Retrospective evaluation of transverse arch dimensional changes in non-extraction and premolar extraction cases using a passive self-ligating bracket system

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KEYWORDS

Arch width

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Damon system

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ABSTRACT

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The effect of extraction and non-extraction treatment protocols on the dental arch width has comprehensively been researched. The effect of non-extraction protocols using passive self-ligating systems has also been adequately investigated. Although the literature comes to contrasting conclusions and further research is always encouraged, the impact on the dental arch width using an extraction protocol in combination with a passive self-ligating system has not been defined thoroughly.

Aim: this study investigated the effect of 2 treatment protocols on transverse arch width, before and after treatment, using a passive self-ligating system. The null hypothesis to be tested was that treatment with a second premolar extraction protocol would result in no difference in transverse arch width changes compared to treatment with a non-extraction protocol.

Methods and materials: a sample of 100 patients of various malocclusions treated by one orthodontist was gathered for this study. There were 2 study groups of 50 patients each. Group non-extraction (NE) contained 50 patients treated non-extraction, and group extraction (Ex) included 50 patients treated with all 4-second premolar extractions. The Pre-treatment (T1) and post-treatment (T2) orthodontic study models of the maxilla and mandible of the 100 patients were assembled, and the inter-canine, inter-first premolar and inter-first molar widths were measured.

Results: In the mandible, the non-extraction group (NE) showed a statistically significant increase in inter-canine 0,95mm ($p = .0001$), inter-first premolar 1,86mm ($p < .001$) and inter-molar width 1,54mm ($p = .00001$).
In the extraction group (Ex) the inter-canine 0,66mm ($p = .02899$) and inter-first premolar width 1,56mm ($p = .00012$) showed statistically significant increases. The inter-molar width showed a significant reduction in arch width of 1,32mm ($p = .00357$).
In the maxilla, the NE group showed a statistically significant increase in all 3 arch widths: inter-canine 0,84mm ($p = .00151$), inter-first premolar 2,61mm ($p < .001$) and inter-first molar 1,96mm ($p < .001$). Group Ex showed an increase in inter-canine 0,55mm ($p = .0768$) and inter-first premolar width 2,79mm ($p < .001$). Only the inter-first premolar increase was statistically significant. As was in the case of the extraction group in the mandible, the inter-molar width showed a significant reduction of 1,29mm ($p = 0.00046$).
There was no statistically significant difference in the inter-canine and inter-first premolar arch width changes between the 2 groups, neither in the maxilla nor the mandible. There was a statistically significant difference in the inter-first molar arch width changes between the 2 groups in the maxilla and mandible ($p < .001$).

Conclusion: Arch width changes experienced in the non-extraction and second premolar extraction groups yielded similar results. There was no significant difference in treatment outcome between the 2 treatment modalities regarding the inter-canine and inter-first premolar width in either arch. The outcome in inter-molar width change between the 2 groups were statistically different in both arches.
A biologically acceptable expansion occurs in the inter-canine width using pre-treatment anatomical landmarks as guidance for archwire contouring, irrespective of the treatment protocol.

DECLARATION

I declare that the *Retrospective evaluation of transverse arch dimensional changes in non-extraction and premolar extraction cases using a passive self-ligating bracket system* 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.

Marthinus Johannes Coetsee November 2022

Signed: …………………………………

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CHAPTER 1

Introduction

The current literature regarding arch dimensional changes that are growth related is predominantly based on longitudinal analyses of reference models. In contrast, our understanding of treatment-related changes and the implication thereof on long-term stability are primarily based on the information garnered through retrospective follow-up studies (Fleming, 2013).

Intra-arch dimensional changes can be quantified by measuring specific landmarks. These landmarks include inter-canine, inter-premolar and inter-molar widths, arch depth, arch length and incisor irregularity. To assess changes in dental inclination, serial radiographs or sequential models can be used for measurement (Fleming, 2013).

Cephalometric data gathered through studies conducted by Forsberg (1979), Behrents (1984) and Fudalej, Kokich and Leroux (2007) prove that the craniofacial skeleton undergoes changes throughout life. Changes in dental arch dimensions during childhood and adolescence have been studied by various authors (Barrow and White, 1952; Dockrell *et al.*, 1954; Moorrees and Reed, 1954). The same cannot be said when considering dental arch dimensional changes during early adulthood and beyond.

A study by DeKock (1972) assessing changes in arch dimensions in subjects between the ages of 12 and 26 found a reduction in arch depth irrespective of gender during the second and third decades of life. There was little change to the transverse dimensions. However, a small but statistically significant increase in arch width was noted in males aged between 12 and 15.

Longitudinal studies conducted by Sillman (1964), Bishara *et al.* (1998) and Carter and McNamara (1998) concerning arch dimensional changes in untreated subjects proved that there is an increase in inter-canine and inter-molar widths until the secondary dentition is established. Thereafter the transverse dental dimensions decrease, predominantly the inter-canine width than the inter-molar width. The maximum rate at which the decrease occurs is 0.025mm per year. This reduction can continue up to the eighth decade of life.

The study by Carter and McNamara (1998) evaluated 53 untreated subjects ranging from late adolescence to the fifth and sixth decade of life. The study found a marked decrease in inter-canine width in males and females, especially the mandibular inter-canine width. In addition, minor changes occurred regarding the transverse maxillary dimension.

CHAPTER 2

Literature review

2.1 Extraction vs non-extraction

The debate between extraction and non-extraction treatment continues to be of the most contentious topics in Orthodontics. In 1911 a meeting was held by the National Dental Association in the USA, where Calvin Case and Martin Dewey presented their opinions regarding extraction and non-extraction protocols (Case, 1964). Edward H. Angle believed that all 32 teeth could be accommodated for in the jaws in an ideal occlusion. This occlusion is characterized by the mesiobuccal cusp of the maxillary first molar occluding with the buccal groove of the mandibular first molar (Angle, 1900).

Extractions were reintroduced into orthodontics during the mid-20th century when Charles Tweed, a student of Angle, observed relapse in non-extraction cases. As a solution, Tweed proposed the extraction of first premolars. In 1944 at the AAO meeting, he presented retreated cases with first premolar extractions where the initial treatment used a non-extraction approach and relapse occurred (Tweed, 1966). However, Tweed emphasised extraction as a last option when the basal arches were too constricted to accommodate the full complement of teeth (Proffit, 1994).

During the 1990s, extractions were discouraged again; McReynolds and Little (1991) and Little (1999) concluded that extractions lead to instability in tooth movement. During the early 20th century, extractions were rare.

Proffit (1994) evaluated the extraction frequency for 40 years and reported an extraction frequency of 30% in 1953. It peaked in 1968 with the decision to extract, averaging 76% of treatment protocols. Thereafter it declined to 28% in 1993 as the non-extraction protocol gained more popularity (Rinchuse *et al*., 2014).

The current tendency is a paradigm shift from extraction therapy to non-extraction therapy to address various malocclusions. This can be ascribed to the advent of systems such as self-ligating brackets and the use of temporary anchorage devices to allow complex tooth movements (Dahiya *et al*., 2018).

2.2 Smile aesthetics

The smile forms an integral part of self-esteem and dictates the need for orthodontic treatment in most patients (Janson *et al.,* 2011). Smile aesthetics have become an important consideration for orthodontists as patients also determine the success of their treatment by their smiles and the change in facial profile and not only the occlusal outcome (Prasad *et al.,* 2018).

Hulsey (1970) compared the smiles of subjects who completed orthodontic treatment to untreated subjects and found that the smile scores for the orthodontically treated group were significantly lower compared to the untreated group.

Smile aesthetics largely depend on arch form and width (Moore *et al*., 2005). Widening the dental arch improves smile attractiveness as it reduces the space between the buccal surface of the posterior teeth and the cheek. This area is known as the buccal corridor. The best method to determine the buccal corridor is yet to be established as it is unclear whether to use the canines or the most posterior tooth visible (Roden-Johnson, Gallerano and English, 2005).
Maurya *et al.* (2012) reported that wider buccal corridors are associated with lower aesthetic scores. The correlation between buccal corridors with the inter-canine and inter-molar widths is inverse. Thus, protocols that diminish dental arch widths can lead to poor smile aesthetics (Moore *et al*., 2005). However, Roden-Johnson, Gallerano and English (2005) state that the buccal corridor has no bearing on smile aesthetics.

Extraction protocols receive criticism since it leads to a constriction in the dental arch in comparison to non-extraction protocols (Spahl and Witzig, 1987). Pre-treatment inter-canine and inter-molar widths ensure muscular balance. Therefore, these values should be maintained to ensure post-retention stability (Strang, 1949; Riedel, 1960).

The literature, however, shows no clear correlation between premolar extraction leading to a reduction in transverse dental arch width. The conclusions vary from study to study and could result from different treatment techniques, the presenting malocclusion or the sample size examined (Golwalker and Shetty, 2013).

Meyer *et al.* (2014) found an increase in maxillary inter-canine width without significant changes to the buccal corridor in cases treated with an extraction or non-extraction protocol. Herzog *et al.* (2017) and Mac Kriel (2008) found that extractions lead to a final occlusion with a narrower dental arch compared to non-extraction treatment. However, Golwalker and Shetty (2013) and Gianelly (2003) found no narrowing of the dental arches in extraction treatment compared to non-extraction treatment. Akyalcin *et al.* (2011), on the other hand, found that there was a slight increase in the post-treatment maxillary inter-canine and inter-molar width within the non-extraction group.

2.3 Self-ligating appliances

Self-ligation is not a new concept. The first self-ligating bracket was introduced in the 1930s and was named the Russel attachment (Stolzenberg, 1935). It did not attract much attention at the time, most probably due to scepticism or a lack of promotion (Chen *et al*., 2010a). The interest in self-ligating brackets was promoted with the invention of the SPEED brackets in the '70s and later the In-Ovation bracket and the Damon SL (Harradine, 2008).

Self-ligating appliances are bracket systems that do not require conventional ligation with elastomeric or steel ligatures. It features a built-in mechanical device such as a clip or metal labial face to secure the slot. Self-ligating brackets can be classified as active or passive depending on the interaction with the archwire. Active self-ligating brackets (ASLB) have a spring clip that presses on the wire whilst the door of the passive self-ligating brackets (PSLB) does not (Harradine, 2001; Harradine, 2008).

Self-ligating systems have gained popularity due to claims of improved treatment efficiency, reduction in chair time, reduced patient discomfort, improved periodontal health, superior torque expression and an improved change in arch dimensions (Harradine, 2008; Zreaqat and Hass, 2011).

These claims are yet to be unanimously accepted (Hamilton, Goonewardene and Murray, 2008; Miles, 2009). In combination with advanced technology and resilient copper-nickel-titanium archwires, self-ligating brackets are supposed to deliver light forces and low friction (Damon, 2005; Roth *et al*., 2005). Chen *et al.* (2010a) concluded that self-ligating brackets allow more significant amounts of arch expansion, less incisor proclination and less need for extractions. Pandis *et al.* (2007) and Vajaria *et al.* (2011) reported a greater inter-molar arch width change in the patients treated with the Damon system compared to the conventional treatment group. However, the wire sequences and arch forms in these 2 studies differed between the 2 bracket systems.

Pandis *et al.* (2010), Jiang and Fu (2008) and Scott *et al.* (2008) investigated transverse changes in arch width and mandibular incisor inclination. All 3 studies used the Damon brackets in the self-ligating group. Pandis *et al.* (2010) and Jiang and Fu (2008) used non-extraction protocols, whereas Scott *et al.* (2008) used an extraction protocol. The 2 studies that used non-extraction protocols reported no significant change in the inter-canine and inter-molar widths between the 2 groups. However, Scott et al. (2008) reported an increase in inter-canine width, but the inter-molar width remained the same. One should note that in the 2 non-extraction studies, the archwire sequences used were different; in the extraction study, the same archwire sequence was used for both groups.

A study conducted by Byun (2019) evaluated the changes that occurred in arch dimension and incisor position in subjects with moderate to severe crowding. Subjects were treated non-extraction using the Damon system. The most significant increase in arch dimension in the maxilla occurred at the first premolar then second premolar, canine and molar. Within the mandible, the sequence of teeth exhibiting the greatest arch dimensional change pattern coincided with that of the maxilla. All the changes were statistically significant.

Romero-Delmastro *et al.* (2017) compared the pattern of dentoalveolar changes in 39 subjects with a Class I malocclusion with moderate crowding treated non-extraction. The appliances used were conventional, passive self-ligating and active self-ligating bracket systems. They reported that the greatest expansion occurred at the premolars, irrespective of the bracket system used. The increase in inter-premolar width observed in the maxilla ranged from 2.8mm to 4.6mm and in the mandible from 1.7mm to 3.5mm.

To establish whether the expansion achieved by self-ligating bracket systems are predominantly buccal tipping or actual bodily movement, Bashir *et al.* (2019) compared the transverse dimensional changes observed in the maxilla in patients requiring premolar extractions of 50 subjects. Pre-treatment cast models and models after 6 months of traction were measured. Active as well as passive self-ligating bracket systems and conventional brackets were compared to one another. Archwire material, wire size and sequence were identical in all 3 groups to eliminate the effects of different archwire materials and sizes.
Both self-ligating bracket systems lead to an increase in vertical dimensions of statistical significance when compared to the conventional brackets. The passive self-ligating brackets produced a greater dimensional change when compared to the active system, with an incremental increase of 4.89mm in the inter-canine width and 3.41mm in the inter-molar width (Bashir *et al*., 2019).

2.4 Damon philosophy

Damon brackets were introduced in 1995. The philosophy of this system is to allow physiologic tooth movement through a low friction system with light forces. The reduced friction is seen as the component that allows the very elastic nickel-titanium archwires to match the low forces of average growth. Expansion of the dental arches occurs due to the low forces and friction (Damon, 1998a). This ensures that the teeth experience a constant force that is optimal for efficient tooth movement (Damon, 1998b).

The Damon philosophy is built on a framework of low forces to allow blood flow and thus oxygen supply to the surrounding bone. This allows good bone metabolism and tooth movement (Damon, 2005). This correlates with the conventional postulate that light forces encourage oxygen availability to the bone and therefor normal metabolism and frontal resorption rather than undermining resorption and cell death that leads to hyalinization (Krishnan and Davidovitch, 2006).

This property is often exploited and leads proponents of the system to treat patients predominantly with a non-extraction protocol (Fleming, 2013). Due to this approach, there have been concerns regarding the stability of results and the viability of long-term retention provided by this technique (Birnie and Harradine, 2008).

As a result of this philosophy, there are very few studies carried out to document the effect of a passive self-ligating system, such as the Damon system, when an extraction protocol is used. Moreover, 2 studies available are a multicenter randomised clinical trial by Scott *et al.* (2008) titled: "Alignment efficiency of Damon3 self-ligating and conventional orthodontic bracket systems: A randomized clinical trial" and a prospective randomised clinical trial by DiBiase *et al.* (2011) titled: "Duration of treatment and occlusal outcome using Damon3 self-ligated and conventional orthodontic bracket systems in extraction patients: A prospective randomized clinical trial."

2.5 Treatment stability

There are various challenges during orthodontic treatment, but one of the most daunting challenges is long-term stability. During the initial phase of retention, the improvement in occlusal contact can be attributed to settling (Hoybjerget, Currier and Kodioglu, 2013). The most significant post-treatment movement is seen during the first 2 years (Al Yami *et al.,* 1999). A decrease in movement can be expected 4 years post-treatment (Greco *et al.,* 2010).

The most prominent amount of relapse seen after expansion treatment is at the mandibular inter-canine width (Shah, 2003; Little *et al.*, 1999; Hoybjerget, Currier and Kodioglu, 2013). The maintenance of this width, specifically the mandibular inter-canine width, is regarded as the most crucial factor in ensuring stability after treatment (Loddi and Scanavini 2002; Martins *et al.,* 2007)). One should strive to keep the change in this dimension to a minimum. Using the pre-treatment width as a guide and not altering this dimension significantly post-treatment is the most effective way to minimise relapse (Weinberg and Sadowsky, 1996; Sadowsky and Sakols, 1982).

The presence of a fixed retainer is a variable that influences the alignment of the mandibular anterior segment (De Bernabe *et al.,* 2016). Little (1990), however, stated that there are no reliable predictors for post-retention crowding of the anterior segment as it is unpredictable and inconsistent.

There is no clear answer whether extracting or not extracting teeth leads to a more stable result. Some authors reported indifferent results when comparing the stability of the 2 groups to another (Little, Wallen and Riedel,1981; Little, Riedel and Artun, 1988; Goldberg *et al.,* 2013; Myser *et al.,* 2013).

The findings of Boley *et al.* (2003) contradict the above statement, as their study reported superior stability in premolar extraction cases with prominent incisor irregularity. Nevertheless, Garib *et al.* (2016) found that a third of the extraction group of all 4 premolar extractions experienced relapse in the form of extraction spaces reopening.

De Bernabe *et al.* (2016) examined the role a number of variables play in the stability of orthodontic treatment. Fixed retainer, retention period and years without retention were some of the variables. They conducted a retrospective longitudinal study of 70 post-treatment patients by measuring the Peer Assessment Rating (PAR) index at the start of treatment and the end of treatment and 4 – 10 years post-treatment. They reported that only 7.1% of cases presented absolute stability. Absolute stability was used when the post-treatment and 4 – 10 year post retention measurements were identical. In addition, the study found that the mandibular incisor alignment was the most unstable occlusal feature.

Ab Rahman *et al.* (2017) conducted a randomised controlled trial to compare the stability of the final occlusal outcome of the mandibular arch widths 6 months into retention. The 2 treatment groups consisted of a passive self-ligating and conventional system, all treated non-extraction. The results of the study showed a significant increase ($p < .01$) in incisor irregularity and a significant decrease ($p < .01$) in inter-premolar width, irrespective of the system used. The relapse experienced regarding the inter-canine, first inter-premolar, second inter-premolar, inter-molar width, arch length and depth were all less than 1mm.

Bhupali *et al.* (2019) evaluated the stability of occlusal outcomes in subjects' treatment non-extraction and premolar extraction protocols. They evaluated 55 debonded patients, 30 of whom had undergone 4 premolar extractions and 25 treated non-extraction. The time frames used were pre-treatment, post-treatment and 3 years retention period. They noted a statistically significant increase in incisor irregularity for both groups. Relapse in the inter-canine width and American Board of Orthodontists (ABO) scores were also deemed statistically significant. The study concluded that the relapse experienced may be similar irrespective of the treatment plan.

2.6 Extraction of second premolars

Once a decision is made to extract premolars, some characteristics form an essential part of the diagnosis that need to be considered, which in turn determine which premolars need to be extracted. The tooth-alveolar bone discrepancy, inter-arch relationships, facial profile and pattern, level of skeletal maturation, tooth asymmetry, patient cooperation, and disease all form part of the decision regarding which premolars to extract.

There may be situations where a single factor determines which premolars to extract (Carlos De Oliveira Ruellas *et al.,* 2010).

A few authors have recognised the advantages of second premolar extractions. They reported that besides the positive rate at which space closure occurs, the margins of the second premolar and first molar form a good marginal relationship (Dewel, 1955; Dewel, 1978; Logan, 1973; Nance, 1949). Nance (1949) was the first to recognise the potential advantages that the removal of second premolars offered. Creekmore (1997) reported that the second premolar extraction space is closed by half the distance due to the mesial movement of the molars. The rest of the space created from the extraction is utilised to relieve crowding and incisor retraction.

Chen *et al.* (2010b) also concluded that the second premolar extraction space is utilised equally by the anterior and posterior segments in patients with mild crowding, slight dental protrusion and Angle Class I relationship.

Schoppe (1964) favours second premolar extractions where there is a need to mesialise the molar but maintain the incisor position. He further states that when the arch length discrepancy is less than 7.5mm, second premolar extraction is the better option as there is no need for incisor retraction. Salzmann (1945) also states that second premolar extraction should be considered when the extraction space is used for tooth alignment and the mesial migration of the molar. Ong and Woods (2001) noted that after the molar's mesial migration occurred, the final occlusal result of second premolar extraction cases yielded a bigger inter-molar width reduction than first premolar extractions.

De Castro (1974) believes that the soft tissue profile and anchorage values form the core principles to dictate which teeth to extract. It is further suggested that second premolar extractions have a bigger influence on the posterior segment in contrast to the removal of first premolars, where the anterior as well as posterior segments are affected.

Proffit and Fields (1993), through clinical observation, attempted to quantify the difference in the mesial movement of the molars and incisor retraction between different extraction protocols. They concluded that the more posterior the extraction space is, the less the amount of anterior retraction will occur. It should be noted that some retraction of the anterior segment would still be evident. Other authors have also confirmed this phenomenon (Schwab, 1971; Schoppe, 1964).

Proffit and Fields (1995) created a guide of procedures to assess the need for extractions in cases where a Class I malocclusion with incisor protrusion or crowding is present. The first premolars are generally removed due to their position and the tooth size corresponding with most discrepancies requiring anterior tooth retraction. When faced with a considerable discrepancy, the removal of second premolars is not indicated (Carlos De Oliveira Ruellas *et al.,* 2010)

Mascarenhas *et al.* (2015) have given 2 guidelines for when to consider removing 4-second premolars:

1. The soft tissue profile is acceptable, and do not want to alter it
2. Mild to moderate anterior crowding, but the incisor angulation is acceptable

There is an element of subjectiveness regarding the amount of crowding. De Castro (1974) regards moderate crowding as a tooth-size arch-length discrepancy of 5mm or more, in contrast to Schoppe (1964), viewing it as 7.5mm or less.

Bishara *et al.* (1994) compared the changes in dental arch width in patients presenting with a Class II division 1 malocclusion between 2 groups: first premolar extraction and non-extraction protocols. Tooth size-arch length discrepancy was one of the criteria evaluated. The study concluded that the extraction of premolars significantly improved the discrepancy between tooth size and arch length.

Other factors playing a role in the decision to extract second premolars rather than first premolars are the presence of posterior crowding, anterior open bite, Class III correction and the intentional loss of anchorage (Sandler *et al.,* 2014). Crowding, ectopic eruption, or impaction associated with second or third molars can be alleviated by creating space in the posterior segments by removing the second premolars. This allows the first molars to move mesially, alleviating the space shortage further posteriorly (Logan, 1973; de Castro, 1974).

Advantages of second premolar extractions according to Mascarenhas et al. (2015) are:

1. Limited distal movement of the mandibular anterior segments
2. The mandibular incisor position is maintained and preserves the soft tissue profile
3. The Curve of Spee and overbite does not change much

Schoppe (1964) reports that extraction of maxillary second premolars can help camouflage Class III malocclusions when combined with mandibular first premolar extractions. This is attributed to the retraction of the mandibular anterior segment while simultaneous mesialisation of the maxillary molars.

Another phenomenon associated with second premolar extractions is the decrease in Facial Vertical Dimension (FVD). The reduction in FVD can be attributed to the "wedge effect concept", where it is postulated that the higher degree of mesial movement experienced in second premolar extractions closes the FVD through the reduction of the wedging effect (Schudy, 1965; Schudy, 1968; Tulley, 1959; Wyatt, 1987; Bowbeer, 1987).

Kim *et al.* (2005) studied the wedging effect by evaluating the change in FVD in patients with a Class I malocclusion and hyperdivergent profile between 2 groups: extraction of all first and all second premolars. The study concluded that irrespective of the extraction protocol, there was no significant difference regarding the change in FVD between the 2 groups.

2.7 Arch dimensional changes

After conducting a systematic review of 30 studies, to evaluate the clinically significant effects of self-ligating brackets, of which one of the outcomes were the change in vertical dimensions, Fleming (2013) concluded that more evidence is required to definitively state that self-ligating bracket systems are superior to conventional orthodontic appliances or vice versa.

The effects observed are indistinguishable regarding the change in maxillary inter-canine or inter-molar width (Fleming, 2013).

A study conducted by Atik *et al.* (2016) corroborates the conclusion made by Fleming (2013). They studied the effects of different bracket types, active and passive self-ligating bracket systems, and conventional brackets using broad archwires in subjects treated with non-extraction. The study specifically evaluated the change in maxillary arch dimensions and incisor and molar inclination. A conclusion was made that no differences were observed between the 3 groups using broad archwires.

The results of the study conducted by Byun (2019) that evaluated the change in arch dimension and incisor position of patients with moderate to severe crowding using a self-ligating bracket system suggest that crowding relief occurs through statistically significant increases in arch width, arch depth as well as incisor inclination and protrusion.

There is a consensus that the greatest arch dimensional change occurs at the premolars, as reported by Romero-Delmastro *et al.* (2017) and Byun (2019). Further studies confirming this statement are Fleming (2013), Weinberg and Sadowsky (1996), Songra *et al.* (2014) and Franchi *et al.* (2006).

The results vary from one study to the next and that a blanket statement on the effects of passive self-ligating systems cannot be made. It is reasonable to assume that expansion will occur at the premolars. Further studies are encouraged to continually update the effects and our understanding of passive self-ligating systems. This is especially critical regarding the use of extractions in combination with these systems.

2.8 Preformed archwires

Classifying the shape of a dental arch remains controversial as the use of a specific method varies between clinicians (Fujita *et al*., 2002). The 3 main arch form shapes that have been identified to describe cases are: tapered, ovoid and square (Chuck, 1934). However, there is not a standardised criteria established to classify dental arches according to shape yet (Arai and Will, 2011).

Mughal *et al.* (2021) conducted a cross-sectional study that compared preformed archwires of 10 manufacturers to natural dental arch forms of 52 Pakistani subjects.
They found that the archwires used in the maxilla were significantly wider at the inter-canine and inter-molar width compared to the dental casts of the subjects. In the mandible it was at the inter-canine width where the preformed archwires were significantly bigger compared to the dental casts. The mean inter-molar width in the mandible were similar between the preformed archwire and the dental casts.

Ahmed, Shaikh and Fida (2019) conducted a similar study to assess the adherence of preformed archwires to mandibular dental arch form in a Pakistani sample. The preformed archwires were wider at the inter-canine and inter-premolar width, however, the preformed archwires were narrower at the inter-molar width.

Tachi *et al.* (2021) conducted an in vitro study to evaluate the orthodontic forces that various preformed archwires exerted onto the brackets. The study assessed the forces exerted onto the central incisors, canines and first molars of the mandible. They found a significant correlation between the arch width measurements of 63 preformed Nickel Titanium archwires and the forces delivered to the central incisors, canines and first molars.

Braun *et al.* (1999) reported that 3M Unitek's Orthoform I and II and Ormco's Broad arch form wires are significantly wider at the inter-canine and inter-molar widths compared to the dental arch width of Caucasian patients.

To reduce buccal corridors and enhance smile attractiveness, the Damon system arch form is wider in the premolar segments to allow for more premolar expansion (Damon and Keim, 2012). Lucchese *et al.* (2019) reported that the change in transverse dimensions in the maxilla and mandible were similar and mentioned that it may be attributed to the use of the same broad archwires (Ormco) for shape and size.

CHAPTER 3

Research design and methodology

3.1 Aim and objectives

To compare the change in transverse arch dimensions of non-extraction and second premolar extraction cases before and after treatment, where the Damon passive self-ligating orthodontic system was used

3.2 Objectives

A. determine the transverse change in dental arch width of the maxilla and mandible in non-extraction cases before and after treatment
B. determine the transverse change in dental arch width of the maxilla and mandible in second premolar extraction cases before and after treatment
C. compare the change in the transverse dental arch width of the non-extraction and premolar extraction groups to each another

3.3 Research hypothesis

The null hypothesis for this study is that there is no significant difference regarding the change in transverse arch dimensions before and after treatment when comparing non-extraction and premolar extraction cases treated with the Damon system.

3.4 Study design

A retrospective descriptive study describing the change in transverse dental arch dimensions from the start to completion of treatment in subjects treated with and without second premolar extractions using the Damon system.

Pre-treatment (T1) and post-treatment (T2) study models of the mandible and maxilla of non-extraction and second premolar extraction cases were measured. The measurements, in mm, were carried out by one operator using a digital calliper correct to the first decimal. Models were placed on a flat surface, and the calliper was perpendicular to the occlusal surfaces for measurements. There were 6 variables measured in this study consisting of 3 in the maxilla and 3 in the mandible:

- inter - canine width
- inter - first premolar width
- inter - first molar width

The reference points for the measurements were:

- incisal tips of canines
- buccal cusp tips of first premolars
- mesiobuccal cusp tips of first molars

All cases should have been finished where finishing archwires were contoured with the aid of predetermined arch shapes to ensure symmetry, as well as making use of digital scans 1:1 pre-treatment models showing the WALA ridge. There are variations in wire sequencing. No auxiliaries were used besides intra-oral elastics.

3.5 Sampling technique

Cases were assembled from a single orthodontist. The subjects were randomly selected in a time frame of 3 years within their respective categories. This was done to ensure that the techniques applied during treatment were as consistent as possible.

3.6 Sample size

The study consisted of 100 completed cases treated with the Damon system.
The study contained 2 groups of 50 subjects, each

- group NE consisting of non-extraction cases
- group Ex consisting of all 4 second premolar extraction cases

3.7 Inclusion criteria

- Informed consent
- Patients treated by the same orthodontist using the Damon passive self-ligating system and Damon archwires
- No previous functional appliances or orthognathic surgery
- Age 13+
- Class I, II, III dental malocclusion
- Males and females
- Cases treated non-extraction
- Cases treated with all 4 second premolar extractions
- Extraction spaces closed, and contact established between adjacent teeth
- Acceptable pre- and post- treatment orthodontic study models

3.8 Exclusion criteria

- Presence of dental anomalies, e.g., congenitally missing laterals
- Fillings on the designated teeth required for transverse measurements
- Craniofacial deformities
- Patients not treated with the Damon passive self-ligating system
- Patients treated outside of the designated orthodontic practice

3.9 Ethics approval and consent

The research protocol was submitted to the Biomedical Research Ethics Committee (BMREC) of the University of the Western Cape for approval as a registered Masters research project. Approval from the BMREC was received on 10 November 2021 for the duration of 10 November 2021 – 10 November 2024. Ethics reference number: BM21/9/18 (Appendix A).

Informed consent has been signed and given verbally to all patients before starting treatment (Appendix B). The subjects were completely anonymous, as names were replaced by numeric values 1 – 50 per group.

Subject information gathered during the research is confidential. Data that may be used in a law or scientific journal will be anonymous, with no information available that may risk the identification of subjects. Research datasets will be kept for 5 years after the completion of the original project.

3.10 Research instruments

Pre- and post-treatment orthodontic study models
Digital calliper correct to the first decimal

3.11 Data collection

All data were obtained through one orthodontic practice with one practising orthodontist.
Only data from cases with informed consent were considered.
Records required for participation were pre- and post-treatment orthodontic study models of non-extraction and second premolar extraction cases.
Subjects treated with the Damon orthodontic system.
Data is handled in accordance with UWC policies and legal, ethical, regulatory and contractual obligations.
Research data was captured via data capturing sheets (Appendix C and D).
Research data entered were allocated numbers for participants to ensure anonymisation to protect the subjects' identities.
In compliance with the POPI Act, study models are stored securely in a storeroom.
The research computer is password encrypted as well as firewall protected.
Research datasets will be kept for 5 years after the completion of the original project.

3.12 Data analysis

3.12.1 Pilot study

A pilot study containing 2 groups - 1 extraction and 1 non-extraction - of 15 study models each were measured and sent to a statistician to estimate sample size.

3.12.2 Statistical methods

The data was sent to a private statistician for analysis. Statistical analysis was performed with NCSS 2022, version 22.0.3, for Windows 10 (IBM, Chicago, USA).

Descriptive statistics for age, gender, pre-treatment values and each of the 6 variables were given in table form, including graphical illustrations of intra-group changes observed in the form of scatter plots. The Paired *t*-test was used to compare the changes seen intra-group (Appendix G, H).

Inter-group changes and significance per variable were presented in table form and graphically illustrated with the use of box plots.
The Two-sample t-test was the statistical test used to compare the changes in arch width between the 2 groups to assess whether the different treatment modalities yielded similar results and whether it was of significance. The tests were carried out for the inter-canine, inter-premolar and inter-molar widths of mandible and maxilla (Appendix G, H).

Intra-rater reliability was assessed by remeasuring 11 cases and using Stem and Leaf plots to display the variation between the initial and repeat measurements (Tables 10, 11, Appendix E). One variable, the pre-treatment inter-canine width of group NE, was measured at 7 different time points. This was done to assess the reliability and variation within measurements by employing a *t*-test (Appendix F).

The confidence interval was set at 95%, and the significance threshold was set at $p \leq .05$

3.13 Limitations of the study

This study used the cusp tips to measure arch widths, as in the case of Basciftci *et al*. (2014) and Kim and Gianelly (2003). This can affect the interpretation of results as it does not explain clearly whether the expansion occurred via bodily movement or tipping of the crowns (Lucchese *et al*. (2019).

CHAPTER 4

Results

4.1 Sample size

The study consisted of 100 completed cases treated with the Damon system.

The study contained 2 groups of 50 subjects each

- group NE consisting of non-extraction cases
- group Ex consisting of all 4-second premolar extraction cases

4.2 Demographic description of sample size

4.2.1 Age

The age of the sample size varied from 13 to 33 years old. The mean age of group NE at the start of treatment was 14.18, with the youngest subject 13 years of age and the oldest 32. The subjects in group Ex were older, with a mean age of 15.82 and with a broader standard deviation. The youngest subject was 13 years of age, and the oldest was 33.

Table 1. Descriptive statistics of Age. Data are presented as mean (SD)

	Non-extraction *n* = 50	Extraction *n* = 50
Age	14.18 (2.89)	15.82 (5.61)

4.2.2 Gender

The study contained more female (n = 58, 58%) than male (n = 42, 42%) subjects. In both the extraction and non-extraction study groups, the male and female count were identical, with 21 males (42%) and 29 females (58%) per group.

Table 2. Descriptive statistics of Gender. Data are presented as n (%)

Gender	Non-extraction *n = 50*	Extraction *n = 50*	Total n (%) *n = 100*
Male	21 (42%)	21 (42%)	42 (42)
Female	29 (58%)	29 (58%)	58 (58)

4.3 Treatment changes

4.3.1 Descriptive statistics of pre-treatment values

Mandible (Table 3)

The mean pre-treatment values for inter-canine and inter-premolar width in the mandible were smaller for group NE (25,66 and 33,10mm) than for group Ex (26,48 and 33,55mm). The opposite was seen for the inter-molar width, and it was slightly bigger for group NE (43,91mm) compared to Ex (43,12mm).

The comparison of the mean pre-treatment inter-canine widths between groups Ex and NE were statistically different, indicating that the samples were not similar (Figure 1). The comparison of the mean pre-treatment inter-premolar and inter-molar widths between the 2 groups were not statistically different, indicating that the samples were similar (Figures 2 and 3).

Maxilla (Table 4)

The pre-treatment inter-canine widths in the maxilla were almost identical, group NE (34,22mm) and Ex (34,25mm), with group Ex being 0,03mm larger. The inter-premolar and inter-molar widths were larger for group NE (40,32mm and 50,60mm) compared to group Ex (39,88mm and 49,53mm).

The comparison of the mean pre-treatment widths of all 3 maxillary variables did not differ statistically between the 2 groups, indicating that the samples were similar for all 3 variables (Figures 4, 5, 6).

Table 3. Descriptive pre-treatment characteristics of the mandible

Variable	**Non-extraction $n = 50$ mean (SD)**	**Extraction $n = 50$ mean (SD)**	***p-value* inter-group**	**Reject H_0 at $\alpha = 0.05$**	**Conclusion**
Inter-canine width	25,66 (1,96)	26,48 (3,11)	.03606	Yes	Samples were different
Inter-premolar width	33,10 (2,01)	33,55 (3,34)	.18662	No	Samples were similar
Inter-molar width	43,91 (3,04)	43,12 (3,89)	.33442	No	Samples were similar

Table 4. Descriptive pre-treatment characteristics of the maxilla

Variable	Non-extraction $n = 50$ mean (SD)	Extraction $n = 50$ mean (SD)	*p-value* inter-group	Reject H_0 at $\alpha = 0.05$	Conclusion
Inter-canine width	34,22 (2,40)	34,25 (3,44)	.62201	No	Samples were similar
Inter-premolar width	40,32 (2,44)	39,88 (3.75)	.50143	No	Samples were similar
Inter-molar width	50,60 (2,95)	49,53 (3,72)	.15154	No	Samples were similar

4.3.2 Graphical illustration of pre-treatment characteristics

Figures 1 – 6 are box plots comparing pre-treatment distribution per variable between the 2 groups. The red box represents the interquartile range. The floor of the box is in the 25th percentile, the midline represents the median, and the roof of the box is in the 75th percentile. Red dots above and below the box represents outliers. Box size represents the distribution of the cases. The upper and lower foot represents the maximum and minimum of the data set.

Figure 1 – Pre-treatment inter-canine width distribution of the mandible

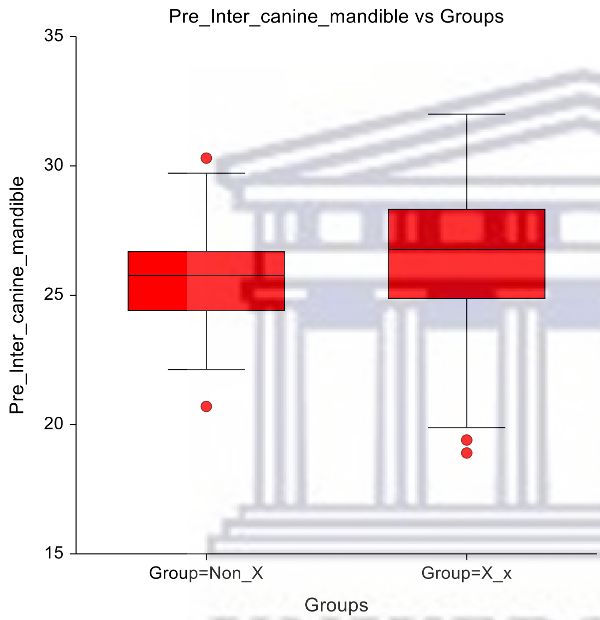


Figure 2 – Pre-treatment inter-premolar width distribution of the mandible

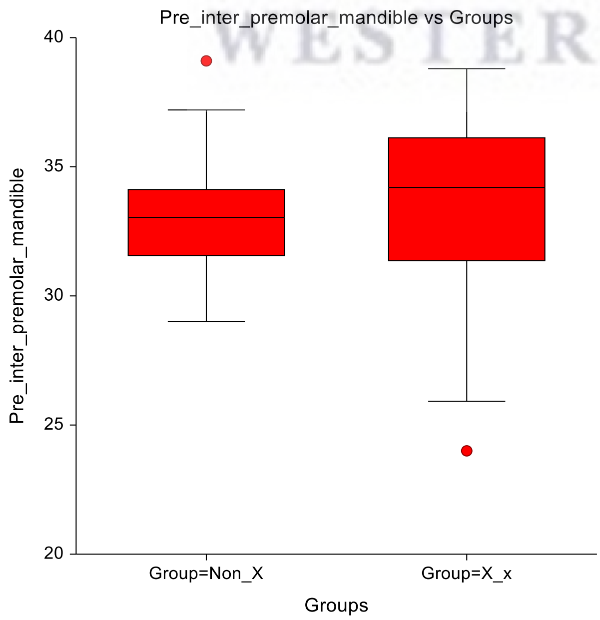


Figure 3 – Pre-treatment inter-molar width distribution of the mandible

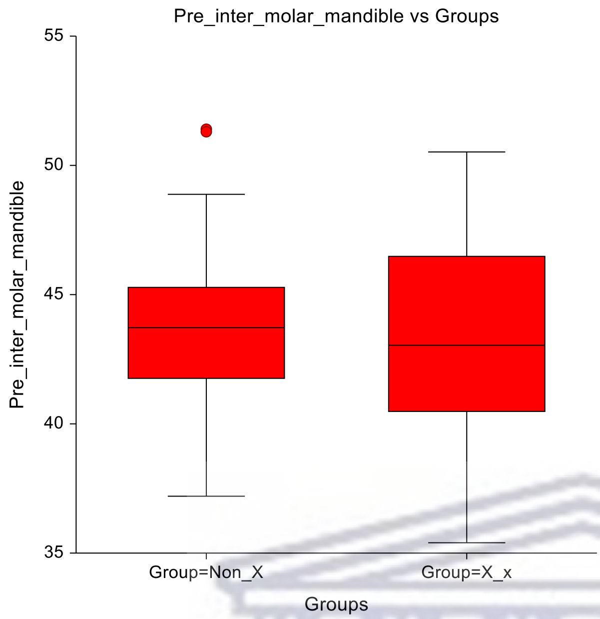


Figure 4 – Pre-treatment inter-canine width distribution of the maxilla

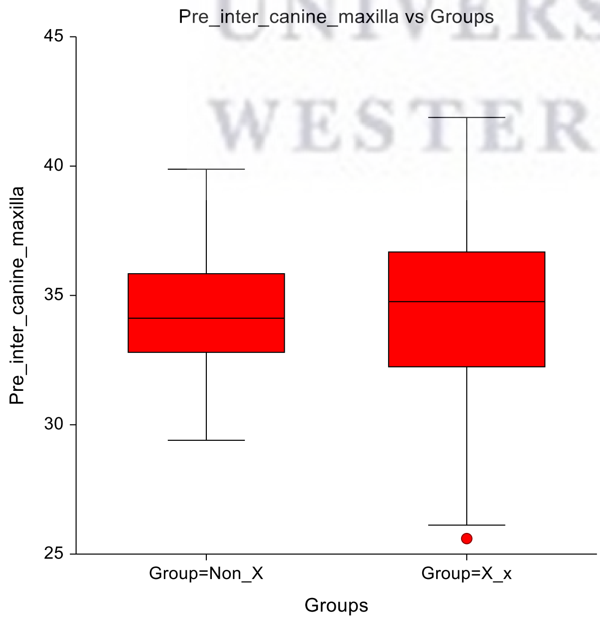


Figure 5 – Pre-treatment inter-premolar width distribution of the maxilla

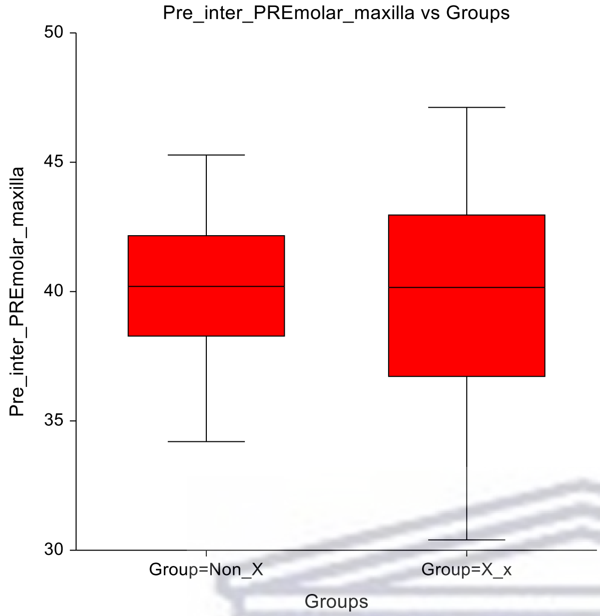
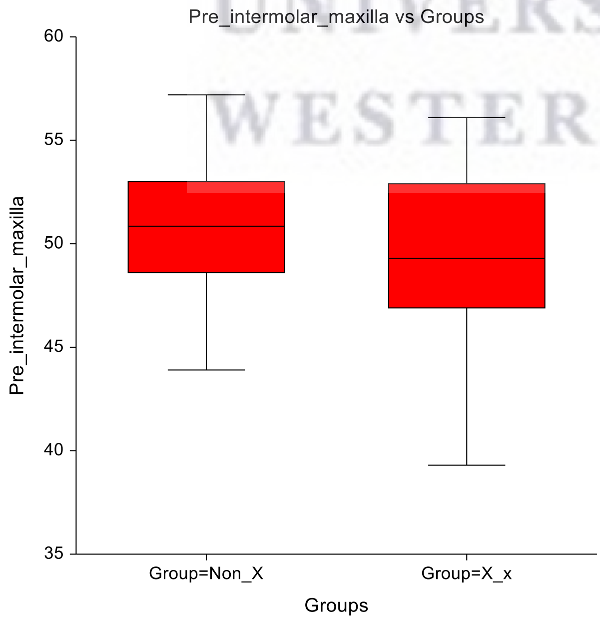


Figure 6 – Pre-treatment inter-molar width distribution of the maxilla



4.3.3 Descriptive statistics of post-treatment values

Mandible (Table 5)

The greatest mean post-treatment value was seen at the inter-molar width of group NE with 45,45mm (2,13). The smallest average width was measured at the inter-canine width of group NE with 26,61mm (1,33).

Maxilla (Table 6)

The greatest mean post-treatment value in the maxilla was seen at the inter-molar width of group NE – 52,56mm (2,30) – like that of the mandible. The smallest value was seen at the inter-canine width of group Ex, which is not the case as was seen in the mandible, where it was group NE which displayed the lowest mean value.

Table 5. Post-treatment arch widths of the mandible. Data are presented as mean (SD)

Variable	Non-extraction *n* = 50	Extraction *n* = 50
Inter-canine	26,61 (1,33)	27,14 (2,55)
Inter-premolar	34,97 (1,51)	35,12 (2,63)
Inter-molar	45,45 (2,13)	41,80 (3,60)

Table 6. Post-treatment arch widths of the maxilla. Data are presented as mean (SD)

Variable	Non-extraction *n* = 50	Extraction *n* = 50
Inter-canine	35,06 (1,77)	34,80 (3,08)
Inter-premolar	42,93 (1,69)	42,67 (2,80)
Inter-molar	52,56 (2,30)	48,24 (3,19)

4.3.4 Graphical illustration of the intra-group change in arch width

Figures 7 – 18 are scattered plots showing the change in arch width (T2 – T1) per variable. The individual observations are indicated by their numbers. A 45-degree line of equity indicates the distribution of the observations with respect to the line of equality. The observations above the line of equality indicate that the post-treatment arch widths were greater than the pre-treatment arch widths, and those below the line of equality indicate that the post-treatment arch widths were smaller than the pre-treatment arch widths.

Group NE: Figures 7 – 12

Figure 7 – Change in inter-canine width of the mandible

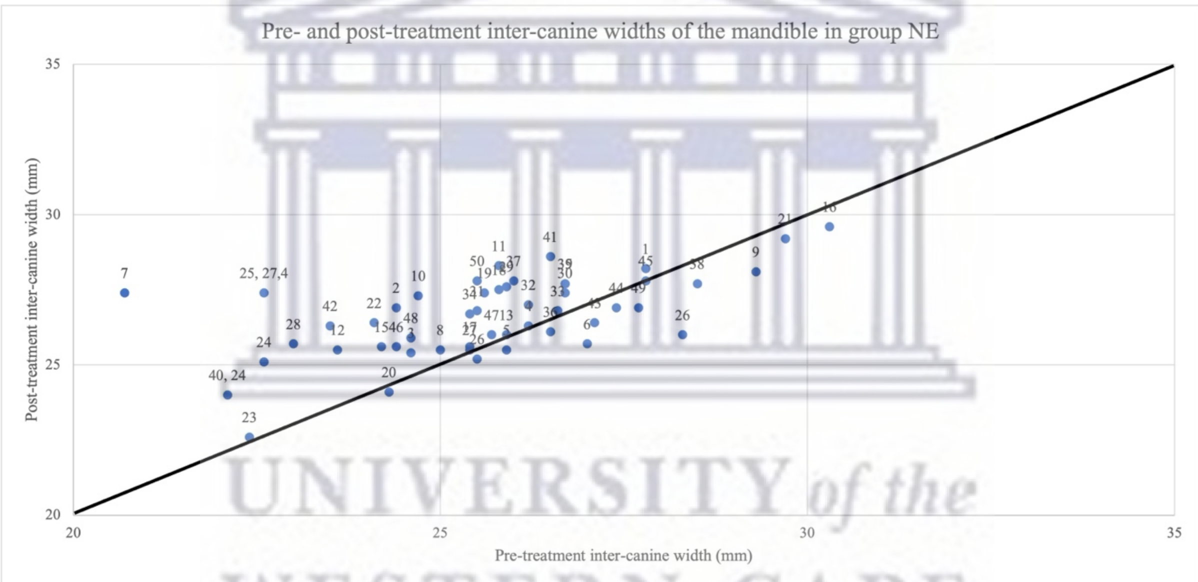


Figure 8 – Change in inter-premolar width of the mandible

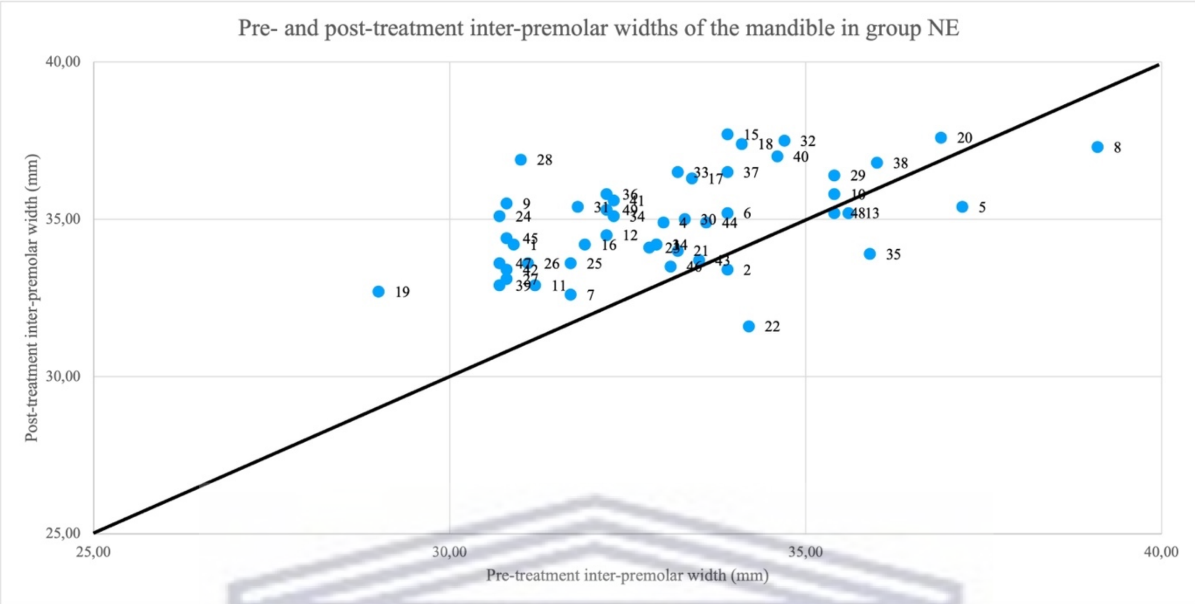


Figure 9 – Change in inter-molar width of the mandible

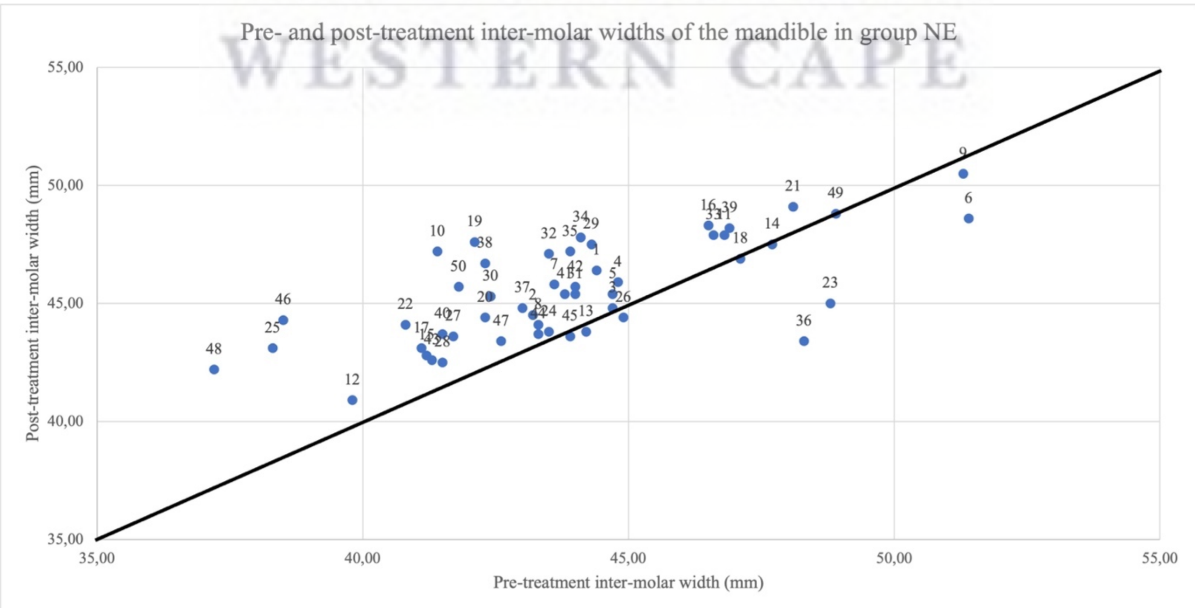


Figure 10 – Change in inter-canine width of the maxilla

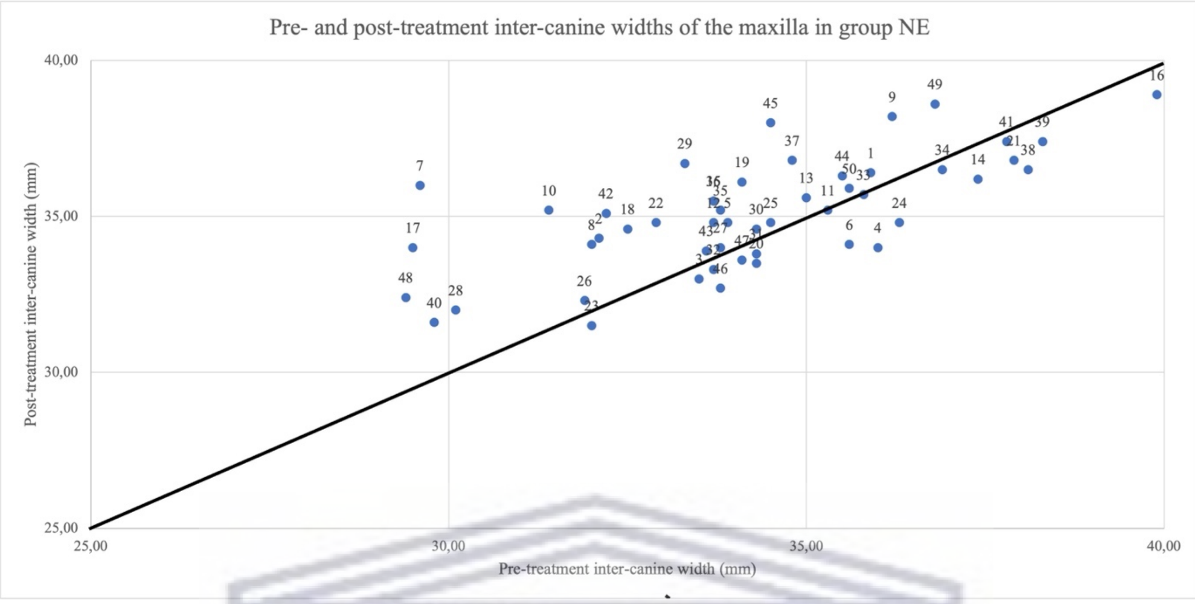


Figure 11 – Change in inter-premolar width of the maxilla

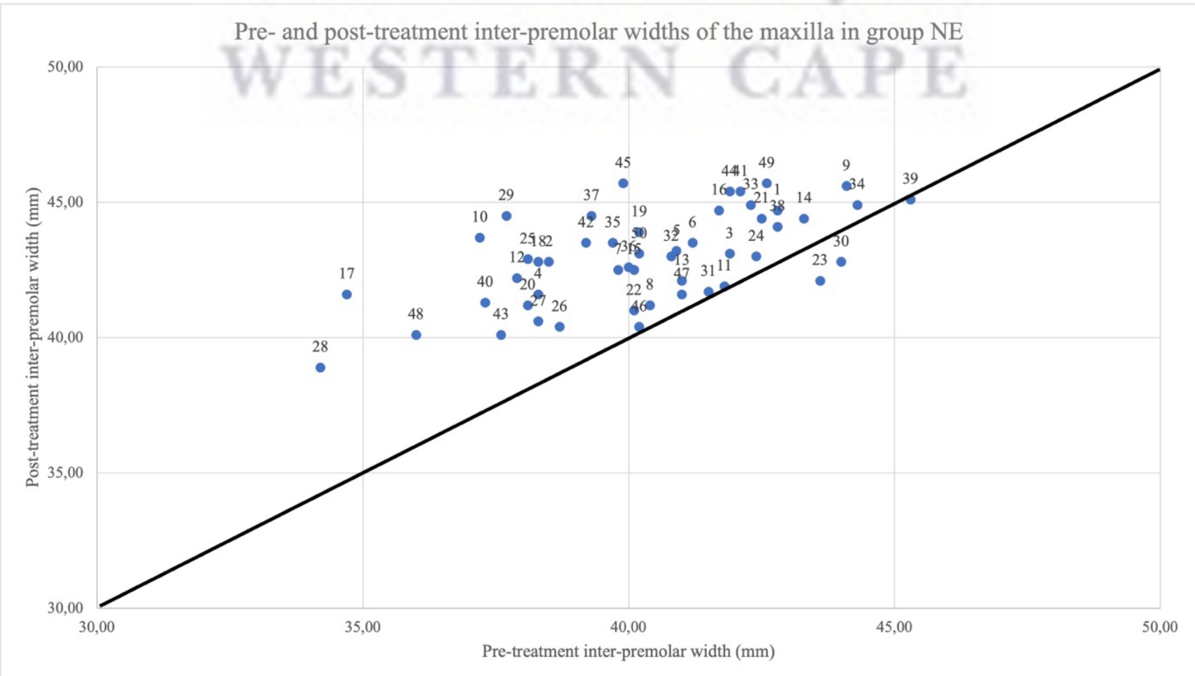
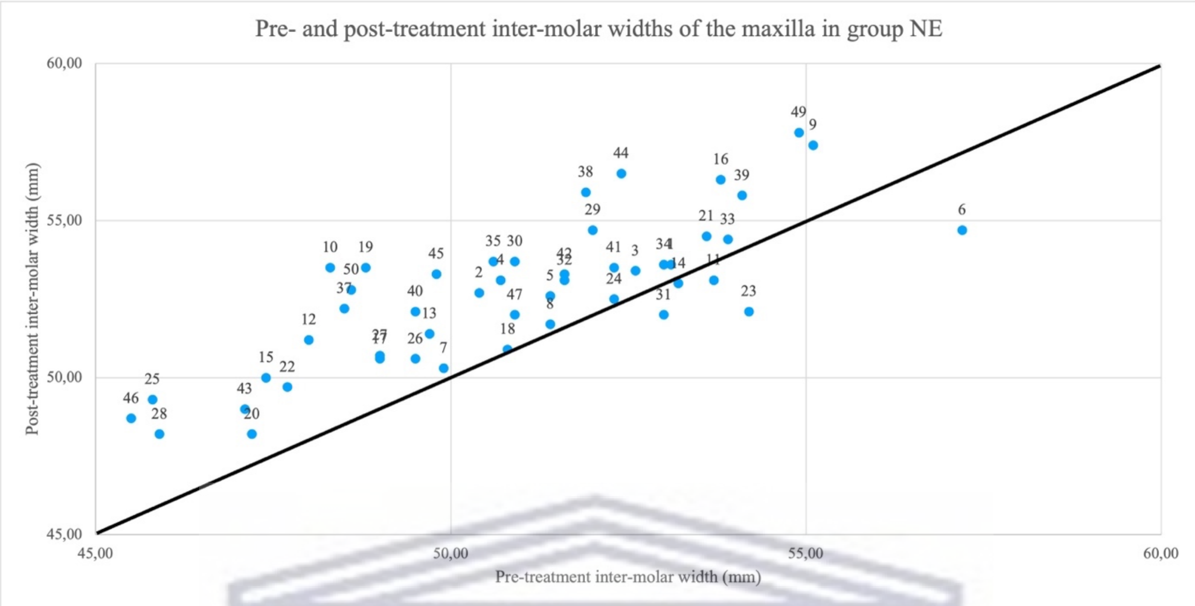


Figure 12 – Change in inter-molar width of the maxilla



Group Ex: Figures 13 – 18

Figure 13 – Change in inter-canine width of the mandible

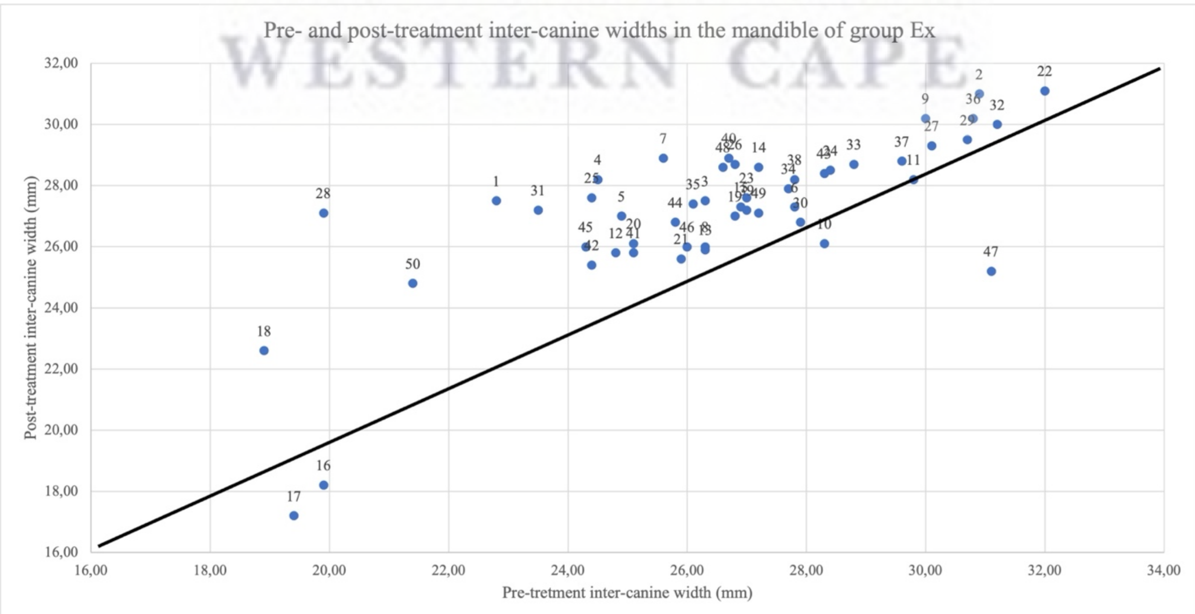


Figure 14 – Change in inter-premolar width of the mandible

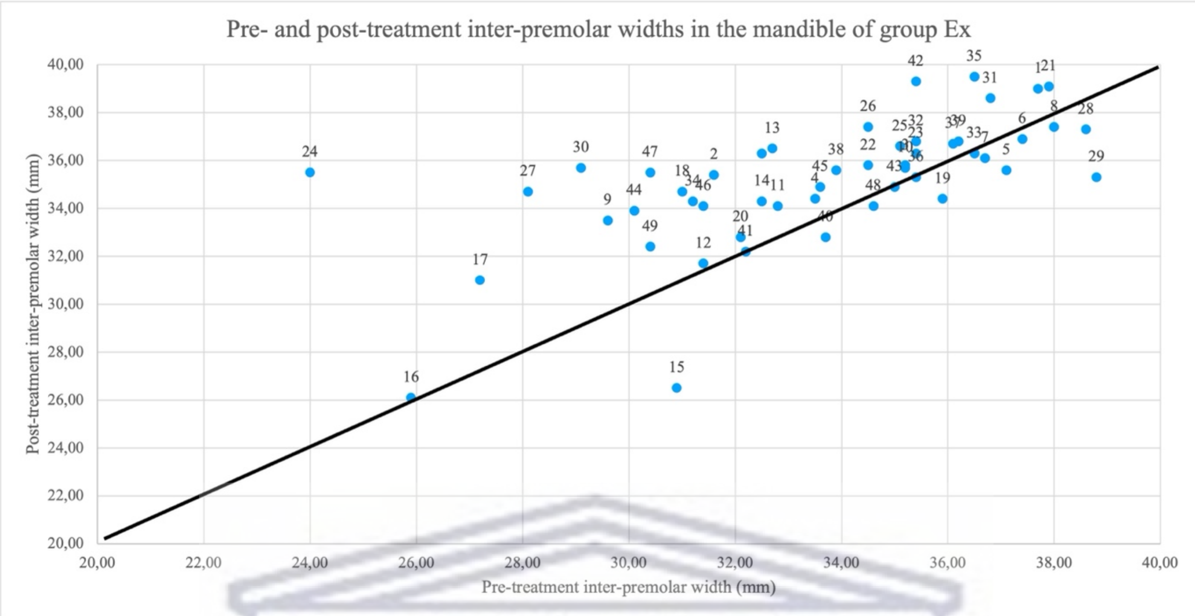


Figure 15 – Change in inter-molar width of the mandible

Figure 16 – Change in inter-canine width of the maxilla

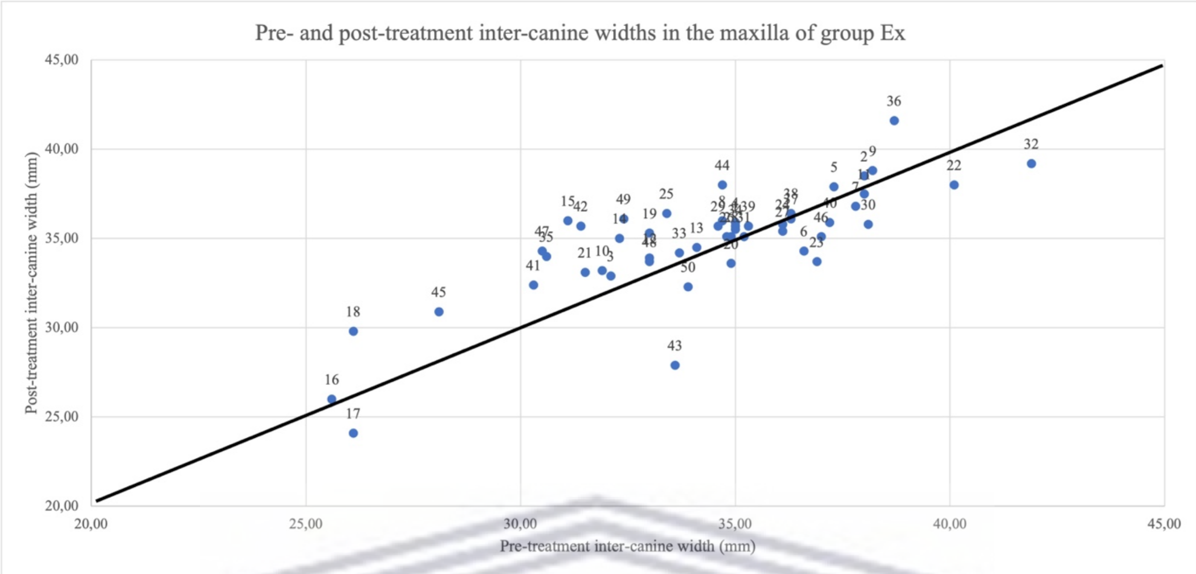


Figure 17 – Change in inter-premolar width of the maxilla

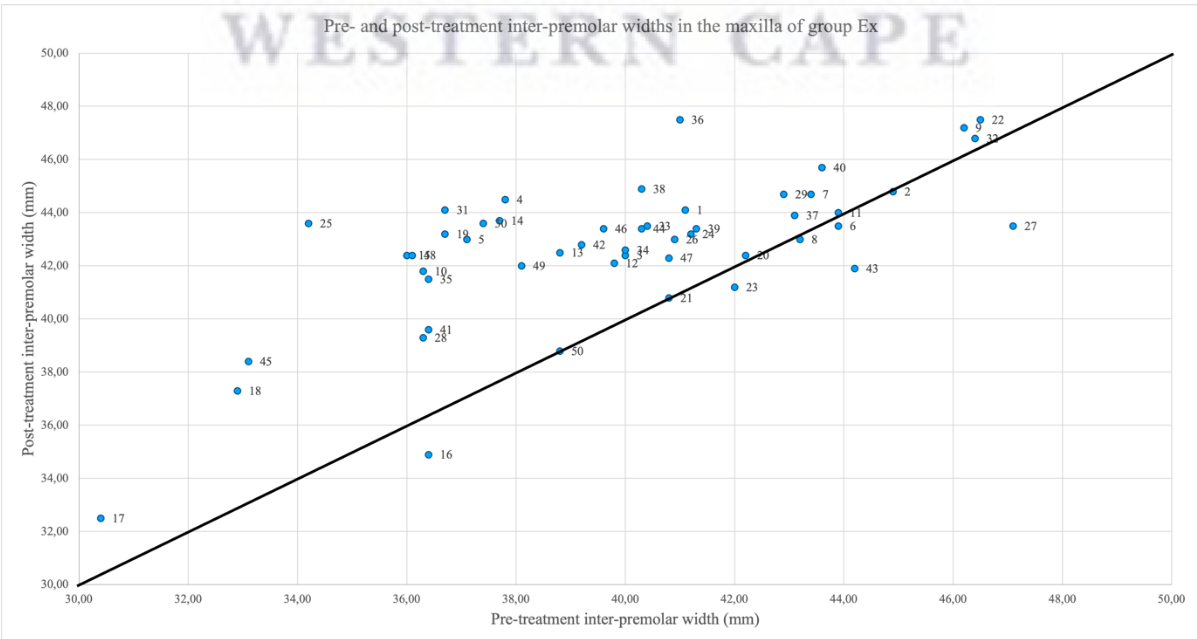
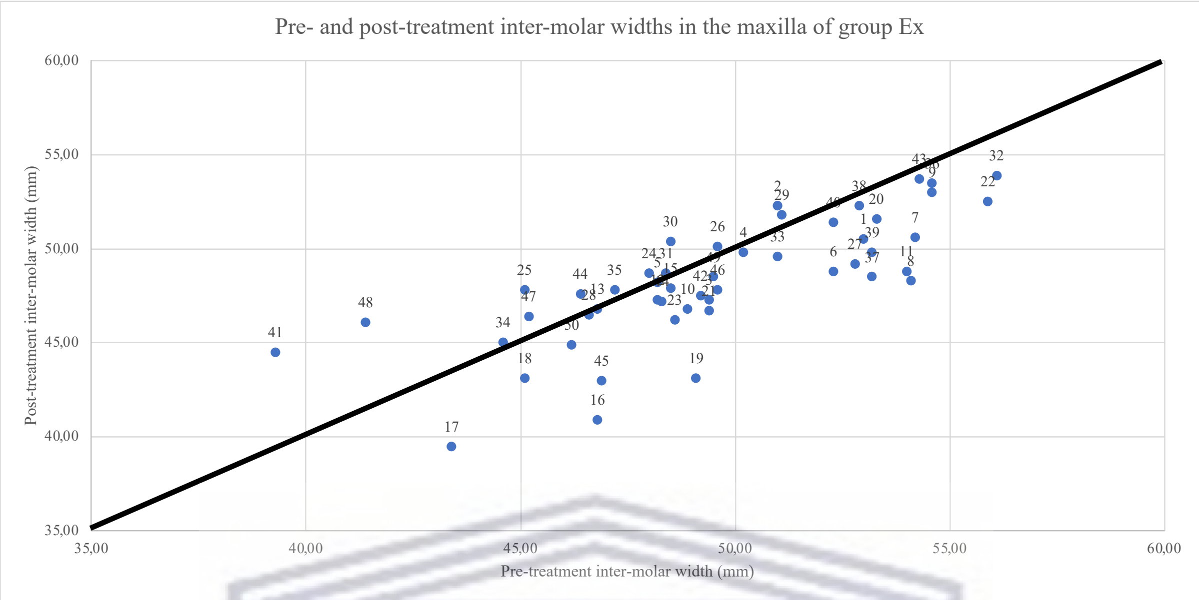


Figure 18 – Change in inter-molar width of the maxilla



4.3.5 Statistical significance of intra-group changes in arch width

Mandible (Table 7, Figures 7 – 9; 13 – 15)

All 3 transverse dimensions in the mandible increased in group NE. The inter-premolar width (1,86mm) showed the highest increase. All 3 of these dimensional increases proved to be of statistical significance.

Similarly, the inter-canine and inter-premolar widths increased in group Ex. Both these increases were statistically significant (p = .02899 and p = .00012). As in the case of group NE, the inter-premolar width (1,56mm) again displayed the highest increase. The inter-molar width decreased on average by 1.32mm and was also of statistical significance (p = .00357)

Maxilla (Table 8, Figures 10 – 12; 16 – 18)

In group NE, all 3 transverse dimensions increased and were statistically significant.

In group Ex, the inter-canine and inter-premolar widths increased, but only the inter-premolar increase was statistically significant. The increase in inter-canine width was not statistically significant.

The mean change in inter-molar width in the maxilla (-1,29mm) mimicked the change in inter-molar width in the mandible (-1,32). Both showed a statistically significant decrease in Group Ex.

The most significant transverse change in the maxilla was the inter-premolar width of group Ex (2,79mm). The most significant change observed in the mandible was the inter-premolar width of group NE (1,86mm).

Table 7. Intra-group changes in arch width of the mandible (T2 – T1). Data are presented as mean (p): Paired *t*-test

Variable	Non-extraction *n* = 50	Extraction *n* = 50
Inter-canine	0,95 *(p = .0001)*	0,66 *(p = .02899)*
Inter-premolar	1,86 *(p < .001)*	1,56 *(p = .00012)*
Inter-molar	1,54 *(p = .00001)*	-1,32 *(p = .00357)*

Table 8. Intra-group changes in arch width of the maxilla (T2 – T1). Data are presented as mean (p): Paired *t*-test

Variable	Non-extraction *n* = 50	Extraction *n* = 50
Inter-canine	0,84 *(p = .00151)*	0,55 *(p = .0768)*
Inter-premolar	2,61 *(p < .001)*	2,79 *(p < .001)*
Inter-molar	1,96 *(p < .001)*	-1,29 *(p = 0.00046)*

4.3.6 Graphical illustration of inter-group differences

Figures 19 – 24 are box plots showing the difference in distribution per variable between the 2 groups.

Figure 19 – Inter-canine width comparison of the mandible

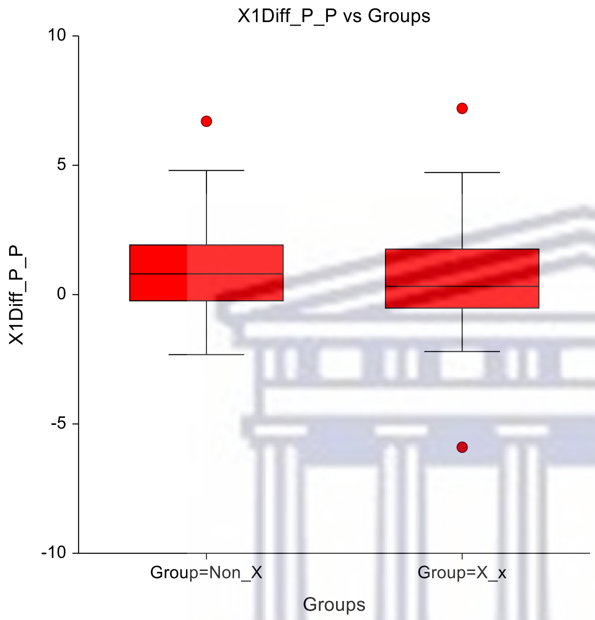


Figure 20 – Inter-premolar width comparison of the mandible

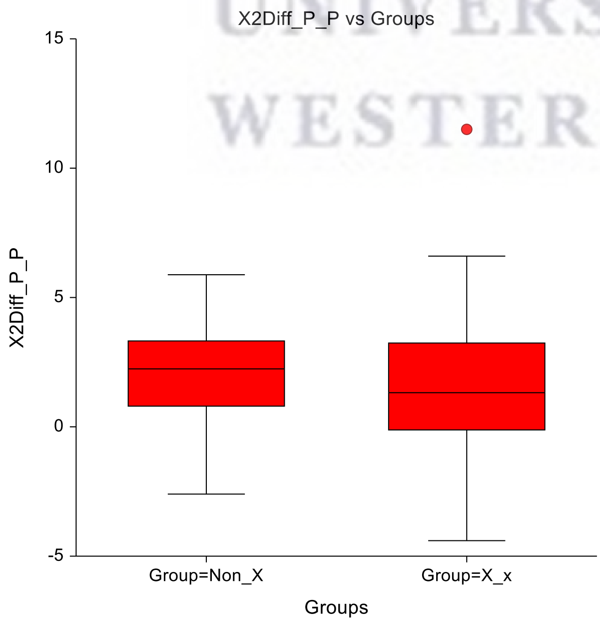


Figure 21 – Inter-molar width comparison of the mandible

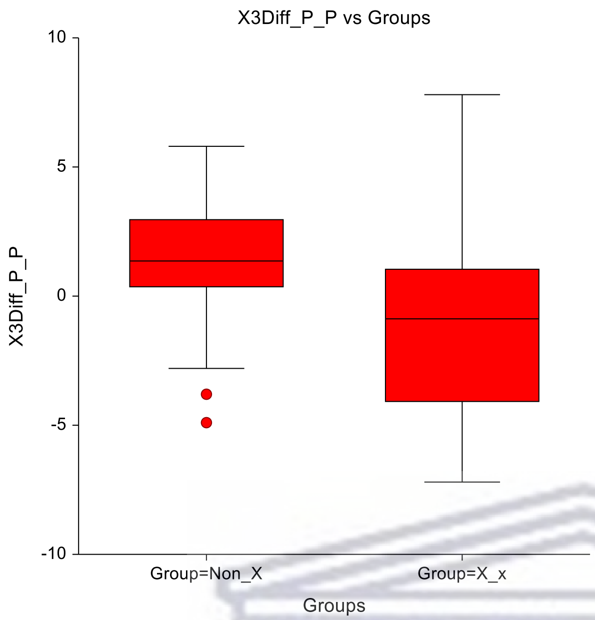


Figure 22 – Inter-canine width comparison of the maxilla

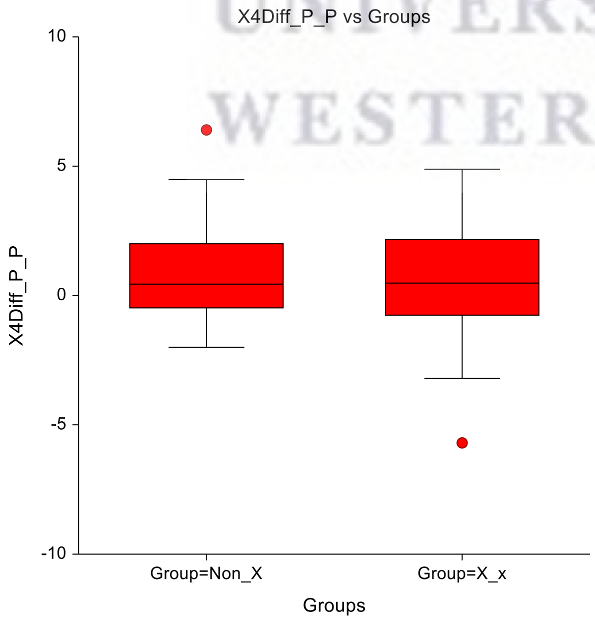


Figure 23 – Inter-premolar width comparison maxilla

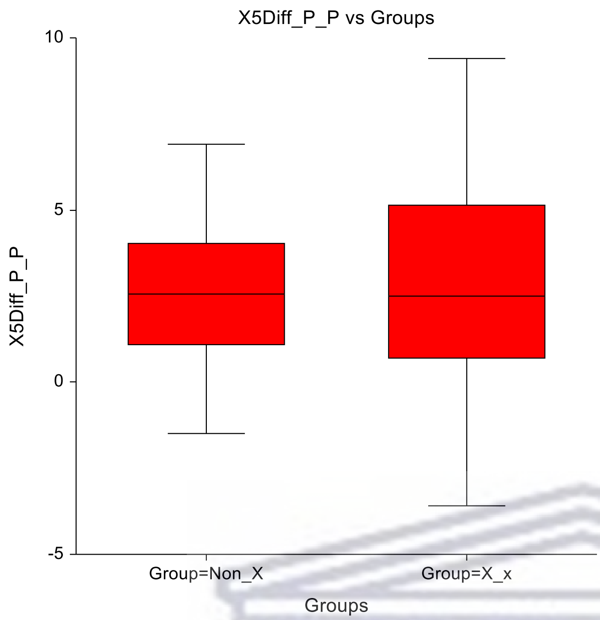
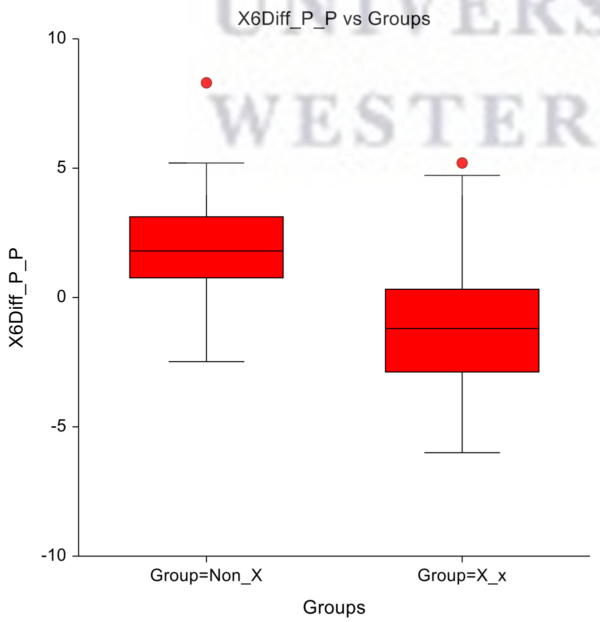


Figure 24 – Inter-molar width comparison of the maxilla



4.3.7 Statistical significance of inter-group differences

Mandible (Table 9, Figures 19, 20, 21)

The comparison between Group Ex and NE regarding the change in the inter-canine width of the mandible yielded similar results. The 2 treatment modalities are not statistically different from one another, and the treatment outcomes were similar. Furthermore, the change in inter-premolar width produced similar findings where the treatment modalities were similar and not statistically different from one another. On the other hand, the changes observed in inter-molar width between the 2 groups were different and statistically significant.

Maxilla (Table 9, Figures 22, 23, 24)

The comparison between group Ex and NE regarding the change in inter-canine and inter-premolar width resembles the results seen in the mandible. There is no statistical difference between the change in inter-canine width of group Ex and NE, and the outcomes were similar. The same description applies to the change in inter-premolar width although the amount of expansion experienced in the mandible is less when compared to the maxilla. Similar to that reported in the mandible, it can be noted that there is a statistical difference between the change observed in the inter-molar width between the 2 groups, indicating that the outcomes were not similar.

Table 9. Statistical significance of inter-group differences (T2 – T1): Two-sample t-test

Variable	*p – value*	Reject H_0 at $\alpha = 0.05$	Conclusion
Inter-canine			
Maxilla	= .74063	No	Similar
Mandible	= .33940	No	Similar
Inter-premolar			
Maxilla	= .87943	No	Similar
Mandible	= .23543	No	Similar
Inter-molar			
Maxilla	< .001	Yes	Different
Mandible	< .001	Yes	Different

4.3.8 Intra-rater reliability

One variable, the pre-treatment inter-canine width of the mandible in group NE, was measured at 7 different time points to analyse the variation and reliability of the measurements. The average difference in measurements was -0,01mm. There was no absolute difference greater than 0,22mm. Two of the absolute differences were 0. All absolute differences are within the 0,0mm – 0,22mm interval. The probability that a measurement falls outside this range is improbable ($p = 0.0078125$) (Appendix F).

Tables 10 and 11 are Stem and leaf plots showing the variation between the initial and repeat measurements of the 11 cases that were remeasured for the mandible's pre- and post-treatment inter-molar width. See Appendix E for all variables and respective Stem and leaf plots. The average difference for pre-treatment measurements was 0,26mm and a median of 0,3mm. Furthermore, for post-treatment measurements, 0,2mm and a median of 0,2mm.

Table 10. Observation distribution of differences of pre-treatment inter-molar width measurements of the mandible in group NE

Observation distribution of Differences			
Stem	**Leafs**	**Frequencies**	
-0,1	X	1	
0.0	X	1	
0,1	XXX	3	
0,3	X	1	
0,4	XXX	3	
0,5		**0**	
0,6	XX	**2**	
	Total observations	11	

Table 11. Observation distribution of differences of post-treatment inter-molar width measurements of the mandible in group NE

Observation distribution of Differences			
Stem	**Leafs**	**Frequencies**	
-0,1	X	**1**	
0.0	XXX	**3**	
0,1		**0**	
0,2	XX	**2**	
0,3	XX	**2**	
0,4	XX	**2**	
0,5	X	**1**	
	Total observations	11	

CHAPTER 5

Discussion

5.1 Age comparison

The mean age for the current study was 14.18 for group NE and 15.82 for group Ex. This is in keeping with studies carried out by Sillman (1964), Bishara et al. (1998) and Carter and McNamara (1998), which conducted longitudinal studies to evaluate arch dimensional changes in untreated orthodontic subjects.

These studies proved that transverse dental arch dimensions such as inter-canine, premolar and molar dimensions develop until the secondary dentition is established. Once the mandibular central and lateral incisors have erupted, the mandibular dental arch width is established with little change in the inter-canine dimension expected.

The effects of growth were not a factor for the current study as the mean age for both treatment groups were over the age of 14 (Lee, 1999). Behrents (1984) has mentioned that there are arch dimensional changes throughout life, albeit at a smaller rate than in adolescence.

5.2 Arch width changes in the maxilla

5.2.1 *Non-extraction comparison*

The inter-canine width of group NE increased on average by 0,84mm and was regarded as statistically significant (*p = .00151)*. Studies conducted with similar results, albeit with a higher degree of change but also statistically significant, those of Atik and Ciger (2014), Atik *et al.* (2016), Cattaneo *et al.* (2011), Fleming (2013), Tecco *et al.* (2009) and Vajaria *et al.* (2011). The increase in inter canine width in these studies ranged from 1,40 – 3,30mm, which is substantially larger compared to the current study, which was only 0,95mm. On the other hand, Shook *et al.* (2016) conducted a similar study and found a decrease in inter-canine width of 0,29mm. However, this was not statistically significant.

The maxillary inter-premolar width increased in both treatment groups. The most significant change in arch width per treatment group also occurred at the premolars. The mean change was quantified as an increase of 2,61mm for group NE and 2,79 for group Ex. Both these changes were statistically significant ($p < .001$ for both groups).

These findings are in keeping with studies conducted by Romero-Delmastro *et al.* (2017), Byun (2019), Fleming (2013) and Tecco *et al.* (2009) whom reported the greatest increase in arch width occurred at the inter-premolar width. The abovementioned authors reported the following increases in this dimension: 4,6mm, 4,39mm, 4,51mm and 4,3mm respectively.

Romero-Delmastro *et al.* (2017) compared the effects of conventional, passive self-ligating and active self-ligating bracket systems on patients treated non-extraction. The study reported that the inter-premolar dimension showed the most significant increase in arch width in both maxilla and mandible, irrespective of the system used.

These findings are in accordance with the results of group NE of the current study, where the greatest increase was at the premolars in both the maxilla [2,61mm, *($p < .001$)*] and mandible [1,86mm *($p < .001$)*].

Lucchese *et al.* (2019) evaluated torque and transverse changes after passive self-ligating fixed orthodontic treatment in non-extraction subjects. They reported an increase in transverse dimension, most notably in the maxillary and mandibular canines and premolars. The increase was associated with a significant positive torque gain, especially at the premolars in the maxilla. All teeth in the mandibular arch, notably the first and second premolars, showed significant torque changes. The only teeth that did not were the central incisors.

Basciftci *et al.* (2014) conducted a similar study to Lucchese *et al.* (2019) and obtained similar results. However, the arch width measurements were only linear and did not consider inclination. Similarly, the current study only used a linear measurement, preventing one from determining whether the movement was that of a bodily or axial nature.

The increase in transverse dimensions is in line with the current study. However, the changes experienced in the studies mentioned above were greater compared to the current study. Basciftci *et al*. (2014) reported a mean increase of 5,08mm and Lucchese *et al.* (2019) reported a mean increase of 3,80mm at the inter-premolar width compared to the current study's 2,61mm.

The average maxillary inter-molar change for group NE was 1,96mm and is of statistical significance *(p < .001)*. The studies conducted by Atik and Ciger (2014), Atik *et al.* (2016), Cattaneo *et al.* (2011), Fleming (2013), Tecco *et al.* (2009) and Vajaria *et al.* (2011) all showed an increase in the inter-molar width.

The change in inter-molar width - from the start to completion of treatment - in these studies ranged from 1,22mm in the multi-centre randomised controlled trial conducted by Fleming (2013) till 3,43mm in the prospective clinical trial carried out by Atik *et al.* (2016). All these changes were statistically significant and supported the current study's findings, showing that the current study documented values that were within this range.

5.2.2 *Extraction comparison*

Due to scant literature on changes in arch dimension using extraction protocols associated with passive self-ligating systems such as the Damon system, the comparisons that follow are from studies where extraction protocols were used with conventional edgewise appliances.

The average increase seen at the maxillary canines for group Ex was 0,55mm; however, this was not significant *(p = .0768)*. A study conducted by Oz *et al.* (2017) reported a similar outcome of a 0,22mm increase in the inter-canine width when comparing 3D models of all four first premolar extraction and non-extraction subjects. This finding did not reach the significance threshold of (*p = .05*) either. Herzog *et al.* (2017) reported a mean increase in inter-canine width of 1,90mm (*p < .001)* in the extraction group when comparing arch width changes in extraction and non-extraction class I borderline cases. Meyer *et al.* (2014) reported a mean increase in inter-canine width of 1,54mm and of statistical significance (*p < .01)* in their study assessing maxillary arch width and buccal corridor changes between premolar extraction and non-extraction treatment outcomes. Shirazi *et al.* (2016) noted a significant increase in the inter-canine width in their extraction group of the study assessing the change in arch width in patients with Class II division 1 malocclusion. The increase was significant at 3,20mm (*p = .001)*. The findings of Herzog *et al.* (2017), Meyer *et al.* (2014) and Shirazi *et al.* (2016) all support the findings of the current study regarding maxillary inter-canine width expansion of 0,55mm of group Ex, albeit the amount of expansion reported in the respective studies being greater than the current study.

The most significant increase in arch width occurred at the inter-premolar width of both groups, Ex and NE. In group Ex, the average increase was 2,79mm in the maxilla and was deemed statistically significant *($p < .001$)*. Işık *et al.* (2005) recorded a small, almost indistinguishable increase in the premolar width of 0,03mm.

Although small, it was deemed highly statistically significant (*$p < .001$)*. Meyer *et al.* (2014) reported a significant increase in this dimension of 3,85mm (*$p < .01$)*.

Oz *et al.* (2017) experienced a more modest increase of 0,31mm but was deemed not significant. In contrast, Kim and Gianelly (2003) found an average decrease of 0,76mm in inter-premolar width. Mac Kriel (2008), assessing arch dimensional changes of extraction and non-extraction treatment between 3 groups - of which 2 were extraction protocols - found that the inter-premolar width decreased in both groups. In the group of all 4 first premolar extractions, the width decreased by 1,01mm, and in the group where maxillary 4's and mandibular 5's was removed, it decreased by 0,29mm.

In the current study, the maxillary inter-molar arch width significantly decreased after treatment, on average, by 1,29mm *($p = .00046$)*. Shirazi *et al.* (2016) experienced similar results, with a more modest amount of constriction of 0,56mm (*$p < .001$)*. Herzog *et al.* (2017) further support these findings with a mean reduction in inter-molar width amounting to 0,69mm (*$p < .001$)*. Meyer *et al.* (2014) further bolster these findings by reporting a mean reduction of 0,60mm; however, this was not deemed statistically significant. Işık *et al.* (2005) also noted a decrease of 0,88mm (*$p < .001$)* in inter-molar width. The change in inter-molar arch width of the studies mentioned above all supplement the current study's findings. However, the amount of arch constriction was greater in the current study compared to the authors' results mentioned above. A plausible explanation for this phenomenon could be the fact that the extraction groups of the abovementioned authors – bar Meyer *et al.* (2014) – made use of first premolar extractions and not second premolar extractions as reported in the current study. There is less chance of the maxillary first molars moving more anterior in the arch.

In contrast, the inter-molar width increased in the study conducted by Oz *et al.* (2017) with 0,81mm and was significant ($p < .001$).

5.3 Arch width changes in the mandible

5.3.1 *Non-extraction comparison*

The inter-canine width increased in both study groups. Group NE showed a mean increase of 0,95mm; although modest, it is highly significant statistically *($p = .0001$)* as well as clinically. Basciftci *et al.* (2014) had a similar increase of 0,83mm (*$p = .024$)* in their study to evaluate the long-term stability of dental, skeletal and soft tissue changes after non-extraction self-ligating therapy. The final stainless steel archwires placed in the mandible were contoured according to the initial arch form. Similar findings in the study, as mentioned earlier, and the current study can be attributed to the contouring of the finishing archwire according to the initial anatomy of subjects.

In the study conducted by Romero-Delmastro *et al.* (2017), the mandibular inter-canine width increased by a significant 1,8mm (*$p = .015$).* Lucchese *et al.* (2019) reported similar findings, with a mean increase of 1,5mm from cusp tip to cusp tip. However, not statistically significant (*$p < .01$).* Lineberger *et al.* (2016) reported a mean increase of 1,7mm, which was statistically significant *($p < .001$).* Pandis *et al.* (2010) also found a mean increase of 1,7mm (*$p < .01$)* in their study assessing the changes occurring in the mandibular arch associated with crowding using self-ligating and conventional brackets. In a separate study, Pandis, Polychronopoulou and Eliades (2007) conducted a prospective clinical trial to evaluate treatment duration and dentoalveolar effects using passive self-ligating and conventional brackets. They found a statistically significant increase in the inter-molar width and a significant increase in inter-canine width. Most of the authors, as mentioned above, reported a greater amount of inter-canine expansion in their studies compared to the current study. However, the type of change that occurred corresponds irrespective of the study.

In group NE of the current study, the inter-premolar width showed the greatest increase in the mandible, averaging 1,86mm *($p < .001$).* The cusp tip to cusp tip transverse diameter also increased in the study by Lucchese *et al.* (2019), although it did not reach the statistical threshold. Basciftci *et al.* (2014) reported a 2,66mm increase (*$p < .001$)* and Lineberger *et al.* (2016) a similar increase of 2,0mm (*$p < .001$).* Romero-Delmastro *et al.* (2017) experienced a 3mm increase (*$p = .0001$).* The abovementioned authors' findings are similar to the current study although the amount of expansion reported in the current study was less.

The inter-molar width showed a mean increase of 1,96mm *($p < .001$)* in the current study. Pandis *et al.* (2011) reported a mean adjusted width of 0,30mm between their 2 treatment groups, comparing the effects of conventional and passive self-ligating appliances on the mandibular inter-molar width.

These findings contradicted a previous study conducted by Pandis *et al.* (2007) which concluded that the self-ligating group exhibited a greater increase in inter-molar width.

The difference in these 2 findings can be ascribed to different wire sequencing and arch forms used in the respective studies. Pandis *et al.* (2011) used the same archwire sequence for both groups, while Pandis *et al.* (2007) did not.

Basciftci *et al.* (2014) reported similar results to the current study, stating a mean increase in inter-molar width of 1,92mm ($p = .001$). Lineberger *et al.* (2016) reported a slightly smaller increase of 1,2mm ($p < .001$).

5.3.2 *Extraction comparison*

The mean increase observed in inter-canine width in the mandible for this study was 0,66mm and deemed statistically significant ($p = .02899$). Işık *et al.* (2005) recorded a similar increase of 0,61mm and was also statistically significant ($p < .05$). Similarly, the study of Kim and Gianelly (2003) also supports the findings of the current study, with their study experiencing a statistically significant increase of 0,51mm ($p < .01$). Oz *et al.* (2017) further support these findings as they noted a similar increase of 0,61mm and of significance ($p = .007$).

Aksu and Kocadereli (2005) noted a more considerable mean increase of 1,79mm and was of statistical significance ($p < .05$).

Luppanapornlarp and Johnston (1993) also evaluated the change in arch dimension in Class II subjects after extraction and non-extraction therapy. They noted that although there was an increase in the mandibular inter-canine width of the non-extraction group, the width was greater in the extraction group. The opposite was seen in the current study, where although both treatment groups showed an increase in inter-canine width, the extraction group showed a smaller amount of expansion.

The inter-premolar width showed an average increase of 1,56mm ($p = .00012$) in the current study. In the study Mac Kriel (2008) conducted, the mandibular inter-premolar width of 1 of the extraction groups increased and 1 decreased.

The group where mandibular 5's were removed, the inter-first premolar width increased on average by 2,45mm (*p = .0001),* and in the group where all 4's were removed, it decreased by 1,66mm (*p = .0014).* Işık *et al.* (2005) noted a decrease, in their extraction group of all four first premolars, as well. The mean reduction of 2,65mm in the mandibular inter-premolar width was statistically significant (*p < .001).* Oz *et al.* (2017) noted a mean increase of 0,8mm which was statistically significant (*p = .015).*

A decrease of 1,32mm was seen in the inter-molar width. It was also statistically significant *(p = .00357).* Kim and Gianelly (2003) experienced a decrease of 0,94mm. Herzog *et al.* (2017) saw a decrease as well, of 1,72mm and was statistically significant (*p < .001).* Mac Kriel (2008) also experienced a constriction in arch width in both extraction groups, 2,16mm and 2,63mm, respectively. Both were deemed significant (*p < .001).*
In contrast to these findings, Oz *et al.* (2017) noted an increase of 0,9mm in the inter-molar width, which is also statistically significant (*p < .001).*
The constriction reported in the inter-molar arch width of the current study finds itself in the midrange of expansion compared to the constriction reported by the authors mentioned above, bar Oz *et al.* (2017).

5.4 Extraction vs non-extraction comparison

There was a statistically significant increase in mandibular inter-canine width in both groups. Group NE showed a greater increase in the respective width, but when the groups were compared, it was not deemed statistically significant. This result corresponds with previous studies conducted by Paquette, Beattie and Johnston (1992), Luppanapornlarp and Johnston (1993) and Bishara *et al.* (1994). In a more recent study, Oz *et al.* (2017) also reported an increase in mandibular inter-canine width, with the change between groups not being significant.

The current study showed that both groups' inter-canine width increased in the maxilla and mandible. The inter-canine width increase in the mandible and maxilla for both groups did not exceed 1mm. These increases showed no statistical difference in outcome between the groups. These results resemble Kim and Gianelly's (2003) results, reporting the same arch width increase and inter-group significance range.

Mac Kriel (2008) reported an increase in inter-premolar width in all 3 of the study groups, non-extraction, extraction of maxillary first premolars and mandibular second premolars, and extraction of all first premolars. Oz *et al.* (2017) also reported a mean increase in both maxillary and mandibular inter-premolar width of both the non-extraction and all four first premolar extraction groups. The comparison between the 2 groups showed that the increase experienced in the maxillary inter-premolar width statistically differed from the non-extraction group, which opposes the findings of the current study which reported no statistical difference when comparing the increase experienced in either group. However, the inter-group comparison of the increase in the mandible did not differ statistically and corroborated the current study's findings.

Işık *et al.* (2005) reported greater maxillary inter-premolar width expansion in the non-extraction than extraction protocols. The comparison between the expansion observed in the 2 groups was statistically significant. This opposes the current study's findings, where a greater amount of expansion occurred in the extraction than in the non-extraction group. However, when compared to one another, the outcomes did not statistically differ.

The current study observed an increase in the inter-molar width in both arches of group NE and a decrease in both arches of group Ex. These results support the findings of Bishara, Cummins and Zaher (1997). Their study investigated the effect of extraction and non-extraction treatment on the dental arch width in Class II division 1 cases. It was reported that the inter-molar width showed a constriction in both arches of the extraction group and an expansion in both arches of the non-extraction group. In contrast, Oz *et al.* (2017) reported an increase in the inter-molar width in both arches of the non-extraction as well as the extraction group, the outcomes between groups did not differ statistically.

The statistically significant difference seen for the change in maxillary inter-molar width between the groups is in accordance with a previous study conducted by Shirazi *et al.* (2016). They also reported the difference between the groups being statistically significant.

5.5 Importance of the mandibular inter-canine width

The inter-canine width of both arches in both groups did not expand excessively. The mean expansion experienced in the groups did not exceed 0,95mm, which was seen in the mandible of the non-extraction group. The mean increase observed in the extraction group was 0,66mm.

In the maxilla a similar range of expansion occurred, with the extraction group expanding on average a modest 0,55mm and the non-extraction group 0,84mm.
When compared to one another, the outcomes did not differ statistically inter-group. This is a positive result compared to the literature guidelines for altering this dimension.

Ensuring the pre-treatment inter-canine width remains intact has been thoroughly discussed in the literature. This dimension is considered necessary for ensuring post-treatment stability (Rosseto *et al*., 2009).
Minimising the amount of expansion or constriction of the initial width allows for a more stable treatment result (Weinberg and Sadowsky, 1996; Sadowsky and Sakols, 1982). The maintenance of the mandibular inter-canine width is especially critical as the relapse associated with expansion treatment is most notable at this width (Shah, 2003; Little *et al*., 1999; Hoybjerg *et al.,* 2013).

The maintenance of the inter-canine width was aided by using diagrams with predetermined arch shapes to ensure symmetry when contouring finishing archwires, as well as digital scans of the pre-treatment models showing the WALA Ridge.
Diagrams of predetermined arch shapes and sizes can be used as a guide for archwire contouring (Brader, 1972; Ricketts, 1978). Another technique to determine the arch size and shape for the mandible is through the use of the WALA Ridge concept. The concept rests on the premise of aligning the dentition in a manner which ensures the roots are placed in basal bone (Conti *et al*., 2011). The ridge is demarcated by the band of keratinized mucosa adjoining the mucogingival margin. This represents the tooth apex (Andrews, 1999).
The use of the WALA Ridge has been supported by various authors as a stable anatomical structure and reliable method in an attempt to ensure stability post-treatment (Conti *et al*., 2011; Ronay *et al*., 2008; Gupta *et al*., 2010). Moura (2010) compared the WALA Ridge values from dental study models, radiographs and CT scans. The study found no significant difference between the 3 methods. It has been shown that the WALA Ridge undergoes changes during expansion treatment, but it is still a clinically valid method (Ronay *et al*., 2008; Gupta *et al*., 2010; Kim *et al*., 2011).

5.6 Interpretation of observations

The change in inter-canine and inter-molar arch widths observed in the maxilla and mandible were similar. This was observed for both study groups. It can be attributed to using the same shaping diagram for either arch and coordinating the arches before placement.

Greater expansion occurred at the inter-premolar width, irrespective of treatment modality. This can be explained through the Damon system arch form, which is wider in the mid-posterior segments, where the premolars are situated. The aim is to reduce the buccal corridors and allow for a broader smile. The use of these broad-shaped archwires during the initial level and aligning phase could have played a role in the amount of expansion reported.

The expansion reported could also be attributed to crowding in the premolar region, and that uprighting and aligning the molars into the arch may be observed as expansion.

The contrasting results observed in the inter-molar width between the 2 study groups may be attributed to the difference in treatment modality, as this was the only dimension which showed a statistically significant difference when the study groups were compared. A statistically significant increase in this width was noted for the non-extraction group, and a statistically significant decrease was noted in the extraction group. This could be explained through the mesial movement of the molar from its original position into the extraction space anterior to it, which is a narrower segment of the arch.

CHAPTER 6

Conclusions and recommendations

The following conclusions can be derived after evaluating the results of this study:

- The study supports the research hypothesis – that treatment with a second premolar extraction protocol would result in no difference in transverse arch width changes compared to treatment with a non-extraction protocol – the exception being the change in inter-molar width between the non-extraction and extraction study group.

- The results were equivalent when comparing the change in transverse arch dimension between non-extraction and extraction cases regarding the inter-canine and inter-premolar widths.

- The Damon system is generally applied in a non-extraction manner. This study provides some evidence that a self-ligating system can be used in combination with second premolar extractions to yield an acceptable outcome without diminishing arch width and smile attractiveness

- Arch width can be controlled by contouring the finishing archwires with the use of diagrams of predetermined arch shapes and sizes and adhering to the initial anatomical limitations

The following recommendations could be considered following this study:

Statistical significance indicates that there was an effect but does not quantify the effect or describe the magnitude thereof. It only indicates that something has happened.
Effect size quantifies the magnitude of the change that occurred. In other words, it indicates how significant a change occurred.

Due to the retrospective nature of this study, one cannot report on correlation and association as the subjects in the study did not receive a random allocation of treatment modality as with a randomized controlled trial. However, subjects in the respective groups were randomly included. This can be ascribed to the fact that the data was gathered from private practice retrospectively and not in an academic setting, such as a university, for a prospective study. Retrospective data also inevitably introduce selection bias. For future studies, it can be advantageous to consider this and use these results as early indicators and encouragement for more rigorous selection criteria and research design.

This study did not use an external control group to compare dimensional changes seen in the premolar extractions group, as the practitioner only uses the Damon passive self-ligating system and no other fixed orthodontic system. The control group was the non-extraction study group. The results do not need a comparison to a control group as the effects observed are clinically relevant and can be applied in the clinical arena.

The results of this study confirm that neither the selection of appliance nor the space-creating protocol dictates arch width. Arch width can be maintained through the proper management and coordination of final archwires, taking special care to incorporate the initial arch shape into the final finishing archwire formation. Inter-canine width is key for arch stability and aesthetics. This study has confirmed that inter-canine width can be maintained irrespective of appliance or treatment protocol. Students and young practitioners need to accept this responsibility and not be influenced by the marketing information of any product. The result of treatment is first and foremost determined by the practitioner and the orthodontic principles that are applied, rather than a product determining which treatment is most suitable.

Inter-premolar width plays an essential role in smile aesthetics when filling the buccal corridor. This study has confirmed that smile aesthetics can be maintained in premolar extraction cases, as well as expansion occurring in the inter-premolar region, irrespective of the protocol. The change of molar width in extraction cases has no clinical significance.

In an era of consumerism, social media and the multitude of orthodontic manufacturing companies worldwide, it is even more important to teach and apply sound diagnostic and treatment principles.

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APPENDICES

Appendix A: BMREC approval

UNIVERSITY of the WESTERN CAPE

60 YEARS of hope, action & knowledge

10 November 2021

Dr MJ Coetsee
Orthodontics
Faculty of Dentistry

Ethics Reference Number: BM21/9/18

Project Title: Retrospective evaluation of transverse arch dimensional changes in nonextraction and premolar extraction cases using a passive self-ligating bracket system

Approval Period: **10 November 2021 – 10 November 2024**

I hereby certify that the Biomedical Science Research Ethics Committee of the University of the Western Cape approved the scientific methodology and ethics of the above mentioned research project and the requested amendment to the project.

Any further amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

Please remember to submit a progress report annually by 30 November for the duration of the project.

For permission to conduct research using student and/or staff data or to distribute research surveys/questionnaires please apply via:
https://sites.google.com/uwc.ac.za/permissionresearch/home

The permission letter must then be submitted to BMREC for record keeping purposes.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

NHREC Registration Number: BMREC-130416-050

FROM HOPE TO ACTION THROUGH KNOWLEDGE.

Appendix B: Informed Consent

Patient: ……………………………………………………………………….

Date: ……………………………………………………….

ACKNOWLEDGEMENT

I hereby acknowledge that I have read and fully understand the treatment considerations and risks presented in this form. I also understand that there may be other problems that occur less frequently than those presented, and that actual results may differ from the anticipated results. I also acknowledge that I have discussed this form with the undersigned orthodontist and have been give the opportunity to ask any questions. I have been asked to make a choice about my treatment. I hereby consent to the treatment proposed and authorise the orthodontist indicated below to proved the treatment. I also authorise the orthodontist to provide my health care information to my other health care providers. I understand that my treatment fee covers only treatment proved by the orthodontist, and that treatment provided by other dental or medical professionals is not included in the fee for my orthodontic treatment.

CONSENT TO UNDERGO ORTHODONTIC TREATMENT

I hereby consent to the making of diagnostic records, including x-rays, before, during and following orthodontic treatment, and to the above doctor(s) and, where appropriate, staff providing orthodontic treatment described by the above doctor(s) for the above individual. I fully understand all of the risks associated with the treatment.

AUTHORISATION FOR RELEASE OF PATIENT INFORMATION

I hereby authorise the above doctor to provide other health care providers with information regarding the above individual's orthodontic care as deemed appropriate. I understand that once released, the above doctor(s) and staff has (have) no responsibility for any further release by the individual receiving this information.

CONSENT TO USE OF RECORDS

I hereby give my permission for the use of orthodontic records, including photographs, made in the process of examinations, treatment, and retention for purposes of professional consultations, research, education, or publication in professional journals.

PRACTICE ADMINISTRATION:

1. Perfect oral hygiene must be maintained at all times. Your dentist must be visited every 6 months through out orthodontic treatment. Your oral hygienist must be visited every 3 months.

2. Results can only be expected where total co-operation can be relied upon.

3. Appointments not kept will be charged according to the prescribed tariffs of the Dental Association and rescheduled between 8H00 and 13H00. Bulk SMS reminders are sent as a courtesy. Please do not reply to sms. You cannot rely on SMS reminders for keeping of appointments.

3. Emergency appointments will be made at 14h00 in the afternoon and must be strictly adhered to. Appointments for fitting the braces, taking off the braces, and long appointments will be made during the morning.

4. A retention period of approximately 1 year follows active treatment. Consultations during this period must be strictly adhered to. The cost of the retainer, placed after active treatment, is included separately in the quoted fee. 5. You hereby acknowledge the responsibility of the account. The initial fee is due on the day of fitting the braces. Monthly debits are charged irrespective of the amounts or frequency of visits. All accounts must first be paid and your refund claimed from your Medical Aid. Interest will be charged after 30 days. Please be advised that this practice does not charge NRPL fees. See website www.doh.gov.za to determine their fees. Our tariffs are determined by the actual cost to maintain the highest standards of excellence. Accounts are sent by email on the 15th of each month. Please contact us if you do not receive it. You are responsible to let us know of any change in address and email address.

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Signature of Patient/Parent/Guardian Date

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Signature of Orthodontist, Dr Marius Coetsee

Appendix C: Data capturing sheet - non-extraction

Subject	Sex	Age	Pre Inter-canine mandib	Pre inter-premolar mandible	Pre inter-molar mandible	Post inter-canine mandible	Post inter-premolar mandible	Post inter-molar mandible	Pre inter-canine maxilla	Pre-interpremolar maxilla	Pre-intermolar maxilla	Post inter-canine maxilla	Post inter-premolar maxilla	Post-intermolar maxilla
						Non-extraction								
1	M	15	27.8	33.4	44.4	28.2	36.8	46.4	35.9	42.8	53.1	36.4	44.7	53.6
2	F	13	24.4	30.9	43.2	26.9	34.2	44.5	32.1	38.5	50.4	34.3	42.8	52.7
3	M	14	24.6	33.9	44.7	25.4	33.4	44.8	33.5	41.9	52.6	33.0	43.1	53.4
4	F	13	26.2	32.9	44.8	26.3	34.2	45.9	36.0	38.3	50.7	34.0	41.6	53.1
5	F	14	25.9	33.0	44.7	25.5	34.9	45.4	33.9	40.9	51.4	34.8	43.2	52.6
6	M	14	27.0	37.2	51.4	25.7	35.4	48.6	35.6	41.2	57.2	34.1	43.5	54.7
7	F	15	20.7	33.9	43.6	27.4	35.2	45.8	29.6	39.8	49.9	36.0	42.5	50.3
8	F	15	25.0	31.7	43.3	25.5	32.6	44.1	32.0	40.4	51.4	34.1	41.2	51.7
9	M	15	29.3	39.1	51.3	28.1	37.3	50.5	36.2	44.1	55.1	38.2	45.6	57.4
10	F	13	24.7	30.8	41.4	27.3	35.5	47.2	31.4	37.2	48.3	35.2	43.7	53.5
11	M	13	25.8	35.4	46.8	28.3	35.8	47.9	35.3	41.8	53.7	35.2	41.9	53.1
12	F	14	23.6	31.2	39.8	25.5	32.9	40.9	33.7	37.9	48.0	34.8	42.2	51.2
13	F	13	25.9	32.2	44.2	26.0	34.5	43.8	35.0	41.0	49.7	35.6	42.1	51.4
14	M	13	28.3	35.6	47.7	26.0	35.2	47.5	37.4	43.3	53.2	36.2	44.4	53.0
15	F	13	24.2	32.9	41.2	25.6	34.2	42.8	33.7	40.1	47.4	35.5	42.5	50.0
16	M	13	30.3	33.9	46.5	29.6	37.7	48.3	39.9	41.7	53.8	38.9	44.7	56.3
17	F	13	25.4	31.9	41.1	25.6	34.2	43.1	29.5	34.7	49.0	34.0	41.6	50.6
18	M	16	25.8	33.4	47.1	27.5	36.3	46.9	32.5	38.3	50.8	34.6	42.8	50.9
19	F	13	25.6	34.1	42.1	27.4	37.4	47.6	34.1	40.2	48.8	36.1	43.9	53.5
20	M	14	24.3	29.0	42.3	24.1	32.7	44.4	34.3	38.1	47.2	33.5	41.2	48.2
21	M	14	29.7	36.9	48.1	29.2	37.6	49.1	37.9	42.5	53.6	36.8	44.4	54.5
22	F	13	24.1	33.2	40.8	26.4	34.0	44.1	32.9	40.1	47.7	34.8	41.0	49.7
23	M	14	22.4	34.2	48.8	22.6	31.6	45.0	32.0	43.6	54.2	31.5	42.1	52.1
24	F	13	22.6	32.8	43.5	25.1	34.1	43.8	36.3	42.4	52.3	34.8	43.0	52.5
25	F	13	22.6	30.7	38.3	27.4	35.1	43.1	34.5	38.1	45.8	34.8	42.9	49.3
26	F	20	25.5	31.7	44.9	25.2	33.6	44.4	31.9	38.7	49.5	32.3	40.4	50.6
27	F	13	25.4	31.1	41.7	25.5	33.6	43.6	33.8	38.3	49.0	34.0	40.6	50.7
28	F	13	23.0	30.8	41.5	25.7	33.1	42.5	30.1	34.2	45.9	32.0	38.9	48.2
29	F	14	25.9	31.0	44.3	27.6	36.9	47.5	33.3	37.7	52.0	36.7	44.5	54.7
30	F	13	26.7	35.4	42.4	27.4	36.4	45.3	34.3	44.0	50.9	34.6	42.8	53.7
31	F	17	25.5	33.3	44.0	26.8	35.0	45.4	34.3	41.5	53.0	33.8	41.7	52.0
32	F	13	26.2	31.8	43.5	27.0	35.4	47.1	33.7	40.8	51.6	33.3	43.0	53.1
33	M	13	26.6	34.7	46.6	26.8	37.5	47.9	35.8	42.3	53.9	35.7	44.9	54.4
34	M	15	25.4	33.2	44.1	26.7	36.5	47.8	36.9	44.3	53.0	36.5	44.9	53.6
35	M	14	26.7	32.3	43.9	27.7	35.1	47.2	33.8	39.7	50.6	35.2	43.5	53.7
36	M	14	26.5	35.9	48.3	26.1	33.9	43.4	33.7	40.0	44.1	35.5	42.6	52.4
37	F	13	26.0	32.2	43.0	27.8	35.8	44.8	34.8	39.3	48.5	36.8	44.5	52.2
38	F	13	28.5	33.9	42.3	27.7	36.5	46.7	38.1	42.8	51.9	36.5	44.1	55.9
39	M	13	26.7	36.0	46.9	27.7	36.8	48.2	38.3	45.3	54.1	37.4	45.1	55.8
40	F	13	22.1	30.7	41.5	24.0	32.9	43.7	29.8	37.3	49.5	31.6	41.3	52.1
41	M	13	26.5	34.6	43.8	28.6	37.0	45.4	37.8	42.1	52.3	37.4	45.4	53.5
42	F	32	23.5	32.3	44.0	26.3	35.6	45.7	32.2	39.2	51.6	35.1	43.5	53.3
43	F	13	27.1	30.8	41.3	26.4	33.4	42.6	33.6	37.6	47.1	33.9	40.1	49.0
44	M	13	27.4	33.5	43.3	26.9	33.7	43.7	35.5	41.9	52.4	36.3	45.4	56.5
45	M	13	27.8	33.6	43.9	27.8	34.9	43.6	34.5	39.9	49.8	38.0	45.7	53.3
46	F	13	24.4	30.8	38.5	25.6	34.4	44.3	33.8	40.2	45.5	32.7	40.4	48.7
47	F	15	25.7	33.1	42.6	26.0	33.5	43.4	34.1	41.0	50.9	33.6	41.6	52.0
48	F	13	24.6	30.7	37.2	25.9	33.6	42.2	29.4	36.0	43.9	32.4	40.1	48.6
49	M	16	27.7	35.4	48.9	26.9	35.2	48.8	36.8	42.6	54.9	38.6	45.7	57.8
50	M	14	25.5	32.2	41.8	27.8	35.3	45.7	35.6	40.2	48.6	35.9	43.1	52.8

Appendix D: Data capturing sheet – extraction

Extraction														
Subject	Sex	Age	Pre Inter-canine mandib	Pre inter-premolar mandible	Pre inter-molar mandible	Post inter-canine mandible	Post inter-premolar mandible	Post inter-molar mandible	Pre inter-canine maxilla	Pre-interpremolar maxilla	Pre-intermolar maxilla	Post inter-canine maxilla	Post inter-premolar maxilla	Post-intermolar maxilla
1	F	13	22.8	32.5	44.2	27.5	36.3	42.5	35.0	41.1	53.0	35.7	44.1	50.5
2	F	13	30.9	37.7	43.1	31.0	39.0	43.8	38.0	44.9	51.0	38.5	44.8	52.3
3	M	13	26.3	31.6	42.2	27.5	35.4	42.2	32.1	40.0	49.4	32.9	42.4	47.3
4	F	13	24.5	35.2	44.1	28.2	35.8	41.3	35.0	37.8	50.2	35.9	44.5	49.8
5	F	14	24.9	33.5	40.3	27.0	34.4	36.8	37.3	37.1	48.2	37.9	43.0	48.2
6	F	13	27.8	37.1	45.5	27.3	35.6	41.4	36.6	43.9	52.3	34.3	43.5	48.8
7	M	15	25.6	37.4	47.9	28.9	36.9	43.3	37.8	43.4	54.2	36.8	44.7	50.6
8	F	15	26.3	36.7	47.3	26.0	36.1	42.3	34.7	43.2	54.1	36.0	43.0	48.3
9	M	13	30.0	38.0	44.6	30.2	37.4	44.1	38.2	46.2	54.6	38.8	47.2	53.0
10	M	13	28.3	29.6	41.0	26.1	33.5	40.2	31.9	36.3	48.9	33.2	41.8	46.8
11	F	13	29.8	35.2	44.0	28.2	35.7	42.5	38.0	43.9	54.0	37.5	44.0	48.8
12	F	13	24.8	32.8	42.8	25.8	34.1	41.8	33.0	39.8	48.2	33.9	42.1	47.3
13	F	13	25.1	31.4	40.5	25.9	31.7	35.3	34.1	38.8	46.8	34.5	42.5	46.8
14	F	13	27.2	32.7	42.0	28.6	36.5	43.2	32.3	37.7	48.3	35.0	43.7	47.2
15	F	13	26.9	32.5	45.1	27.3	34.3	46.1	31.1	36.0	48.5	36.0	42.4	47.9
16	M	14	19.9	30.9	38.1	18.2	26.5	32.4	25.6	36.4	46.8	26.0	34.9	40.9
17	F	14	19.4	25.9	37.2	17.2	26.1	31.4	26.1	30.4	43.4	24.1	32.5	39.5
18	M	14	18.9	27.2	35.5	22.6	31.0	37.2	26.1	32.9	45.1	29.8	37.3	43.1
19	M	13	26.8	31.0	41.5	27.0	34.7	41.1	33.0	36.7	49.1	35.3	43.2	43.1
20	M	16	25.1	35.9	47.1	26.1	34.4	39.9	34.9	42.2	53.3	33.6	42.4	51.6
21	F	15	25.9	32.1	42.4	25.6	32.8	37.8	31.5	40.8	49.4	33.1	40.8	46.7
22	M	13	32.0	37.9	48.3	31.1	39.1	45.4	40.1	46.5	55.9	38.0	47.5	52.5
23	M	19	27.0	34.5	47.3	27.6	35.8	48.5	36.9	42.0	48.6	33.7	41.2	46.2
24	M	15	28.4	35.4	48.3	28.5	36.3	42.9	36.1	41.2	48.0	35.8	43.2	48.7
25	F	13	24.4	24.0	39.1	27.6	35.5	40.7	33.4	34.2	45.1	36.4	43.6	47.8
26	F	27	26.8	35.1	46.3	28.7	36.6	48.8	34.8	40.9	49.6	35.1	43.0	50.1
27	F	19	30.1	34.5	47.6	29.3	37.4	47.3	36.1	47.1	52.8	35.4	43.5	49.2
28	M	13	19.9	28.1	39.3	27.1	34.7	40.1	34.9	36.3	46.6	35.1	39.3	46.5
29	M	13	30.7	38.6	50.4	29.5	37.3	44.9	34.6	42.9	51.1	35.7	44.7	51.8
30	M	13	27.9	38.8	41.3	26.8	35.3	42.5	38.1	37.4	48.5	35.8	43.6	50.4
31	F	13	23.5	29.1	40.4	27.2	35.7	41.8	35.2	36.7	48.4	35.1	44.1	48.7
32	M	13	31.2	36.8	47.2	30.0	38.6	44.4	41.9	46.4	56.1	39.2	46.8	53.9
33	M	13	28.8	35.4	44.0	28.7	36.8	42.1	33.7	40.4	51.0	34.2	43.5	49.6
34	M	25	27.7	36.5	41.3	27.9	36.3	41.7	35.0	40.0	44.6	35.5	42.6	45.0
35	F	13	26.1	31.2	40.9	27.4	34.3	45.0	30.6	36.4	47.2	34.0	41.5	47.8
36	M	13	30.8	36.5	48.2	30.2	39.5	43.7	38.7	41.0	54.6	41.6	47.5	53.5
37	F	33	29.6	35.4	50.5	28.8	35.3	45.2	36.3	43.1	53.2	36.1	43.9	48.5
38	F	13	27.8	36.1	46.3	28.2	36.7	42.2	36.3	40.3	52.9	36.4	44.9	52.3
39	M	13	27.0	33.9	43.8	27.2	35.6	42.3	35.3	41.3	53.2	35.7	43.4	49.8
40	F	13	26.7	36.2	45.2	28.9	36.8	43.4	37.2	43.6	52.3	35.9	45.7	51.4
41	F	28	25.1	33.7	35.4	25.8	32.8	36.7	30.3	36.4	39.3	32.4	39.6	44.5
42	F	13	24.4	32.2	44.1	25.4	32.2	40.3	31.4	39.2	49.2	35.7	42.8	47.5
43	M	33	28.3	35.4	47.8	28.4	39.3	47.4	33.6	44.2	54.3	27.9	41.9	53.7
44	F	13	25.8	35.0	40.8	26.8	34.9	40.3	34.7	40.3	46.4	38.0	43.4	47.6
45	F	32	24.3	30.1	43.0	26.0	33.9	43.1	28.1	33.1	46.9	30.9	38.4	43.0
46	F	24	26.0	33.6	39.8	26.0	34.9	42.1	37.0	39.6	49.6	35.1	43.4	47.8
47	F	16	31.1	31.4	35.8	25.2	34.1	38.9	30.5	40.8	45.2	34.3	42.3	46.4
48	F	13	26.6	30.4	37.1	28.6	35.5	44.9	33.0	36.1	41.4	33.7	42.4	46.1
49	M	13	27.2	34.6	41.6	27.1	34.1	39.1	32.4	38.1	49.5	36.1	42.0	48.5
50	F	13	21.4	30.4	38.6	24.8	32.4	37.8	33.9	38.8	46.2	32.3	38.8	44.9

Appendix E: Intra-rater reliability

Pre inter-canine mandible					Observation distribution of Differencies		
First	Repeat	Difference	Diff sorted		Stem	Leafs	Frequencies
22.1	22.1	0	-0,1		-0,1	X	1
26.5	26.0	0,5	0		0.0	XXX	3
23.5	23.4	0,1	0		0,1	XXX	3
27.1	27.1	0	0		0,2		0
27.4	27.3	0,1	0,1		0,3	X	1
27.8	27.5	0,3	0,1		0,5	XXX	3
24.4	24.3	0,1	0,1				
25.7	25.8	-0,1	0,3			Total Obs	11
24.6	24.1	0,5	0,5				
27.7	27.2	0,5	0,5				
25.5	25.5	0	0,5				

Post inter-canine mandible			Sorted				
Eerste meting	Opvolg meting	Verskil "Diff"	Diff		Observation distribution of Differencies		
First	Repeat				Stem	Leafs	Frequencies
24,0	24,0	0,0	-1		-1	X	1
28,6	28,6	0,0	-0,2		-0,2	X	1
26,3	26,2	0,1	-0,1		-0,1	XX	2
26,4	26,3	0,1	-0,1		0.0	XXX	3
26,9	27,0	-0,1	0.0		0,1	XXX	3
27,8	28,8	-1,0	0.0		0,2		0
25,6	25,8	-0,2	0.0		0,3		0
26,0	26,0	0,0	0,1		0,4	X	1
25,9	26,0	-0,1	0,1			Total Obs	11
26,9	26,8	0,1	0,1		Following method of tucci		
27,8	27,4	0,4	0,4				

Pre inter-premolar mandible					Observation distribution of Differencies		
First	Repeat	Difference	Diff sorted		Stem	Leafs	Frequencies
30.7	30.4	0,3	0		-0,1		0
34.6	34.3	0,3	0		0.0	XX	2
32.3	32.2	0,1	0,1		0,1	X	1
30.8	30.8	0	0,2		0,2	X	1
33.5	33.1	0,4	0,3		0,3	XXXXX	5
33.6	33.6	0	0,3		0,4	XX	2
30.8	30.4	0,4	0,3				
33.1	32.8	0,3	0,3			Total Obs	11
30.7	30.5	0,2	0,3				
35.4	35.1	0,3	0,4				
32.2	31.9	0,3	0,4				

Post inter-premolar mandible				Observation distribution of Differencies		
First	**Repeat**	**Difference**	**Diff sorted**	**Stem**	**Leafs**	**Frequencies**
32.9	32.9	0	-0,2	**-0,2**	X	**1**
37.0	36.8	0,2	-0,1	**-0,1**	X	**1**
35.6	35.1	0,5	0	**0.0**	X	**1**
33.4	33.3	0,1	0,1	**0,1**	XXXX	**4**
33.7	33.9	-0,2	0,1	**0,2**	XXX	**3**
34.9	34.7	0,2	0,1	**0,3**		**0**
34.4	34.3	0,1	0,1	**0,4**		**0**
33.5	33.4	0,1	0,2	**0,5**		**1**
33.6	33.7	-0,1	0,2			
35.2	35.1	0,1	0,2		Total Obs	11
35.3	35.1	0,2	0,5			

Pre inter-canine maxilla				Observation distribution of Differencies		
First	**Repeat**	**Difference**	**Diff sorted**	**Stem**	**Leafs**	**Frequencies**
29.8	29.9	-0,1	-0,1	**-0,1**	X	**1**
37.8	37.3	0,5	0	**0.0**	XXXX	**4**
32.2	31.8	0,4	0	**0,1**		**0**
33.6	33.4	0,2	0	**0,2**	XXX	**3**
35.5	35.5	0	0	**0,3**	X	**1**
34.5	34.5	0	0,2	**0,4**	X	**1**
33.8	33.6	0,2	0,2	**0,5**	X	**1**
34.1	33.8	0,3	0,2			
29.4	29.4	0	0,3		Total Obs	11
36.8	36.6	0,2	0,4			
35.6	35.6	0	0,5			

Post inter-canine maxilla				Observation distribution of Differencies		
First	**Repeat**	**Difference**	**Diff sorted**	**Stem**	**Leafs**	**Frequencies**
31.6	31.3	0,3	**-0,2**	**-0,2**	X	**1**
37.4	37.2	0,2	**0,1**	**-0,1**		**0**
35.1	34.9	0,2	**0,1**	**0.0**		**0**
33.9	33.7	0,2	**0,1**	**0,1**	XXXX	**4**
36.3	36.2	0,1	**0,1**	**0,2**	XXX	**3**
38.0	37.9	0,1	**0,2**	**0,3**	XX	**2**
32.7	32.6	0,1	**0,2**	**0,5**	X	**1**
33.6	33.3	0,3	**0,2**			
32.4	32.3	0,1	**0,3**		Total Obs	11
38.6	38.8	-0,2	**0,3**			
35.9	35.4	0,5	**0,5**			

Pre inter-premolar maxilla				Observation distribution of Differencies		
First	**Repeat**	**Difference**	**Diff sorted**	**Stem**	**Leafs**	**Frequencies**
37.3	37.0	0,3	-0,1	**-0,1**	X	**1**
42.1	41.9	0,2	0	**0.0**	X	**1**
39.2	38.9	0,3	0,1	**0,1**	XX	**2**
37.6	37.5	0,1	0,1	**0,2**	X	**1**
41.9	42.0	-0,1	0,2	**0,3**	XXX	**3**
39.9	39.8	0,1	0,3	**0,4**	X	**1**
40.2	40.2	0	0,3	**0,5**		**0**
41.0	40.4	0,6	0,3	**0,6**	X	**1**
36.0	35.6	0,4	0,4	**0,7**	X	**1**
42.6	42.3	0,3	0,6			
40.2	39.5	0,7	0,7		Total Obs	11

Post inter-premolar maxilla					Observation distribution of Differencies		
First	**Repeat**	**Difference**	**Diff sorted**		**Stem**	**Leafs**	**Frequencies**
41.3	41.4	-0,1	-0,2		**-0,2**	XX	**2**
45.4	45.2	0,2	-0,2		**-0,1**	XX	**2**
43.5	43.4	0,1	-0,1		**0.0**	XX	**2**
40.1	40.3	-0,2	-0,1		**0,1**	X	**1**
45.4	45.5	-0,1	0		**0,2**	X	**1**
45.7	45.4	0,3	0		**0,3**	XX	**2**
40.4	40.1	0,3	0,1		**0,4**	X	**1**
41.6	41.2	0,4	0,2				
40.1	40.1	0	0,3			Total Obs	11
45.7	45.7	0	0,3				
43.1	43.3	-0,2	0,4				

Pre inter-molar maxilla					Observation distribution of Differencies		
First	**Repeat**	**Difference**	**Diff sorted**		**Stem**	**Leafs**	**Frequencies**
49.5	49.1	0,4	0		**0.0**	XX	**2**
52.3	52.3	0	0		**0,1**	XX	**2**
51.6	51.3	0,3	0,1		**0,2**	XXXX	**4**
47.1	46.9	0,2	0,1		**0,3**	X	**1**
52.4	52.4	0	0,2		**0,4**	X	**1**
49.8	49.6	0,2	0,2		**0,5**	X	**1**
45.5	45.0	0,5	0,2				
50.9	50.8	0,1	0,2			Total Obs	11
43.9	43.7	0,2	0,3				
54.9	54.8	0,1	0,4				
48.6	48.4	0,2	0,5				

Post inter-molar maxilla					Observation distribution of Differencies		
First	**Repeat**	**Difference**	**Diff sorted**		**Stem**	**Leafs**	**Frequencies**
52.1	51.8	0,3	-0,4		**-0,4**	X	**1**
53.5	53.3	0,2	-0,1		**-0,1**	X	**1**
53.3	52.9	0,4	0		**0.0**	X	**1**
49.0	48.9	0,1	0,1		**0,1**	X	**1**
56.5	56.6	-0,1	0,2		**0,2**	XXX	**3**
53.3	53.7	-0,4	0,2		**0,3**	XX	**2**
48.7	48.3	0,4	0,2		**0,4**	XX	**2**
52.0	52.0	0	0,3				
48.6	48.3	0,3	0,3			Total Obs	11
57.8	57.6	0,2	0,4				
52.8	52.6	0,2	0,4				

Appendix F: Intra-rater reliability

Non-extraction pretreatment inter-canine mandible												
Observatio	Meting 1	meting 2	meting 3	meting 4	meting 5	meting 6	meting 7					
	0,00	-0,1	-0,20	0,20	0,00	0,10	-0,10		**Observation distribution of differencies**			
					Median of 7 diff's from				**Stem**	**Leafs**	**Frequencies**	
					from above		0,00		-0,20	X	1	
	Diff		Diff						-0,1	XX	2	
	0,00		-0,20			Flat distributior	==>		0,00	XX	2	
	-0,1		-0,1						0,10	X	1	
	-0,20		-0,10						0,20	X	1	
	0,20		0,00									
	0,00		0,10									
	0,10		0,20									
	-0,10											

Appendix G: Statistical summary of the mandible

Variable	T1 mean (SD)	T2 mean (SD)	Change (T2–T1)	*p – value* (T2 – T1)	95% CI lower limit	95% CI upper limit	*p – value* inter-group
3 – 3							
NE	25,66 (1,96)	26,61 (1,33)	0,95	*p = .0001*	0.4984165	1.397583	*p* = .33940
Ex	26,48 (3,11)	27,14 (2,55)	0,66	*p = .02899*	0.07089183	1.257108	
4 – 4							
NE	33,10 (2,01)	34,97 (1,51)	1,86	*p < .001*	1.356757	2.371243	*p* = .23543
Ex	33,55 (3,34)	35,12 (2,63)	1,56	*p = .00012*	0.8121569	2.315843	
6 – 6							
NE	43,91 (3,04)	45,45 (2,13)	1,54	*p = .00001*	0.9230441	2.160956	*p* < .001
Ex	43,12 (3,89)	41,80 (3,60)	-1,32	*p = .00357*	-2.186551	-0.4534492	

Appendix H: Statistical summary of the maxilla

Variable	T1 mean (SD)	T2 mean (SD)	Change (T2 –T1)	*p – value* (T2 – T1)	95% CI lower limit	95% CI upper limit	*p – value* inter-group
3 – 3							
NE	34,22 (2,40)	35,06 (1,77)	0,84	*p = .00151*	0.3370308	1.338969	*p* = .74063
Ex	34,25 (3,44)	34,80 (3,08)	0,55	*p = .0768*	-0.06143112	1.161431	
4 – 4							
NE	40,32 (2,44)	42,93 (1,69)	2,61	*p < .001*	2.058455	3.165545	*p* = .87943
Ex	39,88 (3.75)	42,67 (2,80)	2,79	*p < .001*	2.006245	3.573755	
6 – 6							
NE	50,60 (2,95)	52,56 (2,30)	1,96	*p < .001*	1.422992	2.501008	*p* < .001
Ex	49,53 (3,72)	48,24 (3,19)	-1,29	*p = 0.00046*	-1.974423	-0.5975769	

Appendix I: Information sheet

Project Title: Retrospective evaluation of transverse arch dimensional changes in non-extraction and premolar extraction cases using a passive self ligating bracket system.

What is this study about?

This is a research project being conducted by Dr Marthinus Johannes Coetsee and Prof Angela Harris at the University of the Western Cape in South Africa. We are inviting you to participate in this research project because you meet the set criterion for the population of interest and your participation will help other people. The purpose of this research project is to evaluate the change in transverse arch width of patients treated orthodontically with the Damon system and were either treated without the removal of teeth or those with premolar extractions.

What will I be asked to do if I agree to participate?

You will be asked to sign a consent form agreeing to take part in the study. You will also be asked whether your pre- and post treatment study models may be used. The study will be done in an orthodontic practice in Table View.

Would my participation in this study be kept confidential?

All the data will be kept in password protected computer that is firewall protected and files known only to the researcher. Data collection sheets will be kept safely in a lockable filling cabinet accessed only by the researcher in a store room that is locked. All raw data including written documents will be kept for 5 years after final submission and will be destroyed thereafter. If we write a report or article about this research project, your identity will be protected as numbers are allocated to subjects therefor de-identifying participants.

What are the risks of this research?

Risks from participating in this research study: none

What are the benefits of this research?

This research is not designed to help you personally, but the results will add value to the clinical arena as well as the literature on the effects of a non-extraction and premolar extraction protocol when using the Damon orthodontic system.

Do I have to be in this research and may I stop participating at any time?

Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.

Is any assistance available if I am negatively affected by participating in this study?

If at any time of the study, you feel uncomfortable and need assistance, the researcher will refer you for counselling through social welfare office in your area.

What if I have questions?

This research is being conducted by:
Dr Marnus Coetsee
Prof Angela Harris

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

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