentioned in the introduction, little high-level evidence exists related to the neutral zone concept. An abundance of literature is available related to patient-based outcomes regarding the rehabilitation of edentulous patients, in particular using dental implants. However, there is paucity in published information comparing patient satisfaction and oral health-related quality of life for the two treatment interventions used in this trial.

2.2. EDENTULOUSNESS, ITS CONSEQUENCES AND REHABILITATION

2.2.1. Prevalence of edentulousness

2.2.1.1. Edentulousness and geographic regions

Although reliable data on the prevalence of complete edentulousness are not available for many countries (Carlsson & Omar, 2010), global rates of edentulousness are estimated to vary within 7% to 69% (Felton *et al.,* 2011).

Prevalence of edentulousness differs across countries and continents. In North America, the prevalence of edentulousness in the older population ranges from 25-30%, and in Europe 15-72% (Miller & Locker, 2005; Muller *et al.*, 2007). In Canada, the rate of edentulousness among adults between 60 and 79 years of age was 21.7% (Health Canada 2010 cited by Emami *et al.*, 2013).

Among continents, Petersen *et al.* (2010) reported that edentulousness is lowest in 65-74-year old people of the African and South East Asian regions. It was the highest in the European region.

Because of declining rates of mortality, the actual number of edentulous people may still rise (Miller & Locker, 2005). However, in a recent review, Slade *et al*. (2014) reported that edentulousness in the US has been declining since 1957 and that future edentulousness may be overestimated.

Prevalence of edentulousness seems to vary widely among countries and regions within countries, with respect to socio-economic conditions, age, and gender (Carlsson & Omar, 2010; Slade *et al.,* 2014). These variables are reviewed in the following sections.

2.2.1.2. Edentulousness and socio-economic conditions

Tooth loss is more prevalent among older people with low income (Saub & Evans, 2001; Slade *et al.*, 1990). Even though Petersen *et al.* (2010) reported a high prevalence (35%) of edentulousness in upper-middle income countries, and low (10%) in low-income countries, the prevalence of edentulousness is increasing in low- and middle-income countries (Petersen *et al.*, 2010). Since the beginning of this millennium, there appears to be a trend of reduction of tooth loss among older persons in high-income countries (Douglass *et al.*, 2002; Petersen &Yamamoto, 2005; Slade *et al.*, 2014).

Poor and disadvantaged groups are more vulnerable to become edentulous. (WHO, 2004). A recent publication by Slade *et al.* (2014) reported that higher income groups in the U.S. experienced a greater relative decline in edentulousness than lower income groups. Slade *et al.* (2014) also reported that edentulousness is increasingly becoming concentrated in certain geographic regions within the U.S. The reason for this regional confinement appears to be associated with poverty in rural areas. Institutionalized elderly people suffer from poorer oral health, with higher rates of tooth loss than age-matched counterparts living independently (Muller *et al.*, 2007).

Other socio-economic factors influencing tooth loss are access to dental care, dentist/population ratio and medical insurance (Elani *et al.*, 2012). Slade *et al.* (2014) reported that, in the U.S., there is an inverse association between level of education and prevalence of edentulousness.

2.2.1.3. Edentulousness and age and gender

Loss of teeth and edentulousness is associated with older persons (Carlsson & Omar, 2010). Patients are becoming edentulous later in life than in the past (Allen & McMillan, 2003a). As people age, the influence of socioeconomic and race variables appears to diminish.

According to the United Nations (2007), as cited in Petersen *et al.* (2010), most countries' populations are ageing. Even though older persons in developed countries are proportionally higher than in developing countries, there are older persons living in the developing world. According to the WHO, about 30% of people aged between 65-74 years worldwide have no natural teeth (WHO, 2014b).

In countries where the prevalence of edentulousness has been studied, there is a trend of more women than men being edentulous (McGrath *et al.,* 1998; Haikola *et al.*, 2008). The reasons for this trend are complex. It may be due to a higher proportion of older females in a population (Miller & Locker, 2005), but also to socio-economic factors (e.g. access to health care), personal, cultural attitudes and beliefs (Russel *et al*., 2013). For example, in several regions of the world, prenuptial edentulousness was practised, and in some instances still is: young women's teeth are removed to spare future partners trouble and expense (Russel *et al.*, 2013). In South Africa (SA), a larger percentage of women, among all population groups are edentulous compared to men (van Wyk & van Wyk, 2004).

2.2.1.4. <u>Edentulousness in South Africa</u>

The most recent survey to determine the prevalence of edentulousness in SA was conducted in 1988-1989 (Du Plessis *et al.*, 1994). In the 35-44 years age group, a total of 12.6% was edentulous, of which 3.5% did not have dentures. It is expected that with ageing, this prevalence will increase. Within the edentulous population, there was a large variation among different population groups. The highest prevalence was found in the "Coloured" population group with a prevalence of edentulousness of 51.6%. Therefore, it cannot be disputed that, in SA, there are large numbers of edentulous persons in need of prosthetic treatment.

2.2.2. Consequences of tooth loss and edentulousness

2.2.2.1. <u>Introduction</u>

This section will be divided into biological consequences and psycho-social impact of edentulousness. The review will be limited to those consequences of edentulousness that directly influence prosthetic rehabilitation.

2.2.2.2. <u>Biological consequences of edentulousness</u>

i. Alveolar bone resorption

Loss of alveolar bone is considered one of the most important consequences of tooth loss (Atwood, 1971; Carlsson, 1998; Felton, 2009). All patients experience alveolar bone resorption after tooth extraction. Loss of alveolar bone leads to a progressive reduction of the volume of the residual edentulous ridge (Klemetti, 1996). Resorption affects the mandible four times more than the maxilla and is most rapid during the first year of denture wear (Tallgren, 1972; Karaagaçlioglu & Ozkan, 1994; Felton, 2009). Rate of residual ridge resorption (RRR) slows down with longevity of edentulousness (Karaagaçlioglu & Ozkan, 1994). The rate of alveolar bone loss varies among individuals (Tallgren 1972; Kalk & de Baat, 1989).

Both local and systemic aetiological factors have been implicated in the loss of alveolar bone (Devlin & Ferguson, 1991). Woelfel *et al.* (1976) listed as many as 63 factors that could play a role in bone resorption in edentulous persons. Variables often examined in correlation analyses are gender, age, facial structure, duration of edentulousness, nutrition, general health, medication (e.g. corticosteroids), systemic diseases, and osteoporosis (Carlsson, 1998).

Original ridge size, occlusal load and denture wearing patterns as well as duration of edentulousness have been implicated as important contributory causes for loss of alveolar bone (Devlin & Ferguson, 1991; Boyde & Kingsmill, 1998). Because of the multifactorial nature of alveolar bone resorption, it has been challenging to identify a dominant factor responsible for bone loss after tooth extraction (Carlsson, 1998). A 10-year retrospective study, looking at records of 873 geriatric patients, identified duration of being edentulous as a factor associated with mandibular but not maxillary residual ridge resorption (RRR) (Divaris *et al.*, 2012a).

In addition, Divaris *et al.* (2012a) found that female patients were more likely to exhibit RRR than men of the same age. But this may be partially explained by the fact that women have been edentulous longer than men of the same age (Suominen-Taipale *et al*., 1999).

Patterns of alveolar bone resorption differ for mandibles and maxillae. Pietrokovski *et al.* (2007) studied 123 edentulous dry bone specimens, and found that after tooth loss, maxillary resorption was centripetal and apical, whereas mandibular resorption was centrifugal and also apical. This may result in a reversed horizontal relationship in fully edentulous subjects.

ii. *Changes in jaw morphology*

Contrary to earlier reports (Tallgren, 1967), mandibular basal bone morphology changes following tooth loss. The gonial angle widens (Xie & Ainamo, 2004) and the ramus and condylar heights become shorter (Ohm & Silness, 1999; Huumonen *et al.*, 2010). These findings highlight the importance of rehabilitation and maintaining good functioning of the masticatory system for as long as possible (Huumonen *et al.*, 2010).

iii. *Loss of support for facial tissues*

Support to lips and cheeks are lost as they collapse into the space previously occupied by the natural dentition and its supporting tissues. Also, the tongue expands laterally into this space. Loss of alveolar bone volume and changes in jaw morphology lead to soft-tissue profile changes such as protrusion of the lower lip and chin (Tallgren *et al.,* 1991). Resorption of alveolar ridges during denture wearing is accompanied by a reduction of lower facial height, including the resting facial height (Tallgren, 1972). When dentures do not compensate for lost vertical dimension, the lower facial height remains compromised (Cooper, 2009). Forward-upward posturing of the mandible contributes to the loss of this facial height and this leads to increased mandibular prognathism.

iv. *Loss of masticatory muscle tone*

Although some loss of function may be attributable to muscle atrophy in older persons, aging alone is considered to have little impact on masticatory performance (Hatch *et al.,* 2001). In edentulous persons, the masseter is found to be reduced in size, compared to dentate persons of the same age group (Bhoyar *et al.,* 2012). After insertion of dentures, the masseter thickness increases again, but remains smaller than that of dentate persons, thus impacting on bite force of denture wearers (Bhoyar *et al.,* 2012).

v. *Tongue position and volume*

Wright *et al.* (1949) reported that a “normal” tongue position contributes to the ability of a patient to wear dentures. Several authors made observations of “abnormal”, “retracted” or “retruded” tongue positions, and that such a position may hinder the establishment of a lingual peripheral seal for the mandibular denture (Lee *et al.,* 2009; Kotsiomiti *et al.,* 2005).

Kollias & Krogstad, (1999) found that the position of the tongue changes as adults grow older: the tongue extends more caudally towards the pharynx leading to a more upright position. This change is more pronounced in men. Kotsiomiti *et al.* (2005) found this “abnormal” tongue position to be related to loss of teeth.

There is a popular belief that tongue volume increases when teeth are lost and are not being replaced by prostheses. A hypothesis for this belief is that the tongue muscles hypertrophy when taking over some of the “mastication” previously done by teeth. However, no evidence of this could be found in the literature. A possible reason for tongue volume changes may be related to general weight gain or loss and the deposit or loss of fat in the tongue. In an animal study, it was found that obese rats had 10 to 20% increased “muscle” volume compared to normal controls (Saito *et al.*, 2010).

It is evident that changes in tongue position and volume may influence the shape of the neutral zone (NZ).

2.2.2.3. Impact of edentulousness on psycho-social well-being

Edentulousness has been described as “the dental equivalent of mortality” (Weintraub *et al.*, 1985, in Slade *et al.*, 2014). It has been repeatedly reported that loss of teeth has a negative impact on people’s psycho-social well-being and oral health-related quality of life (OHRQoL) compared to individuals who retained their teeth (Albrektsson *et al.*, 1987; Locker, 1992; Locker & Slade, 1993; Slade *et al.*, 1996; Fiske *et al.*, 1998; Allen & McMillan, 2003b; Steele *et al.*, 2004; Gerritsen *et al.*, 2010; Emami *et al.*, 2013).

Albrektsson *et al.* (1987) reported that the loss of teeth may present itself as a severe handicap. Fiske *et al.* (1998) described feelings reported by edentulous persons as follows: sense of bereavement, lower self-confidence and self-image, poor appearance, individuals wanting to keep the condition secret, inability to talk about edentulousness, and altered social interaction.

Indeed, edentulousness impacts negatively on social life and everyday activities (Heydecke *et al.,* 2005). Papadaki & Anastassiadou (2012) found that the majority of participants in their study had difficulties coming to terms with tooth loss, more so younger persons.

2.2.3. Need for complete denture treatment

Edentulousness without rehabilitation with complete dentures (CDs) is common among disadvantaged groups of both developed and developing countries and there is a considerable unmet need for denture treatment, particularly among the older population (Petersen *et al.,* 2010). Carlsson & Omar (2010) concur. They reported that, even though a reduction in edentulousness in some countries was reported, on a global scale, the need for rehabilitation of edentulousness was not likely to decrease, because of ageing societies. This was particularly so in less developed populations with limited economic resources (Carlsson & Omar, 2010).

For the near future and for the majority of edentulous people, the only therapeutic option will remain CDs. Douglass *et al.* (2002) projected that, in the United States, adults in need of one or two CDs will increase from 33.6 to 37.9 million between 1991 and 2020.

Patients are becoming edentulous later in life than in the past (Allen & McMillan, 2003a). It is generally accepted that older adults have a reduced capacity to adapt to dentures. Furthermore, current generations of adults who become edentulous are less likely to accept the limitations of denture wearing (Mojon & McEntee, 1992).

These two trends will present challenges for the dental professions in terms of delivering a satisfying prosthetic service to the older adult population. In this regard, Fitzpatrick (2006) remarked: "…. treatment should be implemented and undertaken within a culture of prosthodontic scholarship and patient-mediated outcomes."

This implies that it remains important to research prosthetic treatment modalities in response to higher demands and expectations of the edentulous patient, particularly how treatment impacts on satisfaction and OHRQoL of the patient.

2.2.4. Treatment modalities and their impact on satisfaction and OHRQoL

Until about 35 years ago, the only treatment option for edentulousness was the provision of removable conventional CDs. Over the years, many recommendations in terms of impression-making materials and techniques, jaw registration procedures, occlusal schemes and selection of denture teeth have been made in the quest for improved prosthesis quality and patient satisfaction. Most patients appear to benefit from CD treatment (Adam *et al.*, 2007; Ellis *et al.*, 2007; Bellini *et al.*, 2009; Viola *et al.*, 2013) and are satisfied with their CDs (Carlsson, 2006). However, regardless of the quality of conventional dentures, patients still suffer from chronic functional limitations and discomfort due to lack of denture stability and retention. According to Heydecke *et al.* (2003b) unstable dentures cause difficulty in eating some types of foods or speaking clearly. Some people never adapt to their dentures.

Since the discovery of osseointegration, its potential in addressing these lingering limitations associated with conventional CDs was immediately recognized. Since the arrival of the fixed implant-supported prosthesis for the edentulous mandible in the early 80's, a variety of implant-supported and -retained fixed and removable prostheses have been developed for the edentulous jaw (Henry, 1998).

From the early days of implant treatment, most trials reporting on implant treatment outcomes were concerned with technical and clinical issues such as survival of osseo-integrating implants and occlusal forces (Locker, 1998a). Behavioural or psychosocial outcomes were often overlooked.

As a result, a review on studies using patient-based outcomes (PBO) of implant treatment was published (Locker, 1998a).

From Locker's review, it became clear that the majority of patients were more satisfied with their implant-supported dentures than with their previous conventional dentures. Improvements were evident in appearance, self-confidence, self-esteem, and participation in social activities. However, Locker (1998a) warned that the results of these trials should be interpreted with caution due to methodological and measurement problems. This will be discussed further in the section of OHRQoL.

Since this early review by Locker, several more studies reporting on perceived outcomes of implant-overdenture treatment compared to conventional dentures followed (Allen *et al.*, 2001b; Awad *et al.*, 2003; Heydecke *et al*., 2003b; Meijer *et al*., 2009; Thomasen *et al*., 2009; Cakir *et al.*, 2014). Simultaneously, the instruments used to measure treatment effect on OHRQoL were also being improved. By and large, these more recent studies confirmed the earlier reports that improvement in OHRQoL is large(r) for edentulous patients provided with implant treatment. Implant groups usually scored significantly better for comfort, stability and chewing (Awad *et al.*, 2003).

However, results should always be interpreted with caution. One of the reasons for a less dramatic improvement in OHRQoL for conventional CDs was that pre-treatment scores for patients seeking conventional CD treatment were less severe (Allen & Locker, 2002). This trend was also noticed earlier when edentulous persons seeking an implant-driven solution for their predicament were found to have a poorer initial OHRQoL compared with patients requesting conventional complete denture treatment (de Grandmont *et al.*, 1994; Awad *et al.*, 2000b).

Literature dealing with conventional complete denture satisfaction and OHRQoL will be reviewed in more detail in section 4.

An interesting event in edentulousness and its treatment was the McGill Consensus Statement published in 2002 (Feine *et al.,* 2002). It involved the rehabilitation of the edentulous mandible by means of a removable overdenture retained by two implants, either as individual units with retentive attachments or splinted by a retentive bar. Its popularity is probably derived from the fact that it combines maximum benefit with reduced intervention and costs compared to the fixed implant treatment modalities. In the light of the positive results from clinical trials, this type of denture was promoted as the “first-choice” standard of care for the edentulous mandible by the McGill Consensus Statement in 2002 (Feine *et al.*, 2002). However, this statement has since come under review, one of the reasons being that the title of the consensus paper implies the presence of more than one “standard of care”. Another reason is that it immediately categorizes patients, who deliberately refuse implant treatment, to an “inferior” treatment modality, even if their satisfaction with the chosen treatment option is high. In this regard, an interesting finding by Walton & McEntee (2005) was that 36% of a group of patients offered free implants for mandibular overdentures, refused the offer. Reasons for refusal were cited as fear of surgical complications and satisfaction with existing CDs.

2.2.5. Conclusions

Although edentulousness is prevalent worldwide, it is becoming more confined to certain regions and countries. In these regions, conventional CD treatment may remain the only treatment option available and the need for CDs will persist for many years to come.

Edentulousness leads to anatomic changes in the orofacial region and impacts on the well-being of individuals.

2.3. THE NEUTRAL ZONE

2.3.1. Introduction

This chapter on the neutral zone (NZ) will review literature on tooth arrangement and external shape of the mandibular denture and how this may influence its stability.

2.3.2. Mandibular denture stability

Good stability and retention of mandibular dentures contribute to patient satisfaction and OHRQoL (Fenlon & Sherriff, 2008; Komagamine *et al.*, 2012). Complete denture stability is achieved through a combination of properly fitting surfaces, occlusal relationships, tooth arrangement and neuromuscular control (McCord *et al.*, 2010). The influence of the polished surfaces and arch form on mandibular denture stability will be discussed in detail in Section 3.3. The influence of a well-fitting surface, adequate extensions and occlusion will be dealt with in the next paragraph.

Lynch & Allen (2006) mentioned incorrect extensions as a denture-related reason for instability. Of particular interest for complete mandibular dentures, is the lingual extension. A cineradiographic study by Jooste & Thomas (1992a) found that the retromylohyoid extension had a stabilizing effect on mandibular dentures during chewing exercises.

Jacobson & Krol (1983) stated that occlusion is a fundamental factor in establishing denture stability. Complete denture occlusion is inherently different from occlusion as it occurs in the natural dentition. The minimum requirement for CD occlusion is considered to be a “static” balanced occlusion: even, bilateral contact between posterior teeth when the mandible closes in a centric relation position (British Society for the Study of Prosthetic Dentistry, 1996 in: Davies *et al.*, 2001).

For some patients, with a significant horizontal component in their chewing pattern, a "dynamic" balanced occlusal approach or balanced articulation may have to be followed. However, the literature does not seem to have found agreement on this issue and it may indeed be one of the dogmas described by Carlsson (2006, 2009). Some of the conflicting information follows in the next paragraph.

In an effort to create an occlusion that contributes to denture stability, different occlusal patterns and tooth arrangements have been developed. Various denture tooth molds were developed to create "anatomic" or "monoplane" occlusions. Anatomic denture teeth possess cusps with angles in the region of 30-33° (Lang, 2004). Anatomic teeth intercuspate with their antagonists. This may be unacceptable for patients with compromised muscle control (Lang, 2004). Monoplane or 0° degree denture teeth lack cusps and prevent opposing dentures from "locking" into a definite position (Lang, 2004). Sometimes, anatomic and monoplane teeth are used in combination to create a lingualized occlusal pattern. The rationale behind the development of monoplane and lingualized occlusions is to provide patients some freedom of movement and to reduce the risk for incorporating deflecting cuspal contacts, and thus obstruct excursive movements or cause lateral movement of the dentures over the supporting tissues. Murell (1974) recommended lingualized articulation for patients with "difficult" lower ridges.

However, these theories do not necessarily translate into improved patient satisfaction, as shown by conflicting results from RCTs. In one such trial, Clough *et al.* (1983) found that lingualized occlusion was better than monoplane occlusion in terms of chewing ability and comfort for denture wearers. Later, two trials showed that dentures with a lingualized occlusal scheme scored better in terms of retention compared to dentures with a fully balanced occlusion (Kimoto *et al.*, 2006; Matsumaru, 2010). Recently, a small clinical trial compared a new "buccalized" occlusal scheme with a lingualized and fully bilaterally balanced scheme (Shirani *et al*., 2014).

This buccalized occlusion appeared to be similar to lingualized occlusion in improving retention and stability of complete dentures. On the other hand, Peroz *et al*. (2003) found that canine-guided mandibular dentures were more stable in eccentric movements, which is in conflict with the rationale expressed in the previous paragraph. Heydecke *et al.* (2008) found that a comprehensive method for the fabrication of CDs using lingualized teeth in a fully balanced occlusion does not appear to produce improved denture satisfaction ratings compared to using anatomic teeth in a static occlusion. However, in this study, the denture groups had more than one variable. This may have confounded the results.

In 1972, an international workshop on complete denture occlusion concluded that "… *the choice of a posterior tooth form or arrangement for complete dentures is an empirical procedure. Little or no supporting research is available to the profession relative to the overall effect on aesthetics, function, and the long-term maintenance of the supporting tissues*" (Lang, 2004). It appears that little progress has been made since.

Often, laboratory and clinical remounts are performed to eliminate premature or interfering occlusal contacts that may cause denture instability. Shigli *et al.* (2008) found that these procedures indeed increase patient comfort and reduce the number of recall visits after delivery of the dentures. Another factor closely related to occlusal forces is the posterior extent of the occlusal table. A clinical study by Jooste & Thomas (1992b) showed that posterior denture teeth placed over the posterior slope of the mandibular alveolar ridge up to the retromolar pad had a destabilizing effect during function. Removal of the teeth over the incline significantly reduced movement of the mandibular denture.

2.3.3. Definition, terminology and aim of the neutral zone in complete dentures

The neutral zone (NZ) is defined as "the potential space between lips and cheeks on the one side, and the tongue on the other; that area or position where the forces between the tongue and cheeks and lips are equal" (American College of Prosthodontists, 2005). Other terms used that refer to the same area in an edentulous mouth are: functional denture space, zone of minimal conflict (Matthews, 1961), comfortable zone, dead zone (space) (Fish, 1933), stable zone, zone of least interference, zone of equilibrium, biometric denture space and (potential) denture space (Cagna *et al.*, 2009; Porwal & Sasaki, 2013).

The technique for recording the NZ denture space has been referred to as follows: the anthropoidal pouch technique, denture-form impression technique, muscle-formed mandibular denture technique (Walsh & Walsh, 1976), piezograph technique, and border molding technique (Porwal & Sasaki, 2013). The theory supporting the existence of the NZ was coined by Beresin & Schiesser (1976) as the "neutral zone concept". In this dissertation, the term "neutral zone" will be routinely used.

The objective of creating NZ dentures is to produce 3-dimensional shapes that do not interfere with normal muscle function and indeed, forces generated by this muscle action should contribute towards denture stability and retention. In other words, dentures should be shaped and placed as dictated by the surrounding muscles. This concept becomes increasingly important when supporting tissues are compromised due to advanced residual ridge resorption and/or mobile ridges. With advancing ridge resorption, the ratio of intaglio/polished denture surfaces in contact with surrounding tissues progressively decreases. Particularly for the mandibular denture, a reduction in support promotes instability because resistance to lateral displacing forces is poor.

Successful wearing of complete dentures requires neuromuscular skills. When people become edentulous later in life, the capability to adapt to complete dentures for the first time is believed to be diminished (Brill *et al*., 1959, 1960; Fenlon *et al*., 2000). Optimal retention and stability becomes even more important under these conditions. For persons with compromised neuromuscular skills the NZ concept for mandibular denture may be considered advantageous.

Over years, many guidelines were created governing the position of posterior teeth on mandibular dentures. These guidelines were, and still are, predominantly based on the anatomic guidelines visible on casts, with limited consideration given to the dynamics of the surrounding muscles. This has led to a mechanistic and standardized approach to denture construction in a distant laboratory, instead of being an extension of the clinical process. While routine information on the occlusal plane, occlusal vertical dimension, lip support, midline, smile-line, shape and shades of denture teeth are usually provided to the dental technician, information on the artificial dentition's arch shape and modelling of the future polished surfaces are seldom supplied.

When pre-prosthetic surgery, such as dental implants and vestibuloplasty, is not indicated because of its surgical invasiveness or financial restrictions, the NZ-concept may be the only alternative non-invasive option, besides accurate fit and occlusion, in the quest for improved denture retention and stability.

2.3.4. Historical overview

The optimal location of a 3-dimensional volume within the edentulous space to be occupied by prostheses has been the subject of considerable debate. As early as 1746, Fauchard wrote that "*We must consider the form and the curvature that the outside and the inside surfaces must have to avoid discomfort of the tongue, the gingivae, and the inside of both cheeks*" (Lott & Levin, 1966).

Fish, one of the NZ concept pioneers, argued that natural teeth occupy a zone of equilibrium (Fish, 1931). He extrapolated this concept to CD prosthodontics and arrangement of artificial teeth. He is reported as saying that the critical factor in denture stability is *not* the anatomical denture bearing area, but rather the action of surrounding muscles of tongue, lips and cheeks. Since then, several texts on the importance of external denture shape appeared, with differences in opinions on whether the arrangement of denture teeth should be guided by the shape of the residual ridge or by the theory of muscle equilibrium (Weinberg, 1958; Russel, 1959; Raybin, 1963; Schiesser, 1964; Brill *et al.*, 1965; Lott & Levin, 1966; Wright, 1966; Strain, 1969).

While the equilibrium theory kept prosthetic minds occupied, it came under fire in the 1950s and 60's from the orthodontic fraternity. Forces recorded on facial and lingual surfaces of the natural dentition could not support the assumption that the force of the tongue is compensated for by muscle action of the cheeks and lips, and that lingual forces indeed predominated (Kydd, 1957; Winders, 1962). Lear & Moorrees (1969) concluded that the dental arch form did not reflect the influence of the surrounding musculature. However, they did not go so far as rejecting the time-honoured equilibrium theory.

Beresin & Schiesser published a textbook solely devoted to the NZ (Beresin & Schiesser, 1973). This was followed by a publication in a major prosthetic journal by the same authors (Beresin & Schiesser, 1976), reprinted as a "classical article" in 2006 in the same journal. As prosthetists, they wrapped up the seemingly conflicting information as follows: The dental arch is shaped by a combination of genetics and muscular activity and habits. These activity and habits are highly individual and probably prevail throughout life, even after the loss of teeth.

Neill & Glaysher (1982) gave it another twist and wrote that the arch form of the natural dentition seemed genetically determined and that surrounding muscles adapt to this form. However, they doubted if musculature also adapted to the shape of a prosthesis, of which the mechanics differ markedly from the natural dentition it replaces.

Over the previous century, numerous publications appeared describing opinions and theories, clinical techniques in terms of the most appropriate materials to be used and muscle functions to be performed during NZ recording, supported by case reports. However, in terms of patient feedback and satisfaction, strong scientific evidence and clinical relevance of a dynamic NZ technique compared to conventional methods of shaping complete dentures, is to a large extent still lacking today.

Despite it having been, and still is, a popular topic in the dental literature, with many agreeing with the principles, the NZ approach to CD construction has largely been bypassed by clinicians. A possible explanation may be the additional skill, time and materials the technique requires. But arguably the more important reason may be that the technique is not part of the clinical requirements in the majority of dental schools. A survey by Faber (1992) showed that most dental schools (59% of the respondents) in the United States taught students to arrange artificial teeth over the crest of the mandibular residual ridge. Only 6% of the responding schools reported that they taught a "physiologic" method of arranging mandibular teeth. The decision of dental schools not to include it in standard prosthetic curricula may be justified if the lack of high level scientific evidence on the outcome of the technique is considered, as mentioned in the previous paragraph. On the other hand, many prosthetic procedures are not based on high-level evidence, but rather on clinical experience and opinions of experts (Carlsson, 2006).

The next section will review the literature concerning the NZ in more detail. Information will be arranged in sections dealing with "expert opinions" followed by literature with a "higher level" of evidence. It will be followed by different techniques described and employed in the literature.

2.3.5. Literature review of the neutral zone

2.3.5.1. Expert opinions on arranging posterior mandibular teeth

Two main schools of thought dominated the literature on the facial-lingual arrangement of denture teeth and the shaping of the mandibular denture. One of them is the concept that teeth should be placed in the position where the natural teeth once were (Fish, 1933; Murray, 1978; Watt, 1978). Numerous papers were published on techniques and materials to be used to record the NZ and to shape the external flanges of dentures. The other school of thought believes in the use of biometric criteria: the location and shape of the residual ridge should guide the arrangement of denture teeth. Weinberg (1958) recommended that the buccal cusps and fossae of mandibular posterior teeth are to be placed over the crest of the residual ridge. Pound (1970) described how lingual surfaces of mandibular posterior teeth should occupy a triangle bounded by two lines originating from the mesial surface of the canine and extending to the lingual and buccal sides of the retromolar pad, also called "Pound's Triangle". Although this could be regarded as a biometric guide, this does not necessarily follow the crest of the residual ridge. Watt (1978) recommended that posterior mandibular teeth are placed over the lower ridge. He also recommended using narrower teeth buccolingually to provide more lingual space and to prevent a lingual undercut that may trap the tongue. A modification of Pound's Triangle was suggested by Halperin *et al.* (1988) as referred to in Cagna *et al.* (2009). Their triangle had a narrower surface with the most facial line extending from the canine crossing through the central part instead of the external side of the retromolar pad.

Even mathematical models were used to develop guidelines for setting up denture teeth. Keshvad *et al*. (2000) measured intercondylar widths and distances between upper and lower canines and molars from dentate subjects to develop ratios that could aid in the arrangement of denture teeth.

A slightly different approach, deviating from strictly following biometric guidelines, was presented by DeVan (1954). He suggested centralizing the posterior mandibular teeth over the denture base, while also avoiding encroachment of the tongue space. This was called the "neutrocentric" concept. In aging patients, Lammie (1956) recommended placing the mandibular posterior teeth even more facially, over the buccal shelf, to create more tongue space and to encourage a facial seal against vertically-shaped buccal polished surfaces. Wright (1966) also thought that the buccal shelf, considered to be a primary stress bearing region, would be an ideal position for the placement of the mandibular posterior teeth. Martone (1963) recommended setting up posterior mandibular teeth in such a way that the teeth would be placed progressively more facially towards the distal starting from a more lingual position in the more anterior region of the segment.

2.3.5.2. <u>Expert opinions on shaping external denture surfaces</u>

Raybin (1963) suggested that the stabilizing effect of dentures may be related to the shape of the external or polished surfaces. He suggested that more convex facial denture flanges found in NZ impressions may be contributing to improved stability compared to the more concave surfaces found in hand-waxed dentures. For their "flange technique", Lott & Levin (1966) made impressions of the surrounding tissues, not only to create a NZ record for the arrangement of the teeth, but also for establishing an intimate adaptation of the tongue and facial tissues with the flanges. The idea was to create a seal on the surface of the flanges instead of at their peripheral edges. Soft wax was used to first record the NZ. This record was then used to set up teeth. In a consecutive visit, flange impressions were made with the aid of the wax trial dentures.

During these impressions, patients were asked to perform a variety of functions such as read aloud, grin, purse lips, swallow, protrude the tongue, and lick lips. According to Lott & Levin (1966), their flange technique led to increased retention, improved appearance and a more natural speech. Similarly, Tyson & McCord (2000) drew attention to the importance of the external shape of mandibular dentures. They recommended a convex buccal flange. This should help the cheeks to exert a seating force onto the denture and prevent food impaction by filling space. Lingually, occlusal undercuts need to be avoided to prevent tongue movements to unseat the mandibular denture. This may sometimes implicate a reduction of the buccolingual dimension of the posterior denture teeth.

2.3.5.3. Clinical trials

It is only from the mid 1970's that research-based results appeared in the denture literature, testing some of the previously published expert opinions. Because of variable methodologies in terms of materials, functions and size of these trials, it is difficult to make comparisons. Instead, a chronological summary follows.

One of the earliest trials was done by Walsh & Walsh (1976). A method was described whereby a patient's muscle action was used to determine the position of the teeth and to develop the shape and thickness of the denture base using soft wax. Patients were selected on the basis that they perceived their dentures as unacceptable, but apparently technically correct. Of 30 patients tested, 28 patients preferred the dynamically shaped lower denture over the existing conventional denture because of improved stability. However, the study was not controlled. It also does not mention the instrument used to "measure" stability. Karlsson & Hedegard (1979) demonstrated by means of cineradiography studies that there is greater stability during chewing for NZ dentures.

Khamis *et al.* (1981) made NZ impressions using tissue conditioning material at three different occlusal vertical dimensions (OVD). They found that the width of the NZ shape was least at occlusal plane level and increased as it went up or down; the width of the NZ rim was least in the molar region and gradually increased towards the anterior region; with vertical height increasing, the widths of the NZ also increased and *vice versa.*
These findings were independent of degree of ridge resorption. The broader NZ with larger OVD was explained by stretching of the buccinator muscle fibres. A narrower NZ when OVD was decreased was explained by relaxing muscle fibres and increased muscle convexity, diminishing the denture space. Degree of ridge resorption did not influence the width of the NZ.

Neill & Glaysher (1982) measured forces on the buccal and lingual sides of upper and lower first molars on dentures made by three different methods of arranging posterior teeth: (a) according to Fish (concave flanges), (b) biometric guidelines and (c) following a piezographic record. Simultaneously, they recorded denture stability by means of cineradiography. They reported that dentures shaped according to Fish had the most unfavourable muscle balance and hence denture instability. Piezographically and biometrically constructed dentures were more favourable, although the results from the piezographically-made dentures were more inconsistent. The authors suggested that a combination of techniques may be useful: the use of biometric guides to arrange upper teeth and a piezograph to determine lower teeth positions. The limitation of this study is that only four patients were used.

Barrenäs & Ödman (1989) studied comfort and function during wearing of a conventional and NZ set of dentures in 30 patients. Feedback was obtained from patients and included criteria such as self-consciousness, a sense of security in company of others and food trapping. Ridge resorption was classified (slight, moderate, severe).

Twenty three patients preferred the NZ denture. There was consistently less complaining about food trapping under lower NZ dentures. Appearance was also improved by supporting lips and cheeks. Chewing was easier and more comfortable. The more resorbed the ridge, the stronger the preference for a NZ denture. Patients with well-preserved ridges reported less difference between the two dentures. A weakness of the study was that patients were given both dentures simultaneously which may have led to confusion.

In a randomized clinical trial, Fahmy & Kharat (1990) made NZ dentures and conventional dentures for ten patients. Two weeks after insertion, masticatory performance was tested. Mastication was statistically better for conventional dentures. However, when asked which of the dentures the patients preferred, all ten patients preferred the NZ denture. This was based on criteria such as the tongue feels at ease, the tongue fits better in the dentures, better and easier speech, more stability, and feels more secure. None of the patients could indicate superiority in terms of mastication.

Following a trial using 50 patients, Faber (1992) reported that the longer the period of edentulousness, the more buccal the NZ was to the crest. He used modelling compound and swallowing and pursing of the lips to record the NZ. This was done without the upper denture in the mouth, because it might distort the NZ record. A lingual silicone matrix was adapted to the NZ record and the denture teeth were set against the lingual-lateral border. The cross-arch width of the arch was measured from a point on the central fossa of the first mandibular molar teeth. For the anatomic method, the teeth were arranged with the central fossae over the crest of the ridge. The “physiologic” width was on average 2.72 mm wider than the anatomic width. In the female subjects, the mean reduction in anatomic arch width of 3.06 mm was 56% greater than the mean of 1.96 mm recorded for men. No trend could be found correlating the length of denture service and loss of lingual space. Unfortunately, this study did not include any information on the treatment outcome of either type of dentures.

Fahmi (1992) studied the NZ of 21 edentulous patients using a mandibular resin base to support an impression compound rim. Patients were instructed to swallow and suck with the softened rim in position. Different sized metal wires were bent and formed over the crest of the edentulous ridge of the cast and the buccolingual centre of the occlusal surface of the NZ recording. The rim was positioned on the cast and occlusal view radiographs were made for each patient. For persons that became edentulous recently (less than two years) the NZ recording conformed better to the crest of the residual ridge than the group of people who were edentulous for longer than two years. For the group edentulous for longer than two years, 20% of the assessed locations were on the crest of the ridge, 5% were lingual to the ridge and 75% were facial to the ridge. Fahmi (1992) also found that the NZ was located more labially for anterior teeth, contradicting postulations that the NZ moves more lingual as the residual ridge resorbs in this region. Ikebe *et al's*. (2006) results agreed with this finding.

Kawano *et al.* (1996) compared pressure on denture bearing tissue using dentures with teeth arranged over the crest of the residual ridge or buccal or lingual to it. They found that when posterior teeth were set on the ridge, the total pressure was lowest. Therefore, they recommended that teeth should be arranged over the crest of the edentulous ridge to avoid patient discomfort and decrease alveolar bone resorption. This is in line with the "biometric" approach of setting-up of teeth. However, the trial was done using only three patients and it is therefore too small to make general recommendations.

Miller *et al.* (1998) showed, in a study of five experienced denture wearers, that a lower denture with a piezographically produced lingual surface, enhanced tongue retentive ability. An oblique sublingual denture flange maximized the denture's retentive potential and minimized the adaptive burden for the patients. This was in agreement with the findings of a cineradiographic study published by Jooste & Thomas (1992a).

Miller *et al.* (1998) investigated the effect of differently shaped lingual flanges on the ability of patients to resist lifting forces on mandibular dentures. Five experienced edentulous denture wearers were given two types of mandibular denture analogues: one made by a piezograph technique, the second one approximating a more conventional profile. Three miniature pressure transducers were added to the denture analogues, one anteriorly at the midline and one each in the premolar area bilaterally.
Significantly higher pressures were needed to lift the piezographically formed denture analogue. They also found that the highest pressure exerted was on the anterior part of the denture analogues.

Makzoumé (2004) compared the buccolingual dimensions of two types of NZ impressions: one achieved by means of phonetics (using tissue conditioner), the other one by means of swallowing (using modelling impression compound). Generally, the phonetic method resulted in narrower NZ as compared to the swallowing method. With phonetics, the buccal surface was more lingually located. Weaknesses of the study were: Firstly, only nine patients were used for the study; secondly, different impression materials for the two techniques were used: tissue conditioner for phonetics and modelling impression compound for swallowing. The viscosity of the modelling compound may have been too great to be sufficiently modelled by the buccinator muscle; and thirdly, no dentures were made and delivered, and no patient feedback on preference was retrieved. While there was some statistical difference, no decisions on the clinical relevance could be made following this study. It is interesting to note that the only publication reporting a NZ position *lingual* to the crest of the alveolar ridge in the anterior, premolar and molar region was by Raja & Saleem (2010).

It has been speculated that the position of the NZ changes related to period of edentulousness. A fact is that duration of edentulousness influences the volume of residual ridge and as a result its shape (Karaagaçlioglu & Ozkan, 1994; Klemetti, 1996; Närhi *et al.*, 1997; Carlsson, 1998).

According to Lammie (1956), mandibular ridge resorption causes the mentalis muscle attachment to fold over the residual ridge and encroach on the NZ position. This would mean a more lingual positioning of the anterior teeth. However, according to Fahmi's (1992) report, this may only be true for the first two years of edentulousness. After that, the NZ is more labially located. A study by Raja & Saleem (2010), using modelling compound found that the midline of the NZ was located buccal to the alveolar crest in the molar and premolar region for patients edentulous less than two years. Edentulousness longer than two years caused a significant lingual shift of the NZ record. Unfortunately, no mention was made of the impression material used to record the NZ.

The majority of the results of the trials presented in this section seem to favour the construction of a lower denture according to the NZ concept. Limitations of these studies include the low number of participants, poor control and blinding, and often lack of patient-based feedback on treatment outcomes. Another complicating factor is the different methods and materials used in recording the NZ. The next sections will address these differences.

2.3.5.4. <u>Oral functions used for registering the neutral zone</u>

Muscular contraction and relaxation during oral functions such as chewing, talking, swallowing and facial expression shape the boundaries of the NZ (Cagna *et al.*, 2009). Forces exerted during these functions vary in magnitude and direction, differ among individuals and may also be age-related (Beresin & Schiesser, 1976). Therefore, it may be expected that NZ-recordings using different oral functions will generate slightly different shapes.

Swallowing and speech are two important oral functions. It is not surprising then that these two functions have been routinely recommended and used in making recordings of the NZ for the purpose of denture construction.

In a recent review on the NZ, Porwal & Sasaki (2013) reported more movements, beside swallowing and speech, such as sipping water, smiling, pouting, protruding and moving the tongue sideways.

Russell (1959) made patients whistle and grin using soft wax. Lott & Levin (1966) used phonetics by letting patients read aloud. This, together with swallowing of saliva during reading would naturally mould the NZ rims. Beresin & Schiesser (1976) advocated swallowing as the principle function. As previously mentioned, Makzoumé (2004) found that using speech as compared to swallowing produced narrower NZ recordings.
However, they also used different materials with the two different functions which may confound their results. Ladha *et al*. (2014) compared patient satisfaction with complete dentures fabricated using swallowing and phonetic NZ techniques and tissue conditioning material. They found a statistical difference in mean widths between the two techniques, but no difference in patient satisfaction. However, the swallowing technique was preferred by patients with regards to aesthetics, stability, comfort and ability to chew.

2.3.5.5. Materials used for registering the neutral zone

Materials such as modelling impression compound (Schiesser, 1964; Alfano & Leupold, 2001; Raja & Saleem, 2010) zinc oxide eugenol, wax (Russell, 1959; Lott & Levine, 1966; Walsh & Walsh, 1976), silicone material (Barrenäs & Ödman, 1989; Miller *et al.*, 1998; McCord & Grant, 2000), resilient reline materials (Neill & Glaysher, 1982; Fahmy & Kharat, 1990; Ladha *et al.*, 2014) and acrylic resins have been described (Porwal & Sasaki, 2013).

When making an impression of the NZ, two factors are important: the materials should be slow-setting and the NZ should be recorded at an appropriate OVD. Modelling impression compound and tissue conditioner materials have been popular choices for making NZ impressions (Porwal & Sasaki, 2013).

The advantage of thermoplastic modelling compound is its ease of use and low cost. Another advantage of using a thermoplastic material is that the shape can be softened again after excess material has been removed or additional material added until the desired record is achieved. This cannot be done when using a material such as a silicone putty impression material. The advantage of tissue conditioning material is its slow-setting; it is however expensive.

Lack of or excess bulk of material will affect the final piezograph. Ikebe *et al*. (2006) incrementally added tissue conditioning material onto a mandibular baseplate while patients were asked to produce specific sounds for 90 seconds. When adding material, the width of the tongue space decreased significantly, up to a point. The centre of the occlusal table was 1.5 to 1.9 mm buccal to the crest of the alveolar ridge in the molar region for all volumes used. They recommend that if teeth are wider than the recorded NZ, smaller teeth need to be selected or teeth modified. As mentioned earlier, Khamis *et al*. (1981) found that with vertical height increasing, the widths of the NZ shape also increased and *vice versa*.

In 1979, Karlsson & Hedegard studied the reproducibility of functional movement patterns for recording the NZ and the effect of the operator, different materials and methods on the dynamic impression. Two types of tissue conditioning impression materials supported by a central metal “keel” were molded by means of movements of lip, cheeks and tongue and speaking aloud. They also used different application methods (spatula or syringe) and different operators. Using the same technique and material, differences in flange forms were small and found to be clinically reproducible by different operators.

However, there were statistically significant differences among different materials and methods of application. A limitation of this study was that swallowing was not included in the functions.

Porwal & Sasaki (2013) recommend that the influence of the different materials on the NZ should be investigated by a comparative study. Only one study by Makzoumé (2004) was found comparing results from two different techniques. However, as mentioned earlier, their results may have been confounded by the different oral functions performed for each material.

Several publications report the use of rigid occlusal stops to maintain OVD during NZ recording (Lott & Levin, 1966; Razek & Abdalla, 1981). Others prefer not to use them because the presence of an opposing denture or baseplate with stops may distort the plastic functional impression material (Cagna *et al.*, 2009).

Entering the era of computer-aided-design and computer-aided-manufacturing (CAD-CAM), Goodacre *et al.* (2012) proposed a single visit of impression making, NZ recording and jaw registration before the three-dimensional (3D) shape is scanned and the digital data transferred to a CAD software program for designing, milling or 3D printing. The method they elected for NZ recording was by using a medium-body vinyl polysiloxane impression material and swallowing. No reason was given for the selection of this technique.

Finally, it remains unclear when the NZ recording is complete. Despite the many techniques and materials described, this remains a clinical decision by the operator.

2.3.6. Conclusions

Despite the lack of consistency in methodology of a specific NZ technique, a limited number of small clinical trials showed that NZ dentures appear functionally more stable than conventional dentures.

2.4. ORAL HEALTH-RELATED QUALITY OF LIFE

2.4.1. Introduction

Medical and dental treatment should not only aim to "add years to life" but also "life to years". Over the past 30 years, there has been growing recognition in medicine and dentistry that clinical measures of health need to be supplemented by patient-based outcomes (PBO) (Locker & Allen, 2007). When evaluating treatment outcomes in clinical trials, patient-based feedback is becoming increasingly important. There has been a growth in instruments to measure health-related quality of life (HRQoL) and oral health-related quality of life (OHRQoL).

In this chapter, some concepts related to HRQoL, ORQoL and denture satisfaction are explained. In addition, trial designs often used in assessing satisfaction and OHRQoL are summarized. Finally, variables that may impact on treatment satisfaction with complete dentures and OHRQoL are reviewed.

2.4.2. Definitions

Quality of life (QoL) is a broad concept and can be defined differently within the philosophical, political or health-related domains (Fallowfield, 2009). According to Fallowfield (2009), HRQoL involves the physical, functional, social and emotional well-being of persons. It is a patient-reported outcome and is measured by using validated instruments. One of the definitions for oral health reads as follows "*the extent to which oral disorders affect functioning and psychosocial well-being*" (Locker *et al*., 2000) and "*the symptoms and functional and psychosocial impacts that emanate from oral diseases and disorders*" (Locker *et al.*, 2002). Sischo & Broder (2011) describe OHRQoL as "*an individual's subjective assessment of his or her oral health and functional and emotional well-being*".

The ultimate aim for rehabilitating a chronic condition such as edentulousness is improvement of the OHRQoL of the edentulous patient, rather than cure. Therefore, assessment of treatment outcomes by means of patient-based feedback is important. This becomes all the more obvious when it is understood that: a) there is a poor correlation between clinical variables and patient satisfaction (van Waas, 1990a), b) the quality of the denture-bearing tissue is a poor predictor for patient satisfaction (Heydecke *et al.*, 2003a), and c) there is a poor agreement between patients and prosthodontist when rating dentures (Heydecke *et al.*, 2003a).

Although OHRQoL and denture satisfaction are in essence not capturing the same outcomes (Allen *et al.*, 2001a), several papers demonstrated a strong positive association between denture satisfaction and OHRQoL (Veyrune *et al*., 2005; Ha *et al.*, 2012; Michaud *et al*., 2012; Stober *et al.*, 2012; Viola *et al.*, 2013). However, causality that patient satisfaction predicts OHRQoL could not be proven (Stober *et al.*, 2012). This led to the assumption that more than denture satisfaction alone influences OHRQoL.

2.4.3. OHIP-20 as an instrument and its use to measure treatment outcomes in the rehabilitation of edentulousness

A variety of instruments have been used to measure outcomes of CD treatment (Carlsson, 1998). These can be divided in two major categories: 1) objective measures, such as denture quality and mastication efficacy as assessed by the operator and 2) subjective measures which are PBO such as comfort, satisfaction and OHRQoL. In the latter category, visual analogue scales as well as special questionnaires have been developed and used. Unfortunately, due to innumerable variations and scales used to measure treatment outcomes, results are difficult to review systematically.

In 1988, Locker proposed a theoretical model aiming to explain the consequences of oral disease on QoL of patients. This model was built on 5 domains: functional limitation, pain or discomfort, disability, injury and handicap.

Since then, OHRQoL can and is being used in clinical studies to measure the impact of oral conditions or treatment interventions on a person's well-being (Strassburger *et al.*, 2006). For this purpose, several instruments were developed. One of them is the Oral Health Impact Profile (OHIP-49), developed by Slade & Spencer (1994). The OHIP-49 consists of 49 questions, divided into seven domains based on Locker's 1988 model. However, the length of the instrument would be cumbersome in clinical settings, and some reduced versions were developed for specific clinical conditions.

A shorter version, the OHIP-20 was developed from the OHIP-49 using an item impact reduction method (Allen & Locker, 2002). The OHIP-20 consists of 20 questions with similar discriminant properties to the full OHIP-49; the seven domains covered by this 20-item inventory are: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. The validity and reliability of this questionnaire as an OHRQoL measuring instrument have been confirmed (Awad *et al.*, 2003; Slade & Spencer, 1994). For the edentulous scenario, it appeared to measure change as effectively as the 49-item OHIP (Allen & Locker, 2002). Initially, weights were allocated to items on the longer and shorter OHIP-versions. However, it was shown that simple additive scoring was as good for patient assessments (Allen & Locker, 1997). The instrument can be self-administered or completed face-to-face by an interviewer. Evidence suggests that the method of delivery has no major impact on total scores (Slade *et al.*, 1992).

Locker (1998b) drew attention to the difference between statistical and clinical significance. While results from functional, psychosocial or psychological scales may show statistical significant changes, these changes may not be large enough to be of clinical relevance to the patient.

An overreliance on *p*-values from statistical tests and a failure to recognize whether or not these changes are clinically relevant can be misleading when assessing benefit of a particular intervention or treatment (Locker, 1998b). There is no universally accepted method of measuring change (Allen & Locker, 2002). A common concept is the use of "effect size" (ES). Effect size statistics provide a means of recognizing change that may be clinically meaningful. It is calculated by dividing the mean of difference in pre- and post-treatment scores by the standard deviation of the pre-treatment score. Clinically, meaningfulness can be rated as follows: 0.2 = small; <0.6 = moderate; >0.8 = large (Cohen, 1988 in: Allen *et al.*, 2001a). The standardized ES is the most popular distribution-based approach and has been endorsed by the Cochrane Collaboration for meta-analysis (Masood *et al.*, 2014).

By means of an analysis, Sato *et al.* (2000) identified seven variables related to denture satisfaction: chewing, speech, pain (upper), aesthetics, fit (upper), retention (lower) and comfort (upper). These variables cover the major purposes of prosthodontic rehabilitation, namely restoring form and function. These variables are also covered by the domains captured in the OHIP-20 questionnaire. Gjengedal *et al.* (2011) found that maxillary denture aesthetics is significantly associated with denture satisfaction. Although aesthetics or appearance is not a pertinent question asked in the OHIP-20 questionnaire, patients' opinion on appearance may influence their scores in the psychological and social domains.

2.4.4. Methodology of clinical studies

The information in the previous section must be interpreted within the context of the methodologies and the limitations of clinical studies. A summary of the strengths and limitations of clinical study designs will be given in this section.

A complicating factor in assessing literature comparing different treatment modalities, such as conventional dentures and implant overdentures, or in fact any two or more different treatment modalities, are the different study designs and instruments used. Some of the instruments or measures used may not even be appropriate for the research question to be answered (Locker, 1998b).

In terms of design, the *cross-sectional* study is the simplest, but it lacks a longitudinal component. Pre-treatment scores are unknown and changes in health status cannot be measured. For example, in studies comparing implant overdentures and conventional dentures, it is unlikely that the two patient groups had a similar degree of dissatisfaction or dysfunction before treatment.

The *retrospective* study relies on the memory of patients to obtain data on pre-treatment levels of satisfaction, functioning or well-being. The further back the retrospective study, the more problematic reliability of pre-treatment scores becomes. *Prospective studies* are longitudinal. Data are collected at 2 points in time, e.g. before and after intervention. With a *within subject cross-over* strategy, each patient receives both treatments and interventions to be compared. This increases the sensitivity of the measurements meaning that fewer patients are required to detect an effect (Spilker, 1991 in de Grandmont *et al.*, 1994). There are specific requirements for a cross-over design: firstly, the treated condition must be chronic and secondly, carry-over effects must be minimal (Spilker, 1991 in de Grandmont *et al.,* 1994).

Randomized controlled trials (RCTs) are regarded as the gold standard and can provide strong evidence of the effects of an intervention (Locker, 1998b). The CONSORT 2010 Statement provides guidance in developing and reporting RCTs (Schulz *et al., 2010*). Randomized controlled trials most often use two (or more) parallel groups. However, the issue of patient preference may reduce blanket applicability of the results. For example, patients not receiving their treatment of choice may decide not to participate, be non-compliant or drop out. Alternatively, their disappointment may be reflected in their satisfaction rating (Awad *et al.,* 2000b). This is of importance in trials where patients cannot be blinded to the treatment option offered.

2.4.5. Influence of psychosocial factors and expectation on denture satisfaction and OHRQoL

Success with complete denture treatment depends on the patient's ability to adapt to the limitations of complete dentures (Carlsson, 1998). Acceptance of complete dentures is difficult to predict (Allen & McMillan, 2003a).

Although results from studies are inconsistent, personality type, patient-dentist relationship, social factors, and attitude towards removable dentures appear to play a role in achieving denture satisfaction (Baer *et al.,* 1992; Brunello & Mandikos, 1998; Sheiham *et al*., 1999). Some studies related neuroticism to poorer denture satisfaction (Fenlon *et al.,* 2007; Al-Omiri & Karasneh, 2010).

Social and cultural norms and socio-political events to which populations are exposed may shape behaviour and perceptions of health for entire cohorts (Steele *et al.,* 2004). They found that cultural factors, and even place of birth, influenced OHIP scores.

There is disagreement in the literature regarding the relevance of psychological assessment and how patients judge dentures. Bellini *et al*. (2009) tried to establish if patients' locus of control (external or internal) had an influence on expectation and satisfaction with complete dentures.

Using a locus of control questionnaire and visual analogue scales for expectation and satisfaction scoring, they could not establish a statistically significant correlation. This is in agreement with the earlier findings of van Waas (1990c) who found no correlation with locus of control and denture satisfaction. Sivakumar *et al.* (2014) could also not prove that patients' initial expectations had a significant influence on OHRQoL. According to Emami *et al.* (2009a) individual-based coping characteristics such as "sense of coherence" do not help to resolve problems caused by inadequate prostheses.

Increasingly, patients expect to take part in decisions about their health care. When presented with different treatment options, patients may have a preference for a particular option. Feine *et al.* (1998) reported that emotional response of patients being allocated to a particular treatment group which may, or may not, be their preference, strongly influenced their treatment response. As mentioned earlier, this may be of concern in trial designs. Comparing impact scores of groups of patients restored with implant-retained or conventional prostheses, edentulous subjects who received the treatment of their choice reported significantly better improvement in their OHRQoL than those who did not (Allen & Mc Millan, 2003a), regardless of the treatment option itself. Feine *et al.* (1998) reported that level of education is a strong indicator for expressing a preference or no-preference for different treatment options.

The dentist-patient relationship has been proven to influence the subjective judgement of complete dentures, at least for the first two years following prosthetic treatment (Friedman *et al.*, 1988).

De Baat *et al.* (1997) recommend that this is a domain deserving more attention from the dental practitioner and allude to the fact that practitioners can influence denture satisfaction by how patients judge the holistic treatment experience provided by their dentists.

When adapting to other body part prostheses, patients are often assisted by professional services such as physiotherapy or occupational therapy. As a rule, comprehensive and specific care to patients who struggle to adapt to oral prostheses is not provided by dental care services (Bellini *et al.,* 2009). Aspects that are often neglected or even ignored when rehabilitating edentulous patients with complete dentures are advice on nutrition, hygiene, nocturnal wear and speech therapy.

Fromentin & Boy-Lefevre (2001) reported that pre-treatment expectation and attitudes are limited in predicting treatment success. They generally found high post-prosthetic treatment satisfaction rates. It remains important though, to pay attention to patients' preferred treatment option.

What is regarded as the "optimal" treatment option for a particular condition by the clinician may not be what his or her patient prefers or expects. Allen & McMillan (2003a) found that patients who requested and received their treatment of choice reported a significantly higher improvement in satisfaction and QoL compared to those who did not.

2.4.6. Influence of gender, age and denture experience on denture satisfaction and OHRQoL

There may be differences in how male and female patients rate dentures. Panek *et al.* (2006) found that men adapt more easily to dentures. A randomized controlled trial by Pan *et al.* (2008) revealed that female patients rated overall satisfaction lower than males, particularly for aesthetics and chewing ability. This trend was confirmed by a retrospective patient record review by Divaris *et al.* (2012b).

Others again, could not find a relationship between gender and denture satisfaction (Weinstein *et al*., 1988; Brunello & Mandikos, 1998). On the other hand, Sivakumar *et al.* (2014) found a significant difference in mean OHIP-Edent scores between gender, with female patients experiencing a better OHRQoL.

It is generally accepted that older patients' ability to adapt to new dentures is reduced and that this may negatively influence patient satisfaction. However, Steele *et al*. (2004) stated that, as people age, changes in perception and values may have an influence on QoL. Assessed independently, the variable "age" resulted in fewer negative impacts on QoL, than did the variable "tooth loss" when using OHIP (Steele *et al.,* 2004). Allen & McMillan (2003a) reported that older denture wearers tend to have more functional problems.

Denture experience seems to influence denture satisfaction. Weinstein *et al.* (1988) found that patients receiving their first dentures had more difficulties with function, comfort, and appearance than patients with denture experience. Van Waas (1990c) found that people who were edentulous for a longer time were more satisfied with their dentures. In a survey by Divaris *et al.* (2012b) patients satisfied with their CDs had been edentulous for longer (median 7 years) as compared to the dissatisfied group (median 4 years).

2.4.7. Influence of "prosthetic condition" on denture satisfaction and OHRQoL

There is a level of disagreement about the influence of the quality of the dentures and supporting tissues on the PBOs.

The term "prosthetic condition" of a patient was coined by de Baat *et al*. (1997): it combines the quality of the complete dentures with that of its supporting tissues. By means of inter-observer agreement they identified several variables of dentures and supporting tissues, important when assessing their quality.

These variables for the dentures were: occlusion (maximal contact in CR), retention of the maxillary denture, retention of the mandibular denture, and stability of the mandibular denture.

The variables for both mandibular and maxillary ridges were: anatomy, fibrous hyperplasia and hypermobility. De Baat *et al.* (1997) consequently tried to find a relationship between the combined scores of these variables ("prosthetic condition") and patients' complaints and satisfaction. None of the variables of the "prosthetic condition" could be correlated with patients' complaints. This demonstrates the issue that patients' judgement of dentures has poor correlation with the prosthetic condition.

Heydecke *et al.* (2003a) confirmed that the quality of the denture-bearing tissue is a poor predictor for patient satisfaction, and that patients and prosthodontist often don't agree when rating the quality of dentures.
Pan *et al.* (2010) tested the effect of mandibular bone height on the satisfaction and function of 107 patients treated with conventional dentures at a six-month recall. They could not associate bone height and chewing ability with satisfaction ratings.

Brunello & Mandikos (1998) could confirm that, in most instances, real design faults or tissue problems were the reason why CD patients presented with complaints. They found no relationship between age, gender, medical and psychological status with the type or number of complaints.

A study by Ellis *et al.* (2007) comparing patient satisfaction following the construction of new dentures or simply duplicating the existing dentures, found that the pre-treatment scores of the patients initially screened to receive new dentures were higher than those who were screened to receive duplicate dentures. This may point to some ability of the referring clinician to differentiate between levels of correctness of dentures.

Severe RRR is associated with poor mandibular denture stability and retention (Tallgren, 1972; Allen & McMillan, 2003b; Huumonen *et al.*, 2012), especially among women (Huumonen *et al.*, 2012; Joo *et al.*, 2013). Poor denture stability is associated with poor denture satisfaction (Huumonen *et al.*, 2012).

On the other hand, Kurushima *et al.* (2015) compared pre-and post-treatment OHIP scores of groups of patients (31 in total) with "severe' and "moderate" edentulous conditions. Pre-treatment OHIPs of the two groups differed significantly. Pre- and post-treatment OHIPs of the "severe" group also differed for the "severe" group, but not for the "moderate" group. This suggests that patients with "severe" edentulous conditions achieved the same level of OHRQoL after treatment with CDs. Yamaga *et al*. (2013) reported that a favourable oral condition and denture quality were positively associated with patients' perceived chewing ability, denture satisfaction and OHRQoL using the OHIP for edentulous persons. Palac *et al.* (2013) demonstrated a correlation between changes in cephalometric angles and forward shifting of the mandible with loss in OHRQoL. Michaud *et al.* (2012) demonstrated that chewing ability and oral condition were clear determinants for denture satisfaction. They also found that denture satisfaction and OHRQoL were highly positively associated.

Since outcomes of prosthodontic interventions are not reliably assessed by clinical measures, Van Waas, (1990c) warned dentists to be cautious when counselling patients about anatomic conditions and their possible relationship with denture satisfaction. Problems with dentures can occur in people with good denture bearing tissues (Van Waas, 1990c).
On the other hand, optimism at the beginning of treatment may positively influence denture satisfaction despite poor tissue conditions (Van Waas, 1990b).

2.4.8. Conclusions

The previous section highlighted the complexity in assessing patient satisfaction and OHRQoL concerning rehabilitation with complete dentures. Even though many patients experience increased levels of denture satisfaction and OHRQoL, there is a paucity of research in the area of prognostic indicators for this type of treatment.

From the best available data, construction of technically correct dentures, a well-formed mandibular ridge and accuracy of jaw relations appear to be positive indicators for success. Patient neuroticism and a poorly-formed mandibular ridge are negative indicators for success. Other prognostic indicators have not been shown to be of significant value. There exists a minority of patients who will never adapt to any conventional complete denture. This problem is more acute in the mandible than the maxilla. There is need for further research in this area. Worldwide, the need for conventional complete denture treatment will persist, especially in regions that suffer from socio-economic and developmental disadvantages. There is a paucity of high level scientific evidence based on clinical trials, concerning several removable prosthodontic treatment strategies, one of those being strategies based on the NZ concept for mandibular CDs. Assessment of patient satisfaction and OHRQoL following treatment is considered to be an important issue when interventions are being assessed, but remain complicated to interpret due to the many variables that may influence PBOs. Several instruments have been developed, of which the OHIP and its shorter version the OHIP-20 have become accepted as valid tools.

CHAPTER 3: AIM, HYPOTHESES AND RESEARCH QUESTIONS

3.1. AIM

The aim of this study was to perform a clinical trial comparing 'neutral zone' (NZ) and 'anatomic' (ANA) mandibular dentures, based on the transverse dimensions of the two types of dentures and their respective impact on the OHRQoL of patients.

The main objectives of this study were:

1. To compare transverse widths of mandibular dentures made following the neutral zone concept and following biometric principles.
2. To assess patients' OHRQoL following treatment with these two types of dentures, using the OHIP-20 instrument.
3. To make associations between denture dimensions, OHIP-20 scores, period of edentulousness, quality of the denture-bearing tissue, preference, age and gender.

3.2. NULL-HYPOTHESES

The null-hypotheses were as follows:

- Null-hypothesis 1: There is no difference in the transverse width of NZ and ANA mandibular dentures.
- Null-hypothesis 2: None of the two types of mandibular dentures improve OHRQoL.
- Null-hypothesis 3: Treatment with NZ dentures has no larger impact on OHRQoL than treatment with ANA denture.
- Null-hypothesis 4: There is no relationship between denture dimensions, OHIP-20 scores, period of edentulousness, quality of the denture bearing tissue, preference, age and gender.

3.3. RESEARCH QUESTIONS

The research questions were as follows:

1. Is there a difference in transverse width between anatomically and physiologically determined positions of posterior mandibular denture teeth, and how do these positions relate to the mandibular alveolar crest?
2. How do the two types of mandibular dentures impact on summary as well as on domain scores of the OHIP-20?
3. What is the treatment “effect size” (ES) for both types of dentures, as well as the difference in ES between the two new dentures?
4. What is the relationship between the period of edentulousness and difference in OHIP-20 scores?
5. What is the relationship between the quality of the denture-bearing tissue and OHIP-20 scores of existing dentures as well as those of the two new dentures?
6. What is the relationship between the quality of the denture-bearing tissue and differences in widths between the two types of mandibular dentures?
7. What is the relationship between difference in width of the two types of dentures and the period of edentulousness?
8. What is the relationship between the difference in denture widths and the prevalence of cross-bites?
9. What is the relationship between socio-demographic data of patients (gender, age, education, marital status) and OHIP-20 scores?
10. Is there patient preference for ANA or NZ denture sets?
11. What is the influence of gender, period of edentulousness, age and quality of denture-bearing tissues on denture preference?
12. What is the relationship between denture preference and OHIP-20 scores?
13. What is the effect of treatment sequence on OHIP-20 scores?
14. Is there a difference in number of recall interventions for the two types of denture sets?
15. What is the patient-feedback following treatment of the two types of dentures?

CHAPTER 4: METHODOLOGY

4.1. INTRODUCTION

The proposal for this clinical trial was approved by the Senate Research Committee of the University of the Western Cape (4 Feb 2011 - Project registration no. 11/1/49) (Addendum 1). The University provided financial assistance for dental materials and statistical service.

All patients were treated at the Oral Health Centre, Tygerberg Campus, by a single clinician (the author of this dissertation). All related laboratory and technical procedures were also performed by the author.

All patients that volunteered to participate were verbally briefed regarding the nature of the trial, in particular in terms of additional clinical procedures requiring extra visits, compared to routine treatment offered to patients accepted in the mainstream prosthetic clinics. Before being accepted in the trial, patients had to sign a written informed consent form, informing the patient of the key issues of the trial (Addendum 2).

The cost of the treatment was according to rates as determined by the Provincial Government of the Western Cape for a set of complete dentures and associated procedures. The second set of dentures was made without additional clinical cost to the patient. However, cost in terms of transport and time associated with additional visits for the second set of dentures was carried by the patient.

4.2. DESIGN OF THE TRIAL

4.2.1. Introduction

This study was a prospective, randomised, single-blinded (patient), within-subject crossover clinical trial. Because of the cross-over design, the patients acted as their own control.

Screening sessions, during which edentulous and partially edentulous patients are screened for future prosthetic treatment at the Tygerberg Oral Health Centre, happen on a weekly basis. These screening sessions were used to recruit patients for this trial. All patients who satisfied the inclusion and exclusion criteria were selected for the trial (Table 4.1). Selecting patients did not take place at each weekly screening session, but whenever enrolment capacity became available. This was done to avoid the creation of a waiting list. From start (signing of informed consent) to completion (returning for the last and final OHIP-20) covered a period of at least 23 weeks. Near the end of the trial, additional patients were screened with the aim to correct patient attrition during the project and to balance gender.

Table 4.1. Patient inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Between 40 – 75 years old	Signs or symptoms of TMD
Edentulous	Oral pathology
Currently wearing dentures	Parafunction
Requiring new dentures	Xerostomia
Able to read, understand and respond to the OHIP-20 instrument (in English)	Orofacial motor disorders
Informed consent given	Severe oral manifestations of systemic disease
Ability to attend 9-10 visits	Psychological or psychiatric conditions that could influence response to treatment
	Patients wanting dental implants

Signs or symptoms related to TMD and parafunction were the following: pain in or around temporomandibular joint, pain of masticatory and associated muscles, abnormal jaw movements, joint noises, pain or stiffness of the jaw upon awakening and abnormal wear patterns of existing dentures.

These signs or symptoms were reported by the patient over the past month or noticed on examination.

Two sets of complete dentures were constructed for each patient. One set was made following anatomic criteria for constructing complete mandibular dentures; the second set of dentures was made following a functional impression of the potential mandibular denture space. Patients were randomised to receive one of the two treatments first, by means of a “lucky draw”: patients picked one of two folded papers each with the abbreviation of the two types of dentures (“ANA” or “NZ”) written inside. Near the middle of the trial, the sequence was reversed so that an equivalent number of NZ and ANA dentures were worn first.

After completion of all immediate post-insertion visits, each set of dentures was worn for at least eight weeks to minimize carry-over effects (de Grandmont *et al.,* 1994; Sutton & *et al*., 2007). The patients were blinded to the set of dentures worn and were not informed on the nature of the difference between the two sets of dentures, if there were any.

4.2.2. Piloting of the trial and power analysis

A pilot study was performed to test the clinical and laboratory procedures. The clinical and laboratory protocol will be explained in a following section.

A power analysis was done twice to determine and confirm sample size to enable statistical comparisons of the OHIP-20 scores. The first power analysis was done after the collection of the three OHIP-20 questionnaires of the first four patients. It was done as follows:

A one sample *t*-test was used. The basis for the test was to reject the hypothesis that there is no difference between OHIP-20 scores of ANA and NZ dentures if the observed mean falls outside the interval $(-z\sigma/\sqrt{n}, +z\sigma/\sqrt{n})$, where: z was chosen according to the desired significance level, typically approximately 1.96 or 1.645, σ was the standard deviation of the differences, n was the sample size.

The power of the test depends on the value of σ. This was 10.3 for the first four patients. If the true mean (ANA-NZ) difference was $\Delta > 0$, then for moderately large n, the power of a one-sided test at level 0.05 was: $Pr[D > 1.645\sigma / \sqrt{n} IE[D = \Delta] = 1\ \Phi\ [1.645 - \Delta \sqrt{n}/\sigma]$ where Φ is the standard normal c.d.f. Suppose that $\sigma = 10$, $\Delta = 5$, $n = 50$, then the power was 0.97. Inverting the formula gave the sample for a specific power. For example, if $\sigma = 10$, $\Delta = 5$, power is 0.9, then the required sample size was 34.

The second power analysis was done after the completion of the OHIP-20 of 21 patients. It was done as follows: again, an estimate of the standard deviation of the differences in the score for the two methods (ANA and NZ) was obtained. The point estimate of the difference was about 13 and an 80% confidence interval estimate was about 11-16. The parameters of the test are shown in Table 4.2.

Table 4.2. Fixed scenario elements for the power procedure

The Power procedure One-sample *t*-test for mean	
Fixed Scenario Elements	
Distribution	Normal
Method	Exact
Number of sides	2
Nominal power	0.8
Null mean	0
Alpha	0.05

A clinically meaningful mean difference between OHIP-20 scores (ANA-NZ) was arbitrarily determined in the vicinity of five to seven. This estimate was arrived at as follows: the post-treatment OHIP-20 of the first 21 patients was compared to the “preference” of the patients. The difference in OHIP-20 between the NZ and ANA denture was considered valid if the preference of a denture corresponded with a lower OHIP-20 impact score. It was considered invalid if a patient’s preference for a particular denture did not correspond with a lower impact score for that denture. The mean of the “non-valid” OHIP-20 differences was 4.71.

The mean of the valid OHIP-20 differences was 10.96. Therefore, it was decided that a difference in OHIP-20 score between these two values represented a threshold beyond which patients could not discriminate which denture they preferred. With these values in mind, nine different scenarios were looked at: mean differences of 5, 7.5, and 10 and standard deviations of 11, 13, or 16 and a two-sided alternative with a paired *t*-test having a power of 80% (Table 4.3). Taking a 'middle' scenario with a mean difference of 7.5 and a standard deviation of 13, the required sample size would be 26. Based on a more conservative estimate of the standard deviation of 16, the sample size would need to be 38. Smaller numbers would be needed to detect a difference in means of 10.

Table 4.3. Different scenarios of mean, standard deviation, power and sample size

Computed n total				
Index	**Mean**	**SD**	**Actual power**	**n total**
1	5.0	11	0.800	40
2	5.0	13	0.807	56
3	5.0	15	0.802	73
4	5.0	16	0.803	83
5	7.5	11	0.802	19
6	7.5	13	0.807	26
7	7.5	15	0.808	34
8	7.5	16	0.803	38
9	10.0	11	0.817	12
10	10.0	13	0.820	16
11	10.0	15	0.807	20
12	10.0	16	0.817	23

SD = standard deviation

According to Table 4.3, based on a power calculation using 24 patients, assuming that a difference in OHIP-20 score of 7.5 would be of clinical significance, and a standard deviation of 15, a sample size of 34 was appropriate (yellow highlight in Table 4.3). These parameters and sample size were selected for the trial. The pilot sample was included in the trial.

4.2.3. Data collection

4.2.3.1. OHIP-20 questionnaires

Each patient completed OHIP-20 questionnaires three times: 1) pre-treatment, when wearing their existing prostheses, 2) after wearing their first set of new dentures, 3) after wearing their second set of new dentures.

The first OHIP-20 was completed with the investigator present so that any uncertainties concerning the questionnaire could be addressed. The consecutive two OHIP-20 questionnaires were self-administered in the absence of the investigator. After completion of each of the latter two OHIP-20 questionnaires, the patient placed them in an envelope and sealed it.

The patients were re-assured about the fact that the investigator was blinded to the results up until the completion of the trial. The envelopes were only opened after completion of the trial. A copy of the OHIP-20 questionnaires is given in Addenda 3 and 4.

When delivering the second denture, the first denture was temporarily withheld so that patients could not mix the two sets of dentures.

4.2.3.2. Denture dimensions

The following data were collected for analysis of the transverse widths of the two types of dentures. The protocol will be described in detail later.

1. The length of the mouth measured on the definitive cast.
2. The arch width of the residual ridge measured on the definitive cast, along lines 0, 5, 10, 15, 20, 25, 30, 35 and 40.
3. The widths of the ANA and NZ wax trial dentures along the same lines 0, 5, 10, 15, 20, 25, 30, 35 and 40.
4. Images of the NZ and ANA wax trial dentures layered over the image of the cast.

4.2.3.3. Additional data

Besides the routine medical and dental history taking and oral/dental/radiological examination, the following data for the purpose of the trial were recorded before treatment started:

1. General biographic and socio-demographic data.
2. Denture wearing history (period of edentulousness, number of dentures, immediate dentures, age of current dentures, main complaint, additional complaints).
3. Shape of the mandibular and maxillary residual ridge and degree of ridge resorption.
4. Condition of the mucosa over mandibular and maxillary ridge (firm, resilient, flabby).
5. The quality of the denture-bearing tissue was the result of both scores. Higher score means a more favourable tissue; lower score means a less favourable tissue (Kapur, 1967).

The data collection sheet is shown in Addendum 5.

4.2.4. Clinical and laboratory procedures

4.2.4.1. Treatment sequence and materials

All the clinical and laboratory procedures were performed by the researcher, except the duplication of the definitive casts. Duplication of casts was performed by the Dental Services Department of the Cape Peninsula University of Technology.

The sequence of the clinical and laboratory procedures is tabulated in Table 4.4.

Table 4.4. Sequence of the clinical and laboratory procedures

Visit	Clinical work	Laboratory work
1	• Medical and dental history • Dental / oral / radiological examination • Check inclusion/exclusion criteria • Tissue conditioning or diagnostic dentures if needed. It was important to restore occlusal vertical dimension (OVD) as good as possible to facilitate NZ technique • Standard primary impressions with stock trays and irreversible hydrocolloid impression material.	• Manufacturing of primary casts in plaster of paris and special trays using light-cure acrylic resin (depending on clinical situation a close fitting/spaced or combination tray).
2	• Selective muco-compression definitive impressions on mandibular primary support areas (buccal shelves) using special trays. • Functional border molding with impression compound followed by zinc oxide eugenol impression • If necessary, a zinc oxide eugenol wash impression was performed.	• Boxing and pouring of definitive impressions in yellow stone • Duplication of casts: the mandibular cast twice, the maxillary cast once. • Wax record rims made on the duplicate casts.
3	• Jaw registration with wax record rims using standard clinical procedures • Selection of denture teeth.	• Articulation of casts on average value articulator. • Making of ANA wax trial denture • Making of mandibular autopolymerizing acrylic resin base with a rim of modelling compound on top.
4	• Try-in of the ANA wax trial denture • Neutral zone impression using modelling compound rim on resin base.	• Fabrication of a silicone index capturing the position of the upper 6 anterior teeth. Upper 6 anterior teeth set-up in identical 3dimensional position as the first denture • Silicone lingual and facial NZ indices were manufactured for the mandibular NZ-recording • Set up of the 6 lower anterior teeth in similar interincisal relationship as the first set of dentures • Set-up of lower posterior teeth in NZ using the indices • Set-up of upper posterior teeth.

Visit	Clinical work	Laboratory work
5	• Try-in of NZ wax trial dentures • Reduction of facial and lingual surfaces between teeth and denture borders • Verification impressions of facial and lingual surfaces of mandibular dentures using zinc oxide eugenol impression material.	• Finishing of 1 of the wax trial dentures.
6	• Delivery of first set of dentures • Clinical remount	
7	• Recall visits as needed.	
		• Finishing of second set of dentures.
8	• After a minimum of 8 weeks, completion of OHIP-20 • Delivery of second set of dentures • Clinical remount.	
9	• Recall visits as needed.	
10	• After a minimum of 8 weeks, completion of final OHIP-20 • Returning of first set of dentures to the patient.	

A list of materials and equipment used is provided in Addendum 6.

In the following paragraphs, some of the clinical and laboratory procedures are described in more detail.

4.2.4.2. Guidelines for setting-up denture teeth for anatomic dentures

For the ANA trial denture, the position of the upper anterior teeth was guided by a combination of aesthetics (lip support, smile-line and midline), phonetics, occlusal plane, facial features, patient preference and existing dentures. The lower anterior teeth were arranged establishing an appropriate inter-incisal relationship and taking cognisance of the shape and position of the anterior segment of the lower residual ridge. The posterior mandibular teeth were arranged according to the modified Pound’s triangle and occluding with the flat occlusal plane of the upper record rim.

The modified Pound's triangle was formed by connecting the cusp tip of the canine with the anterior tip of the retromolar pad lingually and the facial external border of the retromolar pad. No compensating curves were incorporated, following a flat occlusal plane ("monoplane") (Williamson *et al.*, 2004). Thereafter, the remaining maxillary posterior teeth were placed.

4.2.4.3. Neutral zone impression

For the NZ impression, a greenstick impression compound rim on top of an auto-polymerizing acrylic resin baseplate was fabricated to conform to the general shape of the mandibular residual ridge as well as the occlusal plane and occlusal vertical dimension as determined on the articulated casts. It was placed in the mouth to assess fit and comfort. The NZ impression was done according to Cagna *et al*. (2009): The resin baseplate with the impression compound rim was placed in a thermostatically controlled warm water bath set at a temperature of 51°C until the rim was soft. The softened NZ baseplate with rim was inserted in the mouth without distorting the soft rim material and the patient was asked to drink warm water (51°C), while controlling the baseplate in position on the mandible. After several sips of warm water, the patient repeated the action with water at room temperature until the rim felt firm. The baseplate and rim were removed from the mouth. The external surfaces were assessed for adequate contouring by the surrounding oral tissue (matt appearance) (Figure 4.1).

Figure 4.1. Acrylic baseplate with greenstick compound rim modelled by the patient

The baseplate with rim was repositioned in the articulator and excess material preventing the articulator to close into the previously determined OVD was removed with a knife. In the case of inadequate molding or material, additional modelling compound was added. The NZ impression technique was repeated until successive recordings produced similar shapes, with an acceptable OVD (Figures 4.2 and 4.3). During the NZ impression recording, the upper wax trial ANA denture was not in position to avoid compressive interference and distortion upon occlusal contact.

Figure 4.2. Baseplate with rim repositioned in articulator at previously determined OVD against the ANA wax maxillary trial denture

Figure 4.3. Occlusal view of the occlusal rim after minor adjustment to conform to previously determined OVD

4.2.4.4. <u>Guidelines for setting-up denture teeth for neutral zone dentures</u>

The maxillary six anterior teeth were set-up using a silicone index molded against the six anterior teeth from the ANA wax trial denture to achieve an identical 3-dimensional position for the NZ denture.

Lower silicone lingual and facial NZ indices were manufactured (Figure 4.4) to guide the set-up of the posterior mandibular teeth (Figure 4.5).

Figure 4.4. Silicone indices adapted to the lingual and facial surfaces of the NZ record

Figure 4.5. Mandibular denture teeth set-up within the confines of the silicone indices

The lingual index was molded, so that it completely filled the tongue space and was level with the occlusal plane of the NZ rim (Figure 4.6).

Figure 4.6. Lingual index level with the occlusal plane of the NZ record

The indices were extended onto the land area of the casts so that they could be replaced accurately without the NZ record in place (Figure 4.7).

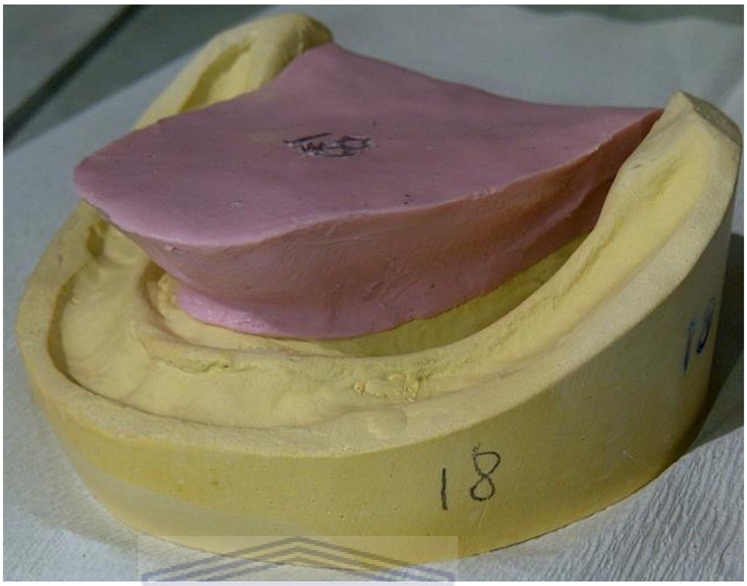

Figure 4.7. Lingual index without NZ record

The lower six anterior teeth were set up in a similar inter-incisal relationship as the ANA wax try-in denture while also fitting inside the boundaries of the neutral zone space (Figure 4.5).

The posterior mandibular denture teeth were set up with their occlusal table level with the occlusal plane of the NZ index (Figure 4.8). The lingual surfaces of the posterior mandibular teeth contacted the lingual index.

Figure 4.8. The mandibular posterior teeth touching and level with the occlusal plane of the index and touching

After the placement of the mandibular teeth, the maxillary teeth were set-up. It was attempted to have the width of the maxillary dentures in the posterior segments the same. This resulted in a cross-bite from time to time.

The same denture teeth were used for both sets of dentures.

4.2.4.5. Verification impression

Zinc oxide eugenol (ZOE) (SS White) verification impressions of the facial and lingual surfaces of the wax trial NZ denture were made. A layer of wax was removed from the cervical area up to the periphery of the dentures facially and lingually to provide space for the verification impression material. A layer of ZOE impression material was applied to the facial external surfaces and the patients were instructed to purse the lips, smile broadly, protrude the mandible, and move the mandible from side to side (Cagna *et al.,* 2009). Patient instructions for the verification impressions are given in Addendum 7. These movements were repeated until complete setting of the impression material. The trial denture was removed from the mouth and material protruding beyond the occlusal plane was removed (Figure 4.9).

Figure 4.9. Facial aspect of verification impression

Consequently, ZOE impression material was applied to lingual surface and the patient was given water to drink. The patient regularly took sips and swallowed the water, extended the tongue and moved it from side to side, and licked the upper and lower lips. These actions were repeated until setting of the impression material had occurred (Figure 4.10).

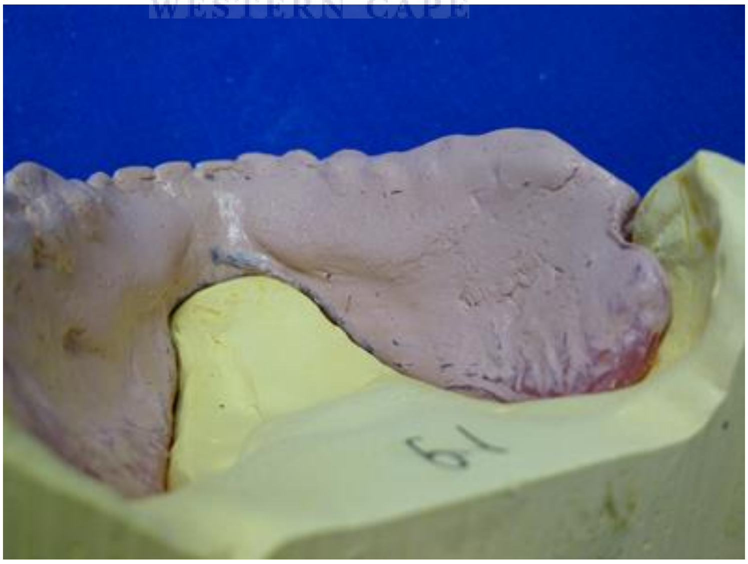

Figure 4.10. Lingual aspect of verification impression

The trial denture was then removed from the mouth and excess impression material protruding beyond the occlusal plane was trimmed. Impression material was removed from the denture teeth, and the denture was invested, polymerized and finished using standard procedures.

Following the result of a lucky draw, either the NZ or ANA denture would be delivered at the next visit. The first prosthesis was finished while the second prosthesis remained on the articulator in the wax trial stage and was only finished two months later, when it was time to exchange the dentures.

When the second set of dentures was delivered, special attention was paid to the extensions and degree of coverage of the mandibular retromolar pads as well as retromyloyoid extensions so that these would be similar for both lower dentures. This was important since both these features have been associated with stability.

Both dentures were subjected to a clinical remount procedure at the delivery visit. A new centric relation jaw relationship was registered with the new dentures in the mouth and re-articulated. Occlusal analysis and adjustment was performed on the articulator.

4.2.5. Measuring the transverse width of the residual ridge, anatomic and neutral zone dentures

The following features were marked on the mandibular master cast with a graphite pacer (Figure 4.11):

a. The crest of the alveolar ridge. The highest point, alternatively the centre of the remaining band of attached mucosa in cases of severe RRR, was considered to be the crest of the residual ridge.
b. The retromolar pads.
c. A transverse line connecting the tips of the retromolar pads or “directrix”.
d. A line bisecting and perpendicular to the directrix, extended up to the anterior ridge crest and border of the cast or “axis”.

e. Five mm intervals along the axis extending from the directrix (0 mm) anteriorly.

Figure 4.11. A mandibular master cast with landmarks

The master cast was positioned with a ruler at the same horizontal level as the residual ridge and parallel to the image retrieving sensor of the camera and a photograph was made. The ruler was necessary for future scaling and calibrating the digital image for distance measuring purposes.

The NZ wax trial denture was placed on the master cast without changing the position of the cast or the camera and a second image was made (Figure 4.12).

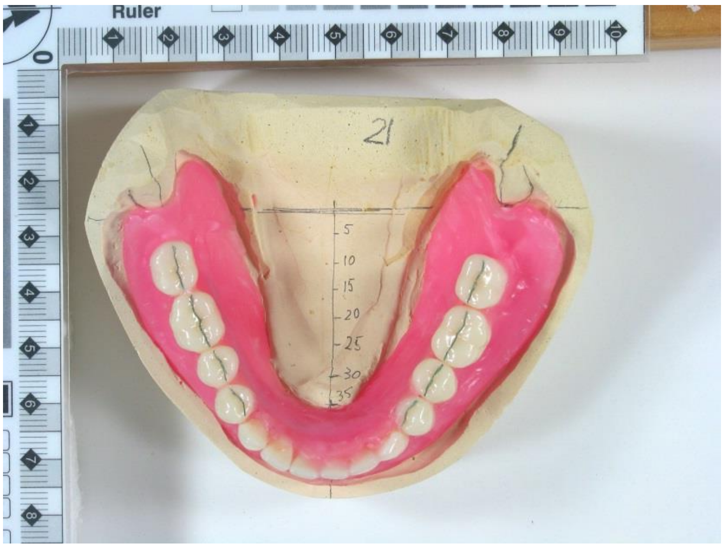

Figure 4.12. Master cast with NZ wax trial denture

The ANA wax trial denture was placed on the master cast and a third image was made (Figure 4.13).

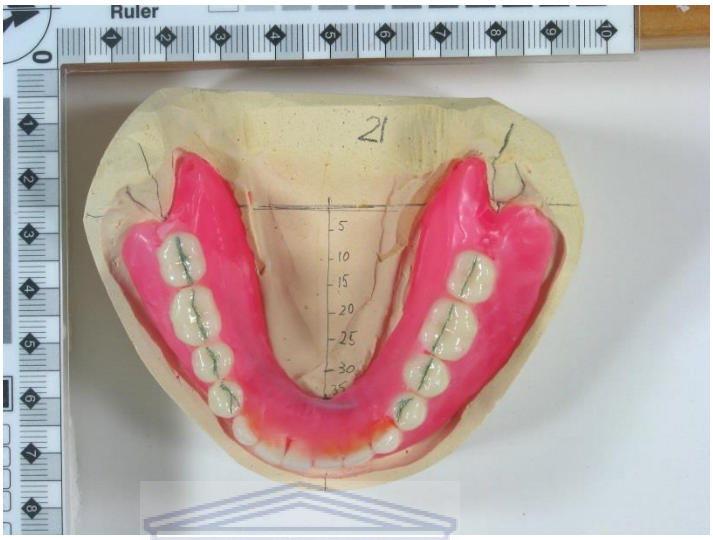

Figure 4.13. Master cast with ANA wax trial denture

The specifications for the images are given in Addendum 8.

All distances were measured on these digital images, each image individually scaled and calibrated with the aid of the ruler and scaling software. Digital measuring software "AnalyzingDigitalImages" was used to measure the dimensions on casts and dentures (http://mvh.sr.unh.edu/software/software.htm). This software is freely available and can be copied and used for educational applications. Version 11, created August 28, 2008, Release 3, was downloaded and used from the start of this trial.

The image of the definitive mandibular master cast was opened using the measuring software. The first step was to calibrate pixels and distance on the image using the ruler on the image (Figure 4.14).

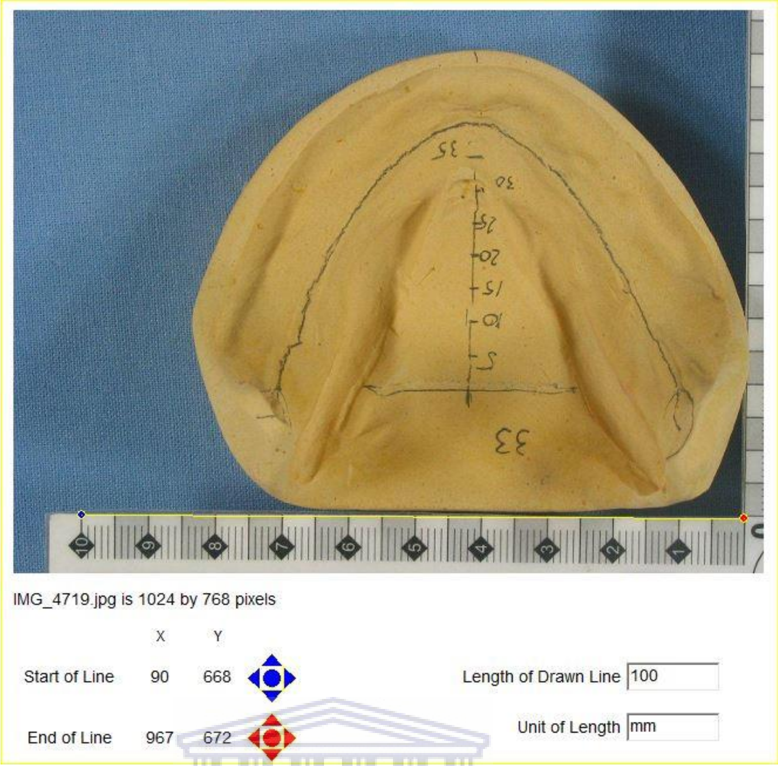

Figure 4.14. Screenshot of the first step of calibrating the digital image: measuring the ruler

A digital "line tool" was used to cover the distance of the ruler on the image and the length of the drawn line and unit of length was entered in the appropriate box.

After calibration, the transverse distances on the cast could be measured using the "line tool". For every level (0, 5, 10, 15, …mm) the start point and end point of the line tool were positioned over the distance that needed to be measured and the distance was automatically calculated. Figure 4.15 shows the digital line tool measuring the width of the residual ridge 15 mm anterior to the directrix. In the example, the length of the line is 47.84mm.

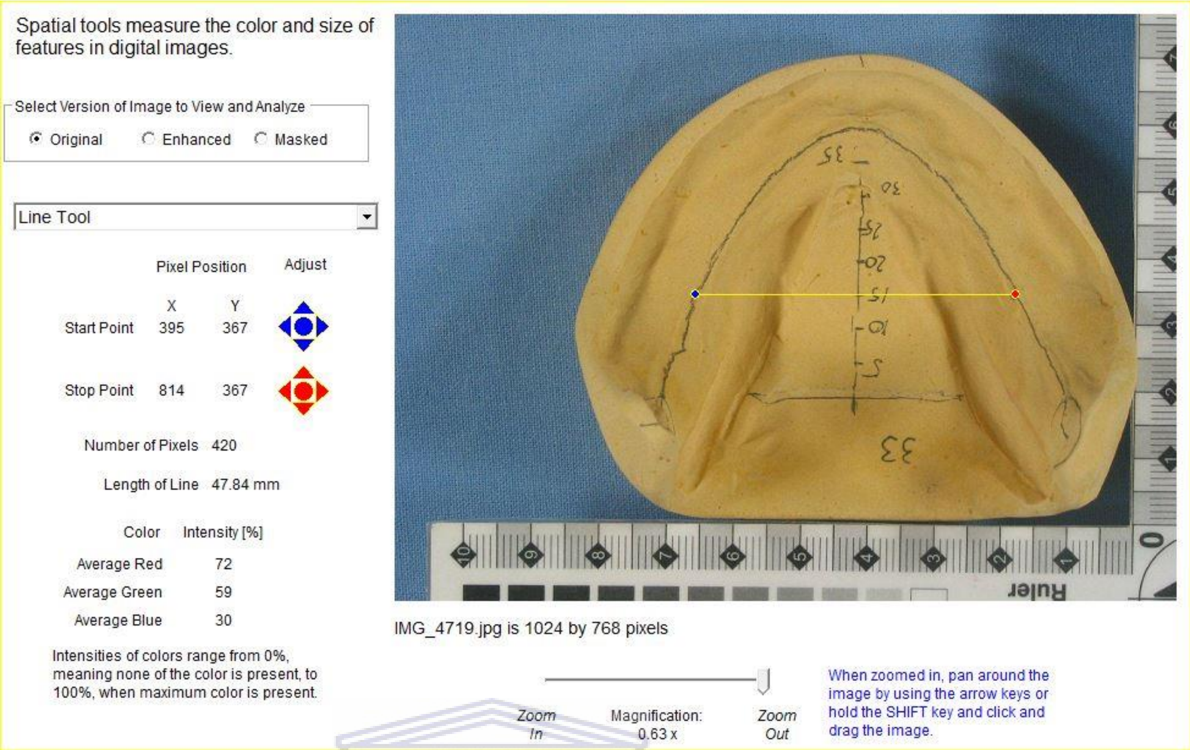

Figure 4.15. Screenshot showing the digital line tool (yellow) measuring width of the alveolar arch at the 15mm distance from the line connecting the tips of the retromolar pads

The image could be zoomed to accurately position the start point or stop point over the feature that needed to be measured. Figure 4.16 shows the zoomed image with the end point of the measuring tool located over the residual ridge line of the previous image.

Figure 4.16. Screenshot of the end point of the measuring tool located over the line indicating the crest of the alveolar ridge

For each calibration, the distances along every horizontal line on the cast were measured and recorded. This was repeated five times. Before each repetition, the image was calibrated again. The average of the five measurements for each width was used for further analysis.

For the wax trial dentures, the transverse widths at each level (5, 10, 15, 20, …mm) were measured using the same methods. The start and the beginning of the line tool were now placed over the central fossae of the denture teeth, made visible by green colourant tracings (Figure 4.17). The image shows the measuring of the anatomic denture for the width 15 mm anterior to the directrix. The width measured is 44.11mm.

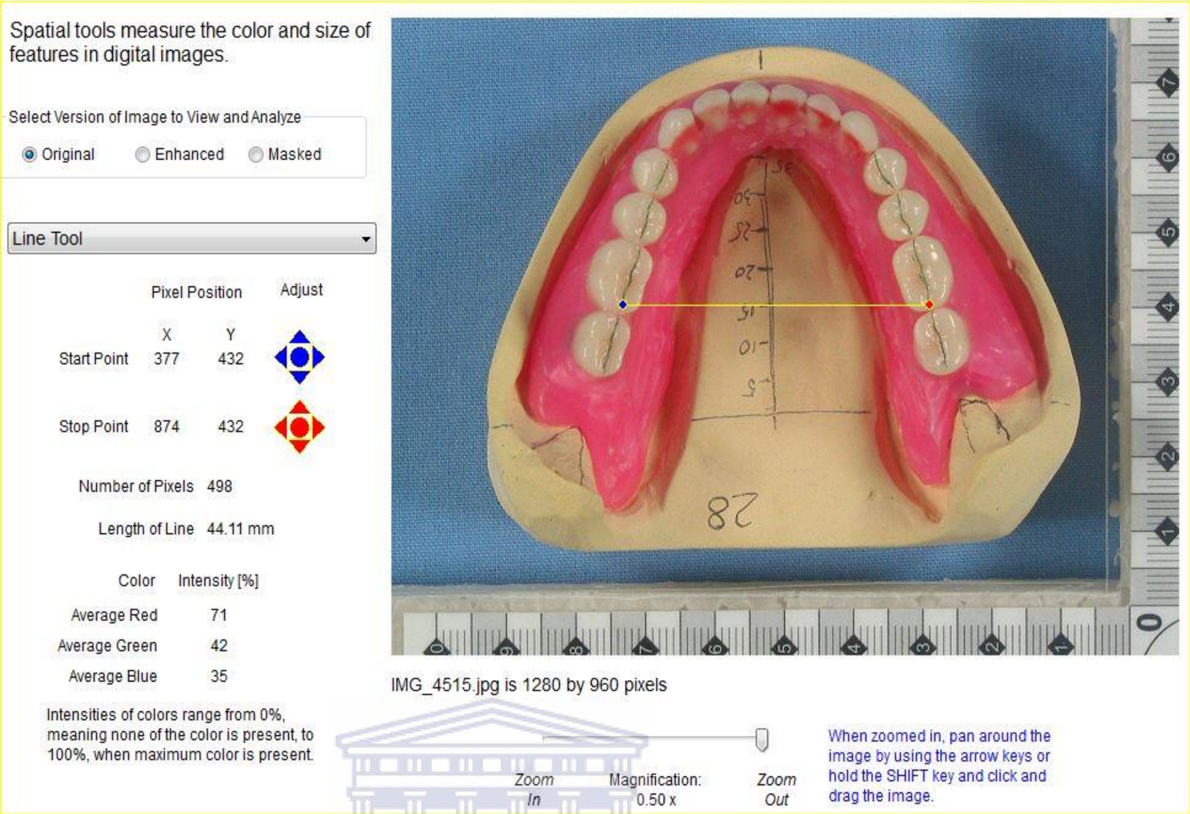

Figure 4.17. Screenshot of measuring the width of wax trial denture by placing the line tool over the central fossae of the posterior teeth at 5mm distance from the line connecting the tips of the retromolar pads

Figure 4.18 shows a magnified view of the line tool positioned over the central fossa of one of the mandibular denture teeth.

Figure 4.18. Screenshot of zoomed image of starting point of line tool positioned over the central fossa of one of the posterior denture teeth

For every level (5, 10, 15, 20, …mm) the transverse distance was measured five times and the mean of these five measurements was used for further analyses.

4.2.6. Layering of mandibular trial dentures over the master cast.

Because of the standardized photographic technique, a 50% transparent image of the master cast could be layered over the image of the trial denture on its master cast (Figure 4.19).

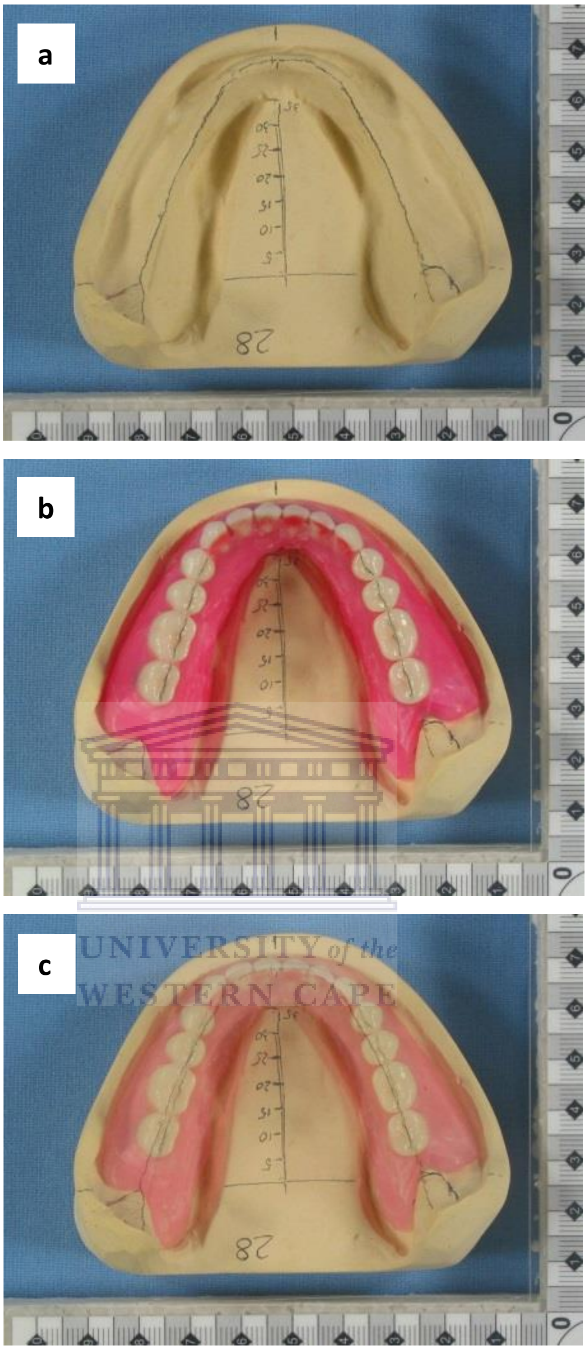

Figure 4.19. From top to bottom: a. Master cast; b. NZ wax trial denture on master cast; c. Transparent image a layered over image b

In this way, the crest of the residual ridge was projected over the trial denture and the horizontal relationship of the denture teeth and crest of the ridge could be visualized.

Corel Paint Shop Pro® X, version 10, was used for layering of the images.

4.2.7. Analysis of data

4.2.7.1. Denture dimensions

Descriptive statistics (means, maximum, minimum, range and standard deviation) for the widths of the residual ridges, ANA and NZ dentures were calculated.

For the analytic statistics, the measured widths at the eight locations (5, 10, …, 40) for each 'subject' and for the alveolar ridge, ANA and NZ dentures conformed to a doubly repeated measures design (with repeated measures made at each location and for each method). This was analyzed by using analysis of variance with both factors being within subjects factors. The analysis was done using the Mixed procedure in SAS v9 (SAS Institute Inc., Cary, NC, USA) with the Repeated option. The correlation structure used was a direct product UN@CS (unstructured with compound symmetry). An interaction term was included in the model. Group means were compared by using least squares means with the False Discovery Rate used to adjust for multiple comparisons (Benjamini & Hochberg, 1995). An adjusted significance level of 0.05 was used.

Since depths of mouths differ, formula for a parabola, symmetric around the y-axis, was translated for the casts and dentures, giving width =√ ($depth-line$), before comparing mean intercepts and slopes using paired *t*-tests.

To examine associations with dimensions and other variables, regression analysis was performed. Software used was R (R Core Team, 2013) and Statistica (StatSoft®, Southern Africa Research (Pty) Ltd).

4.2.7.2. OHIP-20 and denture preference

For each type of treatment (existing denture, ANA denture and NZ denture) OHIP-20 summary scores were calculated by adding the scores of the 20 items. OHIP-20 subscale scores were calculated by adding the scores of the items corresponding to each domain.

A description of magnitude of change in OHIP-20 total and domain scores among the different groups is shown through mean, median, and standard deviation of the change scores. Change scores were obtained by subtracting post-treatment scores with pre-treatment scores.

Between-group comparisons of magnitude of change in the OHIP-20 summary and domain scores (difference between score at pre-treatment and post-treatment) were carried out using non-parametric tests for two independent samples. A statistically significant difference was considered if $p<0.05$. The nature of the tests is indicated in the results section.

In addition to statistical analysis of OHIP-20 data, the clinical effect following treatment of the two types of dentures was assessed by using effect size (ES) statistics. ES is a measure of change: It is calculated by dividing the mean of difference in pre-treatment and post-treatment scores by the SD of the pre-treatment score. Levels of clinical meaningfulness were determined as follows: 0.2 = small; <0.6 = moderate; >0.8 = large (Cohen in Allen *et al.,* 2001a). The standardized ES is the most popular distribution-based approach and has been endorsed by the Cochrane Collaboration for meta-analysis (Masood *et al*., 2014).

To test combined associations between the dependent and independent variables, multiple linear regression analysis was performed. The nature of the tests is indicated in the results section.

Denture preference and its association with variables was analyzed by means of correlation and regression analyses. The nature of the tests is indicated in the results section.

Software used was SAS version 9.4 (SAS/STAT® Software, www.sas.com) and STATA (STATA® Data Analysis and Statistical Software, www.stata.com).

CHAPTER 5: RESULTS

5.1. INTRODUCTION

The clinical trial covered the period from February 2011 to October 2014.

In this chapter, descriptive results are given for sample characteristics, denture features and denture bearing tissues. This is followed by the descriptive results and statistical analysis of the denture dimensions. Next, the OHIP-20 scores and their descriptive results and statistical analysis are presented. Finally, relevant associations for denture dimensions, socio-demographic variables, OHIP-20 scores and denture preference are given.

5.2. SAMPLE CHARACTERISTICS

5.2.1. Sample size

A total of 39 patients were screened and accepted into the trial. For denture dimensions, ANA and NZ wax trial dentures for 39 of the 39 selected patients were made and measured. This represents a 100% retention rate.

For OHIP-20, 35 of those 39 patients could be included, for pre- and post-treatment assessments. This represents a 90% response ratio. Two patients (16 and 18) left the trial after receiving their first denture. Because the post-treatment OHIP-20 questionnaires could not be collected from these two patients, they were excluded from the OHIP-20 analysis. Two patients (35 and 39) were not wearing their dentures at the start of the trial. Therefore, their post-treatment OHIP-20 data could not be used for comparisons with a pre-treatment OHIP-20. CONSORT flow chart for the OHIP-20 and preference analyses are given in Figures 5.1 and 5.2.

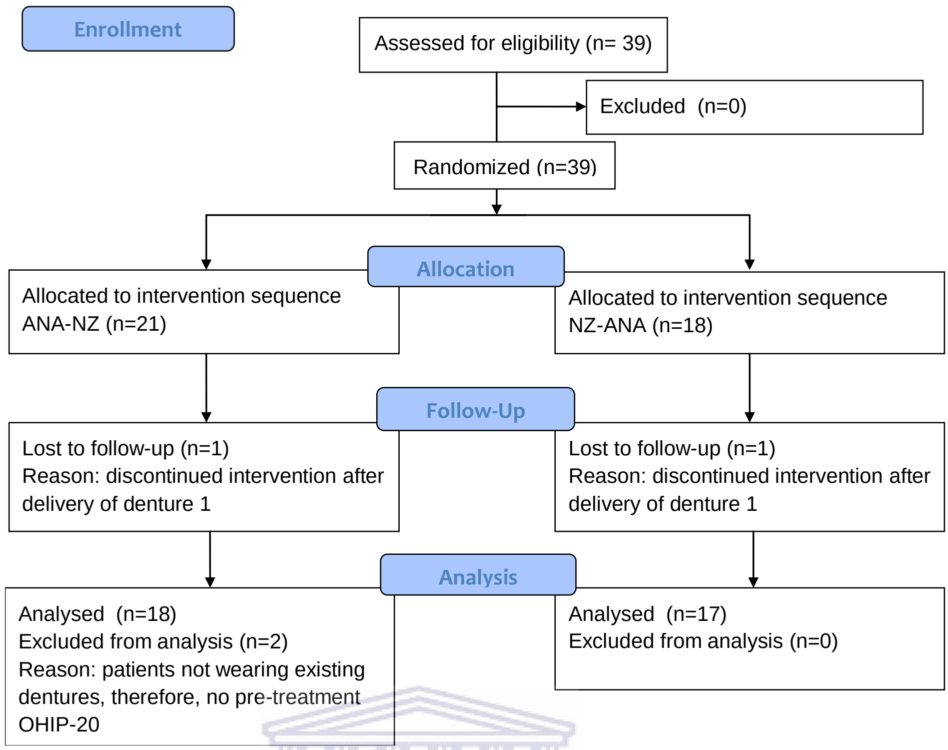

Figure 5.1. CONSORT flow diagram for OHIP-20 analysis

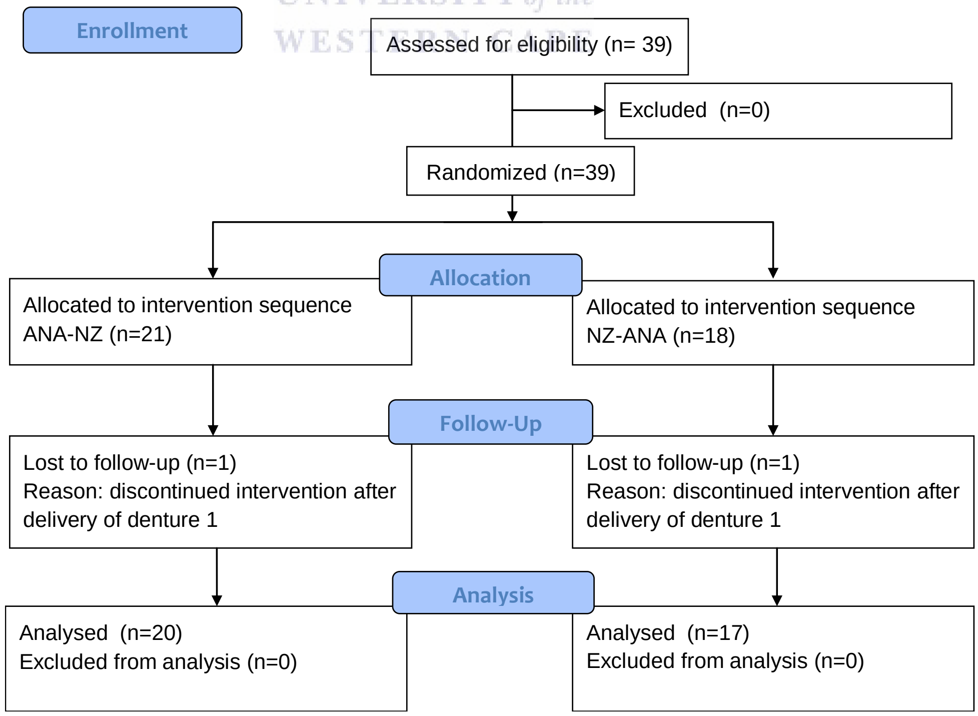

Figure 5.2. CONSORT flow diagram for denture preference analysis

5.2.2. Socio-demographic details

For the denture dimensions study, of a total of 39 patients was used of which 24 were female.

For the OHIP-20 analysis, of a total of 37 (35) patients was used of which 22 (21) patients were female.

At the start of treatment, mean age of the 39 patients was 62.3 years. The youngest patients was 47 years old, the oldest patient was 85 years old.

Twenty-two patients were pensioners, three were unemployed, 14 were working part- or full-time.

Nine patients had attended primary school, 27 high school and three had tertiary education.

Twenty five patients were married and 14 were single (widowed, divorced or not married).

All patients, except three, declared to have a monthly income of less than R5000. One patient declared to earn between R10000 - 15000 and two patients indicated to earn more than R15000.

A table with the socio-demographic data is shown in addendum 9.

5.2.3. Period of edentulousness and denture history

Addendum 9 contains data on number of years patients have been edentulous, the number of dentures the patients had, including the current one, and the age of the current dentures. Table 5.1 provides a summary of these data.

Table 5.1. Summary of denture history

Denture history	**Mean**	**Max**	**Min**
Period of edentulousness (years)	30.9	60	<1
Number of dentures	2.4	8	1
Age of current dentures (years)	14.6	45	1

Max = maximum; Min = minimum

Twenty four patients had had two or less than two denture sets when entering the trial. The mean age of the last denture was 14.6 years. The oldest denture was 45 years old (patient 2); the most recently made denture was one year old (patient 37).

Only six patients received immediate dentures. Only seven patients had a history of removable partial denture-wearing prior to complete denture therapy.

5.2.4. Sequence of denture delivery

Patients received two types of dentures. To eliminate bias related to first and second sets of dentures, it was attempted to deliver an even number of ANA and NZ dentures as first dentures. Twenty one ANA dentures and 18 NZ dentures were delivered first. Because of two patients leaving the trial after the first denture, these figures changed to 20 and 17 respectively. Addendum 9 shows the sequence of denture delivery based on type, for each patient.

Table 5.2 shows the demographic features per sequence group, based on a total of 37 patients.

Table 5.2. Demographic features of the 2 sequence groups

	ANA_NZ n=20		NZ_ANA n=17		Total n=37	
	Mean	SD	Mean	SD	Mean	SD
Age (years)	62.3	7.3	62.6	11.2	62.4	9.2
	n	**%**	**n**	**%**	**n**	**%**
GENDER						
Male	6	30	9	52.9	15	40.5
Female	14	70	8	47.1	22	59.5
EDUCATION						
Primary school	4	20	4	23.5	8	21.6
High school	15	75	11	64.7	26	70.3
Post matric	1	5	2	11.8	3	8.1
MARITAL STATUS						
Married	13	65	10	58.8	23	62.2
Single	7	35	7	41.2	14	37.8
INCOME						
< R5,000	19	95	15	88.2	34	91.9
R10,000-R15,000	1	5	0	0.0	1	2.7
> R15,000	0	0	2	11.8	2	5.4

ANA_NZ is the group of patients who received the anatomic denture first
NZ_ANA is the group of patients who received the neutral zone denture first.
SD = standard deviation

Except for gender, there were no significant differences between the two sequence groups, which indicate that the random allocation of patients in the two groups was successful.

Table 5.3 shows the period of edentulousness and denture history for the two sequence groups, based on a total of 37 patients.

Table 5.3. Edentulousness and denture history for the 2 sequence groups

	ANA_NZ n=20		NZ_ANA n=17		Total n=37	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
Edentulousness (years)	30.6	15.4	31.5	13.9	31.0	14.5
Number of denture sets	2.5	2.0	2.3	1.3	2.4	1.7
Age of current dentures* (years)	15.9	13.2	11.4	7.8	13.9	11.1

ANA_NZ is the group of patients who received the anatomic denture first
NZ_ANA is the group of patients who received the neutral zone denture first
SD = standard deviation
***Two patients didn't wear current dentures, one in each sequence group**

5.2.5. Interalveolar distance of the two types of dentures

Table 5.4 shows the interalveolar distance (IAD) in mm for both types of dentures, as well as the difference in IAD between the two types of dentures.

The mean IAD for all dentures (n=2x37=74) was 21.17 mm. The mean IAD for the ANA dentures (n=37) was 21.16 mm, for the NZ dentures (n=37) it was 21.20 mm. The difference in mean IAD between the groups of denture types was 0.04 mm. The largest difference was 4.5 mm, the smallest difference was 0.0 mm.

Table 5.4. Interalveolar distance (IAD) in mm for both types of dentures, as well as the difference in IAD between the 2 types of dentures

Patient	IAD (ANA)	IAD (NZ)	Diff	Patient	IAD (ANA)	IAD (NZ)	Diff
1	16.0	16.0	0.0	**21**	18.8	19.0	0.3
2	19.0	20.0	1.0	**22**	21.5	21.0	0.5
3	19.0	19.5	0.5	**23**	15.5	15.8	0.3
4	22.0	21.5	0.5	**24**	18.0	18.0	0.0
5	17.5	19.5	2.0	**25**	16.0	16.0	0.0
6	16.0	16.0	0.0	**26**	27.5	27.0	0.5
7	15.0	19.5	4.5	**27**	28.0	28.5	0.5
8	23.5	23.0	0.5	**28**	21.0	19.5	1.5
9	20.3	19.8	0.5	**29**	23.5	23.5	0.0
10	16.3	16.5	0.3	**30**	26.5	27.0	0.5
11	16.0	16.0	0.0	**31**	17.5	18.5	1.0
12	25.0	24.8	0.3	**32**	16.0	15.5	0.5
13	24.5	25.0	0.5	**33**	20.5	20.0	0.5
14	20.5	20.0	0.5	**34**	21.0	20.5	0.5
15	29.0	29.0	0.0	**35**	21.0	21.0	0.0
16	22.0	x	x	**36**	26.0	26.0	0.0
17	25.0	25.0	0.0	**37**	25.0	24.0	1.0
18	x	20.0	x	**38**	19.0	18.0	1.0
19	31.0	30.5	0.5	**39**	22.0	21.0	1.0
20	23.0	23.0	0.0	**Mean**	21.2	21.2	0.04

Diff = difference

Table 5.5 shows the number of patients per IAD difference. Thirty four patients had a difference in IAD between the two dentures of 1.0 mm or less.

Table 5.5. Number of patients per IAD difference

Difference in mm	0.00	0.25	0.50	1.00	1.50	2.00	4.50
n of patients (n total = 37)	11	4	14	5	1	1	1

5.2.6. Presence of posterior cross-bite

Arch width and buccal corridor of the maxillary dentures of both ANA and NZ sets were kept similar. Because of the wider arch shape of the NZ mandibular denture, the set-up of posterior teeth could result in a cross-bite for the NZ dentures. The presence of a cross-bite for the ANA and NZ denture for each patient is shown in Addendum 9. None of the ANA dentures were set-up in a cross-bite situation. For the NZ dentures, 14 dentures had no cross-bite, 25 had either a unilateral or bilateral cross-bite.

5.2.7. Number of recall visits

The number of recall visits according to the delivery sequence and the type of denture for each patient is given in Addendum 9. The total number of recall visits for the 37 patients and both denture sets (n=74) was 106. The total and mean number of recall visits for the dentures delivered first (n=37) was 72 and 1.95 respectively. The total and mean number of recall visits for the second dentures (n=37) was less than half at 34 and 0.92 respectively. Table 5.6 gives the frequencies of recall visits per category.

Table 5.6. Frequency table for number of recall visits per category

Denture	Number of recall visits							
	0	**1**	**2**	**3**	**4**	**5**	**6**	**N**
First	2	18	8	4	0	4	1	37
Second	12	17	7	1	0	0	0	37
ANA	9	16	8	2	0	2	0	37
NZ	5	19	7	3	0	2	1	37

5.2.8. Condition of denture-bearing tissues

The scores for the mandibular and maxillary denture-supporting tissue are presented in Addendum 9 and 10. A higher score represents more favourable denture-supporting tissue. The mean score for mandibulae was 4.21, for maxillae it was 4.77.

Tables 5.7 to 5.9 present the number of patients for each tissue score.

Table 5.7. Frequency table for number of patients per mandibular tissue score

Mandibular score	7	6	5	4	3	2
n patients	3	8	4	5	17	2

Table 5.8. Frequency table for number of patients per maxillary tissue score

Maxillary score	7	6	5	4	3	2
n patients	5	10	7	6	10	1

Table 5.9. Frequency table for number of patients per combined tissue score

Combined score	14	13	12	11	10	9	8	7	6	5	4
n patients	3	1	4	3	5	6	3	4	9	0	1

For female patients, the mean tissue score for the mandible was 3.87, for the maxilla 4.33 and combined 8.21. For male patients, it was 4.73, 5.47 and 10.20 respectively.

Table 5.10 shows the mandibular and maxillary tissue scores for both treatment sequence groups.

Table 5.10. Mandibular and maxillary tissue scores per treatment sequence

Tissue score	ANA_NZ n=20		NZ_ANA n=17		Total n=37	
	Mean	SD	Mean	SD	Mean	SD
Mandible	4.4	1.6	4.0	1.4	4.2	1.5
Maxilla	4.8	1.6	4.8	1.4	4.8	1.5

ANA_NZ = anatomic denture first.
NZ_ANA = neutral zone denture first
SD = standard deviation

5.3. DIMENSIONS OF RIDGES AND DENTURES

5.3.1. Widths and length of residual ridges

Mean width of ridges for lines retro, 5, 10, 15, 20, 25, 30, 35 and 40 for all patients (n=39) are given in Table 5.11. The mean widths for female and male patients are given in Table 5.12. Raw data are shown in Addendum 11.

Table 5.11. Mean width in mm of the residual ridges for lines retro, 5, 10, 15, 20, 25, 30, 35 and 40 for all patients (n=39)

	Line	n	Mean	Min	Max	Range
Width of ridge	retro	39	56.21	46.44	66.29	19.86
n=39	5	39	53.77	44.79	61.67	16.88
	10	39	50.27	41.53	58.12	16.59
	15	39	46.40	37.89	55.78	17.89
	20	39	41.92	33.60	51.67	18.07
	25	39	36.55	28.09	46.98	18.89
	30	39	29.88	17.03	41.38	24.35
	35	23	22.69	11.46	35.06	23.60
	40	4	12.13	1.60	19.06	17.46

n = number of mean observations per line;
Min = minimum; Max = maximum

Table 5.12. Mean width in mm of the residual ridges for lines retro, 5, 10, 15, 20, 25, 30, 35 and 40 according to gender

Gender	Line	Mean	Min	Max	Range
Female n=24	retro	55.01	46.44	60.25	13.82
	5	52.52	44.79	57.05	12.26
	10	48.91	41.53	53.09	11.56
	15	45.01	37.89	49.70	11.81
	20	40.51	33.60	45.85	12.25
	25	35.08	28.09	40.26	12.17
	30	28.24	17.03	33.76	16.72
	35	21.07	11.46	27.37	15.91
	40	8.34	1.60	15.09	13.49
Male n=15	retro	58.12	52.23	66.29	14.07
	5	55.76	49.99	61.67	11.68
	10	52.45	47.85	58.12	10.27
	15	48.63	44.81	55.78	10.97
	20	44.18	40.33	51.67	11.34
	25	38.89	34.21	46.98	12.77
	30	32.51	24.72	41.38	16.66
	35	24.19	16.25	35.06	18.81
	40	15.93	12.79	19.06	6.26

Min = minimum; Max = maximum

Mean widths of residual ridge for male patients were larger for every line.

If the distance between the tips of the retromolar pads is regarded as an indication of the width of the mandible, the widest mandible was 66.29 mm and belonged to a male patient. The narrowest mandible was 46.44 mm, belonging to a female patient. This difference in width was almost 20 mm. Difference in mean mandibular widths between male and female patients was 3.11 mm.

Mean *length of the ridges* for all patients, measured along midline axis bisecting a line connecting the retromolar pads, was 39.05 mm (Table 5.13). Difference in mean lengths of the ridge between male and female patients was 2.08 mm.

Table 5.13. Mean length of the residual ridges in mm, for all, male and female patients

	n	Mean	Min	Max	Range
All patients	39	39.05	32.96	48.14	15.19
Female	24	38.25	32.96	44.33	11.38
Male	15	40.33	34.43	48.14	13.72

Min = minimum; Max = maximum

5.3.2. Widths of anatomic dentures

Mean widths of the ANA dentures for lines 5, 10, 15, 20, 25, 30, 35 and 40 for all 39 patients, females and male patients are shown in Table 5.14 and 5.15. For all lines, mean widths of dentures made for female patients were smaller than those of dentures for male patients. Raw data are shown in Addendum 11.

Table 5.14. Mean widths in mm of ANA dentures for lines 5, 10, 15, 20, 25, 30, 35 and 40 for all 39 patients

Line	n	Mean	Min	Max	Range
5	31	50.92	42.15	58.14	15.99
10	39	47.67	39.00	54.16	15.16
15	39	44.18	36.57	50.08	13.51
20	39	40.47	33.06	46.15	13.10
25	39	36.48	28.46	42.24	13.78
30	37	32.43	26.09	39.13	13.03
35	18	30.24	27.06	33.93	6.87
40	1	27.59	27.59	27.59	

n = number of mean observations per line. Min = minimum; Max = maximum

Table 5.15. Mean widths in mm of ANA dentures for lines 5, 10, 15, 20, 25, 30, 35 and 40 according to gender

Female	Line	n	Mean	Min	Max	Range
n=24	5	19	49.81	42.15	57.79	15.64
	10	24	46.73	39.00	52.43	13.43
	15	24	43.19	36.57	48.46	11.89
	20	24	39.51	33.06	44.58	11.53
	25	24	35.43	28.46	40.71	12.25
	30	22	31.35	27.56	37.26	9.71
	35	7	29.56	27.06	31.86	4.80
	40	1	27.59	27.59	27.59	0.00
Male	5	12	52.67	49.33	58.14	8.81
n=15	10	15	49.18	45.77	54.16	8.39
	15	15	45.76	41.33	50.08	8.75
	20	15	42.00	36.46	46.15	9.69
	25	15	38.17	30.10	42.24	12.14
	30	15	34.01	26.09	39.13	13.03
	35	11	30.67	27.30	33.93	6.63
	40	0				

n = number of mean observations per line; Min = minimum; Max = maximum

5.3.3. Widths of neutral zone dentures

Mean widths of NZ dentures for lines 5, 10, 15, 20, 25, 30, 35 and 40 for all patients, females and males are shown in Table 5.16 and 5.17. Except for line 35, NZ dentures made for female patients were narrower than those made for male patients. Raw data are shown in Addendum 11.

Table 5.16. Mean widths in mm of NZ dentures for lines 5, 10, 15, 20, 25, 30, 35 and 40 for all 39 patients

Line	n	Mean	Min	Max	Range
5	29	53.14	46.24	60.41	14.17
10	38	52.12	44.84	64.45	19.62
15	39	49.43	42.24	61.76	19.52
20	39	46.13	38.03	58.65	20.62
25	39	41.19	31.80	55.11	23.31
30	37	35.53	26.18	49.11	22.94
35	20	31.80	27.36	40.59	13.23
40	2	29.39	28.78	29.99	1.21

n = number of mean observations per line. Min = minimum; Max = maximum

Table 5.17. Mean widths in mm of NZ dentures for lines 5, 10, 15, 20, 25, 30, 35 and 40 according to gender

Gender	Line	n	Mean	Min	Max	Range
Female	5	19	52.93	46.24	60.41	14.17
n=24	10	23	51.09	44.84	60.48	15.64
	15	24	48.62	42.24	59.61	17.37
	20	24	45.49	38.03	56.40	18.37
	25	24	40.37	31.80	53.02	21.22
	30	22	34.71	28.19	47.09	18.90
	35	8	32.27	27.45	39.61	12.16
	40	2	29.39	28.78	29.99	1.21
Male	5	10	53.53	47.61	59.91	12.30
n=15	10	15	53.70	44.91	64.45	19.54
	15	15	50.73	42.80	61.76	18.96
	20	15	47.17	40.66	58.65	17.99
	25	15	42.50	33.02	55.11	22.10
	30	15	36.73	26.18	49.11	22.94
	35	12	31.49	27.36	40.59	13.23
	40	0				

n = number of mean observations per line. Min = minimum; Max = maximum

5.3.4. Differences in widths residual ridge, anatomic and neutral zone dentures

5.3.4.1. Widths residual ridge minus widths anatomic dentures

Differences in widths of residual ridges and ANA dentures are shown in Table 5.18. Negative values indicate that the ANA denture is wider than the ridge. Difference in mean widths was largest for line 35 (-6.6 mm) and smallest for line 25 (0.06 mm). Beyond line 25, ANA denture teeth were located buccally to the residual ridge. In absolute terms, the largest difference between ridge and ANA dentures was -17.17 mm and the smallest difference was -1.07 mm. The value for line 40 was not included in the analysis because it was based on difference of 1 observation.

Table 5.18. Difference in mean widths in mm of residual ridge and ANA denture for lines 5 to 40

Widths ridge minus ANA denture					
Line	**n**	**Mean**	**Min**	**Max**	**Range**
5	31	2.50	-1.07	7.00	8.07
10	39	2.60	-2.59	7.34	9.93
15	39	2.23	-4.22	7.80	12.02
20	39	1.45	-3.57	7.50	11.06
25	39	0.06	-5.21	7.89	13.10
30	37	-2.14	-10.56	7.23	17.78
35	18	-6.61	-17.17	1.13	18.30
(40	1	7.00	7.00	7.00	0)

n = number of observations; Min = minimum; Max = maximum

5.3.4.2. Widths residual ridge minus widths neutral zone dentures

Differences in widths of residual ridges and NZ dentures are shown in Table 5.19. Negative values indicate that the NZ denture is wider than the ridge. Difference in mean widths was largest for line 35 (-8.86 mm) and smallest for line 5 (-0.09 mm).

NZ denture teeth were located buccally to the residual ridge. In absolute values, largest difference between ridge and NZ dentures was -19.18 mm and smallest was 1.80 mm.

Table 5.19. Difference in mean widths in mm of the residual ridge and the NZ denture for lines 5 to 40

Widths ridge minus NZ denture					
Line	**n**	**Mean**	**Min**	**Max**	**Range**
5	29	-0.09	-5.66	8.66	14.32
10	38	-1.92	-10.85	8.26	19.11
15	39	-3.03	-11.72	6.34	18.06
20	39	-4.21	-13.80	4.63	18.42
25	39	-4.64	-15.78	4.97	20.76
30	37	-5.24	-16.72	7.14	23.86
35	19	-8.86	-19.18	1.81	20.98
(40	2	-21.04	-27.18	-14.90	12.28)

Min = minimum; Max = maximum

The value for line 40 was not included in the analysis because it was based on mean difference of two observations.

5.3.4.3. <u>Widths neutral zone dentures minus widths anatomic dentures</u>

Table 5.20 shows the difference in mean widths of NZ and ANA dentures along lines 5 to 35. The mean width for NZ was wider for all lines compared to ANA dentures.

The smallest mean difference was for line 35 (1.81 mm), the largest mean difference was for line 20 (5.66 mm). In absolute values, largest difference between NZ and ANA dentures was -14.48 mm and smallest was -2.60 mm.

Table 5.20. Difference in mean widths in mm of NZ and ANA dentures along lines 5 to 40

Widths NZ minus ANA dentures					
Line	**n**	**Mean**	**Min**	**Max**	**Range**
5	29	2.70	-4.06	7.74	11.80
10	38	4.42	-4.32	13.68	18.00
15	39	5.25	-4.02	13.78	17.80
20	39	5.66	-3.47	14.48	17.95
25	39	4.70	-3.40	13.90	17.30
30	37	3.10	-3.51	12.39	15.90
35	18	1.81	-2.60	9.08	11.68
(40	1	1.19	1.19	1.19	0)

The value for line 40 was not included in further analysis because it was based on the difference of 1 observation.

5.3.4.4. Differences in widths for male and female patients

Difference in mean widths for ridges, ANA and NZ dentures for lines 5 to 35, for male and female patients is shown in Table 5.21. A negative figure means that mean width was larger for the female group.

Differences in mean widths between male and female patients were smaller for the NZ dentures except for line10. Largest mean difference in width between male/female patients was for line 5 for the ANA denture (2.87 mm). The smallest difference in width between males and females was for line 5 for the NZ denture (0.60 mm).

Table 5.21. Difference in mean widths in mm for alveolar ridges, ANA and NZ dentures for lines 5 to 35, between male and female patients

Differences in mean width male – female patients			
Line	**Alveolar ridge**	**ANA denture**	**NZ denture**
5	3.24	2.87	0.60
10	3.54	2.45	2.61
15	3.63	2.57	2.12
20	3.67	2.49	1.68
25	3.81	2.74	2.13
30	4.27	2.66	2.02
35	3.12	1.10	-0.79

Difference in mean widths ridges, ANA and NZ according to gender are shown in Table 5.22.

Table 5.22. Difference in mean widths in mm for ridges, ANA and NZ dentures according to gender

Line	Ridge minus ANA	Ridge minus NZ	NZ minus ANA
	FEMALES		
5	2.72	-0.41	3.12
10	2.18	-2.18	4.36
15	1.82	-3.61	5.43
20	1.00	-4.98	5.97
25	-0.35	-5.29	4.94
30	-3.11	-6.47	3.36
35	-8.50	-11.20	2.71
	MALES		
5	3.09	2.23	0.86
10	3.27	-1.25	4.52
15	2.87	-2.10	4.97
20	2.18	-2.99	5.17
25	0.72	-3.61	4.33
30	-1.50	-4.23	2.72
35	-6.48	-7.30	0.82
	MALES - FEMALES		
5	0.38	2.64	-2.26
10	1.09	0.94	0.16
15	1.06	1.51	-0.46
20	1.18	1.99	-0.81
25	1.08	1.68	-0.60
30	1.61	2.25	-0.64
35	2.02	3.90	-1.89

For both males and females, teeth were positioned closest over the crest of the ridge for line 25. Posterior to line 25, for both males and females, teeth were positioned slightly lingually to the crest of the ridge (negative values in Table 5.20 indicate that denture teeth were positioned buccal to the alveolar ridge). For the ANA dentures, difference in mean width between ridge and denture was relatively larger for female patients in the anterior part of the mouth (lines 30 & 35), compared to male patients. This means that the discrepancy between ridge and position of teeth in the premolar region of the denture was larger for female than for male patients.

For the NZ denture, the discrepancy between ridge and NZ was always larger for the female group of patients compared to the male patients. Negative values indicate that teeth were positioned buccal to the alveolar ridge.

Except for line 10, the difference in NZ and ANA widths were always larger for the female patients compared to the males.

5.3.5. Photo Gallery

Addendum 12 shows photographs of the ANA and NZ wax trial dentures layered over the definitive master cast of the edentulous mandibular ridge. The crest of the ridge was marked with a graphite pacer; the central fossae of the posterior denture teeth were marked with green food colourant. It is important to note the consistency of the position of the mandibular anterior teeth as well as the midline related to the edentulous ridge, between both types of trial dentures. From the photographs it can be confirmed that the posterior teeth of NZ dentures are generally positioned more buccal to the crest of the residual ridge compared to anatomically-positioned posterior denture teeth. Even though the anatomically-positioned teeth (on a straight line connecting the distal slope of the canine to the tip of the retromolar pad), were expected to be located over, or close to, the crest of residual ridge, they are occasionally lingually positioned due to the buccally-curved shape of the residual ridge.

On the image gallery, the Y-axis reflects the “length-line” or “directrix” and the 5 mm interval is 5 mm anterior to the “length of the mouth” as indicated on the Y axis. Parabola are truncated in the anterior region of the ridge, coinciding with the most anterior distances measured, usually in the region of the canines.

5.4. OHIP-20

5.4.1. Pre-treatment OHIP-20 scores

The OHIP-20 item-scores per patient for dentures worn prior to the start of the trial are given in Addendum 13. The mean pre-treatment score for those patients who completed the study and who were wearing dentures at the time (n=35) was 42.14. The highest pre-treatment score was 75 (patient 16), however, this patient did not complete the study and these data were not used for further OHIP-20 analysis. The second highest score was 74 (patients 4 and 15). The lowest score was 4 (patient 23). Patients 35 and 39 were not wearing dentures at the start of the trial. Patient 38 was wearing an upper denture only. He had recently extracted mandibular teeth and needed his lower removable partial denture replaced by a complete denture. Therefore, no initial scores were available for patients 35 and 39. However, they did complete the study and their OHIP-20 for the new NZ and ANA dentures were available. Patients 16 and 18 did not complete the trial. They were excluded from the OHIP-20 analysis. The pre-treatment OHIP-20 scores, per domain, are given in Table 5.23.

Table 5.23. Pre-treatment OHIP-20 scores per domain

Pre-treatment OHIP-20 scores (n=35*)					
Domain	**Item**	**Sum item**	**Mean item**	**Sum domain**	**Mean domain**
Functional limitation	1	97	2.77	291	8.31
	2	106	3.03		
	3	88	2.51		
Physical pain	4	61	1.74	300	8.57
	5	103	2.94		
	6	57	1.63		
	7	79	2.26		
Psychological discomfort	8	80	2.29	170	4.86
	9	90	2.57		
Physical disability	10	96	2.74	288	8.23
	11	70	2.00		
	12	49	1.40		
	13	73	2.09		
Psychological disability	14	80	2.29	163	4.66
	15	83	2.37		
Social disability	16	54	1.54	204	5.83
	17	36	1.03		
	18	52	1.49		
	19	62	1.77		
Handicap	20	59	1.69	59	1.69
Total		1475	42.14	1475	42.14

*** Patients 16, 18, 35 and 39 excluded**

5.4.2. OHIP-20 scores for anatomic dentures

The OHIP-20 item-scores per patient for the ANA dentures are given in Addendum 14. The mean ANA OHIP-20 score was 14.53. Highest ANA OHIP-20 score was 80 for patient 37; Lowest score was 0. This happened 5 times. The scores per domain are given in Table 5.24.

Table 5.24. OHIP-20 scores per domain for the ANA dentures

ANA OHIP-20 scores (n=35*)					
Domain	**Item**	**Sum item**	**Mean item**	**Sum domain**	**Mean domain**
Functional limitation	1	46.00	1.31	137.50	3.93
	2	55.00	1.57		
	3	36.50	1.04		
Physical pain	4	45.00	1.28	149.00	4.26
	5	39.00	1.11		
	6	44.00	1.26		
	7	21.00	0.60		
Psychological discomfort	8	26.00	0.74	45.00	1.28
	9	19.00	0.54		
Physical disability	10	32.50	0.93	99.00	2.83
	11	15.50	0.44		
	12	22.00	0.63		
	13	29.00	0.83		
Psychological disability	14	20.00	0.57	38.00	1.08
	15	18.00	0.51		
Social disability	16	6.00	0.17	28.00	0.80
	17	5.00	0.14		
	18	8.00	0.23		
	19	9.00	0.26		
Handicap	20	12.00	0.34	12.00	0.34
Total		508.50	14.53	508.50	14.53

*** Patients 16, 18, 35 and 39 excluded**

5.4.3. OHIP-20 scores for neutral zone dentures

The OHIP-20 item-scores per patient for the NZ dentures are given in Addendum 15. The mean NZ OHIP-20 score was 14.21. The highest NZ OHIP-20 score was 77 for patient 37; the lowest score was 0. This happened 5 times. The scores per domain are given in Table 5.25.

Table 5.25. OHIP-20 scores per domain for the NZ dentures

NZ OHIP-20 scores (n=35*)					
Domain	**Item**	**Sum item**	**Mean item**	**Sum domain**	**Mean domain**
Functional limitation	1 2 3	50.00 58.00 27.00	1.43 1.66 0.77	135.00	3.86
Physical pain	4 5 6 7	27.00 39.00 34.30 22.00	0.77 1.11 0.98 0.63	122.30	3.49
Psychological discomfort	8 9	17.00 23.00	0.48 0.66	40.00	1.14
Physical disability	10 11 12 13	35.00 20.00 20.00 23.00	1.00 0.57 0.57 0.66	98.00	2.80
Psychological disability	14 15	22.00 12.00	0.63 0.34	34.00	0.97
Social disability	16 17 18 19	9.00 8.00 22.0 14.00	0.26 0.23 0.63 0.40	53.00	1.51
Handicap	20	15.00	0.43	15.00	0.43
Total		497.30	14.21	497.30	14.21

*** Patients 16, 18, 35 and 39 excluded**

5.4.4. Distribution of the differences in OHIP-20 scores

Differences in OHIP-20 item-scores for each patient are shown in Addendum 16. Table 5.26 shows the number and distribution of patients with the nature of differences in OHIP-20 scores. Based on preference scoring, a difference in the total OHIP-20 score of 7.5 was determined to be clinically significant (see power analysis in Methodology Chapter).

Table 5.26. Number and distribution of patients with the nature of differences in OHIP-20 scores

OHIP-20 PRE- minus POST-TREATMENT			
No difference (<7.5)	ANA	5/35	14%
	NZ	6/35	17%
Improved (>7.5 positive values)	ANA	27/35	77%
	NZ	27/35	77%
Worse (>7.5 negative values)	ANA	3/35	9%
	NZ	2/35	6%
OHIP-20 NZ minus ANA			
No difference (<7.5)		18/35	51%
NZ better (>7.5 positive values)		10/35	29%
NZ worse (>7.5 negative values)		7/35	20%

5.4.5. Scores per domain for pre-treatment, anatomic and neutral zone dentures

Table 5.27 shows summary and mean scores per domain for the 3 dentures. The difference in mean OHIP-20 scores for pre-treatment–ANA = 27.61; between pre-treatment and NZ = 27.93 and between ANA and NZ = 0.32.

Table 5.27. Summary and mean pre- and post-treatment OHIP-20 scores

Domain	Pre-treatment (n=35)		Post-treatment ANA (n=35)		Post-treatment NZ (n=35)	
	Sum	**Mean**	**Sum**	**Mean**	**Sum**	**Mean**
Functional limitation	291	8.31	137.50	3.93	135.00	3.86
Physical pain	300	8.57	149.00	4.26	122.30	3.49
Psychological discomfort	170	4.86	45.00	1.28	40.00	1.14
Physical disability	288	8.23	99.00	2.83	98.00	2.80
Psychological disability	163	4.66	38.00	1.08	34.00	0.97
Social disability	204	5.83	28.00	0.80	53.00	1.51
Handicap	59	1.69	12.00	0.34	15.00	0.43
Total	1475	42.14	508.50	14.53	497.30	14.21

5.4.6. OHIP-20 scores per type of denture and sequence

Table 5.28 shows the differences in pre-treatment and post-treatment OHIP-20 scores per type of denture and treatment sequence. The smallest improvement in OHIP-20 scores took place when ANA dentures were delivered first (mean of 23.67; n=18). The highest improvement took place when ANA dentures were delivered after NZ dentures (31.76; n=17). When the NZ denture was delivered first, its mean effect on the OHIP-20 was higher (29.39; n=17) than when it was delivered after the ANA denture (26.56; n=18).

Table 5.28. Differences in pre-treatment and post-treatment OHIP-20 scores for each patient per type of denture and treatment sequence

	OHIP-20			
	Pre - ANA first	**Pre - ANA second**	**Pre - NZ first**	**Pre - NZ second**
	n=18	n=17	n=17	n=18
	3.0	71	59	12
	37.0	74	74	47
	11.0	60	57	17
	29.0	15	14	5
	-8.0	6	2	29
	3.0	36	20	6
	53.0	15	24	44
	14.0	66	72	27
	46.0	28	35	55
	24.0	14	18	22
	25.0	37	20.67	46
	4.0	-7	2	4
	32.5	15	8	7
	47.0	52	48	28
	53.0	51	53	55
	41.0	39	31	46
	29.0	-32	-38	42
	-17.0			-14
Total	426.50	540	499.67	478
Mean	23.67	31.76	29.39	26.56

n = number of patients in each group

5.4.7. Treatment effect size

5.4.7.1. Treatment effect size for the summary scores

Mean pre-treatment OHIP-20 score (n=35) was 42.14. Mean ANA OHIP-20 score (n=35) was 14.53. Mean NZ OHIP-20 score (n=35) was 14.21.

Table 5.29 shows the summary for variables OHIP-20 pre-treatment and both ANA and NZ OHIP-20 scores.

Table 5.29. Summary for variables: pre-treatment OHIP-20 and ANA and NZ OHIP-20 scores by categories of SDD_ANA

Sequence	n	Mean	SD
1	18	42.55 18.86 16.00	20.72 19.68 23.34
2	17	41.71 09.94 12.31	25.07 11.22 14.26
Total	35	42.14 14.53 14.21	22.59 16.54 19.27

Sequence 1: ANA first, NZ second
Sequence 2: NZ first, ANA second
SD = standard deviation.

The treatment ES is calculated as the difference of the mean pre- and post-treatment OHIP-20 scores divided by the standard deviation of the pre-treatment score. Table 5.30 shows the ES values for each treatment sequence and for the complete sample.

Table 5.30. Effect size for each treatment option

Treatment effect size			
Sequence	**ANA vs NZ**	**Pre vs ANA**	**Pre vs NZ**
ANA_NZ	0.15	1.14	1.28
NZ_ANA	0.17	1.17	1.27
Overall	0.02	1.22	1.24

For the ANA dentures, the ES was 1.2; for the NZ dentures, the ES was 1.24. Because ES on both occasions was >0.8, the level of clinical meaningfulness for both treatment options was considered to be "large". Difference in ES between both post-treatment options was always <0.2 and, therefore, was considered to be small.

5.4.7.2. Treatment effect size for the different domains

Table 5.31 shows the difference in ES between NZ and ANA dentures per domain. A negative figure indicates that positive treatment impact was larger for ANA dentures than for NZ dentures. For six out of seven domains, the clinical effect for NZ dentures was marginally higher (improved). For the one remaining domain, "social disability", ANA dentures had a minimally larger positive effect. The domain with the largest difference between the two treatment options was "physical pain", with NZ dentures scoring better. Smallest difference was in the "social disability" domain.

Table 5.31. Differences in effect size per domain

OHIP-20 domain	ES ANA denture	ES NZ denture	ES NZ - ANA denture
Functional limitation	1.06	1.08	0.02
Physical pain	0.73	0.86	0.13
Psychological discomfort	1.08	1.12	0.04
Physical disability	0.97	0.97	0.01
Psychological disability	1.15	1.18	0.04
Social disability	0.74	0.74	0.00
Handicap	0.80	0.81	0.02

ES = effect size

5.5. DENTURE PREFERENCE

5.5.1. Denture preference according to type and treatment sequence

The results of denture preference according to type and sequence can be found in Addendum 9 and in Table 5.32. Out of a total of 37 patients, eight patients preferred the ANA denture, 15 patients preferred the NZ denture, twelve patients did not have a preference, and two patients didn't know if they preferred one of the two types of dentures. For statistical analysis, these last two patients were included in the group of "no preference".

Table 5.32. Number of patients according to preference and sequence of delivery

<table>
<tr><th rowspan="2"></th><th colspan="2">Denture preference</th><th rowspan="2">Total</th><th rowspan="2">%</th></tr>
<tr><th>First</th><th>Second</th></tr>
<tr><td>ANA</td><td>4</td><td>4</td><td>8</td><td>21</td></tr>
<tr><td>NZ</td><td>4</td><td>11</td><td>15</td><td>41</td></tr>
<tr><td>No preference</td><td colspan="2">12 (4 x ANA first; 8 x NZ first)</td><td>12</td><td rowspan="2">38</td></tr>
<tr><td>Don't know</td><td colspan="2">2 (1 x ANA first; 1 NZ first)</td><td>2</td></tr>
<tr><td>Total</td><td colspan="2"></td><td>37</td><td>100</td></tr>
</table>

Eight patients preferred the ANA dentures, four of which were the first set of dentures. Fifteen patients preferred NZ dentures, four of which were the first set of dentures.

Of the 20 ANA dentures delivered first, four preferred it over the second denture, eleven did not, five had no preference.

Of the 17 NZ dentures delivered first, four preferred it over the second denture, four did not, nine had no preference.

Of the patients who did not have a preference, eight of those happened when the NZ denture was given first, and four when the ANA denture was given first.

5.5.2. Denture preference and OHIP-20 scores

Patient preference for a denture type matched OHRQoL impact 23 times (a difference OHIP-20 NZ minus ANA of 7.5 was considered clinically relevant – refer to power analysis); on one occasion, a patient (17) preferred the ANA denture when the OHIP scores were in favour of the NZ dentures; for the remaining thirteen occasions, there was either no preference with a difference in impact or no difference in the OHRQoL impact with a particular preference (Addendum 17).

5.5.3. Denture preference and gender

Half of female patients preferred the NZ dentures. Almost half of male patients (46%) had no preference (Table 5.33). The group with the lowest frequency of preference was the female group preferring the ANA denture (18%).

Table 5.33. Denture preference according to gender

	ANA preference	**NZ preference**	**No preference**
Male patients (n=15)	4 (27%)	4 (27%)	7 (46%)
Female patients (n=22)	4 (18%)	11 (50%)	7 (32%)

5.6. ANALYTICAL STATISTICS

5.6.1. Sample characteristics

5.6.1.1. Sample size

A power analysis was performed to determine the required sample size for the OHIP-20 analysis. The methodology and results of the power analysis were given in the methodology chapter of this dissertation.

5.6.1.2. Denture history, tissue scores, years of edentulousness, recall visits and treatment sequence

The success of randomization of patients into the two sequence groups was checked by comparing age (*t*-test), gender, education and income (Chi-squared test) between two sequence groups. There were no significant differences of these variables between the two sequence groups, indicating that random allocation of patients into the two groups was successful (refer to Table 5.2).

Table 5.34 relates edentulousness, denture history, and tissue scores according to treatment sequence.

Table 5.34. Treatment sequence and edentulousness, denture history and tissue scores

	Group ANA_NZ n=20		Group NZ_ANA n=17		Total n=37	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
Edentulousness (yrs)	30.6	15.4	31.5	13.9	31.0	14.5
Number denture sets	2.5	2.0	2.3	1.3	2.4	1.7
Age of current dentures	15.9	13.2	11.4	7.8	13.9	11.1
Tissue score mandible	4.4	1.6	4.0	1.4	4.2	1.5
Tissue score maxilla	4.8	1.6	4.8	1.4	4.8	1.5

SD = standard deviation

For female patients (n=24), the mean tissue score for the mandible was 3.88, for the maxilla 4.33 and combined 8.21. For male patients (n=15), it was 4.73, 5.47 and 10.20 respectively (refer to Table 5.7-5.9). Difference in mean male-female tissue scores was tested using a *t*-test. Significant male-female differences were found for maxilla (p=0.018) and combined (p=0.021). Male-female difference for mandible was not significant with p=0.084.

The mandibular, maxillary and combined tissue scores were correlated with the period of edentulousness. The correlation coefficients were as follows: mandibular: -0.382; maxillary: -0.073; combined: -0.257. Only the mandibular tissue score correlated significantly with the period of edentulousness.

The relationship of tissue scores and years of edentulousness was analysed using a generalized linear model (GLM) (Table 5.35). There was a significant negative association between years of edentulousness and mandibular tissue score. The mean tissue score for the mandible was 4.21. The mandibular tissue score decreases with 0.039 (coefficient) per year of edentulousness.

Table 5.35. Relationship between mandibular tissue score and years of edentulousness

Tissue score mandible	Coefficient	*p*
Per edentulous year	-0.039	0.012
Constant	4.21	

Similarly, the relationship between the maxillary and combined tissue scores with years of edentulous was analysed using the GLM. The results are shown in Tables 5.36 and 5.37. These relationships were not significant.

Table 5.36. Relationship between maxillary tissue score and years of edentulousness

Tissue score maxilla	Coefficient	*p*
Per edentulous year	-0.007	0.654
Constant	4.77	

Table 5.37. Relationship between combined tissue score and years of edentulousness

Combined tissue score	Coefficient	*p*
Per edentulous year	-0.046	0.106
Constant	8.98	

Number of recall visits for both types of dentures is shown in Addendum 9 and Table 5.8. The total and mean number of recall visits for the ANA dentures (n=37) were 48 and 1.30 respectively; for the NZ dentures (n=37) they were 58 and 1.57. According to a paired *t*-test this difference in mean number of recall visits (0.27=1.57 minus 1.30) between the two types of dentures was not statistically significantly different (t=0.9613, df=6, p=0.343).

A *paired t-test* was similarly used to compare the number of recall visits between first and second dentures. The mean of the pairwise differences was 1.027, being significantly different from zero at level $p<0.001$.

5.6.2. Widths alveolar ridges, anatomic and neutral zone dentures

5.6.2.1. Widths alveolar ridge versus anatomic denture

Figure 5.3 shows the mean differences in widths of ridge – ANA, 95% confidence intervals. Negative values indicate that the NZ values are larger than the ridge values.

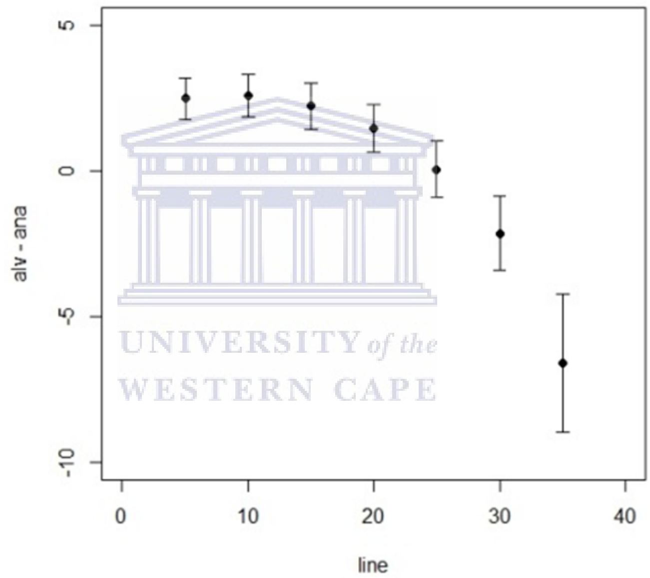

Figure 5.3. Mean differences between alveolar ridge (alv) and ANA denture for each line

5.6.2.2. Widths alveolar ridge versus neutral zone denture

Figure 5.4 shows the mean differences in width between alveolar ridge and the NZ dentures, for each line (95% confidence intervals). Negative values indicate that the NZ values are larger than the ridge values.

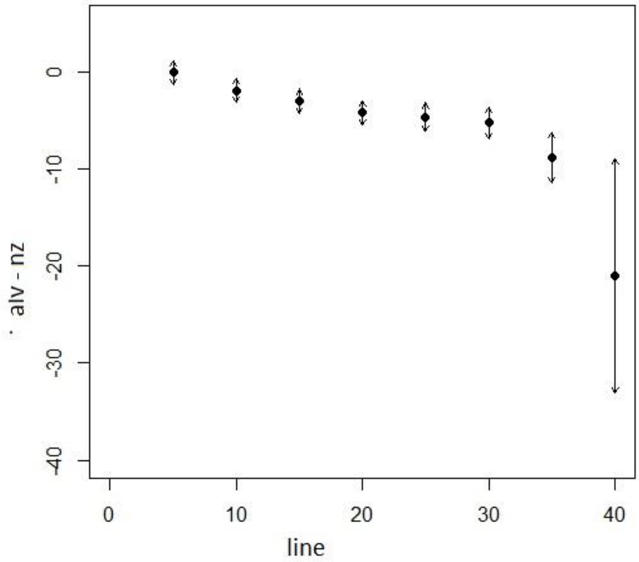

Figure 5.4. Mean difference in width between alveolar ridge (alv) and NZ denture for each line

5.6.2.3. Widths neutral zone versus anatomic dentures

Table 5.38 gives details of summary statistics of the differences in width of NZ-ANA.

Table 5.38. Summary statistics of the differences NZ-ANA

Line	**0**	**5**	**10**	**15**	**20**	**25**	**30**	**35**	**40**
n	39	29	38	39	39	39	37	18	1
Mean	0	2.70	4.42	5.25	5.66	4.70	3.10	1.81	1.19
SE	0	0.51	0.58	0.55	0.54	0.62	0.64	0.81	
Lower	0	1.70	3.29	4.17	4.60	3.49	1.86	0.21	
Upper	0	3.71	5.55	6.34	6.73	5.92	4.35	3.40	

n = number of difference readings per line. SE = standard error of the mean
Lower and upper refer to 95% confidence limits

All means were positive, and so were all the lower limits.

Figure 5.5 shows plots of NZ-ANA differences against line for each patient. The red dots in the graph on left side are the means from Table 5.38, and the confidence intervals are shown as bars in graph on right side.

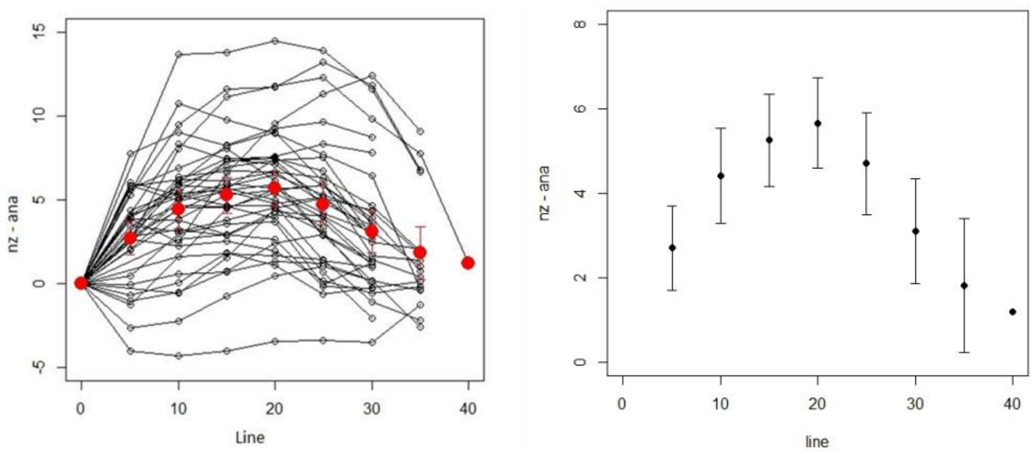

Figure 5.5. Plots of NZ-ANA differences against line for all patients. Graph on the left shows all values; Graph on the right shows means with 95% confidence intervals

Analysis of variance found highly significant interaction (*p*<0.0001). Table 5.39 shows the results of Type 3 tests of Fixed Effects.

Table 5.39. Type 3 tests of Fixed Effects

Effect	Num DF	Den DF	F value	Pr>F
Method	2	76	19.66	<0.0001
Location	7	216	1433.78	<0.0001
Method*location	14	392	44.94	<0.0001

Since there was interaction, comparison of methods had to be done at each location (5, 10, …, 40) separately. The estimated mean values (Least Squares Means) are shown in Table 5.40. For example, for Method=ANA and Location=5, the estimated mean is 51.2.

Table 5.40. Least Square means for methods (ANA, NZ, and ridge) and location (lines 5, 10, …, 40)

Effect	Method	Location	Standard estimate	Error	Lower	Upper
method*location	ANA	5	51.242	0.417	50.422	52.063
	ANA	10	47.671	0.407	46.871	48.471
	ANA	15	44.176	0.407	43.376	44.976
	ANA	20	40.470	0.407	39.670	41.270
	ANA	25	36.483	0.407	35.683	37.283
	ANA	30	32.083	0.409	31.279	32.888
	ANA	35	27.890	0.456	26.994	28.786
	ANA	40	24.119	1.228	21.706	26.533
	R	5	53.769	0.731	52.331	55.207
	R	10	50.271	0.731	48.833	51.708
	R	15	46.401	0.731	44.963	47.839
	R	20	41.922	0.731	40.484	43.360
	R	25	36.546	0.731	35.108	37.983
	R	30	29.878	0.731	28.440	31.316
	R	35	21.456	0.791	19.900	23.012
	R	40	13.433	1.443	10.597	16.269
	NZ	5	54.369	0.710	52.973	55.765
	NZ	10	52.161	0.685	50.814	53.508
	NZ	15	49.430	0.684	48.086	50.773
	NZ	20	46.134	0.684	44.790	47.477
	NZ	25	41.186	0.684	39.842	42.530
	NZ	30	35.207	0.688	33.854	36.559
	NZ	35	29.797	0.759	28.304	31.289
	NZ	40	23.125	1.593	19.993	26.257

Table 5.41 shows the method (Ridge, ANA and NZ) differences at each location (line). For example, at Location=5 the estimated mean difference for ANA minus R is -2.5 (where the minus sign indicates that the R mean is higher). The same differences can be found by looking at the individual least squares means to get 51.24 – 53.76 = -2.5 (rounded). A 95% confidence interval for this estimate is (-3.8, -1.2). The difference is significant (adjusted p=0.00023).

In fact all but three differences are statistically significant. These are highlighted in yellow, being Location=5 (R & NZ), Location=25 (ANA&R), and Location=40 (ANA&NZ).

Table 5.41. Method differences at each location

Obs	Loc	Method _method	Est	SE	Raw_*p*	Fdr_ *p*	Lo	Upp	AdjLo	AdjUpp
1	**5**	**ANA_R**	**-2.527**	0.659	0.000	**0.000**	**-3.822**	**-1.232**	-4.940	-0.114
2	5	ANA_Z	-3.127	0.629	0.000	0.000	-4.363	-1.890	-5.431	-0.822
3	5	R_NZ	-0.600	0.924	0.517	0.560	-2.416	1.217	-3.985	2.786
4	10	ANA_R	-2.600	0.652	0.000	0.000	-3.882	-1.317	-4.989	-0.210
5	10	ANA_Z	-2.600	0.652	0.000	0.000	-3.882	-1.317	-4.989	-0.210
6	10	R_NZ	-1.890	0.905	0.037	0.043	-3.670	-0.111	-5.207	1.426
7	15	ANA_R	-2.225	0.652	0.001	0.001	-3.508	-0.943	-4.615	0.164
8	15	ANA_Z	-5.254	0.604	0.000	0.000	-6.441	-4.067	-7.466	-3.041
9	15	R_NZ	-3.029	0.904	0.001	0.001	-4.806	-1.252	-6.340	0.283
10	20	ANA_R	-1.452	0.652	0.027	0.032	-2.734	-0.170	-3.842	0.938
11	20	ANA_Z	-5.664	0.604	0.000	0.000	-6.851	-4.476	-7.876	-3.451
12	20	R_NZ	-4.212	0.904	0.000	0.000	-5.989	-2.435	-7.523	-0.900
13	25	ANA_R	-0.063	0.652	0.923	0.923	-1.345	1.220	-2.452	2.327
14	25	ANA_Z	-4.703	0.604	0.000	0.000	-5.891	-3.516	-6.916	-2.491
15	25	R_NZ	-4.641	0.904	0.000	0.000	-6.418	-2.864	-7.952	-1.329
16	30	ANA_R	2.205	0.654	0.001	0.001	0.920	3.490	-0.189	4.600
17	30	ANA_Z	-3.124	0.608	0.000	0.000	-4.319	-1.928	-5.351	-0.896
18	30	R_NZ	-5.329	0.907	0.000	0.000	-7.113	-3.545	-8.653	-2.005
19	35	ANA_R	6.434	0.716	0.000	0.000	5.026	7.842	3.810	9.058
20	35	ANA_Z	-1.907	0.676	0.005	0.006	-3.236	-0.578	-4.383	0.569
21	35	R_NZ	-8.341	0.995	0.000	0.000	-10.297	-6.385	-11.986	-4.696
22	40	ANA_R	10.686	1.815	0.000	0.000	7.118	14.255	4.036	17.336
23	40	ANA_Z	0.994	1.609	0.537	0.560	-2.169	4.157	-4.900	6.889
24	40	R_NZ	-9.692	2.045	0.000	0.000	-13.713	-5.671	-17.185	-2.199

Obs = observations; Loc = location (line); Est = estimate; SE = standard error; Lo = lower limit; Upp = upper limit; AdjLo = adjusted lower limit; AdjUpp = adjusted upper limit

Figure 5.6 shows a graph demonstrating where the points of these three instances are closest together. It can also be seen from the graph that neither ANA nor NZ does well at locations 35 and 40 relative to AR (red line).

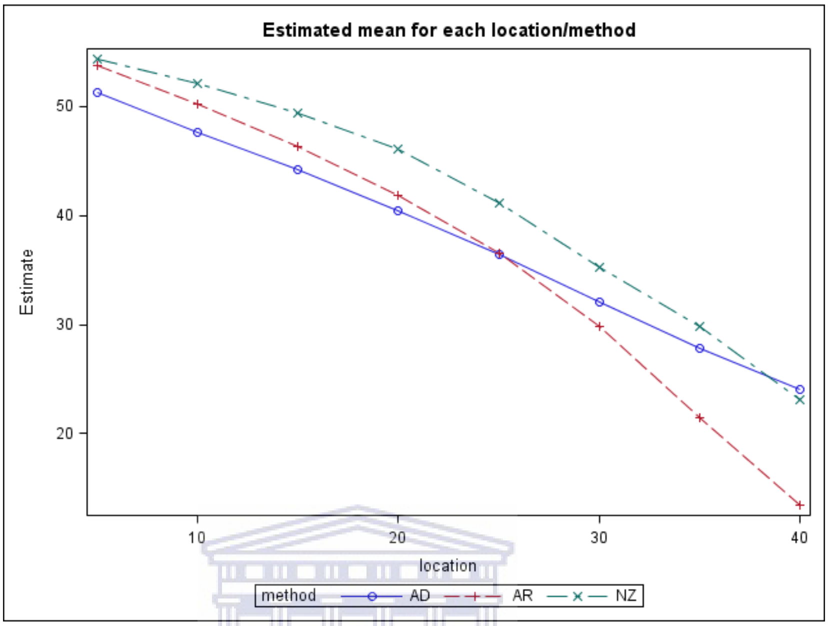

Figure 5.6. Estimated mean for each location and method.
AD = anatomic denture; AR = alveolar ridge; NZ = neutral zone denture

Figures 5.7 to 5.9 shows graphs demonstrating how the methods compare to each other apart from location. The identity reference line is where the two methods would agree. Neither method does well when the alveolar ridge's (R) width is less than 30 mm (locations 35 and 40). All things considered, ANA seems to agree with alveolar ridge (R) a little better than NZ.

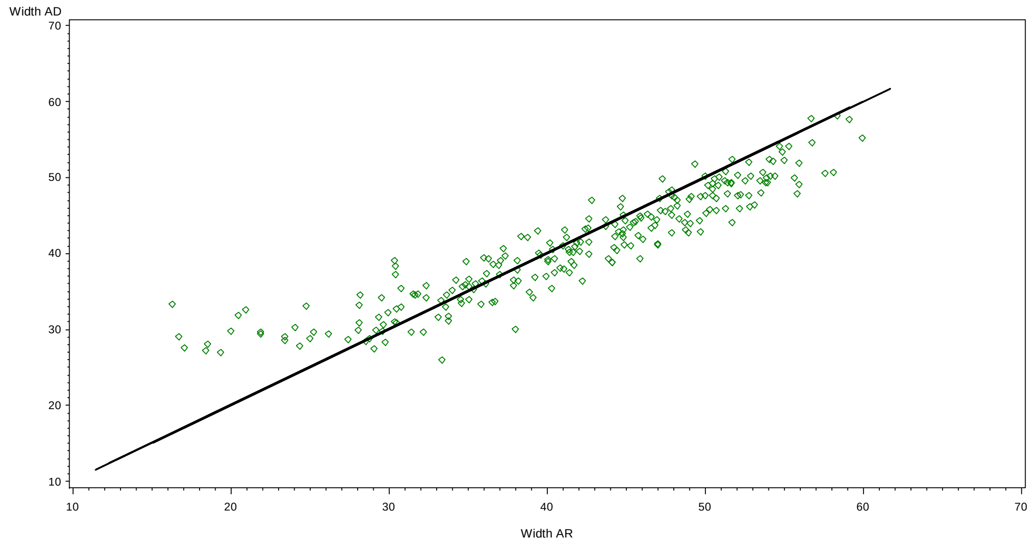

Figure 5.7. Widths of the anatomic denture (AD) versus alveolar ridge (AR). Black line = identity line

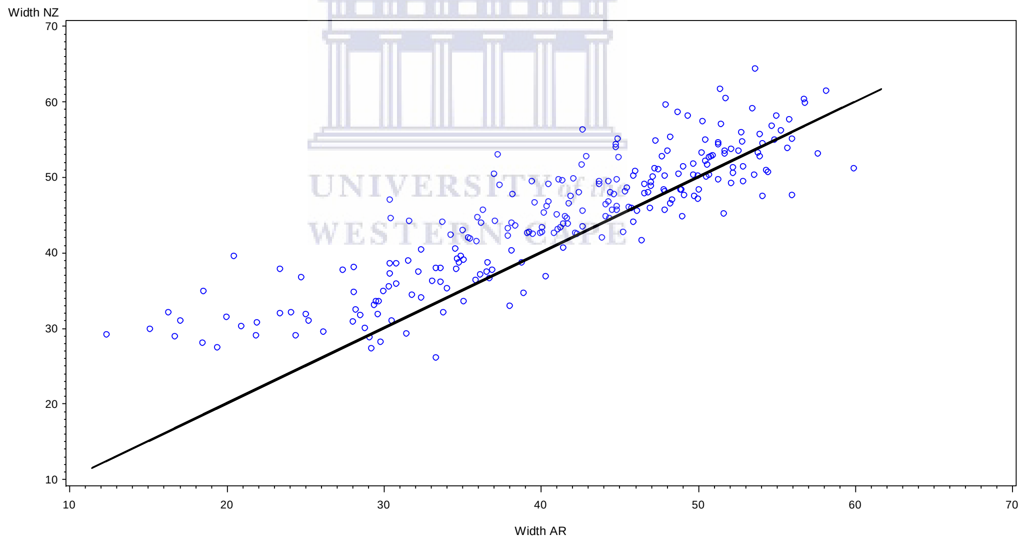

Figure 5.8. Widths of neutral zone (NZ) versus alveolar ridge (AR). Black line = identity line

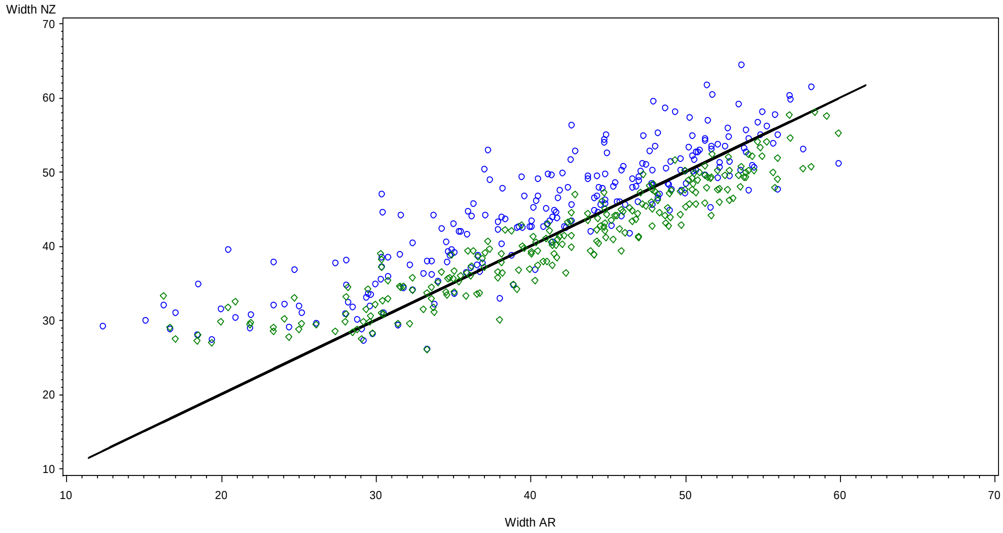

Figure 5.9. Neutral zone (NZ) versus alveolar ridge (AR) and anatomic denture (AD) with identity line
Blue circles are NZ; green diamonds are ANA

5.6.2.4. Analysis of widths using formulae of parabola

The fact that the measurements are taken over outlines that are roughly parabolic in shape provided the motivation to use formula for a parabola. The simple formula for parabola symmetric around the y-axis is y = ax^2. Translating this into the terminology of the measurements of the ridges, ANA and NZ dentures, gives *width* = $\sqrt{depth - line}$ with depth being the "length" of the edentulous arch. This is the motivation for plotting width against $\sqrt{depth - line}$ line in the expectation of seeing plots that can be fitted by straight lines passing through the origin. Examples of such plots can be seen in Addendum 37.

Looking at these plots, data could be fitted by straight lines, but all intercepts were clearly not equal to zero. Nevertheless, slope (b) and intercept (a) of each line could be taken as concise summary of each set of data, encapsulating all width measurements and depth. All graphs showed green lines in lying above the black and red lines, and the tendency is for the black and red to be close to each other.

These trends can be tested more formally using the calculated values of a and b. The a and b values for all parabola (alveolar ridge, ANA and NZ dentures) are shown in Addendum 18.
Results for tests of mean intercepts against zero were as follow:

Test of mean a.alv vs 0: mean (a.alv) = 5.9719, t=6.17, p<0.001
Test of mean a.ANA vs 0: mean (a.ANA) = 9.2959, t=6.95, p<0.001
Test of mean a.NZ vs 0: mean (a.NZ) =15.6666, t=9.61, p<0.001
All three mean intercepts are clearly significantly different from zero.

Results from comparisons of mean intercepts using *paired t-tests* were as follows:
a.alv vs a.ANA: mean (a.ANA-a.alv) = 3.3241, t=2.67, p=0.014
a.alv vs a.NZ: mean (a.NZ-a.alv) = 9.6647, t=6.78, p<0.001
a.ANA vs a.NZ: mean (a.NZ-a.ANA) = 6.3706, t=5.32, p<0.001

Results from comparisons of mean slopes using paired t-tests were as follows:
b.alv =8.1694
b.ANA =7.1786
b.NZ =6.6568

b.alv vs b.ANA: mean (b.ANA-b.alv) = -0.9908, t= -4.85, p<0.001
b.alv vs b.NZ: mean (b.NZ-b.alv) = -1.5127, t= -6.26, p<0.001
b.ANA vs b.NZ: mean (b.NZ-b.ANA) =-0.5219, t= -2.64, p=0.015

The significantly greater mean NZ intercept implies that the tendency is for NZ values to be greater than ANA values at the same line. This is in agreement with the predominantly positive NZ minus ANA differences in Table 5.22. The significantly greater ANA mean slope indicates that the ANA parabolas tend to be more elongated (narrower) than the corresponding NZ ones.

The images of the parabola for each case are given in the Photo Gallery of Addendum 12, together with the corresponding images of the trial ANA and NZ dentures.

5.6.2.5. Widths of alveolar ridges according to gender

A mixed model analysis for repeated measures, showed a significant difference in widths between male and female patients. The graph shown in Figure 5.10 is a plot of alveolar width versus line. The fitted curves were obtained via a mixed model fit of quadratics. The two curves were parallel with intercepts that differed significantly: intercept [Gender=1] = 57.776, intercept [Gender=2] = 54.624 and the difference 3.153 was statistically significantly different from zero at level p=0.007.

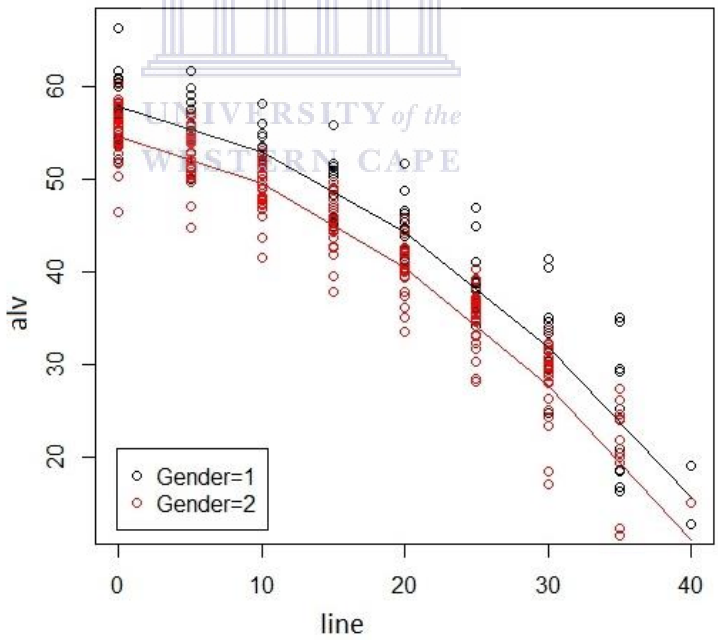

Figure 5.10. Plot of alveolar ridge width versus line, per gender

5.6.2.6. Widths anatomic dentures according to gender

A mixed model analysis for repeated measures was performed to determine if the difference in widths between male and female patients was significant. The graph shown in Figure 5.11 is a plot of ANA versus line. The fitted curves were obtained via a mixed model fit of quadratics. The two curves were parallel with intercepts that differed significantly: intercept [Gender=1] = 55.602, intercept [Gender=2] = 53.096 and the difference 2.506 was statistically significantly different from zero at level p=0.023.

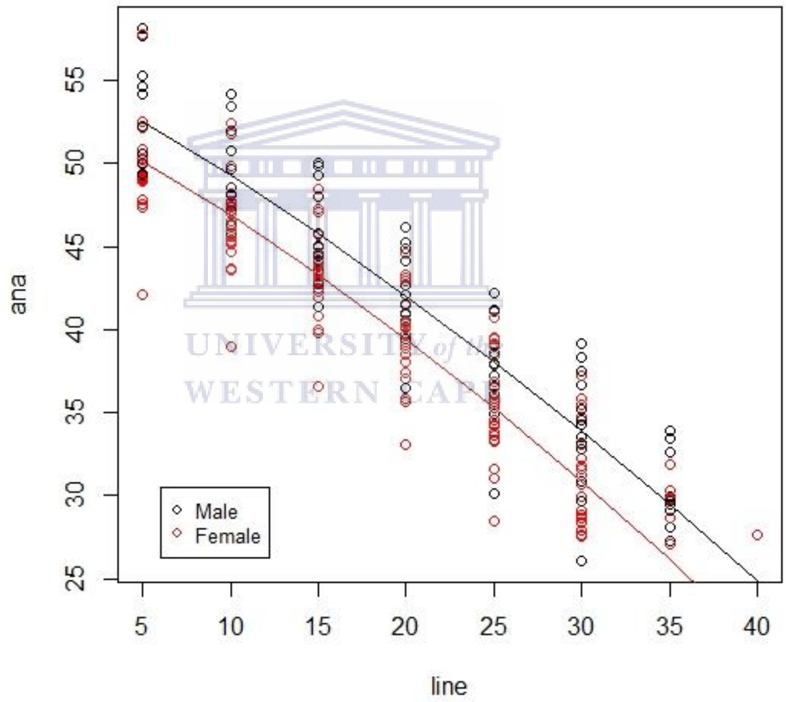

Figure 5.11. Plot of ANA denture-widths versus line, per gender

5.6.2.7. Widths neutral zone dentures according to gender

A mixed model analysis for repeated measures was performed to determine if the difference in widths between male and female patients was significant. The graph shown in Figure 5.12 is a plot of NZ versus line. The fitted curves were obtained via a mixed model fit of quadratics.

The two curves were parallel with intercepts that differed significantly: intercept [Gender=1] = 56.207, intercept [Gender=2] = 53.228 and the difference 2.979 was statistically significantly different from zero at level p=0.030.

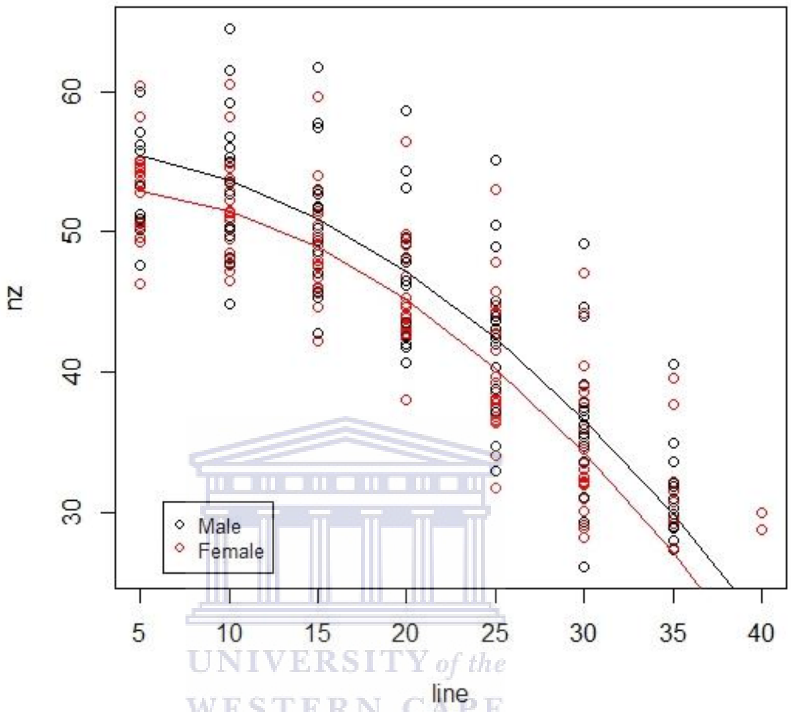

Figure 5.12. Plot of NZ denture-widths versus line per gender

5.6.2.8. Relationship between difference in denture dimensions and tissue scores

A GLM demonstrated a marginal, but not significant, negative relationship between mandibular tissue score and difference in ANA/NZ denture dimensions. The coefficient was -0.601 and p-value was 0.071.

Adjusting for age, mandibular tissue score was negatively associated with the difference in NZ/ANA dimensions. The coefficient was -0.084. This time, the results were significant with a p-value of 0.024. Full test results are available in Addendum 19.

5.6.2.9. Relationship between difference in denture dimensions and period of edentulousness

To establish a relationship between difference in ANA / NZ denture dimensions, the mean ANA – NZ for each patient was calculated and related to the period of edentulousness using a GLM. The coefficient was 0.006, implicating a weak relationship, which was not significant. Full test results are available in Addendum 20.

5.6.2.10. Relationship between difference in denture dimensions and cross-bites

The relationship of difference in width ANA/NZ dentures to the presence of cross-bites was analysed to answer the question if a greater difference in NZ-ANA widths leads to a greater chance of a cross-bite. The mean NZ-ANA difference for every patient was plotted against cross-bite for the NZ dentures and is shown in Figure 5.13.

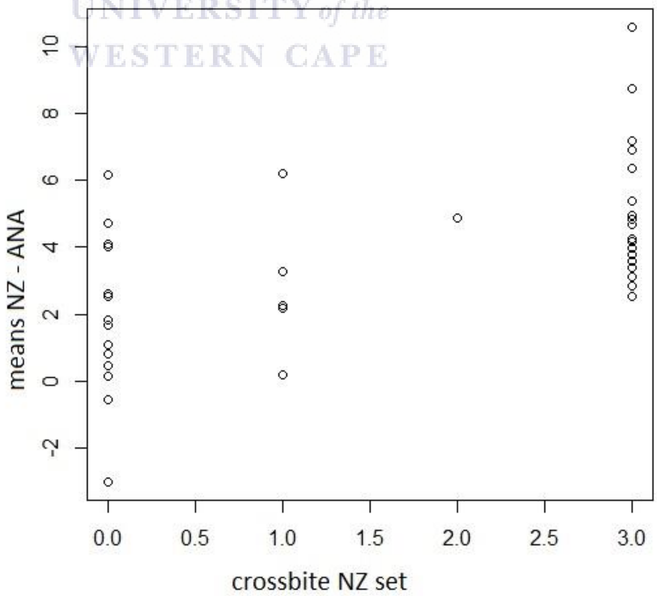

Figure 5.13. Plot of the mean difference of NZ and ANA denture of each patient against the presence of a cross-bite
X-axis: 0 = no crossbite; 1= unilateral crossbite Right; 2 = unilateral cross-bite Left; 3 = bilateral cross-bite

Treating the cross-bite NZ scores as levels of a factor, a one way analysis of variance test of equality of the means of the mean NZ-ANA differences was performed with the result: $F(3,35)=5.943$, $p=0.002$. The mean at cross-bite NZ denture = 3 (bilateral cross-bite) was clearly greater than the mean at cross-bite NZ denture = 0.

While this result seems to support the hypothesis that the larger mean NZ-ANA difference correlates with the presence of cross-bites, the F-test was supplemented with a logistic regression analysis. The presence of a cross-bite (R, L and bilateral) was coded as “yes” and the absence of a cross-bite was coded as “no”. Cross-bite (“yes”, “no”) acted as response and the mean NZ-ANA difference as predictor, with a *p*-value of 0.006, thus supporting the hypothesis.

5.6.2.11. <u>Relationship between difference in denture dimensions and age.</u>

There was a significant negative relationship between difference in denture dimensions and age, with a coefficient of -0.1507 and *p*-value of 0.003. Results for the GLM are shown in Addendum 21.

5.6.3. OHIP-20

5.6.3.1. <u>Preliminary analyses</u>

To determine a possible carry-over and treatment effect between the two treatment periods, a linear regression analysis using GLM was done, with OHIP-20 as the dependent variable, using SAS version 9.4. No significant carry-over (group) or treatment (period) effects between the two types of dentures were found. These results are shown in Addenda 22 and 23. The *t* and *p*-value of both these tests are shown in Table 5.42.

Table 5.42. *t* and *p*-values for Two- sample *t*-test for carry-over and treatment effects

	Carry-over	Treatment
t	1.000	1.533
p	0.324	0.134

As a result of no treatment or carry-over effect, a parametric analysis for comparing the OHIP-20 scores of the groups was appropriate.

Figure 5.14 shows the change in mean OHIP-20 scores of the two treatment sequence groups.

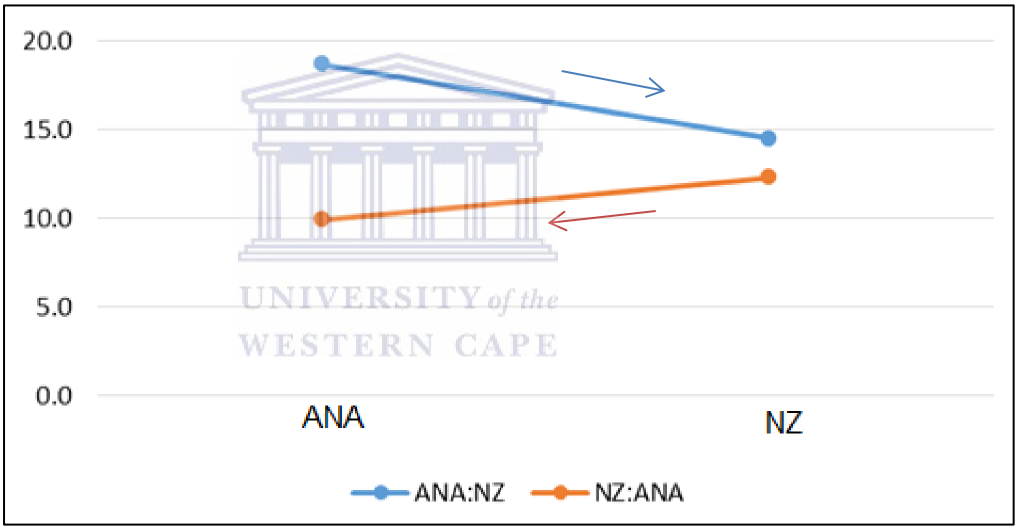

Figure 5.14. OHIP-20 scores per sequence group and type of denture ANA:NZ = group of patients who received ANA denture first; NZ:ANA = group who received NZ denture first

The OHIP-20 scores per sequence and type, in ascending order, are as follows: ANA2 (9.9), NZ1 (12.3), NZ2 (14.5) and ANA1 (18.7), with ANA1 = first anatomic denture delivered, ANA2 = second anatomic denture delivered, NZ1 = first neutral zone denture delivered, NZ2 = second neutral zone denture delivered. When the ANA dentures were delivered as the second denture, it produced the lowest OHIP-20 scores.

To determine whether there was a clear improvement for either ANA or NZ dentures, post-treatment OHIP-20 scores of each patient in each sequence group are plotted in Figure 5.15. These plots confirm the results illustrated by Figure 5.14: The larger differences between NZ and ANA of the ANA:NZ sequence group is reflected in the steeper slope of the same sequence group in Figure 5.15.

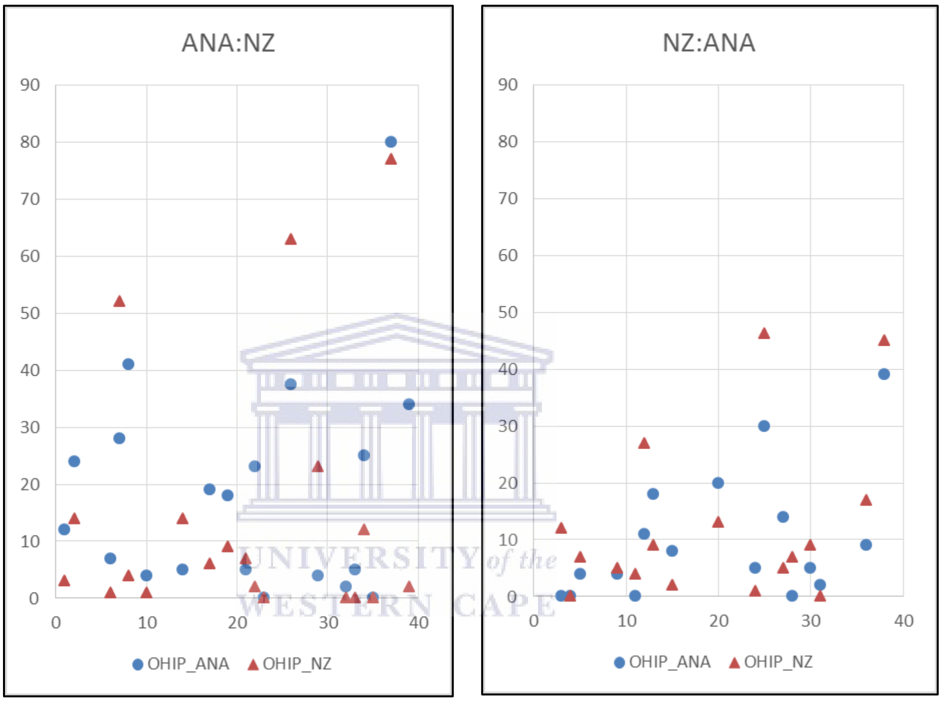

Figure 5.15. OHIP-20 score for ANA and NZ of each patient in each sequence group
ANA:NZ = ANA denture first; NZ:ANA = NZ denture first

The distribution of the difference of the two post-treatment OHIP-20 scores is shown in Addendum 24. Because of the distribution, no transformation was necessary and a parametric analysis was appropriate.

5.6.3.2. <u>Differences in pre-treatment and both post-treatment OHIP-20 scores</u>

Paired *t*-test demonstrated a highly significant difference between pre-treatment and both post-treatment OHIP-20 scores (p<0.001). The full results of the *t*-tests are shown in Addendum 25.

Based on 35 observations, the difference in mean OHIP-20 scores for pre-treatment minus ANA was 27.61, for pre-treatment minus NZ it was 27.93, and for ANA minus NZ it was -0.02.

A statistical significant positive correlation (Spearman's rank correlation coefficient r=0.8752, $p<0.001$) was found between ANA- and NZ OHIP-20 score after adjusting for the pre-treatment OHIP score. Before adjusting for the pre-treatment OHIP the correlation was also statistical significant and positive (r=0.733, $p<0.001$). Figure 5.16 demonstrates this strong correlation between the ANA and NZ treatment methods.

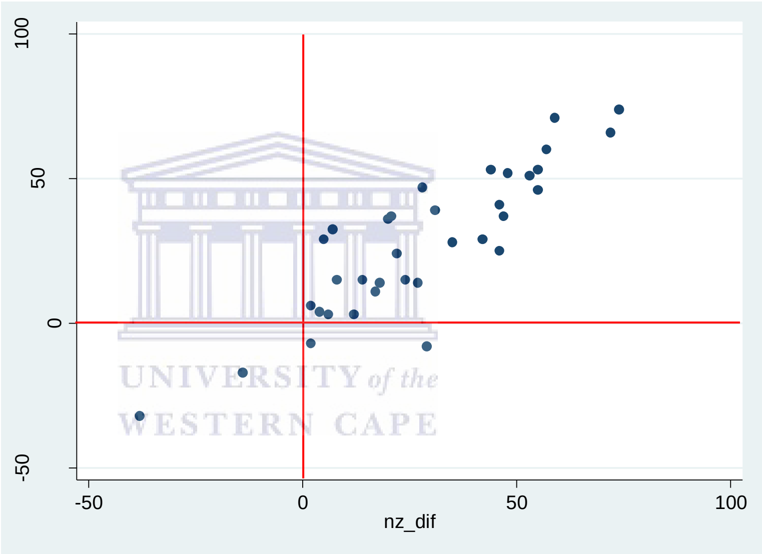

Figure 5.16. Scatterplot for the pre and post treatment OHIP-20 differences for both types of dentures

A negative score equals deterioration between pre- and post-treatment. Figure 5.16 shows that pre-treatment - NZ (nz_dif) resulted in only two patients reporting deterioration in OHIP-20 scores (dots to the left of the vertical red line), while 33 patients' scores improved.

Pre-treatment - ANA (ana_dif) resulted in only four patients reporting deterioration in OHIP-20 scores (dots below the horizontal red line in Figure 5.16). Two of these patients were the same patients who reported deterioration for the NZ dentures. Thirty one patients' scores improved.

5.6.3.3. Correlation between pre-treatment and post-treatment OHIP-20 scores

There is a low positive Spearman correlation between pre-treatment and ANA OHIP-20 scores, although not significant (r=0.196; *p*=0.259) There is a medium positive Spearman correlation between pre-treatment and NZ post-treatment OHIP-20 scores, which is almost significant (r=0.317; *p*=0.064) (Table 5.43).

Table 5.43. Simple statistics and Pearson's correlation pre- and post-treatment OHIP-20

Simple Statistics							
Variable	**N**	**Mean**	**SD**	**Sum**	**Min**	**Max**	**Label**
OHIP_ANA	37	14.66	16.57	542.50	0	80.00	OHIP_ANA
OHIP_NZ	37	13.50	18.98	499.33	0	77.00	OHIP_NZ
OHIP pre_ treatment	37	42.11	23.33	1558.00	4.00	75.00	OHIPpre

Pearson Correlation Coefficients Prob > |r| under H0: Rho=0 Number of Observations	
	OHIP pre_treatment
OHIP_ANA **OHIP_ANA_dentures**	0.19591 0.2594 35
OHIP_NZ **OHIP_NZ_dentures**	0.31691 0.0636 35

5.6.3.4.<u>Relationships between OHIP-20 with other variables</u>

5.6.3.4.1. OHIP-20 scores and tissue scores

The mandibular, maxillary and combined tissue scores were related with the OHIP-20 scores using the GLM. Table 5.44 gives coefficients and significance *p*-value was always larger than 0.05. The complete statistical analysis is provided in Addenda 26-29.

Table 5.44. Coefficients and *p*-values for OHIP-20 and tissue scores

OHIP-20	Tissue score	Coefficient	Constant	*p*-value
Pre-treatment	**Mand**	-3.402	55.992	0.204
	Max	0.334	40.520	0.903
	Combined	-0.944	50.449	0.532
ANA	**Mand**	-3.041	27.485	0.083
	Max	-2.119	24.858	0.252
	Combined	-1.641	29.482	0.103
NZ	**Mand**	-3.267	27.269	0.106
	Max	0.215	12.461	0.921
	Combined	-0.997	22.494	0.400

5.6.3.4.2. OHIP-20 scores and gender

Using the GLM, coefficients and significance for the relationship between OHIP-20 scores and gender were determined and are shown in Table 5.45. Values in the first column are the mean values for OHIP-20 values for male patients. Values in the second column are the values by which the OHIP-20s differ for female patients. None of the relationships were statistically significant with *p*-value always >0.05.

Table 5.45. GLM coefficients and *p*-values for OHIP-20 and gender

OHIP-20	Constant	Coefficient	*p*
Pre-treatment	38.4	5.460	0.493
ANA	13.4	2.122	0.705
NZ	15.9	-3.988	0.534

Male is reference.

The full results are shown in Addendum 30.

5.6.3.4.3.OHIP-20 scores and age

Using the GLM, coefficients and significance for the relationship between OHIP-20 scores and age were determined and are shown in Table 5.46. For pre-treatment OHIP-20, there was a negative relationship between OHIP-20 scores and age: the older the person, the lower the OHIP-20 score. The score would decrease with a factor 0.620 per year of age. There was a weak negative and positive relationship for the ANA and NZ OHIP-20s respectively with age. However, none of the relationships were statistically significant with *p*-values always >0.05.

Table 5.46. GLM coefficients and *p*-values for OHIP-20 and age

OHIP-20	Constant	Coefficient	*p*
Pre-treatment	80.9	-0.620	0.132
ANA	17.6	-0.047	0.877
NZ	10.5	0.048	0.891

The full results are shown in Addendum 31.

5.6.3.4.4.OHIP-20 and education

Using the GLM, coefficients and significance for OHIP-20 scores and education were determined and are shown in Table 5.47.

The constant is the mean OHIP-20 of Education 1 group that was used as reference. The coefficient gives the value by which the OHIP-20 of Education groups 2 and 3 differ from the OHIP-20 of the Education group 1. The only significant difference (p=0.047) was between the pre-treatment OHIP-20 scores of Education groups 1 and 2, with a difference in OHIP-20 of 17.520.

Table 5.47. Coefficients and *p*-values for OHIP-20 and education

OHIP-20	Education	Constant	Coefficient	*p*
Pre-treatment	2	29	17.520	0.047
	3		15.667	0.301
ANA	2	7.4	9.144	0.172
	3		10.625	0.344
NZ	2	3.4	12.945	0.087
	3		12.625	0.319

Education 1 (primary school) was used as reference
Education 2 = high school
Education 3 = post high school

The full results are shown in Addendum 32.

5.6.3.4.5. OHIP-20 and marital status

Using the GLM, coefficients and significance for OHIP-20 scores and marital status were determined and are shown in Table 5.48. The married group was used as reference: its OHIP-20 score are shown in the first column. The second column shows the values by which the OHIP-20 scores of the single group differ from the married group.

Pre-treatment OHIP-20 scores were higher for the unmarried group (positive coefficient); post-treatment OHIP-20 scores were lower for the unmarried group (negative coefficient). However, none of the relationships were statistically significant.

Table 5.48. Coefficients and *p*-values for OHIP-20 and marital status

OHIP-20	Constant	Coefficient	*p*
Pre-treatment	40.1	5.644	0.486
ANA	15.8	-3.019	0.595
NZ	17.3	-9.951	0.114

The full results are shown in Addendum 33.

5.6.3.4.6. OHIP-20 and period of edentulousness

Using the GLM, a very weak positive relationship between period of edentulousness and pre-treatment OHIP-20 was found. There was a very weak negative relationship between pre- and both post-OHIP-20 scores. All these relationships were not significant ($p>0.05$). The coefficients and significance are shown in Table 5.49.

Table 5.49. Coefficients and *p*-values for OHIP-20 and period of edentulousness

OHIP-20	Constant	Coefficient	*p*
Pre-treatment	40.8	0.042	0.879
ANA	17.4	-0.088	0.646
NZ	17.2	-0.120	0.585

The full results are shown in Addendum 34.

5.6.3.4.7. OHIP-20 differences and differences in dimensions

A correlation analysis of the differences in OHIP-20 scores ANA minus NZ and the differences in denture dimensions ANA minus NZ gave a weak positive correlation coefficient of r=0.0343, with *p*-value of 0.839. Therefore, there was no significant correlation between OHIP-20 score differences of the 2 treatment types and differences in denture dimensions.

Full statistical analysis is shown in Addendum 35.

5.6.4. Denture preference

5.6.4.1. <u>Relationship of denture preference and difference in post-treatment OHIP-20 scores</u>

The relationship of difference in post-treatment OHIP-20 scores and denture preference is shown in the box-and-whisker plot of Figure 5.17.

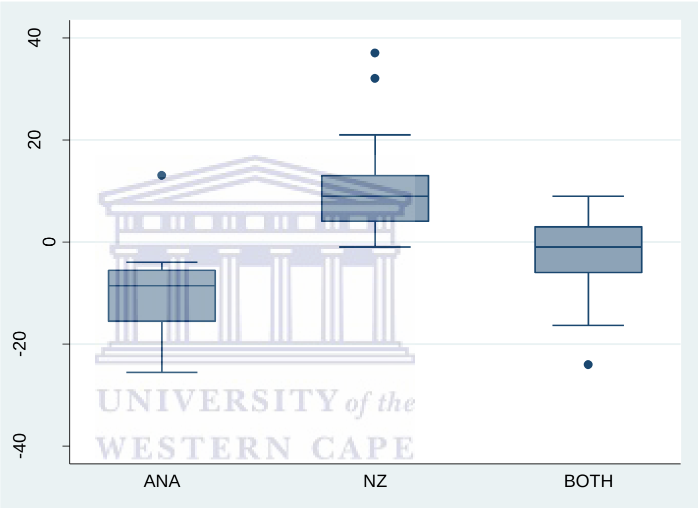

Figure 5.17. Box and whisker plot for denture preference against the difference in OHIP-20 scores ANA-NZ dentures

Using the GLM, the relationship of preferences with OHIP-20 difference was analysed and the results are given in Tables 5.50 and 5.51. Preference for the ANA denture was used as reference. There was no close relationship between OHIP-20 difference and preference, except for preference 2 (NZ denture), with a coefficient of 19.904 which was statistically significant (p=0.000).

Table 5.50. Coefficients and *p*-values for preferences and OHIP-20 difference

OHIP-20 ANA minus NZ						
Preference	**Coefficient**	**SE**	**z**	***p*>|z|**	**[95% Conf Int]**	
NZ	19.904	4.590	4.31	0.000	10.809	28.800
None	5.485	4.646	1.18	0.238	-3.621	14.592
Constant	-8.938	3.707	-2.41	0.016	-16.202	-1.673

Denture preference 1 (ANA) was the reference
SE = standard error. Conf Int = confidence interval

Table 5.51. Relationship between denture preference and difference in OHIP-20 scores ANA-NZ

Preference	n	Mean	SD
ANA	8	-8.94	11.31
NZ	15	10.87	11.04
Both	14	-3.45	9.35
Total	37	1.17	13.19

SD = standard deviation

5.6.4.2. Denture preference and effect of first denture

Table 5.52 gives summary statistics for denture preference according to treatment sequence. No statistical significant effect was found.

Table 5.52. Effect of first denture: summary results and *p*-value following Fisher's exact test

Treatment sequence	Preference			Total
	ANA	NZ	None	
ANA›NZ	4	11	5	20
	20.00	55.00	25.00	100.00
NZ›ANA	4	4	9	17
	23.53	23.53	52.94	100.00
Total	8	15	14	37
	21.62	40.54	37.84	100.00
Fisher's exact (p=0.144)				

Treatment sequence	Preference		Total
	ANA	NZ	
ANA›NZ	4	11	15
	26.67	73.33	100.00
NZ›ANA	4	4	8
	50.00	50.00	100.00
Total	8	15	23
	34.78	65.22	100.00
Fisher's exact (p=0.371)			

Upper Table: all preference groups
Lower Table: "no preference"- group excluded

5.6.4.3. Relationship of denture preference and the difference in OHIP-20 first minus second denture

Figure 5.18 shows a box and whisker plot of the relationship of denture preference against the differences in OHIP-20 scores of the first minus the second denture.

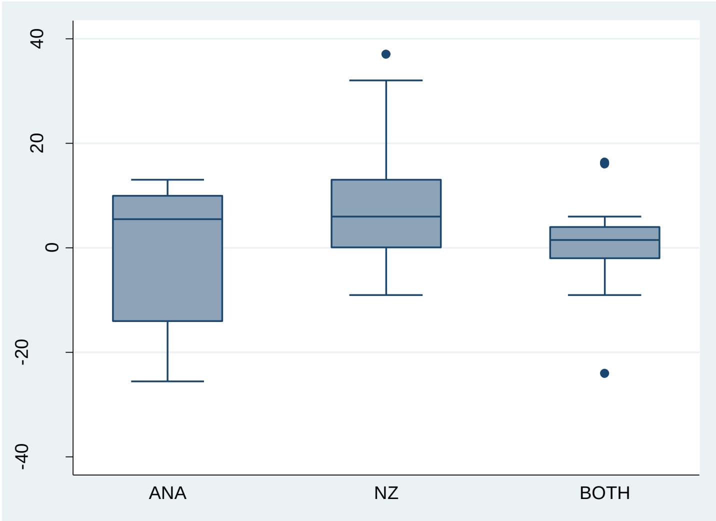

Figure 5.18. Box and whisker plot of denture preference against effect of first denture
(Per_diff = difference of OHIP-20 first denture minus second denture)

Table 5.53 shows summary statistics for denture preference and OHIP-20 score differences according to sequence of denture type delivery.

Table 5.53. Relationship between denture preference and difference in OHIP-20 scores first minus second denture

Dent_pref3	n	Mean	SD
ANA	8	-1.19	14.75
NZ	15	8.33	13.189
Both	14	0.60	9.99
Total	37	3.35	12.80

SD = standard deviation

In Table 5.54, results following regression analysis using the GLM are shown.

Table 5.54. Coefficients and *p*-values for preferences and OHIP-20 difference first minus second denture

OHIP-20 first minus second denture						
Preference	OIM					
	Coefficient	SE	z	*p*>|z|	[95% Conf Int]	
NZ	9.521	5.443	1.75	0.080	-1.148	20.189
None	1.782	5.510	0.32	0.746	-9.018	12.583
Constant	-1.187	4.396	-0.27	0.787	-9.803	7.428

Denture preference 1 (ANA) was the reference
SE = standard error. Conf Int = confidence interval

5.6.4.4. Denture preference and tissue scores

Using the GLM procedure, denture preference was related to mandibular, maxillary and combined tissue scores. Results are shown in Tables 5.55 to 5.57. Preference 1 (ANA) was used as the reference. As an example, the relationship between mandibular tissue score and denture preference is explained (Table 5.55): the mean tissue score for people who preferred the ANA denture was 4. The tissue score for people who preferred the NZ denture was 0.4 higher and those who had no preference was 0.1429 higher. However, there was no statistical significance. Similar deductions can be made for Tables 5.56 and 5.57.

Table 5.55. Relationship between denture preference and mandibular tissue score

Denture preference	**Coefficient**	***p*>|z|**
NZ	0.4	0.559
None	0.1429	0.837
Constant	4	0.000

Preference 1 (ANA denture) was used as reference

Table 5.56. Relationship between denture preference and maxillary tissue score

Denture preference	Coefficient	*p*>|z|
NZ	0.417	0.950
None	0.446	0.506
Constant	4.625	0.000

Preference 1 (ANA denture) was used as reference

Table 5.57. Relationship between denture preference and combined tissue score

Denture preference	Coefficient	*p*>|z|
NZ	0.442	0.714
None	0.589	0.629
Constant	8.625	0.000

Preference 1 (ANA denture) was used as reference

Mandibular or maxillary tissue score were not found to be a significant predictor for denture preference.

5.6.4.5. Denture preference and gender

Table 5.58 shows the results of a Fisher's exact test. There was no significant result (p=0.359). Correlating only the data of ANA and NZ preference (ignoring the data of patients who had no preference) and gender also did not find a significant result (p=0.195).

Table 5.58. Fisher's exact test for denture preference and gender

Denture preference	Gender		Total
	Male	Female	
ANA	4	4	8
	50.00	50.00	100
	26.67	18.18	21.62
NZ	4	11	15
	26.67	73.33	100
	26.67	50.00	40.54
No preference	7	7	14
	50.00	50.00	100
	46.67	31.82	37.84
Total	15	22	37
	40.54	59.46	100
	100	100	100
Fisher's exact test (*p*=0.359)			

5.6.4.6. Denture preference and age

Using a GLM, the relationship between denture preference and age of the patients in years was analysed. Tables 5.59 and 5.60 show the variables, coefficients and significance.

Table 5.59. Summary for variables of denture preference and mean age of patients in years

Dent_pref3	n	Mean	SD
ANA	8	59.13	8.114
NZ	15	63.27	9.647
Both	14	63.43	9.509
Total	37	62.43	9.206

SD = standard deviation

The mean age of patients who preferred ANA was 59.13. The mean age of patients who preferred NZ was 4.14 years more. The mean age of patients who had no preference was 4.30 older. Thus, younger people preferred the ANA denture, older people preferred the NZ treatment option or had no preference. However, none of the relationships were statistically significant ($p>0.05$).

Table 5.60. Association between denture preference and age of patients in years

Denture preference	Coefficient	$p>\|z\|$
NZ	4.142	0.309
None	4.304	0.296
Constant	59.125	0.000

Reference was preference 1 (ANA denture)
Preference 2 = NZ denture; preference 3 = no preference

5.6.4.7. Denture preference and period of edentulousness

Using a GLM procedure, the relationship between denture preference and mean period of edentulousness in years was analysed. Tables 5.61 and 5.62 show the variables, coefficients and significance.

Table 5.61. Mean and standard deviation for years of edentulousness per preference groups

Denture preference	n	Mean period of edentulousness (yrs)	SD
ANA	8	36.25	6.98
NZ	15	29.87	16.35
Both	14	29.18	15.79
Total	37	30.99	14.54

SD = standard deviation

The mean period of edentulousness for the ANA preference was 36.25 years. The mean period of edentulousness for the NZ preference and no preference was 6.38 and 7.07 years less (thus shorter). Therefore, patients with shorter periods of edentulousness preferred the NZ dentures or had no preference.

Table 5.62. Relationship between denture preference and period of edentulousness

Per-edent-yrs	**Coefficient**	***p*>|z|**
NZ Preference	-6.383	0.321
No preference	-7.071	0.277
Constant	36.250	0.000

Preference 1 (ANA denture) was used as reference

5.6.4.8. Denture preference and difference in NZ-ANA dimensions

The association between denture preference and difference in denture dimensions was analysed using a GLM. Results are given in Table 5.63. Preference 1 (ANA denture) was used as reference. The group who preferred the ANA denture had a mean denture dimension difference NZ-ANA of 4.396 mm. Those who preferred the NZ denture had a 0.036 mm larger difference. The difference of the group who had no preference was 0.421 smaller. However, there was no statistical significance found for these relationships with *p*-values >0.05.

Table 5.63. Coefficients and *p*-values for association between preference and difference in denture dimensions

Difference in dimensions	**Coefficient**	***p***
NZ preference	0.036	0.981
No preference	-0.421	0.779
Constant	4.396	

The statistics are shown in Addendum 36.

5.6.4.9. Denture preference and cross-bites

Table 5.64 shows the number of patients for each of the combinations of the different variables.

Table 5.64. Number of patients for preference and NZ cross-bite scenario

Denture preference	Cross-bite NZ				Total
	None	Right	Left	Bilateral	
ANA	2	1	0	5	8
NZ	6	2	0	7	15
No preference	6	2	1	5	17
Total	14	5	1	17	37

In order to assess if the presence of a cross-bite influenced the preference of dentures, a Fisher's exact test of association between the two variables was done. No significant association was found with p=0.922.

5.6.4.10. Denture preference and patient feedback

Of those patients who preferred the NZ dentures, these were the reasons given (patient identity number in brackets):

"From day 1, the second set fitted very nicely." (1)

"From day 1, the dentures fitted nicely. Dentures feel nice and wide." (2)

"The bottom denture seems to give my mouth more freedom, easier to eat and move my mouth." (6)

"Mouth feels a bit tired when I have spoken a lot, otherwise comfortable." (8)

"This set sits more comfortable and biting experience was much better." (9)

"The first set was better because the bottom teeth fitted more firmly." (13)

"This set gives no problems. I can eat an apple, something I could not do with other denture." (19)

"Food doesn't stick to the outside of the dentures (like it did on the other denture)." (20)

“Denture has far better retention. Eats better.” (22)

“Denture sits more comfortable. It doesn’t feel like false teeth. Feels as if it is my own teeth.” (33)

“Denture sits better.” (34)

“Denture fits better. Eats and speaks better.” (35)

“This denture does not make my mouth feel tired like the other set.” (39)

From the feedback from the patients, it appears that the dominant reason for the preference for the NZ denture was related to “fit” and “eating”.

The feedback from patients who preferred the ANA dentures:

“It fits better” (3)

“Less food gets stuck underneath.” (14)

“Was more comfortable” (17)

“This set wears nicer and I don’t bite my cheek (28)

“Don’t bite my tongue like with the other denture” (29)

“This set is much more comfortable” (30)

“Because it fits perfectly and is better to eat with.” (36)

Again, the dominant reason for preferring this denture was related to “fit” and to a lesser degree “eating”.

5.7. CONSORT CHECKLIST

A CONSORT checklist is provided in Addendum 37.

CHAPTER 6: DISCUSSION

6.1. INTRODUCTION

The aim of this study was to perform a clinical trial comparing NZ and ANA mandibular dentures. Denture shapes based on transverse widths of mandibular tooth arches were compared and related to the underlying crest of the residual ridge. The impact on OHRQoL following treatment by the two types of dentures was measured by using the OHIP-20 questionnaire. Several socio-demographic variables and denture history were related to features of the two types of dentures and OHRQoL results.

6.2. SAMPLE CHARACTERISTICS

In this section, patient participation, socio-demographic features and their possible impact on results will be discussed.

6.2.1. Participation and retention rate

Of a total of 39 patients that were screened and included in the study, 37 patients completed the cross-over trial with the two types of intervention (Figure 5.2). This represented a 95% retention rate. Another two patients were not wearing their dentures at the start of the trial and no comparisons of pre and post-treatment OHIP-20 could be done for these patients (Figure 5.1). This represented a 90% retention rate. This high retention rate may have several reasons. The waiting list for complete dentures at the Oral Health Centre of the University of the Western Cape is publicly known to be long and edentulous patients may wait months or even years to be treated with complete dentures. Prosthetic services in public facilities outside the academic oral health centres of the University of the Western Cape are limited or non-existent. To be recruited into a clinical trial and be treated almost immediately presented a unique opportunity for patients to avoid being placed on a waiting list.

Treatment was performed by a senior clinician and not by students. This may also have been perceived as an advantage by potential participants.

However, this does not explain the high percentage of patients returning for the second set of dentures, after wearing the first set for at least two months. Even though there was no additional cost for the patients associated with the manufacturing of the second set of dentures, there were hidden costs in terms of transport and time when the second dentures had to be delivered, as well as potential discomfort during the adaptation period to the second set. A possible explanation for this may be that the majority of patients had limited financial resources. Thirty six of the 39 patients declared an income lower than R5000 per month. A "free" second set of dentures may have been regarded as an opportunity to reduce future costs related to replacing worn or broken dentures. The majority of patients were pensioners and this may explain why time may not have been a major obstacle for attending additional clinical visits.

Patient attrition and its effect on the power of a study is often a problem with clinical trials. A few tools were employed in the methodology to minimize this risk. Firstly, the cross-over period was limited to at least two months. Secondly, patients were screened from time to time, as enrolment capacity became available. This prevented the creation of long waiting lists. From start (signing of informed consent) to completion (returning for the last and final OHIP-20) covered a period of at least 23 weeks.

The reasons why two of the 39 patients did not return for their second dentures were the following: one patient moved to a different province; the second patient was satisfied with the first set of dentures and was not interested in returning for the second set. In the latter case, the patient's decision was respected. It was thought that coercing may have influenced the patient's assessment of the dentures. The informed consent form stated that participation was voluntary and participants were allowed to opt-out of the trial at any stage.

Since the reasons for leaving the trial were not likely to be associated with the prognosis of treatment effect, it was assumed that the loss of these two patients did not introduce bias or influence the validity of results.

For the denture dimension study, both ANA and NZ wax trial dentures were made for all 39 patients and could thus be included in the analysis. This represents a 100% retention rate.

6.2.2. Socio-demographic characteristics

For the denture dimensions study, 38% of the participants were male. For the OHIP-20 analysis, 40% of the patients were male. The higher number of female participants in the study may be a reflection of gender prevalence of edentulousness in the region. A similar gender distribution was reported in the Adam *et al.* (2007) study, also conducted in the Western Cape Province. Van Wyk & Van Wyk (2004) reported that in SA, a larger percentage of females, among all population groups, is edentulous compared to males. Trying to match the number of male volunteers to the number of female participants would have substantially delayed the roll-out of the trial.

At the start of treatment, the mean age of the 39 patients was 62.3 years. The youngest patient was 47 years old; the oldest patient was 85 years of age. According to the original research proposal, the inclusion criteria in terms of age were 40 to 70 years of age. However, it soon became clear that this age range was too narrow to recruit the necessary volunteering patients. While none of the patients was younger than 40 years of age, three patients were older than 70 years of age (77, 78 and 85). They were included based on confirmation of all other inclusion criteria and absence of any exclusion criteria (Table 4.1).

While 27 participants indicated to have attended some years in high school, only three had tertiary education. All patients, except three, declared to have a monthly income of less than R5000. One patient declared to earn between R10000 and R15000, and two patients said they earned more than R15000.

South Africa is classified by the World Bank as an upper middle income country with a gross national income of US$7190 per capita per year (The World Bank, 2014). This means that 36 of the 39 patients in this trial had an income below the national average of about R6525.00 per month per person. (Forex rate 1.00US$-10.89ZAR, 31 October 2014) and therefore, this sample could be regarded as below the "upper middle income" norm. Since the majority of the patients were below the R5000.00 income, the questionnaire could have been structured to provide more detail on income for the "below-R5000.00" group. It may be speculated that the population group in this trial may even belong to the lower middle income or lower income groups as specified by the World Bank.

The majority of patients were pensioners or were unemployed. The Oral Health Centre, where this trial was carried out, provides dental treatment according to level of income of patients, hence for most patients treatment may be cheaper than private tariffs. This has contributed to the fact that most patients volunteering and being recruited in the trial were from average to lower socio-economic background. These conditions may have influenced OHIP-20 scores, as will be discussed later. Even though patients needed to provide proof of income in order to qualify for lower treatment tariffs at the Oral Health Centre, it must be kept in mind that patients could be dishonest or hide additional sources of income or financial support. As a result, individuals may enjoy a comfortable lifestyle without income. Therefore, income as a determinant for socio-economic circumstances of individuals may not always be accurate.

The mean period of edentulousness for this group of participants was 30.9 years. This is a long period of time for this sample with a mean age of 62.3 years at the start of the trial. Becoming edentulous at a relatively young age has been a reality for this group of patients. This is in line with findings by Du Plessis *et al.* (1994), who reported a 12.6% prevalence rate of edentulousness in South Africa within the 35-44 years age group. It also corresponds with findings in the Adam *et al.* (2007) study, where the mean age of the sample was 58 years, with 71% of patients being edentulous longer than 16 years.

The mean age of dentures patients were wearing at the start of the trial was 14.6 years. The oldest denture was 45-years old (patient 2); the most recently-made denture was one-year old (patient 37). Mean number of denture sets per patient was 2.39 over a mean period of edentulousness of 30.92 years for the whole group. This gives a mean age for dentures of almost 13 years.

Since the selection of patients into the two sequence groups was randomized, it could have influenced the distribution of demographic and denture history features. The success of randomization of patients into the two sequence groups was checked by comparing age (*t*-test), gender, education and income (Chi-squared test) between two sequence groups. There were no significant differences of these variables between the two sequence groups, indicating that random allocation of patients into the two groups was successful (Table 5.2). Therefore, it may be concluded that none of the denture and demographic variants of this study confounded the OHIP-20 results of the two treatment sequences. Gender, as a co-morbid factor in assessing denture satisfaction in this study will be analysed in the discussion on OHRQoL results and denture preference.

6.3. METHODOLOGY

In this section, different aspects of the methodology will be discussed. These are: trial design, denture construction techniques, NZ recording techniques and measuring techniques.

6.3.1. Trial design

This trial was designed as a randomized within-subject cross-over clinical study, in which each individual was exposed to a sequence of two interventions ("AB/BA" cross-over) for the management of the same condition. There were several advantages related to this trial design: each patient acted as his or her own control; treatment effect could be estimated with higher precision;

and smaller sample sizes were required. It was also possible to assess patient preference. Possible disadvantages could have been dropping out of patients and carry-over effect. Dropping out of patients was not a problem for this trial with a reported 95% retention rate. Carry-over effect is understood as the influence of the first intervention onto the second. This needs further clarification: important requirements for a cross-over trial are that the condition to be treated is chronic and reversible. In this trial, patients were edentulous - a permanent condition. Treatment was reversible by means of removal of prostheses. Unlike the use of cross-over trials for testing, for example, the effect of medication, where a wash-out period is necessary, minimal carry-over effect was expected for this trial. This was confirmed by preliminary analyses by means of a GLM analysis and two sample *t*-tests, with OHIP-20 as the dependent variable (Table 5.42). To test for carry-over effect, the mean of total OHIP-20 scores were used; for the treatment effect, means of differences between the treatment-sequence groups were used (Addenda 22 and 23). No treatment or carry-over effect was found. Because no literature was found reporting on possible carry-over effects in prosthetic cross-over trials, this statistical analysis was deemed sufficient to confirm no carry-over effect.

The first denture was retained when the second denture was delivered. Therefore, it was impossible for patients to revert to their first denture during the assessment period of the second denture. However, the pre-treatment denture remained in the possession of the patient and the researcher had no control over the use of the pre-treatment denture during the trial. However, the pre-treatment denture was kept by the patient during the wearing period of both types of dentures and its effect may have been similar on both post-treatment OHIP-20 scores.

Patients were blinded to the type of intervention. It was not possible for the single prosthodontist carrying out the trial to be blinded. This may have introduced bias, albeit not deliberate, and could be considered a weakness of the trial.

Kimoto *et al.* (2013) reported that clinical skills could influence patient satisfaction with complete dentures. Carlsson (2006) suggested that patient-based outcomes are influenced not only by dentists' clinical skills but also by patients' psychological and emotional status. The fact that one clinician performed all the clinical and laboratory procedures, standardised the "skills and experience" variable. Although the nature of interpersonal relationship differs depending on each individual involved, at least the clinician in this dentist-patient relationship was the same for all patients in this sample.

The intervention period for each denture was capped at a minimum of eight weeks of denture–wearing, following the last recall visit. It was feared that extending this period would have negatively influenced patient compliance and increased risk for changes in systemic or local patient health-related events or other conditions. It was also shown that trial periods of eight weeks were long enough for establishing patient preferences among different prostheses (de Grandmont *et al*., 1994).

Aarabi *et al. (*2015) followed-up the effect of prosthodontic treatment over a period of two years. They found that for a group of CD-patients, improvement in OHRQoL, using OHIP-49, continued to improve over twelve months post-treatment. It is not inconceivable that this phenomenon could be related to second dentures being scored slightly better, although not significantly, for each sequence group (Figure 5.14). At two years post-treatment follow-up, Aarabi *et al.* (2015) reported that OHIP-scores had risen again, but did not reach pre-treatment level. The follow-up period for the current trial was capped at a minimum of eight weeks of denture-wearing for logistical reasons of this cross-over trial. But it is most probable that pre- and post-treatment differences in OHIP-scores may have been larger than those reflected in this study if a longer post-treatment wearing period was used. However, the main focus of the study was to determine the difference between the two post-treatment modalities, and not the difference in pre- and post-treatment, or the length of treatment effect.

The impact of a disease or treatment of disease on QoL should be acknowledged when assessing health (or lack thereof) and treatment outcomes (Gerritsen *et al.*, 2010). It has been reported that persons with chronic disabling disorders may perceive their QoL better than healthy persons (Sprangers & Aaronson, 1992 in Gerritsen *et al.*, 2010). In an effort to reduce the influence of disease or treatment of disease, there were a number of exclusion criteria for this study. However, conditions affecting mood or attitude towards prosthetic treatment or dentures could have been undiagnosed or deliberately hidden. In addition, life events occurring during treatment could also have influenced OHRQoL-scoring. For example, one of the patients' spouse passed away during the trial. New dentures and their contribution to the patient's well-being or lack thereof might have been minimal during this period. This could be reflected in the way patients score the OHIP-20 questions.

Impact of dentures on OHRQoL and satisfaction with treatment may be related more to the extent of acceptance of the limitations of a denture than the technical correctness of the prosthesis. A level of handicap or discomfort that is accepted by one patient may be unbearable for another one. Therefore, a cross-over design is important, where the same patient is subjected to both types of interventions and acts as his or her own control.

It has been reported that the quality of the professional patient/dentist relationship may influence satisfaction rating (Carlsson, 2006). The clinician was the same for all patients providing a clinical service in the same academic hospital environment. Therefore, it is assumed that, in the present study, the influence of this variable was similar among all patients and treatment interventions.

6.3.2. Denture construction technique

The IAD, interincisal relationship, occlusal plane, shape and width of the maxillary denture for both sets were supposed to be similar. Several features of the two dentures could be used to verify that this was indeed so.

6.3.2.1. Interalveolar distance

The IAD of both completed sets of dentures was measured extra-orally by holding the set of dentures in occlusion. The measuring tips of a Bowley gauge, equipped with a Vernier scale (0.02 mm accuracy), were placed in the incisive papilla area of the maxillary denture and a corresponding point on the intaglio surface of the mandibular denture. This was done after all the adjustments were done at the delivery stage. The mean difference in IAD of the two sets was 0.04 mm. For 34 out of a total of 37 patients, the difference in alveolar distance between the two sets was 1 mm or less (Table 5.4). This difference was deemed to be clinically negligible.

Differences in IAD may have resulted from laboratory processing, occlusal corrections following clinical remounts, instrument and reader inaccuracy. The small difference in IAD for the majority of denture sets served as confirmation that the technique to reproduce OVD was reliable.

One patient had an IAD difference of 4.5 mm. This may have been clinically relevant when comparing the post-treatment OHIP-20 scores. The denture with the smaller IAD (ANA denture) resulted in a lower OHIP-20 impact. The ANA denture was the denture that was delivered first. It was subjected to five recall visits before a clinical decision was made that it could not be improved further. Several clinical remounts may have contributed to loss in IAD. The second denture, with the larger IAD was subjected to only two recall visits. Eventually, this patient could not express denture preference, rejected both dentures and chose to proceed with implant treatment. Only one patient had more recall visits (eight) than this patient. This high number of recall visits may have been a sign of adaptation problems. Although adaptation to CDs is a complex process, the number of recall visits has been identified as an indicator of the adaptation process (Panek *et al.*, 2006). Like the previous patient, this patient did not prefer one denture over the other. Therefore, it was decided not to remove the OHIP-20 data of these patients from the analysis.

If these patients indeed had adaptation problems, the type of denture (ANA or NZ) did not make an impact on denture preference. This could be investigated further.

All dentures in this study were subjected to a clinical remount procedure during the delivery visit. Clinical remounts were repeated at recall visits when it was suspected that occlusion may have contributed to discomfort. It has been shown that a clinical remount procedure is a more reliable method of assessing and adjusting the occlusion and contributes to patient comfort more effectively than intra-oral procedures do (Firtell *et al.*, 1987; Al-Quran, 2005; Wilson & Rees, 2006; Shigli *et al.*, 2008).

6.3.2.2. Midline

The position of the upper six anterior teeth was guided by lip support, phonetics and appearance. The position of the six anterior teeth was duplicated for the second set by means of a silicone index. The midline for the lower denture was determined by the midline of the upper denture. The accuracy of this duplicating technique is displayed by the gallery of photographs (Addendum 12). The blue “mid”- line running over the mandibular casts has a similar relationship to the lower central incisors as it crosses both dentures.

6.3.2.3. Interincisal relationship

Anterior teeth were set-up with similar overbite and overjet relationships for both sets. The accuracy of the horizontal relationship can be verified on the images displayed in the gallery of photographs. These photographs are layered images of the definitive cast over the images of the ANA and NZ wax trial dentures (Figure 4.19). For both ANA and NZ dentures, the horizontal relationship of the six anterior teeth to the line indicating the crest of the residual ridge is very similar for the 39 cases. This confirms accuracy of the laboratory technique in duplicating incisal relationships.

6.3.2.4. Width of the maxillary denture

Appearance may influence acceptance of dentures and satisfaction levels (Bellini *et al.,* 2009). Therefore, it was attempted to have the features of dentures, contributing to their appearance, the same for both types of dentures: shape and colour of denture teeth, midline, lip support and smile-line, level of the occlusal plane and the width of the arch for the maxillary denture and buccal corridors. Because the widths of the mandibular denture differed for ANA and NZ sets, it was to be expected that, as difference in widths increases, the chance of having posterior teeth set-up in a cross-bite also increases. This was confirmed by a regression analysis cross-bite/difference in width. A positive correlation was found between absence of cross-bite and small difference in width, and presence of cross-bite and larger difference in width (Figure 5.13).

6.3.3. Neutral zone recording

As is evident from the literature review, different protocols are being used to record the NZ. It has been shown that different oral functions and impression materials may influence the shape of the NZ-recording (Liu *et al.,* 2008; Ladha *et al.,* 2014), but that reproducibility among different operators was good (Karlsson & Hedegard, 1979). Based on these results, it may be assumed that intra-operator reproducibility among different patients would also be good. In this trial, only one operator carried out all the clinical and technical procedures.

For this trial, a series of oral movements were used over two recording sessions. As in most other NZ trials, swallowing was an important component of the NZ recording. One of the advantages claimed for NZ dentures is its increased stability. However, during swallowing, muscle action is braced by means of occlusal contact and retention and stability may not be such a major issue. Therefore, it may have been more advantageous to replace these functions with other muscle functions, during which no occlusal contact happens, such as speaking and smiling. This could be researched further.

Makzoumé (2004) compared swallowing and phonetics and found that phonetics resulted in narrower transverse dimensions. However, in their study, different materials for both techniques may have confounded results.
On the other hand, Ladha *et al*., (2014) compared phonetic and swallowing NZ impression methods and found no statistical difference in patient satisfaction or denture dimensions between the techniques.

Patients expect to be able to chew with CDs. Increased chewing efficiency is associated with better OHRQoL. This is evident from studies comparing traditional CDs and implant supported overdentures (Boven *et al.,* 2015). However, muscle action as it happens during chewing has never been described as part of the dynamic NZ-recording protocol. This is indeed a challenge, because chewing would distort the NZ recording using a plastic impression material. There is even controversy in the literature with some publications advocating the presence of an opposing denture during NZ recording, and others recommending the removal of the opposing denture to avoid distorting the NZ-recording. For this trial, no opposing denture was used and no phonetics.

For this clinical study, impression compound was selected over other impression materials. It is a routinely-used prosthetic material and economical compared to other materials described in the literature for NZ recordings. It is thermoplastic, hence, impression time can be manipulated and impressions can be repeated and corrected until a clinically acceptable shape is obtained. In this study, patients sipped warm water (52°C) with the pre-heated NZ recording in the mouth. Before removal from the mouth, cold water was consumed to stabilize the shape.

No standards or criteria have been published in terms of “best clinical practice” in terms of NZ impression-making. What has been recommended is that the NZ impression should be made at the correct OVD (Khamis *et al*., 1981) and an appropriate volume of impression material should be used (Ikebe *et al.*, 2006).

For this trial, the baseplate with impression compound was prepared on articulated models, with the upper wax trial denture in position. This prevented the manufacturing of a baseplate with an excessive amount of impression compound material. After each NZ impression attempt, the baseplate with compound rim was returned to the articulated casts, and its occlusal plane levelled with the occlusal plane of the upper ANA trial denture until the OVD was restored. In case of lack of material, additional impression compound was added. Ikebe (2006) found that by adding volume, the midpoints of the occlusal planes did not change, even though the width of the occlusal plane increased. In the methodology used for this trial, excess of material would have decreased the width of the NZ, because a lingual silicone mold was used to guide the transverse position of the posterior denture teeth (Figures 4.4 and 4.5).

A "verification" impression was done during the wax try-in of the NZ dentures (Figures 4.9 and 4.10). This procedure served two purposes: to assess the correctness of the NZ arch shape after setting-up the teeth and to functionally mold the facial and lingual flanges. After this only minor corrections were done to the flanges of the denture when needed: where wax or teeth were exposed through the verification impression, this was reduced.

The NZ technique is reasonably simple, but requires additional laboratory and clinical time.

6.3.4. Measuring widths

The crest of the residual ridge was drawn onto each definitive master cast. The shape of residual ridges resembled the shape of parabola, with the anterior region of the ridge being the "vertex". The "axis of symmetry" was determined to be the line bisecting and perpendicular to the line connecting the tips of the retromolar pads, the "directrix", and running anteriorly until it reached the anterior part of the residual ridge. Transverse widths of the ridge, and both denture types were measured at 5 mm intervals along the directrix (Figures 4.11 – 4.13).

This was done using digital software with exact and identical directrix coordinates locating all 5 mm intervals of the transverse dimension of ridges, ANA and NZ dentures ("Pixel position Y", Figure 4.15). This could be done because the ridges, ANA and NZ dentures were measured positioned on the same master cast.

The central fossa of the posterior teeth was used as start- and end-point for each width (Figures 4.17 and 4.18). Because of variable mouth depths, the number of measurements for each 5mm interval differed. In the case of long anterior-posterior distances, where no more teeth beyond the second molars were present to measure widths, a reduced number of measurements for the 5 and 10 mm intervals would result. On the other hand, for the "shorter" mouths, a reduced number of measurements for the 35, 40 and 45 mm intervals would result. The maximum number of measurements per 5 mm interval was 39 (equalling the number of patients for which ANA and NZ wax trial dentures were made). When an insufficient number of measurements was available, these were not used in analyses, e.g. Table 5.18, 5.19 and 5.20.

6.3.5. OHIP-20 data collection

OHIP-20 questionnaires were anonymous and number-coded. The first, pre-treatment OHIP-20 questionnaire was completed with the investigator present. Because the investigator did not fabricate the existing dentures, there was little risk of bias from the patient. During this first completion any uncertainties regarding questions could be ruled out. This was important, because the second and third OHIP-20 questionnaires were self-administered, in the absence of the investigator. This was done to avoid that the presence of the clinician influenced patients' answers. Patients handed in completed questionnaires in sealed envelopes at the clinic's reception. Envelopes were stored and only opened when the cross-over trial was completed. Patients were fully informed and reminded about anonymity and confidentiality of the trial by means of verbal and written informed consent before the trial and before the completion of each OHIP-20 questionnaire (Addendum 2).

6.4. DENTURE DIMENSIONS

6.4.1. Introduction

In this section, the dimensions of the NZ and ANA dentures will be discussed and related to the residual ridge. In this section, the following null-hypothesis will be answered:

Null-hypothesis 1 (H1): There is no difference in the transverse width of NZ and ANA mandibular dentures.

In order to answer this hypothesis, the widths of the ridges and of the two types of dentures were measured and statistically analysed.

6.4.2. Relating data to the null-hypothesis

6.4.2.1. ANA denture - ridge

The mean transverse distance between the central fossae of the denture teeth of the ANA denture was slightly narrower for lines 5 to 25, and wider for lines 30 to 40 than the alveolar crest. The difference in width was the smallest for line 25 (closest to zero in Figures 5.3, 5.6 and 5.7). This means that, in the molar region, the teeth were more lingual to the crest of the ridge and in the premolar and anteriorly to the premolars, the teeth were more buccally placed.

Least squares analysis found statistical differences among all lines except for line 25. This reflects the widths in the region of the premolars. In this region, the central fossa of the denture teeth coincided with the crest of the alveolar ridge. Posterior denture teeth were set up following a straight line connecting the tip of the canines (usually located labially to the residual ridge) and the tip of the retromolar pad. The edentulous ridge is often not straight, but has an oval or round shape. This was previously reported by Pound (1954). In the region of the premolars, the straight line formed by the central fossae of the denture teeth crossed the curved line crest of the edentulous ridge.

6.4.2.2. NZ denture - ridge

The mean transverse distance between the central fossae of the denture teeth of the NZ denture was wider than the width of the alveolar crest for all lines. The difference was the smallest for line 5 (closest to zero in Figures 5.4, 5.6 and 5.8).

Least squares analysis found statistical differences for all lines, except for line 5. This reflects widths in the region of the second molars of the dentures. In this region, the position of the central fossa of the denture tooth coincided with the crest of the ridge. In this region, the outward action of the tongue muscles on the NZ impression was not as prominent, resulting in a more lingual position of denture teeth compared to the more anterior regions of the edentulous ridge.

6.4.2.3. NZ denture – ANA denture

The mean transverse distance between posterior denture teeth of the NZ dentures was larger than that of the ANA dentures for every line (Figures 5.6 and 5.9). This means that the teeth of the NZ dentures were more buccally positioned than the teeth of the ANA dentures. The difference was the largest for lines 15 and 20 and became smaller towards the anterior and posterior regions of the mouth. This means that the arch shape of the NZ dentures was more rounded compared to the straight set-up of the posterior teeth of the ANA dentures.

Least squares analysis found statistical differences among all lines except for line 40. This reflects widths in the region of the canines. No difference in this region was to be expected, since the position of the canines was to a large extent determined by aesthetic and phonetic criteria of the upper denture and were kept as similar as possible for both types of interventions.

Because the shapes of the ridges and dentures resembled parabola and the depths of the mouths differed for all patients, formula of parabola were used to compare the “parabola”. *Comparisons of mean intercepts and mean slopes for the ANA and NZ dentures using paired t-tests* confirm the results from the *least squares analysis*: parabola for ANA dentures were more elongated, i.e. narrower than the parabola of NZ dentures (Addenda 12 and 18).

Based on these results, the null-hypothesis H1 “there is no difference in transverse width of NZ and ANA mandibular dentures” is rejected. The results of this study are in line with the findings of an early study by Faber (1992), who found that the “physiologic” width of mandibular dentures was on average 2.72 mm wider than “anatomic” dentures. The differences in mean widths between ANA and NZ dentures for all lines varied from 1.8 mm (line 35) to 5.6 mm (line 20). With a mean of 3.9 mm, this is 1.2 mm more than found by Faber (1992).

Fahmi (1992) studied the position of the NZ related to the alveolar crest and found that if patients were edentulous for less than two years, the position of the NZ coincided with the crest of the ridge. If patients were edentulous for longer than two years, the NZ moved towards a more buccal position. This was explained by the resorption pattern of the residual ridge and increased pressure from the tongue. Ikebe *et al.* (2006) found that the midpoints of the NZ were located between 1.5 and 1.9 mm more buccal to the crest of the ridge. These findings are less than both Faber’s (1992) and the present study. These smaller differences may be due to Ikebe (2006) using phonetics instead of impression compound as compared to swallowing used by the other authors. Makzoumé (2004) also reported narrower NZ when using phonetics as compared to swallowing.

The larger difference in the NZ/ANA widths in the present study may also be explained by the longer edentulous period of patients. The period of edentulousness is often not specified in the methodology or results in earlier publications.

It is interesting to note that the only publication reporting a NZ position *lingual* to the crest of the alveolar ridge in the anterior, premolar and molar region was by Raja & Saleem (2010). The present study disagrees with these findings.

In a next paragraph, differences in widths of dentures will be related with patient-based outcomes in an effort to establish clinical relevance to these differences.

6.4.3. Denture dimension difference and tissue scores

When adjusted for age, mandibular tissue scores were negatively associated with difference in NZ-ANA widths (Addendum 19): a smaller difference in NZ/ANA width was associated with a more favourable tissue score. Or *vice versa*: less favourable ridges were associated with a larger difference in NZ-ANA widths. In this instance, null-hypothesis 4 is rejected. This could be expected and is in line with the finding that NZ-ANA differences in widths were larger for female patients (see earlier), who showed a lower tissue score than the male patients in this cohort. If period of edentulousness corresponds with a larger difference in NZ-ANA width, as Faber (1992), Fahmi (1992) and Ikebe *et al.* (2006) suggest, the results of this study would also agree with their findings. However, even though there was a significant negative association between years of edentulousness and mandibular tissue score, the period of edentulousness in this cohort did not correspond with difference in NZ-ANA denture size. This discrepancy could be explored further. It could be that persons in this cohort were not wearing dentures continuously during their period of edentulousness, decreasing the rate of alveolar ridge resorption.

6.4.4. Denture dimension difference and period of edentulousness

There was no significant association between the period of edentulousness and the difference in ANA and NZ dentures. It has been postulated that there is an outward shift of the NZ position the longer a person is edentulous (Faber, 1992). This postulation could not be supported by the present study.

In this instance, null-hypothesis 4 is accepted. For persons that became edentulous recently (less than two years) the NZ recording conformed better to the crest of the residual ridge than the group of people who were edentulous for longer than two years (Fahmi, 1992). For the group edentulous for longer than two years, 20% of the assessed locations were on the crest of the ridge, 5% were lingual to the ridge and 75% were facial to the ridge. Fahmi (1992) also found that the NZ was located more labially for anterior teeth, contradicting postulations that the NZ moves more lingual as the residual ridge resorbs in this region. Fahmi (1992) also reported that the longer the period of edentulousness, the more buccal the NZ was to the crest. Ikebe *et al's*. (2006) results agree with this.

6.4.5. Denture dimension difference and age

There is a significant negative relationship between differences in dimensions and age of the patients. In this instance, null-hypothesis 4 is rejected. The older the patient, the smaller the difference between NZ and ANA dentures. This may be explained by the fact that the influence of the muscles of the tongue decreases in shaping the neutral zone as persons become older.

6.4.6. Denture dimension difference and gender

Compared to males, the mean widths of ridges of female patients was between 3.1 and 4.3 mm narrower for all 5 mm intervals along the axis. This difference was statistically significant (Tables 5.21 and 5.22; Figure 5.10).

Compared to males, the mean widths of ANA dentures for female patients were between 1.1 and 2.9 mm narrower for all 5 mm intervals along the axis. This difference was significant (Tables 5.21 and 5.22; Figure 5.11). It was indeed expected that the ANA dentures for female patients would be narrower than those of the male patients, since their "mandibular widths" were also smaller.

Compared to males, the mean widths of NZ dentures for female patients were between -0.8 and 2.6 mm narrower for all 5 mm intervals along the axis. This difference was statistically significant (Tables 5.21 and 5.22; Figure 5.12).

The length and widths of alveolar ridges and the widths of both types of dentures were larger for the male patients. However, the difference in mean width between the ridge and the ANA denture was relatively larger for female patients in the anterior part of the mouth (lines 30 & 35), compared to male patients. This means that the discrepancy between ridge and position of teeth in the premolar region of the denture was larger for the female than for the male patients. The negative values in Table 5.22 indicate that denture teeth were positioned buccal to the alveolar ridge in this region. Faber (1992) recorded a similar discrepancy in widths based on gender: the mean difference ANA-NZ-widths for women was 56% greater than for men.

For the NZ denture, except for line 5, the discrepancy between ridge and NZ was always larger for the female group of patients compared to the male patients (Table 5.22). The negative values indicate that the teeth were positioned buccal to the alveolar ridge.

For the relationship of difference is denture dimensions and gender, null-hypothesis 4 is rejected: except for line 10, the difference in NZ and ANA widths were always larger for the female patients compared to the males. This may be explained as follows: (a.) the resorption pattern for edentulous mandibles of female individuals may differ from that of the male patients (Divaris 2012a); (b.) although not statistically significant, the mandibular tissue score for the female patients in this sample was lower: 3.88 compared to 4.73 for the male patients. A lower tissue score represents a more unfavourable residual ridge in terms of resorption and soft tissue quality; (c.) different muscular activity, resulting in a more buccally located NZ for female patients. This could be explored further.

6.4.7. Denture dimension difference and denture preference

In this trial, difference in dimensions did not influence patients' preference. In this instance, null-hypothesis 4 is accepted. Patients who preferred the ANA denture had a mean denture dimension difference of 4.396 mm. Those who preferred the NZ denture had a 0.036 mm larger difference. The difference of the group who had no preference was 0.421 smaller. This was not statistically significant and it is doubtful whether these small differences in width would be clinically relevant. Therefore, it does not appear as if the differences in width are a predictor for denture preference. No literature was found to compare this information with and therefore it can be considered unique.

6.5. IMPACT OF THE TWO TYPES OF DENTURES ON OHRQOL

6.5.1. Introduction

In this section, the impact of the 2 types of treatment on the OHRQoL will be discussed in terms of OHIP-20 scores, ES, denture preference, gender and age of the patients, socio-demographics, tissue scores and denture history.

Before embarking on the following discussion, it is important to remember that psychological and personality variables may interact with the socio-demographic and clinical variables mentioned in the previous paragraph. However, their assessment and impact have not been measured in this clinical trial and fall outside the scope of this discussion.

6.5.2. Relating data and null-hypotheses

In this section, the following null-hypotheses will be answered:

- Null-hypothesis 2 (H2): None of the 2 types of mandibular dentures improve OHRQoL.
- Null hypothesis 3 (H3): Treatment with NZ dentures has no larger impact on OHRQoL than treatment with ANA denture.

Oral health-related quality of life was measured using the OHIP-20 instrument. A *paired t-test* demonstrated a highly significant difference between pre-treatment and both post-treatment OHIP-20 scores (Addendum 25). Therefore, both treatment methods decreased the impact on OHRQoL of patients compared to the pre-treatment OHRQoL. Using treatment ES statistics, the difference in pre- and post-treatment results was also considered clinically significant. Hence, null-hypothesis H2 is rejected.

There was a significant positive correlation between both post-treatment methods, indicative of no difference in impact on OHRQoL between the two types of dentures (Figure 5.16). Hence, null-hypothesis H3 is accepted.

Most trials assessing OHRQoL and CD satisfaction found an improvement in impacts and ratings after treatment (Allen *et al.*, 2001b; Fromentin & Boy-Lefevre, 2001; Heydecke *et al*., 2003b; John *et al*., 2004; Adam *et al.*, 2007; Ellis *et al*., 2007; Shigli & Hebbal, 2010; Viola *et al.*, 2013) even though improvement may be small and limited to some domains only (Forgie *et al.*, 2005). The results of the current trial are in line with these studies.

No publications were found reporting on changes in OHRQoL comparing NZ and ANA dentures, using OHIP-20. Therefore, relating data from the current trial with existing published results is difficult. Therefore, this information is unique. Most studies reported on denture satisfaction using visual analog scales where patients rate certain aspects of their dentures, such as perceived chewing and appearance. These variables were not included in this trial and therefore are outside the scope of this discussion. A few studies reported on denture preference and these will be related to the current study in the "preference" section.

6.5.3. Statistical and clinical significance: treatment effect size

While patients may show statistically significant changes in scores from functional, psychosocial or psychological scales, these changes may not be large enough to be of clinical importance. Overreliance on *p*-values derived from statistical tests and ignoring clinically meaningful changes can lead to wrong conclusions about benefits to be derived from certain therapeutic interventions (Locker, 1998b).

After completion of all OHIP-20 questionnaires, an internally referenced approach was followed to recognize change that may be clinically meaningful (Cohen in Allen *et al*., 2001a). For this purpose, treatment ES was used. The use of treatment ES means that data were analysed using differences in scores as recommended by Tsakos *et al.* (2012), instead of only using absolute scores of the different OHIP-20s. Calculation of ES was explained in the methodology chapter. Clinically meaningfulness of ES is quantified as follows: 0.2 = small; <0.6 = moderate; >0.8 = large (Cohen in Allen *et al.,* 2001a). Using OHIP-20 summary scores, the ES for ANA and NZ was 1.22 and 1.24 respectively (Table 5.30). Hence, the level of clinical meaningfulness for both treatment options was considered to be "large". The treatment ES for the NZ dentures was slightly larger, regardless of the treatment sequence. However, this difference in ES was only 0.019 and certainly of no clinical significance.

Treatment ES is influenced by pre-treatment scores: a high score meaning more oral problems and a greater potential for improvement. Since this was a cross-over study, the pre-treatment scores for both treatment interventions were the same and could not have influenced post-treatment scores for the two interventions differently. In addition, a linear regression analysis demonstrated no carry-over or residual effect for the different treatment sequences.

As mentioned in the previous paragraph, treatment ES was 1.2 for both types of dentures. This is even higher than treatment ES in studies reporting on implant overdentures, which are considered to be more efficient in reducing OHRQoL impact than conventional CDs.

Treatment ES scores of previous studies and how they relate to the current study, will be given in the next paragraph. Reasons for this high treatment ES may be multiple: all patients came to the clinic with a perceived treatment need. Hence, they were dissatisfied with their existing prostheses and had high pre-treatment impact scores. Except one patient who hid her treatment preference, all patients received the treatment of their choice. It has been reported that preferred treatment choice could affect satisfaction ratings (Awad *et al*., 2000b; Allen *et al*., 2001b). Gjengedal *et al.* (2013) reported that satisfaction is relative and dependent on treatment acceptance. Patients consenting to become involved in "research" and the provision of care within a school of dentistry by a senior member of staff as opposed to pre-graduate students could have meant that patients perceived the quality of care as superior. The overwhelming effect of these conditions may have dampened the difference in treatment effects between the two types of dentures.

The ES reported in previous studies for interventions with conventional CDs is smaller compared to the ES of the current study. Heydecke *et al.* (2003b) and Jabbour *et al*. (2011) reported an ES of 0.43 and 0.8 respectively for their conventional CD group; Allen *et al*. (2001b) reported an ES of 0.5 for the group of patients requesting renewal of their CD as their treatment of choice. Aarabi *et al*. (2015) reported an ES for their conventional CD group of between 0.14 and 0.28 at different stages up to two years after denture delivery. It is interesting to note that the treatment ES for both types of dentures in this study sample, was similar to the ES found for implant overdentures in studies by Heydecke *et al.* (2003b) (ES = 1.09), Jabbour *et al*. (2011) (ES = 1.2) and Gjengedal *et al.* (2013) (ES = 1.3). They reported that treatment ES for implant overdentures is usually larger than for conventional CDs. The present study on conventional CDs reported an ES higher than the ES reported in these implant overdenture trials.

There was no difference in impact on OHRQoL based on summary OHIP-20 scores between the types of dentures. However, Forgie et al. (2005) reported that changes in OHRQoL may be limited to some domains only. Hence, scores of individual domains were assessed as well (Tables 5.23 to 5.25, and 57).

The present study found improvement of scores in all OHIP-20 domains. This is in contrast with Heydecke *et al.* (2003b) who found improvement in physical pain and psychological discomfort domains only. However, their patients were randomly allocated, and not according to treatment preference, in conventional or implant overdenture groups and this may have confounded the results.

Treatment ES per domain for both interventions are given in Table 5.31. Ten domains scored an ES > 0.8, therefore considered to be "large". The ES scores for the following domains were between 0.6 and 0.8 and therefore considered to be "moderate": physical pain, social disability and handicap for the ANA denture and social disability for the NZ denture. There were no ES scores <0.2, representing "small" changes. Therefore, both interventions led to a moderate or large improvement in OHRQoL in all seven domains of the OHIP-20 instrument.

The ANA dentures had slightly more favourable scores for OHIP-20 domains "social disability" and "handicap" compared to the NZ dentures (Table 5.27). All the other domains had slightly more favourable scores for the NZ dentures. However, translating these differences in ANA and NZ domain scores into differences in ES scores (Table 5.31), these small differences cannot be considered clinically relevant. The domain with the largest difference between the two treatment options was "physical pain", with the NZ dentures scoring better. With an ES difference of 0.13, this is less than the ES = 0.2 which is considered to represent a small clinical effect (Cohen in Allen *et al.,* 2001a). Neutral zone dentures generally appeared to "fit" more properly and caused less painful aching and sore spots. Eating also appeared to be improved with NZ dentures causing less interruption during meals.

The smallest difference was in the “social disability” domain (ES difference of -0.003), with the ANA denture scoring better for ANA dentures: ANA dentures seemed to interfere slightly less with social life and wellness of participants. Again, it must be kept in mind however, that this difference was small and certainly not clinically relevant.

During power calculation, a difference in OHIP-20 score of 7.5 was estimated to be clinically significant for this sample. For a larger difference, a smaller sample size would have been enough. For a more comprehensive explanation of this estimate, the reader is referred to the piloting and power calculation in the methodology chapter of this dissertation. It is important to realize that trials use different estimates for power calculations and this influences sample size and the interpretation of the results. For example, Gjengedal *et al.* (2013) considered a difference of 20 points on the OHIP-20 scale as benchmark for treatment effect, with a standard deviation of 25 points. This required a sample size of only 25 patients for their clinical trial.

6.5.4. OHRQoL and tissue scores

Literature provides conflicting information on the consequences of RRR and denture satisfaction. Severe RRR is associated with poor mandibular denture stability and retention (Tallgren, 1972; Allen & McMillan, 2003a, 2003b; Huumonen *et al.*, 2012), especially among women (Huumonen *et al*, 2012; Joo *et al.*, 2013). Poor denture stability is associated with poor denture satisfaction (Huumonen *et al*, 2012).

On the other hand, van Waas (1990a) established a poor correlation between clinical variables and patient satisfaction and Heydecke *et al.* (2003a) reported that the quality of the denture-bearing tissue is a poor predictor for patient satisfaction. Pan *et al.* (2010) tested the effect of mandibular bone height on the satisfaction and function of 107 patients treated with conventional dentures at a 6-month recall. They could not associate bone height and chewing ability with satisfaction ratings.

Yamaga *et al.* (2013) reported that a favourable oral condition and denture quality were positively associated with patients' perceived chewing ability, denture satisfaction and OHRQoL using the OHIP for edentulous persons.

In this trial, denture-supporting tissue was scored based on the amount of resorption and tissue resiliency. A higher tissue score reflects more "favourable" denture support tissue. The maxilla had a more favourable mean tissue score than the mandible for both male and female patients. The female patients had a poorer score than male patients for both maxilla and mandible. This agrees with the literature: Divaris *et al.* (2012a) also found that females were more likely to exhibit RRR than men of the same age. But this may be partially explained by the fact that, generally, women have been edentulous longer than men of the same age (Suominen-Taipale *et al.,* 1999). In the current trial, men had been edentulous for a mean period of 31 years and the women 32 years. Therefore, based on gender, the period of edentulousness was considered to be the same. Hence, for the same period of edentulousness, female patients in this sample had more RRR. This is in line with the Divaris *et al.* (2012a) findings.

For the mandible, the tissue score was positively associated with the period of edentulousness, but the maxilla was not. This is in agreement with the literature: A 10-year retrospective study, looking at records of 873 geriatric patients, identified duration of being edentulous as a factor associated with mandibular but not maxillary RRR (Divaris *et al.*, 2012a). Indeed, resorption affects the mandible four times more than the maxilla (Tallgren, 1972; Karaagaclioglu & Ozkan, 1994; Felton, 2009).

There was a negative relationship between mandibular tissue scores and OHIP-20 scores for pre- and both post- treatment options (Table 5.44, Addenda 26-29). This means that for a high mandibular tissue score (favourable) there was a low OHIP-20 score (also favourable), which was to be expected. However, with *p*-values all higher than 0.05, this was not significant.

In this instance, null-hypothesis 4 is accepted. The limited effect of tissue scores on OHRQoL may have been influenced by the fact that most patients were experienced denture wearers (see following section).

In a recent study by Kurushima *et al.* (2015), pre and post-treatment OHIP scores of groups of patients with "severe' and "moderate" edentulous conditions were compared. Pre-treatment OHIP scores of the two groups differed significantly. Pre- and post-treatment OHIP scores also differed for the "severe" group, but not for the "moderate" group. This suggests that for patients with a "moderate" condition their edentulousness does not impact that greatly on the OHRQoL as measured by OHIP. Because of the greater impact of CD treatment for "severe" groups, it may be interesting to limit this NZ study to "severe" edentulous conditions only.

While there was minimal effect of tissue scores on the OHIP-scores, it is interesting to analyse denture preference. Barrenäs & Ödman (1989) reported that the more resorbed the ridge, the stronger the preference for a NZ denture, while patients with well-preserved ridges reported less difference between the two types of dentures. This may explain why more women in the present study preferred the NZ denture: tissue scores of women were more unfavourable. This may also explain why male patients expressed less of a preference, because their tissues scores were more favourable.

6.5.5. OHRQoL and gender and age

The literature gives conflicting evidence on the role of gender in CD satisfaction rating. It has been reported that female patients view wearing dentures more positively than male patients do (Awad & Feine, 1998; Baer *et al.*, 1992). Baer *et al.* (1992) argued that men associate wearing dentures with aging more than women do. Awad & Feine (1998) hypothesized that women produce less biting force (Molin, 1972) and therefore find denture-wearing more comfortable than men do.

In this study, there was no significant association between gender and OHIP-20 scores of both treatment interventions (Table 5.45). When a clinical significance difference of 7.5 in OHIP-20 score is accepted, there would also not be a clinically significant association. In this instance, null-hypothesis 4 is accepted.

Age has been identified in the literature as a variable that may impact on denture satisfaction and QoL. Papadaki & Anastassiadou (2012) found that younger people found it more difficult to come to terms with tooth loss than older people and that this impacted on their acceptance of CDs. Steele *et al.* (2004), stated that, as people age, changes in perception and values may have an influence on QoL. In this study, there was no significant relationship between age and OHIP-20 scores of both treatment interventions (Table 5.46). Older patients' reduced adaptation ability (Allen & McMillan, 2003a) did not seem to impact the OHRQoL of this sample of patients. Of course, all patients were experienced denture wearers.

6.5.6. OHRQoL and socio-demographic factors

Steele *et al.* (2004) reported that many variables may influence OHIP-scores. Social, cultural and political events may shape perceptions of OHRQoL of cohorts as a whole. As a result, reports on the effects of socio-demographics on OHRQoL with CDs from studies done globally are inconsistent. For this study, performed in the Cape Town metropolitan area, except for education, none of the socio-demographic variables (age, income, marital status) seemed to have a major impact OHRQoL as measured by the OHIP-20.

In the current study, in terms of education, there was only a difference in impact on OHRQoL of existing denture-wearers (pre-treatment) in the primary and high-school educational groups: people with a higher level of education experienced a higher negative impact when wearing their "old" dentures. This difference in OHIP-20 scores among educational groups disappeared for both post-treatment modalities.

Marital status had no significant influence on OHRQoL related to denture-wearing. The positive impact of receiving new dentures was higher for "singles", although not significantly so. Looking at the absolute values of the coefficients for pre-treatment and ANA dentures, they were smaller than 7.5, thus assumed to represent no clinical difference in scores (refer to power calculations).

6.5.7. OHRQoL and period of edentulousness and denture experience

There was a weak negative association between years of being edentulous and OHIP-20 scores (Table 5.49; Addendum 34). For this cohort of patients, years of being edentulous could not be identified as a variable influencing the impact on OHRQoL significantly. In this instance, null-hypothesis 4 is accepted.

There seems to be agreement in the literature that previous denture experience favours denture satisfaction. Weinstein *et al.* (1988) reported that patients receiving their first dentures had more difficulties with function, comfort, and appearance than patients with denture experience. Van Waas (1990c) reported that people who were edentulous for a longer time were more satisfied with their dentures. In a survey by Divaris *et al.* (2012b) patients satisfied with their CDs had been edentulous for longer (median seven years) as compared to the dissatisfied group (median four years). In this trial, every patient had denture experience and had been wearing dentures soon after becoming edentulous. Therefore, the period of edentulousness was used as a parameter for denture experience. The present study could not confirm the findings of Divaris *et al*. (2012b) that patients who had been edentulous longer were more satisfied with their CDs. Only a very weak association between period of edentulousness and OHIP-20 scores was found. This weak association was positive for the pre-treatment score and negative for both treatment interventions, meaning that, an increasing length of edentulousness only had a minor positive impact on OHRQoL following the provision of dentures. Within the limitation of using period of edentulousness as a determinant for denture experience, it did not impact differently on OHRQoL for both types of dentures.

6.5.8. OHIP-20 as instrument for OHRQoL

An individual's reflection of his or her health is a subjective assessment. These subjective assessments pose a challenge for interpretation. Nevertheless, PBOs are increasingly used as measures for medical and dental interventions.

Heydecke *et al.* (2003b) reported that the OHIP-20 possesses good psychometric properties and is very valuable in trials of oral prostheses. Effect size of scales where significance was detected with OHIP-20, was good (pre- and post-treatment) with ES > 0.8. This was also the case in the present trial.

It is important to recognize the difference between denture satisfaction and the effect CDs have on the OHRQoL. Oral health-related quality of life instruments and denture satisfaction scales are in essence not capturing the same outcomes (Allen *et al.*, 2001a). OHRQoL instruments capture broader outcomes. Nevertheless, several papers demonstrated a moderate to strong positive association between denture satisfaction and OHRQoL (Allen *et al.*, 2001a; Veyrune *et al.*, 2005; Ha *et al.*, 2012; Michaud *et al.*, 2012; Stober *et al.*, 2012; Viola *et al.*, 2013). However, satisfaction as a predictor for OHRQoL could not be proven (Stober *et al.*, 2012). On top of this, it is difficult to predict satisfaction with CDs (Critchlow & Ellis, 2010). This confirms that more than denture satisfaction alone influences OHRQoL. Allen *et al.* (2001b) sum it up as follows: "… *if one relied on denture satisfaction as the only outcome measure, the true impact (or possibly lack of impact) of clinical intervention may be masked. …"*. To treat edentulousness, the patient must be managed holistically and not only the physical condition of missing teeth.

There are conflicting reports in the literature in terms of denture quality (features such as stability, retention, CR, OVD …) as a predictor for patient satisfaction (with features such as wearing patterns, satisfaction, fit and comfort, chewing ability) (Van Waas, 1990a, 1990c; Fenlon & Sherriff, 2004). Against this background, it is challenging to relate the findings of this trial to other studies.

The fact that no differences could be found in OHRQoL between NZ and ANA dentures and only minor differences in preference, may be due to the fact that none of the mandibular dentures is indeed superior, but it may also be related to the population sample or the scoring instrument (OHIP-20) not sensitive enough to discover these differences. Of course, at the time of delivery, all dentures (both ANA and NZ) were judged to be of adequate quality.

6.5.9. Influence of pre-treatment on post-treatment OHIP-20 scores

There was a low positive correlation between pre-treatment and ANA OHIP-20 scores, although not significant (Table 5.43). Therefore, pre-treatment scores did not predict post-treatment scores when patients were treated with ANA dentures. There was a medium positive correlation between pre-treatment and NZ post-treatment OHIP-20 scores, which was almost significant (Table 5.43). This means that patients with a high impact score pre-treatment probably remained high after treatment, and *vice versa.*

Tsakos *et al*. (2012) recommended reporting *changes* in scores, distribution and proportion of participants that improved, remained the same or deteriorated after treatment. This was done in Table 5.28 and Addendum 16.

There is some evidence that pre-treatment OHRQoL predicts post-treatment outcomes (Heydecke *et al.*, 2003b; Awad *et al.*, 2000b). This was confirmed by Jabbour *et al.* (2011) who found the same trend for their complete denture group of patients. This could only be partially confirmed by the present study, for the NZ dentures. Patients' interpretation of "problems" they experience with their existing dentures is subjective. They may compare the prosthesis with their experience of previous dentate status, which may have been positive or negative. Alternatively, they may compare their personal denture experience with (also subjective) feedback from other denture wearers (Ellis *et al*., 2007). It was noted that patients with no changes in pre-post treatment scores, i.e. <7.5 (Addendum 17 and Table 5.28), had either high or low pre-treatment scores.

This is only partially in line with these previous reports: patients with low pre-treatment scores also had low post-treatment impact scores (Allen & Locker, 2002); However, patients with high pre-treatment impact scores had variable results. As mentioned in the first paragraph of this section, correlation between pre and post treatment scores was determined by establishing the Pearson's correlation coefficients. Low positive correlation (r=0.196) was found for pre-treatment and ANA dentures and medium positive correlation (r=0.317) was found for pre-treatment and NZ dentures. Hence, for this study sample, pre-treatment scores could not be reliably considered as predictors for treatment success.

In their study comparing implant supported overdentures and conventional CDs, Allen & Locker (2002) speculated that one of the reasons for a less dramatic improvement in OHRQoL for conventional CDs, was that pre-treatment scores for patients seeking conventional CD treatment were less severe. This trend was also noticed earlier (de Grandmont *et al*., 1994; Awad *et al.*, 2000a): Edentulous persons seeking an implant-driven solution for their edentulous condition, have a poorer initial OHRQoL compared with patients requesting conventional CDs. The results of this study are not in line with these previous observations. Patients with a higher pre-treatment score would not benefit more or less from any of the two types of dentures. In this study, with the exception of two, all patients expected nothing more than conventional dentures and received their treatment of choice. It would be interesting to repeat this study in a group of patients with higher expectations e.g. expecting implant treatment instead of conventional dentures. The expectations of these patients may be higher and they may be more critical in judging the effect that ANA or NZ has on their OHRQoL. Within this context, level of education may play a part.

Two patients (7 and 38) proceeded with implant treatment after conventional denture therapy as both types of dentures failed to satisfy their treatment expectations. These patients did not disclose their implant request (preference) until after completion of the trial.

The pre- and post-treatment scores of these patients may be an illustration of this hidden treatment preference. Patient 7 recorded a good improvement for the ANA denture but not for the NZ dentures, expecting a preference for the ANA denture. However, this patient was one of the 14 patients who did not indicate a preference, which was unexpected. Patient 38's post-treatment OHIP-20 scores were worse than the pre-treatment scores. This could be explained by his hidden implant treatment preference and rejection of the replacement of the conventional CD.

Patient 37 had a relatively high pre-treatment OHIP-20 score, and even higher post-treatment scores for both types of dentures. For the ANA denture this patient scored a maximum of 80 and for the NZ denture an almost maximum of 77. A maximum of 80 post-treatment score is difficult to explain, especially against the background of a large mean ES for this sample for both types of dentures. Mandibular tissue score may have a minor influence on OHRQoL. However, this patient's mandibular tissue score was 3, being rather favourable. Therefore, it is assumed that in this case, the patient's attitude towards dentures caused the poor clinical effect of treatment. With his high pre-treatment score, this patient supported the argument that pre-treatment OHRQoL may be a predictor of post-treatment OHRQoL for conventional CD treatment (Awad *et al.*, 2003; Heydecke *et al.*, 2003b; Jabbour *et al.*, 2011).

6.5.10. Changes of OHRQoL over time

Satisfaction with CDs and their impact on OHRQoL changes over time. Most literature on CD satisfaction and OHRQol assesses short-term effects at the time of delivery or shortly thereafter, up to two years post-delivery. Literature differs on the nature of these changes, with some reporting a gradual deterioration over two years post-delivery (Berg, 1988), others reporting that the effect on OHRQoL remained stable (Jabbour *et al.*, 2011) or mixed results with a gradual improvement for chewing and comfort for the mandibular dentures, but not for the maxillary dentures (Fenlon & Sherriff, 2004), or overall improvement over a one-year post-delivery period (Aarabi *et al.*, 2015).

This is not altogether in line with assumptions that patients continuously adapt to dentures even if the fit of dentures worsens due to continued alveolar ridge resorption.

The lifespan of conventional complete dentures is longer than two years. It is recommended that longitudinal studies measuring the long-term effects of the two types of dentures be conducted. Veyrune *et al.*, 2005 reported that there were no improvements in General Oral Health Assessment Index score six weeks after receiving new dentures, but there was at twelve weeks after placing new CDs.

It may be interesting to follow-up this group of patients to determine what set of CDs are being worn and their impact on OHRQoL, at different stages.

6.6. DENTURE PREFERENCE

6.6.1. Introduction

Even though the OHIP-20 instrument did not pick up clinically relevant differences in OHRQoL between the two denture types, based on preference there appears to be a difference. Almost twice the number of patients preferred the NZ denture over the ANA denture (15 against eight), while 14 patients did not express a preference (Table 5.32). This preference is not as extreme as the results reported by one of the earliest NZ trials by Walsh & Walsh (1976) where 28 out of 30 patients preferred the NZ denture. Preference was also reported by Fahmy & Kharat (1990) in a randomized clinical trial using ten patients: Two weeks after insertion, masticatory performance was statistically better for conventional dentures. However, all ten patients preferred the NZ denture, while none of the patients could indicate superiority in terms of mastication. This study highlights the importance of using PBO measures when assessing different treatment interventions.

6.6.2. Denture preference and OHRQoL

Relating post-treatment OHIP-20 scores with preference, patient preference or no preference for a denture type matched OHRQoL impact 23 times (a difference OHIP-20 NZ minus ANA of 7.5 was considered clinically relevant – refer to power analysis) (Addendum 17). Therefore, it can be concluded that based on impact scores, 23 out of 37 patients were reliable in scoring OHIP-20 and correctly identifying denture preference. In the other 14 instances, patient preference did not match the impact of treatment on OHRQoL. No statistical association could be demonstrated between denture preference and impact on OHRQoL as measured by the OHIP-20 scores. In this instance, null-hypothesis 4 is accepted. Figure 5.17 plots the difference in OHIP-20 ANA-NZ against denture preference. A negative ANA-NZ OHIP-20 value means that ANA had a more positive impact on OHRQoL; the difference would be 0 if there was no difference in impact on OHRQoL by the two types of dentures; the difference would be positive if the NZ denture had a more positive impact on OHRQoL. In spite of the fact that no statistical difference was found among the medians of the OHIP-20 differences according to preference, it is interesting to note that for patients who had no preference, the median of the OHIP-20 difference was located close to 0 and the box was narrow. For patients who preferred the NZ dentures, the box and upper whisker (representing at least 75% of the values) were positioned in the positive half of the plot. For patients who preferred the ANA dentures, the box was predominantly in the negative half of the plot. This provides some validity to the results in the sense that a more positive impact on OHRQoL as measured with the OHIP-20 agrees with most patients' preference. The reason why there is no agreement of preference with impact on OHRQoL for the remainder of the patients could be investigated further. No literature could be found relating denture preference to OHRQoL using the OHIP-20 instrument and the information presented here may be considered to be unique.

6.6.3. Denture preference and effect of first denture

There was no association between the type of denture patients wore first and the denture patients preferred at the end of the trial (*p*=0.144). Fifty five % of those patients who wore the ANA denture first, preferred the NZ denture; those who started with the NZ denture were indecisive of their preference, while 23.5% chose ANA and 53% had no preference.

6.6.4. Denture preference and tissue score

Mandibular or maxillary tissue scores are not a predictor for denture preference (Tables 5.55 to 5.57). In this instance, null-hypothesis 4 is accepted. Literature is divided on the influence of the clinical condition on denture satisfaction and its impact on OHRQol. This trial showed a negative relationship between mandibular tissue score and pre- and both post-treatment OHIP-20 scores. This means that for a high mandibular tissue score (favourable) there was a low OHIP-20 score (also favourable), which was to be expected. However, with *p*-values all higher than 0.05 (Addenda 25-28), these relationships were not significant. Therefore, this lack of association between denture preference and tissue score is in line with the OHIP-20 and tissue score relationship.

6.6.5. Denture preference and gender

A higher ratio of female patients preferred the NZ denture compared to male patients (50% and 27% respectively) (Table 5.33). It is interesting to note that the difference in widths in NZ and ANA denture was also relatively larger for female patients. The majority of male patients (46% of male patients) did not indicate a preference. The group with the smallest number of patients was female patients preferring the ANA denture (18% of female patients). Fisher's exact test could not find a significant difference among the groups (Table 5.58). In this instance, null-hypothesis 4 is accepted.

6.6.6. Denture preference and age

In the present study, younger people preferred the ANA dentures, while older people preferred the NZ dentures or had no preference (Tables 5.59 and 5.60). Again, this relationship was not significant. In this instance, null-hypothesis 4 is accepted. Combined with the information of the previous section, it may be tempting to draw the conclusion that older people that became edentulous later in life (with less denture experience) would benefit more from NZ dentures than younger people with denture experience. This is a hypothesis that could be researched further.

6.6.7. Denture preference and period of edentulousness

In the current study, patients with a shorter period of edentulousness preferred the NZ denture or had no preference (Tables 5.61 and 5.62). If years-of-edentulousness is an indication of denture experience, this relationship may mean that patients with less denture experience may benefit from a NZ denture. This relationship could be further explored in future clinical studies. Since the population in this study had no positive relationship between mandibular tissue scores and period of edentulousness, preference towards a particular denture could not be related to the quality of the mandibular denture-bearing tissue.

6.6.8. Denture preference and difference in NZ-ANA dimensions

Statistical analysis found a significant difference for all locations, except location 40, between NZ and ANA dimensions (Table 5.41). However, these significant differences in denture dimensions could not be related to denture preference (Table 5.63). Therefore, preference for a particular type of denture was not related to their difference is dimensions. In this instance, null-hypothesis 4 is accepted. No literature was found to compare these results to and therefore was considered to be unique.

6.6.9. Denture preference and presence of cross-bites

For the group of patients who preferred the ANA dentures (eight), six NZ dentures had cross-bites (Table 5.64). For the group of patients who preferred NZ dentures (15), more had cross-bites (nine) compared to no cross-bites (six). For those patients who did not have a denture preference (14), six NZ dentures had no cross-bite, while eight had a cross-bite. Based on these results, it does not appear as if the presence of a cross-bite had a negative effect on denture preference. This was confirmed with Fisher's exact test which did not find an association between denture preference and the presence of cross-bites. Patients were not told about the presence of cross-bites at delivery of the dentures. At recall visits, no remarks or complaints from patients could be related to the presence of cross-bites. No literature was found to compare these results to and therefore was considered to be unique. The presence of a cross-bite and its impact on preference or denture satisfaction could be researched further.

6.6.10. Denture preference and number of recall visits

There was a difference in the number of recall visits for dentures delivered first and dentures delivered second (Table 5.6). Because recall visits are associated with some discomfort and inconvenience, it may have affected denture preference. The number of recall visits for ANA and NZ dentures was also analysed and no difference was found in number of recall visits related to type of denture. Because the sequence of delivery was similar for ANA and NZ sets, it is accepted that this variable cancelled out any influence related to number of recall visits.

6.6.11. Denture preference and patient feedback

At the end of the trial, patients were asked in an open-ended question, the reason for preferring or having no preference for the types of dentures they had been wearing.

It is striking however, how vague feedback from patients was when prompted to give reasons for preferring one type of denture over the other one. The comments are given in Section 5.6.4.10.

It may have been advantageous to supplement the OHIP-20 instrument with a questionnaire with more specific denture-related issues. This may have provided an opportunity to identify more specific reasons why patients had a particular preference. When the trial was developed, it was expected that patients would give this information at the end of the final OHIP-20 questionnaire. Since the envelopes containing the completed OHIP-20 were only opened after the trial, this was not noted earlier.

Komagamine *et al*. (2012), using OHIP-Edent found that patient-reported improvement of retention and stability of lower dentures and appropriate appearance correlated with a decrease in impacts on OHRQoL. OHIP-Edent and OHIP-20 are identical, except that the OHIP-20 has an extra question in the physical disability domain that is absent in the OHIP-Edent questionnaire (question 11, Addendum 3). In the present study, patients talked about 'fit" and "comfort". Internal fit was the same for both ANA and NZ dentures because they were made on duplicate definitive casts. Therefore, if there was a difference expressed in comfort and fit, this could only be ascribed to the shape of the "polished" surfaces of the mandibular dentures. Earlier, the differences in widths were also eliminated as a reason for differences in preference. This information, related to differences in width in a cross-over clinical trial, is unique.

Fahmy & Kharat (1990) reported that all ten patients in their trial (with less than five years of edentulousness and no denture experience) preferred the NZ denture. However, no information was given on the demographics and gender of the sample.

6.7. SIMPLIFIED AND TRADITIONAL METHODS OF DENTURE CONSTRUCTION

Several studies have reported on results from traditional and more simplified protocols of CD construction. Generally, the quality of dentures as judged by patient satisfaction rating, did not seem to suffer when using simplified techniques (Kawai *et al.*, 2005; Heydecke *et al*., 2008). Nuňez *et al*. (2013), in a randomized trial, showed that there was no difference in OHIP-Edent scores comparing traditional and simplified protocols for CD construction. The construction of NZ dentures requires more clinical and laboratory procedures. Its benefit as measured by the ES compared with the more simple anatomic approach, is minimal and does not appear to influence patient satisfaction ratings negatively. Based on the minimal treatment ES difference between the two interventions, it appears not to be worthwhile providing the more complex method (NZ) as it is unlikely to be perceived as beneficial by the majority of patients.

6.8. ASSOCIATION BETWEEN DENTURE DIMENSION DIFFERENCE AND OHIP-2

There was a weak positive association between differences in dimensions and OHIP-20 scores differences, which was not statistically significant. Difference in size of the two types of dentures did not influence the OHRQoL (Addendum 35). In this instance, null-hypothesis 4 is accepted.

6.9. CONCLUSIONS AND RECOMMENDATIONS

6.9.1. Limitations

a) The sample of the present trial came from a rather homogenous socio-economic environment - extrapolation of results across different socioeconomic environments is to be done with caution.

b) Treatment allocation followed an AB or BA sequence. No AA or BB sequence was included. The inclusion of AA or BB groups may have provided an indication of patient reliability.

c) The trial could not be operator-blinded.

d) The trial was performed by a single operator. Extrapolation of results across the profession is to be done with caution.

e) Even though the OHIP-20 instrument is considered a valid instrument, its reliability in the South African environment is uncertain. Only one study was conducted previously in SA (Western Cape) using a short OHIP version.

f) Denture dimensions were compared as if symmetrical along the axis.

6.9.2. Conclusions

Within the limitations of this clinical trial, it may be concluded that:

a) Except in the canine region, the NZ dentures were significantly wider than the ANA dentures.

b) While mean widths of ridge and both types of dentures were larger for male patients, the difference in mean widths between the two types of dentures was larger for female patients.

c) Older patients had smaller differences in widths of the two types of dentures. This relationship was significant.

d) Adjusted for age, mean mandibular tissue score was negatively associated with the difference in NZ/ANA dimensions: more unfavourable tissue is associated with a larger difference in the two types of dentures.

e) There was no carry-over or treatment effect between the two treatment periods.

f) Both types of mandibular dentures significantly improved the OHRQoL of patients.

g) Both types of dentures had a high treatment ES.

h) The OHIP-20 instrument could not distinguish a statistical difference in impact on OHRQoL caused by the two treatment options.

i) There was a small difference in treatment ES between the two types of treatment.

j) The only domain representing a small clinical benefit between NZ and ANA dentures was "physical pain", with the NZ dentures scoring better.

k) No correlation was found between pre- and post-treatment scores for both types of dentures.

l) No significant associations could be found between post-treatment OHIP-20 scores on the one hand and tissue scores, gender, age, education, marital status, period of edentulousness and denture dimension differences on the other hand.

m) There was a significant association between denture preference and the NZ dentures, but not for the other preferences.

n) No significant associations were found between denture preference on the one hand and tissue scores, gender, age, period of edentulousness and denture dimension differences on the other hand.

o) Even though no significant relationship was found between preference and gender, the majority of female patients preferred the NZ denture and the majority of male patients did not express a preference.

6.9.3. Recommendations

The following recommendations may be made:

a) Research

i. Analyse the prevalence of asymmetry in ridges, ANA and NZ dentures.

ii. More clinical research to be performed comparing results obtained by the OHIP-20 instrument with other instruments measuring OHRQoL and denture satisfaction.

iii. Analysing patient feedback concerning the different types of dentures by means of qualitative research methods.

iv. Analysing the OHIP-20 results using item-weights to see whether finer discrimination between variables can be achieved.
v. Clinical research assessing the NZ for mandibular dentures to be repeated among a more diverse socio-demographic group of patients to establish trends of OHRQoL results related to socio-demographic variables.
vi. Because of the greater impact of CD treatment for "severe" groups, it may be interesting to limit this NZ study to "severe" edentulous conditions only.
vii. Long-term follow-up of both types of dentures, although this would not be possible within a cross-over design trial.
viii. Study of the carry-over and treatment effects in cross-over trial designs for prosthetic interventions.

b) Clinically

i. Providing new complete dentures improved OHRQoL of edentulous patients.
ii. A majority of female patients preferred the NZ compared to the ANA denture.
iii. The neutral zone technique appeared to have a higher positive impact on OHRQoL of female patients compared to male patients.
iv. Performing cost effectiveness for both treatment methods.

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Addendum 1: Registration of the project and ethical clearance

Office of the Deputy Dean
Postgraduate Studies and Research
Faculty of Dentistry & WHO Collaborating Centre for Oral Health

UNIVERSITY OF THE WESTERN CAPE
Private Bag X1, Tygerberg 7505
Cape Town
SOUTH AFRICA

Date: 04th March 2011

For Attention: Prof GAVM Geerts
Department of Restorative Dentistry

Dear Prof Geerts

STUDY PROJECT: The neutral zone for mandibular complete dentures: a clinical trial

PROJECT REGISTRATION NUMBER: 11/1/49

ETHICS: Approved

At a meeting of the Senate Research Committee held on Friday 4th February 2011 the above project was approved. This project is therefore now registered and you can proceed with the work. Please quote the above-mentioned project numbers in all further correspondence.

Patients participating in a research project at the Tygerberg and Mitchells Plain Oral Health Centres will not be treated free of charge as the Provincial Administration of the Western Cape does not support research financially.

Due to the heavy workload auxiliary staff of the Oral Health Centres cannot offer assistance with research projects.

Yours sincerely

Professor Sudeshni Naidoo

Tel -27-21-937 3148 (w); Fax -27-21-931 2287 e-mail: suenaidoo@uwc.ac.za

Addendum 2: Patient information and consent form

Title of the study: The neutral zone for mandibular complete dentures: a clinical trial.

Researcher: Professor Greta Geerts
021 9373133; ggeerts@uwc.ac.za
Department of Restorative Dentistry, Faculty of Dentistry,
University of the Western Cape.

Patient Name: . . . .

1. I am a senior lecturer and specialist in the department of Restorative Dentistry since 1992. If you decide to participate in this clinical study, the quality of your prosthetic treatment remains my most important consideration and not the acquisition of data for the study.
2. This study examines the treatment outcomes of a lower denture using 2 different clinical techniques. After a full oral and denture examination, two new set of complete dentures will be made for you. None of the two methods used for the study is “experimental” and both are established treatment methods for making dentures. The results of this study would supply us with information about what type of treatment leads to higher patient comfort and satisfaction with lower dentures and guide us on technical and clinical skills to be taught to dental students.
3. This study has been approved by the University of the Western Cape Research and Ethical Committee.
4. In order to take part in the study, you must fulfil the inclusion and exclusion criteria. If it becomes clear that you do not fulfil these criteria, you will be referred to the appropriate clinical section for further management. This may mean that you are placed on a waiting list.
5. Taking part in the study would involve more frequent visits (2 to 3 visits more) than usual for the manufacturing of complete dentures. Costs involved with your transport to and from the institution will not be reimbursed. At certain stages of the treatment, you will have to complete a questionnaire asking you to rate the dentures that you have been wearing. Some appointments may take slightly longer than usual. There are no other burdens or risks involved by taking part in this project.
6. The costs involved with the new set of dentures will be according to the Provincial Government of the Western Cape guidelines. However, you will receive an additional set of dentures free of charge.
7. Taking part in this study does not involve or entitle you to treatment with dental implants. Should you wish to have implants at a later stage, you will be referred to the appropriate department.
8. Your involvement with the study is voluntary. You may refuse to participate or terminate your involvement with the study without compromising your further treatment and management at this institution.
9. You will be informed about any pathology or disease noticed during the examination or treatment and you will be appropriately advised on further management.
10. Your confidentiality will be respected at all times.
11. Photographs may be taken and if you agree to, you will be required to sign a separate consent form.
12. Results of the study will be reported in a thesis and will be published in dental scientific journals but will be done anonymously.

13. The research is being carried out independently. The researcher has no conflicts of interests nor any vested interest in any of the products or materials bought or donated for the study.
14. If you require more information on the study or your treatment you can contact me at the above contact details.
15. You will give informed consent to participate in this study by signing this form below.

I understand the information that has been provided and what will be required of me to take part in the study. I agree to participate in the research being undertaken by Prof Greta Geerts. I understand that at any time I may withdraw from this study without giving a reason and without affecting my treatment or management in the future.

__________________	__________________	__________________
Researcher Name	Patient Name	Date
__________________	__________________	__________________
Witness Signature	Patient Signature	Date

Addendum 3: OHIP-20 questionnaire (1 and 2)

Patient code: …………...   Date: …………………………..

This questionnaire is designed to evaluate how your oral condition has affected your quality of life **during the past month**. For each of the following questions, mark the response that you feel is the best.

		In the last month	Very often	Fairly often	occasionally	Hardly ever	never
Functional limitation	1	Do you have difficulty chewing because of problems with your dentures?					
	2	Do you have food catching in your dentures?					
	3	Do you feel that your dentures are not fitting properly?					
Physical pain	4	Do you have painful aching in your mouth?					
	5	Do you find it uncomfortable to eat some foods because of problems with your dentures?					
	6	Do you have sore spots in your mouth?					
	7	Are your dentures uncomfortable? (if not, mark ‘never’)					
Psychological discomfort	8	Are you worried by dental problems?					
	9	Are you self-conscious because of problems with your dentures?					
Physical disability	10	Do you avoid eating some foods because of problems with your dentures?					
	11	Is your diet unsatisfactory because of problems with your mouth or dentures?					
	12	Are you unable to eat with your dentures?					

	13	Do you have to interrupt meals because of problems with your mouth or dentures?					
Psychological disability	14	Are you upset because of problems with your dentures?					
	15	Are you embarrassed because of problems with your dentures?					
Social disability	16	Do you avoid going out because of problems with your dentures?					
	17	Are you less tolerant of your spouse or family because of problems with your dentures?					
	18	Are you irritable because of problems with your dentures?					
	19	Are you unable to enjoy other people's company as much because of problems with your dentures?					
Handicap	20	Do you find life less satisfying because of problems with your dentures?					

Thank you for your kind coöperation.

Addendum 4: OHIP-20 questionnaire (3)

Patient code: …………...   Date: …………………………..

This questionnaire is designed to evaluate how your oral condition has affected your quality of life **during the past month**. For each of the following questions, mark the response that you feel is the best.

	In the last month	Very often	Fairly often	occasionally	Hardly ever	never
1	Do you have difficulty chewing because of problems with your dentures?					
2	Do you have food catching in your dentures?					
3	Do you feel that your dentures are not fitting properly?					
4	Do you have painful aching in your mouth?					
5	Do you find it uncomfortable to eat some foods because of problems with your dentures?					
6	Do you have sore spots in your mouth?					
7	Are your dentures uncomfortable? (if not, mark 'never')					
8	Are you worried by dental problems?					
9	Are you self-conscious because of problems with your dentures?					
10	Do you avoid eating some foods because of problems with your dentures?					
11	Is your diet unsatisfactory because of problems with your mouth or dentures?					
12	Are you unable to eat with your dentures?					
13	Do you have to interrupt meals because of problems with your mouth or dentures?					

14	Are you upset because of problems with your dentures?					
15	Are you embarrassed because of problems with your dentures?					
16	Do you avoid going out because of problems with your dentures?					
17	Are you less tolerant of your spouse or family because of problems with your dentures?					
18	Are you irritable because of problems with your dentures?					
19	Are you unable to enjoy other people’s company as much because of problems with your dentures?					
20	Do you find life less satisfying because of problems with your dentures?					

Which set of dentures did you prefer? (tick)	The first set	The second set	No preference	Don’t know

If you preferred one set of dentures over the other, can you tell me why?
……………………………………………………………………………………………
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Thank you for your kind coöperation.

Addendum 5: Socio-demographic details and clinical examination

Name ………………………………………

Date of birth ……………………………………

Age at start of treatment ………………………………………..

Gender ……………………………………….

Marital status …………………………………………

Highest level of education

Primary school …....

Secondary or high school ……

Professional or technical training ……

University qualification ……

Profession ……………………………………….

Work

Full-time ……

Part-time ……

At home ……

Unemployed ……

Retired ……

Nett income (Rand per month)

< 5 000

5 000-10 000

10 000-15 000

15 000-25 000

>25 000

MEDICAL HISTORY

(Retrieve from patient file)

CLINICAL EXAMINATION

Main complaint

…………………………………………………………………..

How long

…………………………………………………………………..

Additional complaints

…………………………………………………………………..

Denture-wearing history

Period of edentulism (when were last tooth/teeth lost) …………………………..

How many sets of dentures …………………………..

Immediate dentures? …………………………..

Partial dentures? …………………………..

Age of current dentures …………………………..

Additional comments …………………………..

…………………………………………………………………………………………………

………………………………………………………………………..…………………

…………………………………………………………………………………………………

…………………………………………………………………………………………………

…………………………………………………………………………………………………

Examination of edentulous ridges

Mandibular tissue score

Bone resorption	Score	Tissue resilience	Score
Extreme (flat)	1	Flabby	1
Severe (V-shaped)	2	Resilient	2
Moderate (U to V-shaped)	3	Firm	3
Little (U-shaped)	4		

Maxillary tissue score

Bone resorption	Score	Tissue resilience	Score
Extreme (flat)	1	Flabby	1
Severe (V-shaped)	2	Resilient	2
Moderate (U to V-shaped)	3	Firm	3
Little (U-shaped)	4		

Extra-oral denture examination

	Mandibular	***Maxillary***
Underextended	……………	…………
Overextended	……………	…………
Fractured	……………	…………
Worn teeth	……………	…………
Hard deposits	……………	…………
Soft deposits	……………	…………
Discoloured	……………	…………

Intra-oral denture examination

	Mandibular	***Maxillary***
Underextended	……………	…………
Overextended	……………	…………
Retention*	……………	………… (*Poor, reasonable, very good)
Stability*	……………	…………(*Poor, reasonable, very good)

RFH …………..

OVD …………..

FWS …………..

IAD …………..

Occlusion

……..………………………………………………………………………………

……………………………………………..

Addendum 6: List of materials and equipment

Material	Supplier	Address
Eezitray edentulous stock trays	Wright Health Group	Dundee, Scotland
Blue Print alginate impression material	Dentsply De Trey GmbH	Konstanz, Germany
Dental Plaster	Formula Saint Gobain	Nottinghamshire, UK
GPS Model Dental Stone	Zeus	Novi Ligure, Italy
White periphery wax	Kemdent	Wiltshire, U.K.
Denture modelling wax sheets	Kemdent	Wiltshire, U.K.
Megatray light-cure custom tray material	Megadenta	Radeberg, Germany
SS White impression paste	SS White	Lakewood, USA
Kelly's impression paste	Waterpik Technologies Inc.	Fort Collins, USA
Greenstick impression compound	KerrHawe SA	Bioggio, Switzerland
Rapid-repair self-curing acrylic resin	Dentsply	Surrey, UK
Boxing-in wax sheets	Metrodent	Huddersfield, UK
Boxing-in wax strips		
Sticky wax	Kemdent	Wiltshire, UK
Lab silicone putty	Coltène Whaledent	Altstätten, Switzerland
Acrotone denture teeth	Wright Health Group Ltd	Dundee, Scotland
Vertex Rapid Simplified heat curing acrylic	Vertex Dental	Zeist, The Netherlands
Duplitop duplication gel	Dentaurum	Ispringen, Germany
Aluwax bite registration wax	Aluwax Dental products Company	Allendale, Michigan, USA
Fit Checker II	GC Corporation	Tokyo, Japan
Warm water bath	Mestra	Bilbao, Spain
ASA dental articulator	ASA Dental S.p.A.	Bozano, Italy
Megalight lightcure oven	Megadenta	Radeberg, Germany
Biosonic plaster and stone remover	Coltène Whaledent	Altstätten, Switzerland
Biosonic ultrasonic bath	Whaledent	Altstätten, Switzerland
Camera Canon EOS 550D	Canon Inc	Tokyo, Japan
Analyzing Digital Images (version 11, 2008)	Museum of Science	Boston, MA
Corel Paint Shop Pro X, (version 10, 2005)	Corel Corporation	Canada, USA and/or other countries

Addendum 7: Instructions for verification impressions

A. Facial aspect
   1. Pucker lips
   2. Smile broadly
   3. Move lower jaw to the front
   4. Move lower jaw to the right and to the left
   5. Repeat several times

B. Lingual flanges

   1. Drink water and swallow
   2. Extend tongue
   3. Move tongue from side to side
   4. Lick upper lip
   5. Lick lower lip
   6. Repeat several times

Addendum 8: Camera settings used for photographs

Camera Canon EOS 550D
Shooting aperture – Priority AE
Shutter speed 1/80
Aperture value 9.0
Metering mode centre–weighted average metering
Exposure compensation – 2/3
ISO speed 400
Lens EF100mm f/2.8 Macro USM
Focal length 100.0mm
Image size 1024 x 768 pixels or larger
Image quality fine
Flash off
With balance mode auto
AF mode one-shot AF
Picture style standard
Sharpness 3
Colour space sRGB
Auto lighting optimizer strong

Addendum 9: All data

Patient	gender	age	education	marital status	income	Period of edentulousness (yrs)	No. of denture sets	Immediate dentures	Partial dentures	Age of current dentures (yrs)	sequence denture delivery ANA	sequence denture delivery NZ	IAD ANA denture	IAD NZ denture	crossbite ANA set	crossbite NZ set	tissue score mandible	tissue score maxilla	tissue score combined	denture preference	number of recall visits denture no.1	number of recall visits denture no.2	number of recall visits ANA denture	numberof recall visits NZ denture	OHIP pre-treatment	OHIP ANA dentures	OHIP NZ dentures
1	1	68	1	1	1	10	1	no	no	10	1	2	16	16	0	0	6	4	10	2	1	1	1	1	15	12	3
2	2	63	2	1	1	45	1	yes	no	45	1	2	19	20	0	3	2	4	6	2	1	2	1	2	61	24	14
3	1	63	2	1	1	43	5	yes	no	3	2	1	19	19.5	0	3	6	6	12	1	1	1	1	1	71	0	12
4	2	49	2	2	1	14	2	no	no	7	2	1	22	21.5	0	0	4	3	7	3	5	0	0	5	74	0	0
5	2	54	2	2	1	30	3	no	no	5	2	1	17.5	19.5	0	1	3	6	9	3	6	2	2	6	64	4	7
6	2	76	2	2	1	60	2	no	yes	25	1	2	16	16	0	0	5	6	11	2	2	1	2	1	18	7	1
7	2	70	2	1	1	30	5	no	yes	2	1	2	15	19.5	0	1	5	6	11	4	5	2	5	2	57	28	52
8	2	64	2	1	1	46	3	no	no	21	1	2	23.5	23	0	3	4	5	9	2	1	1	1	1	33	41	4
9	2	54	2	1	3	40	reme	no	no	11	2	1	20.25	19.75	0	3	3	3	6	2	3	2	2	3	19	4	5
10	2	60	2	1	1	14	1	no	no	7	1	2	16.25	16.5	0	2	6	6	12	3	0	0	0	0	7	4	1
11	1	61	2	1	1	14	1	no	no	7	2	1	16	16	0	0	7	7	14	3	2	1	1	2	6	0	4
12	1	65	3	1	3	20	4	no	no	6	2	1	25	24.75	0	3	3	4	7	3	1	1	1	1	47	11	27
13	1	53	3	1	1	32	2	yes	no	5	2	1	24.5	25	0	0	3	4	7	2	2	1	1	2	33	18	9
14	2	48	2	1	1	29	3	yes	yes	5	1	2	20.5	20	0	0	3	3	6	1	2	1	2	1	58	5	14
15	2	71	1	2	1	40	3	no	no	20	2	1	29	29	0	3	3	3	6	3	1	0	0	1	74	8	2
16	2	52	2	1	1	13	1	no	yes	13	1	2	22	X	0	3	5	5	10	n/a	1	n/a	1	n/a		x	x
17	2	55	2	1	1	30	1	no	no	30	1	2	25	25	0	3	3	3	6	1	2	1	2	1	33	19	6
18	2	67	1	1	1	47	1	no	no	40	2	1	X	20	0	3	3	3	6	n/a	1	n/a	n/a	1		x	x
19	2	62	1	2	1	27	2	no	no	22	1	2	31	30.5	0	1	3	3	6	2	1	2	1	2	64	18	9
20	2	47	2	2	1	27	1	no	no	27	2	1	23	23	0	3	4	5	9	2	1	0	0	1	48	20	13
21	1	73	2	1	1	50	2	no	no	30	1	2	18.75	19	0	0	3	6	9	3	1	0	1	0	29	5	7
22	2	71	2	2	1	31	8	no	no	6	1	2	21.5	21	0	1	3	3	6	2	1	1	1	1	48	23	2
23	2	61	1	2	1	43	4	no	no	8	1	2	15.5	15.75	0	3	4	4	8	3	3	3	3	3	4	0	0
24	2	85	1	2	1	22	2	no	no	22	2	1	18	18	0	0	3	4	7	2	1	1	1	1	19	5	1
25	2	78	2	2	1	52	2	yes	no	2	2	1	16	16	0	0	3	7	10	3	3	2	2	3	67	30	46.33
26	2	54	2	1	1	33	5	no	yes	19	1	2	27.5	27	0	3	2	2	4	1	5	1	5	1	70	37.5	63
27	1	65	1	1	1	45	2	no	no	12	2	1	28	28.5	0	3	3	3	6	4	1	0	0	1	7	14	5
28	2	52	1	2	1	30	2	no	no	13	2	1	21	19.5	0	1	6	5	11	1	1	0	0	1	15	0	7
29	1	63	2	1	1	35	5	no	no	14	1	2	23.5	23.5	0	3	6	7	13	1	2	1	2	1	51	4	23
30	1	66	2	1	1	45	4	no	no	21	2	1	26.5	27	0	3	3	5	8	1	1	0	0	1	57	5	9
31	1	52	2	1	1	36	3	no	no	5	2	1	17.5	18.5	0	0	6	6	12	3	2	1	1	2	53	2	0
32	1	66	1	1	1	39	2	no	no	4	1	2	16	15.5	0	0	7	7	14	2	3	1	3	1	55	2	0
33	2	67	2	2	1	25	3	no	no	11	1	2	20.5	20	0	3	4	6	10	2	1	0	1	0	46	5	0
34	2	60	3	2	2	3	1	yes	yes	3	1	2	21	20.5	0	0	6	6	12	2	2	2	2	2	54	25	12
35	1	58	2	1	1	1	0	no	no	n/a	1	2	21	21	0	3	7	7	14	2	0	1	0	1		0	0
36	1	72	2	1	1	45	2	no	no	17	2	1	26	26	0	0	3	6	9	1	1	0	0	1	48	9	17
37	1	52	2	1	1	20	1	no	no	1	1	2	25	24	0	3	3	5	8	3	1	0	1	0	63	80	77
38	1	77	2	1	1	<1	1	no	yes	n/a	2	1	19	18	0	0	5	5	10	3	5	1	1	5	7	39	45
39	2	55	2	2	1	40	0	no	no	40	1	2	22	21	0	3	6	3	9	2	1	0	1	0		34	2

Gender: 1=male; 2= female

Crossbite: 0=none; 1=unilateral R; 2=unilateral L; 3=bilateral

Denture preference: ANA=1; NZ=2; no preference=3; don't know=4

Education: in primary school=1; in high school=2; post-high school training=3

Income: <5000=1; 10000-15000=2;>15000=3

Marital status: married = 1; single = 2

Addendum 10: Tissue scores

Patient		Mandibula			Maxilla			Combined score mand + max
		Resorption	Tissue-resiliency	Score	Resorption	Tissue-resiliency	Score	
1	M	3	3	**6**	3	1	**4**	**10**
2	F	1	1	**2**	3	1	**4**	**6**
3	M	3	3	**6**	3	3	**6**	**12**
4	F	3	1	**4**	2	1	**3**	**7**
5	F	2	1	**3**	3	3	**6**	**9**
6	F	2	3	**5**	3	3	**6**	**11**
7	F	2	3	**5**	3	3	**6**	**11**
8	F	1	3	**4**	2	3	**5**	**9**
9	F	2	1	**3**	2	1	**3**	**6**
10	F	3	3	**6**	3	3	**6**	**12**
11	M	4	3	**7**	4	3	**7**	**14**
12	M	2	1	**3**	3	1	**4**	**7**
13	M	2	1	**3**	3	1	**4**	**7**
14	F	2	1	**3**	2	1	**3**	**6**
15	F	1	2	**3**	2	1	**3**	**6**
16	F	2	3	**5**	2	3	**5**	**10**
17	F	2	1	**3**	2	1	**3**	**6**
18	F	2	1	**3**	2	1	**3**	**6**
19	F	2	1	**3**	2	1	**3**	**6**
20	F	1	3	**4**	2	3	**5**	**9**
21	M	2	1	**3**	3	3	**6**	**9**
22	F	2	1	**3**	2	1	**3**	**6**
23	F	3	1	**4**	3	1	**4**	**8**
24	F	2	1	**3**	1	3	**4**	**7**
25	F	2	1	**3**	4	3	**7**	**10**
26	F	1	1	**2**	1	1	**2**	**4**
27	M	2	1	**3**	2	1	**3**	**6**
28	F	3	3	**6**	2	3	**5**	**11**
29	M	3	3	**6**	4	3	**7**	**13**
30	M	2	1	**3**	2	3	**5**	**8**
31	M	3	3	**6**	3	3	**6**	**12**
32	M	4	3	**7**	4	3	**7**	**14**
33	F	1	3	**4**	3	3	**6**	**10**
34	F	3	3	**6**	3	3	**6**	**12**
35	M	4	3	**7**	4	3	**7**	**14**
36	M	2	1	**3**	3	3	**6**	**9**
37	M	2	1	**3**	2	3	**5**	**8**
38	M	2	3	**5**	3	2	**5**	**10**
39	F	3	3	**6**	2	1	**3**	**9**
Mean				**4.205**			**4.77**	**8.97**

Addendum 11: Raw data: widths of ridges (AR), anatomic (ANA) and neutral zone (NZ) dentures measurements

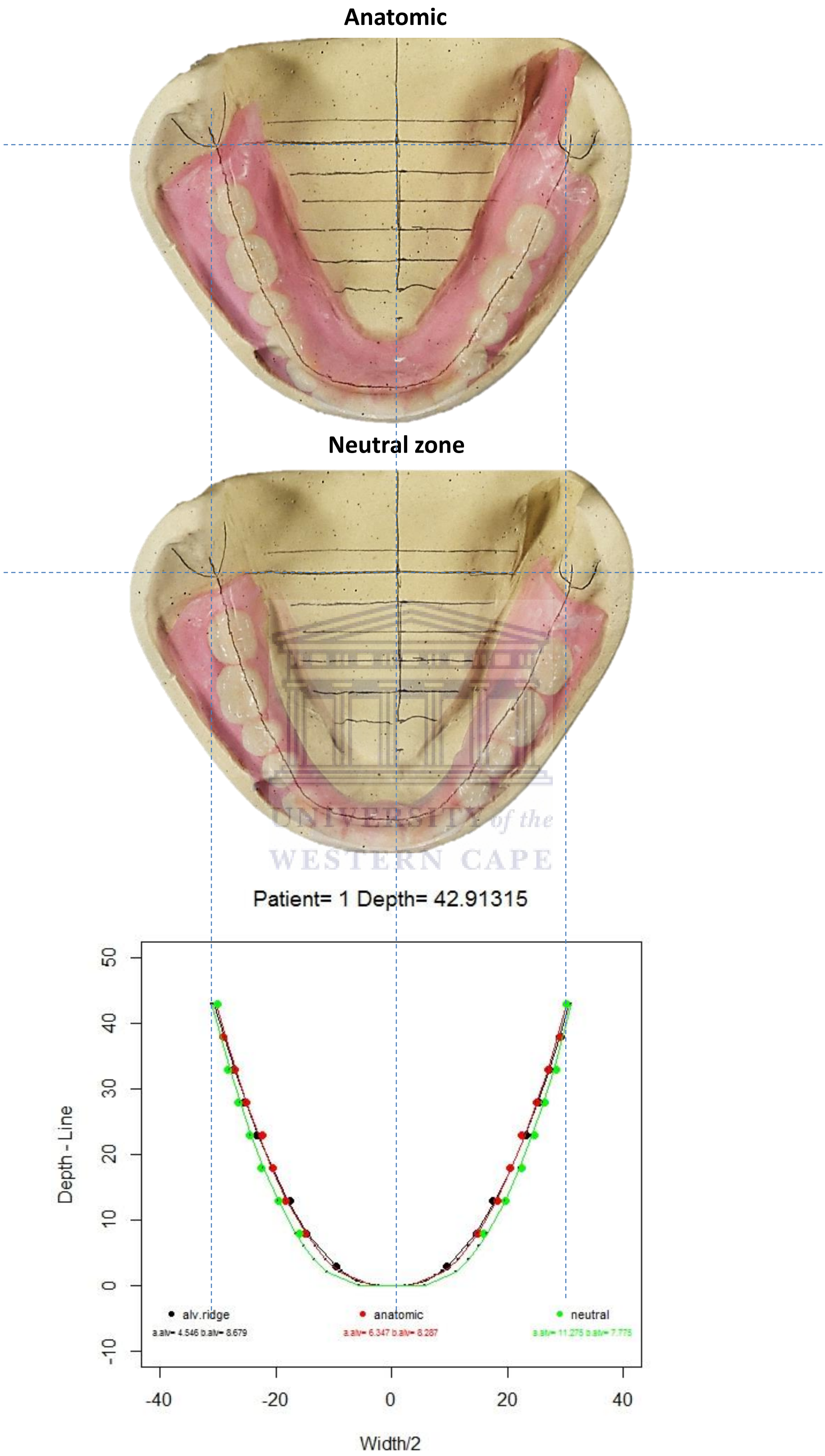
(All values are the mean of 5 measurements)

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
AR	0	60.39017	58.38024	55.0303	54.0342	57.30033	53.888	54.2198	58.5873	50.30338	51.78461	52.22502	57.35303	66.2944	55.36733	56.59458	56.06075	56.77846	51.69833	58.12535	55.76798
	5	58.35309	55.64618	54.59596	51.64176	57.0495	52.20996	52.8096	54.96837	47.07585	50.17721	49.98743	55.78495	61.66617	50.44978	53.91637	54.04878	52.75407	49.68799	55.92321	54.19026
	10	54.66695	52.16542	52.73737	47.86162	53.09061	48.85811	49.98919	51.24467	43.68028	47.45114	47.84759	53.59932	58.1145	45.95202	50.02582	50.44147	48.0183	46.81742	52.82891	52.06497
	15	50.88381	48.90293	49.64646	44.24472	48.71728	44.49351	46.91593	47.17864	39.55659	44.24717	44.8062	51.37737	55.78026	41.88406	46.05814	46.55978	42.59147	42.60974	49.70073	49.04872
	20	46.58332	44.0896	45.30303	39.91476	44.07131	40.06959	41.65443	42.40698	35.01983	40.43501	41.21084	48.68923	51.66516	36.13692	40.80098	41.71277	37.34756	37.85039	45.8498	44.38051
	25	41.00022	36.71453	41.06061	33.27375	39.09815	34.63714	35.88719	37.03449	30.35006	35.35213	38.08256	44.85076	46.97656	28.09095	35.81933	36.49996	31.61586	33.08169	40.25974	39.21114
	30	35.03988	28.74211	34.55555	24.99182	32.16191	28.03091	30.77156	30.75377	23.3909	29.62845	33.96582	40.43107	41.38243	17.03234	29.76858	29.06176	23.38415	26.2185	33.75494	29.93967
	35	29.56456							21.88815			29.16477	34.54017	35.06389		24.55551			11.46358	24.18972	12.30626
	40	19.05583																			
ANA	0	60.39017	58.38024	55.0303	54.0342	57.30033	53.888	54.2198	58.5873	50.30338	51.78461	52.22502	57.35303	66.2944	55.36733	56.59458	56.06075	56.77846	51.69833	58.12535	55.76798
	5	58.141	49.97711		49.4314		47.83889		52.28716	47.36437	48.9881	50.24811			49.2096	49.33362	52.48209	52.13416	47.51403	49.1133	
	10	54.1622	45.99127	47.70707	45.10497	46.48936	45.2506	47.72891	49.6742	43.58698	45.57741	47.6738	50.77714	50.77714	44.68234	45.3464	47.71838	47.46952	43.70803	46.24426	47.65337
	15	50.07548	42.76362	44.37374	40.79574	43.19517	42.84446	44.46006	45.74079	39.82356	42.27533	45.07775	47.97702	47.97702	41.3957	41.87686	43.45237	43.41464	39.96752	42.92332	44.02255
	20	44.8566	38.9042	41.0101	37.03699	38.90837	39.27339	40.17944	43.26756	35.68941	39.39687	42.14498	44.16692	44.16692	37.3937	38.07688	38.49567	39.73578	35.87164	39.41036	40.49335
	25	41.08262	33.79281	37.9798	33.82012	34.28344	35.64301	36.47282	39.13153	31.07501	35.31272	39.08187	41.2156	41.2156	33.29665	33.37371	33.58976	34.55286	31.61679	35.4682	36.89024
	30	36.70476	28.84219	33.49495	28.8572	29.70214	29.8903	33.03859	35.49855	28.62428	30.66373	35.18237	37.51436	37.51436	27.58879	28.40622	27.5564	29.13617		31.20978	32.28012
	35	29.83615							29.71371			29.95771	33.93408	33.93408							
	40																				
NZ	0	60.39017	58.38024	55.0303	54.0342	57.30033	53.888	54.2198	58.5873	50.30338	51.78461	52.22502	57.35303	66.2944	55.36733	56.59458	56.06075	56.77846	51.69833	58.12535	55.76798
	5		53.9575		53.51253		50.62344		58.15529	50.16485	53.33162	50.20343			54.98801	52.80256	54.53382	54.81056	50.32382	55.1214	
	10	56.78996	51.37277	56.03032	50.25293		48.45357	47.16881	54.58606	49.521	51.08368	48.21657	64.45251	61.49899	50.86379	48.4418	52.22816	53.49995	48.08908	51.50762	53.80852
	15	52.98248	48.35152	51.80809	46.77831	50.50588	45.68188	46.02119	51.26131	46.74961	49.56333	45.73029	61.76044	57.74648	47.54843	45.64476	47.97231	51.71188	45.64862	47.60023	51.51879
	20	49.18565	44.8363	48.14142	42.69306	46.49245	43.40182	44.64988	48.01339	43.04744	46.85929	43.42857	58.64489	53.11871	44.05333	42.61646	43.87897	48.99929	43.30167	44.08809	48.00112
	25	45.08684	36.65709	43.11111	38.01437	42.6099	39.29515	41.59607	44.28351	38.57543	42.02675	40.30172	55.11192	48.92354	38.13661	36.44973	37.53074	44.20401	36.33563	36.86053	42.72921
	30	39.14353	30.10914	37.85859	31.92519	37.50587	30.97162	35.90663	38.59092	32.05988	33.55241	35.35086	49.11071	43.94366	31.00159	28.19073	28.887	37.8848		32.18521	34.98292
	35	31.90596							30.747			27.36	40.58681	33.59155							29.22168
	40																				

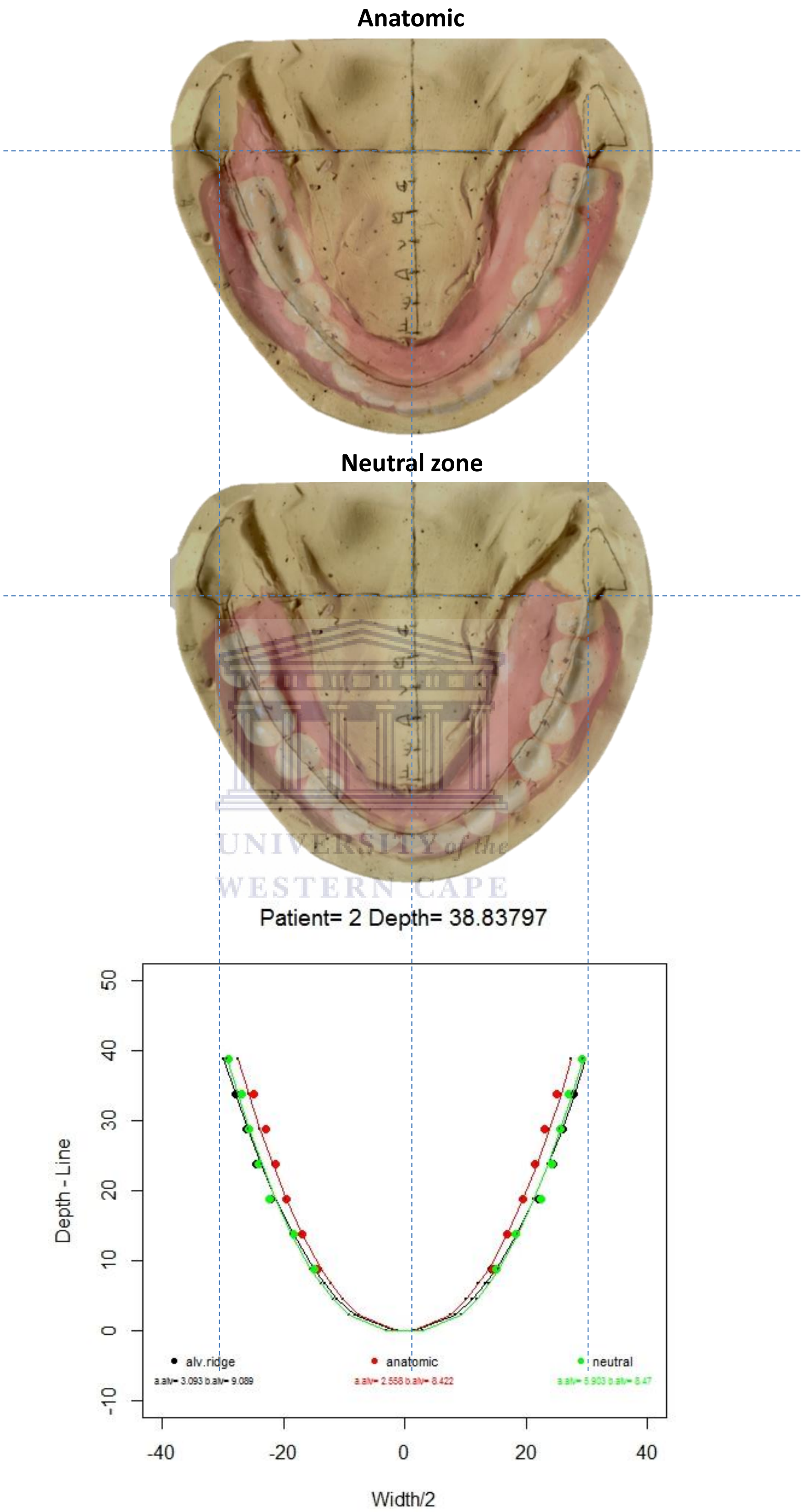
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
AR	0	60.39017	58.38024	55.0303	54.0342	57.30033	53.888	54.2198	58.5873	50.30338	51.78461	52.22502	57.35303	66.2944	55.36733	56.59458	56.06075	56.77846	51.69833	58.12535	55.76798
	5	58.35309	55.64618	54.59596	51.64176	57.0495	52.20996	52.8096	54.96837	47.07585	50.17721	49.98743	55.78495	61.66617	50.44978	53.91637	54.04878	52.75407	49.68799	55.92321	54.19026
	10	54.66695	52.16542	52.73737	47.86162	53.09061	48.85811	49.98919	51.24467	43.68028	47.45114	47.84759	53.59932	58.1145	45.95202	50.02582	50.44147	48.0183	46.81742	52.82891	52.06497
	15	50.88381	48.90293	49.64646	44.24472	48.71728	44.49351	46.91593	47.17864	39.55659	44.24717	44.8062	51.37737	55.78026	41.88406	46.05814	46.55978	42.59147	42.60974	49.70073	49.04872
	20	46.58332	44.0896	45.30303	39.91476	44.07131	40.06959	41.65443	42.40698	35.01983	40.43501	41.21084	48.68923	51.66516	36.13692	40.80098	41.71277	37.34756	37.85039	45.8498	44.38051
	25	41.00022	36.71453	41.06061	33.27375	39.09815	34.63714	35.88719	37.03449	30.35006	35.35213	38.08256	44.85076	46.97656	28.09095	35.81933	36.49996	31.61586	33.08169	40.25974	39.21114
	30	35.03988	28.74211	34.55555	24.99182	32.16191	28.03091	30.77156	30.75377	23.3909	29.62845	33.96582	40.43107	41.38243	17.03234	29.76858	29.06176	23.38415	26.2185	33.75494	29.93967
	35	29.56456							21.88815			29.16477	34.54017	35.06389		24.55551			11.46358	24.18972	12.30626
	40	19.05583																			
ANA	0	60.39017	58.38024	55.0303	54.0342	57.30033	53.888	54.2198	58.5873	50.30338	51.78461	52.22502	57.35303	66.2944	55.36733	56.59458	56.06075	56.77846	51.69833	58.12535	55.76798
	5	58.141	49.97711		49.4314		47.83889		52.28716	47.36437	48.9881	50.24811			49.2096	49.33362	52.48209	52.13416	47.51403	49.1133	
	10	54.1622	45.99127	47.70707	45.10497	46.48936	45.2506	47.72891	49.6742	43.58698	45.57741	47.6738	50.77714	50.77714	44.68234	45.3464	47.71838	47.46952	43.70803	46.24426	47.65337
	15	50.07548	42.76362	44.37374	40.79574	43.19517	42.84446	44.46006	45.74079	39.82356	42.27533	45.07775	47.97702	47.97702	41.3957	41.87686	43.45237	43.41464	39.96752	42.92332	44.02255
	20	44.8566	38.9042	41.0101	37.03699	38.90837	39.27339	40.17944	43.26756	35.68941	39.39687	42.14498	44.16692	44.16692	37.3937	38.07688	38.49567	39.73578	35.87164	39.41036	40.49335
	25	41.08262	33.79281	37.9798	33.82012	34.28344	35.64301	36.47282	39.13153	31.07501	35.31272	39.08187	41.2156	41.2156	33.29665	33.37371	33.58976	34.55286	31.61679	35.4682	36.89024
	30	36.70476	28.84219	33.49495	28.8572	29.70214	29.8903	33.03859	35.49855	28.62428	30.66373	35.18237	37.51436	37.51436	27.58879	28.40622	27.5564	29.13617		31.20978	32.28012
	35	29.83615							29.71371			29.95771	33.93408	33.93408							
	40																				
NZ	0	60.39017	58.38024	55.0303	54.0342	57.30033	53.888	54.2198	58.5873	50.30338	51.78461	52.22502	57.35303	66.2944	55.36733	56.59458	56.06075	56.77846	51.69833	58.12535	55.76798
	5		53.9575		53.51253		50.62344		58.15529	50.16485	53.33162	50.20343			54.98801	52.80256	54.53382	54.81056	50.32382	55.1214	
	10	56.78996	51.37277	56.03032	50.25293		48.45357	47.16881	54.58606	49.521	51.08368	48.21657	64.45251	61.49899	50.86379	48.4418	52.22816	53.49995	48.08908	51.50762	53.80852
	15	52.98248	48.35152	51.80809	46.77831	50.50588	45.68188	46.02119	51.26131	46.74961	49.56333	45.73029	61.76044	57.74648	47.54843	45.64476	47.97231	51.71188	45.64862	47.60023	51.51879
	20	49.18565	44.8363	48.14142	42.69306	46.49245	43.40182	44.64988	48.01339	43.04744	46.85929	43.42857	58.64489	53.11871	44.05333	42.61646	43.87897	48.99929	43.30167	44.08809	48.00112
	25	45.08684	36.65709	43.11111	38.01437	42.6099	39.29515	41.59607	44.28351	38.57543	42.02675	40.30172	55.11192	48.92354	38.13661	36.44973	37.53074	44.20401	36.33563	36.86053	42.72921
	30	39.14353	30.10914	37.85859	31.92519	37.50587	30.97162	35.90663	38.59092	32.05988	33.55241	35.35086	49.11071	43.94366	31.00159	28.19073	28.887	37.8848		32.18521	34.98292
	35	31.90596							30.747			27.36	40.58681	33.59155							29.22168
	40																				

		21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
AR	0	60.84247	54.17085	46.43471	56.406	54.74683	57.80167	56.88634	55.15957	57.7479	57.04103	57.46341	54.27403	60.25089	53.57924	53.75131	60	60.91696	61.64306	52.80855
	5	59.10996	51.25628	44.78989	54.41972	51.12397	53.97596	54.28844	52.85461	53.8925	55.25391	54.0878	53.78323	56.71611	52.06801	51.40365	57.58123	56.77025	59.90557	50.77933
	10	54.85223	47.67839	41.52881	50.68636	47.25011	49.32963	50.47755	49.07802	50.65801	52.51953	48.9561	51.26789	51.699	48.22033	48.18854	53.51986	53.42842	55.93957	47.81885
	15	50.56053	43.69849	37.88744	45.72587	42.83064	44.71798	45.42502	45.56738	46.96015	45.85936	45.22927	47.86299	47.89062	44.30304	44.89758	48.33935	50.24962	51.62417	44.80933
	20	44.60423	40.13065	33.59954	40.04783	39.40419	41.07721	40.32474	42.12766	42.24282	41.73828	41.36585	43.86503	42.59977	39.48101	41.36001	42.63538	44.73765	46.35505	42.0645
	25	38.33088	34.85427	28.49401	32.35233	35.95592	36.26908	34.21203	36.89716	37.98888	35.47853	36.07805	38.84458	37.24061	34.77828	38.12594	36.58845	36.98421	38.76298	38.14332
	30	30.37028	28.17085	18.42557	24.34484	31.50372	32.33935	24.71824	31.79078	33.31788	28.07617	30.47805	31.41104	30.3763	29.33982	33.61154	29.49458	30.43301	30.31161	33.72219
	35	20.91495				19.98036	24.05224		26.15248	24.05931	18.41797	21.85366		20.43333	19.34778	25.19917	16.6787	18.52267	16.25118	27.36987
	40													1.598174		12.79401				15.08675
ANA	0	60.84247	54.17085	46.43471	56.406	54.74683	57.80167	56.88634	55.15957	57.7479	57.04103	57.46341	54.27403	60.25089	53.57924	53.75131	60	60.91696	61.64306	52.80855
	5	57.6749	50.89447	42.14727	50.29106			52.23992	50.2305	50.03753	54.2084	50.27291	49.3865	57.78791	50.33818	49.33257	50.58652	54.64641	55.30753	48.96484
	10	53.41861	48.21105	39.00238	47.33888	49.84181	51.77436	48.54332	47.60638	45.77219	49.67893	47.154	45.9407	52.42873	47.03601	46.33154	48.09602	49.66375	52.00151	46.00586
	15	49.89812	44.47236	36.57007	42.45322	47.0492	47.27778	44.1685	44.23759	41.33091	44.9893	43.56725	42.79141	48.46066	43.83331	44.4192	44.6129	45.81211	49.30772	43.17383
	20	46.15124	41.42714	33.05463	39.03326	42.96935	43.11641	40.54828	41.57801	36.46407	40.94183	40.19493	39.40695	44.58381	40.08355	40.57559	41.54486	42.65335	45.20109	40.32226
	25	42.23455	38.96482	28.45606	34.18919	39.50039	39.41742	36.546	38.45745	30.09845	36.09652	36.08187	34.92843	40.70696	35.87627	37.85856	38.62119	37.26309	42.18706	36.44531
	30	38.32919	34.57286		27.86902	34.68966	35.79933	33.15503	34.73404	26.09192	30.89123	30.89669	29.6728	37.2634	31.61926	34.55458	34.25374	32.75932	39.12593	31.77734
	35	32.57868				29.83527	30.30863		29.50355		27.30103	29.49318		31.85861	27.06385	29.67907	29.09221	28.11291	33.4181	28.66211
	40													27.59407						
NZ	0	60.84247	54.17085	46.43471	56.406	54.74683	57.80167	56.88634	55.15957	57.7479	57.04103	57.46341	54.27403	60.25089	53.57924	53.75131	60	60.91696	61.64306	52.80855
	5		54.34347	46.24301	50.71212			50.95043	49.54747	55.71414	56.18621	47.61071	53.25831	60.41049	49.28414	57.06714	53.19495	59.9083	51.2473	52.80855
	10	55.00849	52.85542	44.83709	50.3171	54.90453	58.15029	50.13851	47.64862	52.69256	53.51346	44.91032	49.69821	60.47891	46.53013	55.33466	50.32491	59.17473	47.67956	48.45706
	15	51.6695	49.08506	42.24375	45.99231	52.85325	54.02312	48.62929	46.06921	49.3651	50.29134	42.8042	45.70844	59.61231	44.59137	52.63657	47.11191	57.4325	45.28853	49.76563
	20	47.82117	45.3147	38.02603	42.72793	49.44899	49.80347	46.18397	42.67968	42.59895	46.51571	40.65913	42.03581	56.39681	42.4836	49.58819	43.50181	54.37596	41.73021	49.86328
	25	43.65592	39.63403	31.80394	34.11996	44.76814	45.74566	42.42048	37.79947	33.0152	41.97687	37.11001	34.77238	53.02166	38.795	43.95531	38.77256	50.48395	38.78383	47.78321
	30	37.24958	32.47537		29.11944	38.97436	40.47399	36.80387	34.46318	26.17483	34.77501	31.08426	29.36061	47.09236	33.06822	36.23024	33.66426	44.61538	35.62082	44.16994
	35	30.35654				31.58756	32.19653	29.92644	29.60071		28.04938	29.05613		39.61231	27.45081	31.02339	28.91697	34.91595	32.1284	37.74414
	40													28.77993						29.99024

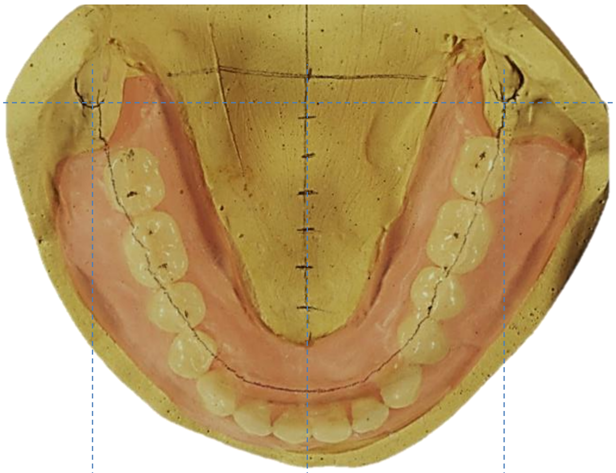
Addendum 12: Picture gallery of the 2 types of wax trial dentures overlaying the mandibular master cast



Anatomic
Neutral zone
Patient= 1 Depth= 42.91315
Depth - Line
Width/2
alv.ridge
a.alv= 4.546 b.alv= 8.679
anatomic
a.alv= 6.347 b.alv= 8.287
neutral
a.alv= 11.275 b.alv= 7.775
50
40
30
20
10
0
-10
-40
-20
0
20
40

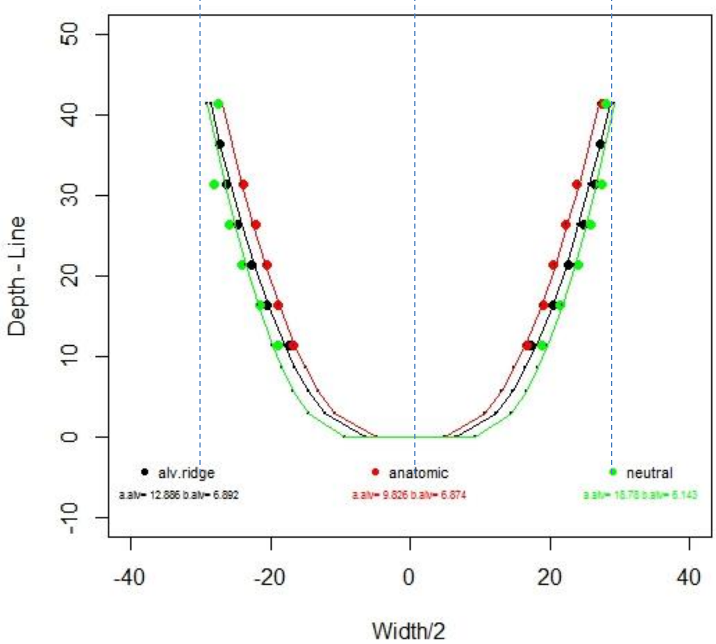

Anatomic
Neutral zone
Patient= 2 Depth= 38.83797
Depth - Line
Width/2
alv.ridge
a.alv= 3.093 b.alv= 9.089
anatomic
a.alv= 2.558 b.alv= 8.422
neutral

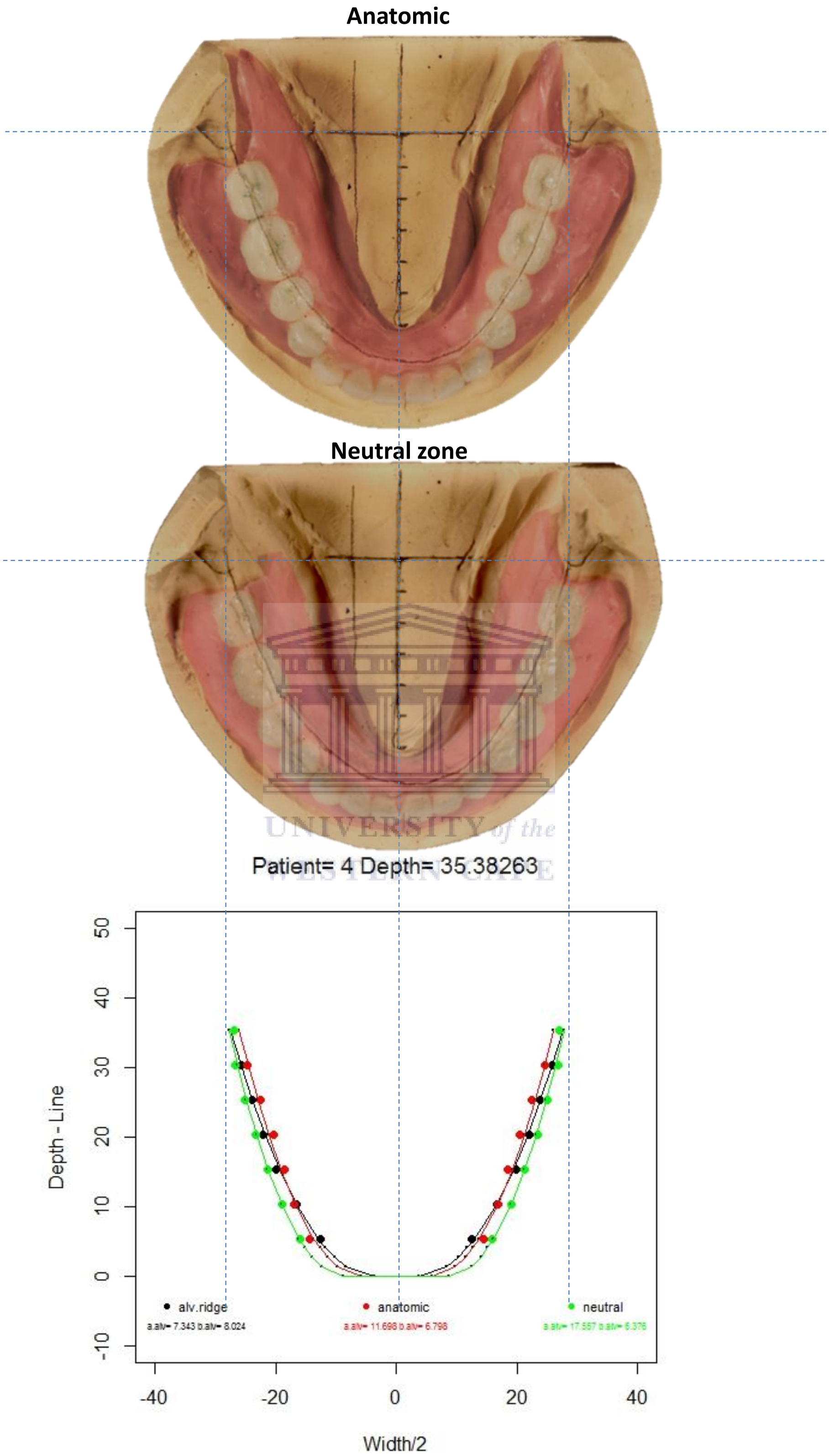
Anatomic



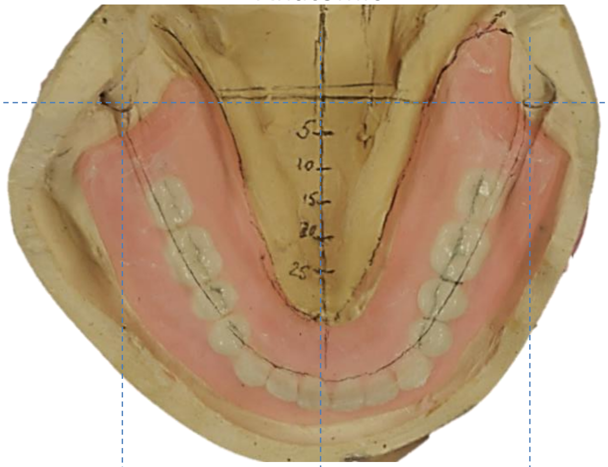
Neutral zone

Patient= 3 Depth= 41.34068

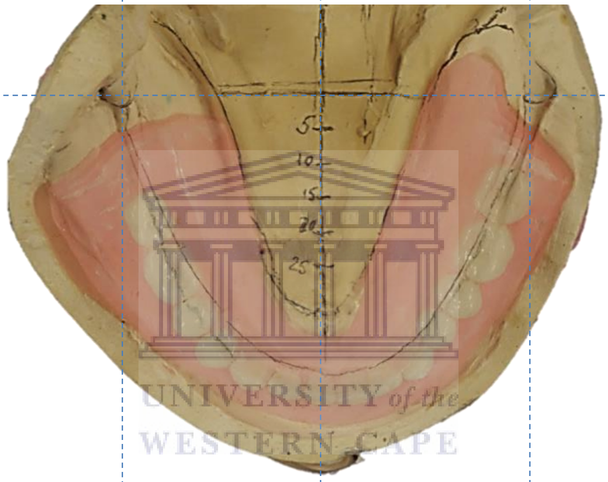



Anatomic
Neutral zone
Patient= 4 Depth= 35.38263
Depth - Line
Width/2
alv.ridge
a.alv= 7.343 b.alv= 8.024
anatomic
a.alv= 11.696 b.alv= 6.796
neutral
a.alv= 17.557 b.alv= 6.376
50
40
30
20
10
0
-10
-40
-20
0
20
40

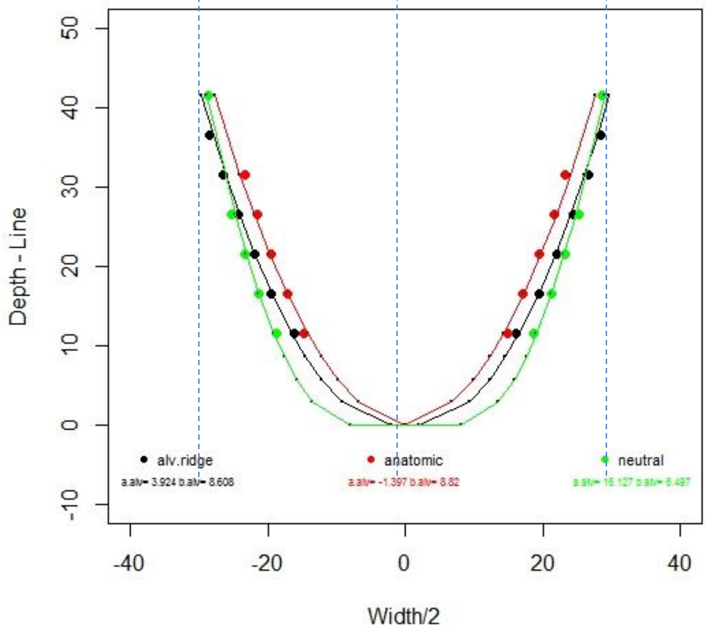
Anatomic

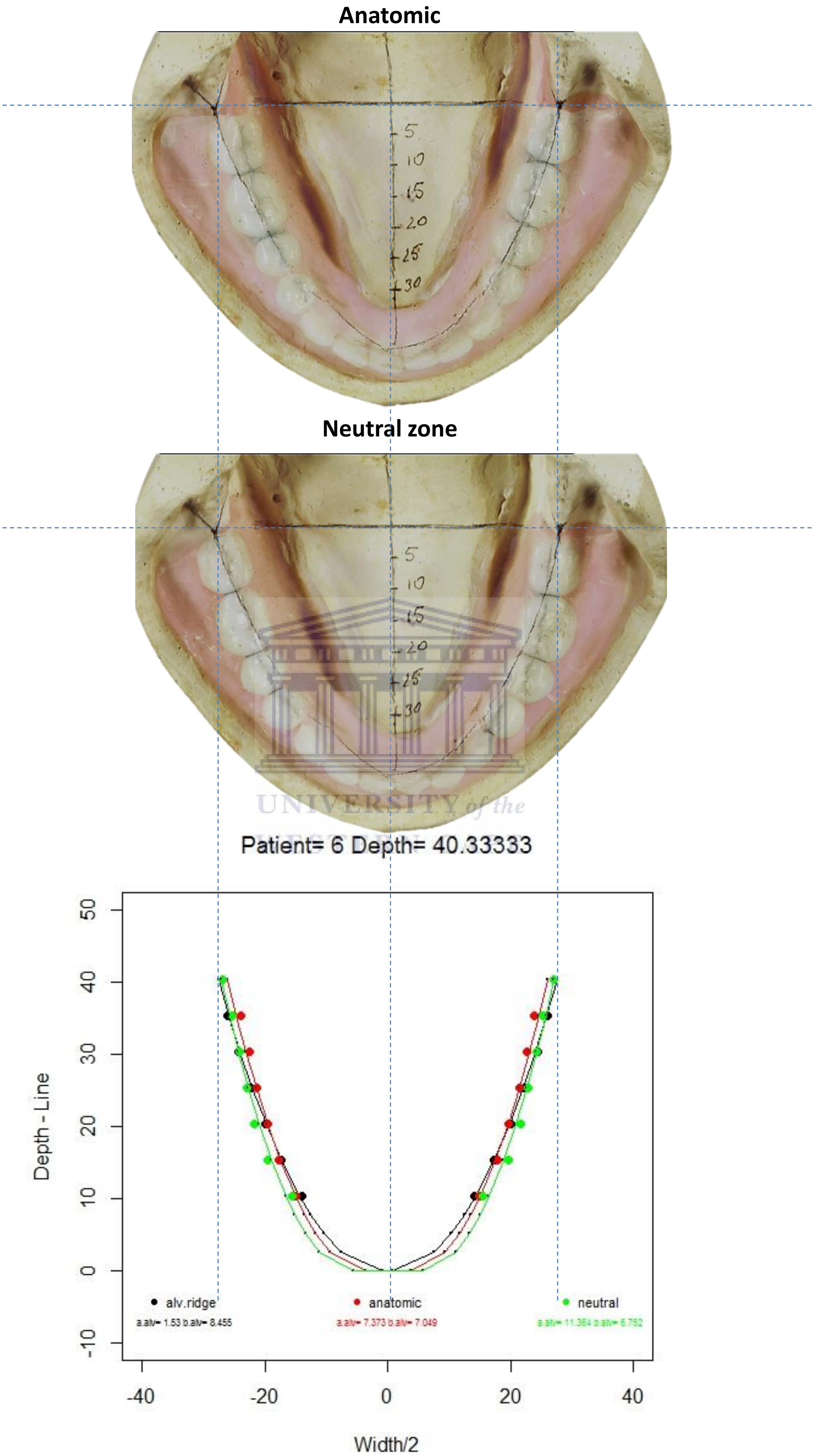


Neutral zone

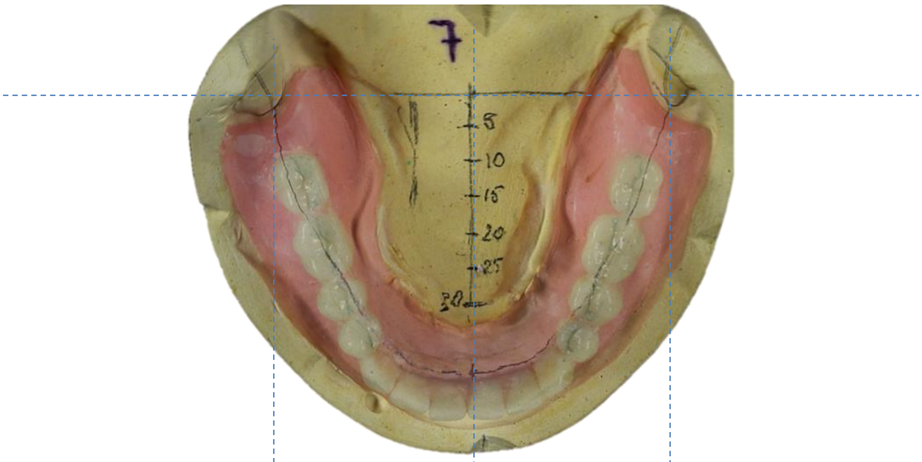


Patient= 5 Depth= 41.48008

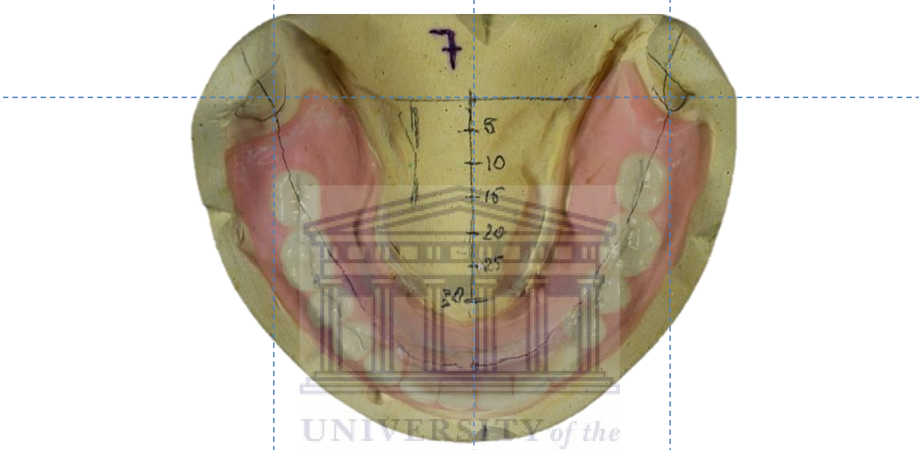


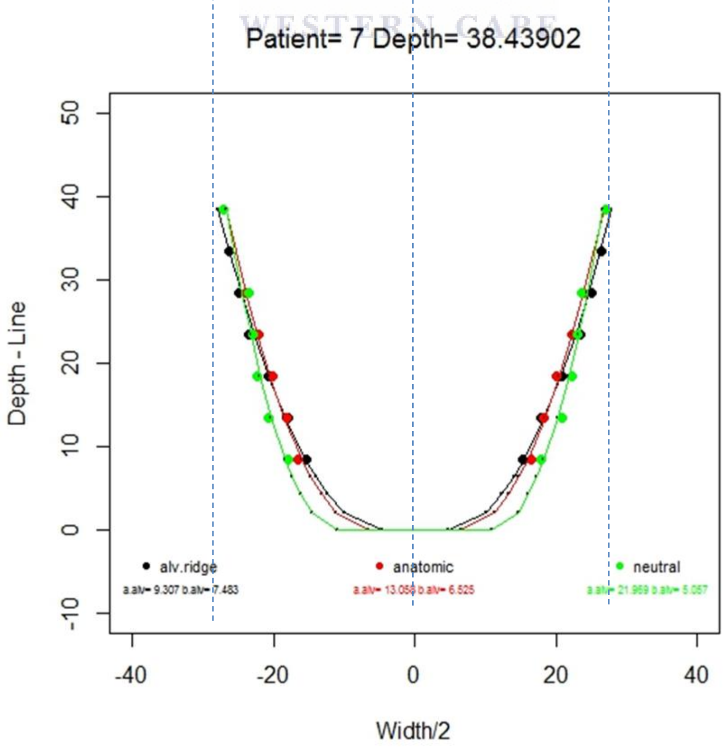

Anatomic
Neutral zone
Patient= 6 Depth= 40.33333
Depth - Line
Width/2
alv.ridge
a.alv= 1.53 b.alv= 8.455
anatomic
a.alv= 7.373 b.alv= 7.049
neutral
a.alv= 11.364 b.alv= 6.752

Anatomic

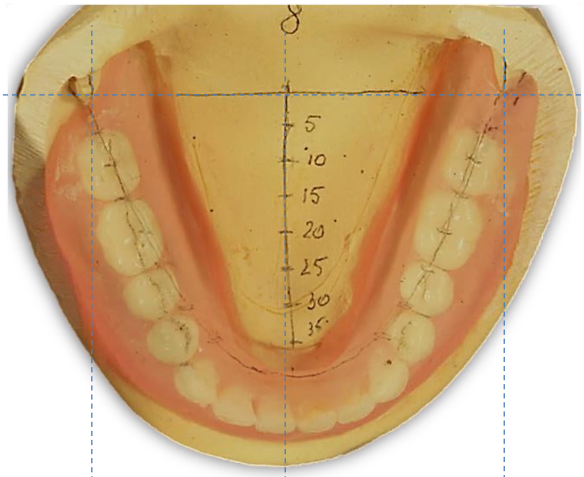


Neutral zone

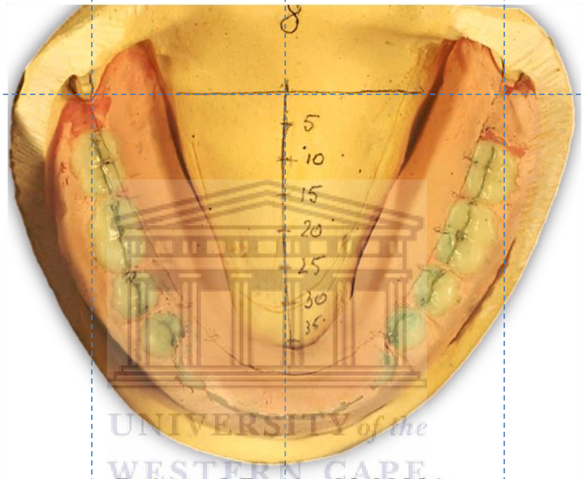




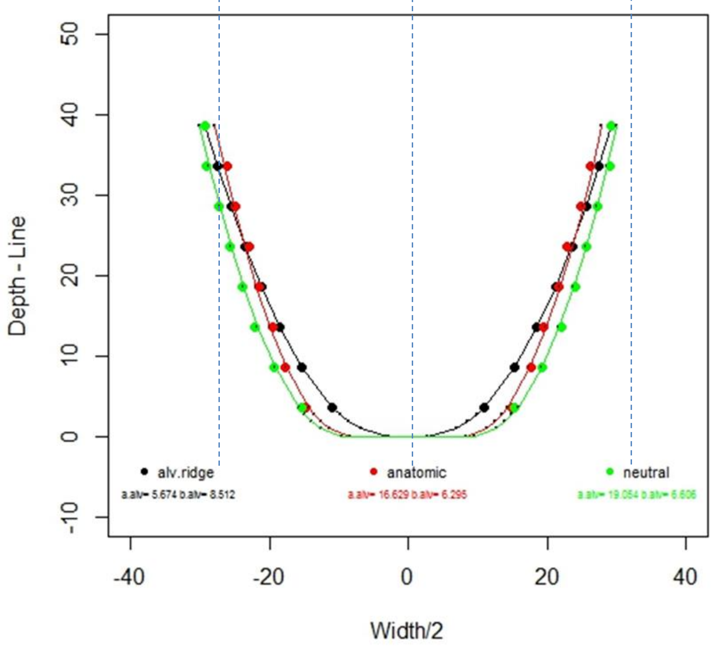
Anatomic



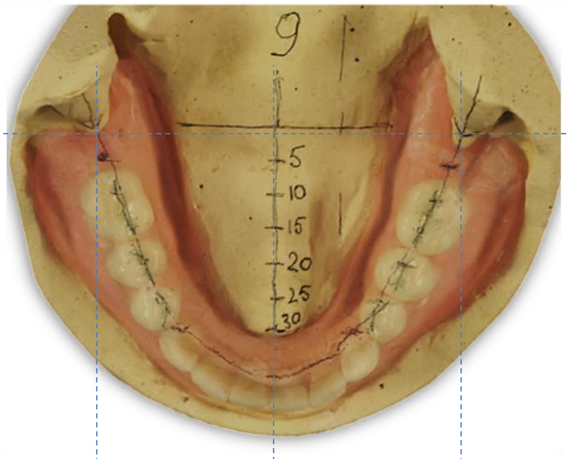
Neutral zone



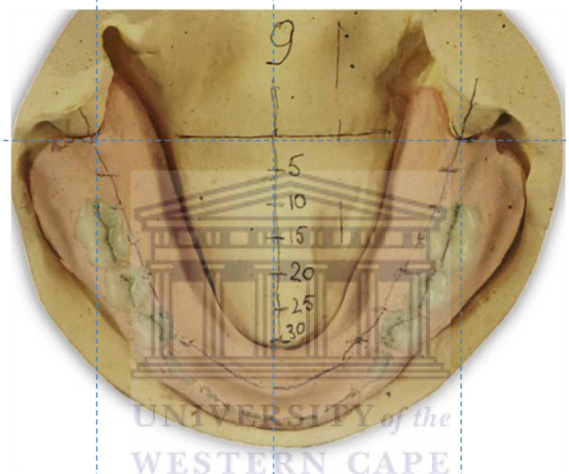
Patient= 8 Depth= 38.63981

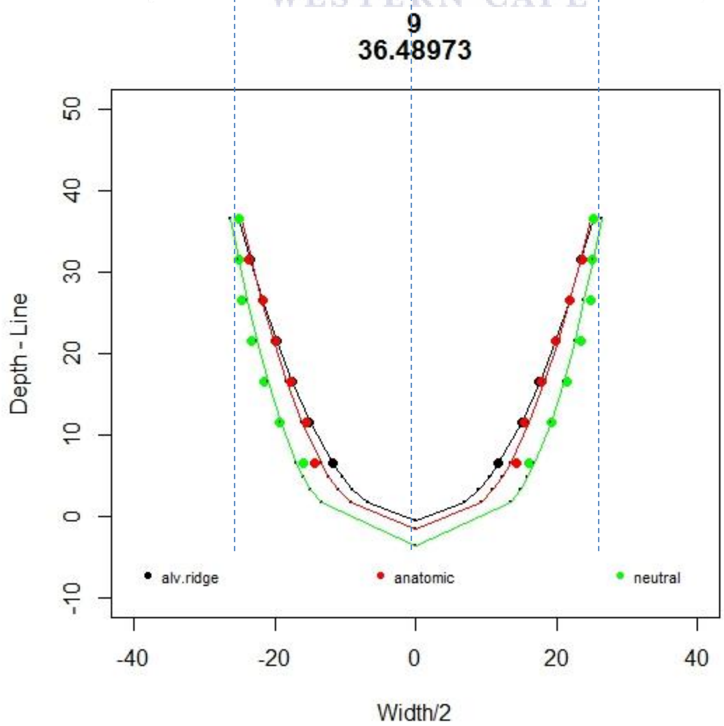


Anatomic

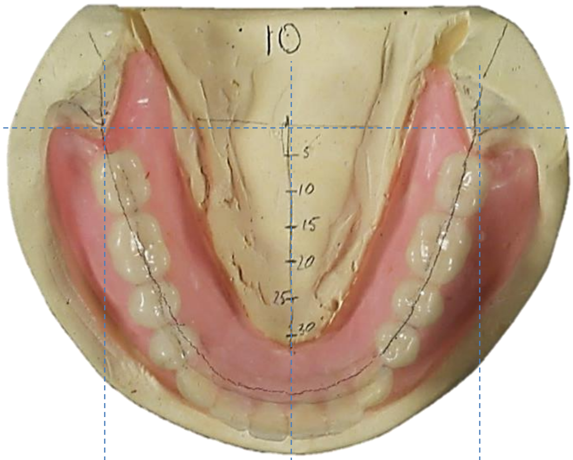


Neutral zone

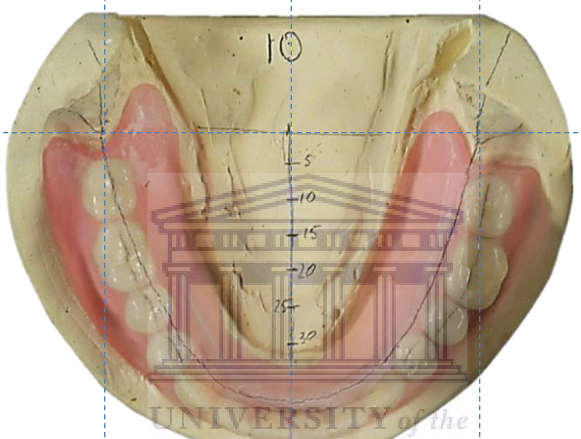




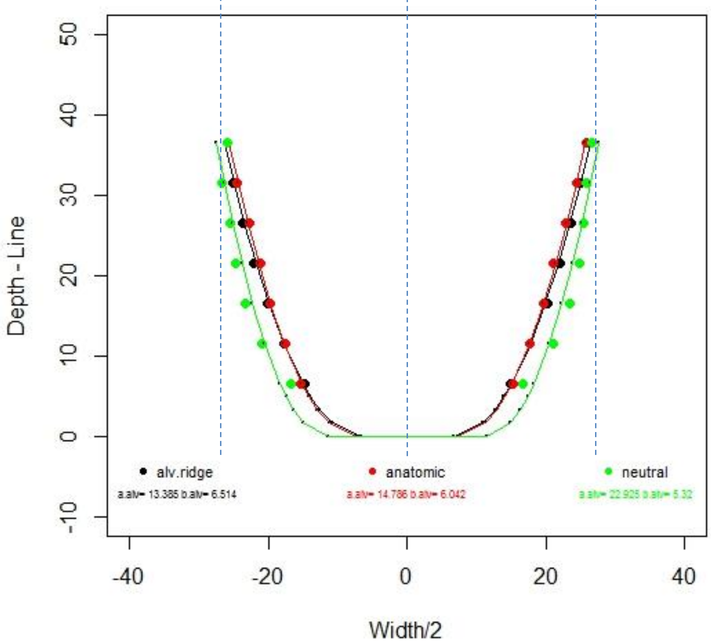
Anatomic

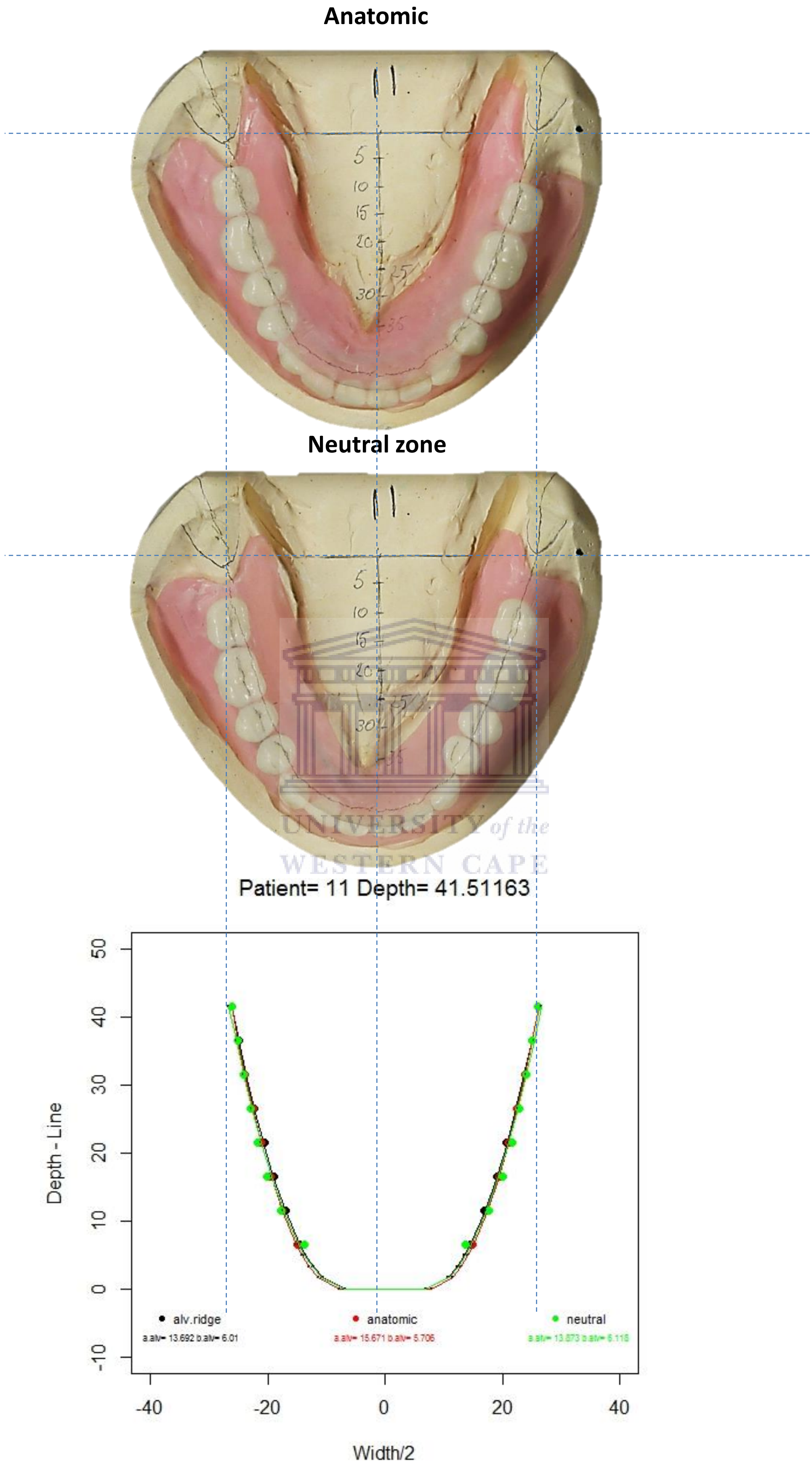


Neutral zone

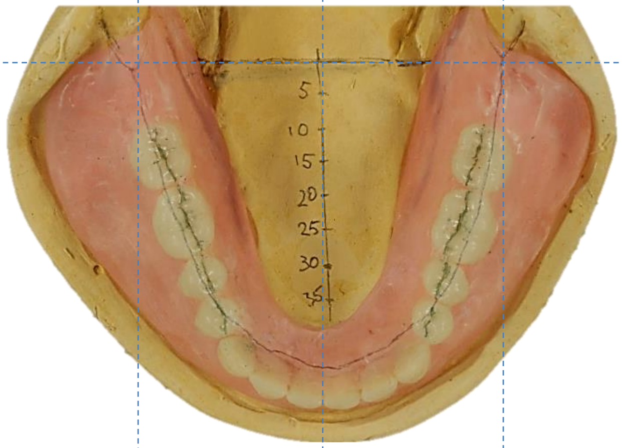


Patient= 10 Depth= 36.60202

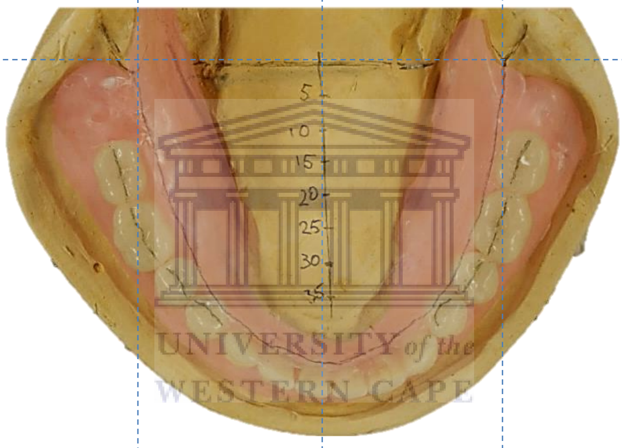


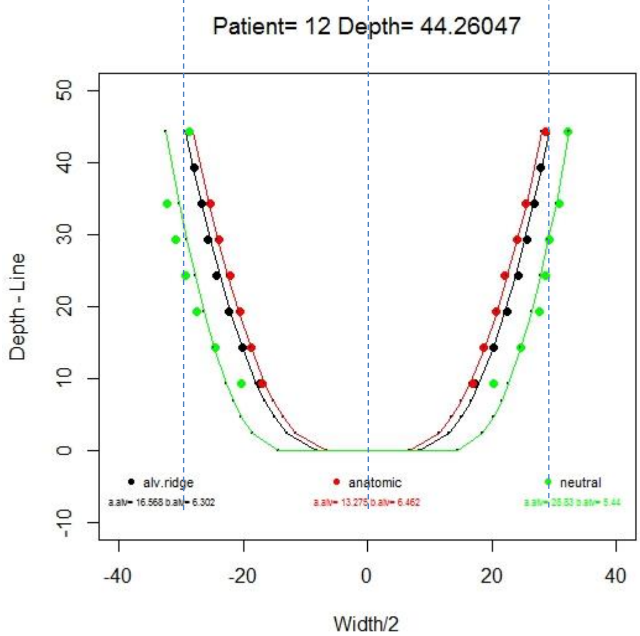

Anatomic
11
5
10
15
20
25
30
35
Neutral zone
Patient= 11 Depth= 41.51163
Depth - Line
Width/2
alv.ridge
a.alv= 13.692 b.alv= 6.01
anatomic
a.alv= 15.671 b.alv= 5.706
neutral
a.alv= 13.873 b.alv= 6.118
50
40
30
20
10
0
-10
-40
-20
0
20
40

Anatomic

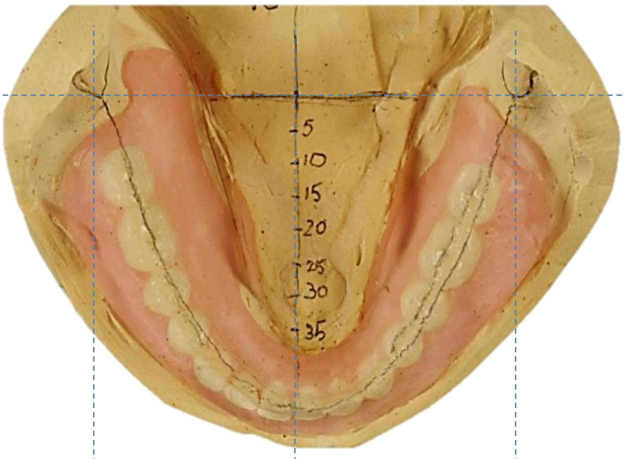


Neutral zone

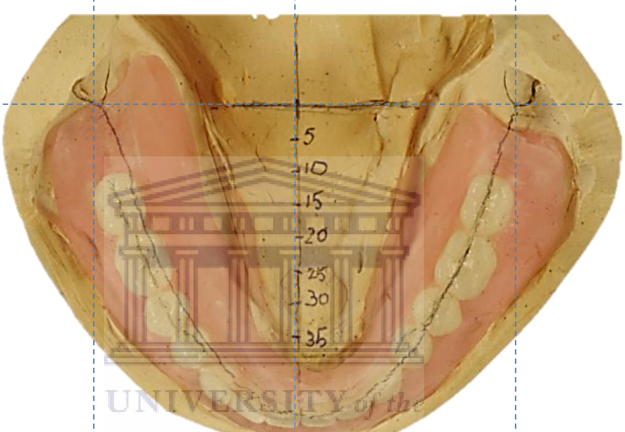


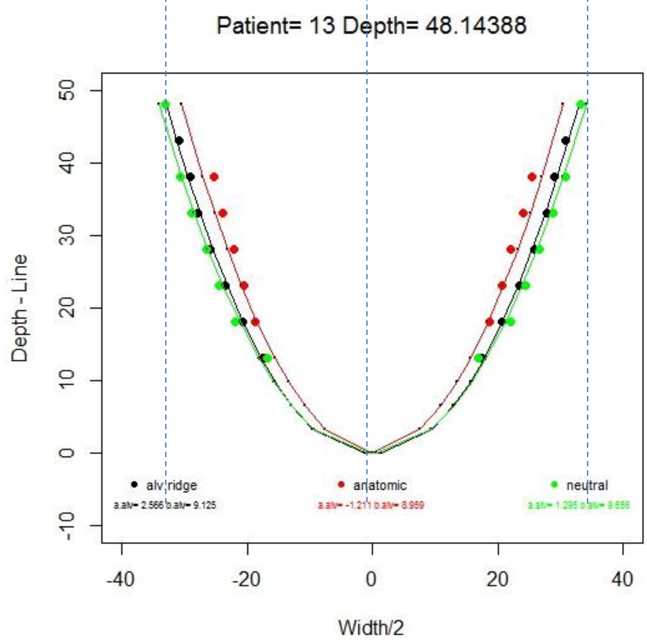


Anatomic

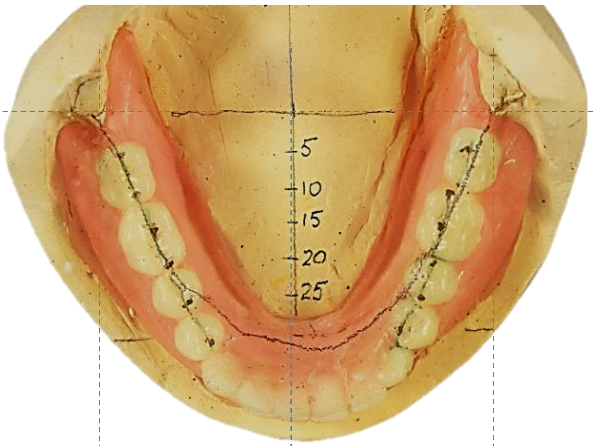


Neutral zone

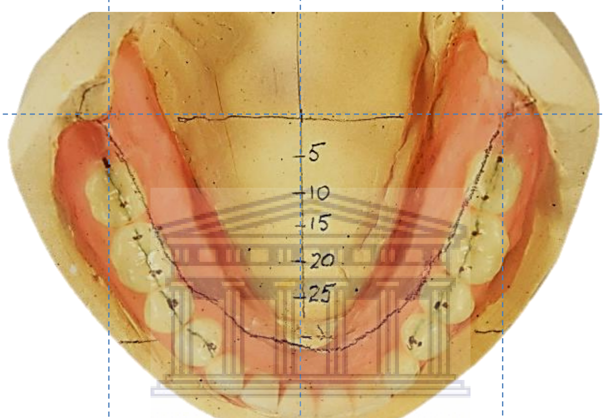


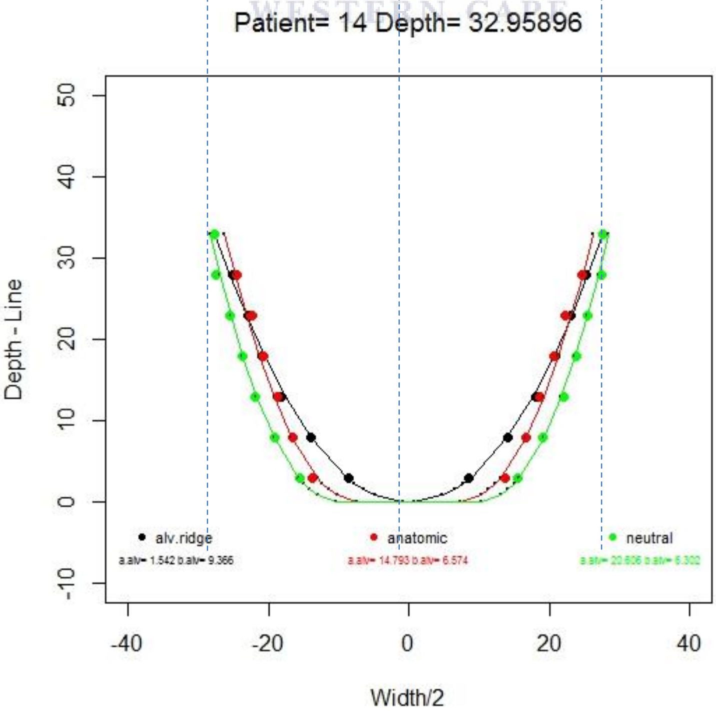


Anatomic

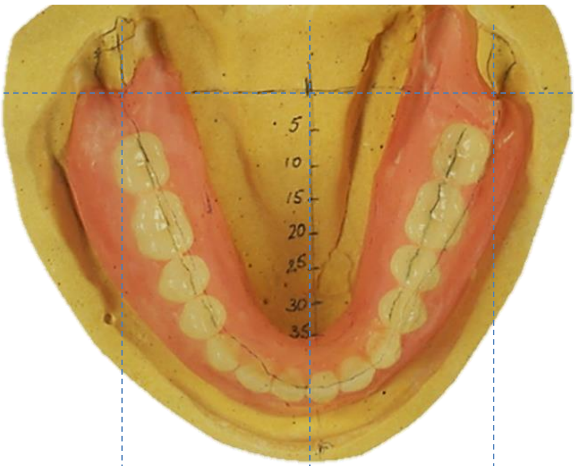


Neutral zone

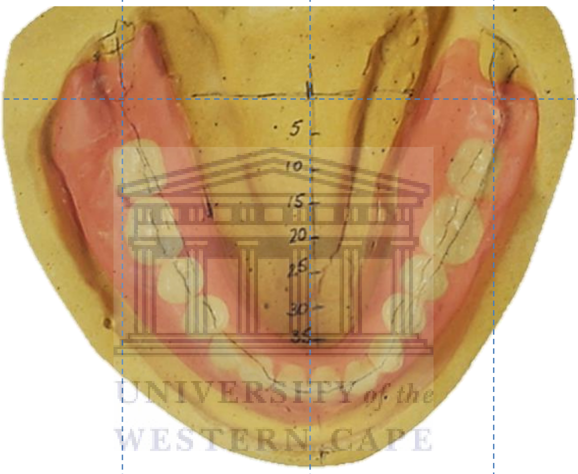


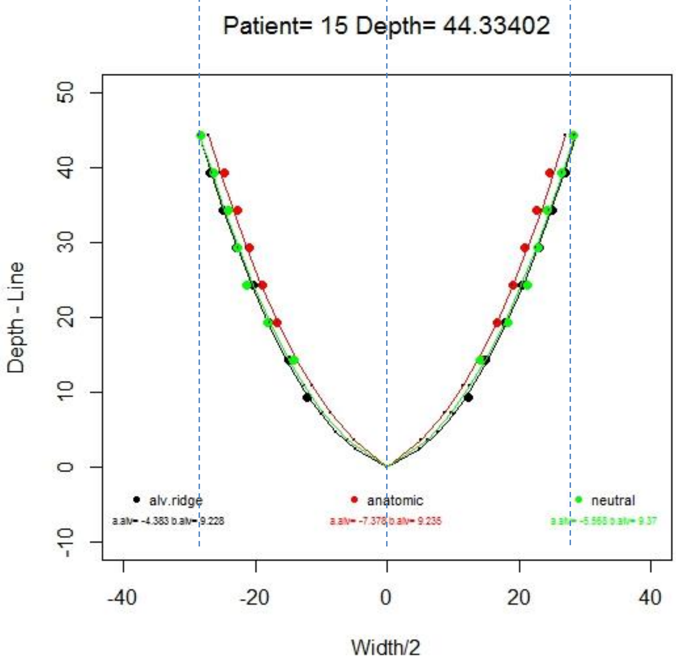


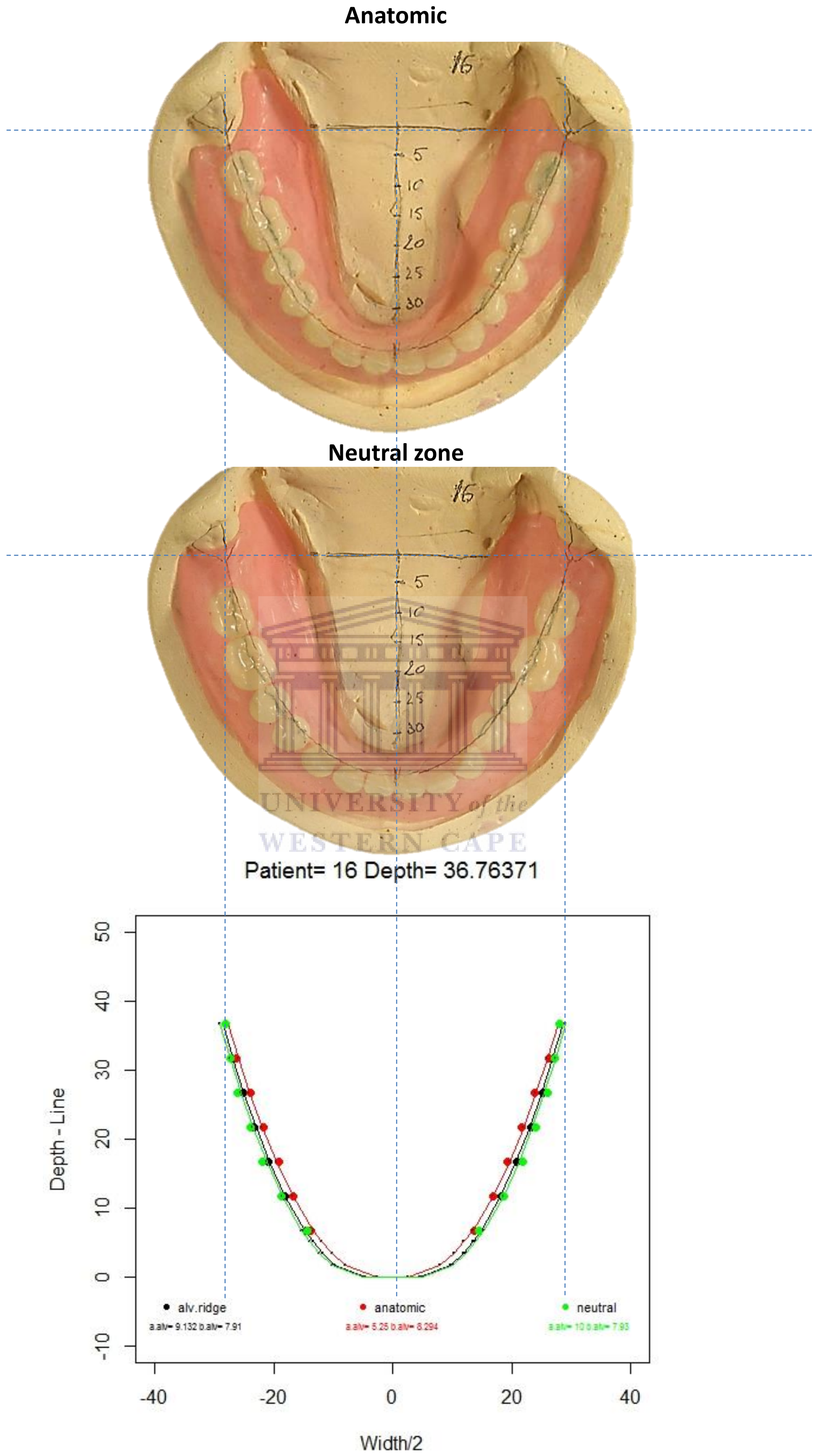
Anatomic



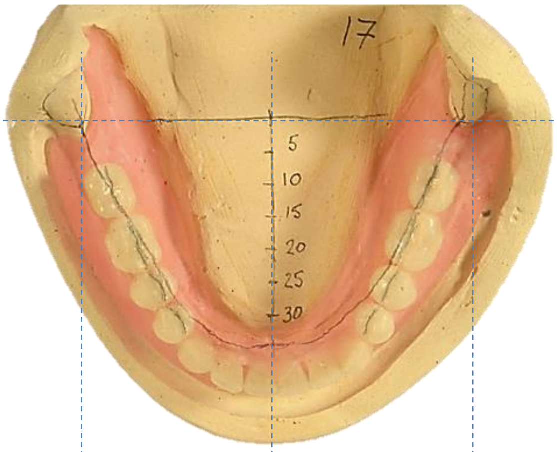
Neutral zone



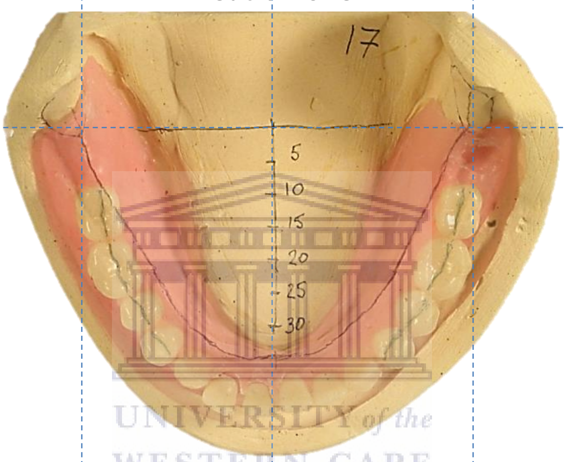


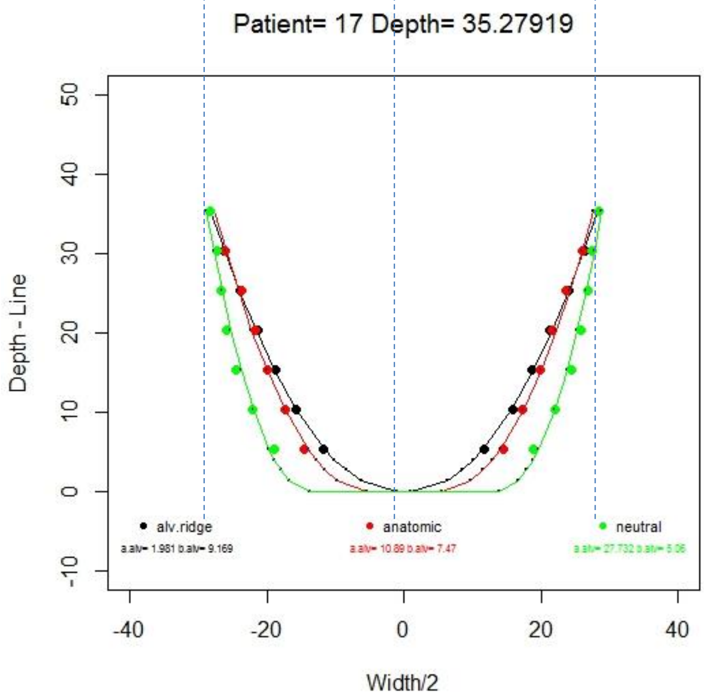

Anatomic
16
5
10
15
20
25
30
Neutral zone
16
5
10
15
20
25
30
Patient= 16 Depth= 36.76371
Depth - Line
50
40
30
20
10
0
-10
alv.ridge
a.alv= 9.132 b.alv= 7.91
anatomic
a.alv= 5.25 b.alv= 8.294
neutral
a.alv= 10 b.alv= 7.93
-40
-20
0
20
40
Width/2

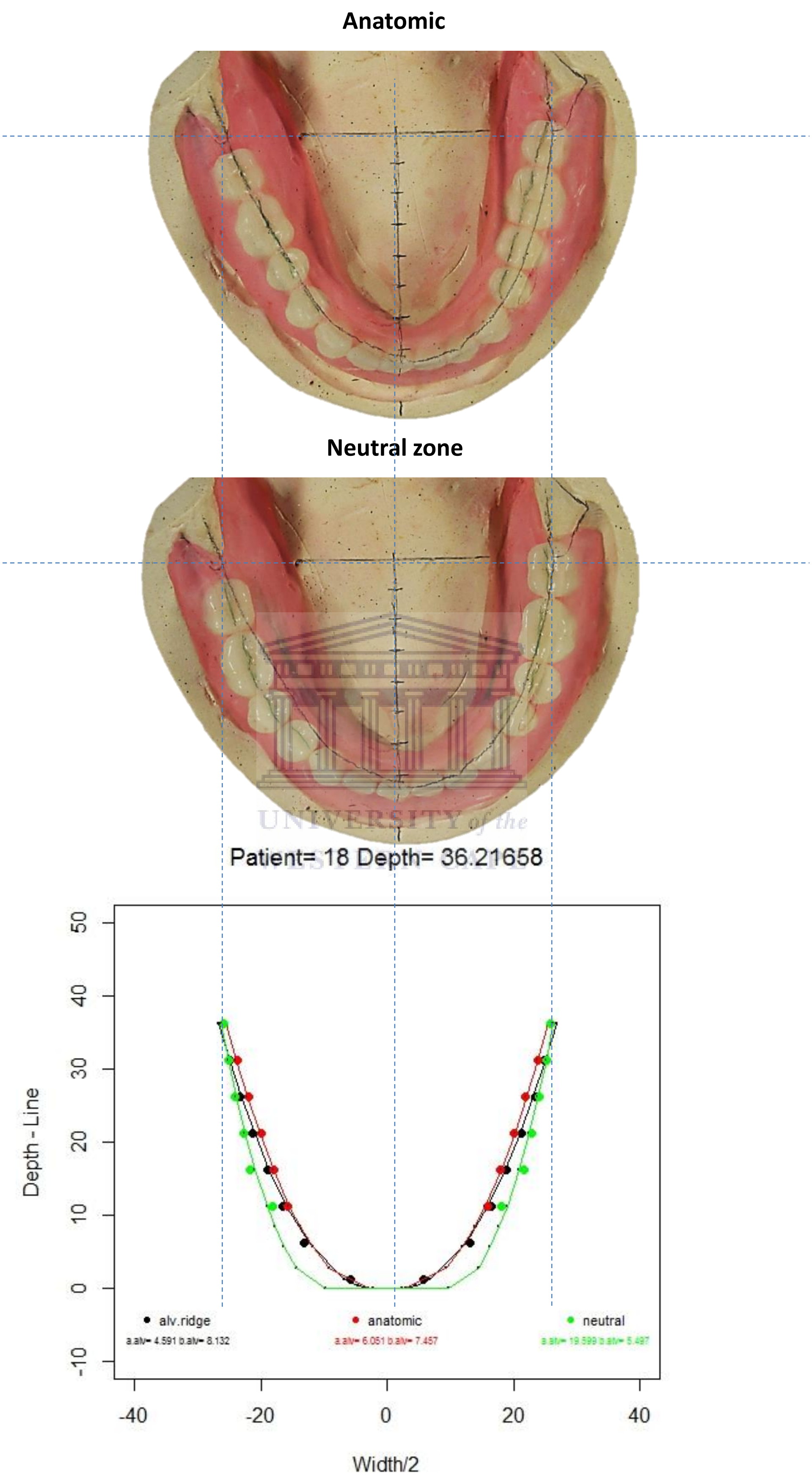
Anatomic



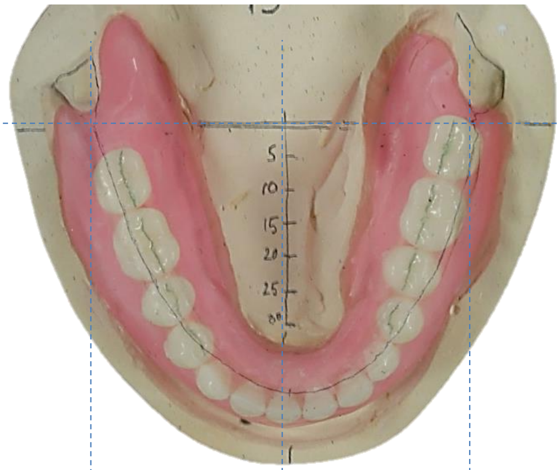
Neutral zone



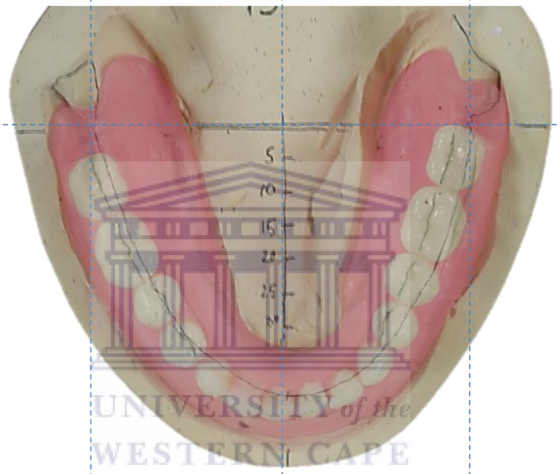


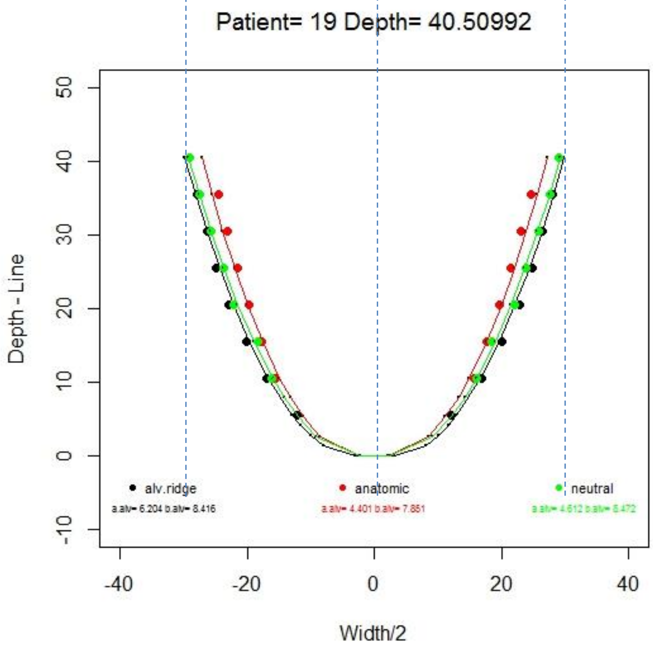

Anatomic
Neutral zone
UNIVERSITY of the
Patient= 18 Depth= 36.21658
Depth - Line
Width/2
alv.ridge
a.alv= 4.591 b.alv= 8.132
anatomic
a.alv= 6.051 b.alv= 7.457
neutral
a.alv= 19.599 b.alv= 5.497
50
40
30
20
10
0
-10
-40
-20
0
20
40

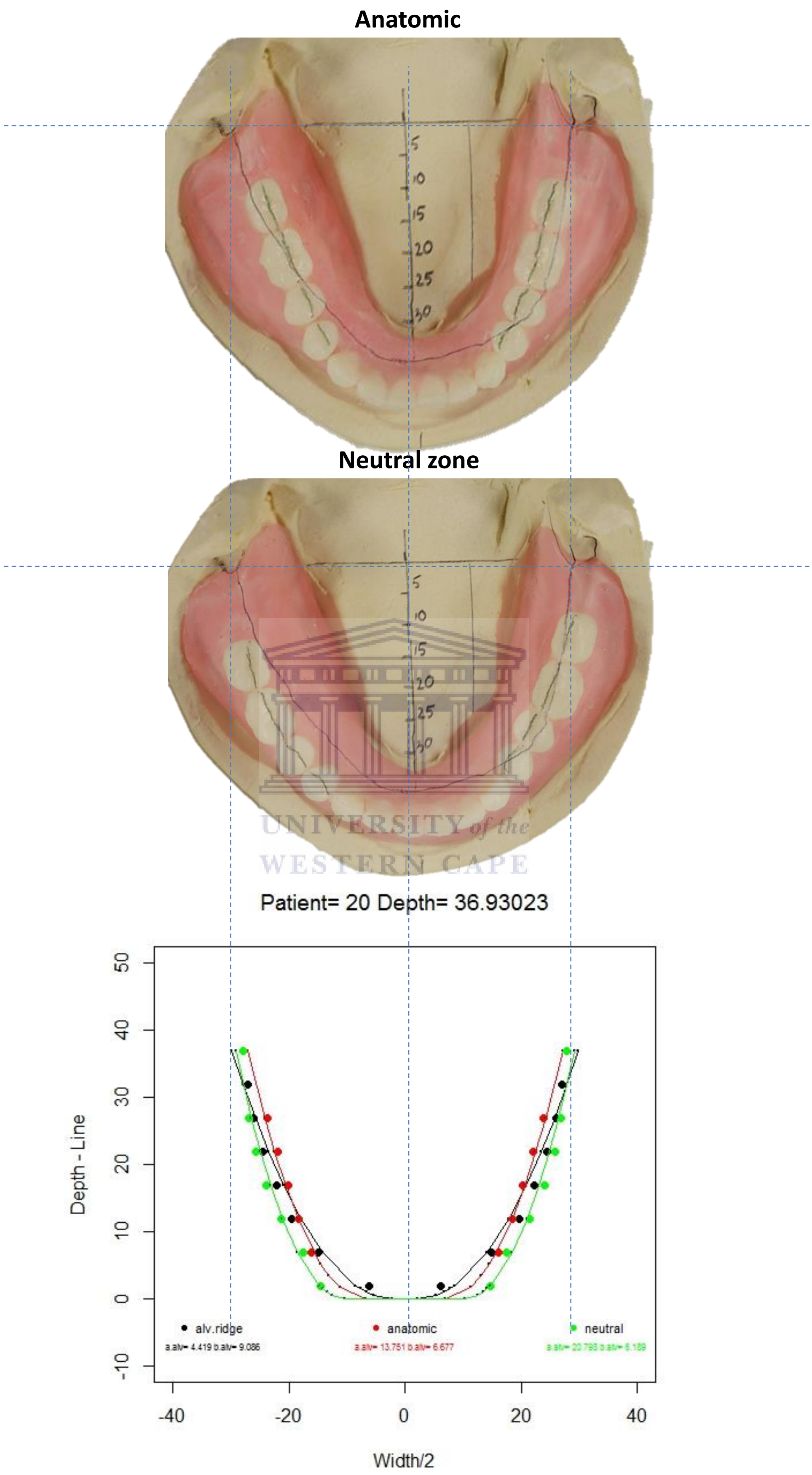
Anatomic



Neutral zone

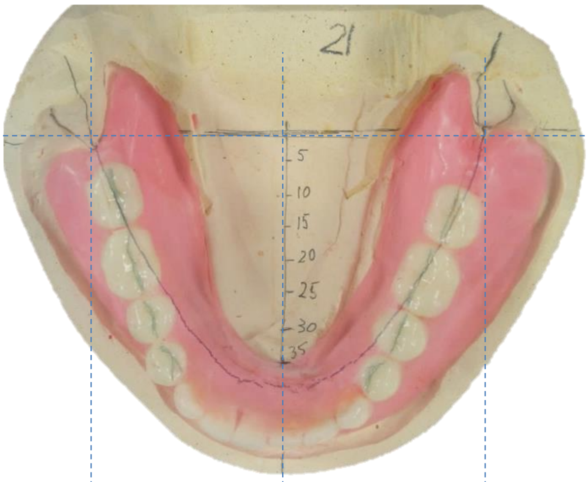




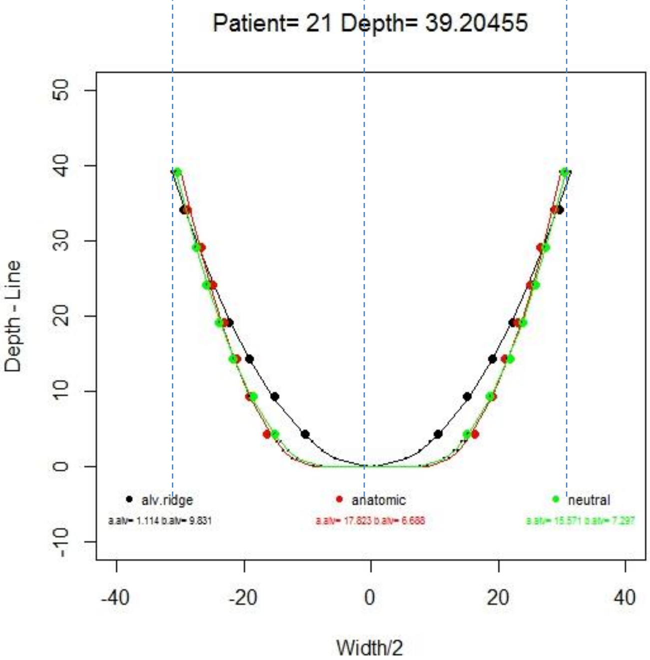


Anatomic
5
10
15
20
25
30
Neutral zone
5
10
15
20
25
30
Patient= 20 Depth= 36.93023
Depth - Line
Width/2
alv.ridge
a.alv= 4.419 b.alv= 9.086
anatomic
a.alv= 13.751 b.alv= 6.677
neutral
-40
-20
0
20
40
-10
0
10
20
30
40
50

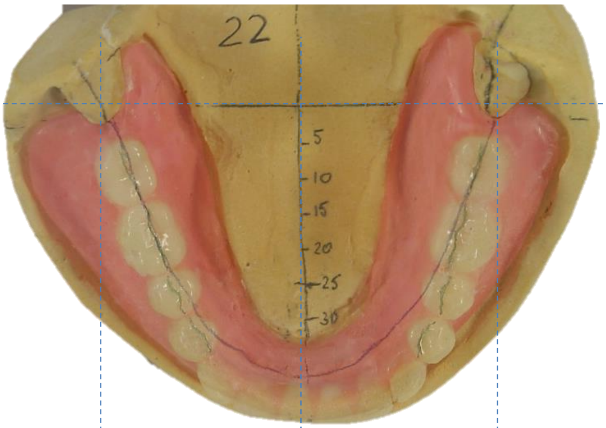
Anatomic



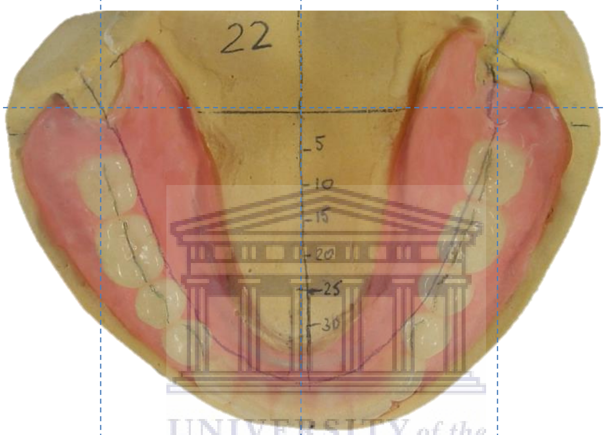
Neutral zone

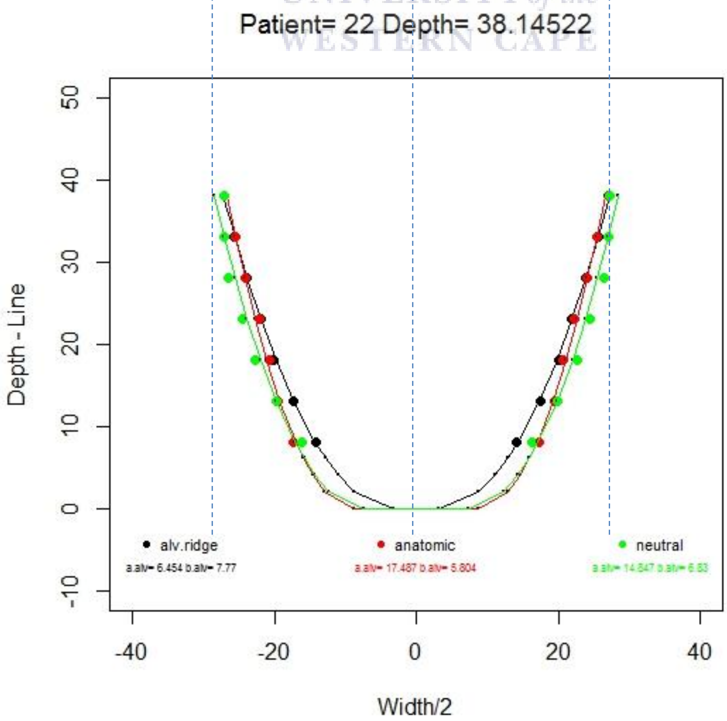


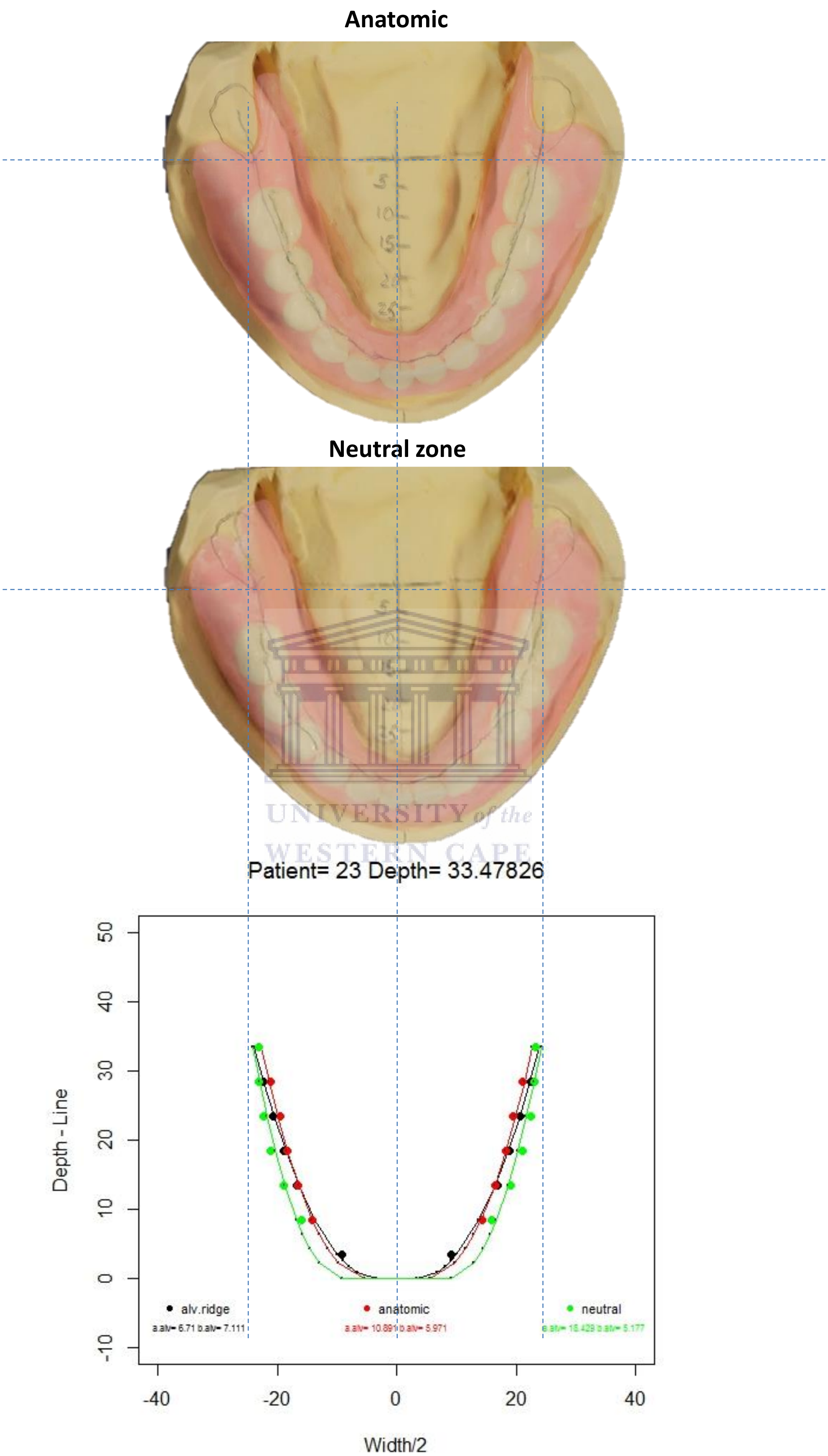
Anatomic



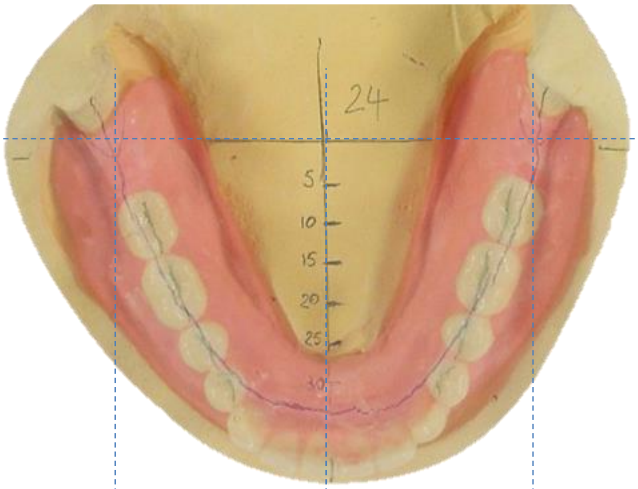
Neutral zone





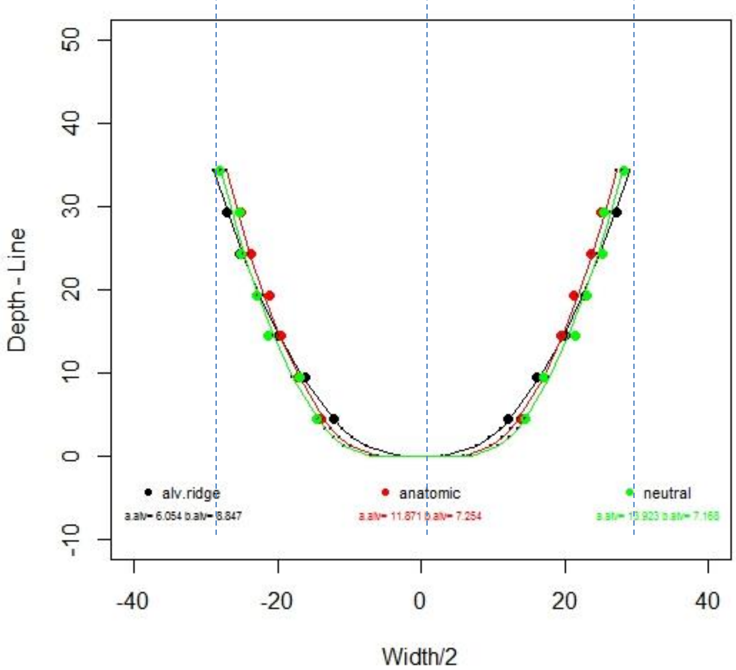

Anatomic
Neutral zone
Patient= 23 Depth= 33.47826
Depth - Line
Width/2
alv.ridge
a.alv= 6.71 b.alv= 7.111
anatomic
a.alv= 10.891 b.alv= 5.971
neutral
50
40
30
20
10
0
-10
-40
-20
0
20
40

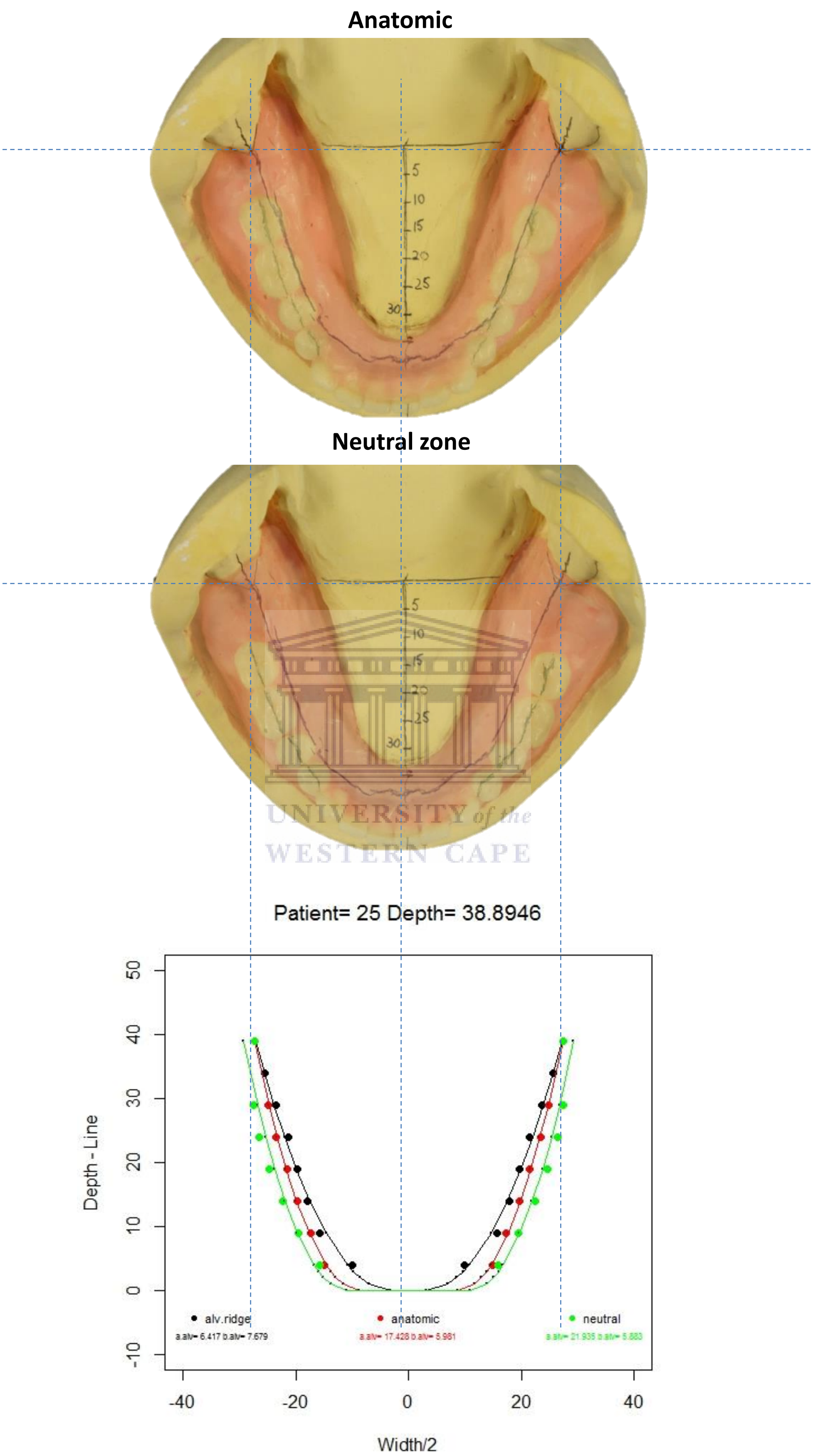
Anatomic



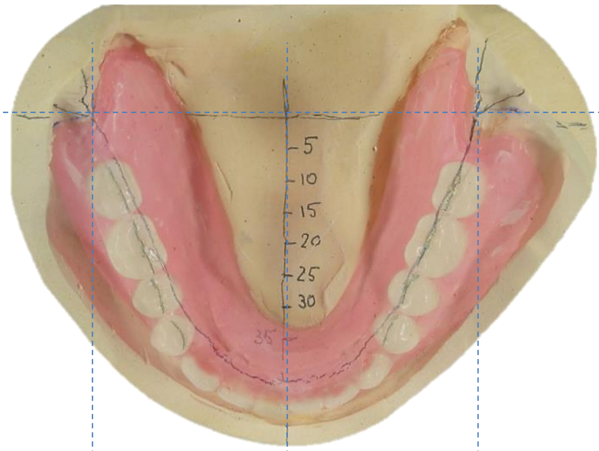
Neutral zone

Patient= 24 Depth= 34.37685

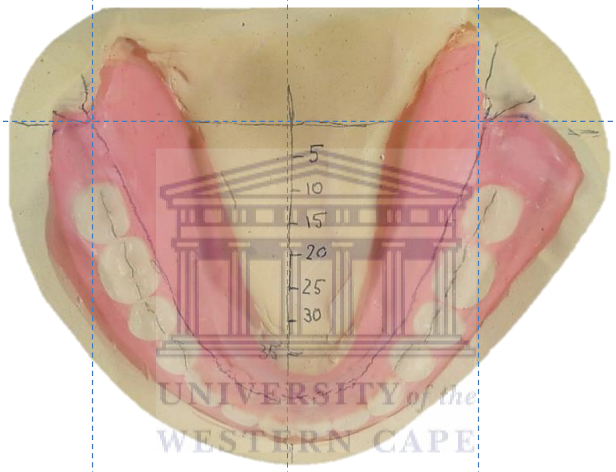


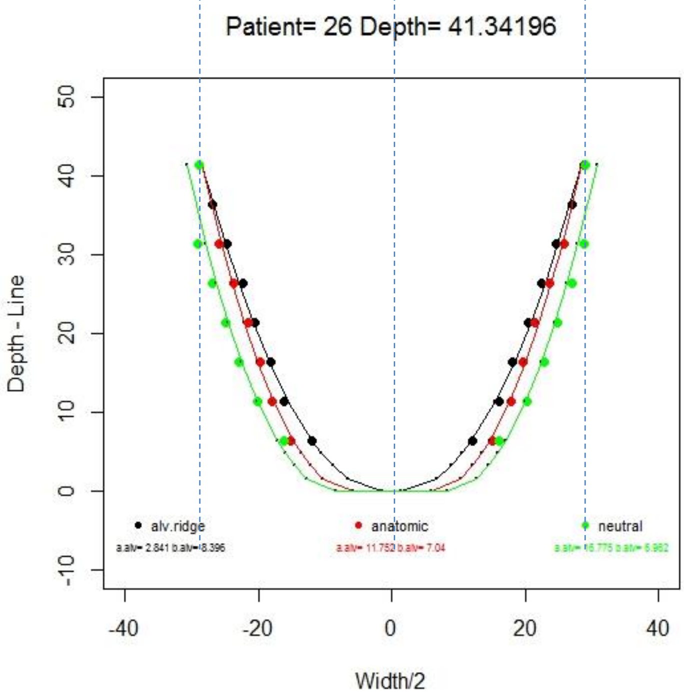

Anatomic
5
10
15
20
25
30
Neutral zone
5
10
15
20
25
30
Patient= 25 Depth= 38.8946
Depth - Line
Width/2
-40
-20
0
20
40
-10
0
10
20
30
40
50
alv.ridge
a.alv= 6.417 b.alv= 7.679
anatomic
a.alv= 17.428 b.alv= 5.981
neutral
a.alv= 21.935 b.alv= 5.883

Anatomic

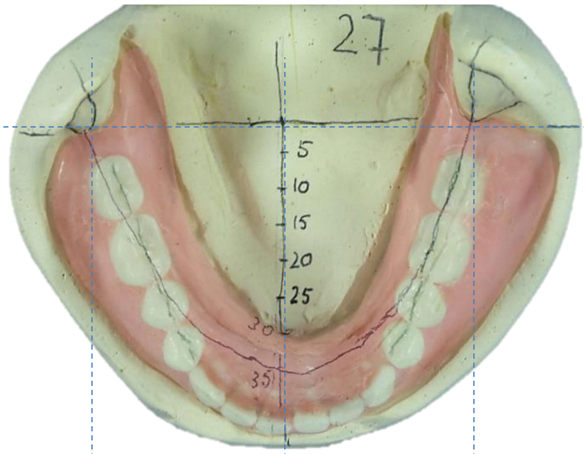


Neutral zone

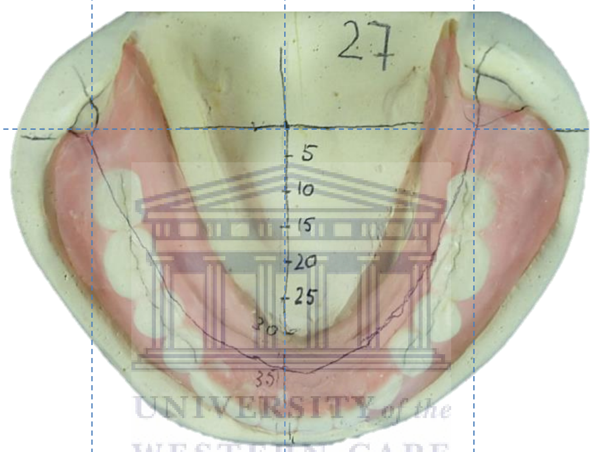




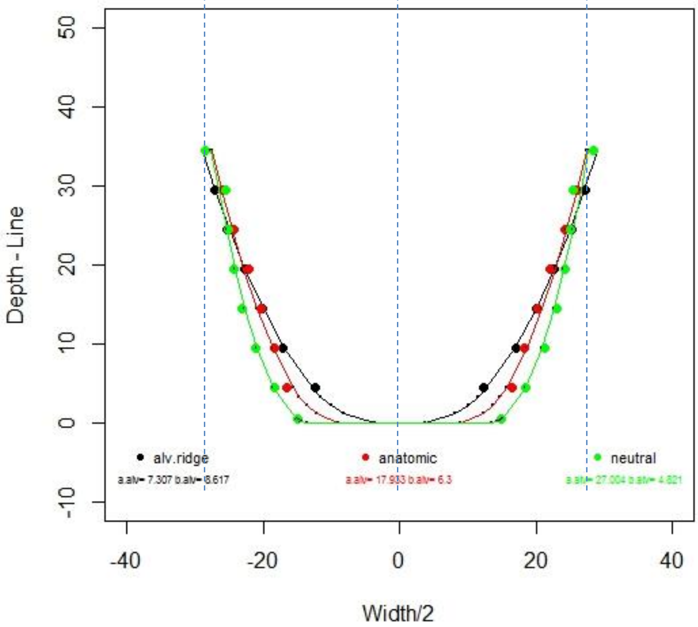
Anatomic

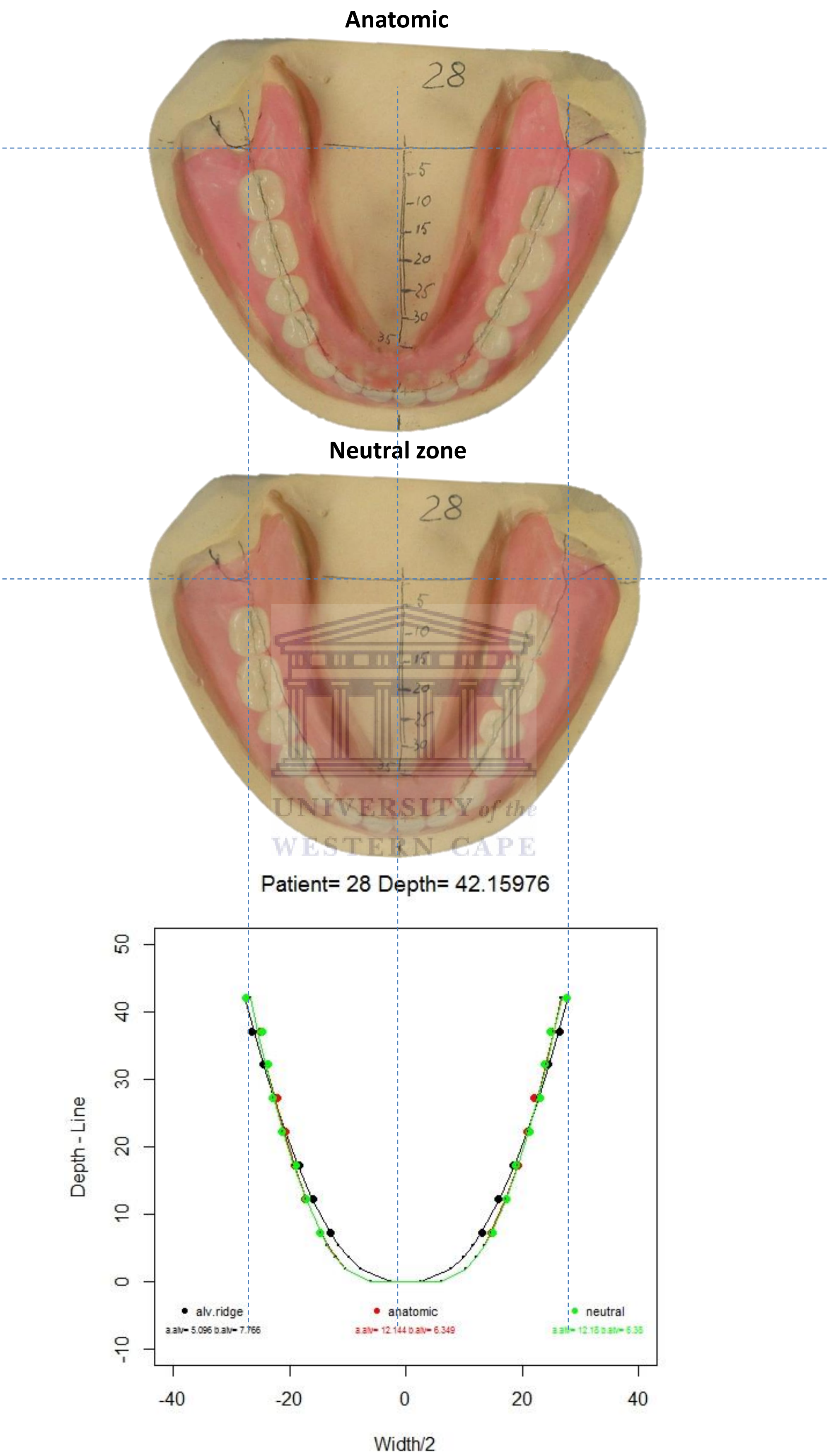


Neutral zone



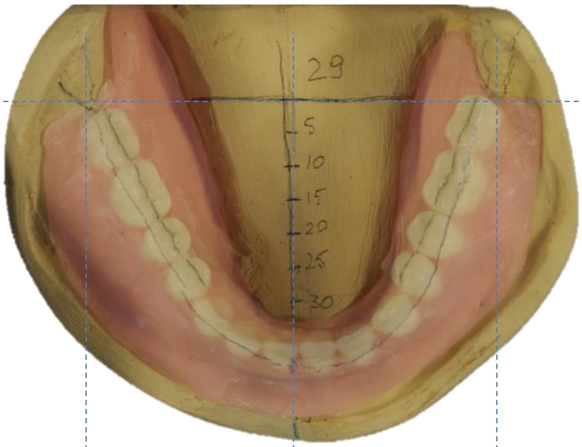
Patient= 27 Depth= 34.42623



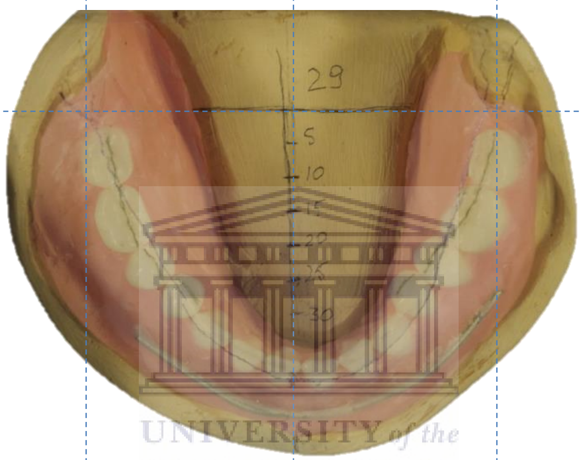


Anatomic
28
5
10
15
20
25
30
35
Neutral zone
28
Patient= 28 Depth= 42.15976
Depth - Line
Width/2
-10
0
10
20
30
40
50
-40
-20
0
20
40
alv.ridge
a.alv= 5.096 b.alv= 7.766
anatomic
a.alv= 12.144 b.alv= 6.349
neutral
a.alv= 12.18 b.alv= 6.38

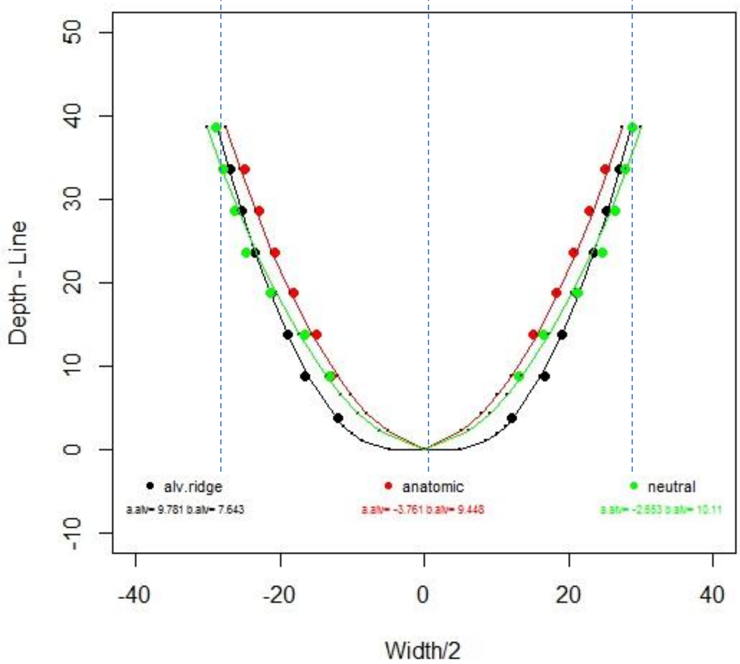
Anatomic

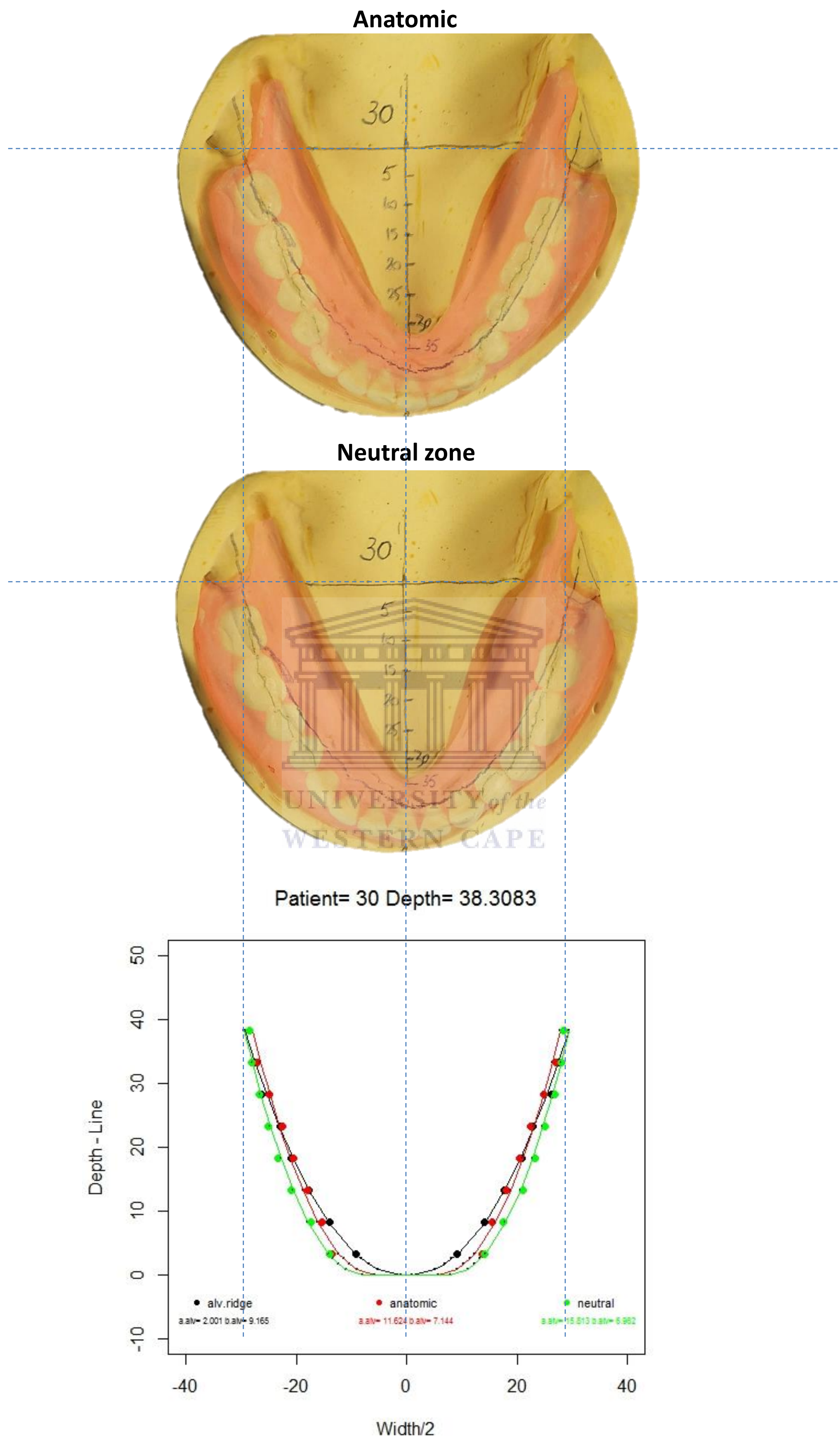


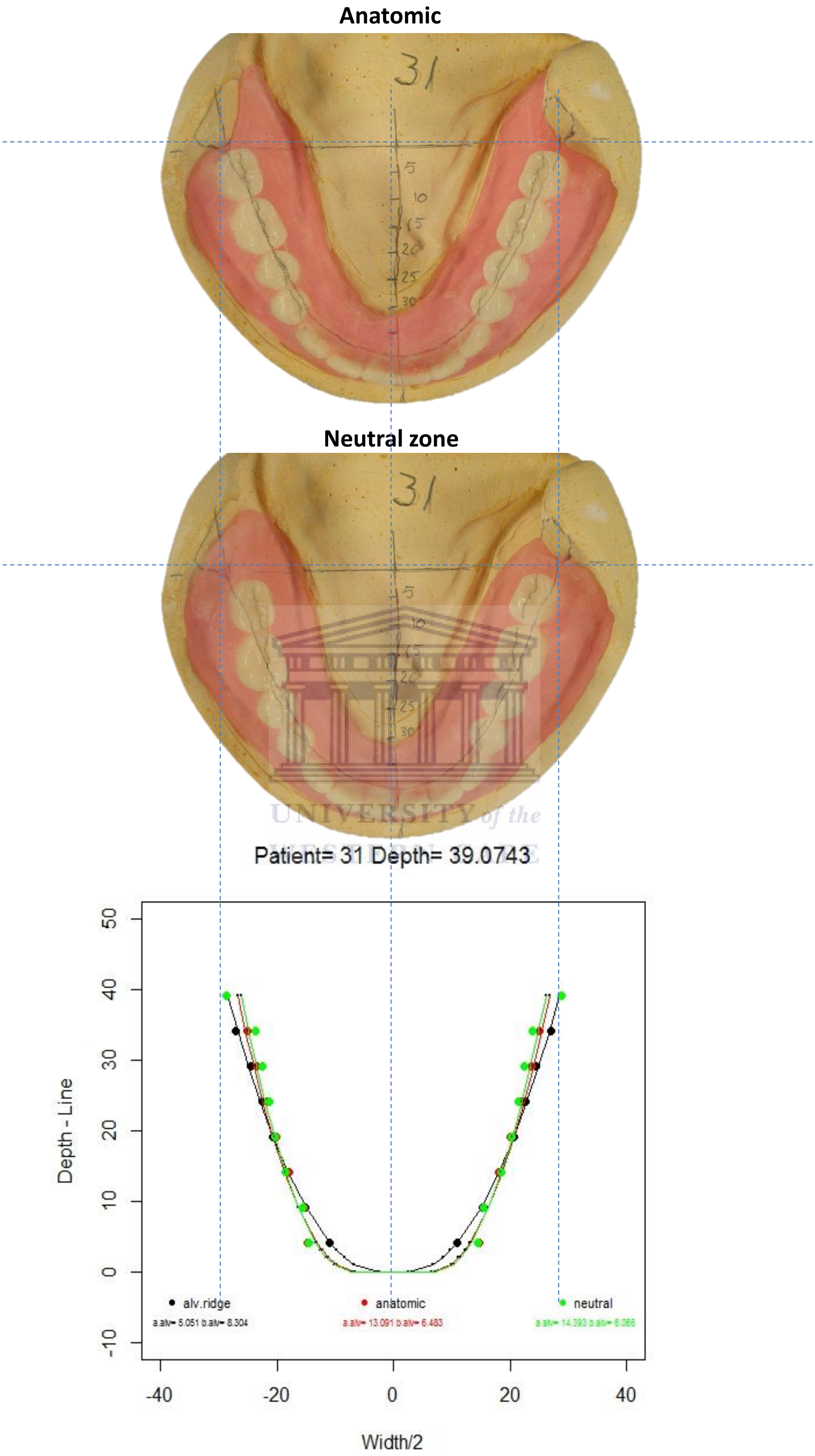
Neutral zone



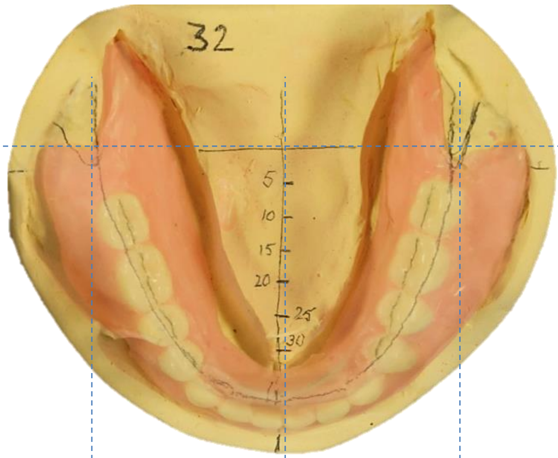
Patient= 29 Depth= 38.69379



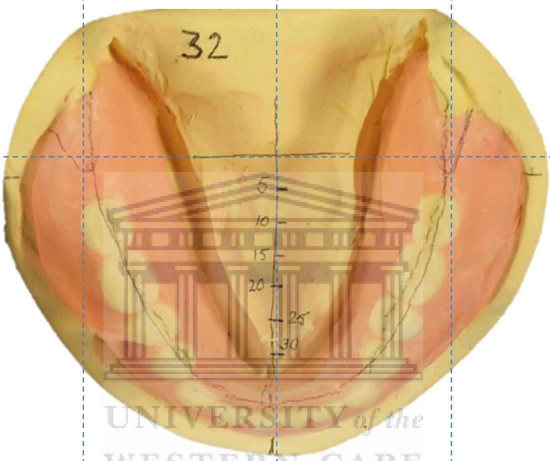

Anatomic
30
5
10
15
20
25
30
35
Neutral zone
30
Patient= 30 Depth= 38.3083
Depth - Line
Width/2
alv.ridge
a.alv= 2.001 b.alv= 9.165
anatomic
a.alv= 11.624 b.alv= 7.144
neutral
-40
-20
0
20
40
-10
0
10
20
30
40
50

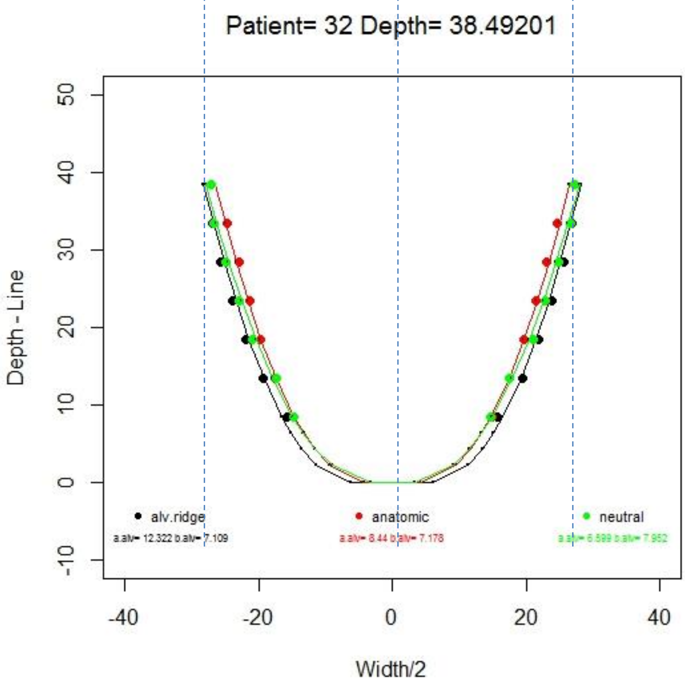

Anatomic
31
5
10
15
20
25
30
Neutral zone
31
Patient= 31 Depth= 39.0743
Depth - Line
Width/2
alv.ridge
a.alv= 5.051 b.alv= 8.304
anatomic
a.alv= 13.091 b.alv= 6.483
neutral
a.alv= 14.393 b.alv= 6.066
-40
-20
0
20
40
-10
0
10
20
30
40
50

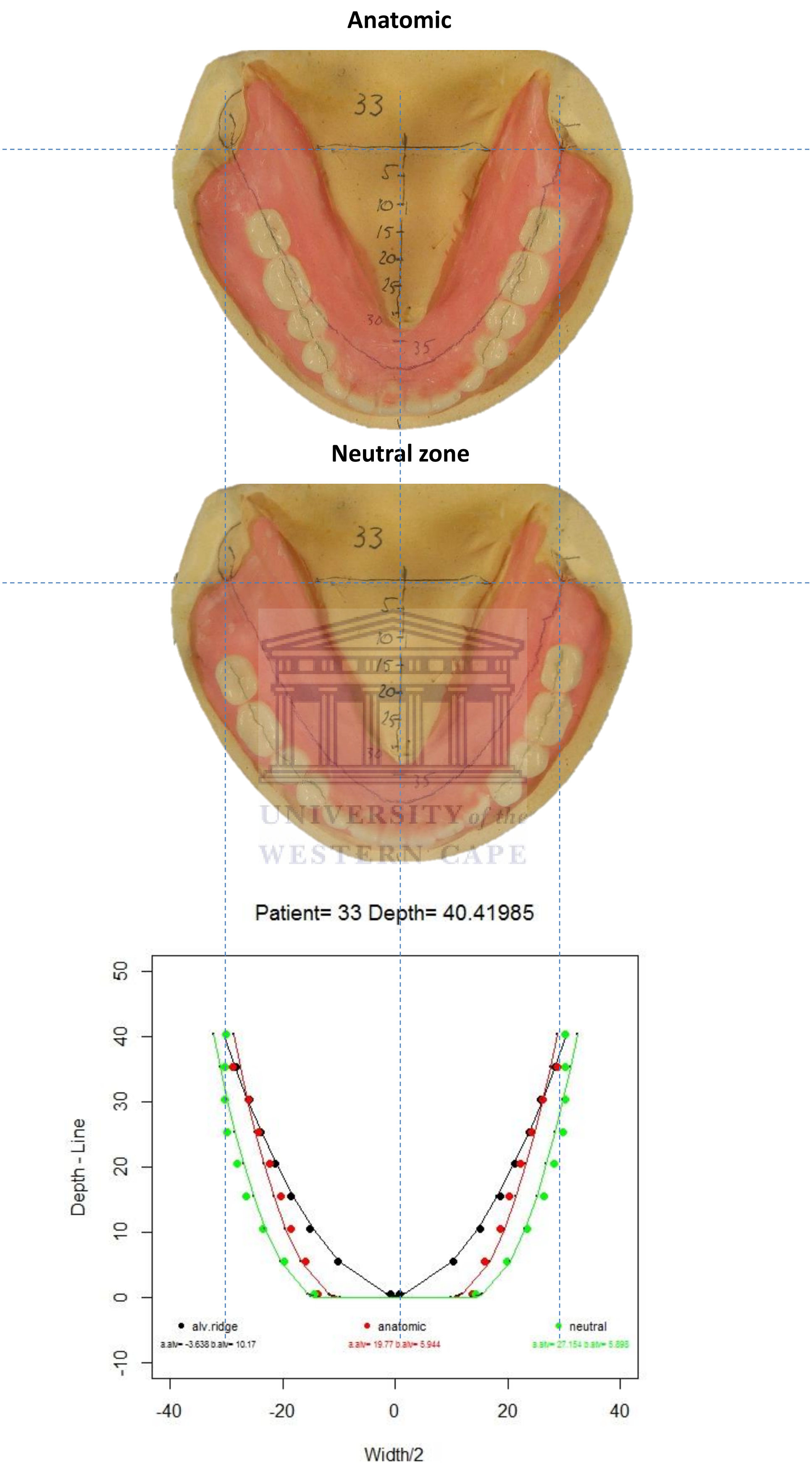
Anatomic



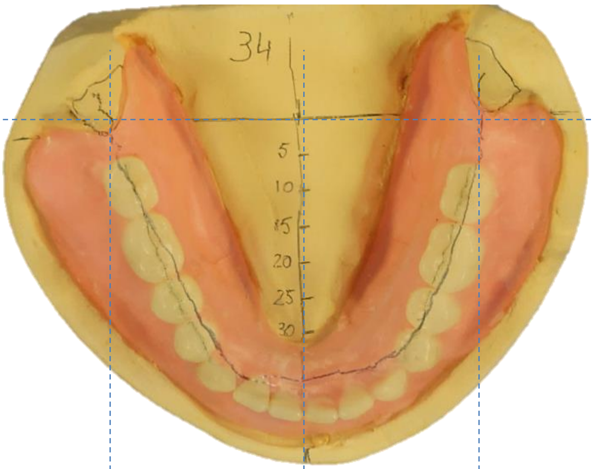
Neutral zone



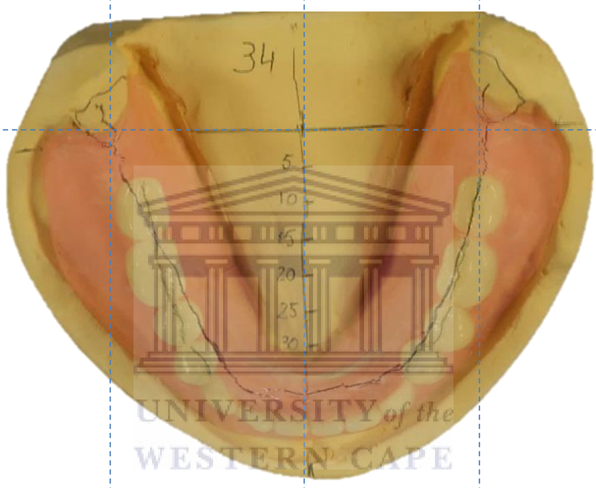


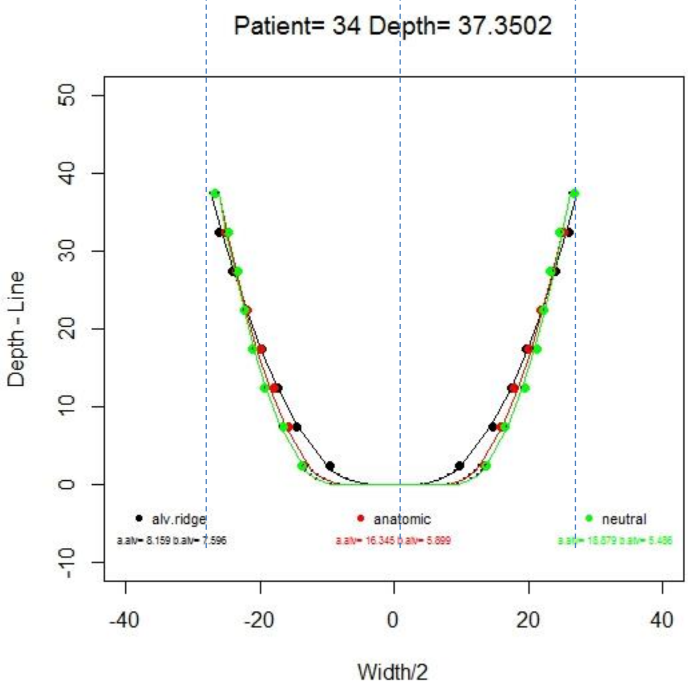

Anatomic
33
5
10
15
20
25
30
35
Neutral zone
33
Patient= 33 Depth= 40.41985
Depth - Line
50
40
30
20
10
0
-10
alv.ridge
a.alv= -3.638 b.alv= 10.17
anatomic
a.alv= 19.77 b.alv= 5.944
neutral
-40
-20
0
20
40
Width/2

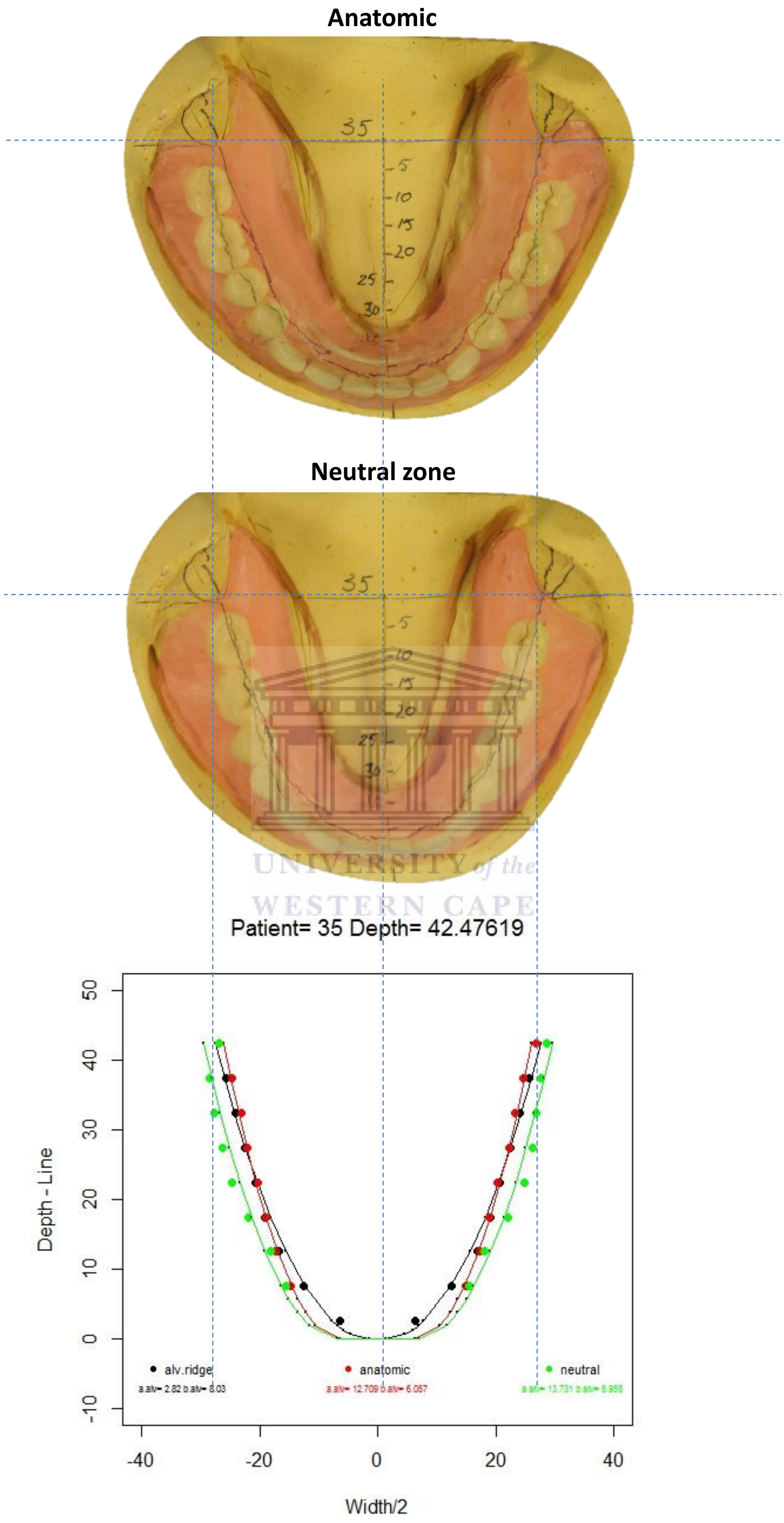
Anatomic



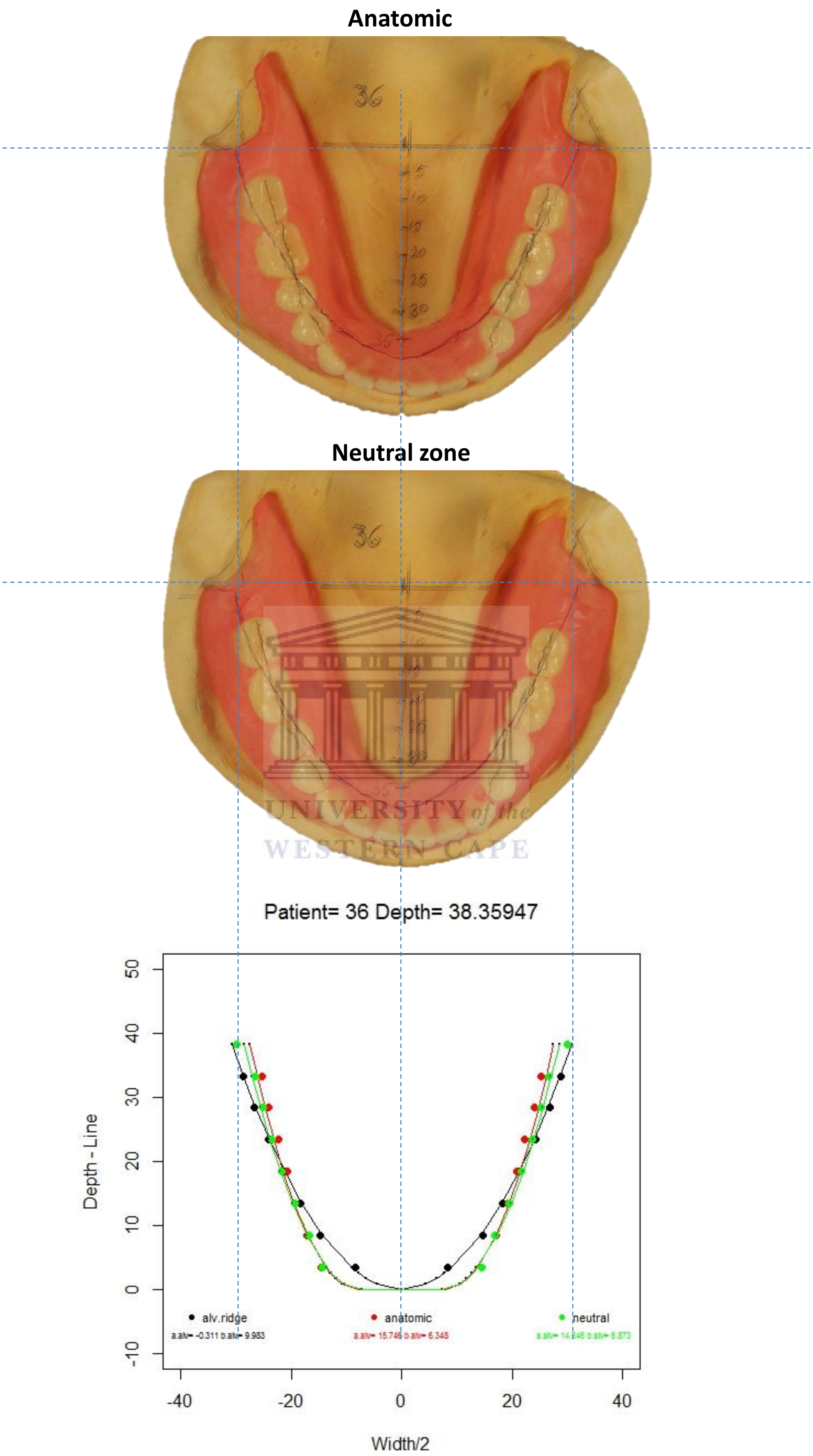
Neutral zone

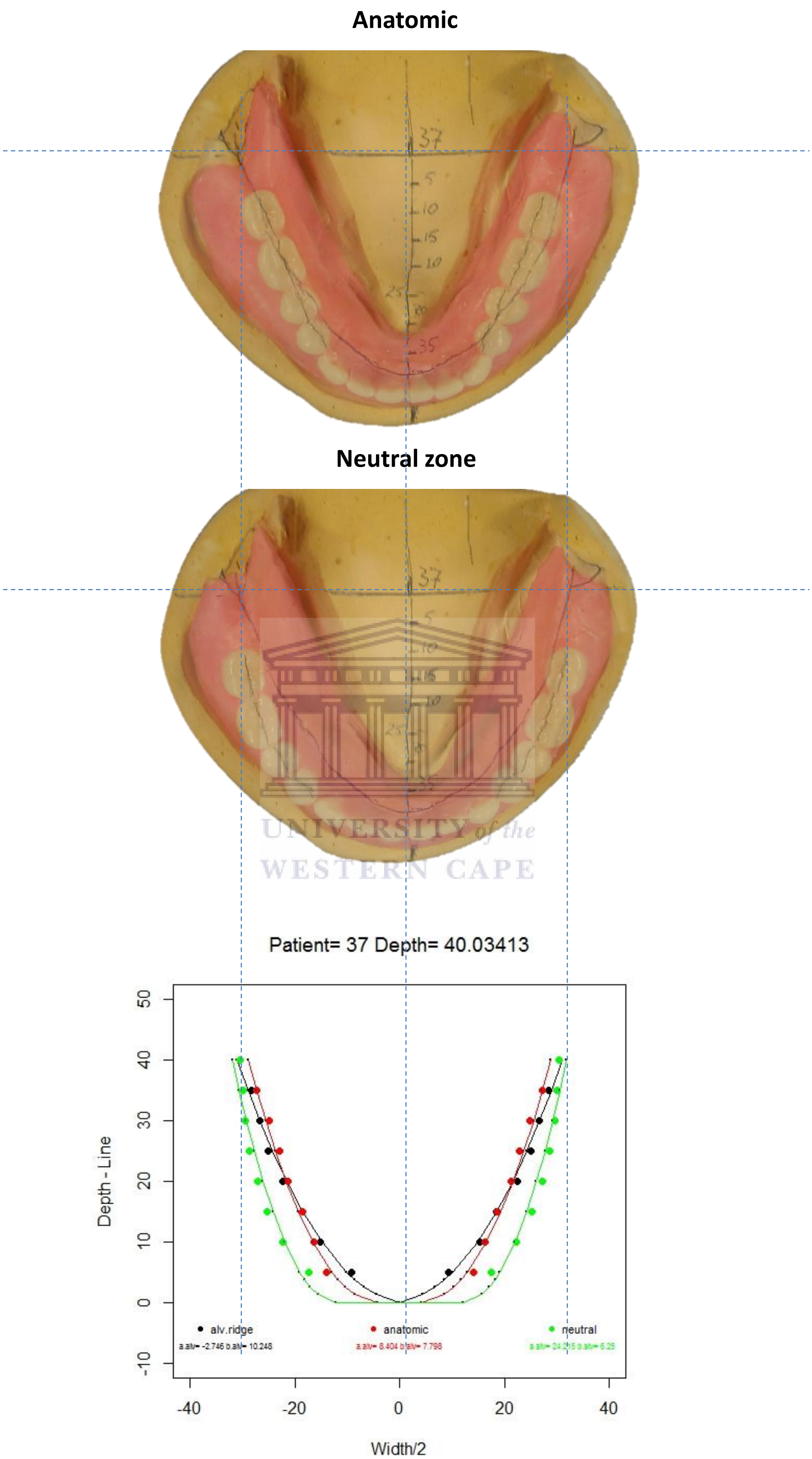




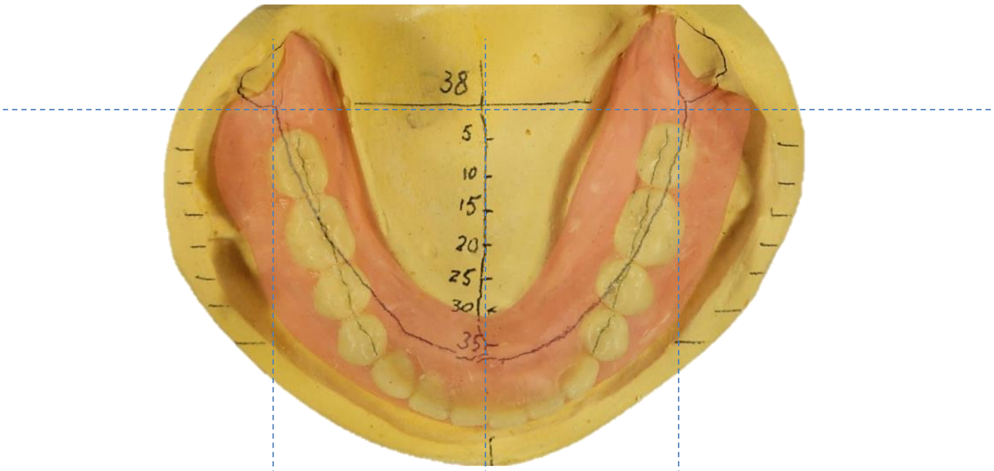


Anatomic
35
5
10
15
20
25
30
Neutral zone
35
5
10
15
20
25
30
Patient= 35 Depth= 42.47619
Depth - Line
Width/2
alv.ridge
a.alv= 2.82 b.alv= 8.03
anatomic
a.alv= 12.709 b.alv= 6.057
neutral
a.alv= 13.731 b.alv= 6.958

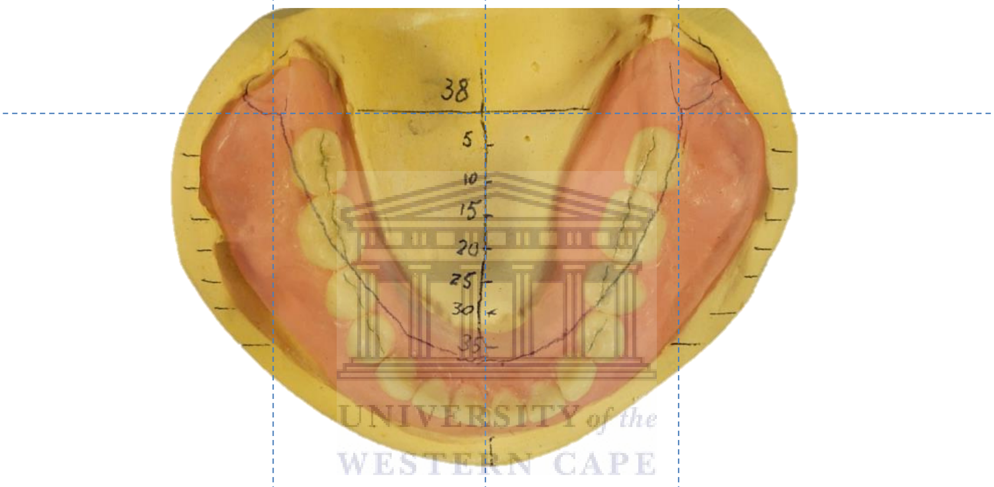

Anatomic
36
Neutral zone
36
Patient= 36 Depth= 38.35947
Depth - Line
Width/2
alv.ridge
a.alv= -0.311 b.alv= 9.983
anatomic
a.alv= 15.746 b.alv= 6.348
neutral
-40
-20
0
20
40
-10
0
10
20
30
40
50

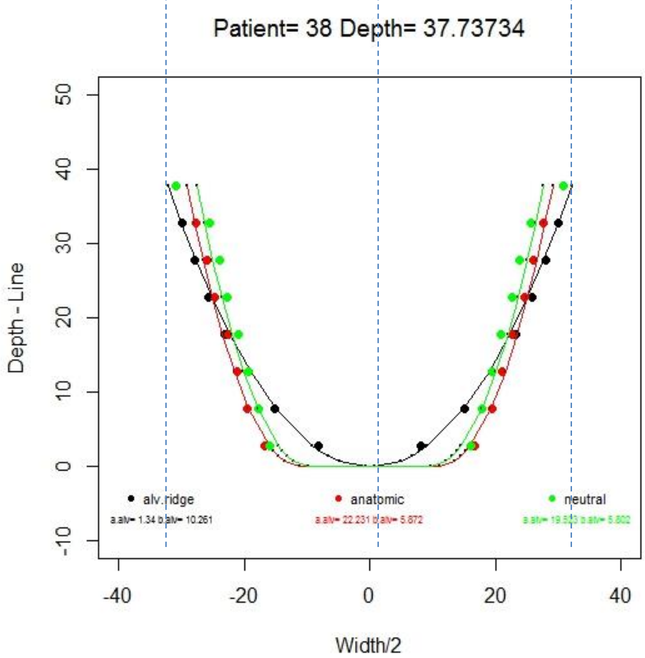

Anatomic
Neutral zone
Patient= 37 Depth= 40.03413
Depth - Line
Width/2
alv.ridge
a.alv= -2.746 b.alv= 10.248
anatomic
a.alv= 8.404 b.alv= 7.798
neutral
a.alv= 24.215 b.alv= 6.25

Anatomic

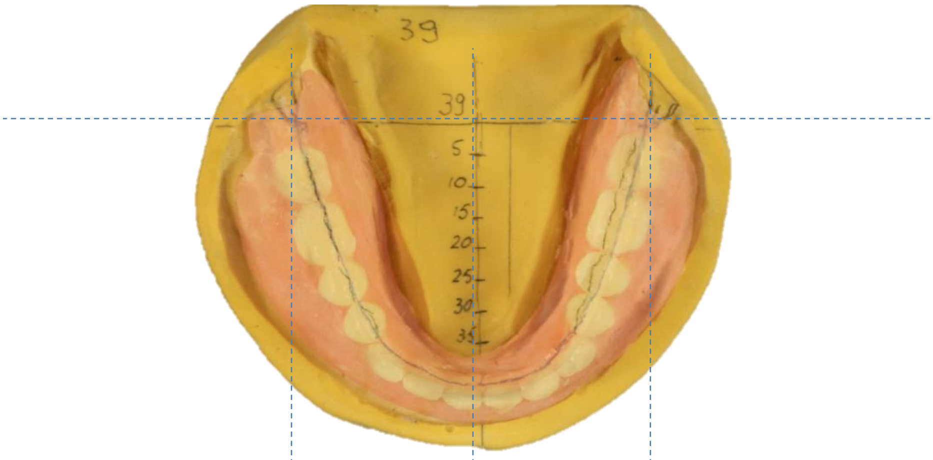


Neutral zone

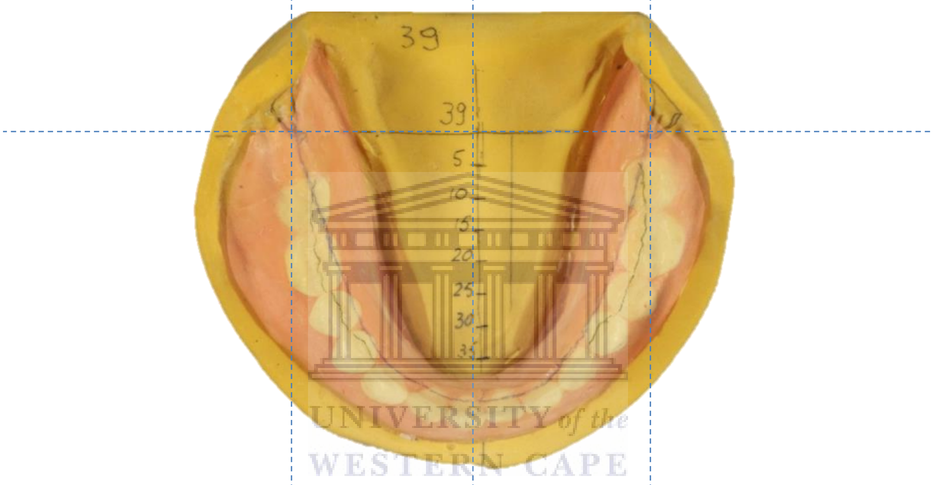


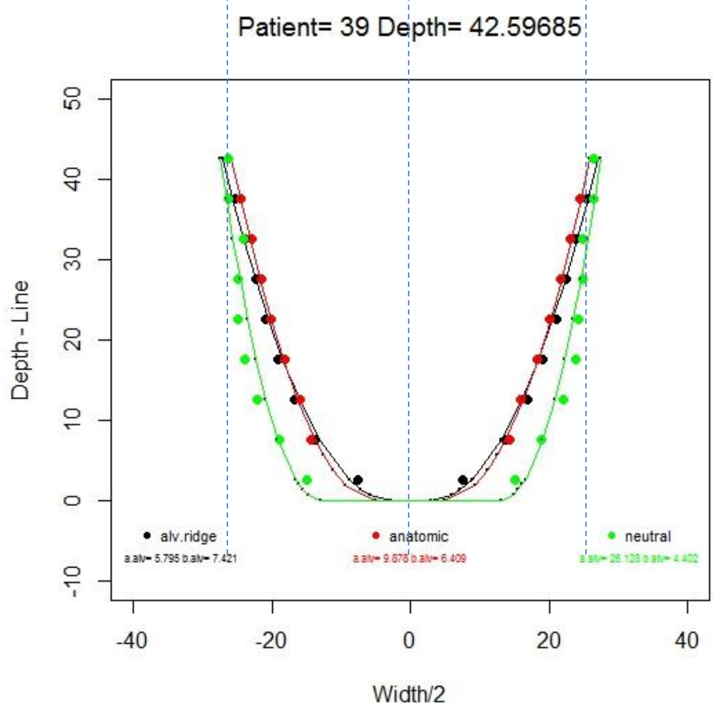


Anatomic



Neutral zone





Addendum 13: Pre-treatment OHIP-20 scores for each patient

Item	PATIENT																																					
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
1	3	3	3	4	3	2	3	1	2	0	0	4	2	4	4	4	2	4	4	3	2	3	0	3	4	4	3	1	2	4	4	4	4	3	n/a	4	4	1	n/a
2	1	4	4	4	3	3	4	0	3	4	3	3	3	4	4	4	3	2	2	3	2	4	0	3	4	4	4	3	4	4	3	1	4	4		3	4	0	
3	3	4	3	3	4	0	4	3	0	0	0	3	3	4	4	4	0	0	3	3	0	4	0	2	4	4	0	2	3	4	4	3	4	4		3	3	0	
4	0	4	3	3	2	3	1	0	2	0	0	1	1	3	4	2	4	0	0	2	0	2	0	0	2	4	0	1	0	3	4	3	0	2		4	3	0	
5	3	4	4	3	4	2	3	3	3	0	0	4	2	2	4	4	3	1	4	3	4	4	4	3	4	4	0	2	3	4	4	4	2	3		4	3	0	
6	0	3	3	3	3	3	1	0	2	0	0	2	1	3	4	3	2	0	4	3	1	2	0	0	0	4	0	2	0	2	2	3	2	2		0	0	0	
7	2	4	4	3	3	0	4	2	0	0	0	3	3	4	4	4	0	0	4	3	0	4	0	0	4	4	0	1	3	3	1	1	4	4		4	3	0	
8	0	0	4	4	3	0	4	3	0	0	0	4	3	4	4	4	1	0	4	3	3	3	0	0	4	4	0	0	3	2	2	4	4	3		4	3	0	
9	0	3	4	4	4	0	4	2	0	0	0	3	3	3	4	4	2	0	4	3	4	3	0	0	4	4	0	1	3	3	2	4	4	4		4	4	3	
10	0	4	3	4	4	2	4	3	2	0	0	4	2	4	4	4	2	1	3	3	3	3	0	3	4	4	0	2	4	3	4	3	3	4		4	4	0	
11	0	3	3	4	3	0	3	1	3	0	0	1	1	3	3	4	2	0	1	3	1	2	0	3	3	4	0	0	3	2	2	3	1	4		2	3	3	
12	0	3	4	4	2	0	3	2	0	0	3	1	0	0	3	2	0	0	0	0	1	1	0	0	2	2	0	0	3	0	2	2	2	3		2	4	0	
13	3	4	3	4	3	0	3	0	0	1	0	3	1	3	3	4	1	0	3	3	2	2	0	2	4	2	0	0	2	3	2	3	3	2		4	4	0	
14	0	3	4	4	4	3	4	2	2	0	0	3	3	4	3	4	2	0	4	2	0	4	0	0	4	2	0	0	4	3	2	3	3	2		2	4	0	
15	0	3	4	4	4	0	3	2	0	2	0	3	3	3	4	4	2	0	4	3	2	3	0	0	4	4	0	0	4	4	3	4	4	2		2	3	0	
16	0	3	3	4	4	0	3	2	0	0	0	0	1	2	4	4	1	0	4	0	1	0	0	0	2	4	0	0	2	3	2	2	1	3		0	3	0	
17	0	3	3	3	3	0	0	1	0	0	0	1	0	2	3	4	0	0	4	0	0	0	0	0	4	2	0	0	2	1	2	0	0	0		0	2	0	
18	0	0	4	4	2	0	0	1	0	0	0	1	0	2	4	4	2	0	4	2	2	2	0	0	4	2	0	0	2	3	3	2	0	1		2	3	0	
19	0	3	4	4	3	0	3	2	0	0	0	2	1	2	4	4	2	0	4	3	1	2	0	0	3	4	0	0	2	3	2	3	0	2		0	3	0	
20	0	3	4	4	3	0	3	3	0	0	0	1	0	2	3	4	2	0	4	3	0	0	0	0	3	4	0	0	2	3	3	3	1	2		0	3	0	
TOTAL	15	61	71	74	64	18	57	33	19	7	6	47	33	58	74	75	33	8	64	48	29	48	4	19	67	70	7	15	51	57	53	55	46	54	n/a	48	63	7	n/a

Addendum 14: OHIP-20 scores for the anatomic dentures for each patient

Item	PATIENT																																						
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
1	3	3	0	0	1	2	1	3	0	0	0	1	2	1	0		2		4	0	0	4	0	0	3	2	4	0	0	0	0	0	0	1	0	1	4	4	4
2	3	0	0	0	1	0	2	0	1	3	0	2	1	2	4		2		3	2	1	4	0	3	4	1	0	0	2	1	0	0	1	1	0	3	4	4	4
3	0	3	0	0	0	0	2	3	0	0	0	1	2	0	0		0		0	3	0	2	0	1	4	1.5*	3	0	0	0	0	1	2	1	0	0	4	3	3
4	0	3	0	0	1	2	0	3	0	0	0	1	2	0	4		3		3	4	1	0	0	0	2	4	2	0	0	2	0	0	0	2	0	1	4	1	2
5	3	0	0	0	0	0	1	3	1	0	0	1	2	1	0		3		0	2	1	4	0	0	2	4	2	0	0	0	0	0	0	2	0	0	4	3	2
6	0	3	0	0	0	3	0	3	2	0	0	2	1	1	0		2		2	2	0	4	0	1	2	3	3	0	0	2	0	0	2	2	0	0	4	0	4
7	0	0	0	0	1	0	2	2	0	0	0	0	2	0	0		0		0	2	0	0	0	0	2	2	0	0	0	0	0	1	0	2	0	1	4	0	2
8	0	0	0	0	0	0	3	2	0	0	0	0	2	0	0		0		0	0	0	2	0	0	3	4	0	0	0	0	0	0	0	4	0	0	4	2	0
9	0	0	0	0	0	0	2	2	0	0	0	0	2	0	0		0		3	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	0	1	4	2	0
10	0	3	0	0	0	0	1	3	0	0	0	1	1	0	0		2		0	2	1	0.5*	0	0	3	3	0	0	2	0	1	0	0	2	0	0	4	3	2
11	0	0	0	0	0	0	2	3	0	0	0	0	0	0	0		2		0	0	0	0.5*	0	0	1	2	0	0	0	0	0	0	0	1	0	0	4	0	1
12	3	3	0	0	0	0	2	3	0	0	0	0	0	0	0		0		0	0	1	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	4	4	4
13	0	3	0	0	0	0	2	3	0	1	0	1	0	0	0		3		3	0	0	0	0	0	1	2	0	0	0	0	1	0	0	0	0	1	4	4	1
14	0	0	0	0	0	0	2	3	0	0	0	0	1	0	0		0		0	0	0	1	0	0	3	2	0	0	0	0	0	0	0	1	0	0	4	3	0
15	0	3	0	0	0	0	2	2	0	0	0	0	0	0	0		0		0	2	0	0	0	0	0	1	0	0	0	0	0	0	0	2	0	0	4	2	0
16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0		0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	4	1	0
17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	1	0
18	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0		0		0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	4	1	2
19	0	0	0	0	0	0	2	0	0	0	0	1	0	0	0		0		0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	4	0	0
20	0	0	0	0	0	0	2	2	0	0	0	0	0	0	0		0		0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	1	0	0	4	1	3
TOTAL	12	24	0	0	4	7	28	41	4	4	0	11	18	5	8		19		18	20	5	23	0	5	30	38	14	0	4	5	2	2	5	25	0	9	80	39	34

*The score for this item was missing. The average value of the other scores within the same domain was used to complete the data set

Addendum 15: OHIP-20 scores for the neutral zone dentures

Item	PATIENT																																						
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
1	0	3	3	0	3	0	4	1	1	0	0	2	1	2	0		2		0	1	1	0	0	0	4	4	1	1	2	1	0	0	0	1	0	4	4	4	0
2	3	0	0	0	2	1	4	1	1	1	2	3	2	3	1		1		3	3	1	0	0	1	2	4	0	2	4	2	0	0	0	1	0	3	4	3	2
3	0	3	0	0	0	0	4	0	0	0	0	1	1	1	0		0		3	0	0	0	0	0	4	2	0	0	0	0	0	0	0	1	0	0	4	3	0
4	0	3	3	0	0	0	0	0	0	0	0	2	0	0	0		1		0	3	0	0	0	0	4	4	0	1	0	0	0	0	0	0	0	3	3	0	0
5	0	0	0	0	1	0	4	1	1	0	2	2	0	2	0		1		0	2	2	0	0	0	4	4	0	0	3	2	0	0	0	1	0	0	4	3	0
6	0	2	3	0	1	0	1	0	1	0	0	3	2	1	1		0		0	1	0	0	0	0	.33	4	2	2	0	3	0	0	0	0	0	0	3	1	0
7	0	3	3	0	0	0	4	0	0	0	0	0	0	0	0		0		0	0	0	0	0	0	2	4	0	1	0	0	0	0	0	0	0	0	3	2	0
8	0	0	0	0	0	0	3	0	0	0	0	1	0	0	0		0		0	0	0	0	0	0	3	4	0	0	0	0	0	0	0	1	0	0	4	1	0
9	0	0	0	0	0	0	4	0	1	0	0	2	0	0	0		0		0	0	0	0	0	0	0	3	1	0	2	0	0	0	0	2	0	1	4	3	0
10	0	0	0	0	0	0	3	1	0	0	0	2	1	2	0		1		0	1	2	1	0	0	4	4	1	0	4	1	0	0	0	2	0	0	4	1	0
11	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0		0		0	0	0	0	0	0	3	4	0	0	4	0	0	0	0	1	0	1	4	1	0
12	0	0	0	0	0	0	3	0	0	0	0	1	0	0	0		0		0	1	1	0	0	0	3	3	0	0	0	0	0	0	0	0	0	0	4	4	0
13	0	0	0	0	0	0	4	0	0	0	0	2	1	2	0		0		3	0	0	0	0	0	2	2	0	0	0	0	0	0	0	0	0	0	4	3	0
14	0	0	0	0	0	0	4	0	0	0	0	2	0	1	0		0		0	0	0	0	0	0	4	3	0	0	0	0	0	0	0	1	0	1	4	2	0
15	0	0	0	0	0	0	2	0	0	0	0	2	0	0	0		0		0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	4	2	0
16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0		0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	4	3	0
17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		0		0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	1	4	1	0
18	0	0	0	0	0	0	2	0	0	0	0	1	1	0	0		0		0	1	0	0	0	0	1	2	0	0	4	0	0	0	0	0	0	3	4	3	0
19	0	0	0	0	0	0	2	0	0	0	0	1	0	0	0		0		0	0	0	0	0	0	2	2	0	0	0	0	0	0	0	0	0	0	4	3	0
20	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0		0		0	0	0	1	0	0	1	4	0	0	0	0	0	0	0	1	0	0	4	2	0
TOTAL	3	14	12	0	7	1	52	4	5	1	4	27	9	14	2		6		9	13	7	2	0	1	46	63	5	7	23	9	0	0	0	12	0	17	77	45	2

*The score for this item was missing. The average value of the other scores within the same domain was used to complete the data set

Addendum 16: difference in OHIP-20 scores for each patient

Patient	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	17	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	36	37	38
Pre-treatment	15	61	71	74	64	18	57	33	19	7	6	47	33	58	74	33	64	48	29	48	4	19	67	70	7	15	51	57	53	55	46	54	48	63	7
ANA	12	24	0	0	4	7	28	41	4	4	0	11	18	5	8	19	18	20	5	23	0	5	30	37.5	14	0	4	5	2	2	5	25	9	80	39
NZ	3	14	12	0	7	1	52	4	5	1	4	27	9	14	2	6	9	13	7	2	0	1	46.3	63	5	7	23	9	0	0	0	12	17	77	45
Pre- minus ANA	3	37	71	74	60	11	29	-8	15	3	6	36	15	53	66	14	46	28	24	25	4	14	37	32.5	-7	15	47	52	51	53	41	29	39	-17	-32
Pre- minus NZ	12	47	59	74	57	17	5	29	14	6	2	20	24	44	72	27	55	35	22	46	4	18	20.7	7	2	8	28	48	53	55	46	42	31	-14	-38
ANA minus NZ	9	10	-12	0	-3	6	-24	37	-1	3	-4	-16	9	-9	6	13	9	7	-2	21	0	4	-16.3	-25.5	9	-7	-19	-4	2	2	5	13	-8	3	-6

Addendum 17: Relationship of denture preference and post-treatment OHIP-20 scores

Patient	OHIP-20 NZ minus ANA*	Favourable impact	Preference	"Match" **
1	-9	NZ	NZ	Y
2	-10	NZ	NZ	Y
3	12	ANA	ANA	Y
4	0	none	none	Y
5	3	none	none	Y
6	-6	none	NZ	N
7	24	ANA	none	N
8	-37	NZ	NZ	Y
9	1	none	NZ	N
10	-3	none	none	Y
11	4	none	none	Y
12	16	ANA	none	N
13	-9	NZ	NZ	Y
14	9	ANA	ANA	Y
15	-6	none	none	Y
16	-13	NZ	ANA	N
17	-9	NZ	NZ	Y
18	-7	none	NZ	N
19	2	none	none	Y
20	-21	NZ	NZ	Y
21	0	none	none	Y
22	-4	none	NZ	N
23	16.33	ANA	none	N
24	25.5	ANA	ANA	Y
25	-9	NZ	none	N
26	7	none	ANA	N
27	19	ANA	ANA	Y
28	4	none	ANA	N
29	-2	none	none	Y
30	-2	none	NZ	N
31	-5	none	NZ	N
32	-13	NZ	NZ	Y
33	0	none	NZ	N
34	8	ANA	ANA	Y
35	-3	none	none	Y
36	6	none	none	Y
37	-32	NZ	NZ	Y

* A difference in OHIP-20 scores of <7.5 was considered not clinically relevant.
**N = no; Y = yes.

Addendum 18: Intercept (a) and slope (b) values for the 3 series of “parabola”

Patient	Alveolar ridge		ANA denture		NZ denture	
	a	b	a	b	a	b
1	4.546	8.679	6.347	8.287	11.275	7.775
2	3.093	9.089	2.558	8.442	5.903	8.470
3	12.886	6.892	9.826	6.874	18.780	6.143
4	7.343	8.024	11.698	6.798	17.557	6.376
5	3.924	8.608	1.397	8.820	16.127	6.497
6	1.530	8.455	7.373	7.049	11.364	6.752
7	9.307	7.483	13.058	6.525	21.969	5.057
8	5.674	8.512	16.629	6.295	19.054	6.606
9	4.000	7.679	10.311	6.499	20.023	5.417
10	13.385	6.514	14.786	6.042	22.925	5.320
11	13.692	6.010	15.671	5.706	13.873	6.118
12	16.568	6.302	13.275	6.462	28.830	5.440
13	2.566	9.125	1.211	8.959	1.295	9.555
14	1.542	9.366	14.793	6.574	20.606	6.302
15	4.383	9.228	7.378	9.235	5.553	9.370
16	9.132	7.910	5.250	8.294	10.000	7.930
17	1.981	9.169	10.890	7.470	27.732	5.050
18	4.591	8.132	6.051	7.457	19.599	5.497
19	6.204	8.416	4.401	7.851	4.612	8.472
20	4.419	9.086	13.751	6.677	20.798	6.189
21	1.114	9.831	17.823	6.688	15.571	7.297
22	6.454	7.770	17.487	5.804	14.847	6.830
23	6.710	7.111	10.891	5.971	18.429	5.177
24	6.054	8.847	11.871	7.254	13.923	17.168
25	6.417	7.679	17.428	5.981	21.935	5.883
26	2.841	8.396	11.752	7.040	16.775	6.952
27	7.307	8.617	17.933	6.300	27.004	4.821
28	5.096	7.766	12.144	6.349	12.180	6.330
29	9.781	7.643	3.761	9.448	2.653	10.110
30	2.001	9.165	11.624	7.144	15.813	6.952
31	5.051	8.304	13.091	6.483	14.393	6.066
32	12.322	7.109	8.440	7.178	6.599	7.952
33	3.638	10.170	19.770	5.944	27.154	5.893
34	8.159	7.596	16.345	5.899	18.879	5.435
35	2.620	8.030	12.709	6.057	13.731	6.953
36	0.311	9.983	15.746	6.348	14.545	6.873
37	2.746	10.248	8.404	7.798	24.215	6.250
38	1.340	10.261	22.231	5.872	19.523	5.302
39	5.795	7.421	9.878	6.409	25.123	4.402

Addendum 19: Relationships of difference in dimensions and mandibular tissue scores, without and with adjusting for age

```
. glm dimension tissue_score_mandible , family(gaussian) link(identity)

Iteration 0:   log likelihood = -98.374526

Generalized linear models                          No. of obs      =        39
Optimization     : ML                              Residual df     =        37
                                                   Scale parameter =  9.579392
Deviance         =   354.437519                    (1/df) Deviance =  9.579392
Pearson          =   354.437519                    (1/df) Pearson  =  9.579392

Variance function: V(u) = 1                        [Gaussian]
Link function    : g(u) = u                        [Identity]

                                                   AIC             =  5.147412
Log likelihood   = -98.37452624                    BIC             =  218.8857

------------------------------------------------------------------------------
                      |                 OIM
            dimension |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
----------------------+-------------------------------------------------------
tissue_score_mandible |  -.6018038   .3330545    -1.81   0.071    -1.254579    .0509709
                _cons |   6.918391   1.485641     4.66   0.000     4.006589    9.830193
------------------------------------------------------------------------------
```

```
. glm dimension tissue_score_mandible age , family(gaussian) link(identity)

Iteration 0:   log likelihood = -93.969994

Generalized linear models                          No. of obs      =         39
Optimization     : ML                              Residual df     =         36
                                                   Scale parameter =   7.854917
Deviance         =  282.7770129                    (1/df) Deviance =   7.854917
Pearson          =  282.7770129                    (1/df) Pearson  =   7.854917

Variance function: V(u) = 1                        [Gaussian]
Link function    : g(u) = u                        [Identity]

                                                   AIC             =    4.97282
Log likelihood   = -93.96999431                    BIC             =   150.8888

------------------------------------------------------------------------------------
                     |                 OIM
           dimension |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
---------------------+--------------------------------------------------------------
tissue_score_mandible |  -.6842859   .3028239   -2.26   0.024     -1.27781    -.090762
                 age |  -.1507323   .0499042   -3.02   0.003    -.2485428   -.0529219
               _cons |   16.65316    3.49247    4.77   0.000     9.808043    23.49827
------------------------------------------------------------------------------------
```

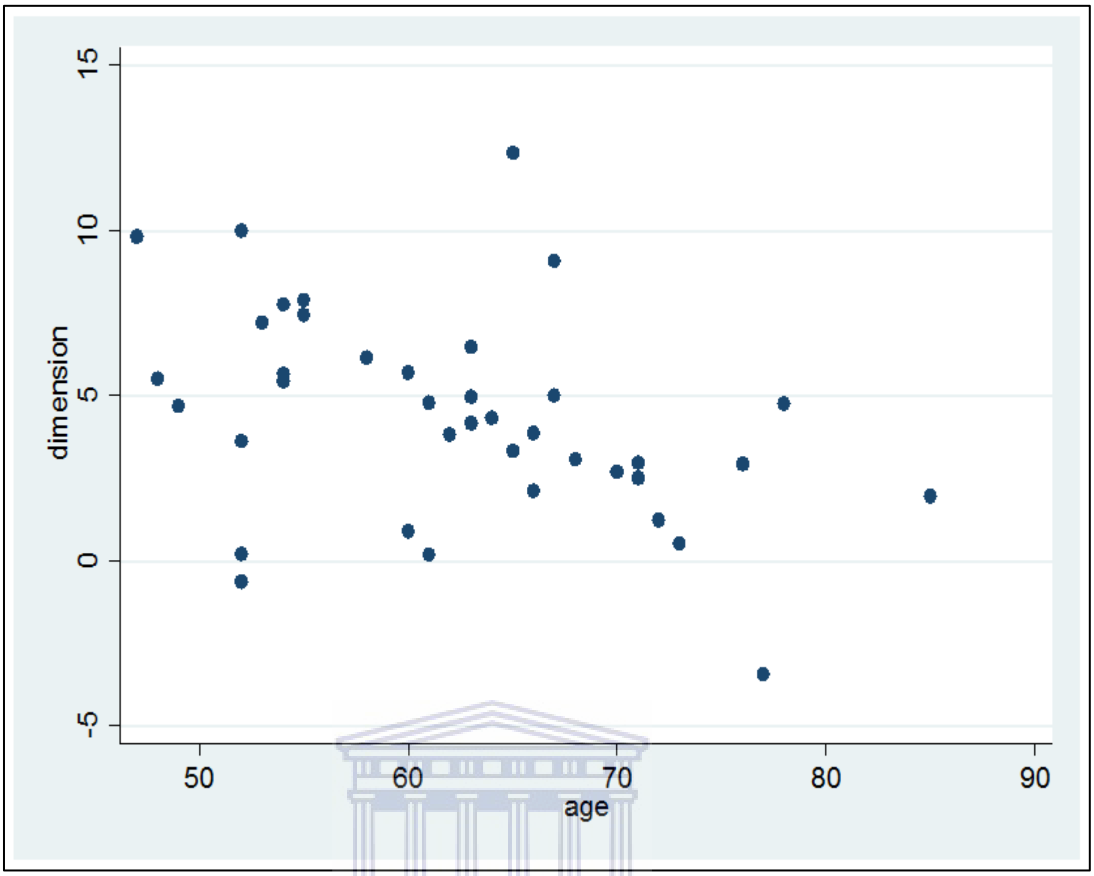
Addendum 20: Relationship between difference in denture dimensions and period of edentulousness

```
. glm dimension per_edent_yrs

Iteration 0:   log likelihood = -100.00943

Generalized linear models                          No. of obs      =         39
Optimization     : ML                              Residual df     =         37
                                                   Scale parameter =  10.41717
Deviance         =  385.4351838                    (1/df) Deviance =  10.41717
Pearson          =  385.4351838                    (1/df) Pearson  =  10.41717

Variance function: V(u) = 1                        [Gaussian]
Link function    : g(u) = u                        [Identity]

                                                   AIC             =  5.231253
Log likelihood   =  -100.009425                    BIC             =  249.8834
```

dimension	Coef.	OIM Std. Err.	z	P>|z|	[95% Conf.	Interval]
per_edent_yrs	.0058328	.0356553	0.16	0.870	-.0640504	.075716
_cons	4.207286	1.218106	3.45	0.001	1.819843	6.594729

Addendum 21: Relationship between difference in dimensions NZ-ANA and age

```
. glm dimension age, family(gaussian) link(identity)

Iteration 0:   log likelihood = -96.556458

Generalized linear models                          No. of obs      =        39
Optimization     : ML                              Residual df     =        37
                                                   Scale parameter =  8.726636
Deviance         =   322.88552                     (1/df) Deviance =  8.726636
Pearson          =   322.88552                     (1/df) Pearson  =  8.726636

Variance function: V(u) = 1                        [Gaussian]
Link function    : g(u) = u                        [Identity]

                                                   AIC             =  5.054177
Log likelihood   = -96.55645844                    BIC             =  187.3337

------------------------------------------------------------------------------
             |                 OIM
   dimension |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
         age |  -.1405632   .0523862    -2.68   0.007    -.2432382   -.0378881
       _cons |   13.14229   3.296832     3.99   0.000     6.680621    19.60396
------------------------------------------------------------------------------
```


dimension
15
10
5
0
-5
50
60
70
80
90
age

Addendum 22: The GLM Procedure with Dependent Variable: outcome OHIP-20 using SAS version 9.4

Class Level Information		
Class	**Levels**	**Values**
group	2	1 2
Patient	37	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 17 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39
period	2	1 2
treat	2	ANA NZ

Number of Observations Read	74
Number of Observations Used	74

Dependent variable: outcome OHIP

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	38	19938.20489	524.68960	6.26	<.0001
Error	35	2934.81470	83.85185		
Corrected Total	73	22873.01959			

R-Square	Coeff Var	Root MSE	Outcome OHIP Mean
0.871691	65.04159	9.157066	14.07878

Source	DF	Type I SS	Mean Square	F Value	Pr > F
group	1	547.91838	547.91838	6.53	0.0151
Patient(group)	35	19168.14176	547.66119	6.53	<.0001
period	1	207.21444	207.21444	2.47	0.1249
treat	1	14.93030	14.93030	0.18	0.6756

Source	DF	Type III SS	Mean Square	F Value	Pr > F
group	1	547.91838	547.91838	6.53	0.0151
Patient(group)	35	19168.14176	547.66119	6.53	<.0001
period	1	196.96030	196.96030	2.35	0.1344

Source	DF	Type III SS	Mean Square	F Value	Pr > F
treat	1	14.93030	14.93030	0.18	0.6756

Tests of Mixed Model

Dependent OHIP-20

Hypotheses for Analysis of Variance

Variable: outcome

Source	Type III Expected Mean Square
group	Var(Error) + 2 Var(Patient(group)) + Q(group)
Patient(group)	Var(Error) + 2 Var(Patient(group))
period	Var(Error) + Q(period)
treat	Var(Error) + Q(treat)

Source	DF	Type III SS	Mean Square	F Value	Pr > F
group	1	547.918379	547.918379	1.00	0.3241
Error	35	19168	547.661193		
Error: MS(Patient(group))					

Source	DF	Type III SS	Mean Square	F Value	Pr > F
Patient(group)	35	19168	547.661193	6.53	<.0001
period	1	196.960302	196.960302	2.35	0.1344
treat	1	14.930302	14.930302	0.18	0.6756
Error: MS(Error)	35	2934.814703	83.851849		

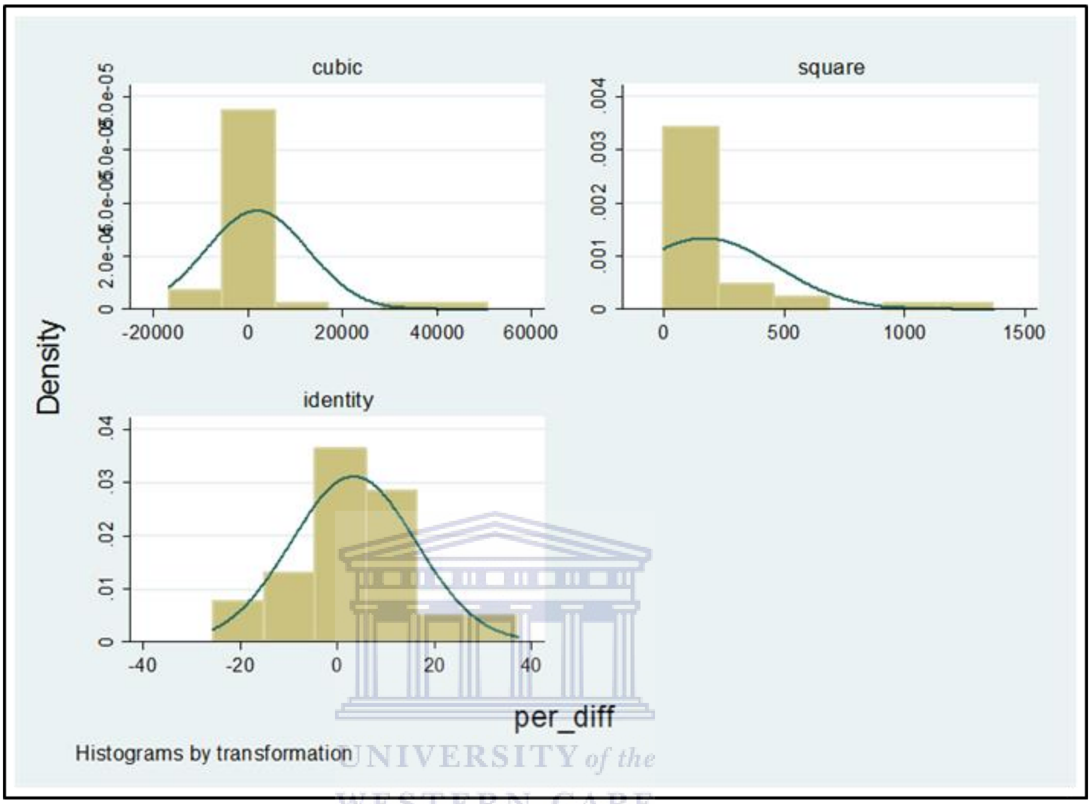
Dependent Variable: outcome OHIP-20

Parameter	Estimate	Standard Error	t Value	Pr > |t|
Treatment Difference: NZ reference	0.90132353	2.13600727	0.42	0.6756

Addendum 23: Two-sample *t*-tests with equal variance using STATA

```
. ttest sum_, by(SDD_ANA)

Two-sample t test with equal variances
------------------------------------------------------------------------------
   Group |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
       1 |      20      33.175    8.709891    38.95182    14.94499    51.40501
       2 |      17    22.25471    5.912551    24.37807    9.720658    34.78875
---------+--------------------------------------------------------------------
combined |      37    28.15757    5.440928    33.09587    17.12285    39.19228
---------+--------------------------------------------------------------------
    diff |            10.92029    10.91773               -11.24388    33.08447
------------------------------------------------------------------------------
    diff = mean(1) - mean(2)                                      t =   1.0002
Ho: diff = 0                                     degrees of freedom =       35

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.8380         Pr(|T| > |t|) = 0.3241          Pr(T > t) = 0.1620

. ttest dif_,by(SDD_ANA)

Two-sample t test with equal variances
------------------------------------------------------------------------------
   Group |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
       1 |      20       4.175    3.569106    15.96153   -3.295225    11.64523
       2 |      17   -2.372353    1.945009    8.019476   -6.495587    1.750881
---------+--------------------------------------------------------------------
combined |      37    1.166757    2.168494    13.19043   -3.231152    5.564666
---------+--------------------------------------------------------------------
    diff |            6.547353    4.272015               -2.125298       15.22
------------------------------------------------------------------------------
    diff = mean(1) - mean(2)                                      t =   1.5326
Ho: diff = 0                                     degrees of freedom =       35

    Ha: diff < 0                 Ha: diff != 0                 Ha: diff > 0
 Pr(T < t) = 0.9328         Pr(|T| > |t|) = 0.1344          Pr(T > t) = 0.0672
```

Addendum 24: Distribution of the difference between the scores of the two treatment periods



Addendum 25: Difference between pre- and post-treatment OHIP-20 scores

```
. ttest OHIPpre_treatment == OHIP_ANA

Paired t test
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
OHIPpr~t |      35    42.14286    3.819046    22.59378    34.38162    49.90409
OHIP_ANA |      35    14.52857    2.794874     16.5347    8.848704    20.20844
---------+--------------------------------------------------------------------
    diff |      35    27.61429    4.267824    25.24879    18.94102    36.28755
------------------------------------------------------------------------------
     mean(diff) = mean(OHIPpre_treatm~t - OHIP_ANA)               t =   6.4703
 Ho: mean(diff) = 0                              degrees of freedom =       34

 Ha: mean(diff) < 0           Ha: mean(diff) != 0           Ha: mean(diff) > 0
 Pr(T < t) = 1.0000         Pr(|T| > |t|) = 0.0000          Pr(T > t) = 0.0000

. ttest OHIPpre_treatment == OHIP_NZ

Paired t test
------------------------------------------------------------------------------
Variable |     Obs        Mean    Std. Err.   Std. Dev.   [95% Conf. Interval]
---------+--------------------------------------------------------------------
OHIPpr~t |      35    42.14286    3.819046    22.59378    34.38162    49.90409
 OHIP_NZ |      35    14.20943    3.257918     19.2741    7.588543    20.83031
---------+--------------------------------------------------------------------
    diff |      35    27.93343      4.1609    24.61622    19.47746    36.38939
------------------------------------------------------------------------------
     mean(diff) = mean(OHIPpre_treatm~t - OHIP_NZ)                t =   6.7133
 Ho: mean(diff) = 0                              degrees of freedom =       34

 Ha: mean(diff) < 0           Ha: mean(diff) != 0           Ha: mean(diff) > 0
 Pr(T < t) = 1.0000         Pr(|T| > |t|) = 0.0000          Pr(T > t) = 0.0000
```

Addendum 26: Relationship - OHIP-20 pre-treatment and tissue scores

```
.
. glm OHIPpre_treatment tissue_score_mandible

Iteration 0:   log likelihood = -167.70583

Generalized linear models                          No. of obs      =         37
Optimization     : ML                              Residual df     =         35
                                                   Scale parameter =   535.3243
Deviance         =  18736.34996                    (1/df) Deviance =   535.3243
Pearson          =  18736.34996                    (1/df) Pearson  =   535.3243

Variance function: V(u) = 1                        [Gaussian]
Link function    : g(u) = u                        [Identity]

                                                   AIC             =   9.173288
Log likelihood   = -167.7058285                    BIC             =   18609.97

------------------------------------------------------------------------------------
                      |                 OIM
    OHIPpre_treatment |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
----------------------+-------------------------------------------------------------
tissue_score_mandible |  -3.402025    2.675982    -1.27   0.204    -8.646854    1.842804
                _cons |   55.99205    11.56435     4.84   0.000     33.32633    78.65777
------------------------------------------------------------------------------------

. glm OHIPpre_treatment tissue_score_maxilla

Iteration 0:   log likelihood = -168.53312

Generalized linear models                          No. of obs      =         37
Optimization     : ML                              Residual df     =         35
                                                   Scale parameter =   559.8066
Deviance         =  19593.23121                    (1/df) Deviance =   559.8066
Pearson          =  19593.23121                    (1/df) Pearson  =   559.8066

Variance function: V(u) = 1                        [Gaussian]
Link function    : g(u) = u                        [Identity]

                                                   AIC             =   9.218007
Log likelihood   =  -168.533124                    BIC             =   19466.85

-----------------------------------------------------------------------------------
                     |                 OIM
   OHIPpre_treatment |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
---------------------+-------------------------------------------------------------
tissue_score_maxilla |    .333815    2.735501     0.12   0.903    -5.027668    5.695298
               _cons |   40.52023    13.58105     2.98   0.003     13.90186     67.1386
-----------------------------------------------------------------------------------

. glm OHIPpre_treatment tissue_score_combined

Iteration 0:   log likelihood = -168.33558

Generalized linear models                          No. of obs      =         37
Optimization     : ML                              Residual df     =         35
                                                   Scale parameter =   553.8606
Deviance         =  19385.12233                    (1/df) Deviance =   553.8606
Pearson          =  19385.12233                    (1/df) Pearson  =   553.8606

Variance function: V(u) = 1                        [Gaussian]
Link function    : g(u) = u                        [Identity]

                                                   AIC             =   9.207328
Log likelihood   = -168.3355758                    BIC             =   19258.74

------------------------------------------------------------------------------------
                      |                 OIM
    OHIPpre_treatment |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
----------------------+-------------------------------------------------------------
tissue_score_combined |  -.9437278    1.509639    -0.63   0.532    -3.902565    2.015109
                _cons |   50.44862     13.8916     3.63   0.000     23.22158    77.67566
------------------------------------------------------------------------------------
```

Addendum 27: Relationship - OHIP-20 ANA and tissue scores

```
. glm OHIP_ANA tissue_score_mandible

Iteration 0:   log likelihood = -154.35654

Generalized linear models                         No. of obs      =         37
Optimization     : ML                             Residual df     =         35
                                                  Scale parameter =    260.158
Deviance         =   9105.53143                   (1/df) Deviance =    260.158
Pearson          =   9105.53143                   (1/df) Pearson  =    260.158

Variance function: V(u) = 1                       [Gaussian]
Link function    : g(u) = u                       [Identity]

                                                  AIC             =   8.451705
Log likelihood   = -154.3565355                   BIC             =   8979.149

------------------------------------------------------------------------------------
                      |                 OIM
             OHIP_ANA |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
----------------------+-------------------------------------------------------------
tissue_score_mandible |  -3.041373    1.757039    -1.73   0.083    -6.485106    .4023607
                _cons |   27.48525    7.868329     3.49   0.000     12.06361    42.90689
------------------------------------------------------------------------------------

. glm OHIP_ANA tissue_score_maxilla

Iteration 0:   log likelihood = -155.19388

Generalized linear models                         No. of obs      =         37
Optimization     : ML                             Residual df     =         35
                                                  Scale parameter =   272.2038
Deviance         =  9527.134328                   (1/df) Deviance =   272.2038
Pearson          =  9527.134328                   (1/df) Pearson  =   272.2038

Variance function: V(u) = 1                       [Gaussian]
Link function    : g(u) = u                       [Identity]

                                                  AIC             =   8.496967
Log likelihood   = -155.1938805                   BIC             =   9400.752

-----------------------------------------------------------------------------------
                     |                 OIM
            OHIP_ANA |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
---------------------+-------------------------------------------------------------
tissue_score_maxilla |  -2.119403     1.84835    -1.15   0.252    -5.742103    1.503297
               _cons |   24.85821    9.296539     2.67   0.007     6.637327    43.07909
-----------------------------------------------------------------------------------

. glm OHIP_ANA tissue_score_combined

Iteration 0:   log likelihood = -154.52138

Generalized linear models                         No. of obs      =         37
Optimization     : ML                             Residual df     =         35
                                                  Scale parameter =   262.4865
Deviance         =  9187.028073                   (1/df) Deviance =   262.4865
Pearson          =  9187.028073                   (1/df) Pearson  =   262.4865

Variance function: V(u) = 1                       [Gaussian]
Link function    : g(u) = u                       [Identity]

                                                  AIC             =   8.460615
Log likelihood   = -154.5213782                   BIC             =   9060.646

------------------------------------------------------------------------------------
                      |                 OIM
             OHIP_ANA |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
----------------------+-------------------------------------------------------------
tissue_score_combined |  -1.641724    1.006761    -1.63   0.103    -3.614939    .3314908
                _cons |   29.48205    9.470322     3.11   0.002     10.92056    48.04354
------------------------------------------------------------------------------------
```

Addendum 28: Relationship - OHIP-20 NZ and tissue scores

```
. glm OHIP_NZ tissue_score_mandible

Iteration 0:   log likelihood =  -159.5606

Generalized linear models                          No. of obs      =         37
Optimization     : ML                              Residual df     =         35
                                                   Scale parameter =   344.6709
Deviance         =  12063.48301                    (1/df) Deviance =   344.6709
Pearson          =  12063.48301                    (1/df) Pearson  =   344.6709

Variance function: V(u) = 1                        [Gaussian]
Link function    : g(u) = u                        [Identity]

                                                   AIC             =   8.733005
Log likelihood   = -159.5606017                    BIC             =    11937.1

------------------------------------------------------------------------------------
                      |                 OIM
              OHIP_NZ |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
----------------------+-------------------------------------------------------------
tissue_score_mandible |   -3.26679   2.022391    -1.62   0.106    -7.230603    .6970241
                _cons |    27.2689   9.056622     3.01   0.003     9.518244    45.01955
------------------------------------------------------------------------------------

. glm OHIP_NZ tissue_score_maxilla

Iteration 0:   log likelihood = -160.88552

Generalized linear models                          No. of obs      =         37
Optimization     : ML                              Residual df     =         35
                                                   Scale parameter =   370.2607
Deviance         =  12959.12616                    (1/df) Deviance =   370.2607
Pearson          =  12959.12616                    (1/df) Pearson  =   370.2607

Variance function: V(u) = 1                        [Gaussian]
Link function    : g(u) = u                        [Identity]

                                                   AIC             =   8.804623
Log likelihood   = -160.8855219                    BIC             =   12832.74

-----------------------------------------------------------------------------------
                     |                 OIM
             OHIP_NZ |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
---------------------+-------------------------------------------------------------
tissue_score_maxilla |   .2149695   2.155713     0.10   0.921    -4.010151    4.440089
               _cons |   12.46123   10.84246     1.15   0.250    -8.789613    33.71207
-----------------------------------------------------------------------------------

. glm OHIP_NZ tissue_score_combined

Iteration 0:   log likelihood = -160.51979

Generalized linear models                          No. of obs      =         37
Optimization     : ML                              Residual df     =         35
                                                   Scale parameter =   363.0128
Deviance         =  12705.44776                    (1/df) Deviance =   363.0128
Pearson          =  12705.44776                    (1/df) Pearson  =   363.0128

Variance function: V(u) = 1                        [Gaussian]
Link function    : g(u) = u                        [Identity]

                                                   AIC             =   8.784853
Log likelihood   = -160.5197879                    BIC             =   12579.07

------------------------------------------------------------------------------------
                      |                 OIM
              OHIP_NZ |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
----------------------+-------------------------------------------------------------
tissue_score_combined |  -.9968817   1.183951    -0.84   0.400    -3.317383     1.32362
                _cons |   22.49428    11.1371     2.02   0.043     .6659631     44.3226
------------------------------------------------------------------------------------
```

Addendum 29: Relationship - OHIP-20 average and tissue scores

```
. glm OHIP_av tissue_score_mandible

Iteration 0:   log likelihood =  -154.1813

Generalized linear models                         No. of obs      =        37
Optimization     : ML                             Residual df     =        35
                                                  Scale parameter =  257.7054
Deviance         =  9019.690258                   (1/df) Deviance =  257.7054
Pearson          =  9019.690258                   (1/df) Pearson  =  257.7054

Variance function: V(u) = 1                       [Gaussian]
Link function    : g(u) = u                       [Identity]

                                                  AIC             =  8.442233
Log likelihood   = -154.1813019                   BIC             =  8893.308

------------------------------------------------------------------------------
                      |                 OIM
              OHIP_av |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
----------------------+-------------------------------------------------------------------
tissue_score_mandible |  -3.154081   1.748737    -1.80   0.071    -6.581543    .2733812
                _cons |   27.37707   7.831153     3.50   0.000     12.02829    42.72585
------------------------------------------------------------------------------

. glm OHIP_av tissue_score_maxilla

Iteration 0:   log likelihood = -155.68944

Generalized linear models                         No. of obs      =        37
Optimization     : ML                             Residual df     =        35
                                                  Scale parameter =  279.5939
Deviance         =  9785.786848                   (1/df) Deviance =  279.5939
Pearson          =  9785.786848                   (1/df) Pearson  =  279.5939

Variance function: V(u) = 1                       [Gaussian]
Link function    : g(u) = u                       [Identity]

                                                  AIC             =  8.523754
Log likelihood   = -155.6894407                   BIC             =  9659.405

------------------------------------------------------------------------------
                     |                 OIM
             OHIP_av |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
---------------------+-------------------------------------------------------------------
tissue_score_maxilla |  -.9522167   1.873273    -0.51   0.611    -4.623764     2.71933
               _cons |   18.65972    9.42189     1.98   0.048     .1931529    37.12628
------------------------------------------------------------------------------
```

```
. glm OHIP_av tissue_score_combined

Iteration 0:   log likelihood = -154.95965

Generalized linear models                          No. of obs      =         37
Optimization     : ML                              Residual df     =         35
                                                   Scale parameter =   268.7792
Deviance         =   9407.27211                    (1/df) Deviance =   268.7792
Pearson          =   9407.27211                    (1/df) Pearson  =   268.7792

Variance function: V(u) = 1                        [Gaussian]
Link function    : g(u) = u                        [Identity]

                                                   AIC             =   8.484306
Log likelihood   = -154.9596529                    BIC             =    9280.89

------------------------------------------------------------------------------
                       |                 OIM
               OHIP_av |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-----------------------+------------------------------------------------------
tissue_score_combined  |  -1.319303   1.018757    -1.30   0.195     -3.31603    .6774242
                 _cons |   25.98817   9.583168     2.71   0.007     7.205503    44.77083
------------------------------------------------------------------------------
```

Addendum 30: Relationship - OHIP-20 and gender

OHIPpre_treatment	Coef.	OIM Std. Err.	z	P>|z|	[95% Conf.	Interval]
_Igender_2	5.459627	7.968772	0.69	0.493	-10.15888	21.07813
_cons	38.71429	6.282818	6.16	0.000	26.40019	51.02838

OHIP_ANA	Coef.	OIM Std. Err.	z	P>|z|	[95% Conf.	Interval]
_Igender_2	2.122727	5.615833	0.38	0.705	-8.884103	13.12956
_cons	13.4	4.330366	3.09	0.002	4.912638	21.88736

OHIP_NZ	Coef.	OIM Std. Err.	z	P>|z|	[95% Conf.	Interval]
_Igender_2	-3.98803	6.408703	-0.62	0.534	-16.54886	8.572796
_cons	15.86667	4.941748	3.21	0.001	6.181019	25.55231

OHIP_av	Coef.	OIM Std. Err.	z	P>|z|	[95% Conf.	Interval]
_Igender_2	-.9326515	5.617382	-0.17	0.868	-11.94252	10.07722
_cons	14.63333	4.331561	3.38	0.001	6.143629	23.12304

Addendum 31: Relationship - OHIP-20 and age

OHIPpre_treatment	Coef.	OIM Std. Err.	z	P>|z|	[95% Conf.	Interval]
age	-.6204279	.4115524	-1.51	0.132	-1.427056	.1862
_cons	80.94354	26.03537	3.11	0.002	29.91516	131.9719

OHIP_ANA	Coef.	OIM Std. Err.	z	P>|z|	[95% Conf.	Interval]
age	-.0470635	.3041442	-0.15	0.877	-.6431752	.5490481
_cons	17.60045	19.18827	0.92	0.359	-20.00787	55.20877

OHIP_NZ	Coef.	OIM Std. Err.	z	P>|z|	[95% Conf.	Interval]
age	.04764	.3483154	0.14	0.891	-.6350455	.7303256
_cons	10.52112	21.975	0.48	0.632	-32.54909	53.59133

OHIP_av	Coef.	OIM Std. Err.	z	P>|z|	[95% Conf.	Interval]
age	.0002882	.3038325	0.00	0.999	-.5952124	.5957889
_cons	14.06079	19.1686	0.73	0.463	-23.50898	51.63056

Addendum 32: Relationship - OHIP-20 and education

OHIP_ANA	Coef.	OIM Std. Err.	z	P>|z|	[95% Conf.	Interval]
_Ieducation_2	9.144231	6.699998	1.36	0.172	-3.987525	22.27599
_Ieducation_3	10.625	11.21909	0.95	0.344	-11.36401	32.61401
_cons	7.375	5.858979	1.26	0.208	-4.108387	18.85839

OHIP_NZ	Coef.	OIM Std. Err.	z	P>|z|	[95% Conf.	Interval]
_Ieducation_2	12.94538	7.569268	1.71	0.087	-1.890109	27.78088
_Ieducation_3	12.625	12.67467	1.00	0.319	-12.21691	37.46691
_cons	3.375	6.619133	0.51	0.610	-9.598263	16.34826

OHIP_av	Coef.	OIM Std. Err.	z	P>|z|	[95% Conf.	Interval]
_Ieducation_2	11.04481	6.608522	1.67	0.095	-1.907657	23.99727
_Ieducation_3	11.625	11.06591	1.05	0.293	-10.06379	33.31379
_cons	5.375	5.778985	0.93	0.352	-5.951602	16.7016

OHIPpre_treatment	Coef.	OIM Std. Err.	z	P>|z|	[95% Conf.	Interval]
_Ieducation_2	17.52	8.831486	1.98	0.047	.210606	34.82939
_Ieducation_3	15.66667	15.14587	1.03	0.301	-14.0187	45.35203
_cons	29	7.572937	3.83	0.000	14.15732	43.84268

Addendum 33: Relationship - OHIP-20 and marital status

```
------------------------------------------------------------------------------
             |                 OIM
    OHIP_ANA |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
_Imarital_s_2 |  -3.018634   5.673862    -0.53   0.595     -14.1392    8.101932
       _cons |   15.80435   3.490133     4.53   0.000     8.963813    22.64488
------------------------------------------------------------------------------
------------------------------------------------------------------------------
             |                 OIM
     OHIP_NZ |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
_Imarital_s_2 |  -9.951584   6.303018    -1.58   0.114    -22.30527    2.402104
       _cons |   17.26087   3.877142     4.45   0.000     9.661811    24.85993
------------------------------------------------------------------------------
------------------------------------------------------------------------------
             |                 OIM
     OHIP_av |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
_Imarital_s_2 |  -6.485109   5.582366    -1.16   0.245    -17.42635    4.456128
       _cons |   16.53261   3.433851     4.81   0.000     9.802384    23.26283
------------------------------------------------------------------------------
----------------------------------------------------------------------------------
                 |                 OIM
OHIPpre_treatment |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-----------------+----------------------------------------------------------------
    _Imarital_s_2 |   5.644231   8.093538     0.70   0.486    -10.21881    21.50727
           _cons |     40.125   4.797436     8.36   0.000      30.7222     49.5278
```

Addendum 34: Relationship - OHIP-20 and period of edentulousness

```
------------------------------------------------------------------------------
             |                 OIM
    OHIP_ANA |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
per_edent_yrs |  -.0881465   .1920163    -0.46   0.646    -.4644915    .2881985
       _cons |   17.39351   6.556597     2.65   0.008     4.542819    30.24421
------------------------------------------------------------------------------

------------------------------------------------------------------------------
             |                 OIM
     OHIP_NZ |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
per_edent_yrs |  -.1200149   .2196125    -0.55   0.585    -.5504475    .3104178
       _cons |   17.21424   7.498901     2.30   0.022     2.516668    31.91182
------------------------------------------------------------------------------

------------------------------------------------------------------------------
             |                 OIM
     OHIP_av |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
per_edent_yrs |  -.1040807    .191524    -0.54   0.587    -.4794608    .2712994
       _cons |   17.30388   6.539787     2.65   0.008     4.486131    30.12163
------------------------------------------------------------------------------

----------------------------------------------------------------------------------
                 |                 OIM
OHIPpre_treatment |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-----------------+----------------------------------------------------------------
    per_edent_yrs |    .042407   .2787282     0.15   0.879    -.5038903    .5887043
            _cons |   40.77229   9.602795     4.25   0.000     21.95115    59.59342
----------------------------------------------------------------------------------

------------------------------------------------------------------------------
             |                 OIM
    OHIP_dif |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
per_edent_yrs |   .0318684   .1532126     0.21   0.835    -.2684229    .3321596
       _cons |   .1792685   5.231607     0.03   0.973    -10.07449    10.43303
```

Addendum 35: Correlation between post-treatment OHIP-20 difference and denture dimension differences

```
. corr dimension Ohip_ANA_NZ
(obs=37)

             | dimens~n Ohip_A~Z
-------------+------------------
   dimension |   1.0000
 Ohip_ANA_NZ |   0.0343   1.0000


. glm  dimension Ohip_ANA_NZ

Iteration 0:   log likelihood = -95.799864

Generalized linear models                          No. of obs      =        37
Optimization     : ML                              Residual df     =        35
                                                   Scale parameter =  10.97987
Deviance         =  384.2955286                    (1/df) Deviance =  10.97987
Pearson          =  384.2955286                    (1/df) Pearson  =  10.97987

Variance function: V(u) = 1                        [Gaussian]
Link function    : g(u) = u                        [Identity]

                                                   AIC             =  5.286479
Log likelihood   =  -95.7998638                    BIC             =  257.9134

------------------------------------------------------------------------------
             |                 OIM
   dimension |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
 Ohip_ANA_NZ |   .0085007   .0418686     0.20   0.839    -.0735603    .0905616
       _cons |   4.381826   .5469366     8.01   0.000      3.30985    5.453802
------------------------------------------------------------------------------
```

Addendum 36: Relationship denture preference and difference in dimensions

```
. xi: glm dimension i.dent_pref3 if !(Patient==16|Patient==18|Patient==35|Patient==39)
i.dent_pref3      _Ident_pref_1-3     (naturally coded; _Ident_pref_1 omitted)

Iteration 0:   log likelihood = -90.785095

Generalized linear models                          No. of obs      =        35
Optimization     : ML                              Residual df     =        32
                                                   Scale parameter =  11.46679
Deviance         =  366.9371899                    (1/df) Deviance =  11.46679
Pearson          =  366.9371899                    (1/df) Pearson  =  11.46679

Variance function: V(u) = 1                        [Gaussian]
Link function    : g(u) = u                        [Identity]

                                                   AIC             =  5.359148
Log likelihood   = -90.78509464                    BIC             =  253.1661

------------------------------------------------------------------------------
             |                 OIM
   dimension |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
_Ident_pref_2 |   .0365674   1.521647     0.02   0.981    -2.945805     3.01894
_Ident_pref_3 |  -.4213916   1.500801    -0.28   0.779    -3.362908    2.520125
       _cons |   4.396351   1.197225     3.67   0.000     2.049832    6.742869
------------------------------------------------------------------------------
```

Addendum 37: CONSORT checklist

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title: *the study was not identified as "randomised" in the title.*	i
	1b	Structured summary of trial design, methods, results, and conclusions: *yes.*	v-vi
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale: *yes.*	1-2
	2b	Specific objectives or hypotheses: *yes.*	2-3
Methods			
Trial design	3a	Description of trial design including allocation ratio: *yes.*	48 and 75
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons: *N/A.*	N/A
Participants	4a	Eligibility criteria for participants: *yes.*	49
	4b	Settings and locations where the data were collected: *yes.*	49
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered: *yes.*	50 to73
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed: *yes: socio-demographic details, denture history, tissue scores, interalveolar distance, denture dimensions, OHIP-20, treatment effect size, denture preference.*	53-56, 64-71
	6b	Any changes to trial outcomes after the trial commenced, with reasons: *no.*	N/A
Sample size	7a	How sample size was determined: *power analysis1.*	50-51
	7b	When applicable, explanation of any interim analyses and stopping guidelines: *power analysis 2.*	51-52

Section/Topic	Item No	Checklist item	Reported on page No
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence: *lucky draw.*	50
	8b	Type of randomisation; details of any restriction (such as blocking and block size): *N/A.*	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned: *folded papers.*	50
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions: *researcher-clinician.*	48 and 50
Blinding	11a	If done, who was blinded after assignment to and how: *participants were blinded. They were not told what the difference between the 2 interventions were, IF there was a difference. Participants were also not informed about the sequence.*	48 and 50
	11b	If relevant, description of the similarity of interventions: *Both interventions rehabilitated edentulousness with complete dentures. Upper dentures were similar. Lower dentures were similar for all denture parameters, except the width of the dental arch and the shape of the polished surfaces.*	56, 61 and 63
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes: *yes.*	72-73
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses: *randomisation into sequence groups.*	77-78

Section/Topic	Item No	Checklist item	Reported on page No
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome: *yes. CONSORT flow charts.*	75
	13b	For each group, losses and exclusions after randomisation, together with reasons: *yes. CONSORT flow charts.*	74-75
Recruitment	14a	Dates defining the periods of recruitment and follow-up: *yes.*	74
	14b	Why the trial ended or was stopped: *Sample size was reached according to power analysis.*	74
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group: *yes.*	76-79
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups: *yes.*	74-165
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval): *yes.*	74-165
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended: *yes.*	102-103
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory: *N/A.*	N/A
Harms	19	All important harms or unintended effects in each group: *there were no important harms*.	N/A

Section/Topic	Item No	Checklist item	Reported on page No
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses: *yes.*	143, 145, 147, 148, 150, 181
Generalisability	21	Generalisability (external validity, applicability) of the trial findings: *yes.*	181
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence: *yes.*	142-181
Other information			
Registration	23	Registration number and name of trial registry: *yes.*	48
Protocol	24	Where the full trial protocol can be accessed, if available: *Faculty and University Research Committee Meeting minutes.*	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders: *yes.*	48