

**An oral health-related quality of life assessment of cleft patients
at the Wentworth Foundation Clinic (Kwazulu-Natal)**

Dr Leticia Singh BChD (UWC), PDD (Int. Ortho) (UWC)

Student number: 2820206



**A thesis submitted in partial fulfilment of the requirements for
The degree of MSc in Orthodontics in the Department of Orthodontics,
University of the Western Cape**

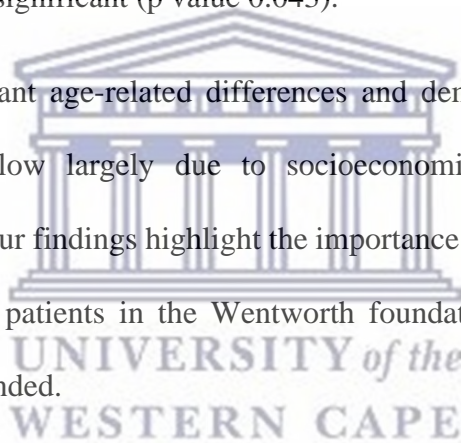
December 2020

**Supervisor: Prof Amenah Shaikh\
BChD, MSc, MChD (Orthodontics)**

Abstract:

An analysis of the oral health related quality of life (OHRQoL) of patients with orofacial clefts at the Wentworth Foundation in Durban, KZN is presented. **Objectives:** To assess whether the OHRQoL of orofacial cleft patients varies amongst different age groups, genders or cleft types as well as demographic factors. **Method:** 46 participants, aged 8- 18, completed a self-administered Child Oral Health Impact Profile (COHIP) questionnaire. **Results:** The most prevalent cleft type was the Unilateral Cleft Left, 45.7%. The COHIP mean score was 84.195 (SD 18.244) ranging from 35 to 110. The age related subscales which were statistically significant included Functional well-being (p value: 0.0456), School Environment (p value: 0.0145) and Treatment Expectancy. The subscale School Environment was statistically significant for: Transport (p value: 0.0267) and Place of accommodation (p value 0.028). The Oral Health subscale and the Educational level were statistically significant (p value 0.043).

Conclusion: Statistically significant age-related differences and demographic factors were noted. The OHRQoL of cleft patients was low largely due to socioeconomic factors and difficulty accessing multidisciplinary care. Therefore, our findings highlight the importance of establishing a Cleft lip and palate multidisciplinary facility for these patients in the Wentworth foundation and subsidised transport to the Wentworth Foundation is recommended.



Key words: Orofacial cleft, Oral Health-related Quality of Life, Self-perception, KZN, Child Oral Health Impact Profile

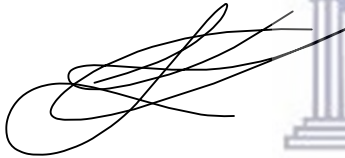
Declaration

I declare that “An oral health-related quality of life assessment of cleft patients at the Wentworth Foundation Clinic (Kwazulu-Natal)” is my own work, that it has not been submitted before for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged as complete references.

Leticia Singh

06/12/2020

Signed:



Dedicated to my Family



UNIVERSITY *of the*
WESTERN CAPE

Acknowledgements:

I would like to thank my Supervisor, Professor Amenah Shaikh, for her ongoing guidance, support and motivation. It was a pleasure to work with Prof. Shaikh. I would also like to thank Dr Surandar Singh for his ongoing guidance, assistance and support. Dr Surandar Singh granted the permission to access the Wentworth Foundation patient database, as well as the premises, without which this study would not be possible.

Thank you to all the members of the Wentworth Foundation, in particular Mrs Savitri Singh and Ms Sureka Singh for accommodating me at the Foundation premises and making all the research information easily available to me. Thank you to Ms Sureka Singh for sharing her Masters thesis with me, which allowed additional insight into the socioeconomic situation of orofacial cleft patients in KZN.

Thank you to Dr Faheema Kimmie, the statistician for assisting and advising on the statistical analysis of the study.

Thank you to Sister Staff Dlamini and Mr Yeniv Jaynath for assisting with conducting the study efficiently and ensuring the process ran smoothly. Thank you especially to Sister Staff Dlamini for sharing her knowledge as a teacher to create a comfortable set up for the participants and assisting in explaining the study to participants.

Thank you to Dr Broder for creating and validating the COHIP form. This instrument was pivotal in the study.

Thank you to my parents and sister, Mrs Ashna Singh, Dr Taks Singh and Avani Singh for assisting me in making lunch and care packs for the clinic at every visit. I really appreciate your support and help.

Finally, I thank my Family for their love, encouragement and support. Especially, my parents, Mrs Ashna Singh and Dr Takurjith Singh for enabling me to pursue my education and supporting me. Mrs Rita Singh and Dr Vidwan Singh, for their support and encouragement. I would like to thank my Husband, Nashil Singh for believing in me, supporting and encouraging me.

Contents

Abstract				i
Declaration				ii
Dedication				iii
Acknowledgments				iv
Contents				a-e
CHAPTER 1	Introduction			1-3
CHAPTER 2	Literature Review	Anatomy of the Palate	Figure 1: Primary and Secondary Palate Anatomy	4
		Embryology		5
			Figure 2: Embryology of the Palate	6
		Classification of Orofacial clefts		7
		The Veau Classification	Figure 3: Veau Classification	8
		Kernahan & Stark Classification		8
		Classification by International Confederation for Plastic & Reconstructive surgery		8
		Kernahan striped Y Classification		8
		Iowa Classification	Figure 4: Kernahan striped Y classification	9
		Lahsal Code	Figure 5: Iowa Classification	10
			Figure 6: Lahsal Code	11
		Aetiology of Orofacial clefts		12
		Epidemiology	Global Epidemiology	13-14

		Epidemiology of orofacial clefts in South Africa	14-16
		Developing Nations and Third World context	17-18
		Socioeconomics in KZN	19-20
		Health Related Quality of Life (HRQoL)	21-25
		Oral Health Related Quality of Life (OHRQoL)	26-28
		OHRQoL in Children	28-29
		Child Oral Health Impact Profile (COHIP)	29-30
		COHIP in relation to craniofacial patients	30
		Age in relation to COHIP scores	31-32
		COHIP measurements and scoring	32-35
		Table 1: COHIP score summarised	36
CHAPTER 3	Materials and Methods	Aim of the study	37
		Objectives	
		Null Hypothesis	
		Research question	
		Study design	
		Location	38
		Sample size	
		Table 2: To indicate the inclusion and exclusion criteria for cleft participants	
		Data Collection Tool	39

	Measurement		40
	Informed Consent Procedure		
	Confidentiality		41
	Socio-demographic & COHIP Questionnaire procedure		
	Data Management	Data Capture	Figures 7& 8: Classroom setup
		Data Analysis	
		Data Protection	43
		Data Storage	
	Risk of the study		
	Referral strategy		
	Study approval & Ethical consideration		44
CHAPTER 4	Results	Sociodemographic data	Table 3: Sociodemographic data
		Cleft Classification data	Table 4.1: Cleft Classification results summary
			46
			47
		COHIP scores	Table 5: Summary for total COHIP/OHRQoL and COHIP subscale scores
			48
		Age in relation to COHIP scores	Table 6: Age comparison with COHIP scores and subscale scores
			49
			Figure 7: Box graph to show Age related to subscale: School environment
			50
			Figure 8: Box graph to show Age related to subscale Functional well-being

	Transport in relation to COHIP score	Table 7: Transport in relation to COHIP & subscale: School Environment	51
	Accommodation in relation to COHIP	Table 8: Place of Accommodation in relation to COHIP & subscale: School environment	52
	Educational Level in relation to COHIP	Table 9: Educational level in relation to COHIP & subscale: Oral Health	
	Gender in relation to COHIP	Table 10: Gender in relation to COHIP scores	53
Cleft Classification in relation to COHIP scores	Overview		
	Cleft Type	Table 11: Cleft Type in relation to COHIP and subscale: School Environment	
	Cleft Description	Table 12: Cleft Description in relation to COHIP score	54
	Cleft Laterality	Table 13: Cleft Laterality in relation to COHIP score	
	Cleft Anatomical Location	Table 14: Cleft Anatomical Location in relation to COHIP	55
		Table 15: Cleft Anatomical Location in relation to COHIP subscale scores	
		Table 16: Cleft Anatomical Location in relation to COHIP score (Lip involvement or Palate only)	
		Table 17: Cleft Anatomical Location in relation to COHIP subscale scores (Lip involvement or Palate only)	56



	Treatment Expectancy and Global Health	Treatment Expectancy	Figure 9: Box graph to show Age related to subscale Treatment Expectancy (not in COHIP score)	57
		Global Health		58
CHAPTER 5	Discussion			59-65
	Limitations of the study			66
	Recommendations			
	Conclusion			67-68
References	EndnoteX8	Harvard Style		69-75
Appendices	Appendix 1	Information Sheet		76-78
	Appendix 2	Consent form		79
	Appendix 3	Assent form		80
	Appendix 4	Demographic profile		81
	Appendix 5	COHIP form		82-85
	Ethical Approval			86
Letters	Letter of Permission to conduct study from Wentworth Foundation			87
	Letter of no relation			88-89

CHAPTER 1

Introduction:

In a comprehensive overview of orofacial clefts done by Mossey and Modell (2012), including systematic reviews and a review of major international registries, the overall data indicated that the incidence of oral cleft lip and palate is 1 in 700 births internationally (Mossey and Modell, 2012). The estimated prevalence of oro-facial cleft individuals within the public sector in South Africa is 0.3 per 1000 live births with a provincial variation of between 0.1/1000 up to 1.2/1000 (Hlongwa, 2019). Thus orofacial cleft has marked prevalence as a craniofacial anomaly both internationally and in the South African context (Gkantidis et al., 2015, Hlongwa, 2019). An orofacial cleft affects the quality of life of an individual in various ways, including psychosocial well-being as well as functional well-being and aesthetic outcomes (Broder et al., 2014a). Thus the impact of the cleft lip and palate on the quality of life of an individual is significant (Broder et al., 2014a).

The World Health Organisation defines health as being a state of complete mental, physical and social well-being and not just the absence of disease (Bennadi and Reddy, 2013, WHO, 2002). Quality of life assessments are not a substitute to measuring the outcomes of disease but an addition to them (Bennadi and Reddy, 2013).

Cleft lip and palate care and treatment begins soon after birth and is required until early adulthood to allow adequate function, aesthetics and psycho-social well-being (Gkantidis et al., 2015). Cleft lip and palate care entails prolonged treatment and care and thus has a direct impact on an individual's quality of life (Broder et al., 2014a). Orofacial clefts are associated with many different health challenges such as feeding and thus general growth, craniofacial growth, speech and physical health problems such as recurrent middle ear infections related to nasal regurgitation (Nackashi et al., 2002). Furthermore, psychological adjustment is difficult for cleft patients due to difficulties in speech, hearing and aesthetic concerns (Kapp-Simon and Mcguire, 1997). Children with craniofacial birth defects are also at risk of developmental problems which include cognitive performance (Jelliffe-Pawlowski et al., 2003). It is thus necessary for children with orofacial clefts to undergo multidisciplinary treatment such as surgical, medical, dental, speech, hearing, psycho-social and other health interventions (Nackashi et al., 2002).

Multidisciplinary care is required for the functional, aesthetic, and social well-being of a cleft patient. Insufficient rehabilitation of these patients results in the deterioration of their quality of life (Marcusson et al., 2001). Multidisciplinary care aims to improve the patient's quality of life in aspects such as the appearance of the nasolabial complex; improve function in relation to mastication, speech, hearing, nasal breathing and psycho-social adaptation (Marcusson et al., 2001).

Health Related Quality of Life (HRQoL) assessments assist in assessing the impact of a disease on an individual's physical, emotional, social and psychological well-being. It has been reported that children with a visible craniofacial anomaly have a lower quality of life and that it can be likened to children with chronic illnesses (Topolski et al., 2005).

The concept of Oral Health-Related quality of life (OHRQoL) began in the 1980s, this was 20 years after the notion of Health- Related Quality of life emerged (Bennadi and Reddy, 2013). Oral Health-Related quality of life (OHRQoL) aims to assess individuals' general well being in relation to their Oral Health. Aspects such as the influence of oral health on self- esteem, eating, sleeping and social interactions are encompassed in the Oral Health- Related Quality of Life (Bennadi and Reddy, 2013).

Adolescents and children offer reliable information on the subject of their OHRQoL when validated and appropriate questionnaires are used (Jokovic et al., 2002). The Child Oral Health Impact Profile (COHIP), was designed to assess the self- report of the oral health related quality of life of teenagers and children (Broder et al., 2007). Broder and Genderson (2007) found that the COHIP has excellent validity and reliability (Broder and Wilson-Genderson, 2007).

Ward and coworkers found that the literature lacks age- related differences in the OHRQoL in children with orofacial clefts (Ward et al., 2013). Thus, they explored the topic further and found that there is a statistically significant difference in relation to age groups and social emotional well-being when children with orofacial clefts and children without orofacial clefts were compared (Ward et al., 2013).

A significant component of the HRQoL required for cleft patients was found to be related to their OHRQoL (Bennadi and Reddy, 2013). Conditions affecting the mouth and teeth can have a direct impact on the self-

esteem, social interactions, school experience, eating, speaking and thus the overall well-being of cleft individuals (Bennadi and Reddy, 2013).

Orthodontic treatment and dental treatment are especially important in cleft management. Thus, in order to initially assess the Health-related quality of life of cleft patients at the Wentworth Foundation Clinic, the OHRQoL was evaluated with a validated assessment tool. The assessment tool used was the Child Oral Health Impact Profile, established by Broder et al in 2007 (Broder et al., 2007). Further studies will be required to fully assess the wholistic quality of life or HRQoL of cleft patients at the Wentworth Foundation.



CHAPTER 2

Literature Review

Anatomy of the Palate (Figure 1)

The oral palate consists of the bony hard palate and the fibromuscular soft palate. The hard palate can be further divided into the primary palate and secondary palate (Friedman et al., 2010). The primary palate comprises of the region anterior to the incisive foramen which includes the anterior incisors (central and lateral incisors.) The secondary palate is the bony palate posterior to the primary palate and anterior to the soft palate. The soft palate separates the oral cavity from the nasopharynx (Friedman et al., 2010).

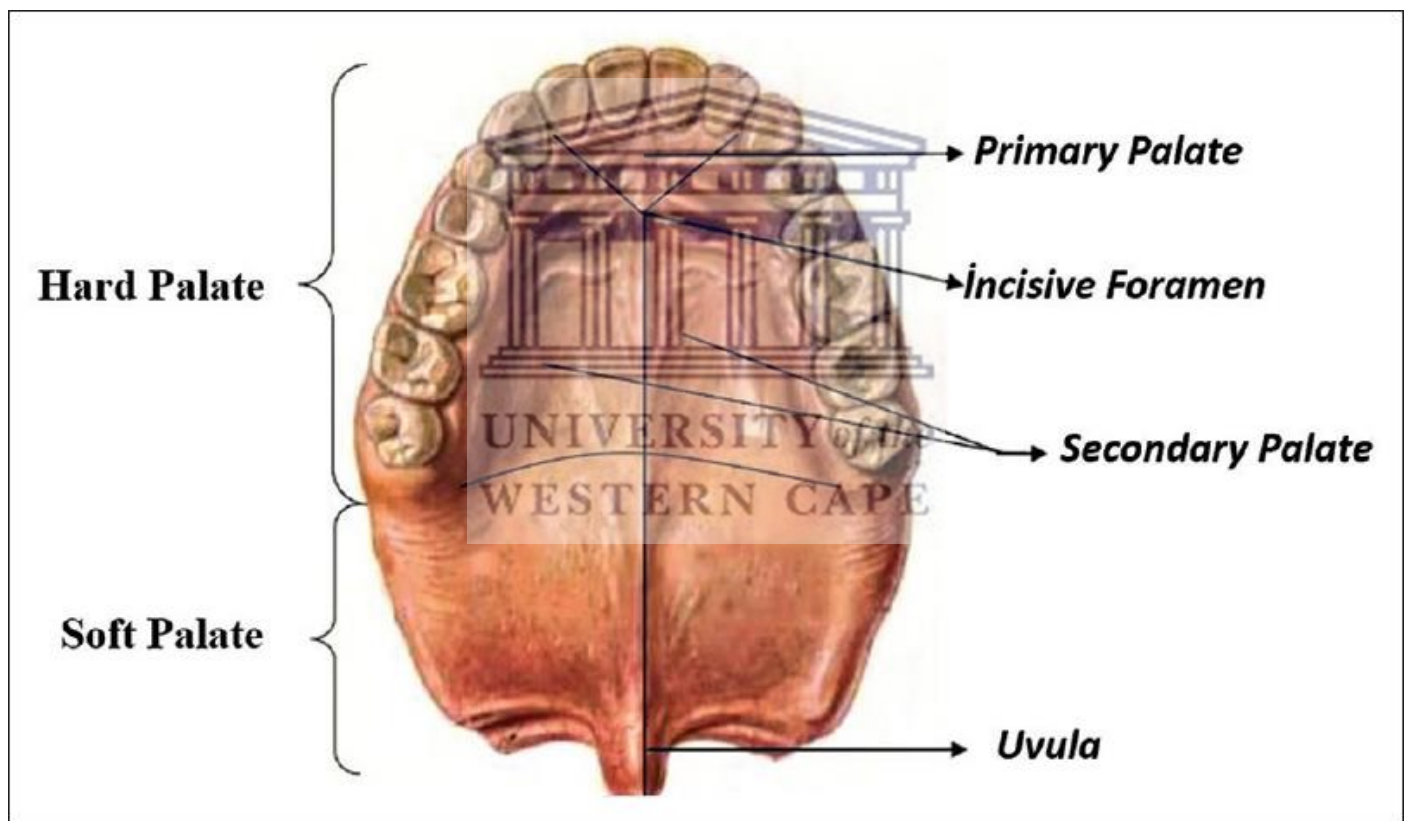


Figure 1: Hard and Soft Palate (Akbulut, 2020)

Source: AKBULUT, Y. 2020. Approach to patients with cleft lip and palate in orthodontics. *Journal of Cleft Lip Palate and Craniofacial Anomalies*[Online], Available: <https://www.jclpca.org/article.asp?issn=2348-2125;year=2020;volume=7;issue=1;spage=8;epage=16;aulast=Akbulut>

Embryology:

The embryonic development of the face occurs between the 4th and 12th week of embryonic development. The facial complex forms from 5 facial prominences known as the frontonasal, paired maxillary and paired mandibular prominences (Afshar et al., 2012). The facial prominences are derived from neural crest cells which arise from the ectoderm germ layer (Afshar et al., 2012). The maxillary and mandibular prominences are formed from the first pharyngeal arch also known as the mandibular arch. Two nasal placodes with nasal pits form on the frontonasal prominence which create ridges of ectodermal tissue known as the medial nasal prominences and the lateral nasal prominences (Afshar et al., 2012). The medial nasal prominence and the maxillary prominence merge on either side and give rise to the primary palate, upper alveolar processes containing the central and lateral incisors and the upper lip. The lateral nasal prominence merge with the maxillary process on either side and form the alae of the nose (Afshar et al., 2012). This is a critical time for the formation of the primary palate, any disturbance in growth during this time will compromise the primary palate development (Sperber, 2002).

In the 6th week, the pair of palatal shelves from the maxillary processes begin to grow (Sperber, 2002). At the 8th week of embryonic development the palatal shelves of the maxillary prominences rotate from a vertical position and thereafter elevate into a horizontal position around the tongue (Sperber, 2002). Following the rotation and elevation of the palatal shelves, adhesive contact of the shelves, followed by seam fusion of the medial aspects of the palatal shelves and apoptosis of the epithelium between the shelves are very important for secondary palatogenesis thus forming the secondary hard palate and soft palate (Sperber, 2002). With the growth of the secondary palate, the mandibular prominences also grow and the tongue can then move more anteriorly with the increased growth of the mandible (Diewert and Lozanoff, 2002). The anterior movement of the tongue allows for the medial aspects of the palatal shelves to fuse (Sperber, 2002). During the 10th week of embryogenesis the secondary palate and its close structural relations being, the anteriorly positioned primary palate and the superiorly positioned nasal septum; all fuse (Sperber, 2002) (Figure 2)

Orofacial clefts vary in extent and location and can include one of, or a combination of: lip, alveolus, nasal floor, nasal arch, hard palate and soft palate. Clefts of the mandible do occur, however, much rarely than that of the maxilla. The extent of the cleft depends on the point at which the development was disrupted (Friedman et al., 2010).

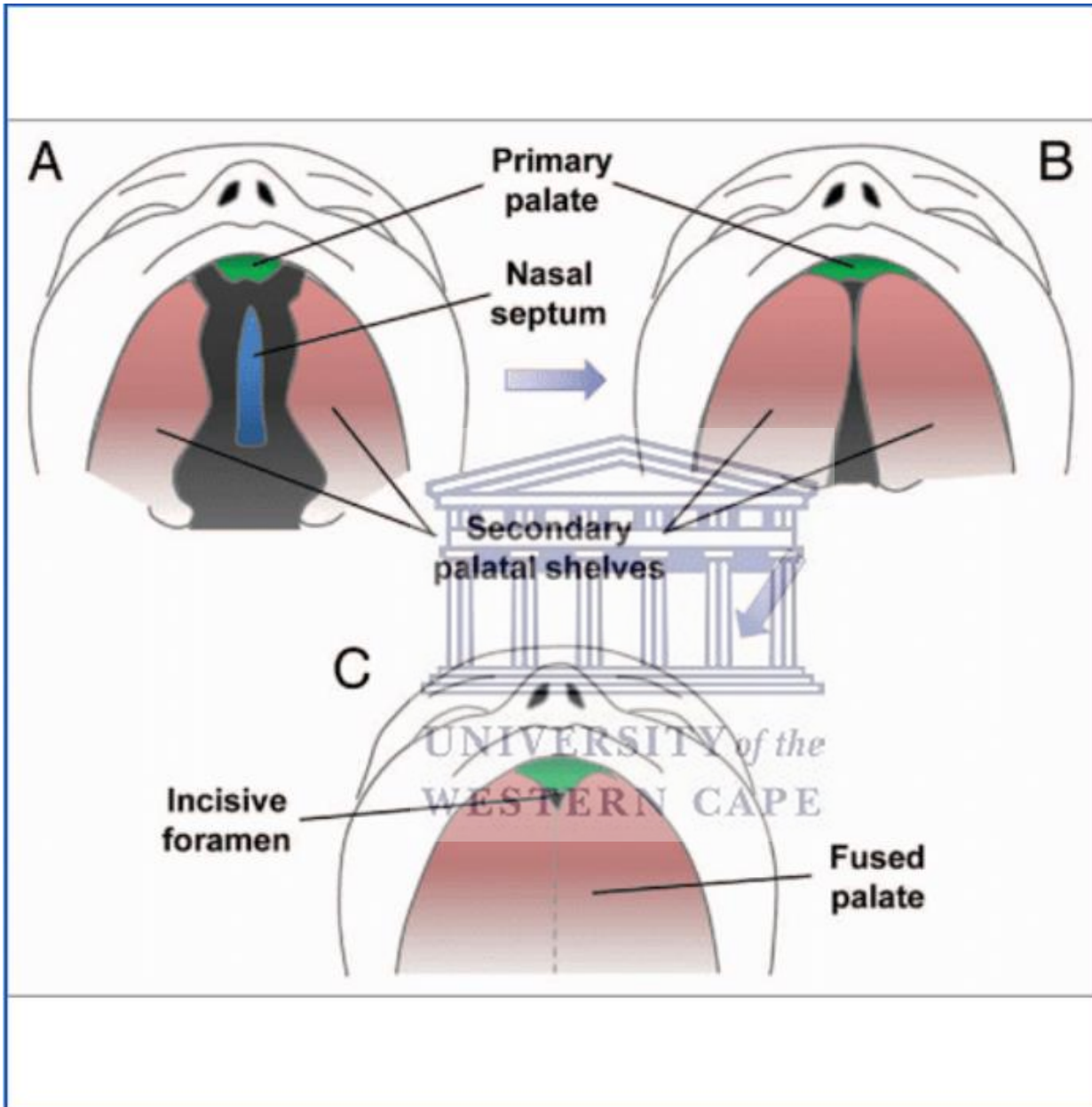


Figure 2: Embryology of the palate (Levi et al., 2011)

Source: LEVI, B., BRUGMAN, S., WONG, V., GROVA, M., LONGAKER, M. & WAN, D. 2011. Palatogenesis: engineering, pathways and pathologies. *Organogenesis* [Online], 7 4. Available: <https://www.semanticscholar.org/paper/Palatogenesis%3A-engineering%2C-pathways-and-Levi-Brugman/05f2d2f215a8eef370fe3ef64250ab669f09b51c>.

Classification of Orofacial clefts:

Orofacial clefts can be divided into two groups, as a broad classification: Non- syndromic and Syndromic clefts. Syndromic clefts involve additional structural bodily malformations that are separate from the orofacial clefts. Non-syndromic clefts have no associated syndromic bodily anomalies (Watkins et al., 2014). Orofacial clefts without any other associated malformations are known as isolated clefts.

Syndromic orofacial clefts have been noted in more than 400 syndromes (Gorlin et al., 2001).

There are different systems used to classify orofacial clefts.

The Veau classification (1931) (Figure 3)

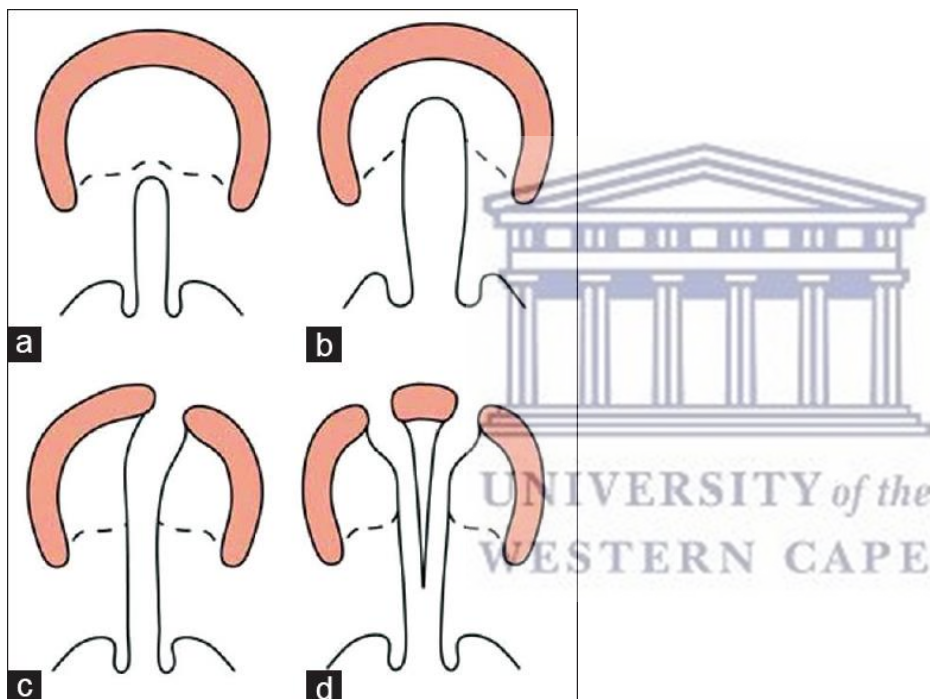


Figure 3: The Veau classification (Akbulut, 2020)

Source: AKBULUT, Y. 2020. Approach to patients with cleft lip and palate in orthodontics. *Journal of Cleft Lip Palate and CraniofacialAnomalies*[Online],.Available:<https://www.jclpca.org/article.asp?issn=2348-2125;year=2020;volume=7;issue=1;spage=8;epage=16;aulast=Akbulut>

This system uses four groups based on the anatomy of the palate.

- a) Cleft of soft palate
- b) Cleft of soft and hard palate with extension from incisive foramen to the secondary palate
- c) Complete unilateral cleft extending from the uvula to the incisive foramen, further extension on one side through the alveolus in the region of the future lateral incisor tooth
- d) Complete bilateral cleft extending from the incisive foramen to the alveolus, the premaxilla remains suspended from the nasal septum

(Zreayat et al., 2017)

Kernahan and Stark classification (1958)

This system uses 2 groups which are based on embryology. The groups could be further described as complete or incomplete or unilateral, bilateral or incomplete.

1. Cleft of primary palate which is from the alveolus up to the incisive foramen
2. Cleft of secondary palate which is from the soft and hard palate to the incisive foramen. (Zreayat et al., 2017)

Classification by International Confederation for Plastic and Reconstructive Surgery (1966)

This classification makes use of 3 groups

1. Cleft of anterior primary palate, involving the lip and alveolus
2. Clefts of anterior and posterior palate, involving the alveolus and hard palate
3. Cleft of the hard palate, involving the hard and soft palate (Zreayat et al., 2017)

Kernahan striped “Y” classification (Figure 4)

This classification describes the anatomy of the palate in a striped Y shape. The Right and Left areas of the Lip, Alveolus and Primary palate are identified by the fork of the Y. The straight midline of the Y is

represented by the hard and soft palate. The Y pattern is broken into numbered blocks from 1 – 9. The various numbers represent the specific areas affected in the orofacial cleft (Zreaqat et al., 2017).

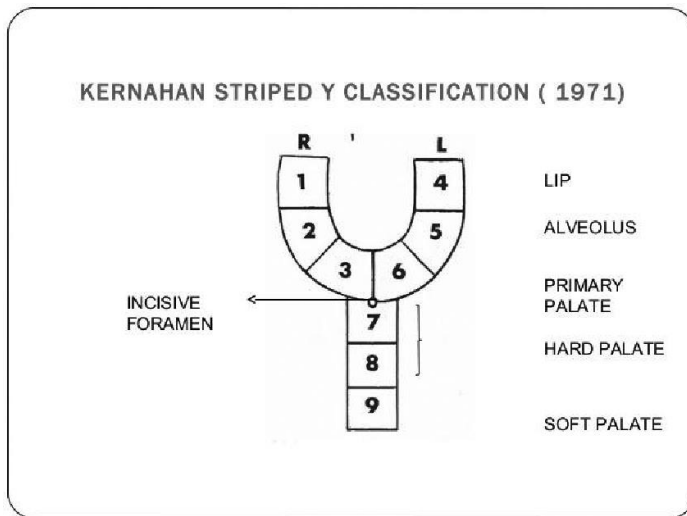


Figure 4: Kernahan’s striped “Y” classification (Zreaqat et al., 2017)

Source: ZREAQAT, M. H., HASSAN, R. & HANOUN, A. 2017. Cleft Lip and Palate Management from Birth to Adulthood: An Overview. *Insights into Various Aspects of Oral Health* [Online]. Available: <https://www.intechopen.com/books/insights-into-various-aspects-of-oral-health/cleft-lip-and-palate-management-from-birth-to-adulthood-an-overview> [Accessed 12/11/2020].

Iowa Classification: (Figure 5)

This classification is a more commonly used, variation of the Veau classification. This system makes use of 5 groups

Group I: Clefts of lip only

Group II: Cleft of palate only (secondary palate)

Group III: Clefts of lip, alveolus and palate

Group IV: Clefts of lip and alveolus (primary palate and lip)

Group V: Miscellaneous

Iowa Classification CLCP

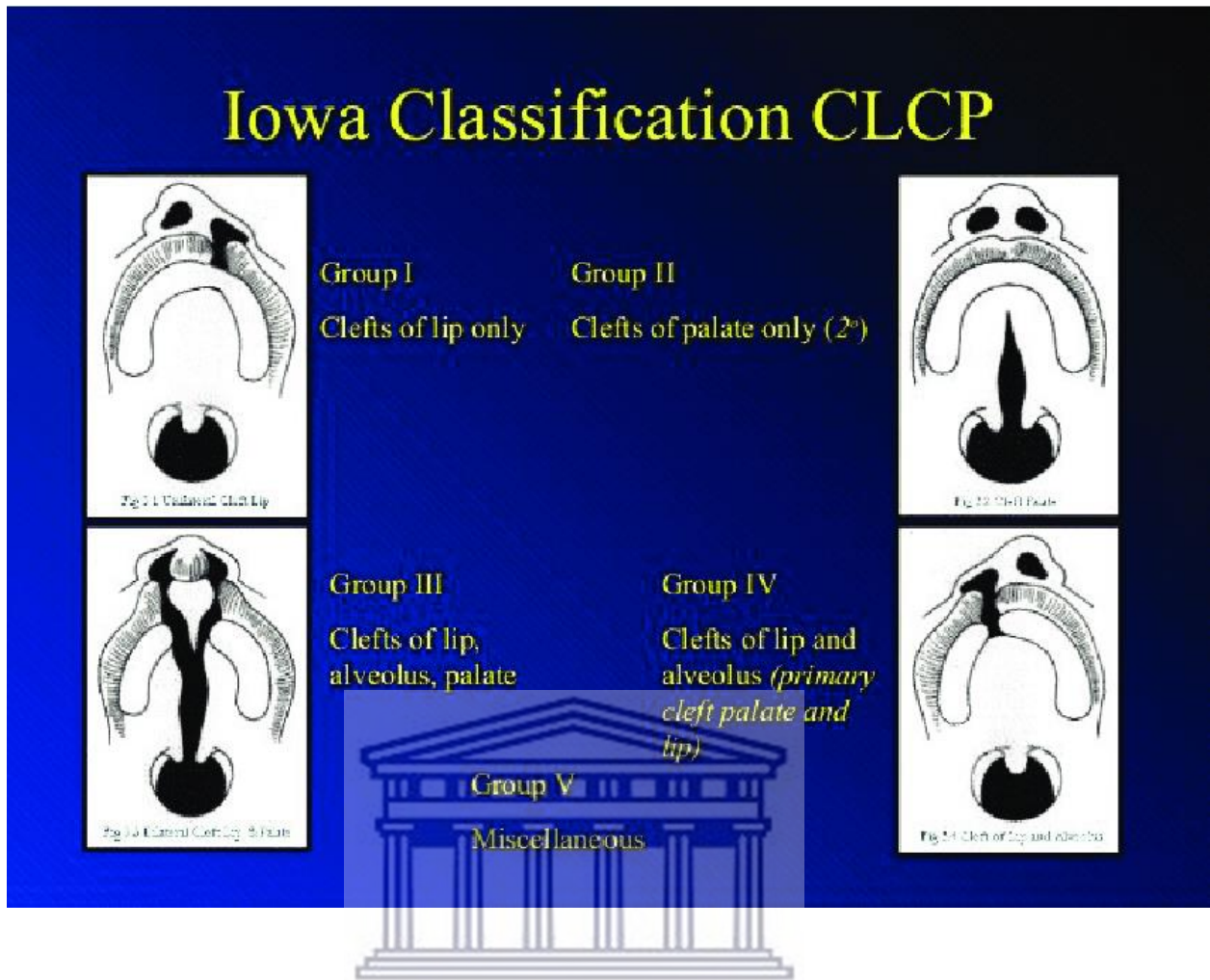


Figure 5: Iowa Classification (Zreaqat et al., 2017)

Source: ZREAQAT, M. H., HASSAN, R. & HANOUN, A. 2017. Cleft Lip and Palate Management from Birth to Adulthood: An Overview. *Insights into Various Aspects of Oral Health* [Online]. Available: <https://www.intechopen.com/books/insights-into-various-aspects-of-oral-health/cleft-lip-and-palate-management-from-birth-to-adulthood-an-overview> [Accessed 12/11/2020].

Lahsal Code (Figure 6)

The Lahsal code is used at the Wentworth Foundation clinic. The Lahsal code is established on Kernahan's diagrammatic Y Classification. The mouth is portioned into 6 anatomical parts, right lip, right alveolus, hard palate, soft palate, left alveolus, left lip (Hodgkinson et al., 2005). The code is established by analysing the site, size and extent of the cleft. The first character of the code describes the right lip and the last character

describes the left lip (Hodgkinson et al., 2005). The code describes a complete cleft with capital letters, and incomplete cleft is described with lower case letters and no cleft with a dot or full stop (Hodgkinson et al., 2005). The Lahsal code is used commonly in the UK (Zhang et al., 2017).

For example:

Bilateral complete cleft lip and palate (LAHSAL)

Left incomplete cleft lip and alveolus (...al)

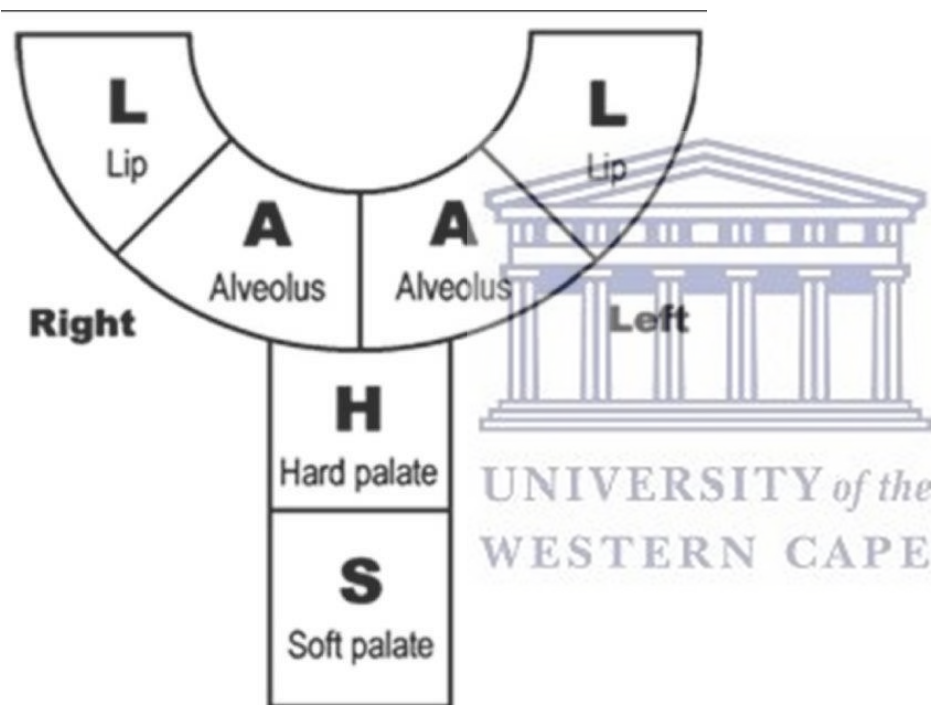


Figure 6: Lahsal code (Zhang et al., 2017)

Source: ZHANG, Z., STEIN, M., MERCER, N. & MALIC, C. 2017. Post-operative outcomes after cleft palate repair in syndromic and non-syndromic children: a systematic review protocol. *Systematic reviews* [Online], Available:<https://systematicreviewsjournal.biomedcentral.com/articles/10.1186/s13643-017-0438-2> [Accessed 09/11/2020].

Aetiology of orofacial clefts:

The aetiology of orofacial cleft is multifactorial. The risk factors involved include teratogenic exposure with teratogens such as alcohol (Meyer et al., 2003, Chevrier et al., 2005, Bille et al., 2007, Romitti et al., 2007, Bell et al., 2014) or smoking during pregnancy (Little et al., 2004, Honein et al., 2007, Leite and Koifman, 2009). Other risk factors are medical or environmental factors, chromosome abnormalities or single gene disorders. Mutations in genes such as IRF6 and MSX1, have the potential to cause orofacial clefts (Gorlin et al., 2001). Tobacco and alcohol exposure during pregnancy are reported as common risk factors for orofacial clefts (Romitti et al., 1999).

The other teratogens associated with orofacial clefts include chemicals such as corticosteroids, anticonvulsants (Shaw et al., 1995, Park-Wyllie et al., 2000, Hill et al., 2010), exposure to agricultural chemicals and organic solvents (Shaw et al., 2003), viral infections (Weichert et al., 2010, Molnárová et al., 2018) and vitamin deficiencies (Munger et al., 2004, Shaw et al., 2006) .



Epidemiology:

Global epidemiology:

Globally cleft lip and palate is the most common congenital craniofacial anomaly, 1 in 700 births (Mossey and Castilla, 2003, Centers for Disease Control and Prevention, 2006, Mossey and Modell, 2012). Mossey and coworker (2003), noted that in their sample (births during the period 1993 – 1997) the prevalence of cleft palate without cleft lip births was 1.93 per 10000 (Mossey and Castilla, 2003).

It has been reported that congenital anomalies contribute 2-3% to childhood morbidity and infant mortality (Mossey and Castilla, 2003). An estimate of 1% of these new-borns have multiple anomalies or syndromes that do involve craniofacial anomalies. Approximately 30% of orofacial cleft cases are syndromic and 70% are non-syndromic (Mossey and Castilla, 2003).

It has also been shown that the prevalence of orofacial clefts does differ based on race or ethnicity, socio-economic status and gender (Messer et al., 2010). The highest rate of occurrence was noted in the Asian population with approximately 8.2- 40.4 per 10000 live births, moderate rate in the Caucasian population with approximately 9.0-26.9 per 10000 live births and the lowest rate in the African population with approximately 1.8- 16.7 per 10000 live births (Mossey and Castilla, 2003, Centers for Disease Control and Prevention, 2006).

Cleft lip with or without cleft palate, has the highest reported prevalence in Bolivia with 2.28 per 10000 births. Most of the data was relevant in a city 4000 metres above sea level (Rosano and Mastroiacovo, 2001, Wyszynski, 2002). Interestingly, a very similar prevalence was seen in an ethnic Mongolian population from Tibet, where this population also resides at a similar altitude above sea level (Zhang, 2001). A Eurocat study found the highest reported prevalence rate of Cleft palate only is in Finland with 10 to 14 per 10000 births (Cuschieri and Working Group EUROCAT, 2001). Thus, the prevalence for Cleft lip with or without cleft palate is reportedly highest in Bolivia, whilst Cleft palate only is in Finland.

Collaborative data shows that there is a higher prevalence for Cleft Palate only among infant females whereas prevalence of Cleft Lip and Palate was found to be more predominant in males (Mossey and Castilla, 2003, Mossey and Modell, 2012). A study conducted by Conway et al (2015) revealed that the ratio of boys to

girls to be 2:1 for cleft lip and palate, thus expressing a higher incidence in boys. However, the study did also corroborate that females had a higher risk for cleft palate only (Conway et al., 2015).

Prevalence rates in Africa were approximately 0.2- 1.7 per 1000 live births, with the highest prevalence noted in Kenya with 1.7 per 1000 live births (Khan, 1965, Hlongwa, 2019) , followed by Nigeria, with 0,5 per 1000 live births (Butali et al., 2014) and the lowest rate noted in Ethiopia with 0,2 per 1000 live births (Eshete et al., 2017).

Epidemiology of orofacial clefts in South Africa:

Cleft lip and palate (CLP) is of the five most common congenital anomalies in South Africa (Kromberg and Jenkins, 1982). There have been numerous CLP prevalence studies conducted in various parts of South Africa including Pretoria, Johannesburg and Cape Town through the last three decades (Penn and Jack, 1953, Braude, 1981, Kromberg and Jenkins, 1986, Bütow and Kleynhans, 1987, Delport et al., 1995, Butow et al., 2007). These studies revealed a prevalence rate of 0.1-0.4 per 1000 live births in South Africa.

In a study conducted in 2018 at the Sefako Makgatho Oral Health Centre in Pretoria, it was found that 30% of the cleft cases were cleft palate, 23% were bilateral cleft lip and palate and 47% of patients presented with unilateral cleft lip and palate. Cleft laterality for unilateral clefts was most seen on the left side. In this particular study, for all orofacial clefts, the prevalence was greater in females than males (Moodley et al., 2018).

More recently, Hlongwa and her co-workers (2019) conducted an extensive study in South Africa, the aim of which was to obtain epidemiological data and to assess the level of care of orofacial cleft individuals. Their study included data gathered of patients attending 11 academic centres from 6 of the 9 provinces (Gauteng, Limpopo, KwaZulu Natal, Free State, Eastern Cape and the Western Cape) over a two year period (January 2013 to December 2014). Their study objectives also included the analysis of the current approach of care for cleft patients, the level of interprofessional collaboration (IPC) of the teams treating cleft patients , the level of support services and the perceptions of the caregivers of these patients (Hlongwa, 2019).

The study used information based on verified government statistics (Statistics South Africa) to calculate the overall prevalence in the public (83%) and private sector (17%) throughout South Africa. (Statistics South Africa, 2016, Hlongwa, 2019).

The prevalence rate in the public sector of individuals with orofacial clefts was 0.3 per 1000 live births with a provincial variation of 0.1/1000, 1.2/1000, which was calculated using live births during the period of the study via Statistics South Africa of all 9 provinces (2300 897 total live births 01/2013-12/2014). The calculated rate for the private sector was calculated as 0.4 per 1000 live births (Hlongwa, 2019).

The highest prevalence rate for orofacial cleft individuals was found in the Free State (1.2 per 1000 live births), followed closely by the Western Cape (1.0 per 1000 live births) and lowest prevalence rate was in the Northern Cape and Eastern Cape (0.1 per 1000 live births). KwaZulu Natal had a prevalence rate of 0.2 per 1000 live births, this was the same as Limpopo and North West province (Hlongwa, 2019).

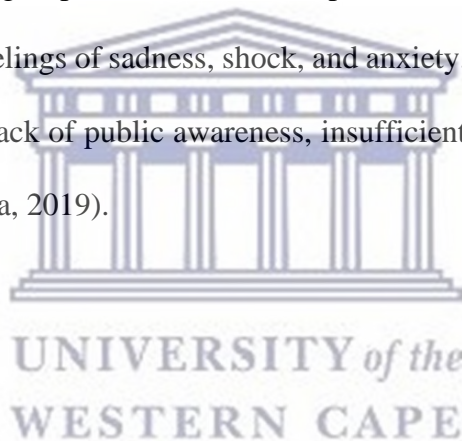
Contrary to international findings mentioned earlier from Mossey et al and the Centers for disease Control and Prevention, racial or ethnic orofacial cleft prevalence rates varied with the majority in the African Black population, followed by White/Caucasian population followed by the Coloured and Indian populations. The study did not aim to pay homage to racial group classifications, however, they motivated that race and socioeconomic circumstances do play a role in access to care in South Africa post- apartheid (Moyo, 2016, Hlongwa, 2019).

Hlongwa and coworkers' study revealed that for all orofacial clefts, females were more prevalent than their male counterparts. This finding was similar to that at Sefako Makgatho Oral Health centre (Moodley et al., 2018). As far as the prevalence of the type of clefts was analysed a greater prevalence of CLP was noted in males (Hlongwa, 2019).

With regards to the types of clefts in this study sample Hlongwa and colleagues found Cleft lip and palate (CLP) was the most prevalent 44%, followed by Cleft palate 35 % and Cleft lip 19%. Most of clefts were unilateral 46%, followed by Palatal clefts 36% and with Bilateral clefts 16%. The laterality of the clefts was predominantly on the left side (Hlongwa, 2019).

In terms of the type of care that was administered in these centres, the treatments dominating cleft care were plastic surgery, surgical repair of the lip and palate and speech therapy. Thus, highlighting the lack of a wholistic and comprehensive approach with multidisciplinary team involvement such as ENT specialists, nutrition and feeding assistance as well as dental intervention. All of which, is required for wholistic care of cleft patients (Hlongwa, 2019).

Regarding the Interprofessional collaboration (IPC), the study identified a high score for the domain: care expertise. Care expertise being described as the working together of healthcare professionals, as well as their patients and their patient's family to enhance patient care. However, effective group function obtained the lowest score. Effective group function is described as the health care system, which should promote interprofessional teamwork, to improve patient care and decrease workload for the treating professionals. Therefore identifying that effective group function can be improved in cleft care in South Africa (Hlongwa, 2019). The caregivers expressed feelings of sadness, shock, and anxiety. The caregivers also expressed stress with the burden of care provision, lack of public awareness, insufficient support services and experiences of health system deficiencies (Hlongwa, 2019).



Developing Nations and Third World context

Challenges and complications due to insufficient multidisciplinary care and awareness

African cleft patients are faced with additional challenges, such as: a lack of facilities and resources and limited or difficult access to health care. These challenges are coupled with high levels of poverty thereby, adding an additional strain to cleft treatment (Conway et al., 2015). Cleft palate care is intensive and long term, therefore demanding more time and commitment from parents to ensure adequate care for their children.

In many developing nations, multidisciplinary cleft care in the public or the state setting is not easily accessible and there are still many barriers to overcome to establish adequate state cleft palate care. A 10 year study across Africa revealed challenges faced by the third world and developing nations in relation to the public sector (Conway et al., 2015). Cleft conditions in developing or under developed regions are associated with an increased infant mortality and raised morbidity (Conway et al., 2015). Oro-facial cleft patients with insufficient multidisciplinary care are at risk of many challenges which directly impact their quality of life. Some of the challenges experienced include difficulty in feeding or suckling during infancy due to inability to obtain a palatal seal. This may result in failure to thrive; eustachian tube dysfunction which causes chronic otitis media, which in turn may result in loss of hearing; difficulty in speech and pronunciation of words and mid face hypoplasia (Conway et al., 2015).

The loss of hearing or speech in cleft patients does add to difficulty in social interactions. Furthermore, the aesthetic difference associated with an unrepaired or poorly repaired cleft makes it difficult for a child to socialise with peers in school or in general. There are also many stigmas and traditional beliefs associated with clefts that can further ostracise a cleft child. Proper education and awareness directed to the public in developing regions is required to help reduce negativity towards the condition (Conway et al., 2015).

The aesthetic concern of cleft treatment has been noted in Africa. As the majority of the cleft cases treated are cleft lip cases, which has an aesthetic influence, as the lip is visible during social interactions. A study in Uganda 2012, noted a higher number of cleft lip repairs as opposed to cleft palate repairs (Wilson and Hodges,

2012). The cleft lip is more aesthetically visible, thus, the aesthetic perception of cleft patients has been noted (Wilson and Hodges, 2012). With regard to the cleft lip and palate patients, the second surgery of palatal repair is not always possible (Orkar KS, 2002, Wilson and Hodges, 2012, Conway et al., 2015). The 10 year study in association with Operation Smile by Conway et al, as well as studies by Orkar as well as Wilson and Hodges, have attributed this reluctance for palatal second stage of surgery to patients who cannot survive until the second palatal surgery, a general lack of funds as well as a lack of funds for transport and a reduced desire for surgery by the parents. As aesthetics associated with the easily visible labial clefts and associated stigmas are more apparent than functional difficulty related to the cleft palate only, in the population assessed (Orkar KS, 2002, Wilson and Hodges, 2012, Conway et al., 2015).

A study conducted at the University of Witwatersrand in Johannesburg (Bhabha Z, 2013) explored the impact of the quality of life of mothers with cleft lip and palate children. The study was a descriptive study involving 42 mothers. The study revealed that the mothers experienced being tired or exhausted and the mothers experienced difficulties with their partners due to lack of awareness or insufficient counselling. Mothers expressed that more emotional support was required, and that prenatal diagnosis is preferred (Bhabha Z, 2013). The study revealed the strain cleft patients' parents experience in a South African setting, however the treatment in various provinces is not consistent and further research in KwaZulu Natal (KZN) is required.

It is thus important to identify that the quality of care for cleft patients is not internationally consistent and more challenges are experienced in developing nations. Therefore, cleft patients and parents in these developing nations are under an additional strain due to a developing infrastructure and social issues such as poverty and lack of transport. In South Africa, cleft treatment is available in both private and public sectors. The study will assess the public sector attending the Wentworth clinic in KZN.

Currently no studies have been found assessing the quality of life of cleft patients in KZN.

The need to begin assessing the Health- Related Quality of Life in KZN is crucial. The chosen aspect of study being the Oral health of Cleft individuals, is the beginning of assessing the Health- related quality of life of cleft patients in KZN.

Socioeconomics in KZN

A quantitative study in 2017 by Singh was conducted at the Wentworth Foundation clinic. The study assessed absconded dental treatments by cleft patients at the Wentworth foundation clinic via a structured interview process; the study brought to light many pertinent socioeconomic reasons the patients did not attend the clinic for their appointments (Singh, 2017).

Five main areas were identified on analysis of the data: Socioeconomic factors related to financial problems, Socioeconomic factors related to spatial disruptions, Socioeconomic factors related to education and exposure, Socioeconomic factors related to inadequate public health care, Service gaps at the Wentworth Foundation. Each aspect will be explored briefly for understanding of the socioeconomic situation in KZN (Singh, 2017).

Socioeconomics related to financial problems was the main reason patients could not attend their appointments. The financial difficulties experienced were associated with poverty and inequality in South Africa (Singh, 2017). Income inequality has an impact on the population health therefore people from disadvantaged social backgrounds are prone to have a lower health as compared to the wealthier population (Barkan, 2012).

In the study 75 percent of the participants reported that they had to discontinue their treatment due to unemployment and reliance on social grants (Singh, 2017). This theme of unemployment and social grant reliance was noted in other studies as well (Cronje, 2014, Kuada, 2015).

Large households with a median of 6 people with only one employed family member have difficulty with funds. Prioritising food over transport is often necessary to sustain the large household (Singh, 2017)

Spatial disruptions in South Africa related to patients located in rural areas give rise to lack of access to infrastructure and health care services. Health care infrastructure in the rural areas is not as advanced as in the cities and therefore does not support advanced health care services, therefore patients need to travel great distances and incur increased transport costs to obtain the necessary healthcare required (Singh, 2017).

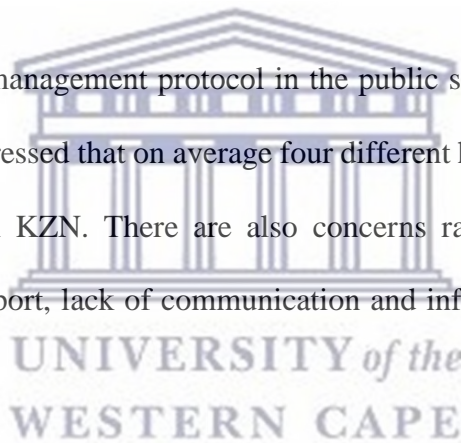
Lack of exposure and education often result in cleft patients' parents feeling shock and at times depressed, regarding a cleft diagnosis at birth. Many cleft babies are abandoned at birth and one third of mothers who

give birth to children with a facial deformity consider committing suicide (The Wentworth Foundation, 2015). Due to insufficient education and exposure to the orofacial cleft condition many cleft patient parents are unable to adequately support the cleft multidisciplinary treatment. Limitations in the sharing and exposure of knowledge of orofacial cleft care in the public sector is a critical area of concern (Singh, 2017).

Social issues pertaining to cleft patients having difficulty integrating into society are further aggravated by a lack of awareness in the public (Singh, 2017). The children with orofacial clefts notice the difference in their appearance when they are teased in school during a critical stage in their development. Early in the child's life, psychological challenges are placed more on the family and later in the child's life psychological pressures are placed more on the child, which are commonly associated to the school environment (Singh, 2017, Kummer, 2014). Thus the difficulties in navigating the orofacial cleft condition can be noted in both the child and their families.

Lack of specialist knowledge and management protocol in the public sector was noted in the study (Singh, 2017). Participants of the study expressed that on average four different hospitals were required to adequately treat the orofacial cleft patients in KZN. There are also concerns raised about long waiting period for surgeries/interventions, lack of support, lack of communication and information and lack of follow up care (Singh, 2017).

Service gaps in the organisation were related to: Lack of understanding of the completeness of treatment which is not limited to the aesthetic value of the treatment, complications related to interrupted treatment such as pain in the teeth and speech and hearing deterioration, difficulty taking time off from school and lack of understanding from teachers/schools regarding time required to treat the condition, lack of open communication and language barrier (Singh, 2017)



Health-Related Quality of Life (HRQoL)

Health related quality of life measures have been adapted from the World Health Organisation's definition of health. The definition of health by WHO: "A state of complete social, mental and physical well-being and not merely the absence of disease or infirmity" (WHO, 2002). The HRQoL is significant in patients with chronic health conditions. The goal of treatment being to restore the patients' health by means such as improving the patient's ability to cope with their condition, treatment adherence and management of symptoms (Varni et al., 1999). Chronic health conditions involve lifelong treatment and thus impact on the HRQoL in an immense manner. It has been proposed that HRQoL assessments maybe a better indicator of well-being for patients undergoing chronic treatment than biomedical markers (Varni et al., 1999). In order to ensure that children receive the best chronic health care with the best recommended professionals in the most suitable settings, HRQoL surveys are required (Varni et al., 1999, Seid et al., 2004).

The HRQoL can be reviewed via self-report of patients and helps improve understanding of a patient affected by a condition or illness by quantifying their health-related quality of life. Children with both a chronic disease and low HRQoL had average healthcare costs that were reported to be approximately twelve times greater than children with chronic disease and a higher HRQoL (Seid et al., 2004). Thus, HRQoL can be used to recognize patients that would benefit from more intense preventative care or various other treatment modalities. Improving the health related quality of life of a patient can possibly reduce the total healthcare costs (Seid et al., 2004). HRQoL allows clinicians to better understand their patient's perception and how the disease influences their patient's life therefore enabling clinicians to make more informed treatment recommendations (Ralstrom, 2010).

Marcusson and coworkers, compared the quality of life of Swedish adults with repaired cleft lip and palate to people without an orofacial cleft in Sweden (Marcusson et al., 2001). The study revealed that the cleft group rated their quality of life lower in areas such as private economy, life meaning and family life. The cleft palate group perceived a significant impact of the cleft with social aspects of their life and their well-being. The study revealed that overall the cleft participants did adapt well to daily living (Marcusson et al., 2001). It is

however important to note that this survey was conducted in a first world country and subjects involved in the study underwent multidisciplinary care as opposed to South Africa which is a third world setting.

The HRQoL scores are determined as based on the chosen verified questionnaires or survey format of scoring.

The HRQoL scores are described as low or high based on comparison with other studies with the same questionnaires.

Adults with orofacial clefts showed lower scores in certain subscales pertaining to their overall HRQoL score, such as: emotional role and social functioning; however not in subscales mental health, vitality, general health, physical functioning, bodily pain and physical role (Sinko et al., 2005). The orofacial cleft adults who would have liked further treatment had scored lower in their HRQoL compared to the participants who did not want further treatment specifically in subscales vitality and physical role (Sinko et al., 2005).

An assessment of the quality of life of adolescents in a Children's Hospital in Seattle was conducted in 2005. The study compared the quality of life of children with facial deformities to those without facial deformities but with invisible diseases such as attention deficiency or hyperactivity and those without facial deformities but with mobility disorders. The study revealed the quality of life for children with facial deformities as lower than those without facial deformities. However the study also revealed that patient's with facial deformities had a stronger relationship with family than those without facial deformities (Topolski et al., 2005).

The HRQoL of children with dental caries were compared to children with orofacial clefts, few differences were found in the HRQoL scores, specifically in their emotional well-being and oral symptoms (Locker et al., 2005). Orofacial cleft children have been reported to have a marginally lower HRQoL, as evaluated by healthcare workers who offer treatment to orofacial cleft children in the United States (Wehby et al., 2006).

Gkantidis, et al, aimed to evaluate the satisfaction of cleft patients and their parents on their aesthetic and functional outcomes, as well as the impact of the cleft palate and lip on their everyday lives. The study was conducted in association with the Department of Orthodontics in Athens, Greece and involved 33 patients and 30 parents. The participants were involved in a guided interview questionnaire (Gkantidis et al., 2015).

The study highlighted the importance of early intervention and long-term multidisciplinary care in cleft patients. Every step of cleft care plays an important role in the outcome of aesthetics and function and each step has a large impact on a cleft patient's quality of life. The study reported that different types of cleft patients reported different concerns.

The cleft palate patients were more satisfied with their aesthetics whilst the unilateral and bilateral cleft lip and palate patients were less satisfied with their aesthetics. A direct correlation between the satisfaction of aesthetics and ease in socialising was evident. Participants who were unsatisfied with their aesthetic outcomes were also unsatisfied with their social interactions. With regard to function and aesthetics, it was found that older subjects were more satisfied with their hearing and dental appearance (Gkantidis et al., 2015). The study does highlight the need to review or assess the quality of life of cleft patients as their treatment is long lasting, intensive and involves various vital disciplines (Gkantidis et al., 2015). To gauge the outlook of the cleft patient on an aspect of their HRQoL, such as the Oral Health-related quality of life (OHRQoL), allows identification of areas of strength and weakness in that specific aspect.

Warschausky and co-workers (2002) studied the perception of parents on the HRQoL of their children aged 5 to 18 years old, with orofacial clefts as well as other craniofacial anomalies using the Child Health Questionnaire version PF28 (Warschausky et al., 2002). They found that children with orofacial clefts had psychosocial and physical scores that were within the normal range. Their parents were less concerned about the global health status of children with orofacial clefts than those with other craniofacial anomalies. No significant correlation was made between sex and age in relation to psychosocial and physical health (Warschausky et al., 2002).

Preadolescent children with non-syndromic orofacial clefts scored lower than children without orofacial clefts in the psychosocial health component scale of the Paediatric Quality of Life (PedsQL) survey and the use of telephone interviews (Damiano et al., 2007). High household income was directly proportional to higher quality of life, psychosocial and physical scores. The greater the number of household members, the higher the quality of life scores were registered. The parent's awareness of their child's happiness in relation to their facial appearance was associated with higher HRQoL and psychosocial scores. The speech ability of the child

was related to the HRQoL, psychosocial and physical score of the child. The children with cleft lip and palate had lower HRQoL scores than children with cleft palate. The children who were younger such as ages 5-7 and 2-4 scored higher in their HRQoL than children aged 8-12 years. Therefore, the study shows that the aesthetics of the outward appearance which is directly related to the lip anatomy has a greater significance as the child grows into an adolescent (Damiano et al., 2007).

The Beck Inventory for Depression was also used to assist in identifying depression in the cleft children. The Beck Self-concept inventory for youth involves 20 items aimed to measure competence, self-perception and self-worth. The study concluded that a positive psycho-social disposition directly correlates with an improved OHRQoL. Conversely depression correlates with a poorer OHRQoL (Broder et al., 2014a).

The KINDL questionnaire is an instrument used to assess HRQoL. The KINDL questionnaire was developed by Prof Ravens-Sieberer and Prof Bullinger in 1994 and was revised in 1998 to form the KINDL- R (Ravens-Sieberer and Bullinger, 1998, Bullinger et al., 2008). The KINDL- R questionnaire shows good scale fit, moderate internal consistency and good scale utilisation. There have been differences noted between scores of healthy and chronically ill children (Bullinger et al., 2008).

In a study done by Kramer and co-workers (2008) the KINDL questionnaire was used to assess the HRQoL of 5-6 year old children with orofacial clefts and their family's perception of their HRQoL. Their study revealed that the children scored lowest in the subscale of self-esteem. The study noted that the orofacial cleft children scored higher in all aspects of their KINDL score as compared to their parents perceived view of their HRQoL (Kramer et al., 2008). Therefore, the orofacial cleft participants scored themselves higher in the KINDL questionnaire than their caregivers had reported.

In a subsequent study Kramer and co-authors (2009) reported on 170 children with orofacial clefts aged 8-12 years (school aged) and their respective families. The study involved the KINDL questionnaire and Impact on Family scale (Kramer et al., 2009). In the domain of Family functioning scores were higher in children with cleft lip than with children with cleft palate or cleft lip and palate. The scores of children with cleft lip and palate suggested difficulty socially with family and friends. Boys displayed a lower HRQoL than girls. Children with cleft lip only, displayed a higher quality of life than children with cleft palate or cleft lip and

palate. This is a surprising finding as compared with Gkantidis study in 2015, where the cleft lip patients were less satisfied with their aesthetics which had a negative correlation with their social interactions. Many limitations on the HRQoL of the orofacial cleft children were noted, however difficulty in social interactions was most prominent (Kramer et al., 2009).

Highlighting the need for cleft specific surveys; a study from Mount Sinai School of Medicine in New York discussed the importance of assessing the outcomes of cleft patient care using survey's which assess cleft patient's self- image, functional ability to chew and speak and the patient's perception of their aesthetics. The study highlighted that although important objective measures such as morbidity, mortality, photographs and anatomic measures are necessary; more thorough research is required for cleft patient treatment satisfaction due to the chronic and intensive nature of treatment (Eckstein et al., 2011).

Italian research conducted by Piombino et al in 2014, made use of the Quality-of-Life Adolescent Cleft questionnaire (QoLAdoCleft Questionnaire). This questionnaire was specifically developed to assess adolescent patients with Cleft Lip and Palate (Piombino, 2014). A multidisciplinary team was used to develop the questionnaire, the team comprised of 2 speech therapists, 2 statisticians and 5 surgeons. The survey consisted of 36 items and was adapted around 3 main domains. The 3 domains encompassed were psychological, physical and social (Piombino, 2014).

The questionnaire was conducted on a randomised sample of 40 young adults (aged 16 to 24) with CLP and 40 young adults without CLP. The study revealed the QoLAdoCleft questionnaire had good reliability and validity. The QoLAdoCleft questionnaire comprised of 2 sections, the first being the clinical profile of the patient which requested information such as name, age, sex, level of education, cleft type and the surgical work performed to date. The second section of the questionnaire focussed on physical, social and psychological health (Piombino, 2014). The study does recognise that further validation on a larger population is recommended to confirm the findings of the research by Piombino et al, no further published studies were found related to the use of the QoLAdoCleft Questionnaire. Due to the need for further validation this questionnaire was not used for the dissertation.

Oral Health-Related Quality of Life (OHRQoL)

The Oral health- related quality of life (OHRQoL) is the chosen aspect of the HRQoL which will be the focus of this study, specifically for orofacial cleft patients. The influence of an individual's oral health on their quality of life is described as oral health related quality of life (OHRQoL). OHRQoL is multidimensional, it consists of both the absence and presence of oral disease and includes psychological components of oral health (Gift et al., 1997).

The initial Oral Health Impact Profile- 49, developed by Slade in 1997, contained 49 items or questions and is known as the OHIP-49 (Slade, 1997). This questionnaire assesses individuals' oral health impact on their well-being. A subset questionnaire was established known as the Oral Health Impact Profile- 14 (OHIP- 14). The OHIP- 14 form underwent secondary analysis from an epidemiological study of 1217 people in South Australia. The subset questionnaire was developed on participants aged 60+ years. Regression analysis, factor analysis and internal reliability were used to obtain a subset questionnaire known as the OHIP-14 questionnaire. The validity of the OHIP-14 was assessed using associations with clinical oral status and sociodemographic variables. The internal reliability of the subset questionnaire was evaluated using Cronbach's coefficient. The regression analysis lead to the 14 questions. The subset questionnaire accounted for 94% variance in the OHIP-49, acceptable distribution of prevalence for each question, the questionnaire had high reliability ($\alpha=0.88$) and the OHIP-14 questionnaire addressed each of the 7 dimensions in the OHIP-49 questionnaire as mentioned above. The OHIP-14 and OHIP-49 displayed the same pattern of variance in the sociodemographic group of older adults. The study revealed that the OHIP- 14 has good reliability, precision and validity (Slade, 1997).

Slade describes that the OHIP- 49 is based on Locker's theoretical formula of oral health. The 7 dimensions as mentioned above are handicap, social disability, psychological disability, functional limitation, physical pain, physical disability and psychological discomfort (Slade, 1997).

Antoun et al (2015) compared 3 different groups of adolescents requiring comprehensive oral health care. Their sample comprised of 83 adolescent subjects of whom 30 presented with severe malocclusion, 24 with cleft lip and or palate and 29 subjects requiring orthognathic surgery and fixed orthodontic treatment. All the participants completed the OHIP-14 questionnaire before and after their treatment. The results revealed that the participants who underwent orthognathic surgery experienced the greatest improvement in their OHRQoL after treatment and had the lowest OHRQoL before treatment. The cleft participants reported the least improvement in their OHRQoL in comparison to the other subjects. The surgery participants felt a greater improvement in their OHRQoL. The postulated reasons for the higher score with the surgery participants, is that they may have experienced a marked improvement in their appearance and thus an improvement in their ability to socialise. The aesthetic improvement for the orthognathic surgery participants was rapid as opposed to the cleft participants who underwent a lengthy treatment from the time of birth. Hence the results for the orthognathic surgery participants were more immediate in comparison to the gradual changes in the cleft participants (Antoun et al., 2015). Another possible reason for the higher score in the surgery patients is that the orthodontic treatment in adolescent cleft patients is more of a functional improvement and that most of the aesthetic work such as lip and palate surgery has already been completed. Therefore the changes are not as pronounced for orofacial cleft patients as for the orthognathic surgery patients.

The study also highlighted that the OHIP-14 form does not address all the specific challenges cleft patients may experience such as speech problems, hearing problems, nasal deformity and soft tissue scarring. This was because the sample of participants was heterogenic thus not specific to cleft participants. The study does also discuss the importance of the appearance of the nose and lip to cleft participants, as the appearance of such is related to social cues. It is noted that clefts which are visible (lip, nose) can have a negative impact socially on aspects such as peer interactions and marriage. The satisfaction of the cleft patient's appearance is also influenced by the satisfaction of the people they are surrounded by, such as the cleft patient's parents. The study also noted that participants with a cleft lip reported less improvement with OHRQoL than participants with only a cleft palate. Thus the aesthetic component of the cleft lip does have a large role in OHRQoL (Antoun et al., 2015). However, it is noted that cleft patients' quality of life should ideally be assessed relative

to the specific challenges they experience such as their ability to swallow, chew, speak, hear (Antoun et al., 2015).

As stated previously, no widely used and thoroughly validated questionnaire is currently available to assess the wholistic quality of life of orofacial cleft patients, each aspect of the cleft patients' quality of life can be assessed individually. In 2011, a study investigated validated HRQoL surveys that pertain to the multidisciplinary care required in orofacial cleft treatment. The analysis found a craniofacial specific measure called the Youth Quality of Life-Facial Differences, 2 voice QoL measures known as the Cleft Audit Protocol for Speech and the Patient Voice-Related Quality of Life, and 2 OHRQoL measures known as Child Oral Health Quality of Life and the Child Oral Health Impact Profile. Of these surveys, none was created solely for Orofacial cleft patients, therefore limitations did arise in assessing the complete HRQoL (Eckstein et al., 2011).

In 2014, Piombino et al worked on developing a cleft specific HRQoL survey. An instrument known as the QoLAdoCleft Questionnaire was developed. The aim was to assess if the multidisciplinary needs of orofacial cleft individual were met. The study did conclude that further research is required to investigate orofacial cleft patient needs and the developed questionnaire would need to be further validated (Piombino, 2014).

Oral Health related quality of life (OHRQoL) in Children:

There are two main survey tools which have been developed to assess the OHRQoL in children: The Child Oral Health Impact Profile (COHIP) and the Child Perceptions Questionnaire (CPQ).

The CPQ was formulated to evaluate children's view on the effect of oral disorders on psychosocial and physical functioning. The CPQ (8-10) and CPQ (11-14) were established for children of different ages according to their lifestyle and cognitive ability. Research has shown varied results in relation to the CPQs ability to pick up OHRQoL differences between control groups and orofacial cleft groups (Wogelius et al., 2009). One study found the CPQ 11-14 to be reliable and valid in determining OHRQoL differences in children with orofacial clefts versus those in paediatric and orthodontic dentistry groups (Jokovic et al., 2002).

A study using the CPQ (8-10), formulated for 8-10 year olds, showed a somewhat greater level of effect on the orofacial cleft group than in the paediatric dentistry group. However, overall discriminative validity was not evident. The discriminative validity between orofacial cleft children and children without orofacial cleft is limited, as found by Danish forms of the CPQ(11-14) and CPQ(8-10) (Wogelius et al., 2009).

Child Oral Health Impact Profile (COHIP):

The Child Oral Health Impact Profile is a survey used to assess the OHRQoL of children using self-report. It is the chosen instrument used to assess the OHRQoL of children in this study. The OHIP-14 form was not chosen as it does not address many of the challenges cleft patients may experience such as speech problems, hearing problems, ability to eat and facial appearance (Antoun et al., 2015). The QoLAdoCleft Questionnaire was not chosen as it needs to be further validated (Piombino, 2014).

The importance of the psychological component in cleft care is highlighted in a study by Broder et al (2014b). This was an observational study conducted over 5 years, in which youth with clefts completed surveys to allow for analysis of their psychological status and they were evaluated for surgery. The observational study was based on the Child Oral Health Impact Profile (COHIP) which is guided by 5 domains: self-esteem, emotional well-being, functional well-being and specific oral symptoms such as toothache and school environment. The COHIP makes use of Likert scale, with 5 points associated with descriptive terms ranging from almost always to never (Broder et al., 2014b). The alternative method to be used for the survey is the visual analogue scale (VAS). Both the Likert scale and the Visual analogue scale show validity (Sinko et al., 2005).

The validity and reliability of the COHIP, were established by Broder and Wilson-Genderson in 2007. This was established in a study with 523 children of various ethnic backgrounds from elementary schools, craniofacial clinics and orthodontic clinics (Broder and Wilson Genderson, 2007). The study found that the COHIP had particularly good test and retest reliability and exceptional scale reliability.

The Child Oral Health Impact Profile has proven excellent validity and reliability (Broder and Wilson-Genderson, 2007). Broder and Wilson- Genderson's study, which compared the OHRQOL of children from

craniofacial, paediatric and orthodontic clinics revealed that the craniofacial group had a more negative impact on their OHRQOL when compared to the other groups. The validity of discrimination was emphasized by substantial differences on the COHIP scores amongst the various clinic groups. The craniofacial patients had lower COHIP scores than the non-clinic subjects, orthodontic patients and paediatric patients. The children in the orthodontic group with severe malocclusions showed lower OHRQoL scores. Therefore the COHIP was capable of acknowledging variances between the different groups and also variances in disease severity for a particular clinical condition (Broder and Wilson-Genderson, 2007).

Convergent validity testing indicated that a noteworthy positive relationship between COHIP scores and Global Health was evident. The suitable validity and reliability exhibited support for the COHIP to be used a psychometric tool (Slade and Reisine, 2007).

COHIP in relation to craniofacial patients

Broder and Wilson-Genderson conducted a study including 523 children. They were enlisted from the craniofacial, orthodontic and paediatric clinics. The total sample comprised of 104 community-based participants, 152 orthodontic patients, 157 paediatric patients and 110 patients with craniofacial malformations. As discussed, the craniofacial group had a lower OHRQoL, therefore reporting a more significant negative impact on their OHRQoL than the other groups. Craniofacial patients did also score lower in subscales such as School Environment, Social or Emotional well-being and Functional well-being (Broder and Wilson-Genderson, 2007, Broder et al., 2007)

Age in relation to COHIP scores/ OHRQoL:

In 2007, Broder and Wilson-Genderson did find that there were age related differences in the COHIP scores (Broder et al., 2007). Children in the age group of 8 years had lower subscale scores in Functional well-being when compared with those in the 11-12-year old group. This may be attributed to the small sample size of the 8-year-old group. The children in the age group 15 years old, had lower functional well-being scores than children in the age group 11-13. A possible explanation for this was that the older children (age 15) had gone

through the untreated condition for longer than the younger children (ages 11-13). The study is limited on age-related variances in the OHRQoL in adolescents with an orofacial cleft (Broder and Wilson-Genderson, 2007). The mean age of the children in this group was 11.6 years (SD 1.6). The craniofacial group which had the lowest scores had a mean overall COHIP score of 87.1 with a comparison of the mean values depicted by SE as 3.0. The various subscale scores in the craniofacial group were Functional wellbeing 14.7 (SE 0.61), Social/Emotional wellbeing 21.6 (SE 1.2) and School environment 11.9 (SE 0.4) (Broder and Wilson-Genderson, 2007).

Damiano et al found that there was significant difference in the HRQoL in children with orofacial clefts with regards to age. The study also found that the difference in external aesthetics of the nasolabial complex has a greater influence as the child reaches closer to adolescence (Damiano et al., 2007).

Ward (2013) assessed the oral health related quality of life of patients with orofacial clefts, their ages ranging from 8-18 years. Additionally, the study sample included their parents as well as a control group aged 8- 18 years. A self- reported questionnaire, the COHIP form, was used, to obtain the information from the participants (Ward et al., 2013).

The total number of subjects involved in the study were 75 orofacial participants and their parents and 75 control participants. Results of the study showed that children with orofacial clefts appeared to have a lower quality of life in aspects such as the Oral health related quality of life, social/emotional well-being and the functional well-being. The study also revealed that the negative impact of social/ emotional well- being experienced by orofacial cleft patients aged 15-18 years was greater than younger subjects (Broder and Wilson-Genderson, 2007, Ward et al., 2013).

Ward's study noted a greater negative influence of cleft lip and or palate in the 15 to 18 year old group than in the younger age groups (Ward et al., 2013). The overall mean scores for cleft children in Ward's study was 95.6 with a standard deviation of 18.3.

The study was conducted on children and adolescents and made use of the COHIP which is a reliable and valid tool. The need to investigate the given age group was because it is a critical period for restoring the

aesthetics and function as the child is still developing. The age range is specific to school going age and would be apt to assess the school environment.

A study conducted by Abebe et al (2018) aimed to assess the OHRQoL of children with orofacial clefts and their parents in an Ethiopian sample. They assessed patients between the ages of 8 and 17 years using a translated Amharic COHIP form. The study included 41 orofacial cleft participants and their parents.

The study revealed that 7.3% (3) were born with cleft palate only, 4,9% (2) were born with bilateral cleft lip only, 7.3% (3) were born with unilateral cleft lip only, 22 % (9) born with bilateral cleft lip and palate, 58,5% (24) of participants had unilateral cleft lip and palate. The mean overall COHIP score for the patients and their parents was 155. The parents COHIP scores were between 67 to 186. The patients COHIP score were between 78 and 190 (Abebe et al., 2018). The majority of the cleft cases in the study were unilateral cleft lip and palate. It is important to note that the Likert scale did involve scores from 1-5 and not 0-4 therefore scores were higher.

Measurements/ Scoring in the COHIP

The COHIP was designed for children and teenagers aged 8-15 years old (Broder and Wilson-Genderson, 2007). It consists of 38 items in total. 34 items form 5 distinct subscales which reflect the COHIP score or OHRQoL.

The 5 subscales in the COHIP are:

1. Oral Health
2. Self- Image
3. Social/Emotional well being
4. Functional well being
5. School environment

The additional 2 subscales excluded in the scoring are:

6. Treatment expectancy
7. Global Health

(Broder and Wilson-Genderson, 2007, Broder et al., 2007)

Listed below are the 5 subscales as well as the additional 2 subscales with their corresponding 2 items each, these 2 subscales are not included in calculating the overall COHIP. An item is a word used to describe a question in the COHIP questionnaire, as per Broder and Wilson-Genderson who developed the questionnaire.

1. Oral Health: This comprises of oral symptoms which are not specifically related to each other. Such as pain or spots on the teeth.
Items: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10
2. Functional well-being: This measures the child's ability to carry out activities or specific tasks. Such as chewing or speaking clearly.
Items: 11, 15, 20, 23, 25, 27
3. Social/Emotional well-being: This relates to mood states or peer interactions.
Items: 12, 16, 17, 19, 22, 24, 28, 29
4. School environment: This is related to tasks involved in the school environment.
Items: 13, 18, 21, 30
5. Self- image: This identifies positive feelings about self.
Items: 14, 26, 31, 32, 33, 34

A further 4 items measure the global health and treatment expectancy. These are not included in the overall COHIP scale as these items are used when the COHIP is required for treatment assessment.

6. Treatment expectancy: This assesses the expectations regarding treatment outcomes and process.

Items: 35 and 36

7. Global Health: This assesses the overall feelings of systemic and oral health.

Items: 37 and 38

(Broder and Wilson-Genderson, 2007, Ralstrom, 2010, Ward et al., 2013)

As mentioned, the COHIP was designed for children and teenagers aged 8- 15 years old. The readability score of the COHIP has been established at grade 3.5 level, thus making it suitable for children in grade 3 and above who are first language English (Broder and Wilson-Genderson, 2007).

The items are designed to elicit self- report from the participants. There are 7 positively worded items which are positively scored. The last 2 items are also positively scored. Therefore 9 items are positively scored, namely:

- Items 14, 26

Never= 0, Almost Never= 1, Sometimes = 2, Fairly Often = 3, Almost all the time= 4

- Items 31,32,33,34, 35

Strongly Disagree= 0, Somewhat Disagree= 1, Don't Agree or Disagree = 2, Somewhat Agree= 3, Strongly Agree= 4

- Items 37, 38

Poor= 0, Fair = 1, Average = 2, Good = 3, Excellent = 4

Scoring of the remaining negatively worded items are reversed:

- Items 1-13, 15- 25, 27- 30

Never= 4, Almost Never= 3, Sometimes=2, Fairly Often = 1, Almost all the time= 0

- Item 36

Strongly Disagree= 4, Somewhat Disagree= 3, Don't Agree or Disagree = 2, Somewhat Agree= 1, Agree= 0

Once again it is important to note that the final COHIP score comprises of items 1 – 34 in the first 5 subscales. Treatment expectation and Global Health do not contribute to the overall score. Therefore, the overall score can range from 0- 136 (Broder et al., 2007, Ward et al., 2013).

Higher COHIP scores indicate a higher or more positive OHRQOL, a lower COHIP score reflects a more negative OHRQOL (Broder et al., 2007, Ward et al., 2013).



Table 1: COHIP score summarised

COHIP scoring summarised				
COHIP Subscale	Description	Number of items per Subscale	Subtotal (0-4 per item)	Item numbers:
Oral Health	Measures oral symptoms, which are not necessarily related (for example: spots on teeth, pain)	10	40	1,2,3,4,5,6,7,8,9,10
Functional Well being	Measures the child's ability to perform everyday tasks (for example: chewing, speech)	6	24	11,15,20,23,25,27
Social- Emotional Well being	Measures ability to interact with peers and mood	8	32	12,16,17,19,22,24,28, 29
School Environment	Associated with carrying out tasks in the school environment	4	16	13,18,21,30
Self Image	Pertains to positive feelings of self	6	24	14,26,31,32,33,34
Treatment Expectancy *	To assess the expectations of the patient on treatment outcomes and process	2	8	35,36
Global Health *	To assess the overall feeling on the patient's oral and systemic wellbeing	2	8	37, 38

((Broder and Wilson-Genderson, 2007, Ralstrom, 2010, Ward et al., 2013)

Chapter 3

Materials and Methods:

Aim of the study

To assess the oral health- related quality of life of cleft patients attending the Wentworth Foundation clinic in KwaZulu-Natal

Objectives

- To Assess:
1. The oral health-related quality of life of cleft patients attending the Wentworth Foundation Clinic in KwaZulu Natal
 2. If the oral health related quality of life of cleft patients varies amongst different age groups
 3. If the oral health related quality of life of cleft patients varies amongst different genders
 4. If the oral health- related quality of life of cleft patients varies amongst different cleft types
 5. Demographic factors of the cleft patients at the Wentworth foundation using a socio-demographic profile form.

Null Hypothesis:

H₀1. The oral health related quality of life cleft participants does not differ amongst different cleft types

H₀2. The oral health related quality of life of cleft participants varies in different age groups

H₀3. The oral health related quality of life of cleft participants varies in different genders

Research question:

Are cleft participants at the Wentworth Foundation clinic satisfied with their oral health?

What are the effects of the cleft patients' oral health on the patients' quality of life?

Study design:

Quantitative study- Cross sectional study



Location:

The Wentworth Foundation Clinic in Durban, KwaZulu-Natal.

Inclusion and Exclusion criteria

Table 2: To indicate the Inclusion and Exclusion criteria for Cleft participants	
<u>Inclusion Criteria</u>	<u>Exclusion criteria</u>
*Diagnosis of an orofacial cleft Participants between the ages 8- 18 years attending the clinic Participant undergoing orthodontic treatment Guardians of participants under 18 years (minors) Consent forms signed by participants and guardians of minors Cognitive ability to answer a questionnaire	Individuals with diagnosed mood disorder such as Bipolar disorder which would impair answering the questionnaire consistently Individuals with diagnosed moderate to severe mental retardation which would impair cognitive ability to answer the questionnaire, patient must be able to answer questions in COHIP

Sample size:

The sample size calculation as determined in consultation with the Statistician assuming the expected population standard deviation to be 26.2, and a population size of 63, the study required a sample size of 45 to estimate a mean with 95% confidence and a precision of 4.1 (Abebe et al., 2018) (Dhand, 2014).

A total of 62 individuals attending the Wentworth Foundation clinic from August to October 2019 were included. It is important to note that many patients attended the clinic more than once in the 3month period as they were recalled for follow up. Therefore, this is not the total number of attendees but the total number of individuals excluding repeat visits. Of the 62 individuals, there were 46 participants that met the inclusion criteria. The criteria was given to the Wentworth foundation management, who had access to the medical history and ages of the various patients, the patients who fell into the selection criteria were invited to join the study. 16 patients were excluded as they did not fall into the required selection criteria. It is worth noting that

individuals who did not fall into the correct age category or were not English speaking, were interested in participating in the study.

Data Collection Tool:

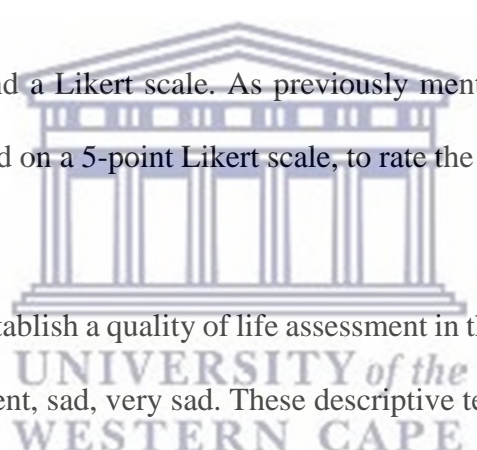
Appendix 1- Information sheet, was handed to the patients to gain insight on the study. Thereafter Appendix 2 or 3- Consent form or Assent form, were given to the patient if the patient was interested in participating in the study.

The Socio- demographic profile (Appendix 4) was used to assess the sociodemographic overview of the participants (Ward et al., 2013).

The Child Oral Health Impact Profile (COHIP) (Appendix 5) was used to assess the OHRQoL (Broder and Wilson-Genderson, 2007).

The COHIP makes use of items and a Likert scale. As previously mentioned, an item refers to a question within a domain. Each item is scored on a 5-point Likert scale, to rate the impact of treatment on health status and quality of life.

The Likert scale has been used to establish a quality of life assessment in the COHIP. It uses descriptive terms such as very happy, happy, indifferent, sad, very sad. These descriptive terms can then be ranked from 0-4 to allow for points to be calculated (Broder et al., 2014a). For example:



0	1	2	3	4
Never	Almost Never	Sometimes	Fairly Often	Almost all of the time

Measurement:

The assessment was structured as follows, after the prospective participant has read through the Information sheet (Appendix 1) and verbally consents to participate in the study, then the following filled forms are required:

1. Informed Consent form or Assent form (to be filled by patient or patient and respective guardian)

Appendix 2 and Appendix 3

2. Socio-demographic profile (Form to be filled by patient and guardian)

The cleft palate diagnosis was checked by the researcher and correlated with the diagnosis on the file
The age of the patient was also added to the form as date of birth and the age itself to counter the overlap on the sociodemographic forms

Appendix 4

Orofacial cleft patient and respective guardian were required to complete the socio-demographic questionnaire pertaining to the patient; after consenting to participate in the study.

3. Questionnaire: Child Oral Health Impact Profile (COHIP) (Broder et al., 2007) (filled by the patient only)

Appendix 5

Informed Consent explanation and Information sheet procedure:

The researcher verbally explained the details of the study to the prospective participants with the use of A1 images of the Informed Consent form, Consent and Assent forms and the COHIP. The study was explained in a comfortable classroom set up.

Participants and their guardians were invited to participate in the study. If the patient and guardian were comfortable to participate in the study, an information sheet about the study was provided (Appendix 1).

Confidentiality

Confidentiality was assured to participants and their guardians, in the consent and assent letters (Appendices 2 &3). In the case of minors (under 18), guardians were requested to fill the assent form, which was filled alongside in the presence of the minor.

Sociodemographic form and Questionnaire (COHIP) procedure

Subsequently the questionnaires were answered in a classroom set up at the Wentworth foundation clinic. Each question was read aloud with the use of an enlarged copy of the questionnaire displayed on an easel, where the informed consent procedure, sociodemographic profile and COHIP questionnaire were explained.

The sociodemographic form required assistance from the researcher as the orofacial cleft diagnosis was the same as the diagnosis in the patients file, which the patient carried with them. The researcher confirmed the orofacial cleft diagnosis was correct. The patients were also requested to provide their date of birth and age on top of the sociodemographic profile, this would assist with any confusion caused by the overlap in the age categories.

A team including a School teacher with the position of Departmental Head at St Martin de Porres school and a final year medical student assisted in handing out the questionnaires. They also assisted with clarification of any questions raised prior to the commencement of the process of completing the questionnaire. The School teacher assisted in the classroom set up and recommended the best way to explain the process prior to commencing the questionnaire. During the process of completing the COHIP questionnaire the team ensured that there was no discussion of the questionnaire, ensuring self-assessment and the process ran smoothly. The entire clinic was given lunch and a care pack, this was handed out without their knowledge and did not influence their participation as everyone did receive lunch and care packs, regardless of participation



Figure 7: The classroom setup used for answering questionnaires.



Figure 8: The classroom setup used for answering questionnaires, parents were allowed to sit next to their children during the explanation of the process, signing of consent and sociodemographic profile forms. Thereafter the children had to fill the COHIP forms independently without their parents.

Verbal consent was given to take this photo and patients gave consent to add the image to the thesis. The patients' faces have been blurred for privacy. The image is used to depict the set up.

Data Management:

Data Capture

All COHIP forms were collected and numbered. The data was transferred to an excel spreadsheet manually and numerically using the COHIP scoring system. The data was transferred by the researcher and checked 3 times on different weeks to avoid fatigue and risk of error. There was special attention made to ensure the scoring of the negatively and positively worded items were correct. There was no checking of data by a 2nd researcher, and no inter and intra observer checking. The raw data is available with the University of the Western Cape.

Data Analysis:

The data was analysed using STATA Version 15.0 (StataCorp LLC, Texas, USA). Normality of distribution for the OHRQoL (COHIP) variable was assessed. Once the assumption of normality was confirmed, outcomes

across the different categories of independent variables, for example: age category, gender and type of cleft lip was assessed. The Analysis of variance (ANOVA) was used to test differences for statistical significance and an independent samples t-test was used to analyse differences between groups. A $p < 0.05$ was deemed statistically significant.

Data protection:

All data collected is confidential and anonymous. A unique coding system was used to link all documents. After consenting to participate, subjects were allocated a number to identify them, to protect their confidentiality throughout the study.

No names or address were used or released to any staff member of the clinic, to any family member or any treating clinician. Participants' existing records were accessed only to obtain clinical and demographic information, for record purposes. The participants assessments were kept in a locked safe place.

Data storage:

After consenting to treatment, the subjects were identified using a numbering system. All data in hard and soft copies has been kept in a locked password protected safe place. The data will be kept with the Orthodontics department, University of the Western Cape. The data will be kept for 5 years before destruction.

Risk of the study:

Patient expectations for the survey may not be met. Patients' may be offended if they do not meet inclusion/exclusion criteria.

Referral strategy:

The patients were able to be referred to the counsellor at the Wentworth foundation clinic if their expectations were not met, however this was not required.

Study approval and Ethical consideration:

Informed consent from each participant was required.

Ethical clearance was been obtained from the University of the Western Cape through the Biomedical Science Research Ethics Committee (BMREC).

Ethics Reference Number: BM19/3/18

(Appendix 6)

The online guidelines for research proposal submission in KZN state that ethical approval from an institution with an ethics reference number and date of ethical approval was required to apply for ethical approval with the PHREC (Health-Research&Knowledge-Management, 2017). The KZN Department of Health via the Provincial Health Ethics and research committee (PHREC) was consulted and no clearance was required from the body to continue research as the study involved a private non-government organization without the use of state facilities.

Letter of permission from the Wentworth Foundation clinic to use their premises, facilities, database after ethical approval was obtained. (Letter attached)

Letter confirming no conflict of interest: No relation at all, between the researcher Dr Leticia Singh and the Wentworth Foundation Chairperson Dr Surandar Singh, no relation to the Manager of the Foundation Ms. Sureka Singh had been obtained.

Study was ethically cleared.

Chapter 4

Results:

A total of 46 participants answered the Sociodemographic profile and Child Oral Health Impact Profile at the Wentworth Foundation Clinic in Durban, KZN.

Table 3: Sociodemographic Results Summary

Sociodemographic variable	Description	n (%)
Age (years)	8	8(17.39)
	9 to 10	11(23.91)
	11 to 12	7(15.22)
	13 to 14	5(10.87)
	15 to 16	8(17.39)
	17 to 18	7(15.22)
Gender	Female	23(50)
	Male	23(50)
Transport	Private	14(30.43)
	Public	32(69.6)
Place of Accommodation	Rural	20(43.5)
	Urban	26(56.5)
Educational Level	High School grad or Tertiary Education	5(10.9)
	In School	41(89.13)

KEY:

n= number

%= percent of total participants (46)

Sociodemographic Data: Summarised in Table 3

The patients were requested to provide their date of birth and age on the sociodemographic form to eliminate any confusion regarding the overlap in the age categories on the sociodemographic profile. The ages were then divided as above based on the data received in the format of date of birth and ages. The 8 year old age group was separated as there were a high number of candidates in this group.

The tertiary education and high school groups were joined due to the low number of candidates in the groups.

The Sociodemographic variable of Age revealed most of the subjects fell in the age category 9 to 10 years (23,91%). The lowest number of participants came from the 15 to 16 age group. In terms of gender there were 23 Female (50%) and 23 Male (50%).

Most of the participants made use of Public transport (69.6 %) and (30.43%) made use of private transport. Majority of the participants were in School (89.13%) and (10.9%) were High School graduates or pursuing Tertiary Education.

Cleft Classification Data:

Table 4.1: Cleft Classification Results Summary

Classification	Description	n (%)
Cleft Type	Complete	31(67.4)
	Incomplete	15(32.6)
Cleft Description	Palate	5(10.9)
	Unilateral	30(65.2)
	Midline	2(4.35)
	Bilateral	9(19.6)
Cleft Laterality	Left	21(45.7)
	Bilateral	9(19.45)
	Midline	2(4,35)
	Palate	5(10.9)
	Right	9(19.6)
Cleft Anatomical Location	Hard and Soft Palate	5(10.87)
	Lip, alveolus	10(21.7)
	Lip, alveolus, palate	31(67.4)

The above table is adjusted from the information received in Appendix 4: Sociodemographic profile. The cleft diagnosis was made with the diagnosis from the patient’s file and the researcher assisted in recording this information. The information from Appendix 4 was then transferred into the above format, similar to that of

a study by Hlongwa (Hlongwa, 2019). The information recorded is the same as that in the questionnaires, the format had been adjusted for ease of interpretation. There was no hard palate only on the form.

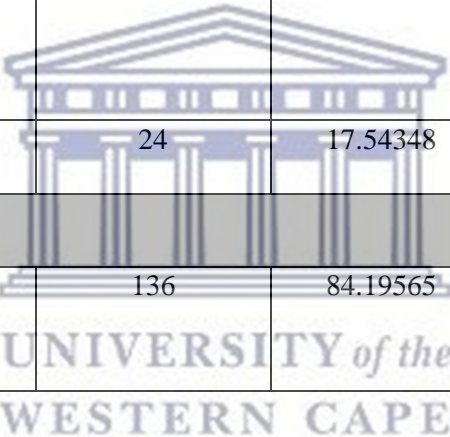
The majority of these patients presented with complete clefts (67.4%). The most commonly seen cleft description was the unilateral cleft (65.2%) followed by Bilateral cleft (19.6 %). Of the Unilateral cleft type, in terms of laterality, the left side seemed to be the more affected side (45.7%). The number of Right Unilateral cleft patients were equal to the number of Bilateral cleft patients. The most frequently noted cleft anatomical location was seen in lip, alveolus and palate (67.4%), followed by lip and alveolus (21.7%) and the least number of patients had clefts of the Hard and Soft Palate (10.87 %).

Table 4.2 Orofacial Cleft Diagnosis Summary (Appendix 4)

Orofacial Cleft Diagnosis.	n (%)
Bilateral cleft lip & alveolus, incomplete	1(2.17)
Bilateral cleft lip, complete	8(17.39)
Cleft palate hard and soft, incomplete	4(8.69)
Cleft soft palate only, incomplete	1(2.17)
Unilateral cleft lip & alveolus left, incomplete	6(13.04)
Unilateral cleft lip & alveolus right, incomplete	2(4.35)
Unilateral cleft lip & alveolus, midline, incomplete	1(2.17)
Unilateral cleft lip left, complete	15(32.60)
Unilateral cleft lip right, complete	7(15.22)
Unilateral cleft lip, midline, complete	1(2.17)

In Table 4.2 it can be noted that the most frequent diagnosis is Unilateral cleft lip left, complete (32.6 %), followed by Bilateral cleft lip complete (17.39 %) and thereafter Unilateral cleft lip right, complete (15.22%).

Child Oral Health Impact Profile (COHIP) scores

Table 5: Summary for total COHIP/OHRQoL and COHIP Subscales					
COHIP Subscales	Number of Items	Total score achievable	Overall Mean score for study	Standard Deviation (SD)	Score expressed as %
Oral Health Subscale	10	40	21.826	5.606	54.565
Functional Well-being Subscale	6	24	13.8913	4.6247	57.88
Social/ Emotional Well-being Subscale	8	32	18.065	8.6984	56.45
School Environment Subscale	4	16	12.86957	3.095	80.43
Self Image	6	24	17.54348	5.07	73.0
					
Total COHIP score / OHRQoL score	34	136	84.19565	18.244	61.9

The COHIP mean score was 84.19565 (Standard Deviation (SD) 18.244) overall. The highest score in the respective subscale was School Environment with an overall mean of 12.86957 (SD 3.095) out of 16. The lowest overall mean score in the respective subscale was Oral Health with an overall mean score of 21.826 (SD 5.606) out of a total of 40. The highest individual COHIP score was 110 and the lowest individual COHIP score was 35. For ease of interpretation, these mean figures will be expressed as a percentage of the total score achievable in each subscale. The COHIP mean score of 84.19565 (SD 18.244) is an expression of the mean OHRQoL, therefore achieving a mean score expressed as percentage being 61.9 % of OHRQoL. Note the higher the score the greater the OHRQoL.

Age in relation to COHIP:

Table 6: Age comparison with COHIP scores and Subscale scores

Age	n (%)	COHIP Mean (SD)	p value	Oral Health Mean (40) (SD)	p value	Functional well-being Mean (24) (SD)	p value	Social Emotional well-being Mean (32)(SD)	p value	School Environment Mean (16) (SD)	p value	Self-image Mean (24) (SD)
8	8 (17.39)	76.25 (24.38)	0.3199	18.87 (7.33)	0.1425	9.75 (4.26)	0.0456	16.62 (10.5)	0.4055	12.12 (3.13)	0.0145	18.87 (3.56)
9 to 10	11 (23.91)	86.72 (21.65)		20.72 (3.92)		14.54 (5.29)		21 (9.96)		13.90 (2.62)		16.54 (7.118)
11 to 12	7 (15.22)	90.14 (8.76)		22.71 (4.029)		14.14 (3.97)		19.71 (6.44)		15 (1.52)		18.57 (3.59)
13 to 14	5 (10.87)	83.4 (9.86)		20 (6.04)		15.6 (2.96)		14.6 (7.79)		13.2 (2.68)		20 (3.60)
15 to 16	8 (17.39)	92.25 (14.73)		26.1 (4.05)		16.75 (4.68)		20.37 (7.53)		13 (3.58)		16 (4.95)
17 to 18	7 (15.22)	74.7 (17.24)		22.42 (6.7)		12.857 (2.60)		13.28 (7.58)		9.57 (2.43)		16.57 (5.34)

The OHRQoL/ COHIP score was not statistically significant for Age (p value 0.3199).

The subscales of Functional well-being and School environment were statistically significant amongst various age groups (p 0,0456). As previously mentioned, the Functional well-being refers to the child’s ability to carry out activities and specific everyday tasks. The total score for Functional well-being is 24. The highest score obtained was that of the 15 to 16 year olds with a mean of 16.75 (SD 4.68) and the lowest score was that of the 8 year olds with a mean of 9.75 (SD 4.26). When expressed as a percentage the 15 to 16 year olds score was 83.75% and the 8 year olds score 48.75%.

The statistically significant subscale, School environment p value is 0,0145. The School environment refers to tasks involved in the school environment. The total score for School environment in the COHIP is 16. The lowest score was the age group 17 to 18 year olds with a mean of 9.57 (SD 2.439). The highest score for school environment score was amongst ages 11 to 12 year olds with a mean of 15 (SD 1.52). When expressed as a percentage the 11 to 12 year olds score was 93.75% and the 17 to 18 year olds score 59.8125%. The age groups 9 to 10 scored 13.9 (SD 2.62), 13 to 14 scored 13.2 (SD 2.68) and 15 to 16 scored 13 (SD 3.58); these age groups scored similarly.

Figure 7: Box Graph to show Age related to subscale School Environment

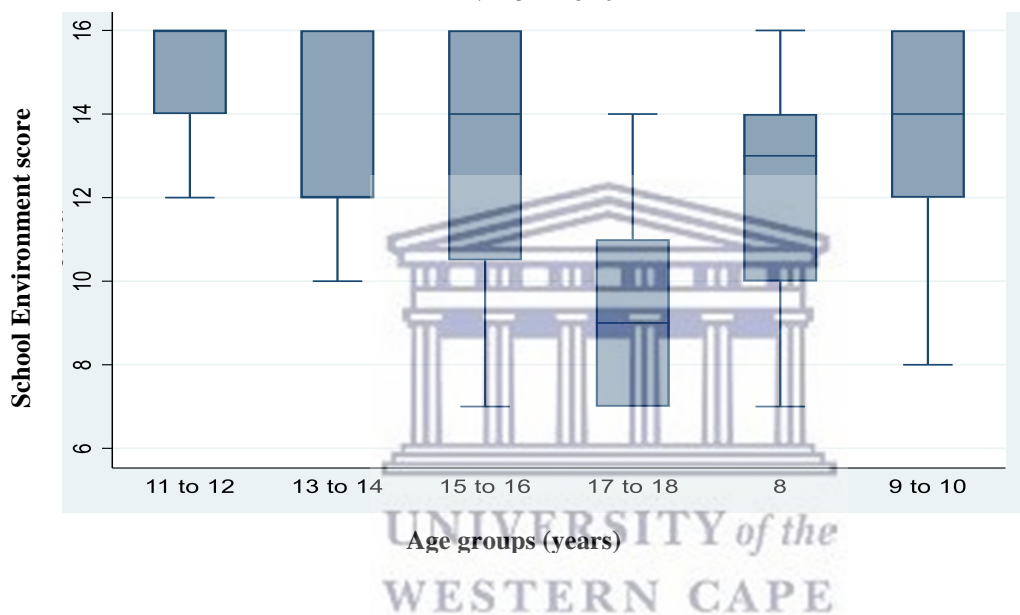
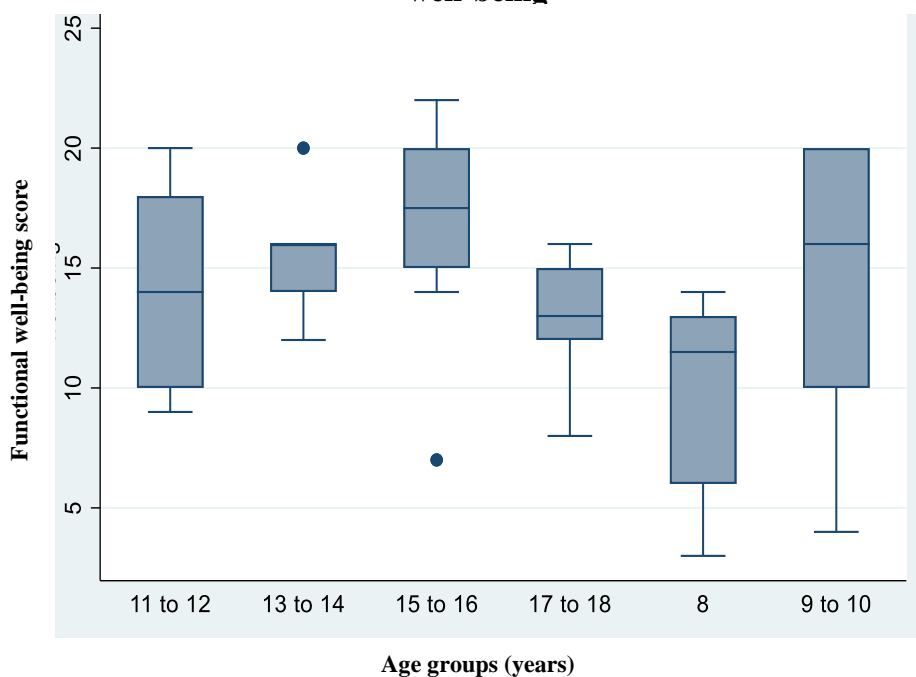


Figure 8: Box Graph to show Age related to subscale Functional well-being



Transport in relation to COHIP

Table 7: Transport in relation to COHIP and subscale: School Environment		
	Private	Public
n (%)	14 (30.43)	32 (69.6)
COHIP Mean (SD)	80.78 (21.26)	85.68 (16.9)
p value	0.4078	
School Environment	11.35 (3.05)	13.53 (2.91)
p value	0.0267	

The OHRQoL is not statistically significant however the subscale of School environment is statistically significant with a p value of 0.0267. The COHIP scores of individuals travelling in public transport (mean: 85.68, SD 16.9) revealed they had a higher OHRQoL score than those travelling in private transport (mean: 80.78, SD 21.268). The subscale of School environment was statistically significant with a p value of 0.0267. Participants who travelled in public transport (mean: 13.53, SD 2.91) scored higher for the subscale school environment than participants travelling in private transport (mean: 11.357, SD 3.05).



Place of Accommodation in relation to COHIP

Table 8: Place of Accommodation in relation to COHIP and subscale: School Environment		
	Rural	Urban
n (%)	20(43.5)	26(56.5)
COHIP Mean (SD)	84.2 (17.188)	84.19 (19.35)
p value	0.9989	
School Environment	14 (2.97)	12 (2.95)
p value	0.0281	

Place of accommodation had little impact on the OHRQoL total score, however the Rural place of accommodation scored fractionally marginally higher than the Urban place of accommodation. The subscale, School environment in relation to place of accommodation is statistically significant with a p value of 0.0281. For the School environment in relation to Accommodation, the Rural participants scored a mean of 14 (SD 2.97) which was a higher score than the Urban participants who scored a mean of 12 (SD 2.95).

Educational level in relation to COHIP

Table 9: Education level in relation to COHIP and subscale: Oral Health		
	High School graduate or Tertiary Education	In School
n (%)	5(10.9)	41(89.13)
COHIP Mean (SD)	86 (15.24)	83.97 (18.72)
p value	0.8178	
Oral Health Mean (SD)	26.6 (3.36)	21.24 (5.57)
p value	0.0432	

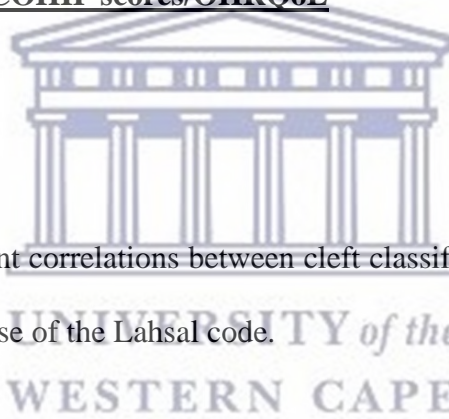
Educational level was not statistically significant for COHIP/OHRQoL scores. A statistically significant difference was noted in the subscale of Oral Health in relation to educational level, p value is 0.0432. In the subscale Oral Health, in relation to Educational level, High School graduates or students in Tertiary education scored 26.6 (SD 3.36) and students in School scored 21.24 (SD 5.57). High School graduates or Tertiary education students (mean: 86, SD 15.24) also had a higher mean COHIP score than students in school (mean: 83.97, SD 18.72).

Table 10 : Gender in relation to COHIP scores

Gender	n %	COHIP Mean (SD)	p value
Female	23 (50)	84.65 (17.31)	0.87
Male	23 (50)	83.73 (19.51)	

Gender in relation to COHIP scores:

Gender COHIP score and subscales were not statistically significant. An analysis of gender revealed Females (mean: 84.65, SD 17.31) had a slightly higher total COHIP/OHRQoL score than males (mean: 83.73, SD 19.51).

Cleft Classification in relation to COHIP scores/OHRQoL

Overview:

There were no statistically significant correlations between cleft classification and COHIP scores/OHRQoL. The Wentworth foundation makes use of the Lahsal code.

Cleft Type:**Table 11: Cleft Type in relation to COHIP and subscale: School Environment**

	Complete	Incomplete
n (%)	31(67.4)	15(32.6)
COHIP Mean (SD)	84.09 (19.88)	84.4 (14.9)
p value	0.9586	
School Environment Mean (SD)	12.258 (3.15)	14.133 (2.64)
p value	0.053	

The subscale of school environment was borderline statistically significant with the incomplete cleft group scoring a (mean:14.133, SD 2.64) higher than the complete cleft group (mean: 12.258, SD 3.15) with a p value of 0,053.

Cleft Description in relation to COHIP scores:

Table 12: Cleft Description in relation to COHIP scores			
Cleft Description	n %	COHIP Mean (SD)	p value
Palate	5(10.9)	77.4 (15.88)	0.6879
Unilateral	30(65.2)	86.16 (17.22)	
Midline	2(4.35)	88.5 (7.77)	
Bilateral	9(19.6)	80.44 (24.46)	

The OHRQoL/COHIP was not statistically significant. Participants with Midline cleft scored the highest OHRQoL (mean:88.5, SD 7.77) followed by Unilateral cleft (mean: 86.16, SD 17.22). The lowest scores were that of cleft Palate (mean: 77.4, SD 15.88) and Bilateral cleft (mean: 80.44, SD 24.46).

Cleft Laterality in relation to COHIP scores:

Table 13: Cleft Laterality in relation to COHIP score			
Cleft Laterality	n %	COHIP Mean (SD)	p value
Left	21(45.7)	84.19 (19.12)	0.6883
Bilateral	9(19.45)	80.44 (24.46)	
Midline	2(4.35)	88.5 (7.77)	
Palate	5(10.9)	77.4 (15.88)	
Right	9(19.6)	90.77 (11.28)	

The OHRQoL/COHIP scores were not statistically significant for cleft laterality. Right Unilateral cleft scored the highest (mean 90.77, SD 11.28) followed by Midline cleft (mean: 88.5, SD 7.77). The lowest score was that of cleft palate (mean 77.4, SD 15.88).

Cleft Anatomical Location in relation to COHIP scores:

Table 14: Cleft Anatomical Location in relation to COHIP scores			
Cleft Anatomical Location	n %	COHIP Mean (SD)	p value
Hard and Soft Palate	5 (10.869)	77.4 (15.88)	0.5854
Lip, alveolus	10 (21.7)	87.9 (13.88)	
Lip, alveolus, palate	31 (67.4)	84.09 (19.88)	

Table 15: Cleft Anatomical Location in relation to COHIP subscale scores			
	Hard and Soft Palate	Lip, alveolus	Lip, alveolus, palate
Oral Health Mean (SD)	20.2 (7.563)	23.3 (5.57)	21.61 (5.38)
P value	0.57		
Functional wellbeing Mean (SD)	12.8 (3.89)	14.2(4.68)	13.967 (4.81)
P value	0.85		
Social and Emotional wellbeing Mean (SD)	13.2 (6.26)	19.5 (7.27)	18.38 (9.36)
P value	0.399		
School Environment	14.2 (2.48)	14.1 (2.84)	12.258 (3.151)
P value	0.157		
Self Image	17 (1.58)	16.8 (4.022)	17.87 (5.748)
P value	0.824		

Table 16: Cleft Anatomical Location in relation to COHIP scores			
Lip involvement or Palate only			
Cleft Anatomical Location	n %	COHIP Mean (SD)	p value
Hard and Soft Palate only	5 (10.869)	77.4 (15.88)	0.3836
Lip involvement	41 (89.13)	85.02 (18.51)	

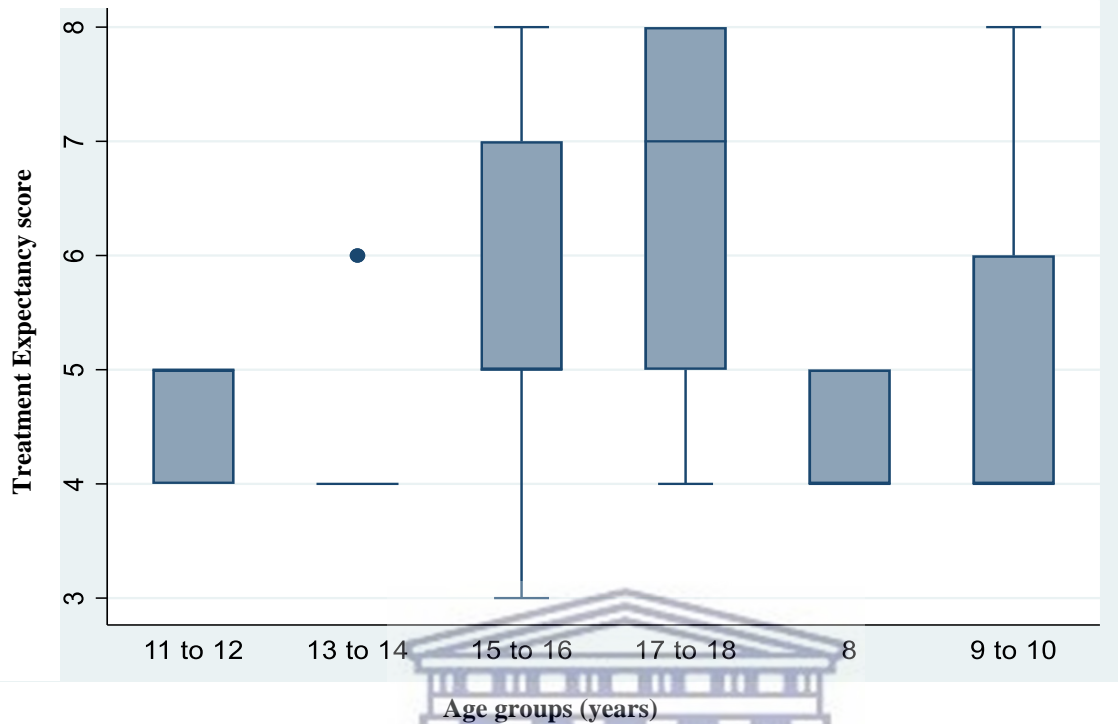
Table 17: Cleft Anatomical Location in relation to COHIP subscale scores**Lip involvement or Palate only**

	Lip involvement	Palate only
Oral Health Mean (SD)	22.02 (5.41)	20.2 (7.56)
P value	0.498	
Functional wellbeing Mean (SD)	14.02 (4.73)	12.8 (3.89)
P value	0.58	
Social and Emotional wellbeing Mean (SD)	18.65 (8.82)	13.2 (6.26)
P value	0.188	
School Environment	12.7 (3.14)	14.2 (2.489)
P value	0.3141	
Self Image	17.61 (5.352)	17 (1.581)
P value	0.8	

The OHRQoL/COHIP scores and subscales were not statistically significant. The COHIP scores were highest in the Lip, alveolus group (mean: 87.9, SD 13.88), followed by the Lip, alveolus, palate (mean: 84.09, SD 19.88) and the lowest COHIP score for Hard and Soft palate only (mean: 77.4, SD 15.88). The trend for the scores to be highest in Lip, alveolus, followed by Lip, alveolus, palate and lastly Hard and Soft Palate continues for the subscales except for School environment and Self Image.

For the subscale Oral Health, Lip, alveolus scored (mean: 23.3, SD 5.57) highest, followed by Lip, alveolus, palate (mean: 21.6129, SD 5.38) and lastly Hard and Soft Palate scored (mean: 20.2, SD 7.56) the lowest. For the subscale Functional well-being; Lip, alveolus scored (mean: 14.2, SD 4.68) highest, followed by Lip, alveolus, palate (mean: 13.96, SD 4.81) and lastly Hard and Soft Palate scored (mean: 12.8, SD 3.89) the lowest. For the subscale Social/Emotional well-being, Lip, alveolus scored (mean: 19.5, SD 7.27) highest, followed by Lip, alveolus, palate (mean: 18.3871, SD 9.36) and lastly Hard and Soft Palate scored (mean: 13.2, SD 6.26) the lowest. For the subscale, School environment Hard and Soft Palate scored (mean: 14.2, SD 2.48) the highest, followed by lip, alveolus (mean: 14.1, SD 2.84) and lip, alveolus, palate scored (mean: 12.25, SD 3.151) the lowest.

Figure 9: Box Graph to show Age related to subscale Treatment Expectancy (not included in COHIP score)



Treatment expectancy and Global Health do not form part of the COHIP score. The subscales scores will however be analysed. Each subscale consisted of 2 items; therefore, each subscale had a total score of 8.

Treatment Expectancy:

Treatment expectancy is described as an assessment of expectations of the treatment outcomes and process; it is not included in the COHIP score (Broder and Wilson-Genderson, 2007). The mean score for treatment expectancy is 5.04 with a standard deviation of 1.3498. The score is out of 8. The treatment expectancy score if expressed as a percentage would be 62.5%.

The Age category had statistically significant results with 17 to 18 year old group scoring the highest (mean: 6.4, SD 1.5) and the 8 year old group scoring the lowest (mean: 4.37, SD 0.5).

Global Health:

Global Health is described as an assessment of the overall feeling of systemic and oral health; it is not included in the COHIP score (Broder and Wilson-Genderson, 2007). The mean score for global health is 6.043 with a standard deviation of 1.577. The score is out of 8. For ease of interpretation if expressed as a percentage the score would be 75.5%.



Chapter 5

Discussion:

The results of the study show that the most commonly seen cleft type is Unilateral cleft type (65.2%). In terms of laterality, Left Unilateral cleft was predominant (45.7%). The anatomical location most seen was lip, alveolus and palate (67.4%). These findings are similar to a study at Sefako Makgatho Oral Health Centre in Pretoria, where 47% of patients presented with unilateral cleft lip and palate (Moodley et al., 2018). However, the percentage of unilateral cleft type was greater for this study (65%) as compared to that at Sefako Makgatho Oral Health centre (47%). Cleft laterality for unilateral clefts was most commonly seen on the left side (Moodley et al., 2018). Hlongwa and coworkers' study have similar findings, in the academic centres in 6 provinces throughout the country, CLP was found to be the most prevalent 44%. Additionally, they also found that most of the orofacial clefts were unilateral 46%; and in terms of the laterality, the clefts were predominantly on the left side (Hlongwa, 2019).

The results of the study show that orofacial cleft patients OHRQoL as determined by the COHIP form at the Wentworth Foundation clinic were similar, but slightly lower than Broder and Wilson Genderson's study in 2007. The questionnaire or COHIP form in Appendix 5 is the same as that used in Broder and Wilson Genderson's and Ward et al. study. The COHIP form and the scoring of the negatively worded items were adapted from these studies (Broder and Wilson-Genderson, 2007, Ward et al., 2013). In our study (Wentworth foundation), the COHIP score ranged from 35 to 110 with a mean score of 84.19 (SD 18.24).

In the study by Broder and Wilson-Genderson the craniofacial group obtained the lowest scores and had a mean overall COHIP score of 87.1 with a comparison of the mean values depicted by SE as 3.0 (Broder and Wilson-Genderson, 2007). The score from Wilson- Genderson's study is similar to score obtained in our study (Wentworth foundation). The Broder and Wilson- Genderson score was found to be slightly higher than the present study, which indicates that the Wentworth foundation is doing well as they are from a third world setting.

Similarly, Ward et al. study also appeared to have a higher overall mean COHIP score of 95.6 for cleft children with a standard deviation of 18.3 (Ward et al., 2013). When compared with the scores obtained by Ward et al. and Broder and Wilson Genderson's studies, the Wentworth Foundation score is slightly lower.

The COHIP scores of this study could not be compared with Abebe et al. COHIP study because the Likert scale used was not the same, Abebe et al. study was 1-5 and this study used a scale from 0-4 (Abebe et al., 2018).

The proposed possible reasons for the marginally lower scores obtained at the Wentworth Foundation will be discussed. The Wentworth foundation is providing orofacial cleft treatment which can be comparable to a first world setting, despite their lack of resources and funds being located in a third world setting. Ward et al. study and Broder and Wilson Genderson's study were both based in the USA. Therefore, these results were established in a first world setting. The resources and socioeconomic stability in a first world country are far greater than in a third world or developing country such as South Africa. The socioeconomic situation in KZN does have an impact on the OHRQoL of cleft children in KZN, as orofacial cleft multidisciplinary care is intensive, costly and long term. Thus, orofacial cleft care does require better accessibility to care, as well as more time and commitment from parents to ensure adequate healthcare for their children. Income inequality does have an impact on population health, therefore disadvantaged social backgrounds are susceptible to have a lower health related quality of life than wealthier populations (Barkan, 2012).

Orofacial cleft patients with insufficient multidisciplinary care are at risk of many challenges which directly impact their quality of life. Some of the challenges experienced are difficulty feeding in infancy due to inability to obtain a palatal seal, eustachian tube dysfunction which causes chronic otitis media and results in loss of hearing, difficulty in speech and pronunciation of words and mid face hypoplasia (Conway et al., 2015). Loss of hearing and difficulty in speech add to difficulty in social interactions (Conway et al., 2015).

The aesthetic concern of cleft treatment has been noted in Africa, as majority of cleft cases treated are cleft lip (Conway et al., 2015). The cleft lip has an aesthetic component as the lip is visible, during social interaction. Participants in Conway's study who had cleft lip and palate, did not always return for their second surgery of palatal closure. Therefore, it is noted that the parents found aesthetics to be a greater concern than function.

The study found that a lack of funds for transport was the primary reason patients did not return for further management (Conway et al., 2015).

Socioeconomics was the main reason patients at the Wentworth Foundation could not attend their appointments (Singh, 2017). The financial strain experienced were associated with poverty and inequality in South Africa (Singh, 2017).

The spatial disruptions in South Africa which are related to patient's located in rural areas give rise to lack of access to health care services and infrastructure (Singh, 2017). Health care infrastructure in rural areas is not advanced and therefore patients need to travel long distances to obtain adequate health care for conditions such as orofacial cleft. This therefore involves transport costs and time away from work to obtain the necessary healthcare required (Singh, 2017).

Lack of specialist knowledge and management protocol was noted in the public sector in KZN (Singh, 2017). Singh's study noted that orofacial cleft patients required an average of four different hospitals to adequately treat the orofacial cleft patients in KZN, further increasing transport costs, decreasing interaction between multidisciplinary care, decreased convenience and ease of use. In the USA there are facilities that can provide all the multidisciplinary care required for orofacial cleft patients in one setting. In KZN, patients expressed concerns about long waiting times for interventions, lack of communication and information, lack of support and lack of follow up care (Singh, 2017).

Although the OHRQoL/COHIP score was not statistically significant amongst various age groups, the subscales Functional well-being and School environment were found to be statistically significant amongst various Age groups. With regard to the Functional well-being, the 15 to 16 year old age group scored the highest and the lowest score was that of the 8 year old age group. Functional well-being refers to the child's ability to carry out activities and everyday tasks (Broder and Wilson-Genderson, 2007). A postulated reason for this may be that 8 year olds would still be very early in their cleft management as compared with the 15 to 16 year olds, who would be further along with their treatment. Therefore, the 15 to 16 year olds would be benefiting from many years of multidisciplinary care, allowing them better function on a daily basis. The 17 to 18 year olds did not score as high, this is possibly because their functional daily pressures have increased

with completing school or beginning a whole new tertiary education or job. Thus, their daily functional responsibility and stress is greater. It is also important to note that the same number of 8 year olds and 15 to 16 year olds participated in the study.

Age- related differences were also noted in a study by Jokovic et al., in which a lower OHRQoL in the age group 11-14 was found, using another questionnaire (Jokovic et al., 2002).

A study by Damiano and coworkers noted age-related differences in the HRQoL of pre-adolescent children with orofacial clefts. They reported that the difference in the external aesthetics related to lip involvement, has a greater importance when the child grows closer to adolescence (Damiano et al., 2007). In the present study, the social emotional well-being of the orofacial cleft participants was lowest in the 17 to 18 and the 13 to 14 age group, and highest in the 9 to 10 age group. This could be because social interaction and emotional well-being becomes more challenging as the child comes closer to adolescence

In 2007, Broder and Wilson- Genderson also noted age – related differences in the COHIP scores of their study. The craniofacial group of patients scored lower in the subscales School environment, Social or Emotional well-being and Functional well-being (Broder and Wilson-Genderson, 2007). Children within the age group 8 years had lower subscale scores in Functional well-being than children in the 11 to 12 year old group. The children in the 15 year old subscale had lower functional well-being scores than children in the 11-13 age group. Broder and Wilson- Genderson postulated that the lower score in the 8 year old group was due to the smaller size of the group (Broder and Wilson-Genderson, 2007).

The Age-related subscale School environment was also statistically significant. School environment refers to tasks involved in the school environment (Broder and Wilson-Genderson, 2007). The highest score was from the 11 to 12 year olds and the lowest score was from the 17 to 18 year olds. The remaining age groups scored similarly. The reason for this could be because the 11 to 12 year olds would have better adapted to school life and with their school environment being more consistent than the 17 to 18 year olds who would be experiencing the pressure of matric and grade 11 as well as important life choices. Therefore, there is less consistency in the 17 to 18 year old school environment.

The subscale school environment was also statistically significant in relation to transport. The students travelling in public transport had greater scores for school environment than the students travelling in private transport. A possible reason for this is that the children travelling in public transport usually travel with their peers and this involves long walks from residences to public transport as well as time in the facility of transport. The time involved in the public transport may create better bonds with students and their peers, instilling more confidence at carrying out school tasks.

Following from the above, the subscale School environment was also statistically significant for place of accommodation. As the students in the Rural areas scored higher than the students in the Urban areas. This can be related to transport as the Rural areas most commonly use Public transport and the Urban areas most commonly use private transport. Urban areas also suggest a more affluent population and therefore more demanding in relation to aesthetics and function. An Urban Rural happiness gradient was studied from in 1972 to 2008 in the United States and found that the well – being gradient is lowest in Urban or City regions and higher in the Rural regions (Berry and Okulicz-Kozaryn, 2011). Factors such as the size and density of these areas were taken into account (Berry and Okulicz-Kozaryn, 2011).

Gender scores for COHIP were not statistically significant and the scores did not differ significantly.

With relation to Educational level, COHIP or OHRQoL were not statistically significant. However, the subscale Oral Health in relation to educational level was statistically significant. Oral health is a measure of oral symptoms which are not necessarily related, for example spots on teeth or pain (Broder and Wilson-Genderson, 2007). The Tertiary education and High school graduates scored higher than the students in school for Oral Health. The possible reason for this is because Tertiary education or High school graduates would have received many years of education on their Oral health as well as more years of treatment than the students in school. Therefore, the Tertiary education and High school graduates are more equipped to take care of themselves independently and can score higher in their Oral health.

There were no statistically significant correlations between cleft classification and COHIP scores. The subscale of School environment was borderline statistically significant with the incomplete cleft group scoring higher than the complete cleft group. This may be because the incomplete cleft group does not extend

completely and therefore children may not necessarily experience as many challenges as children with complete cleft.

The cleft laterality and location of cleft were not statistically significant. Right Unilateral cleft scored the highest COHIP score, followed by Midline cleft and the lowest score was that of the cleft palate. It can be postulated that cleft palate participants would score higher in aesthetics and lower regarding speech, however the number of cleft palate only participants were low (5). The COHIP scores and subscales were not statistically significant for cleft anatomical location. The COHIP scores were highest in the Lip, alveolus group, followed by the Lip, Alveolus and Palate group and the lowest COHIP score was for Hard and Soft Palate only group. The more palatal involvement of the cleft, the lower the COHIP scores. However, as previously mentioned the number of cleft palate only participants were low.

The overall mean scores for the subscales Oral Health, Social Emotional well-being and Functional well-being were the lowest scores. These findings are familiar with orofacial cleft patients. Orofacial cleft patients often have related malocclusions such as maxillary hypoplasia, maxillary arch form constriction, rotated teeth, missing teeth and skeletal discrepancies which make oral hygiene more difficult and therefore Oral Health more challenging (Gorlin et al., 2001). All the subjects were also still undergoing orthodontic treatment which also can make Oral hygiene more difficult and create temporary Functional difficulties such as with mastication and speech (Liu et al., 2011).

Cleft palate is associated with velopharyngeal incompetence or oronasal fistulas which result in hypernasality of speech directly impacting the functional well-being score (Gorlin et al., 2001). This may also be a reason as to why the greater the palate involvement in the cleft, the lower the scores for functional well-being and social emotional well-being.

The low social emotional well-being subscale score was found to be consistent with other studies. Patient's with orofacial cleft are more inclined to experience anxiety, teasing or bullying, be concerned about what people think and be uncomfortable in social interactions (Hunt et al., 2006).

Treatment expectancy and Global health do not form part of the COHIP score. Treatment expectancy is described as an assessment of expectations of the treatment outcomes and process (Broder and Wilson-Genderson, 2007). The Age-related treatment expectancy was found to be statistically significant. With the 17 to 18 year old group scoring the highest whilst the 8 year old group scored the lowest. The possible reason for this is because the 17 to 18 year old group are generally already in the advanced stages of their treatment in comparison with the 8 year old group who are still early in their treatment. Similar findings were made in Ward's study, with the 15 – 18 year old orofacial cleft age group having a higher treatment expectancy than the younger age groups. The older groups were not as nervous to receive treatment and felt more confident about how they would feel after treatment (Ward et al., 2013).

The Global health score was not statistically significant. However, it is worth noting that the score was high. Global health is an assessment of the overall feeling of systemic and oral health (Broder et al., 2007).



Limitations of the study

There could have been an overestimation of OHRQoL variables as participants could have felt pressured to say that they were experiencing a condition for fear of giving the “wrong answer” and may answer for social desirability. As the study is voluntary, participation may be influenced by extremes, such as participants who felt they have a low QoL or on the opposite end of the spectrum may experience a marked improvement in QoL.

Language barriers did also pose a challenge. Some of the orofacial cleft patients are also hearing impaired. Most of the patients are first language isiZulu in KZN.

The total number of participants was small and therefore limits the data analysis.

The questionnaire was long and some of the participants did become restless towards the end of the questionnaire.

Recommendations:

To validate a COHIP form in other commonly used South African languages such as Zulu, Sotho, Tswana, Xhosa and Afrikaans to name a few.

To validate a COHIP assessment for the hearing impaired.

To create a shortened COHIP form.

To assess age groups over 18

To develop and validate a reliable cleft specific multidisciplinary quality of life assessment tool.



Conclusion:

The OHRQoL of orofacial cleft patients at the Wentworth foundation clinic in KZN is low due to socioeconomic factors (finances, transport, lack of access to infrastructure in rural areas) and difficulty in accessing multidisciplinary care. It is important to reiterate that the OHRQoL as assessed by the COHIP form, encompasses various aspects such as Oral Health, Functional- wellbeing (eating, speaking), Social Emotional well-being, School Environment, Self Image and furthermore Treatment expectancy and Global Health.

The study shows a need for a cleft specific care facility where all orofacial cleft care can be accessed, therefore reducing transport costs to multiple locations. A cleft specific care facility will also allow better integration between various disciplines allowing more cohesive orofacial cleft care. Transport assistance for cleft care can possibly be state subsidized as it is continuous treatment from birth to adulthood.

The OHRQoL did not vary significantly amongst different age groups.

The Subscales of Functional well-being and School Environment are significantly affected by Age differences (these subscales form part of the COHIP score).

Functional well-being scores are highest in the age group 15 to 16 years old and lowest in the age group 8 years old. School environment scores are highest in the age group 11 to 12 years old and lowest in the age group 17 to 18 years old.

Treatment Expectancy (does not form part of the COHIP score) was statistically significant for different age groups. The age group 17 to 18 years old had the highest treatment expectancy, the age 8 years old scored the lowest for treatment expectancy.

The OHRQoL did not vary significantly amongst different genders. The OHRQoL did not vary significantly amongst different cleft types.

Demographic factors that did significantly influence subscale scores were Transport, Accommodation and Educational level. Transport was significantly relevant for the subscale School Environment, as the Public

transport participants scored higher than the Private transport participants. Accommodation was significantly relevant for the subscale School Environment, as the Rural participants scored higher than the Urban participants. Educational level was significantly relevant for the subscale Oral Health, as the High School graduates or Tertiary Education participants scored higher than participants in School.

The most seen cleft type in the study is Unilateral cleft left.



References: Using EndNote X8

- ABEBE, M. E., DERESSA, W., OLADUGBA, V., OWAIS, A., HAILU, T., ABATE, F., HAILU, A., DEMISSIE, Y., DEGU, S., ALEMAYEHU, B., GESSESSE, M., DERIBEW, M., GRAVEM, P. E., MOSSEY, P. & BUTALI, A. 2018. Oral Health–Related Quality of Life of Children Born With Orofacial Clefts in Ethiopia and Their Parents. *Cleft Palate-Craniofacial Journal* [Online], 55, 8, 1153-1157. Available: <http://search.ebscohost.com/login.aspx?direct=true&db=ddh&AN=131278429&site=ehost-live> [Accessed 09/03/2020].
- AFSHAR, M., BRUGMANN, S. A. & HELMS, J. A. 2012. Embryology of the craniofacial complex. *Plastic Surgery* [Online], 3, 503-516. Available: <https://www.sciencedirect.com/topics/neuroscience/frontonasal-prominence> [Accessed 11/12/2018].
- AKBULUT, Y. 2020. Approach to patients with cleft lip and palate in orthodontics. *Journal of Cleft Lip Palate and Craniofacial Anomalies* [Online], 7, 1, 8-16. Available: <https://www.jclpca.org/article.asp?issn=2348-2125;year=2020;volume=7;issue=1;spage=8;epage=16;aulast=Akbulut> [Accessed 16/06/2020].
- ANTOUN, J. S., FOWLER, P. V., JACK, H. & FARELLA, M. 2015. Oral health–related quality of life changes in standard, cleft, and surgery patients after orthodontic treatment. *American Journal of Orthodontics and Dentofacial Orthopedics* [Online], 148, 4, 568-575. Available: <http://www.sciencedirect.com/science/article/pii/S0889540615005430> [Accessed 09/04/2019].
- BARKAN, S. E. 2012. A Primer on Social Problems. *An Introduction to Medical Sociology. USA: Rowman and Littlefield Publishers.* [Online], 1. Available: https://books.google.co.za/books/about/A_Primer_on_Social_Problems.html?id=lvPgtAEACAAJ&redir_esc=y [Accessed 09/10/2019].
- BELL, J. C., RAYNES-GREENOW, C., TURNER, R. M., BOWER, C., NASSAR, N. & O'LEARY, C. M. 2014. Maternal alcohol consumption during pregnancy and the risk of orofacial clefts in infants: a systematic review and meta-analysis. *Paediatric and perinatal epidemiology* [Online], 28, 4, 322-332. Available: <https://onlinelibrary.wiley.com/doi/abs/10.1111/ppe.12131> [Accessed 04/03/2018].
- BENNADI, D. & REDDY, C. 2013. Oral health related quality of life. *Journal of International Society of Preventive & Community Dentistry* [Online], 3, 1, 1-6. Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3894098/> [Accessed 17/05/2018].
- BERRY, B. J. & OKULICZ-KOZARYN, A. 2011. An urban-rural happiness gradient. *Urban geography* [Online], 32, 6, 871-883. Available: <https://www.tandfonline.com/doi/abs/10.2747/0272-3638.32.6.871> [Accessed 06/05/2018].
- BHABHA Z, W. A., SMITH T. 2013. An Analysis of the impact on the Quality of Life of Mothers who have a child with Cleft Lip and Palate. *Research report for Masters degree in Family Medicine* [Online], Department of Family Medicine. (Doctoral Dissertation). Available: <https://core.ac.uk/download/pdf/39674023.pdf> [Accessed 12/10/2018].
- BILLE, C., OLSEN, J., VACH, W., KNUDSEN, V. K., OLSEN, S. F., RASMUSSEN, K., MURRAY, J. C., ANDERSEN, A. M. N. & CHRISTENSEN, K. 2007. Oral clefts and life style factors—a case-cohort study based on prospective Danish data. *European journal of epidemiology* [Online], 22, 3, 173-181. Available: https://scholar.google.com/scholar?hl=en&as_sdt=0%2C5&q=oral+clefts+and+lifestyle+factors+bille&btnG= [Accessed 04/06/2019].
- BRAUDE, B. 1981. Congenital facial abnormalities establishment of a unit in the Western Cape. *South African medical journal= Suid-Afrikaanse tydskrif vir geneeskunde*, 59, 512-513.
- BRODER, H., WILSON-GENDERSON, M. & SISCHO, L. 2014a. Examination of a Theoretical Model for Oral Health-Related Quality of Life Among Youths with Cleft. *American Journal of Public Health* [Online], 104, 5, 865-871. Available: <http://web.a.ebscohost.com.ezproxy.uwc.ac.za/ehost/detail/detail?vid=2&sid=d6fa2e97-5ac1-4059-a84c-a343220b776c%40sessionmgr4009&bdata=JnNpdGU9ZWhvc3QtbG12ZQ%3d%3d#AN=95475818&db=s3h> [Accessed 30/01/2018].
- BRODER, H. L., MCGRATH, C. & CISNEROS, G. J. 2007. Questionnaire development: face validity and item impact testing of the Child Oral Health Impact Profile. *Community dentistry and oral epidemiology* [Online], 35, 1, 8-19. Available: <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1600-0528.2007.00401.x> [Accessed 30/01/2018].
- BRODER, H. L., WILSON-GENDERSON, M. & SISCHO, L. 2014b. Examination of a Theoretical Model for Oral Health-Related Quality of Life Among Youths With Cleft. *American Journal of Public Health* [Online], 104, 5, 865-871. Available: <https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2013.301686> [Accessed 02/02/2018].

- BRODER, H. L. & WILSON-GENDERSON, M. 2007. Reliability and convergent and discriminant validity of the Child Oral Health Impact Profile (COHIP Child's version). *Community dentistry and oral epidemiology* [Online], 35, 1, 20-31. Available: <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1600-0528.2007.0002.x> [Accessed 05/02/2018].
- BULLINGER, M., BRÜTT, A. L., ERHART, M., RAVENS-SIEBERER, U. & GROUP, B. S. 2008. Psychometric properties of the KINDL-R questionnaire: results of the BELLA study. *European child & adolescent psychiatry* [Online], 17, 11, 125-132. Available: <https://link.springer.com/article/10.1007/s00787-008-1014-z> [Accessed 01/11/2020].
- BUTALI, A., ADEYEMO, W., MOSSEY, P., OLASOJI, H., ONAH, I., ADEBOLA, A., AKINTUBUBO, A., JAMES, O., ADEOSUN, O. & OGUNLEWE, M. 2014. Prevalence of orofacial clefts in Nigeria. *The Cleft Palate-Craniofacial Journal* [Online], 51, 3, 320-325. Available: <https://journals.sagepub.com/doi/full/10.1597/12-135> [Accessed 03/05/2018].
- BÜTOW, K. & KLEYNHANS, E. 1987. Incidence and clinical appearance of cleft deformities in the Transvaal. *The Journal of the Dental Association of South Africa= Die Tydskrif van die Tandheelkundige Vereniging van Suid-Afrika*, 42, 403-406.
- BUTOW, K., VAN WYK, P. & ZWAHLEN, R. 2007. Differences in the clinical appearances of white versus black patients with facial cleft deformities: a retrospective study of a South African clinic: scientific. *South African Dental Journal* [Online], 62, 7, 298-304. Available: <https://pubmed.ncbi.nlm.nih.gov/18019810/> [Accessed 05/04/2020].
- CENTERS FOR DISEASE CONTROL AND PREVENTION. 2006. Improved national prevalence estimates for 18 selected major birth defects--United States, 1999-2001. *Morbidity and mortality weekly report* [Online], 54, 51, 1301-1305. Available: <https://pubmed.ncbi.nlm.nih.gov/16397457/> [Accessed 12/05/2019].
- CHEVRIER, C., PERRET, C., BAHUAU, M., NELVA, A., HERMAN, C., FRANCANNET, C., ROBERT-GNANSIA, E. & CORDIER, S. 2005. Interaction between the ADH1C polymorphism and maternal alcohol intake in the risk of nonsyndromic oral clefts: an evaluation of the contribution of child and maternal genotypes. *Birth Defects Research Part A: Clinical and Molecular Teratology* [Online], 73, 2, 114-122. Available: <https://onlinelibrary.wiley.com/doi/abs/10.1002/bdra.20103> [Accessed 05/04/2019].
- CONWAY, J. C., TAUB, P. J., KLING, R., OBEROI, K., DOUCETTE, J. & JABS, E. W. 2015. Ten-year experience of more than 35,000 orofacial clefts in Africa. *BMC Pediatrics* [Online], 15, 1, 1-9. Available: <https://doi.org/10.1186/s12887-015-0328-5> [Accessed 14/02/2019].
- CRONJE, F. 2014. A Time Traveller's Guide to Our Next Ten Years. *Tafelberg* [Online], Kindle edition. Available: <https://irr.org.za/reports/books/a-time-travellers-guide-to-our-next-ten-years> [Accessed 19/04/2019].
- CUSCHIERI, A. & WORKING GROUP EUROCAT, E. A. 2001. Descriptive epidemiology of isolated anal anomalies: a survey of 4.6 million births in Europe. *American journal of medical genetics* [Online], 103, 3, 207-215. Available: <https://onlinelibrary.wiley.com/doi/abs/10.1002/ajmg.1532> [Accessed 09/11/2019].
- DAMIANO, P. C., TYLER, M. C., ROMITTI, P. A., MOMANY, E. T., JONES, M. P., CANADY, J. W., KARNELL, M. P. & MURRAY, J. C. 2007. Health-related quality of life among preadolescent children with oral clefts: the mother's perspective. *Pediatrics* [Online], 120, 2, 283-290. Available: <https://pediatrics.aappublications.org/content/120/2/e283.short> [Accessed 08/10/2019].
- DELPORT, S., CHRISTIANSON, A., VAN DEN BERG, H., WOLMARANS, L. & GERICKE, G. 1995. Congenital anomalies in black South African liveborn neonates at an urban academic hospital. *South African Medical Journal* [Online], 85, 1, 11-15. Available: <https://www.ajol.info/index.php/samj/article/view/149601> [Accessed 06/08/2018].
- DHAND, N. K., & KHATKAR, M. S. 2014. *Statulator: An online statistical calculator. Sample Size Calculator for Estimating a Single Mean* [Online]. Available: <http://statulator.com/SampleSize/ss1M.html> [Accessed].
- DIEWERT, V. M. & LOZANOFF, S. 2002. Animal models of facial clefting: experimental, congenital, and transgenic. *Understanding Craniofacial Anomalies: Etiopathogenesis of Craniosynostoses and Facial Clefting* [Online] 251-272. Available: https://www.researchgate.net/publication/227816175_Animal_Models_of_Facial_Clefting_Experimental_Congenital_and_Transgenic [Accessed 14/07/2018].
- ECKSTEIN, D. A., WU, R. L., AKINBIYI, T., SILVER, L. & TAUB, P. J. 2011. Measuring quality of life in cleft lip and palate patients: currently available patient-reported outcomes measures. *Plastic and reconstructive surgery* [Online], 128, 5, 518-526. Available: https://journals.lww.com/plasreconsurg/Abstract/2011/11000/Measuring_Quality_of_Life_in_Cleft_Lip_and_Palate.31.aspx [Accessed 14/03/2019].
- ERICKSON, J. D. 2000. Introduction: Birth defect surveillance in the United States. *Teratology* [Online], 61. Available: <https://onlinelibrary.wiley.com/doi/epdf/10.1002/%28SICI%291096-9926%28200001%2961%3A1%2F%3C1%3A%3AAID-TERA1%3E3.0.CO%3B2-V> [Accessed 13/04/2019].

- ESHETE, M., BUTALI, A., DERESSA, W., PAGAN-RIVERA, K., HAILU, T., ABATE, F., MOHAMMED, I., DEMISSIE, Y., HAILU, A. & DAWSON, D. V. 2017. Descriptive epidemiology of orofacial clefts in Ethiopia. *The Journal of craniofacial surgery* [Online], 28, 2, 334-337. Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5344734/> [Accessed 06/04/2020].
- FRIEDMAN, O., WANG, T. & MILCZUK, H. 2010. Cleft lip and palate. *Cummings Otolaryngology: Head & Neck Surgery. 5th ed. Philadelphia, Pa: Mosby Elsevier*.
- GIFT, H. C., ATCHISON, K. A. & DAYTON, C. M. 1997. Conceptualizing oral health and oral health-related quality of life. *Social science & medicine* [Online], 44, 5, 601-608. Available: <https://pubmed.ncbi.nlm.nih.gov/9032828/> [Accessed 15/06/2019].
- GKANTIDIS, N., PAPAMANOU, D. A., KARAMOLEGKOU, M. & DOROTHEOU, D. 2015. Esthetic, functional, and everyday life assessment of individuals with cleft lip and/or palate. *BioMed research international* [Online], 2015. Available: <https://www.hindawi.com/journals/bmri/2015/510395/> [Accessed 15/10/2019].
- GORLIN, R. J., COHEN JR, M. M. & HENNEKAM, R. C. 2001. Syndromes of the head and neck. Oxford university press.
- HEALTH-RESEARCH&KNOWLEDGE-MANAGEMENT, K. 2017. Guidelines for submitting research proposals to the KwaZulu- Natal department of health for approval. Available: <http://www.kznhealth.gov.za/research/Guidelines-for-Submitting-Research-Protocols-August2017.pdf> [Accessed 06/10/2018].
- HILL, D. S., WLODARCZYK, B. J., PALACIOS, A. M. & FINNELL, R. H. 2010. Teratogenic effects of antiepileptic drugs. *Expert review of neurotherapeutics* [Online], 10,6,943-959. Available: <https://www.tandfonline.com/doi/abs/10.1586/ern.10.57> [Accessed 15/10/2018].
- HLONGWA, P. 2019. Epidemiology and care of individuals with cleft lip and palate in South Africa. (Doctoral dissertation) Available: <http://wiredspace.wits.ac.za/handle/10539/27981> [Accessed 14/01/2020].
- HODGKINSON, P., BROWN, S., DUNCAN, D., GRANT, C., MCNAUGHTON, A., THOMAS, P. & MATTICK, C. R. 2005. Management of children with cleft lip and palate: a review describing the application of multidisciplinary team working in this condition based upon the experiences of a regional cleft lip and palate centre in the United Kingdom. *Fetal and maternal medicine review* [Online], 16, 1, 1-22. Available: <https://www.cambridge.org/core/journals/fetal-and-maternal-medicine-review/article/management-of-children-with-cleft-lip-and-palate-a-review-describing-the-application-of-multidisciplinary-team-working-in-this-condition-based-upon-the-experiences-of-a-regional-cleft-lip-and-palate-centre-in-the-united-kingdom/547AEE13606A6453BD0027C2EB01247A> [Accessed 15/06/2019].
- HONEIN, M. A., RASMUSSEN, S. A., REEFHUIS, J., ROMITTI, P. A., LAMMER, E. J., SUN, L. & CORREA, A. 2007. Maternal smoking and environmental tobacco smoke exposure and the risk of orofacial clefts. *Epidemiology* [Online] 8, 2, 225-233. Available: https://www.jstor.org/stable/20486350?seq=1#metadata_info_tab_contents [Accessed 01/10/2020].
- HUNT, O., BURDEN, D., HEPPER, P., STEVENSON, M. & JOHNSTON, C. 2006. Self-reports of psychosocial functioning among children and young adults with cleft lip and palate. *The Cleft palate-craniofacial journal* [Online], 43, 5, 598-605. Available: <https://journals.sagepub.com/doi/abs/10.1597/05-080> [Accessed 09/07/2019].
- JELLIFFE-PAWLOWSKI, L. L., SHAW, G. M., NELSON, V. & HARRIS, J. A. 2003. Risk of mental retardation among children born with birth defects. *Archives of pediatrics & adolescent medicine* [Online], 157, 6, 545-559. Available: <https://jamanetwork.com/journals/jamapediatrics/article-abstract/481356> [Accessed 05/07/2018].
- JOKOVIC, A., LOCKER, D., STEPHENS, M., KENNY, D., TOMPSON, B. & GUYATT, G. 2002. Validity and reliability of a questionnaire for measuring child oral-health-related quality of life. *Journal of dental research* [Online], 81, 7, 459-463. Available: <https://journals.sagepub.com/doi/full/10.1177/154405910208100705> [Accessed 08/09/2018].
- KAPP-SIMON, K. A. & MCGUIRE, D. E. 1997. Observed social interaction patterns in adolescents with and without craniofacial conditions. *The Cleft palate-craniofacial journal* [Online], 34, 5, 380-384. Available: https://journals.sagepub.com/doi/abs/10.1597/1545-1569_1997_034_0380_osipia_2.3.co_2 [Accessed 15/10/2018].
- KHAN, A. A. 1965. Congenital malformations in African neonates in Nairobi. *J Trop Med Hyg*, 68, 272-4.
- KRAMER, F.-J., GRUBER, R., FIALKA, F., SINIKOVIC, B., HAHN, W. & SCHLIEPHAKE, H. 2009. Quality of life in school-age children with orofacial clefts and their families. *Journal of Craniofacial Surgery* [Online], 20, 6, 2001-2006. Available: https://journals.lww.com/jcraniofacialsurgery/Abstract/2009/11000/Quality_of_Life_in_School_Age_Children_With.22.aspx [Accessed 18/09/2019].

- KRAMER, F.-J., GRUBER, R., FIALKA, F., SINIKOVIC, B. & SCHLIEPHAKE, H. 2008. Quality of life and family functioning in children with nonsyndromic orofacial clefts at preschool ages. *Journal of Craniofacial Surgery* [Online], 19, 3, 580-587. Available: https://journals.lww.com/jcraniofacialsurgery/Abstract/2008/05000/Quality_of_Life_and_Family_Functioning_in_Children.5.aspx [Accessed 15/04/2020].
- KROMBERG, J. & JENKINS, T. 1982. Common birth defects in South African blacks. *South African medical journal* [Online], 62. Available: <https://europepmc.org/article/med/6750816> [Accessed 15/08/2019].
- KROMBERG, J. & JENKINS, T. 1986. Incidence of cleft lip and palate in the Western Cape. *South African medical journal*, 69, 220-221.
- KUADA, J. 2015. The human side of economic development in Africa: a paradigm shift. *African Journal of Economic and Management studies* [Online], 6, 4, 334-342. Available: <https://www.emerald.com/insight/content/doi/10.1108/AJEMS-09-2015-0104/full/html> [Accessed 09/08/2019].
- KUMMER, A. W. 2014. Cleft Palate and craniofacial anomalies: Effects on speech and resonance. *3rd edition*, New York: Delmar Cengage Learning.
- LEITE, I. C. G. & KOIFMAN, S. 2009. Oral clefts, consanguinity, parental tobacco and alcohol use: a case-control study in Rio de Janeiro, Brazil. *Brazilian oral research* [Online], 23, 1, 31-37. Available: https://www.scielo.br/scielo.php?pid=S1806-83242009000100006&script=sci_arttext [Accessed 09/10/2019].
- LEVI, B., BRUGMAN, S., WONG, V., GROVA, M., LONGAKER, M. & WAN, D. 2011. Palatogenesis: engineering, pathways and pathologies. *Organogenesis* [Online], 7, 4, 242-254. Available: <https://www.semanticscholar.org/paper/Palatogenesis%3A-engineering%2C-pathways-and-Levi-Brugman/05f2d2f215a8eef370fe3ef64250ab669f09b51c>.
- LITTLE, J., CARDY, A. & MUNGER, R. G. 2004. Tobacco smoking and oral clefts: a meta-analysis. *Bulletin of the World Health Organization* [Online], 82, 213-218. Available: <https://www.scielosp.org/article/bwho/2004.v82n3/213-218/en/> [Accessed 12/05/2019].
- LIU, Z., MCGRATH, C. & HÄGG, U. 2011. Changes in oral health-related quality of life during fixed orthodontic appliance therapy: an 18-month prospective longitudinal study. *American journal of orthodontics and dentofacial orthopedics* [Online], 139. Available: <https://www.sciencedirect.com/science/article/pii/S0889540607009754> [Accessed 07/07/2019].
- LOCKER, D., JOKOVIC, A. & TOMPSON, B. 2005. Health-related quality of life of children aged 11 to 14 years with orofacial conditions. *The Cleft palate-craniofacial journal* [Online], 42, 3, 260-266. Available: <https://journals.sagepub.com/doi/abs/10.1597/03-077.1> [Accessed 11/06/2019].
- MARCUSON, A., AKERLIND, I. & PAULIN, G. 2001. Quality of life in adults with repaired complete cleft lip and palate. *The Cleft palate-craniofacial journal* [Online], 38, 4, 379-385. Available: https://journals.sagepub.com/doi/abs/10.1597/1545-1569_2001_038_0379_qoliaw_2.0.co_2 [Accessed 03/08/2018].
- MESSER, L. C., LUBEN, T. J., MENDOLA, P., CAROZZA, S. E., HOREL, S. A. & LANGLOIS, P. H. 2010. Urban-rural residence and the occurrence of cleft lip and cleft palate in Texas, 1999-2003. *Annals of epidemiology* [Online], 20, 1, 32-39. Available: <https://www.sciencedirect.com/science/article/abs/pii/S1047279709003184> [Accessed 16/04/2020].
- MEYER, K. A., WERLER, M. M., HAYES, C. & MITCHELL, A. A. 2003. Low maternal alcohol consumption during pregnancy and oral clefts in offspring: the Slone Birth Defects Study. *Birth Defects Research Part A: Clinical and Molecular Teratology* [Online], 67, 7, 509-514. Available: <https://pubmed.ncbi.nlm.nih.gov/14565622/> [Accessed 17/02/2018].
- MOLNÁROVÁ, A., PALENČÁR, D., FEKIAČOVÁ, D., BIELIKOVÁ, E., TICHÁ, E. & UJHÁZY, E. 2018. Orofacial clefts and infections during pregnancy. *Biologia*, 73, 6, 629-635.
- MOODLEY, P., SETHUSA, M. P. S. & KHAN, M. I. 2018. The distribution of orofacial clefts at the medunsa oral health centre, cleft clinic. *Journal of Cleft Lip Palate and Craniofacial Anomalies* [Online], 5, 1, 20-27. Available: <https://www.jclpca.org/article.asp?issn=2348-2125;year=2018;volume=5;issue=1;spage=20;epage=27;aulast=Moodley;type=0> [Accessed 16/05/2019].
- MOSSEY, P. A. & CASTILLA, E. E. 2003. Global registry and database on craniofacial anomalies: Report of a WHO Registry Meeting on Craniofacial Anomalies. *WHO Registry Meeting on Craniofacial Anomalies (2001: Baurú, Brazil)* [Online]. Available: <https://www.who.int/genomics/anomalies/en/Chapter00.pdf> [Accessed 19/04/2019].
- MOSSEY, P. A. & MODELL, B. 2012. Epidemiology of oral clefts 2012: an international perspective. *Cleft Lip and Palate* [Online], 16. Available: <https://www.karger.com/Article/Abstract/337464> [Accessed 20/09/2019].
- MOYO, K. 2016. Realising the right to health in South Africa. *Socio-economic rights—Progressive realisation* [Online]. Available: <http://www.fhr-mirror.org.za/files/7215/1247/1732/Health.pdf> [Accessed 06/01/2020].

- MUNGER, R. G., SAUBERLICH, H. E., CORCORAN, C., NEPOMUCENO, B., DAACK-HIRSCH, S. & SOLON, F. S. 2004. Maternal vitamin B-6 and folate status and risk of oral cleft birth defects in the Philippines. *Birth Defects Research Part A: Clinical and Molecular Teratology* [Online], 70, 7, 464-471. Available: <https://pubmed.ncbi.nlm.nih.gov/15259036/> [Accessed 16/06/2019].
- NACKASHI, J. A., DEDLOW, E. R. & DIXON-WOOD, V. 2002. Health care for children with cleft lip and palate: comprehensive services and infant feeding. *Cleft Lip & Palate: From Origin to Treatment*, 25, 1 [Online]. Available: <https://doctorlib.info/surgery/treatment/26.html> [Accessed 08/02/2018].
- ORKAR KS, U. B., MOMOH JT 2002. Cleft lip and palate: the Jos experience. *East Africa Med Journal*, 79(10):510-3.
- PARK-WYLLIE, L., MAZZOTTA, P., PASTUSZAK, A., MORETTI, M. E., BEIQUE, L., HUNNISETT, L., FRIESEN, M. H., JACOBSON, S., KASAPINOVIC, S. & CHANG, D. 2000. Birth defects after maternal exposure to corticosteroids: prospective cohort study and meta-analysis of epidemiological studies. *Teratology* [Online], 62, 6, 385-392. Available: <https://pubmed.ncbi.nlm.nih.gov/11091360/> [Accessed 09/10/2020].
- PENN, H. & JACK, C. 1953. The treatment of cleft lip and palate in South Africa: A review of 500 cases. *South African Medical Journal* [Online], 27, 27, 484-487. Available: https://journals.co.za/content/m_samj/27/23/AJA20785135_28797 [Accessed 03/09/2019].
- PIOMBINO, P., RUGGIERO, F., GIOVANNI DELL' AVERSANA, O., ET AL. 2014. Development and Validation of the Quality-of-Life Adolescent Cleft QUESTIONNAIRE in Patients with Cleft Lip and Palate. *The Journal of Craniofacial Surgery* [Online], 25, 5, 1-5. Available: <https://pubmed.ncbi.nlm.nih.gov/25010834/> [Accessed 18/09/2018].
- RALSTROM, E. F. 2010. The Impact of Oral Health in Adolescent Patients with Sickle Cell Disease. Available: https://etd.ohiolink.edu/apexprod/rws_olink/r/1501/10?p10_etd_subid=71602&clear=10 [Accessed 08/01/2018].
- RAVENS-SIEBERER, U. & BULLINGER, M. 1998. Assessing health-related quality of life in chronically ill children with the German KINDL: first psychometric and content analytical results. *Quality of Life Research* [Online], 7, 5, 399-407. Available: <https://doi.org/10.1023/A:1008853819715> [Accessed 29/10/2020].
- ROMITTI, P. A., LIDRAL, A. C., MUNGER, R. G., DAACK-HIRSCH, S., BURNS, T. L. & MURRAY, J. C. 1999. Candidate genes for nonsyndromic cleft lip and palate and maternal cigarette smoking and alcohol consumption: evaluation of genotype-environment interactions from a population-based case-control study of orofacial clefts. *Teratology* [Online], 59, 1, 39-50. Available: <https://pubmed.ncbi.nlm.nih.gov/9988882/> [Accessed 08/11/2019].
- ROMITTI, P. A., SUN, L., HONEIN, M. A., REEFHUIS, J., CORREA, A., RASMUSSEN, S. A. & STUDY, N. B. D. P. 2007. Maternal periconceptional alcohol consumption and risk of orofacial clefts. *American journal of epidemiology* [Online], 166, 7, 775-785. Available: <https://academic.oup.com/aje/article/166/7/775/94789> [Accessed 07/05/2019].
- ROSANO, A. & MASTROIACOVO, P. 2001. Global distribution of craniofacial anomalies. *Unpublished document presented at the WHO Registry Meeting on Craniofacial Anomalies, Baurú, Brazil* [Online] 4- 6. Available: <https://apps.who.int/iris/bitstream/handle/10665/42840/9241591102.pdf> [Accessed 16/10/2019].
- SEID, M., VARNI, J. W., SEGALL, D. & KURTIN, P. S. 2004. Health-related quality of life as a predictor of pediatric healthcare costs: a two-year prospective cohort analysis. *Health and quality of life outcomes* [Online], 2, 1, 48. Available: <https://link.springer.com/article/10.1186/1477-7525-2-48> [Accessed 17/04/2019].
- SHAW, G., WASSERMAN, C., O'MALLEY, C., LAMMER, E. & FINNELL, R. 1995. Orofacial clefts and maternal anticonvulsant use. *Reproductive Toxicology* [Online], 9, 1, 97-98. Available: <https://pubmed.ncbi.nlm.nih.gov/8520135/> [Accessed 08/09/2019].
- SHAW, G. M., CARMICHAEL, S. L., LAURENT, C. & RASMUSSEN, S. A. 2006. Maternal nutrient intakes and risk of orofacial clefts. *Epidemiology* [Online] 17, 3, 285-291. Available: https://journals.lww.com/epidem/fulltext/2006/05000/maternal_nutrient_intakes_and_risk_of_orofacial.13.aspx [Accessed 08/07/2018].
- SHAW, G. M., NELSON, V., IOVANNISCI, D. M., FINNELL, R. H. & LAMMER, E. J. 2003. Maternal occupational chemical exposures and biotransformation genotypes as risk factors for selected congenital anomalies. *American journal of epidemiology* [Online], 157, 6, 475-484. Available: https://journals.lww.com/epidem/fulltext/2006/05000/maternal_nutrient_intakes_and_risk_of_orofacial.13.aspx [Accessed 09/05/2019].
- SINGH, S. 2017. An exploratory study into reasons why Cleft Lip/Palate patients abscond from treatment at Wentworth Foundation, Durban, KwaZulu-Natal. . Management College of Southern Africa (MANCOSA) (Doctoral Dissertation).

- SINKO, K., JAGSCH, R., PRECHTL, V., WATZINGER, F., HOLLMANN, K. & BAUMANN, A. 2005. Evaluation of esthetic, functional, and quality-of-life outcome in adult cleft lip and palate patients. *The Cleft palate-craniofacial journal* [Online], 42, 4, 355-361. Available: <https://pubmed.ncbi.nlm.nih.gov/16001915/> [Accessed 08/10/2019].
- SLADE, G. D. 1997. Derivation and validation of a short-form oral health impact profile. *Community Dentistry & Oral Epidemiology* [Online], 25, 4, 284-290. Available: <https://pubmed.ncbi.nlm.nih.gov/9332805/> [Accessed 08/12/2017].
- SLADE, G. D. & REISINE, S. T. 2007. The child oral health impact profile: current status and future directions. *Community dentistry and oral epidemiology* [Online], 35, 50-53. Available: <https://pubmed.ncbi.nlm.nih.gov/17615050/> [Accessed 07/09/2017].
- SPERBER, G. H. 2002. Palatogenesis: closure of the secondary palate. *Cleft lip and palate: from origin to treatment* [Online] 14. Available: <https://doctorlib.info/surgery/treatment/3.html> [Accessed 19/08/2017].
- STATISTICS SOUTH AFRICA 2016. General Household Survey 2015. [Accessed: 23 October 2019].
- THE WENTWORTH FOUNDATION. 2015. *Wentworth Foundation* [Online]. Available: <http://www.wentworthfoundation.org.za/> [Accessed 25/05/20].
- TOPOLSKI, T. D., EDWARDS, T. C. & PATRICK, D. L. 2005. Quality of life: how do adolescents with facial differences compare with other adolescents? *The Cleft palate-craniofacial journal*, 42, 25-32.
- VARNI, J. W., SEID, M. & KURTIN, P. S. 1999. Pediatric health-related quality of life measurement technology: A guide for health care decision makers. *JCOM-WAYNE PA-* [Online], 6, 33-44. Available: <https://www.semanticscholar.org/paper/Pediatric-Health-Related-Quality-of-Life-A-Guide-Varni-Seid/cb7f0bc972fb3efde328ff13a141ca7e90df57fd> [Accessed 17/09/2017].
- WARD, J. A., VIG, K. W., FIRESTONE, A. R., MERCADO, A., DA FONSECA, M. & JOHNSTON, W. 2013. Oral health-related quality of life in children with orofacial clefts. *The Cleft Palate-Craniofacial Journal* [Online], 50, 2, 174-181. Available: <https://journals.sagepub.com/doi/full/10.1597/11-055> [Accessed 07/07/2017].
- WARSCHAUSKY, S., KAY, J. B., BUCHMAN, S., HALBERG, A. & BERGER, M. 2002. Health-related quality of life in children with craniofacial anomalies. *Plastic and reconstructive surgery* [Online], 110, 2, 409-416. Available: https://journals.lww.com/plasreconsurg/Abstract/2002/08000/Health_Related_Quality_of_Life_in_Children_with.4.aspx [Accessed 09/05/2017].
- WATKINS, S. E., MEYER, R. E., STRAUSS, R. P. & AYLSWORTH, A. S. 2014. Classification, epidemiology, and genetics of orofacial clefts. *Clinics in plastic surgery* [Online], 41, 2, 149-163. Available: [https://www.plasticsurgery.theclinics.com/article/S0094-1298\(13\)00157-0/abstract](https://www.plasticsurgery.theclinics.com/article/S0094-1298(13)00157-0/abstract) [Accessed 18/08/2017].
- WEHBY, G. L., OHSFELDT, R. L. & MURRAY, J. C. 2006. Health professionals' assessment of health-related quality of life values for oral clefting by age using a visual analogue scale method. *The Cleft palate-craniofacial journal* [Online], 43, 4, 383-391. Available: <https://journals.sagepub.com/doi/abs/10.1597/05-066.1> [Accessed 03/12/2017].
- WEICHERT, A., VOGT, M., DUDENHAUSEN, J. W. & KALACHE, K. D. 2010. Evidence in a human fetus of micrognathia and cleft lip as potential effects of early cytomegalovirus infection. *Fetal diagnosis and therapy* [Online], 28, 4, 225-228. Available: <https://www.karger.com/Article/Abstract/320203> [Accessed 10/07/2018].
- WHO 2002. World Health Organisation: Global strategy to reduce the health-care burden of craniofacial anomalies. . *Human Genetics Programme of the World Health Organization, Geneva, Switzerland.*
- WILSON-GENDERSON, M., BRODER, H. L. & PHILLIPS, C. 2007. Concordance between caregiver and child reports of children's oral health-related quality of life. *Community dentistry and oral epidemiology* [Online], 35, 32-40. Available: <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1600-0528.2007.00403.x> [Accessed 08/01/2018].
- WILSON, J. & HODGES, A. 2012. Cleft lip and palate surgery carried out by one team in Uganda: where have all the palates gone? *The Cleft palate-craniofacial journal*, 49, 3, 299-304.
- WOGELIUS, P., GJØRUP, H., HAUBEK, D., LOPEZ, R. & POULSEN, S. 2009. Development of Danish version of child oral-health-related quality of life questionnaires (CPQ 8–10 and CPQ 11–14). *BMC oral health* [Online], 9. Available: <https://link.springer.com/article/10.1186/1472-6831-9-11> [Accessed 25/02/2018].
- WYSZYNSKI, D. 2002. Chapter 12: Cleft lip and palate. From origin to treatment. Oxford University Press.
- ZHANG, J. 2001 Descriptive epidemiology of oral clefts and NTDs in China. Unpublished paper presented at the WHO Meeting on the Prevention of Craniofacial Anomalies, Park City, Utah, USA. 24-26.
- ZHANG, Z., STEIN, M., MERCER, N. & MALIC, C. 2017. Post-operative outcomes after cleft palate repair in syndromic and non-syndromic children: a systematic review protocol. *Systematic reviews* [Online], 6, 1, 1-7. Available: <https://systematicreviewsjournal.biomedcentral.com/articles/10.1186/s13643-017-0438-2> [Accessed 09/11/2020].

ZREQAT, M. H., HASSAN, R. & HANOUN, A. 2017. Cleft Lip and Palate Management from Birth to Adulthood: An Overview. *Insights into Various Aspects of Oral Health*, 100-121.



INFORMATION SHEET

**Project Title: An oral health-related quality of life assessment
at the Wentworth Foundation Clinic (KwaZulu-Natal)**

What is this study about?

This is a research project being conducted by Dr Leticia Singh 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 assess the oral health-related quality of life of orofacial cleft patients in KwaZulu Natal (KZN). The information gained by this research will be used to assess how patients feel about their oral health in KZN. This information is very useful to understand how the youth feel about their oral health and well being in KZN.

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

You will be asked to sign a form agreeing to take part in the study. You will also be asked to answer a sociodemographic form and a questionnaire known as the Child Oral Health Impact Profile. The study will be done at the Wentworth Foundation in Durban North, KZN. The interview will last approximately half an hour.

Would my participation in this study be kept confidential?

Your personal information will be kept confidential. To help protect your confidentiality, your real names will not be included in the data collection sheets and all information collected will be locked in cabinets and password protected computers. After consenting to treatment, participants will be allocated a number to identify them, this will protect their confidentiality throughout the study.

No names or address will be used or released to any staff member of the clinic, to any family member or any treating clinician. Participants' existing records will be

accessed only to obtain clinical and demographic information, for record purposes.

Participants' assessments and parents' socio demographic responses will be kept in a locked safe place. Only the researcher will have access to the data material. All raw data including written documents will be destroyed after 5 years of the final dissertation being marked and graded.

What are the risks of this research?

There are no risks involved in participation.

What are the benefits of this research?

The study will not provide any direct benefits to you as an individual. However, the information received from you will assist in scientific research that can help improve the information on cleft patients in KZN.

Do I have to be involved 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 Leticia Singh

Contact number: 0823042222

Email: singhleticia@gmail.com



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:

Researcher:

Dr Leticia Singh

Tel: 0823042222

Email: singhleticia@gmail.com

BMREC:

UWC

Private Bag x17

Bellville

7535

Tel: + 27 21 959 4111

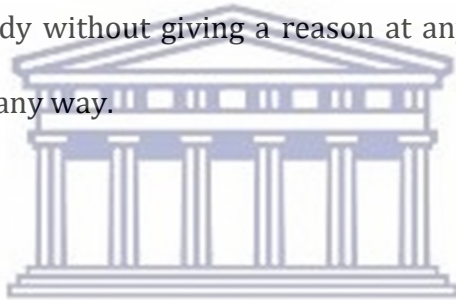
Email: research-ethics@uwc.ac.za



CONSENT FORM

Title of Research Project: An oral health-related quality of life assessment at the Wentworth Foundation Clinic (KwaZulu- Natal),

The study has been described to me in language that I understand, and I freely and voluntarily agree to participate. My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way.



Participant's name.....

Participant's signature.....

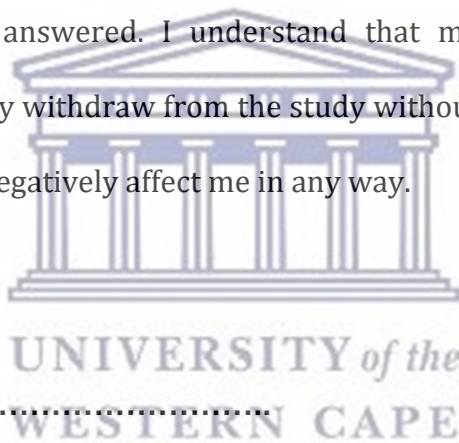
Date.....

UNIVERSITY of the
WESTERN CAPE

ASSENT FORM

Title of Research Project: An oral health-related quality of life assessment at the Wentworth Foundation Clinic (KwaZulu- Natal)

This research study is a way to understand and learn more about how people feel about their health. The study has been described to me in language that I understand, and I freely and voluntarily agree to participate. My questions about the study have been answered. I understand that my identity will not be disclosed and that I may withdraw from the study without giving a reason at any time and this will not negatively affect me in any way.



Participant's name.....

Participant's signature.....

Date.....

Guardians name:

Guardians signature:

Date:

Appendix 4:

<u>DEMOGRAPHIC PROFILE</u>					
(Please mark the appropriate box with an X)					
Age:	8-10	10-12	12-14	14-16	16-18
Gender:	Male			Female	
Craniofacial Diagnosis	None	Unilateral cleft lip Right	Unilateral Cleft Lip Left	Unilateral Cleft Lip Complete	
	Unilateral Cleft Lip Incomplete	Unilateral Cleft Alveolus right	Unilateral Cleft Alveolus Left	Bilateral Cleft Lip Complete	
	Bilateral Cleft lip incomplete	Bilateral cleft alveolus	Cleft Palate Hard and Soft	Cleft Palate Soft Palate only	
Education Level	None	In School	High School graduate	Tertiary education	
Place of Accommodation during treatment	Rural			Urban	
Mode of transport used to obtain treatment	Public			Private	

Appendix 5:

CHILD ORAL HEALTH IMPACT PROFILE

(Broder, McGrath et al. 2007) (Ward, et al. 2013)

Hi!

Thank you for being part of our study. We are doing this study to understand how children or teenagers feel about their oral health and their well-being.

DIRECTIONS: Please read the questions carefully, choose the answer that best describes you in the past 3 months regarding your teeth, mouth or face. There are no right or wrong answers. We want to know how you truly feel.

You should think about each question and cross the answer to the right of the question, to indicate how often you have had the problem during the past 3 months.

Keep in mind:

Answer the questions as honestly as you can.

Don't talk to other participants about the questions when you answer them.

Before you answer the question, ask yourself, does this happen to you because of your teeth, mouth or face?

Choose the answer that best describes you in the past 3 months.

In the past 3 months, how often have you?

(place a cross on your answer)

1. Had <u>pain</u> in your teeth/toothache?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
2. Been <u>breathing through your mouth</u> or <u>snoring</u> ?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
3. Had <u>discoloured teeth</u> or <u>spots</u> on your teeth?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
4. Had <u>crooked teeth</u> or <u>spaces</u> between your teeth?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
5. Had <u>sores</u> or <u>sore spots</u> in or around your mouth?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
6. Had <u>bad breath</u> ?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time

7. Had <u>bleeding gums</u> ?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
8. Had <u>food sticking in or between</u> your teeth?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
9. Had <u>pain or sensitivity</u> in your teeth with <u>hot or cold</u> things?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
10. Had <u>dry mouth or lips</u> ?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
11. Had <u>trouble biting off or chewing</u> food such as apple, carrot or firm meat?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
12. Been <u>unhappy or sad</u> because of your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
13. <u>Missed school</u> for any reason because of your teeth mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
14. Been <u>confident</u> because of your teeth mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
15. Had <u>difficulty eating foods</u> because of your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
16. Felt <u>worried or anxious</u> because of your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
17. Felt <u>shy or withdrawn</u> because of your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
18. Had <u>difficulty paying attention</u> in school because of your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
19. <u>Avoided smiling or laughing</u> with other children because of your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time

20. Had <u>trouble sleeping</u> because of your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
21. Not wanted to <u>speak or read out loud</u> in class because of your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
22. <u>Been teased, bullied or called names</u> by other children because of your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
23. Had <u>difficulty saying certain words</u> because of your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
24. Felt that you <u>look different</u> because of your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
25. Had <u>people have difficulty understanding</u> what you were saying because of your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
26. Felt that you were <u>attractive (good looking)</u> because of your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
27. Had <u>difficulty keeping your teeth clean</u> , because of your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
28. Been <u>worried about what other people think</u> about your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
29. Been <u>upset or uncomfortable</u> with being asked questions about your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
30. <u>Not wanted to go to school</u> because of your teeth, mouth or face?	Never	Almost Never	Sometimes	Fairly Often	Almost All the time
31. I have <u>good</u> teeth?	Strongly Disagree	Somewhat Disagree	Don't Agree or Disagree	Somewhat Agree	Strongly Agree

32. When I am <u>older</u> , I believe (think) <u>I will have good teeth</u>	Strongly Disagree	Somewhat Disagree	Don't Agree or Disagree	Somewhat Agree	Strongly Agree
33. When I am <u>older</u> , I believe (think) <u>I will have good health</u>	Strongly Disagree	Somewhat Disagree	Don't Agree or Disagree	Somewhat Agree	Strongly Agree
34. <u>I feel good about myself</u>	Strongly Disagree	Somewhat Disagree	Don't Agree or Disagree	Somewhat Agree	Strongly Agree
35. I will <u>feel better about myself</u> when <u>treatment</u> for my teeth, mouth or face is <u>completed</u>	Strongly Disagree	Somewhat Disagree	Don't Agree or Disagree	Somewhat Agree	Strongly Agree
36. I am <u>nervous (anxious) about the treatment that I need</u> for my teeth, mouth or face	Strongly Disagree	Somewhat Disagree	Don't Agree or Disagree	Somewhat Agree	Strongly Agree
37. Overall, I feel my health is	Poor	Fair	Average	Good	Excellent
38. Overall, I feel my oral health is	Poor	Fair	Average	Good	Excellent



Thank you for your time!

Reference for the COHIP questionnaire:

Broder, H. L., C. McGrath and G. J. Cisneros (2007). "Questionnaire development: face validity and item impact testing of the Child Oral Health Impact Profile." *Community dentistry and oral epidemiology* 35(s1): 8-19.

Ward, J. A., K. W. Vig, A. R. Firestone, A. Mercado, M. Da Fonseca and W. Johnston (2013). "Oral health-related quality of life in children with orofacial clefts." *The Cleft Palate-Craniofacial Journal* 50(2): 174-181.

10 June 2019

Dr L Singh
Faculty of Dentistry

Ethics Reference Number: BM19/3/18

Project Title: An oral health-related quality of life assessment of cleft patients at the Wentworth Foundation Clinic (Kwazulu-Natal).

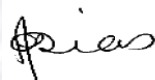
Approval Period: 10 June 2019 – 10 June 2020

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.

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

Please remember to submit a progress report in good time for annual renewal.

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*



Wentworth Foundation

NPO No.055/852, 195 Kenneth Kaunda Road,
Tel: +27 (0) 31 564 6501 Fax: +27 (0) 31 564 8061
P.O.Box 201213 Durban North 4016
email: sureka@orthoassist.co.za

26 – 03 – 2018

BMREC: Biomedical Research Ethics Administration
University of Western Cape
Research Office, New Arts Building, C-Block, Room 28
Western Cape
South Africa

To Biomedical Research Ethics Committee

**RE: LETTER OF PERMISSION TO CONDUCT A STUDY REGARDING THE
WENTWORTH FOUNDATION**

This letter serves to confirm that the Wentworth Foundation has granted Ms Leticia Singh permission to conduct a study relating to a quality of life survey of Cleft Lip Palate patients at the Wentworth Foundation as part of her Master's Degree Dissertation 2018.

This letter is also to confirm that Ms Leticia Singh will be granted permission in her personal capacity to have access to all the Cleft Lip / Palate patients, clinical files, and records. She will also be given access to appropriate facilities in which to conduct interviews. This will be done with due consideration to strict code of ethics and the patients' consent and well-being.

Thank you kindly

Ms S SINGH

(MANAGING OFFICER – WENTWORTH FOUNDATION)

"Creating Smiles for Africa!"

CHAIRPERSON: DR SURANDAR SINGH | WEBSITE: www.wentworthfoundation.org.za



Wentworth Foundation

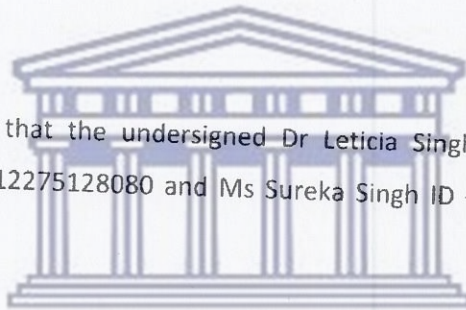
NPO No.055/852, 195 Kenneth Kaunda Road,
Tel: +27 (0) 31 564 6501 Fax: +27 (0) 31 564 8061
P.O.Box 201213 Durban North 4016
email: sureka@orthoassist.co.za

03 - 05 - 2018

To whom it may concern

Dear Sir / Madam,

This letter is to verify that the undersigned Dr Leticia Singh ID – 8911120189089, Dr Surandar Singh ID – 4512275128080 and Ms Sureka Singh ID – 7301290232086 share no family relation.



Dr Surandar Singh is an orthodontist and Founder and current Chairperson of the Wentworth Foundation for the treatment of indigent Cleft Lip Palate patients of KZN. The clinic is large and has a tremendous amount of research material. Dr Leticia Singh requested permission to use the Wentworth Foundation patients for research and this permission was granted to her.

Also note that Sureka Singh is the Chief Managing Officer of the Wentworth Foundation and has no relationship to Dr Leticia Singh.

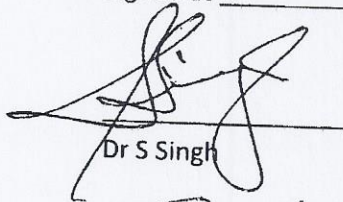
"Creating Smiles for Africa!"

CHAIRPERSON: DR SURANDAR SINGH | OUR WEBSITE: www.wentworthfoundation.org.za

Therefore there is no conflict of interest in Dr Leticia Singh research proposed with the Wentworth Foundation. Thank you for your understanding in this matter. Please accept this as an official declaration.

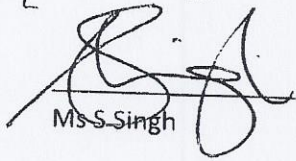
Signed at DURBAN

By



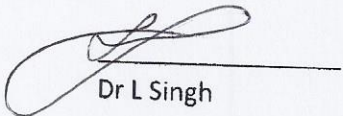
Dr S Singh

04/05/2018
Date



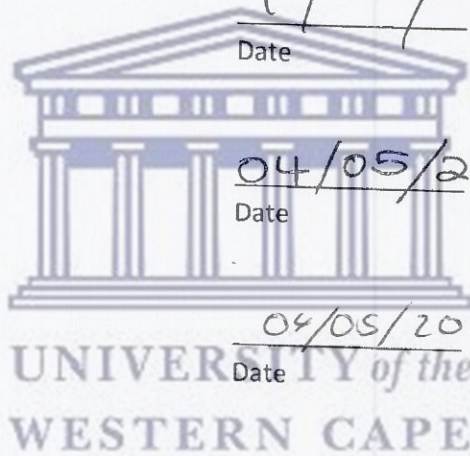
Ms S Singh

04/05/2018
Date



Dr L Singh

04/05/2018
Date



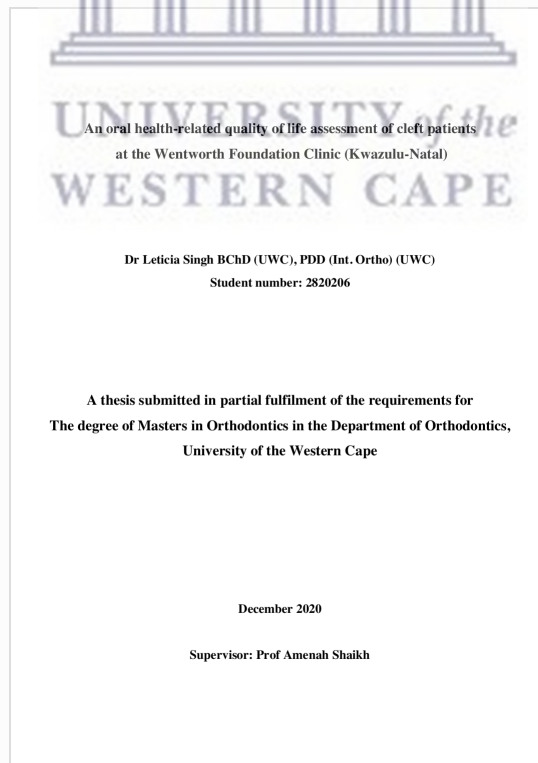


Digital Receipt

This receipt acknowledges that Turnitin received your paper. Below you will find the receipt information regarding your submission.

The first page of your submissions is displayed below.

Submission author: Leticia Singh
Assignment title: Thesis draft
Submission title: An oral health-related quality of life ...
File name: L_Singh_thesis_turn_it_in.docx
File size: 1.26M
Page count: 77
Word count: 18,171
Character count: 98,141
Submission date: 06-Dec-2020 10:55PM (UTC+0200)
Submission ID: 1454985374



Welcome to your new class homepage! From the class homepage you can see all your assignments for your class, view additional assignment information, submit your work, and access feedback for your papers. Hover on any item in the class homepage for more information.

Class Homepage

This is your class homepage. To submit to an assignment click on the "Submit" button to the right of the assignment name. If the Submit button is grayed out, no submissions can be made to the assignment. If resubmissions are allowed the submit button will read "Resubmit" after you make your first submission to the assignment. To view the paper you have submitted, click the "View" button. Once the assignment's post date has passed, you will also be able to view the feedback left on your paper by clicking the "View" button.

Assignment Inbox: Postgrad writing

Assignment Title	Info	Dates	Similarity	Actions
Thesis draft	①	Start: 19-Nov-2020 5:52 PM Due: 30-Apr-2021 11:59 PM Post: 30-Apr-2021 12:00 AM	13%	Resubmit View ↓