PONTIFÍCIA UNIVERSIDADE CATÓLICA DO RIO GRANDE DO SUL
FACULDADE DE ODONTOLOGIA
PROGRAMA DE PÓS-GRADUAÇÃO EM ODONTOLOGIA
DOUTORADO EM PRÓTESE DENTÁRIA

MARINA RECHDEN LOBATO PALMEIRO

QUALIDADE DE VIDA E CAPACIDADE MASTIGATÓRIA EM SUJEITOS COM FISSURAS LABIOPALATINAS E USUÁRIOS DE PRÓTESE TOTAL SUPERIOR

Porto Alegre
2013

MARINA RECHDEN LOBATO PALMEIRO

QUALIDADE DE VIDA E CAPACIDADE MASTIGATÓRIA EM SUJEITOS COM FISSURAS LABIOPALATINAS E USUÁRIOS DE PRÓTESE TOTAL SUPERIOR

Tese apresentada como requisito para a obtenção do grau de Doutor em Odontologia, área de concentração Prótese Dentária, pelo Programa de Pós-Graduação em Odontologia, Faculdade de Odontologia da Pontifícia Universidade Católica do Rio Grande do Sul.

Orientador: Profa. Dra. Rosemary Sadami Arai Shinkai

Porto Alegre

2013

MARINA RECHDEN LOBATO PALMEIRO

QUALITY OF LIFE AND MASTICATORY ABILITY OF SELECTED FOODS IN CLEFT LIP AND PALATE SUBJECTS AND MAXILLARY DENTURE WEARERS

A thesis submitted in partial fulfillment of the requirements for the Doctoral degree in Dentistry, area of concentration Prosthodontics, at the Postgraduate Program in Dentistry, School of Dentistry of Pontifical Catholic University of Rio Grande do Sul.

Supervisor: Professor Rosemary Sadami Arai Shinkai

Porto Alegre

2013

Dados Internacionais de Catalogação na Publicação (CIP)

P172q Palmeiro, Marina Rechden Lobato

Qualidade de vida e capacidade mastigatória em sujeitos com fissuras labiopalatinas e usuários de prótese total superior / Marina Rechden Lobato Palmeiro. – Porto Alegre, 2013.
100 f. : il.

Tese (Doutorado em Odontologia) – Fac. de Odontologia - PUCRS.
Orientador: Profª. Drª. Rosemary Sadami Arai Shinkai.

1. Odontologia. 2. Fenda Labial. 3. Fissura Labiopalatal. 4. Qualidade de Vida. 4. Capacidade mastigatória. 5. Depressão. 6. Prótese Dentária. I. Shinkai, Rosemary Sadami Arai. II. Título.

CDD 617.69

Ficha Catalográfica elaborada por
Vanessa Pinent
CRB 10/1297

This work is dedicated to my dear husband Luiz Amâncio, who always gives me support and incentive to continue my professional development. I am so grateful for your love and understanding.

Also to my parents, José Fernando and Doris, who are examples of dedication to both family and work.

ACKNOWLEDGMENTS

First and foremost, I would like to thank God for granting me the ability to complete this work.

My most important acknowledgments are towards my supervisor Prof. Dr. Rosemary Sadami Arai Shinkai. I am so grateful for her unlimited support, patience and guidance throughout this project. I would also like to thank her for giving me the opportunity to study abroad which had a very positive outcome on this work.

Thanks are also due to Prof. Dr. Angus Walls and Dr. Justin Durham, my co-advisors at Newcastle. I am very grateful for their advice, support and timely feedback on many drafts of the research manuscript. I have learned so much from them.

Of course, I would also like to thank all the participants who gave up their time to take part in this work.

I am very thankful to Pontifical Catholic University of Rio Grande do Sul, here represented by Prof. Dr. Alexandre Bahlis, Director of the School of Dentistry, for providing me with a high level of education and giving several opportunities for both academic and personal growth.

I wish to express my gratitude to CAPES of the Brazilian Ministry of Education, for awarding me a doctoral scholarship to study in Newcastle. Thanks for the support and wonderful opportunity to discuss my thesis topics with experts in this research area.

I also express my thanks to Newcastle University for welcoming me. I would like to thank all the teachers and staff who helped me and invited me to attend seminars and observe at the clinic. It was a great and productive time. A special thanks to Dr. Robert Wassell for teaching me a great deal about Occlusion.

I also thank Prof. Dr. Ana Maria Spohr, Coordinator of the Postgraduate Program in Dentistry at PUCRS, and Prof. Dr. Eduardo Rolim and Prof. Dr. Márcio Grossi, who are faculty of the area of concentration of Prosthodontics.

I would like to thank my dear colleagues in the Specialty Training in Prosthodontics at PUCRS: Alexandre Bahlis, Américo Schaeffer Löf, Edson Mesquita, Hugo Oshima, Paulo Cesar Armani Maccari, Regênio Mahfuz Herbstrith Segundo. I am so glad to work with you all. Many thanks for your teaching, contributions made and true friendship.

I am very grateful to all the teachers that I have had during my academic time and for all the knowledge that I have learned from them, especially Prof. Edson Mesquita for believing in me since I began the graduation course and for continuously encouraging me to move forward.

I would also like to thank my colleagues and friends within PUCRS and Newcastle University: Caio, Caroline, Leonardo, Mariana, Raphael, Tomas, Radhika and Wafa. I am very grateful for all their advice and friendship.

I would like to acknowledge the kind help and understanding I received from members of the Dental Office: Dr. Dante, Dr. Edson, Dr. Renata, Aline and Bruna. Thanks for conducting the office well during my time away.

I am very grateful for the help and support I received from my English teachers: Ana Buede-Fletcher helped with English classes, and Martin Fletcher proof read this thesis and helped with presentation.

Last but not least, I would like to thank my dear family for their unconditional support and understanding shown especially by my dear husband during this study time. Without them this work would have been incomplete.

RESUMO

Problemas relacionados à alimentação, fala, aparência e integração social influenciam a qualidade de vida (QoL) dos indivíduos. A reabilitação oral pode ter efeitos positivos na QoL. Esta tese é formada por dois manuscritos sobre o impacto da reabilitação oral em sujeitos adultos com grande perda tecidual. O primeiro manuscrito compõe um artigo original de pesquisa comparando variáveis de interesse em sujeitos fissurados e usuários de prótese total. O segundo manuscrito apresenta um relato de caso em que foi realizada reabilitação protética de um dos sujeitos do grupo de fissurados que compôs a amostra do artigo de pesquisa no primeiro manuscrito. O primeiro manuscrito comparou QoL, depressão e capacidade mastigatória entre indivíduos adultos fissurados, usuários de prótese total superior e controles saudáveis. A QoL foi avaliada através do instrumento OHIP-14. A capacidade mastigatória foi avaliada através de questionário e da mensuração da força máxima de mordida (MBF). O grau de depressão foi avaliado através do instrumento RDC/TMD Eixo II. Os resultados sugerem que as variáveis de mastigação e a QoL em adultos fissurados e usuários de prótese total superior são piores que no grupo controle, embora os impactos psicológicos e funcionais sejam diferentes para cada grupo. Pode-se concluir que a reabilitação oral nestes indivíduos não foi suficiente para restaurar os níveis similares de capacidade mastigatória e QoL em indivíduos saudáveis. O segundo manuscrito descreveu uma reabilitação oral de paciente fissurado adulto, considerado como um sucesso clínico. O plano de tratamento deste caso consistiu na confecção de prótese parcial removível associada a coroas telescópicas a fim de selar comunicação oronasal e restabelecer a estabilidade oclusal, dimensão vertical de oclusão assim como o suporte labial. A abordagem protética adotada neste caso foi efetiva visto ter restabelecido a função mastigatória e a estética do sujeito fissurado. Contudo, mais estudos que utilizem métodos de avaliação quantitativa e qualitativa são necessários para melhor entender as variáveis estudas nesses sujeitos a fim de otimizar o respectivo tratamento odontológico.

Palavras-chave[1]: Qualidade de vida. Fenda labial. Fissura palatina. Mastigação. Depressão. Prótese total superior.

[1] Decs: descritores em ciência da saúde [internet]. São Paulo: Bireme; 2013. [cited 2013 Jul 26]. Available from: http://decs.bvs.br.

ABSTRACT

Problems related to chewing, speech, appearance and social integration influence the individual's quality of life (QoL). Oral rehabilitation may have positive effects on QoL. This thesis consists of two manuscripts about oral rehabilitation in treated adult subjects with large loss of oral tissues. The first manuscript consists of an original research article comparing variables of interest in cleft lip and palate (CLP) subjects and maxillary denture wearers. The second manuscript presents a case report where a prosthetic rehabilitation was performed in one of the CLP subjects from the sample of the research article in the first manuscript. The first manuscript has compared QoL, depression and perception of masticatory ability between CLP subjects, maxillary denture wearers and healthy controls. OHIP-14 was used to assess QoL. Chewing was evaluated by a masticatory ability questionnaire and by maximum bite force (MBF). RDC/TMD Axis II was used to assess depression. The results suggest that adults with treated CLP or maxillary dentures still report chewing impairment and poorer QoL than healthy subjects, with different psychological and functional impacts for each group. It can be concluded that the oral rehabilitation in these subjects was not sufficient to restore the similar levels of masticatory capacity and QoL in healthy subjects. The second manuscript describes an oral rehabilitation of a CLP patient, which was considered successful. The treatment plan of the present case consisted of a maxillary rehabilitation using an association of removable partial denture, attachments and telescopic crowns in order to seal the oronasal communication and restore dental occlusion, vertical dimension and lip support. The prosthetic approach adopted in this case was effective since it restored masticatory function and aesthetics of the CLP subject. Further studies using quantitative and qualitative approaches are needed to better understand those variables studied in these subjects in order to optimize their dental treatment.

Key words (MeSH)[2]: Quality of life. Cleft lip. Cleft palate. Mastication. Depression. Denture, Complete, Upper.

[2] MeSH Browser [Internet]. Bethesda (MD): National Library of Medicine (US); 2002. [cited 2013 Jul 26]; Available from: http://www.ncbi.nlm.nih.gov/mesh.

LIST OF ABBREVIATIONS

CERLAP - Cleft Rehabilitation Center

CLP - Cleft Lip and Palate

ICD - International Classification of Diseases

FPD - Fixed Partial Denture

MBF - Maximum Bite Force

OHIP - Oral Health Impact Profile

OHRQoL - Oral Health-Related Quality of Life

PUCRS - Pontifical Catholic University of Rio Grande do Sul

QoL - Quality of Life

RDC/TMD - Research Diagnostic Criteria for Temporomandibular Disorders

RPD - Removable Partial Denture

SPSS - Statistical Package for Social Sciences

TMD - Temporomandibular Disorders

WHO - World Health Organization

SUMMARY

1 INTRODUCTION

Oral rehabilitation throughout prosthodontics procedures aims to provide good oral function. However, this terminology “oral rehabilitation” can be used to encompass several levels of oral therapy including the individual’s well-being and quality of life (QoL). This is a relatively new field of research where oral functionality needs to be defined based on the individual patient, not only on masticatory and occlusal characteristics as in the past (GOTFREDSEN; WALLS, 2007). QoL has become an integral element of outcome assessment, so treatment should take into account a patient’s needs and preferences (SLADE, 1997). This is particularly essential when dealing with cleft lip and palate (CLP) subjects, where patient’s treatment extends over a long period (FOO *et al.,* 2012).

According to Gotfredsen and Walls (2007), an acceptable level of oral function became a matter of individual oral health-related quality of life (OHRQoL) (GOTFREDSEN; WALLS, 2007). Social and psychological aspects of oral function have been categorized in different specific OHRQoL measures, like the instrument Oral Health Impact Profile (OHIP) (SLADE; SPENCER, 1994).

While studies have indicated that oral rehabilitation has broad positive implications and increasing QoL of treated patients (HULTIN *et al.,* 2012; NORDENRAM *et al.,* 2013), the investigation has not been done yet if treated adult subjects who have experienced large defects in the upper jaw due to congenital and acquired conditions have different masticatory function abilities and perceptions of their QoL.

1.1 CLEFT LIP AND PALATE

CLP are nonsyndromic orofacial defects, which comprise a range of disorders affecting the normal facial structure, especially lips and oral cavity (MOSSEY *et al.*, 2009; DIXON *et al.*, 2011). Development of the lip and palate involves a complex sequence of cellular events such as migration, growth, differentiation and apoptosis

between the 4th and 10th week of embryogenesis (MOSSEY *et al.*, 2009). Etiologically, CLP is thought to be multifactorial involving multiple genetic and environmental factors. Researchers are currently striving to identify etiologic variants in order to better understand the developmental disturbances leading to these abnormalities (MOSSEY *et al.*, 2009; DIXON *et al.*, 2011). Since the developmental origins of the lip and primary palate are different from the secondary palate, the defects vary in terms of width and other characteristics. CLP can be subdivided into cleft lip with cleft palate, called complete cleft, and isolated cleft lip or cleft palate in which the palate or lip is not affected, called incomplete; it also can affect only one side, unilateral, or both sides, bilateral (MOSSEY *et al.*, 2009; GLENNY *et al.,* 2011).

These defects arise in approximately 1/700 live births, with wide ethnic and geographic variation (MOSSEY *et al.*, 2009; DIXON *et al.*, 2011). Few studies have been done to determine the prevalence rates of CLP in Brazil. A study analyzing 31,058 maternity ward records from a Hospital in Porto Alegre- RS/Brazil, between 1983 and 1993, reported a prevalence of 1/757.5 live births (COLLARES *et al.*, 1995). Recent data showed the prevalence of dental abnormalities in 200 CLP patients from the Cleft Rehabilitation Center (CERLAP) of Pontifical Catholic University of Rio Grande do Sul (PUCRS): mean patient age was 13.5 years old; 86% were white; and 57% male. Complete cleft lip and palate was found at higher frequency (83%); the left side was most affected (48.5%). Agenesis was found in 66.6% of patients (MENEZES *et al.*, 2010).

Due to functional and cosmetic deformities and dental abnormalities, CLP patients may experience problems related to chewing, speech, hearing, appearance, social integration (MOSSEY *et al.*, 2009; DIXON *et al.*, 2011; GLENNY *et al.*, 2011). The long-lasting adverse outcomes can impact on QoL and well-being of both the affected individuals and their families (HUNT *et al.*, 2005; FOO *et al.*, 2012). An interdisciplinary team must be involved in the CLP patient treatment to meet medical, dental, and psychological needs. The full treatment may take decades, from birth up until early adulthood (REISBERG, 2000; MOSSEY *et al.*, 2009; VARGERVIK; OBEROI; HOFFMAN, 2009). Foo *et al.* (2012) reported that CLP adults treated had showed poorer QoL when compared to control subjects. These results suggest that

oral rehabilitation for CLP subjects does not entirely remove the factors contributing to poor QoL.

Regarding oral rehabilitation, proper surgical timing and orthodontic treatment coupled with proper prosthetic procedures can lead to better results and maximum long-term benefit (MOORE; MCCORD, 2004). A surgical approach is preferable in the treatment of congenital CLP. However, especially in the older generation of CLP, born in the 20th century, and also in developing countries, where the surgical timing is not achievable, there are still many patients with acquired defects, both in primary or secondary palate, which remain essentially a prosthetic problem (REISBERG, 2000; MOORE; MCCORD, 2004).

In reviewing the existing literature, it was suggested that the first attempt to obliterate a cleft palate was used by Demosthenes (384-323 B.C), the famous Greek orator. In the 19th century, after many early efforts, a description of prosthetic designs for obturation of palatal defects was made (ARAMANY, 1971; REISBERG, 2000). For a long time, the treatment was focused on the area of acquired rather than congenital defects. The significant advances in treatment resulting from these early efforts have enabled CLP patients to enjoy more comfortable lives. At present, due to increased knowledge, techniques development and improved surgical and orthodontic treatment, better care in less time has become possible (CUNE; MEIJER; KOOLE, 2004; OOSTERKAMP *et al.*, 2007). However, in more specific approaches, prosthetic treatment still has an important role and remains an integral part of CLP care especially as the final restoration.

CLP patients have shown a high prevalence of agenesis of maxillary lateral incisor on the cleft side, however cuspids and central incisors may also be affected (MENEZES *et al.*, 2010). If not missing, these teeth also may be abnormal, malformed, misaligned or misplaced. The teeth adjacent to the cleft usually have compromised bone support. Particularly in bilateral clefts, the bone support is even more deficient which may compromise the central incisors (REISBERG, 2000).

After surgical correction, orthodontic treatment can be done to close edentulous space due to congenital absence. In the absence of lateral incisor,

frequently, the cuspid is moved to the position at which the lateral incisor would be and the premolar is moved to the cuspid's position (MOORE; MCCORD, 2004). Crown lengthening procedure may be necessary in order to eliminate gingival margin level discrepancy. The prosthetic procedures are required to achieve better aesthetics results. In some instances the prosthetic masking or reshaping of teeth is necessary by some enameloplasty to flatten the buccal surface, whitening, and provision of direct composite addition or fitting of ceramic veneers or crowns to make it appear more like a lateral incisor (MOORE; MCCORD, 2004). The premolar may need some of these modifications to be similar to a cuspid. Ceramic laminate veneer is also recommended to correct malformed teeth adjacent to the cleft (REISBERG, 2000).

Depending on the width of the cleft, when the edentulous space and cleft are not fully closed by orthodontics and surgical treatment, greater prosthetic intervention is necessary. Bone grafts are often used to create sufficient bone support for implants and to create a suitable alveolar ridge for dentures (CUNE; MEIJER; KOOLE, 2004; KRAMER *et al.*, 2005; OOSTERKAMP *et al.*, 2007). Once there is adequate volume of bone in edentulous space, dental implants can be placed at the site of missing teeth (MOORE; MCCORD, 2004). After the osseointegration period a ceramic crown is attached to it. Recent studies were made to evaluate the success of this approach that does not require the involvement of adjacent natural teeth. Cune, Meijer and Koole (2004) evaluated the success of implants placed in the anterior region of patients with clefts. A total of 10 implants were placed in 9 patients aged 18 to 22. Clinical evaluations and radiographic monitoring were performed in follow-up visits. No implants were lost during osseointegration, and the implants functioned well over 3.4 years without objective or subjective problems (CUNE; MEIJER; KOOLE, 2004). However, Krieger *et al.* (2009) compared the failure and complication rates of tooth and implant-supported prostheses in patients with clefts and obtained differing results. This systematic review demonstrated that complications occur early and in the majority of cases of implant-supported reconstructions (KRIEGER *et al.*, 2009). So far, the possible risks for osseointegration and long-term maintenance in CLP patients have resulted in a rather restricted application of implants (CUNE; MEIJER; KOOLE, 2004; OOSTERKAMP *et al.*, 2007). Therefore, if the implant

placement conditions are not ideal and adjacent teeth need cosmetic corrections, conventional prostheses might be a better treatment option.

Despite improvements in surgical therapy, a sizeable number of CLP patients have not undergone the alveolar graft procedure. Some individuals have been deemed to be unsuitable to secondary grafts because of the extent of their defect, or this has been unsuccessful; others did not have the opportunity for such treatment and so have showed residual fistulae (scarring) (MOORE; MCCORD, 2004; KRIEGER *et al.*, 2009). Furthermore, in many developing countries, public health services cannot afford treatment for CLP patients. Accordingly these patients, who have not received grafting and orthodontic realignment, are the greatest prosthodontic challenge because the prosthesis needs to seal the oronasal communication and also rehabilitate masticatory function, restoring satisfactory function, aesthetics and QoL (MOORE; MCCORD, 2004; OOSTERKAMP *et al.*, 2007; FOO *et al.*, 2012). There are different alternatives for conventional prosthetic rehabilitation of these CLP patients: fixed partial dentures, resin bonded fixed partial dentures, removable partial dentures, complete dentures (CUNE; MEIJER; KOOLE, 2004; KRAMER *et al.*, 2005; MAÑES FERRER *et al.*, 2006). Choosing between these options is based on the specific situation of each patient in order to achieve a complete oral rehabilitation. There is no single method of treatment, it must differ in approach, design and method. MOORE; MCCORD (2004) stated that all CLP patients are unique and present their own diagnostic and prosthodontic problems.

A resin bonded fixed partial denture, commonly called the Maryland bridge, is used when no other restoration or misalignment correction need to be done in the abutment tooth. By means of this conservative restoration, very little tooth preparation is needed and a very good aesthetic result is achieved (REISBERG, 2000). However it is not recommended for definitive treatment in patients with clefts due to some vertical movement of the premaxilla or mobility of the abutment tooth that can cause cement failure (MURRAY, 1998). As an alternative, a conventional fixed partial denture (FPD) can be applied. Tooth preparation for full crown should be performed on at least one tooth on each side of the edentulous space. When

connected by two abutment teeth and one pontic, the bridge has limited mobility and long-term success is more predictable (MURRAY, 1998; REISBERG, 2000).

A removable partial denture (RPD) is indicated in adult CLP patients that need tooth replacement with obturation of any residual oronasal communication, even after surgical approach (MAÑES FERRER *et al.*, 2006). This defect may affect the speech and also the appearance by the absence of lip support. RPD consists of a resin palatal plate, like an obturator, with retention clasps (REISBERG, 2000; MAÑES FERRER *et al.*, 2006). This type of prosthesis is also required when multiple teeth are missing, resulting in a long edentulous space to be spanned by a FPD (PJETURSSON *et al.*, 2004). Currently, the resistance of the patients in using RPD is based on cosmetic concerns, due to the clamp's visual effects. Furthermore, part of this type of prosthesis must rest on soft tissue and may cause movement and discomfort for the patient. In connection with this concern, telescopic crowns are retentive elements widely used for treating partially edentulous patients. Telescopic crowns could be connected to RPD to increase prosthetic stability and to allow for transmission of masticatory forces to the long axis of the supporting tooth as well as cosmetic improvements (BAYER *et al.*, 2012; BREITMAN *et al.*, 2012). Authors have reported that RPD attached to telescopic crowns eliminate the movement during function and provide good aesthetics due to stabilization of the maxillary segments and individual teeth (REISBERG, 2000; MAÑES FERRER *et al.*, 2006).

1.2 MAXILLARY EDENTULOUS STATUS

Studies about people's perceptions of loss of teeth have demonstrated both physiologic and psychosocial impacts (NORDENRAM *et al.*, 2013). Clinical factors, like number and location of missing teeth, as well as sociodemographic factors, such as socioeconomic status and level of education, strongly influence the perception of disability and treatment needs (HULTIN *et al.*, 2012). For most people, impaired appearance could be associated with tooth loss in the maxillary arch, whereas impairment in masticatory ability may be the result of losing several posterior teeth (RIBEIRO *et al.*, 2011; HULTIN *et al.*, 2012). Maxillary edentulous represents a

singular group of patients who require oral rehabilitation to restore aesthetics and oral function considering the dental status in the opposite arch.

Over the last decade, a considerable variation can be noted between rates of edentulism and patterns of dental care in different countries (PRESHAW *et al.*, 2011, RIBEIRO *et al.*, 2011; NORDENRAM *et al.*, 2013). According to a recent epidemiological survey in the UK, the proportion of adults who were edentate has fallen from 28 per cent in 1978 to 6 per cent in 2009 (STEELE; O' SULLIVAN, 2011; WHITE *et al.*, 2012). In the same survey, 13 per cent of the population were composed of adults with both natural teeth and dentures.

While rates of edentulism are decreasing in developed countries, tooth loss is highly prevalent in developing countries (PRESHAW *et al.*, 2011, RIBEIRO *et al.*, 2011; NORDENRAM *et al.*, 2013). Despite advances in preventive dentistry, Brazil still shows higher prevalence of edentulism than other countries such as those within the African continent (RIBEIRO *et al.*, 2011). In 2003, a population-based epidemiological study indicated 54.7 per cent of complete edentate subjects in the age group 65 to 74 years. Complete edentulism was 18.2 per cent in the maxilla and 1.9 per cent in the mandible (RIBEIRO *et al.*, 2011). According to the Brazilian Oral Health Survey conducted in 2010 there were approximately 30 million edentate people, 63 per cent were wearing maxillary complete dentures as opposed to a partially dentate mandible (MINISTÉRIO DA SAÚDE (BR), 2010). Despite the fact that denture use is more frequent in the upper than in the lower jaw, few studies were done related to this matter. There is a lack of information about perceived masticatory ability and QoL among maxillary denture wearers.

Moreover tooth loss can affect daily functional activities, such as chewing, and the selection of foods during meals (CHEN *et al.*, 2012). Nordenram *et al.* (2013) described in a systematic review that loss of teeth is associated not only with compromised oral function, but also with loss of social status and mental health-related quality of life (NORDENRAM *et al.*, 2013). For many treated patients, oral rehabilitation provides a return to social life and improved QoL. Hultin *et al.* (2012) found very few quantitative studies regarding the influence of oral rehabilitation following total or partial tooth loss on self-perceived OHRQoL (HULTIN *et al.*, 2012).

According to these authors, oral rehabilitation has positive effects on QoL, however there is a lack of scientific evidence to support general conclusions about this influence.

This point is also sustained by the last Adult Dental Health Survey in the UK, which assessed QoL in both dentate and edentate adults. The report of this large survey showed that 40 per cent of edentate and 39 per cent of dentate adults experienced at least one OHIP-14 (NUTTALL et al., 2011). In Brazil, there is little information about people's QoL as the national surveys have not assessed this outcome until now. Bianco *et al.* (2010) evaluated the influence of socio-demographic variables and oral health conditions in the QoL of people aged 50 or above living in São Paulo. Of the 224 participants, 117 were complete denture wearers, and from these 43 participants wear only maxillary dentures. In general OHIP scores for the sample were low and tended to be lower with the increase of the age. Bianco *et al.*, (2010) stressed the importance of creating an instrument to compare edentate and dentate people (BIANCO *et al.*, 2010).

Over the last decades, since dental implants have been used, different treatment approaches have been suggested for patients with an edentulous maxilla (LYNCH; ALLEN, 2003; ALLEN, 2005). Choice of treatment modality ultimately depends on the patient's needs, oral conditions, preferences for fixed or removable prosthesis, as well as the amount of time and money the patient is willing to spend on the treatment (LYNCH; ALLEN, 2003; ALLEN, 2005). Maxillary complete denture is a less invasive and less complex method for replacing teeth for edentulous patients than a surgical approach and the use of dental implants. The performance of conventional dentures is often related to their support and retention (ALLEN, 2005; CHEN *et al.*, 2012). Accurate application of the principles of complete denture construction and restoring a stable posterior occlusion can provide improvements in the overall quality and stability of the maxillary denture (ALLEN, 2005).

Wennerberg *et al.* (2001) evaluated masticatory and prosthetic problems in 109 consecutive patients with maxillary complete dentures opposing mandibular implant-supported. These authors showed that two thirds of the sample reported no problems with their maxillary complete dentures at all (WENNERBERG *et al.*, 2001).

Chen *et al.* (2012) described how a stable and retentive maxillary complete denture with adequate occlusion contributes to good oral function and well-being (CHEN *et al.*, 2012). Additional studies have shown that the quality of complete dentures and adaptability factors are related to the patient's satisfaction with complete dentures (FENLON; SHERRIFF, 2008; CRITCHLOW; ELLIS; FIELD, 2012). However, improvements in denture quality may have limited impact on masticatory ability and diet quality (MOYNIHAM *et al.*, 2000; SHINKAI *et al.*, 2001; BRADBURY *et al.,* 2006).

1.3 QUALITY OF LIFE

Individual perception of oral health status is an important outcome in oral rehabilitation, which includes prosthodontic treatment. This individual perception of oral health is characterized by OHRQoL (JONH *et al.*, 2004; LOCKER; ALLEN, 2007). OHRQoL's measures reveals how oral health affects the individual's ability to function, as well as his or her psychological and social well-being (LOCKER; ALLEN, 2007). Therefore, oral health has an effect on QoL through its impact on important activities such as chewing and tasting food, speech and social functioning (PRESHAW *et al.*, 2011).

One of the most used instruments for the assessment of OHRQoL is the OHIP (SLADE; SPENCER, 1994). OHIP is a technically advanced instrument, based on Locker's theoretical model of oral health and derived from the World Health Organization (WHO) International Classification of Impairments, Disabilities and Handicaps (WORLD HEALTH ORGANIZATION, 1980), that measures people's perception of the social impact of oral disorders on their well-being. It was developed in Australia by Slade and Spencer (1994) and has been tested and validated in other countries (SLADE, 1997). The 49 items in the OHIP capture seven conceptually formulated dimensions: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap (SLADE; SPENCER, 1994; SLADE, 1997).

In addition, the development, reliability and validity of a short version, called OHIP-14, were also described (SLADE, 1997). OHIP-14 has been used widely in surveys of dental status to recognize that oral disease not only causes physical impairment, but also social and psychological effects. Furthermore, it was translated and cross-culturally validated in different languages, including Brazilian Portuguese (OLIVEIRA; NADANOVSKY, 2005).

The short version is comprised of 14 items from which responses are made on a Likert-type scale as in the full form. For each item, people are asked how frequently they have experienced the impact of each item in the preceding 12 months (SLADE, 1997). Ordinal values are coded for each item 4 = “very often”, 3 = “fairly often”, 2 = “occasionally”, 1 = “hardly ever”, 0 = “never”. Three summary variables can be computed: (1) prevalence: the percentage of people reporting one or more items; (2) extent: the number of items reported “fairly often” or “very often”; and (3) severity: the sum of ordinal responses, thus taking into account impacts experienced occasionally or hardly ever, and could range from 0 to 56 (SLADE *et al.*, 1998; MOUFTI *et al.*, 2011).

Tooth loss (SLADE, 1997) and denture status (JONH *et al.*, 2004) are strong predictors of OHRQoL (SLADE, 1997; JONH *et al.*, 2004). Studies had showed that CLP patients are less satisfied with their appearance and also have a poor oral health related quality of life (OOSTERKAMP *et al.*, 2007; FOO *et al.*, 2012). Foo *et al.* (2012) compared oral health impact among treated adults CLP and population norms in Australia. According to these authors, CLP participants experienced poorer QoL in comparison to the general population, and their prevalence of OHIP items was 2.7 fold higher (FOO *et al.*, 2012).

An association between prosthesis quality and OHRQoL also has been reported (JONH *et al.*, 2004; PRESHAW *et al.*, 2011). Montero *et al*. (2013) assessed the changes in OHRQoL after different conventional prosthetic treatments. Patients perceived benefits in chewing ability, aesthetics and satisfaction using dental prostheses, although in more than 20 per cent it can cause some discomfort (MONTERO *et al*. 2013).

In certain ways, CLP subjects and those who are edentulous in the maxilla can be considered as having a mutilated dentition; both have aesthetic discomfort and speech, chewing and swallowing difficulties although with different aetiologies (FOO et al., 2012; NORDENRAM et al., 2013). Poor oral health has both physiological and social impacts and it also affects self-esteem and overall experience of life. The subjective experiences of losing teeth, adjusting to living with edentulism and the response to prosthetic rehabilitation of this condition have impacts on patients' QoL.

1.4 MASTICATORY ABILITY

Chewing is a highly neuromuscular function, which is especially important in the digestion process. It serves to comminute food and convert it into a bolus to be swallowed (WALLS *et al.*, 2000). The relationship between masticatory efficiency and food choice has been established for elderly people (WALLS *et al.*, 2000; MARSHALL *et al.,* 2002). The number and the distribution of teeth and thereby the ability to chew, particularly the presence of dentures, is believed to be also important for nutritional status (GOTFREDSEN; WALLS, 2007; NORDENRAM *et al.*, 2013). However, studies of the relationship between occlusal status, masticatory function, and diet present unclear results (MOYNIHAM *et al.,* 2000; SHINKAI *et al.*, 2001). Regarding CLP patients, there is little information on this matter. Hence, perceived masticatory ability of treated CLP patients was first investigated in the present study.

Research into masticatory function could be quantitative or qualitative. There are a wide variety of objective techniques to assess masticatory performance, such as comminution ability, chewing strokes/cycles, chewing time, swallowing threshold, mixing ability, bite force and nutritional status (SHINKAI *et al.*, 2001; ÖSTERBERG *et al.*, 2002; GOTFREDSEN; WALLS, 2007). On the other hand, qualitative measures are usually evaluated through interviews or self-assessed masticatory ability questionnaires (OBREZ; GRUSSING, 1999; ÖSTERBERG *et al.*, 2002; GOTFREDSEN; WALLS, 2007). Considering that objective assessments seems to be less biased than subjective assessments, quantitative techniques may be recognized as more reliable tools for evaluating treatment outcomes. However, only

patients' subjective assessments reflect their overall satisfaction and changes in QoL. Qualitative methods are convenient to achieve a deeper understanding of patients' perceptions and experiences of certain phenomenon (NORDENRAM et al., 2013). Another advantage of self-assessed questionnaires is the ease of application at chairside (MATSUYAMA et al., 2007). Although some discrepancies have been demonstrated between those qualitative or quantitative tests, both have shown that tooth loss is associated with reduced chewing ability. Thus, a minimum of 20 teeth with 9-10 pairs of contacting units is associated with adequate masticatory function (GOTFREDSEN; WALLS, 2007; UENO *et al.*, 2010).

Maximum bite force (MBF) represents the effort exerted between the maxillary and mandibular teeth when the mandible is elevated (SHINKAI *et al.,* 2007). Therefore the capacity to exert sufficient bite force is an indicator of normal masticatory function (HATCH *et al.*, 2001). The interaction of factors, such as gender, age, body mass index, dental occlusal status, temporomandibular disorders, size and direction of muscles, periodontal and psychological factors, results in the large intersubject variability of this measure (SHINKAI *et al.*, 2007; HATCH *et al.*, 2001). Hatch *et al.* (2001) described gender as the most important factor influencing bite force, whereas masseter muscle thickness as the major contributing factor of bite force. However the association between gender and masseter cross-sectional area was not strong enough to explain gender differences in MBF (HATCH *et al.*, 2001).

Sipert *et al.* (2009) compared MBF between 27 patients with repaired unilateral CLP and non-CLP controls. The CLP group showed a decrease in MBF only in male subjects, however the reasons for these findings were not clearly understood by the authors (SIPERT *et al.*, 2009). Regarding the fixed prosthodontic approach in CLP subjects, Suzuki *et al.* (1995), based on MBF measures, stated that two teeth in each segment should be included in the abutment of the splint across the cleft in order to increase the functional loading capability since their maxillary bone structure is weak (SUZUKI *et al.*, 1995).

Additionally, a relationship between masticatory ability and food choice has been reported in the literature. According to reviews by Walls *et al*. (2000), Walls and Steele (2004), it is possible to assume that masticatory ability and occlusal status

might influence a considerable part of quality food intake (WALLS *et al.*, 2000; WALLS; STEELE, 2000). Sheiham *et al.* (1999), in a cross sectional survey among a representative sample of older people, had found that the selection of foods are affected by numbers of teeth, occluding pairs of posterior and presence of full dentures (SHEIHAM *et al.*, 1999). The diet of partially dentate patients has been reported to be higher in fat and lower in dietary fibre compared with guideline intakes (MOYNIHAM *et al.*, 2000). Subjects with more deteriorated dental status had a higher intake of porridge, pasta and sausage than those with well-preserved dental status (ÖSTERBERG *et al.*, 2002). In relation to CLP subjects, there are studies that show feeding practices among children with defects (GLENNY *et al.,* 2011), but not for adult patients after oral rehabilitation.

Denture fit, as opposed to denture type, might have more impact on diet and nutrition, once well-fitting dentures were associated with higher and more varied nutrient intakes and greater dietary quality in older people (MARSHALL *et al.,* 2002). According to Marshall *et al.* (2002), nutrients mean daily intake did not differ between those with well-fitting dentures (either partial or complete) and those with natural teeth (MARSHALL *et al.,* 2002). Österberg *et al.* (2002) analysed a sample of older adults and found that dental status, bite force and self-assessed masticatory ability had only minor influence on dietary intake. The author's interpretation for the high nutrient intake of this sample was that many subjects with few or no teeth and removable dentures had adapted well to an impaired dentition and small bite force (ÖSTERBERG *et al.*, 2002). A wide range of adaptation to tooth loss could be found among people (ETTINGER, 1998; GOTFREDSEN; WALLS, 2007; NORDENRAM *et al.*, 2013). Interestingly, improvements in masticatory ability with oral rehabilitation, either conventional or implant-supported dentures, brings greater QoL, however few changes in diet pattern have been shown (ALLEN, 2005). To ensure better diets, it is probably necessary to combine the oral treatment with nutrition counselling (SHINKAI *et al.*, 2001; ÖSTERBERG *et al.*, 2002; BRADBURY *et al.*, 2006; MOYNIHAM *et al.,* 2012).

1.5 TEMPOROMANDIBULAR DISORDERS & DEPRESSION

Temporomandibular Disorders (TMD) is a collective term embracing orofacial conditions as pain in the temporomandibular region, painful palpation and tenderness in the masticatory muscles and the temporomandibular joint, joint sounds and limitations or disturbances in mandibular movement (DWORKIN *et al.*, 2002). The most common presenting symptom of TMD is chronic pain which is known to involve psychological, behavioural, and social factors in addition to physical pathology (OHRBACH, 2010). Despite an extensive scientific literature extending over decades, up to now the precise aetiology and mechanism of TMD remain largely unknown. So, TMD diagnosis is made by descriptive methods based on presenting signs and symptoms (DWORKIN *et al.*, 2002).

Since 1992, with the introduction of the Research Diagnosis Criteria for Temporomandibular Disorders (RDC/TMD), researchers are allowed to make reliable diagnoses (DWORKIN; LERESCHE, 1992; DURHAM; WASSELL, 2011). RDC/TMD is an internationally recognized and widely adopted tool for TMD research. Actually, it is a two-axis approach which allows physical diagnosis through Axis I, to be coordinated with assessment of psychological distress and psychosocial dysfunction associated with chronic TMD pain and orofacial disability by Axis II (DWORKIN; LERESCHE, 1992).

The RDC/TMD Axis II is comprised of measures that assess the following depression, non-specific physical symptoms, and graded chronic pain scale (DWORKIN; LERESCHE, 1992; OHRBACH, 2010). This second axis is a history questionnaire which contains more than 20 questions regarding facial pain, pain intensity and impact on daily life, jaw disability, depression and non-specific physical symptoms (DWORKIN; LERESCHE, 1992).

Further, Marcusson *et al.* (2001) reported that TMD was not more common in adults with repaired CLP than in controls. Although the CLP group had a significantly reduced jaw-opening pattern, probably related to the previous surgeries, the overall TMD pain was not more common in this group (MARCUSSON *et al.*, 2001). The prevalence of TMD also has been studied in patients with prostheses. Patients with fixed partial dentures had a significantly higher prevalence of temporomandibular disorders signs than both complete denture wearers and dentate people (AL-OMARI

et al., 2012). On the other hand, findings suggest that both tooth loss and oral birth defects may be related to impairment in psychosocial functioning and concern over facial appearance (RAMSTAD *et al.*, 1995). Additionally, dissatisfaction with facial appearance has been found to be a predictor of depressive symptoms among CLP subjects (MARCUSSON; PAULIN; OSTRUP, 2002; HUNT *et al.*, 2005; FOO *et al.*, 2012).

According to the International Classification of Diseases (ICD), a classification list by the World Health Organization (WHO), the most typical symptoms of depression are: depressed mood, loss of interest and enjoyment, and increased fatigability. Other common symptoms are: reduced concentration and attention; reduced self-confidence; ideas of guilt; disturbed sleep; diminished appetite; ideas of self-harm or suicide. For a definitive diagnosis of depressive episodes, at least two of the typical symptoms, plus at least two of the other symptoms later described, should usually be present for at least two weeks (WORLD HEALTH ORGANIZATION, 2013).

In a sample of 233 adults with repaired CLP, depression was reported to be twice as prevalent in the CLP group as in control (RAMSTAD *et al.*, 1995). Recently, Foo *et al.* (2012), based on a general health-related quality of life called Short Form-36, showed that CLP patients have lower vitality and mental health functions compared with controls without CLP. These findings concur with evidence reviewed by Hunt *et al.* (2005) and Sinko *et al.* (2005), where it was suggested that, besides oral rehabilitation, psychological counselling and support is needed for CLP patients (HUNT *et al.*, 2005; SINKO *et al.*, 2005; FOO *et al.*, 2012).

1.6 OBJECTIVES

The present thesis was designed to present two manuscripts about oral rehabilitation in treated adult subjects who had large loss of oral tissues. The first manuscript comprises of an original research article comparing variables of interest in CLP subjects and maxillary denture wearers. The second manuscript presents a

case report where a prosthetic rehabilitation was performed in one of the CLP subjects from the sample of the research paper in the first manuscript.

4 DISCUSSION

This is a novel study approach about oral rehabilitation in adult subjects with treated CLP and maxillary denture wearers. There is no previous study about masticatory ability in adult CLP subjects and little evidence related to maxillary edentulous subjects. Manuscript One investigated if treated adult subjects with congenital or acquired major loss of oral tissues have different masticatory function abilities and perceptions of their QoL. In contrast, Manuscript Two described a case report about an oral rehabilitation approach that improved masticatory ability in one CLP subject from the previous manuscript.

In Manuscript One, the CLP group contains distinct subgroups of treated adult subjects (i.e., subjects treated with fixed partial dentures (FDP), subjects treated with telescopic crown-retained dentures, subjects treated with clasp-retained metal frame prostheses). Regarding the dental status of the opposite arch, subgroups of maxillary denture wearers also could be found (i.e., subjects partial dentate, subjects treated with clasp-retained metal frame prostheses, subjects treated with implant retained overdenture). Although such heterogeneity of dental status may influence the results, the present sample size was too small to investigate such subgroups. With respect to the type of CLP, the literature has shown that it has little influence on the severity of psychosocial impairment (SINKO *et al.*, 2005; HUNT *et al*., 2005).

As was pointed out in the introduction to this thesis, the most frequent assumption is that children and adults with CLP must experience increased psychosocial problems as result of their condition (RAMSTAD *et al.*, 1995; HUNT *et al*., 2005; FOO *et al.*, 2012). These findings further support the idea of Manuscript One where adults with repaired CLP had worse depression scores and poorer OHRQoL than both denture wearers and healthy subjects. However there is some conflicting evidence in the literature about this area. Despite the high number of research projects in this field, authors still argue about the possibility of suffering some kind of a psychosocial problem as a result of having a CLP. A recent systematic review did point out the large variation in study design along with the methodological weaknesses of research which makes it impossible to draw definitive conclusions (HUNT *et al*., 2005). However, the literature showed total agreement on

the need for a multidisciplinary approach in view of the complexity of CLP treatment (HUNT *et al*., 2005; FOO *et al.*, 2012).

Furthermore, based on Manuscript One, it seems that the CLP group is more unsatisfied with aesthetic and facial appearance than with oral function. OHIP-14 sub-analysis showed higher prevalence of psychological items. In agreement with Ramstad *et al.* (1995), these findings suggest that adults with CLP may be at risk of impaired psychosocial functioning as a result of CLP (RAMSTAD *et al.*, 1995). Further studies also suggest the dissatisfaction with facial appearance and speech, depression and anxiety as common characteristics of CLP subjects (HUNT *et al*., 2005; FOO *et al.*, 2012). Additionally, dissatisfaction with facial appearance has been found to be a predictor of depressive symptoms among CLP subjects (MARCUSSON; PAULIN; OSTRUP, 2002; HUNT *et al*., 2005; FOO *et al.*, 2012). In a cross-sectional study, FOO *et al.* (2012) have described higher OHIP-14 scores among a CLP sample when compared with their general population counterparts (South Australian 2002 state-level norms) (FOO *et al.* 2012). However differences in study protocols make comparison difficult; these results are in line with Manuscript One.

Although the Brazilian government has conducted nationwide epidemiological surveys such as the Oral Health Survey in 1986, 1996, 2003, 2006 and 2010, the prevalence of CLP subjects was never reported. In addition, the oral health impact on Brazilians' QoL was never assessed. Since data for both CLP subjects and maxillary denture wearers has not previously been reported by national surveys in Brazil, there was an absence of OHRQoL level in the general Brazilian population (norms) to use as a control in Manuscript One. Thus, further studies are warranted in order to better describe and also assess QoL in this population are warrant. Future epidemiological surveys should adopt new ways of measuring oral status not only physically, but also in terms of its impact on QoL.

In addition, OHIP is one of the most widely used patient-centred outcome measures and it has been translated and validated in many languages (SLADE, 1997; JONH *et al.*, 2004; LOCKER; ALLEN, 2007; WHITE *et al.*, 2012). OHIP assesses impacts that are related to oral conditions in general, rather than impacts

that may be attributed to specific oral disorders. Furthermore, OHIP is concerned with impairment and also conceptualizes all impacts as adverse outcomes. So, this instrument does not assess any positive aspects of oral health (SLADE, 1997). Tsakos *et al*. (2012) has argued that simple OHIP score analysis is insufficient once a given score can be derived from different sets of responses with different items affected to a varying degree. Hence, according to those authors, providing one "profile" for a specific score is impossible (TSAKOS *et al*., 2012). Regarding this limitation, prevalence scores have been calculated in Manuscript One (MOUFTI *et al*., 2011; TSAKOS *et al*., 2012). OHIP prevalence refers to the proportion of subjects with one or more items experienced "fairly often" or "very often" (FOVO). This scoring format is a more sophisticated approach to provide complementary information about OHRQoL data (SLADE *et al.*, 1998; MOUFTI *et al*., 2011; TSAKOS *et al*., 2012). To the best of the author's knowledge, this was the first study to use this scoring format in Brazil.

As was reported in Manuscript One, the CLP group showed predominance of psychological complaints whereas maxillary denture wearers showed scattered distribution of OHIP items in multiple domains. Although the pattern of OHIP-14 responses was heterogeneous, the median score in the denture wearers group showed good satisfaction and well-being which may be explained by a number of different factors related to OHRQoL. These findings corroborate the ideas of Chen *et al*. (2012), who has suggested that a stable and retentive maxillary denture with adequate articulation produces a favourable impact on the satisfaction and well-being of denture wearers. According to these authors, there is a strong relationship between the essential functional qualities of complete dentures and OHRQoL.

Furthermore, Wennerberg *et al*. (2001) did research focused on the patient's opinion on masticatory and prosthetic function and problems of subjects with mandibular implant-supported fixed prostheses opposing maxillary complete dentures. Their study reported that most part of the 109 patients were very satisfied with their present dental status and masticatory function and only one third of them reported problems with their maxillary denture (WENNERBERG *et al*., 2001).

As pointed out in the introduction to this thesis, although extensive research has been done over the last decades, the TMD's aetiology remains unclear (DWORKIN *et al.,* 2002; DURHAM; WASSELL, 2011). Psychosocial factors, such as stress, anxiety, and depression, may be related to TMD (MARCUSSON *et al.*, 2001; DWORKIN *et al.,* 2002). In addition, common clinical and psychosocial conditions are readily diagnosable using criteria such as RDC/TMD (DURHAM; WASSELL, 2011). In Manuscript One, RDC/TMD Axis II was used to identify symptoms of depression between subjects although the diagnosis of TMD was not an outcome of the study. According to Dworkin *et al.* (2002), Axis II has low TMD-related psychosocial interference without regard to Axis I diagnosis (DWORKIN *et al.,* 2002). Marcusson *et al*. (2001) also have used this instrument to compare CLP and non-CLP subjects. In contrast to the findings of Manuscript One, no significant difference was found between the two groups concerning psychosocial distress.

In the absence of specific validated instruments for CLP subjects, researchers have leaned to use generic questionnaires that assess OHRQoL in the general population. Recently, Eckstein *et al.* (2011) performed a literature review to identify questionnaires validated for CLP. According to those authors, there is a lack of valid and reliable instruments created specifically for CLP, resulting in the use of generic instruments such as OHIP (ECKSTEIN *et al.,* 2011). Although OHIP has been recommended for assessing the impact of oral health on masticatory ability and psychosocial function, a systematic literature review did point out the specific characteristics of the CLP group (HUNT *et al*., 2005). Additionally, it was questioned if a generic instrument could disguise the specific problems that this particular group has in relation to adjustment, self-esteem, facial appearance, depression, and speech (HUNT *et al*., 2005). In agreement with those authors, Manuscript One suggested that for thorough assessment of QoL in the CLP population, further research is needed in order to develop and validate specific instruments. Furthermore, qualitative studies are encouraged to achieve a deeper understanding of CLP subject's perception of QoL and masticatory ability with a view to complete quantitative studies such as Manuscript One.

As far as masticatory ability is concerned, both physiological and contextual factors are related to this complex outcome (HATCH *et al.*, 2001). While the capacity to exert sufficient bite force is an indicator of normal masticatory ability (HATCH *et al.*, 2001), it is also possible to assume that not only the occlusal status might influence masticatory performance and diet (WALLS *et al.*, 2000; WALLS; STEELE, 2004). Manuscript One has shown significant differences in MBF between test groups and control. A possible explanation for this might be that MBF represents the effort exerted between the maxillary and mandibular teeth, whereas both test groups were affected in the maxilla (SHINKAI *et al.*, 2007). Beyond that and according to previous studies the interaction of factors such as age, gender, body mass index, dental occlusal status, temporomandibular disorders, size and direction of muscles, periodontal sensitivity and psychological factors, could explain the large variability of MBF results (HATCH *et al.*, 2001; SHINKAI *et al.*, 2007).

There is little information on masticatory function of adults with treated CLP, although it is recognized that such information is essential for evaluating the outcome of oral rehabilitation in this specific group of subjects. Furthermore, perceived masticatory ability is closely related to comfort when patients chew certain foods, which may affect food selection patterns (OBREZ; GRUSSING, 1999; SHEIHAM *et al.*, 1999; SHINKAI *et al.*, 2001) or lead to coping strategies for chewing (ETTINGER, 1998). According to Manuscript One, self-perceived masticatory ability might be a significant factor in food selection in CLP subjects and also in maxillary denture wearers due to their major tissue loss involving the maxillary bone. Obrez and Grussing (1999) have described that both perceived masticatory ability and food texture influence the choice of food. Thus the decreased masticatory ability could have limited the selection of foods that are difficult to chew in the CLP group. As previously reported in denture wearer subjects (TOSELLO *et al.*, 2001), maybe the poor masticatory ability in CLP subjects could be in the future associated with health problems as gastrointestinal disorders and lower nutritional intake. So further investigation to assess perceived masticatory ability and diet pattern especially in adults with repaired CLP is required.

Concerning the long-standing assumption that healthy dentate subjects eat faster, no difference between mean meal duration was observed in the Manuscript One sample. It seems that tested groups, CLP and denture wearers, have adaptive strategies for chewing. Future studies to investigate those strategies are warranted.

Although the three groups in Manuscript One were matched for gender, other confounders, such as age and socioeconomic status could have influenced results. Hatch *et al.* (2001), through a theoretical multivariate model of masticatory performance, had shown a slight direct effect of age on masticatory performance. The direct effects of age on functional units and bite force also were relatively small. However, the effects of posterior functional tooth and bite force on masticatory performance were much larger (HATCH *et al.*, 2001; UENO *et al.*, 2010). Additionally, regarding the difference of age between individuals with CLP, a recent literature review reported that the age does not influence psychosocial problems (HUNT *et al.*, 2005). Despite differences relating to age and socioeconomic status, the reported experiences of congenital oral defects have some common characteristics that can be broadly interpreted as loss of QoL. Indeed, those experiences seem to have effects on both self-esteem and social life.

As explained earlier, there are many treatment options for CLP adult patients. Manuscript Two described one of the alternatives to rehabilitate CLP patients who present with extensive loss of tooth, bone and lip support (MAÑES FERRER *et al.*, 2006). Despite the advances in restorative dentistry, telescopic crowns continue to be a good treatment option which allows better transmission of masticatory forces, cleaning by the patient, retaining teeth longer as well as cosmetic improvements (BAYER *et al.*, 2012; BREITMANN *et al.*, 2012). Regarding CLP patients, RPD attached to telescopic crowns decreases the mobility during chewing due to stabilization of the maxillary segments and remaining teeth (REISBERG *et al.*, 2000; MAÑES FERRER *et al.*, 2006).

From Manuscript Two, it might be concluded that in this particular case the use of an RPD connected to telescopic crowns has restored oral function and patient's overall satisfaction. However the outcomes of this successful approach are in contrast with the majority of CLP subjects assessed in Manuscript One. Although

all subjects have had oral rehabilitation, disappointingly few improvements in masticatory ability were noted in the CLP group. In order to enhance the ability to eat more healthily, it could be suggested that there is a need for dietary intervention in CLP group. It is possible that dietary counselling could be effective in CLP patients, as has been demonstrated in previous studies with denture wearers (MOYNIHAM *et al.*, 2012). According to Moyniham *et al.* (2012), positive dietary effects should be perceived as an important health benefit of the combination of treatments such as prosthetic rehabilitation and diet intervention. Moreover, Shinkai *et al.* (2001) stressed that oral rehabilitation without nutrition counselling is not sufficient to ensure better diets (SHINKAI *et al*., 2001). Since eating problems are an essential reason for seeking oral rehabilitation, the dental treatment provides a strategic moment for the recommendation of dietary counselling (BRADBURY *et al.*, 2006).

In Brazil, as in other countries where the public health service cannot afford comprehensive treatment for complex cases of CLP subjects, local hospitals and universities should incorporate and adopt the most appropriate forms of aid for these circumstances. Since 1987, CERLAP at PUCRS has been a valuable reference service in the south of Brazil. To meet the demands of this population following the assistance examples from developed countries, CERLAP should incorporate an updated treatment protocol for management of CLP subjects considering patient-centred outcomes research. Further investigation on psychological, QoL as well as economic status are still needed in this population.

Finally, another urgent issue is the need to create a collaborative multidisciplinary group, including a nutritionist which is not present yet, to develop this new protocol. If more progress could be made in the surgical approach, particularly respecting optimal timing for grafts interventions, better results in greater arch stability and occlusion could be achieved. Consequently, prosthetic procedures could be reduced while QoL and masticatory ability outcomes might increase.

5 FINAL CONSIDERATIONS

Considering the limitations of the present study, it may be concluded that adults with treated CLP and maxillary denture wearers still have both impaired masticatory ability and poorer OHRQoL in comparison with healthy dentate subjects, however with different psychological and functional impacts for each group. With few exceptions, oral rehabilitation performed in CLP subjects was not sufficient to improve patient-centred outcomes to optimal levels. Maxillary denture wearers also have significant self-perceived chewing problems after technically successful oral rehabilitation. Furthermore, maxillary denture wearers represent a subgroup of the adult population that has not been investigated in depth in comparison with completely edentate subjects.

Further studies with specific quantitative and qualitative approaches are needed to better understand the main factors that influence CLP and maxillary denture patients's QoL. The right answers to the right questions may lead us to achieve real cost-effectiveness of the oral treatment for these patients that require more complex oral healthcare.

REFERENCES

Allen F. Management of the flabby ridge in complete denture construction. Dent Update. 2005 Nov;32(9):524-6, 528.

Al-Omari WM, Al-Hashedi AA, Marashdeh M, Al-Hrazi GA. Prevalence of temporomandibular disorders' signs and symptoms and chewing ability in patients with prosthodontic prostheses. Eur J Prosthodont Restor Dent. 2012 Sep;20(3):111-20.

Aramany MA. A history of prosthetic management of cleft palate: Paré to Suersen. Cleft Palate J. 1971 Oct;8:415-30.

Bayer S, Stark H, Gölz L, Keilig L, Kraus D, Hansen A, Enkling N. Telescopic crowns:extra-oral and intra-oral retention force measurement in vitro/in vivo correlation. Gerodontology. 2012 Jun;29(2):e340-7.

Bianco VC, Lopes ES, Borgato MH, Moura e Silva P, Marta SN. The impact on life quality due to oral conditions. Cien Saude Colet. 2010 Jul;15(4):2165-72.

Bradbury J, Thomason JM, Jepson NJ, Walls AW, Allen PF, Moynihan PJ. Nutrition cousenling increases fruit and vegetable intake in the edentulous. J Dent Res. 2006 May;85(5):463-8.

Breitman JB, Nakamura S, Freedman AL, Yalisove IL. Telescopic retainers: an old or new solution? A second chance to have normal dental function. J Prosthodont. 2012 Jan;21(1):79-83.

Chen YF, Yang YH, Chen JH, Lee HE, Lin YC, Edinger J, et al. The impact of complete dentures on the oral helath-related quality of life among elderly. Journal of Dental Sciences. 2012;7:289-95.

Collares MVM, Westephalen ACA, Costa TCD, Goldim JR. Fissuras lábio-palatinas: incidência e prevalência da patologia no Hospital de Clínicas de Porto Alegre.Um estudo de 10 anos. Revista AMRIGS. 1995;39(3):183-8.

Critchlow SB, Ellis JS, Field JC. Reducing the risk of failure in complete denture patients. Dent Update. 2012 Jul-Aug;39(6):427-30, 433-4, 436.

Cune MS, Meijer GJ, Koole R. Anterior tooth replacement with implants in grafted alveolar cleft sites: a case series. Clin Oral Implants Res. 2004 Oct;15(5):616-24.

Dixon MJ, Marazita ML, Beaty TH, Murray JC. Cleft lip and palate: understanding genetic and environmental influences. Nat Rev Genet. 2011 Mar;12(3):167-78.

Durham J, Wassell RW. Recent advancements in Temporomandibular Disorders (TMDs). Rev Pain. 2011;5:18-23.

Dworkin SF, Huggins KH, Wilson L, Mancl L, Turner J, Massoth D, et al. A randomized clinical trial using research diagnostic criteria for temporomandibular disorders-Axis II to target clinic cases for tailored self-care tmd treatment program. J Orofac Pain. 2002 Winter;16(1):48-63.

Dworkin SF, LeResche L. Research diagnostic criteria for temporomandibular disorders: review, criteria, examinations and specifications, critique. J Craniomandib Disord. 1992 Fall;6(4):301-55.

Eckstein DA, Wu RL, Akinbiyi T, Silver L, Taub PJ. Measuring quality of life in cleft lip and palate patients: currently avaiable patient-reported outcomes measures. Plast Reconstr Surg. 2011 Nov;128(5):e518-526.

Ettinger RL. Changing dietary patterns with changing dentition: how do people cope? Spec Care Dentist. 1998 Jan-Feb;18(1):33-9.

Fenlon MR, Sherriff M. An investigation of factors influencing patients' satisfaction with new complete dentures using structural equation modelling. J Dent. 2008 Jun;36(6):427-34.

Foo P, Sampson W, Roberts R, Jamieson L, David D. General health-related quality of life and oral health impact among australians with cleft compared with population norms; age and gender differences. Cleft Palate Craniofac J. 2012 Jul;49(4):406-13.

Glenny AM, Hooper L, Shaw WC, Reilly S, Kasem S, Reid J. Feeding interventions for growth and development in infants with cleft lip, cleft palate or cleft lip and palate. Cochrane Database Syst Rev. 2011;(2):CD003315.

Gotfredsen K, Walls AW. What dentition assures oral function? Clin Oral Implants Res. 2007 Jun;18 Suppl 3:34-45.

Hatch JP, Shinkai RS, Sakai S, Rugh JD, Paunovich ED. Determinants of masticatory performance in dentate adults. Arch Oral Biol. 2001 Jul;46(7):641-8.

Hultin M, Davidson T, Gynther G, Helgesson G, Jemt T, Lekholm U, et al. Oral rehabilitation of tooth loss: a systematic review of quantitative studies of OHRQoL. Int J Prosthodont. 2012 Nov-Dec;25(6):543-52.

Hunt O, Burden D, Hepper P, Johnston C. The psychosocial effects of cleft lip and palate: a systematic review. Eur J Orthod. 2005 Jun;27(3):274-85.

John MT, Slade GD, Szentpétery A, Setz JM. Oral health-related quality of life in patients treated with fixed, removable, and complete dentures 1 month and 6 to 12 months after treatment. Int J Prosthodont. 2004 Sep-Oct;17(5):503-11.

Kramer FJ, Baethge C, Swennen G, Bremer B, Schwestka-Polly R, Dempf R. Dental implants in patients with orofacial clefts: a long-term follow-up study. Int J Oral Maxillofac Surg. 2005 Oct;34(7):715-21.

Krieger O, Matuliene G, Hüsler J, Salvi GE, Pjetursson B, Brägger U. Failures and complications in patients with birth defects restored with fixed dental prostheses and single crowns on teeth and/or implants. Clin Oral Implants Res. 2009 Aug;20(8):809-16.

Locker D, Allen F. What do measures of 'oral health-related quality of life' measure? Community Dent Oral Epidemiol. 2007 Dec;35(6):401-11.

Lynch CD, Allen PF. Case report: management of the flabby ridge: re-visiting the principles of complete denture construction. Eur J Prosthodont Restor Dent. 2003 Dec;11(4):145-8.

Mañes Ferrer JF, Martínez González A, Oteiza Galdón B, Bouazza Juanes K, Benet Iranzo F, Candel Tomás A. Telescopic crowns in adult case with lip and palate cleft. Update on etiology and management. Med Oral Patol Oral Cir Bucal. 2006 Jul 1;11(4):e358-62.

Marcusson A, List T, Paulin G, Dworkin S. Temporomandibular disorders in adults with repaired clef lip and palate: a comparison with controls. Eur J Orthod. 2001 Apr;23(2):193-204.

Marcusson A, Paulin G, Ostrup L. Facial appearance in adults who had cleft lip and palate treated in childhood. Scand J Plast Reconstr Surg Hand Surg. 2002;36(1):16-23.

Marshall TA, Warren JJ, Hand JS, Xie XJ, Stumbo PJ. Oral health, nutrient intake and dietary quality in the very old. J Am Dent Assoc. 2002 Oct;133(10):1369-79.

Matsuyama M, Tsukiyama Y, Tomioka M, Koyano K. Subjective assessment of chewing function of obturador prosthesis wearers. Int J Prosthodont. 2007 Jan-Feb;20(1):46-50.

Menezes LM, Rizzatto SMD, Azeredo F, Vargas DA. Characteristics and distribution of dental anomalies in a Brazilian cleft population. Rev Odonto Ciênc. 2010;25: 137-41.

Ministério da Saúde (BR). Secretaria de Atenção à Saúde. Coordenação Nacional de Saúde Bucal. Projeto SB Brasil 2010: resultados principais. Brasília: Ministério da Saúde; 2011.

Montero J, Castillo-Oyagüe R, Lynch CD, Albaladejo A, Castaño A. Self-perceived changes in oral health-related quality of life after receiving different types of conventional prosthetic treatments: a cohort follow-up study. J Dent. 2013 Jun;41(6):493-503.

Moore D, McCord JF. Prosthetic dentistry and the unilateral cleft lip and palate patient. The last 30 years. A review of the prostodontic literature in respect of treatment options. Eur J Prosthodont Restor Dent. 2004 Jun;12(2):70-4.

Mossey PA, Little J, Munger RG, Dixon MJ, Shaw WC. Cleft lip and palate. Lancet. 2009 Nov 21;374(9703):1773-85.

Moufti MA, Wassell RW, Meechan JG, Allen PF, John MT, Steele JG. The oral health impact profile: ranking of itens for temporomandibular disorders. Eur J Oral Sci. 2011 Apr;119(2):169-74.

Moynihan PJ, Butler TJ, Thomason JM, Jepson NJ. Nutrient intake in partially dentate patients: the effect of prosthetic rehabilitation. J Dent. 2000 Nov;28(8):557-63.

Moynihan PJ, Elfeky A, Ellis JS, Seal CJ, Hyland RM, Thomason JM. Do implant-supported dentures facilitate efficacy of eating more healthily? J Dent. 2012 Oct;40(10):843-50.

Murray J, Great Britain. Clinical Standards Advisory Group. Cleft lip and/or palate. London: Stationery Office; 1998.

Nordenram G, Davidson T, Gynther G, Helgesson G, Hultin M, Jemt T, et al. Qualitative studies of patients' perceptions of loss of teeth, the edentulous state and prosthetic rehabilitation: A systematic review with meta-synthesis. Acta Odontol Scand. 2013 May-Jul;71(3-4):937-51.

Nuttall N, Tsakos G, Lader D, Hill K, O' Sullivan I. The Health and Social Care Information Centre. 7: Outcome and impact – a report from the Adult Dental Health Survey 2009. Leeds, UK: NHS; 2011.

Obrez A, Grussing PG. Opinions and feelings on eating with complete dentures: a qualitative inquiry. Spec Care Dentist. 1999 Sep-Oct;19(5):225-9.

Ohrbach R. Assessment and further development of RDC/TMD Axis II biobehavioural instruments: a research programme progress report. J Oral Rehabil. 2010 Oct;37(10):784-98.

Oliveira BH, Nadanovsky P. Psychometric properties of the Brazilian version of the Oral Health Impact Profile –short form. Community Dent Oral Epidemiol. 2005 Aug;33(4):307-14.

Oosterkamp BC, Dijkstra PU, Remmelink HJ, van Oort RP, Goorhuis-Brouwer SM, Sandham A, et al. Satisfaction with treatment outcome in bilateral cleft lip and palate patients. Int J Oral Maxillofac Surg. 2007 Oct;36(10):890-5.

Osterberg T, Tsuga K, Rothenberg E, Carlsson GE, Steen B. Masticatory ability in 80-year-old subjects and its relation to intake of energy, nutrients and food items. Gerodontology. 2002 Dec;19(2):95-101.

Pjetursson BE, Tan K, Lang NP, Brägger U, Egger M, Zwahlen M. A systematic review of the survival and complication rates of fixed partial dentures (FPDs) after an observation period of a least 5 years. Clin Oral Implants Res. 2004 Dec;15(6):625-42.

Preshaw PM, Walls AW, Jakubovics NS, Moynihan PJ, Jepson NJ, Loewy Z. Association of removable partial denture use with oral and systemic health. J Dent. 2011 Nov;39(11):711-9.

Ramstad T, Ottem E, Shaw WC. Psychosocial adjustment in Norwegian adults who had undergone standardized treatment of complete cleft lip and palate.II. Self-reported problems and concerns with appearance. Scand J Plast Reconstr Surg Hand Surg. 1995 Dec;29(4):329-36.

Reisberg DJ. Dental and prosthodontic care for patients with cleft or craniofacial conditions. Cleft Palate Craniofac J. 2000 Nov;37(6):534-7.

Ribeiro MT, Rosa MA, Lima RM, Vargas AM, Haddad JP, Ferreira E Ferreira E. Edentulism and shortened dental arch in Brazilian elderly from the National Survey of Oral Health 2003. Rev Saude Publica. 2011 Oct;45(5):817-23.

Sheiham A, Steele JG, Marcenes W, Finch S, Walls AW. The impact of oral health on stated ability to eat certain foods; findings from the National Diet and Nutrition Survey of Older People in Great Britain. Gerodontology. 1999 Jul;16(1):11-20.

Shinkai RS, Hatch JP, Rugh JD, Sakai S, Mobley CC, Saunders MJ. Dietary intake in edentulous subjects with good and poor quality complete dentures. J Prosthet Dent. 2002 May;87(5):490-8.

Shinkai RS, Hatch JP, Sakai S, Mobley CC, Saunders MJ, Rugh JD. Oral function and diet quality in a community-based sample. J Dent Res. 2001 Jul;80(7):1625-30.

Shinkai RS, Lazzari FL, Canabarro SA, Gomes M, Grossi ML, Hirakata LM, et al. Maximum occlusal force and medial mandibular flexure in relation to vertical facial pattern: a cross-sectional study. Head Face Med. 2007;2:3-18.

Sinko K, Jagsch R, Prechtl V, Watzinger F, Hollmann K, Baumann. A Evaluation of esthetic, functional, and quality-of-life outcome in adult cleft lip and palate patients. Cleft Palate Craniofac J. 2005 Jul;42(4):355-61.

Sipert CR, Sampaio AC, Trindade IE, Trindade AS Jr. Bite force evaluation in subjects with cleft lip and palate. J Appl Oral Sci. 2009 Mar-Apr;17(2):136-9.

Slade GD. Derivation and validation of a short-form oral health impact profile. Community Dent Oral Epidemiol. 1997 Aug;25(4):284-90.

Slade GD, Spencer AJ. Development and evaluation of the Oral Health Impact Profile. Community Dent Health. 1994 Mar;11(1):3-11.

Slade GD, Strauss RP, Atchison KA, Kressin NR, Locker D, Reisine ST. Conference summary: assessing oral health outcomes – measuring health status and quality of life. Community Dent Health. 1998 Mar;15(1):3-7.

Steele J, O' Sullivan I. The Health and Social Care Information Centre. Executive summary: adult dental health survey 2009. Leeds, UK: NHS; 2011.

Suzuki R, Taniguchi H, Ohyama T. Prosthodontic abutment in four patients with unilateral cleft lip and palate. Cleft Palate Craniofac J. 1995 Sep;32(5):442-7.

Tosello A, Foti B, Sédarat C, Brodeur JM, Ferrigno JM, Tavitian P, et al. Oral Functional characteristics and gastrointestinal pathology: an epidemiological approach. J Oral Rehabil. 2001 Jul;28(7):668-72.

Tsakos G, Allen PF, Steele JG, Locker D. Interpreting oral health-related quality of life data. Community Dent Oral Epidemiol. 2012 Jun;40(3):193-200.

Ueno M, Yanagisawa T, Shinada K, Ohara S, Kawaguchi Y. Category of functional tooth units in relation to the number of teeth and masticatory ability in Japanese adults. Clin Oral Investig. 2010 Feb;14(1):113-9.

Vargervik K, Oberoi S, Hoffman WY. Team care for the patient with cleft: UCSF protocols and outcomes. J Craniofac Surg. 2009 Sep;20 Suppl 2:1668-71.

Walls AW, Steele JG. The relationship between oral health and nutrition in older people. Mech Ageing Dev. 2004 Dec;125(12):853-7.

Walls AW, Steele JG, Sheiham A, Marcenes W, Moynihan PJ. Oral health and nutrition in older people. J Public Health Dent. 2000 Fall;60(4):304-7.

Wennerberg A, Carlsson GE, Jemt T. Influence of occlusal factors on treatment outcome: a study of 109 consecutive patients with mandibular implant- supported fixed prostheses opposing maxillary complete dentures. Int J Prosthodont. 2001 Nov-Dec;14(6):550-5.

White DA, Tsakos G, Pitts NB, Fuller E, Douglas GV, Murray JJ, et al. Adult Dental Health Survey 2009: common oral health conditions and their impact on the population. Br Dent J. 2012 Dec;213(11):567-72.

World Health Organization. International classification of impairments, disabilities and handicaps: a manual of classification. Geneva: WHO; 1980.

World Health Organization. The ICD-10 classification of mental and behavioural disorders [Internet]. Genebra: WHO; 2013. [cited 2013 Jul 26]; Available from: http://www.who.int/classifications/icd/en/bluebook.pdf.

ANNEX B - School of Dentistry Ethics Committee Approval

Comissão Científica e de Ética
Faculdade da Odontologia da PUCRS

Porto Alegre 16 de Março de 2011

O Projeto de: Tese

Protocolado sob nº:	0013/11
Intitulado:	Avaliação mastigatória e da qualidade de vida de sujeitos com fissuras labiopalatinas reabilitados com próteses dentárias
Pesquisador Responsável:	Profa. Dra. Rosemary Sadami Arai Shinkai
Pesquisadores Associados	Marina Rechden Lobato
Nível:	Tese / Doutorado

Foi ***aprovado*** pela Comissão Científica e de Ética da Faculdade de Odontologia da PUCRS em *16 de Março de 2011.*

Este projeto deverá ser imediatamente encaminhado ao CEP/PUCRS

Profa. Dra. Ana Maria Spohr
Presidente da Comissão Científica e de Ética da
Faculdade de Odontologia da PUCRS

Pós-Graduação em Odontologia - PUCRS PROTOCOLO Recebido em 16 / 03 / 2011

Av. Ipiranga, 6681, Prédio 06 sala 210
Porto Alegre /RS – Brasil – Cx. Postal:1429
90619-900
Fone/Fax: (51) 3320-3538
e-mail: odontologia-pg@pucrs.br

ANNEX C – PUCRS Institutional Review Board Approval

Pontifícia Universidade Católica do Rio Grande do Sul
PRÓ-REITORIA DE PESQUISA E PÓS-GRADUAÇÃO
COMITÊ DE ÉTICA EM PESQUISA

OF. CEP-840/11

Porto Alegre, 16 de maio de 2011.

Senhora Pesquisadora,

O Comitê de Ética em Pesquisa da PUCRS apreciou e aprovou seu protocolo de pesquisa registro CEP 11/05413 intitulado **"Avaliação da função mastigatória e da qualidade de vida de sujeitos com fissuras labiopalatinas e usuários de prótese total superior"**.

Salientamos que seu estudo pode ser iniciado a partir desta data.

Os relatórios parciais e final deverão ser encaminhados a este CEP.

Atenciosamente,

Prof. Dr. Rodolfo Herberto Schneider
Coordenador do CEP-PUCRS

Ilma. Sra.
Profa. Dra. Rosemary Sadami Arai Shinkai
Faculdade de Odontologia
Nesta Universidade