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Retrospective study on the clinical performance of distal extension removable partial dentures

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ABSTRACT

Background: The support and stability of distal extension removable partial dentures are dependent on both teeth, underlying tissues and prosthetic design. Rotational movements of the prosthesis in different axes are unavoidable and contribute to changes on abutment teeth and residual ridge resorption. The aim of our study was both to assess the clinical performance of Kennedy class I removable partial dentures (RPD), and to establish a predictive model of bone loss in the areas under the saddle.

Keywords:

Distal extension Removable Partial Denture;

Residual ridge resorption;

Abutment teeth;

Oral health-related quality of life;

Material and Methods: Patients rehabilitated at the Area of Dentistry of the Faculty of Medicine of the University of Coimbra between 2006 and 2013 with bilateral distal extension removable partial dentures were called to a follow-up appointment. These patients underwent intraoral and prosthetic evaluation. Vertical measurements of the residual ridge were performed in panoramic radiographs. Patients responded to a satisfaction questionnaire for RPD wearers.

Results: Sixty patients fulfilled all inclusion criteria. Abutment tooth failure was detected in 27.5% of the cases. Regarding the RPD, loss of retention of the direct retainers was identified as the most prevalent failure (50.8%). Inconsequential deformations of the major connector were found in 23.3% cases and statistically associated to the lingual bar connector ($p=0.046$). Statistically significant decreases in residual ridge vertical heights were verified for the abutment tooth (0.55 ± 2.06, $p=0.02$) and for the molar region (0.42 ± 0.86 mm, $p<0.001$). The following predictive bone loss model was established: -1.014 + 0.498*(buccal shelves extension) + 0.493*(retromolar pad tissue) – 0.424*(quality of residual ridge). A mean score of 1.97± 0.72 was obtained in the prosthetic quality of life questionnaire.

Conclusion: Primary stress-bearing area anatomy and prosthetic design have an important role in residual ridge resorption prediction in removable partial denture wearers.

RESUMO

Introdução: O suporte e estabilidade de próteses parciais removíveis de extremo livre estão dependentes de peças dentárias, tecidos subjacentes e do próprio desenho protético. São inevitáveis os movimentos de rotação do dispositivo protético em diferentes eixos, contribuindo para alterações ao nível dos dentes pilares e reabsorção do rebordo residual. O objetivo do nosso estudo foi avaliar o desempenho clínico de próteses parciais removíveis (PPR) Classe I de Kennedy, bem como estabelecer um modelo preditivo da perda óssea nas áreas sob a sela.

Palavras-Chave:

Prótese parcial removível de extremo livre

Reabsorção do rebordo residual

Dente pilar

Qualidade de vida associada a saúde oral

Material e Métodos: Para o estudo foram incluídos doentes reabilitados com próteses parciais removíveis de extremo livre bilateral na Área de Medicina Dentária da Faculdade de Medicina da Universidade de Coimbra entre os anos de 2006 e 2013. Os pacientes foram submetidos a avaliação intraoral e protética. Em ortopantomografias foram feitas medições verticais do rebordo residual. Foi ainda preenchido um inquérito de satisfação para portadores de prótese parcial removível.

Resultados: Sessenta pacientes foram incluídos no estudo. Fracassos ao nível do dente pilar foram detetados em 27.5% dos casos. A nível protético, perda de retenção foi identificada como o fracasso mais prevalente (50,8%). Foi encontrada deformação do conetor maior em 23.3% dos casos, contudo não inviabilizando o uso da prótese. Tal deformação associou-se estatisticamente ao conector barra lingual ($p = 0,046$). Foram verificadas reduções significativas das alturas verticais rebordo residual para o dente pilar ($0,55 \pm 2,06$, $p=0.02$) e para a região molar ($0,42 \pm 0,86$ mm, $p<0.001$). O seguinte modelo de previsão de perda óssea foi estabelecido: -1,014 + 0,498*(extensão área de Fish) + 0,493*(tecido do corpo periforme) - 0.424*(qualidade do rebordo residual). No questionário de satisfação para portadores de prótese removível foi obtida uma pontuação média de $1,97 \pm 0,72$.

Conclusão: A anatomia das áreas de suporte primário e o desenho protético são fatores a ter em conta na previsão da reabsorção do rebordo residual em portadores de prótese parcial removível de extremo livre.

INTRODUCTION

Evidence from various national dental health surveys indicates that the proportion of totally edentulous people is declining over time and that more people retain teeth into elder ages [1, 2]. Oral rehabilitation is mandatory to correct the problems that arise from lost teeth, such as impaired function or esthetics, and is of major importance for the improvement of self-perceived oral health-related quality of life [3]. Treatment modalities for partial edentulism include multiple options using either tooth- or implant-supported fixed crowns and prostheses or tooth-supported removable prostheses [3]. The age-related increased tooth retention suggests that partially edentulous cohorts will be older than before and probably less disposed to extensive treatments with tooth- or implant-supported fixed partial dentures. Consequently, socioeconomic factors and population trends suggest increased future treatment needs with different partial prostheses, namely with removable partial dentures which have been considered a good non-invasive and low-cost solution to restore oral function and to preserve the remaining oral structures to the greatest extent possible [4-6].

Posterior edentulism may result in loss of neuromuscular stability of the jaw, reduction of masticatory efficiency, loss of vertical dimension of occlusion and attrition of the anterior teeth, and should be rehabilitated with elements that ensure stability[7]. Because Class I removable partial dentures exhibit bilateral extension bases, they must derive support from the remaining teeth and residual ridges [8]. The greatest movement possible is found because of the reliance on the distal extension supporting tissue to share the functional loads with the teeth. There are three possible movements of distal extension partial dentures. A typical movement found is rotation around an axis passing through the most posterior abutments, named fulcrum line. A second movement is rotation around a longitudinal axis formed by the crest of the residual ridge. A third movement is the rotation about an imaginary vertical axis located near the center of the dental arch. The consequence of prosthesis movement under load is an application of stress to the teeth and tissue that are contacting the prosthesis [7]. Consequently, practitioners must carefully consider the effects of removable partial denture design upon the remaining oral structures [9, 10].

A proper load distribution and correct application of the forces has a direct impact on the success and longevity of the prosthetic device. These forces should be reported according to the long axis of the abutment tooth, through the occlusal support [8]. Conversely, it is assumed that horizontal and lateral stress on abutment teeth may

cause or favor the breakdown of periodontal structures and increase in tooth mobility [10]. The loading and movement of abutment teeth are strongly influenced by such factors as the number and location of rests, type and rigidity of connectors and extension of the denture bases [11, 12]. Furthermore denture design, denture base adaptation and residual ridge inclination are factors that affect force distribution from the removable partial dentures to the abutment teeth and edentulous ridge [13]. Additionally, removable partial denture wearing leads to changes in the quality and quantity of plaque and the periodontal condition of the remaining teeth may be compromised. Then, properly designed and maintained dentures can provide long-term clinical service without any detrimental effects on pre-prosthetic periodontal health, maintained with meticulous oral hygiene [13]. Long term studies of clinical performance of distal extension removable partial dentures are sparse in the literature, however there are some publications assessing treatment outcomes with removable partial dentures (**Table I**).

Residual alveolar ridge has an important role on stabilization and support of removable dentures, but bone resorption in edentulous alveolar processes is a chronic, progressive and irreversible process in all patients [14, 15]. Gender, genetics, systemic conditions, tooth loss sequence, duration of edentulism, and other unknown factors influence the remodeling/ resorption process of edentulous jaw [16]. In distal extension removable partial dentures, there are inadequate stresses around abutment teeth, increasing the possibility of unequal bone resorption. This phenomenon usually starts at the saddle and can progress to the abutment teeth, resulting in periodontal involvement [11]. The lack of mechanical stress, absence or presence of dentures, number of years of denture use, number of sets of dentures and muscle tone are known functional factors [14]. Moderate intermittent forces exerted on the bony ridge by a prosthesis may be stimulating and help preserve, rather than destroy. On the other hand, an excessive force can cause accelerated resorption of the residual ridge (Kelly 2003 cit in [17]). Ozan *et al.* concluded that vertical and horizontal alveolar bone resorption was found to be higher in the RPD-wearing patients when comparing the dentate and edentulous sites [18]. A model of bone loss establishment is important to understand the process of residual ridge resorption.

Because of the potential impact of an unsuccessful removable partial denture on both patient and provider, it may be useful to know the level of satisfaction of patients using this type of prostheses, to determine the factors associated with

dissatisfaction [19]. Satisfaction with removable partial denture seems to have a multidimensional character. In addition to the patient's satisfaction, the patient's attitude towards a removable partial denture prior to receiving one appears to play an important role [20]. Besides the clinician's skill and the quality of dentures, the following factors related to the patient are very important on the final satisfaction with removable partial dentures: personality, attitude toward the dentures, prior RPD experience and motivation for wearing dentures [19, 21]. According to the results of recent studies, the most frequent areas of dissatisfaction are fit (34%), eating-chewing (30%), natural tooth problems (26%), mouth cleanliness (20%), speech (18%), appearance (18%), denture cleanliness (15%), and odor (13%) [19, 21]. The success of removable partial denture treatment, however, is often judged differently by clinicians and patients. Prosthodontists consider their dentures to be successful if they meet certain technical standards, whereas patients evaluate them from the viewpoint of their personal satisfaction [22]. Knowledge about patient satisfaction with the treatment outcomes of their removable partial dentures would be helpful to both clinicians and patients as they decide on prosthodontic treatment [20].

The aim of our study was to assess the clinical performance of Kennedy class I removable partial dentures (RPD), and to establish a model to predict bone loss in the areas under the saddle.

Table I: Summary of the studies evaluating the clinical performance of distal extension removable partial dentures. Data on number of patients/prosthesis, mean age, follow-up time, intervention, retention, failure rate, abutment teeth loss and prosthetic failure

Author	Kapur *et al.* [23]	Bergman *et al.* [24]	Wagner *et al.* [25]	Saito *et al.* [26]	Vanzeveren *et al.* [27]	Piwowarczyk *et al.* [28]	Schmitt *et al.* [29]	Jorge *et al.* [17]	Rehmann *et al.* [30]
Year	**1994**	**1995**	**2000**	**2002**	**2003**	**2007**	**2011**	**2012**	**2013**
Type of study	RCT	Prospective	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective	Coorte prospective	Retrospective
Patients/ Prosthesis	59 RPDs 59 patients	18 patients 20 prosthesis	74 patients 101 prosthesis	65 patients 91 prosthesis	254 patients 292 prosthesis	97 patients 97 dentures	23 patients 28 prosthesis	53 patients 53 prosthesis	52 patients 65 prosthesis
Mean age		70.8 years	64.6±12.6 years	54.8 years	55.8±13 years	59.8 ± 8.4		68.6 years	59 years
Follow-up time	5 years	25 years	10 years	2-10 years	4-17 years	4.9±2.8 years	5 years	5 years	Mean: 3.11 ± 0.29 (Max: 10 years)
Intervention	Conventional RPD	Cobalt-chromium RPD: 17 mandibular; 3 maxillary	Conical crown-retained dentures (59.4%) Clasp-retained RPD (7.9%) Combination of both (32.7%)	Telescopic dentures: n=27 Ordinary Clasp dentures: n=16 Modified clasp dentures: n=37 Combination dentures: n=11	Conventional RPD (47%Mandibular Class I Kennedy)	Conical crown-retained removable dentures.	Class I: Bilaterally retained (BR) RPD: n=20 (71%) Class II: Unilaterally retained (UR) RPD: n=8 (29%)	RPD Group 1: Kennedy Class III Group 2: Kennedy Class I	Maxillary and mandibular conventional RPD
Retention	Circunferential Retentive Clasp	Retentive clasp	Conical crowns; Retentive clasps	Telescopic crown Retentive clasp	Retentive clasp	Conical crowns	Precision attachement	Retentive clasp Class III: Circunferential clasp Class I: T-clasp	Retentive clasp
Failure Rate	27%	35%	n=40 (39.6%)		Lower Jaw: 33% 83% (Kennedy Class I) Upper Jaw: 12.7%		Bilaterally retained BR RPD: 30% Unilaterally retained UR RPD: 75%		9,2% (more survival in mandibular RPD)
Prosthetic Failure	Fracture of framework: n=4 (7%)		Facing Lost: n=16 (22.2%) Loss of retention: n=13 (18.1%) Fractures in acrylic: n=12 (16.7%)	- Fracture and deformation of retainers (> in OCD) - Connector failure (> in CD) - Denture base failure: <10% Retainer> Artificial tooth> Denture base> Major connector	Periodontal disease: n=6 Fracture of RPD: n=2 Fracture of clasp: n=1 Failed Repair: n=4 Wear and tear: n=7 Wish of the patient: n=3		**Irreversible mechanical wear of attachment:** UR RPD: n=4	**Group 2:** Reciprocal clasp fracture: n=1 (4%) Major connector fracture: n=(4%) Displacement of denture base: n=13 (48%)	
Abutment teeth Loss	n=4 (%NR)		Prosthesis that lost at least 1 abutment tooth: n=33 (44.6%) (51.7% in CRPD)	TD: n=15 (11.4%) OCD: n=3 (5.2%) MD: n=7 (3.6%) CD: n=2 (3.4%)	Lower Jaw: n=2	n=30 (6,7%)	**Fracture of abutment teeth:** BR RPD: n=4 UR RPD: n=1	Group 1: n=1 (4%) Group 2: n= 2 (7%)	5.8%

MATERIAL AND METHODS

1. Patient Sample:

This retrospective clinical study recruited volunteer Kennedy Class I patients rehabilitated with removable partial dentures at the Area of Dentistry of the Faculty of Medicine of the University of Coimbra between 2006 and 2013 and provided by graduation and post-graduation students under the supervision of clinical instructors. The study, approved by the Ethical Committee of Faculty of Medicine of the University of Coimbra, comprised a clinical and radiographic evaluation along with the administration of satisfaction questionnaires. All patients read and signed the informed consent form **(Supplementary Material 1)**.

Inclusion criteria were mandibular bilateral distal extension edentulism (Kennedy Class I) missing a minimum of two and a maximum of four teeth per quadrant. Two hundred and eighty four patients fulfilled the inclusion criteria and were analyzed for the exclusion criteria detailed in **Table II**.

The clinical files were checked for individual information on the case and rehabilitation procedure and existence of panoramic radiographs. Forty-five files were lacking the panoramic radiograph and the patients were excluded from the study. One additional patient was excluded due to a congenital osseous defect of the facial complex.

For the remaining 238 cases, the panoramic radiographs were examined to look for other exclusion criteria: 76 patients presented modifications to the Kennedy-Applegate classification and 5 patients had at least one of the mandibular canines absent and were therefore excluded. Additionally, it was perceptible from both the clinical process and the panoramic radiograph that 15 patients had extractions or any other kind of surgical intervention adjacent to the abutment teeth, which led to exclusion. An attempt was made to invite all the 142 included patients via telephone to recall examinations. After several attempts at different days and hours, 19 patients were not contactable via telephone. Two other patients had died, 13 expressed their unwillingness to participate in a clinical study, 9 were unavailable due to professional or personal reasons and 5 accepted but consecutively missed the appointments.

Ninety-four patients showed up for the follow-up appointment. From these, another 34 patients were excluded: 2 had acrylic prosthesis; 2 presented new mandibular RPDs; 3 had not been wearing the mandibular RPD for a period superior to 1 year; 2 were still going through the rehabilitation process and 1 presented a modification of the removable due to abutment loss posterior to the rehabilitation. In 14

additional cases the edentulous site had more than four teeth and in 10 cases less than two. Sixty patients were considered for statistical analysis. Significant changes in the projection geometry of the follow up panoramic radiograph compared to the initial were detected in 15 patients. Thus, only 45 patients were considered for bone level measurement.

Table II: Inclusion and exclusion criteria

Inclusion Criteria
1. Partially edentulous patients with mandibular Kennedy class I with a minimum of two and a maximum of four missing teeth per saddle rehabilitated at the Faculty of Medicine of the University of Coimbra with removable partial dentures within the years 2006-2013
Exclusion Criteria
1. Non-existence of panoramic radiograph prior to the rehabilitation;
2. Less than two missing teeth per edentulous site;
3. More than eight missing teeth;
4. Any modification to the Kennedy-Applegate edentulism classification.
5. Surgical interventions adjacent to the RPD abutment teeth subsequent to the initial panoramic radiograph
6. Congenital osseous defects of the facial complex
7. Partial or total mandibular resections due to malign or benign tumors
8. Tooth loss adjacent to the distal saddle posterior to the rehabilitation.
9. Exchange or modifications the of prosthetic rehabilitation posterior to the removable denture insertion
10. Absence of any of the mandibular canines
11. Incomplete records or poor quality data relating to the prosthetic rehabilitation.
12. Not contactable via telephone
13. Unwillingness to participate
14. Unavailable

2. Follow-up Prosthodontic Procedure:

The patients were scheduled for a follow-up appointment in the Area of Dentistry of the Faculty of Medicine of University of Coimbra between December 2013 and May 2014. During this follow-up appointment the patients underwent clinical and

radiographic evaluation and filled a patient satisfaction questionnaire specifically built for partial denture wearers.

A. Clinical Evaluation:

Patients were evaluated in 5 dimensions: general and oral health, condition of the edentulous areas and abutment teeth; condition of the removable prosthesis.

Regarding general health, data were collected for age, morbidities, medication and changes in feeding habits. Oral health was evaluated by quantitative determination of plaque over the dental and prosthetic surfaces and assessment of the presence of prosthetic stomatitis. Fill in of periodontogram with probing depth and bleeding on probing registration was performed to evaluate the general periodontal status of the mandibular teeth. The items are presented in the **Supplementary Material 2** and specific items evaluated fully detailed in the text.

a) General Health Issues:

General health information was obtained from the medical records of the process of the patient and from the interview at the follow-up appointment.

b) Oral Health Issues:

Oral and prosthesis hygiene were clinically assessed and classified into a three point scale as Good, Satisfactory or Poor considering the proportion of the surfaces covered by dental plaque: less than 20%, 20 to 60% and more than 60% respectively. The presence of prosthetic stomatitis was also considered as an oral health index. General periodontal condition was analyzed through the completion of a dental periodontogram, with probing depth, gingival recession, mobility and bleeding on probing registration and subsequent determination of the loss of clinical attachment level.

Figure 1: Intra-oral image of patient rehabilitated with distal extension removable partial dentures

c) Edentulous Area:

Edentulous area was evaluated for factors potentially affecting the stability and clinical performance of the RPD. The residual ridge was qualitatively assessed as good, medium or bad according to the vertical height, thickness, shape and relining soft tissue. Primary support areas as the buccal shelves and the retromolar pad were evaluated for size/length, mobility and type of mucosa. Saddle length was obtained by measurement with a metal ruler of the distance from the distal marginal ridge of the abutment tooth to the most anterior portion of the retromolar pad.

Figure 2: Mandibular residual ridge

d) Abutment Tooth:

Abutment tooth were assessed for periodontal and pulpal condition as well as the presence and type of restoration. Location of rest seats and the presence of guiding planes were also registered.

e) Removable Prosthesis:

The removable partial denture was clinically characterized according to the type of major connector, type and symmetry of direct retainers, number and symmetry of indirect retainers and rest seats. Failures were registered as deformities of the prosthesis components, loss of retention of the claps and fracture of the denture base.

Figure 3 and 4: Distal extension removable partial denture with lingual plate as major connector

B. Residual Ridge Resorption Assessment:

All patients were submitted to a follow-up panoramic radiographic examination. The main objective was to assess the changes in vertical dimensions of the mandibular edentulous sites from the initial situation, prior to the rehabilitation, to the follow-up appointment. The initial panoramic radiograph was collected from the data stored in the individual chart of each patient in the VixWin software. The follow-up panoramic radiograph was taken at the day of the appointment. Panoramic radiographs were taken with Gendex® Orthoralix 9200 DDE panoramic and cephalometric system **(60-80kV anode voltage, 3-15mA anode current)** and stored in the VixWin software. Linear measurements were then carried out with the imaging software **Image J** (imagej.nih.gov/ij/) as exemplified in **figures 5** and **6**.

The measurement method is largely described in literature [14, 31-33]. In the present study, six measurements were performed per radiograph, three per quadrant, determining the vertical linear distance between the crest and the inferior border of the mandible: distally to the abutment tooth, in the pre-molar and in the molar area [31]. Auxiliary lines were drawn to ensure correct positioning and verticality of the measurements. The first line to be drawn was a tangent to the most inferior points of the lower border of the mandibular body on each quadrant. Secondly, a line corresponding to the midline was drawn from the anterior nasal spine and crossing the middle of the two mental protuberances. Then, another line was drawn parallel to the tangent above the lower border of the mandible guaranteeing that it crossed the midline at the inferior border of the mandible and that it passed in the transition of the angle of the mandible to the posterior border of the ramus. The length of this section was considered to represent the mandibular length and was used to calculate the sites of measurement, as referred in the[14, 31, 33], corresponding to the locations of first premolar and first molar obtained from the estimates recorded in dentate subjects: at 35% distance from midline (premolar area), at 55% distance from midline (molar area) of the total length of the mandibular body from the midline [33]. The proportions were calculated dividing the length of mandibular body from midline to the posterior border of the ramus by the length up to the distal surface of lower first premolar from the midline, and by the length up to the distal surface of lower first molar from the midline. Finally, vertical lines were drawn normal to the tangent line at the 3 measurement sites (distally to the abutment tooth, in the premolar and in the molar area). Vertical height was obtained in pixels by determination of the linear distance between the crest of the edentulous sites and the lower border of the mandible. Conversion of the

measurements in pixels to millimeters was done considering the CCD sensor pixel size of 48µm provided by the manufacturer.

Only radiographs with horizontal and sagital positioning of the head similar to that of the initial radiograph, and with clear images of the inferior and posterior borders of the mandible were considered for analysis.

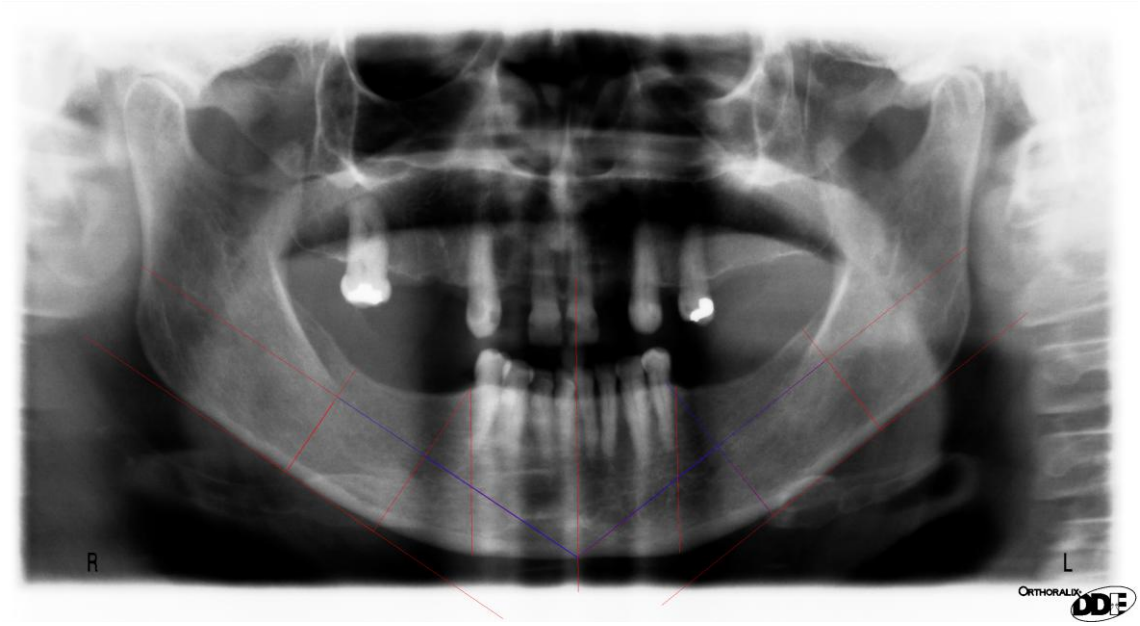


Figure 5: Initial panoramic radiograph with measurements on the abutment teeth and molar region at both quadrants. Premolar region as only measured on 4th quadrant

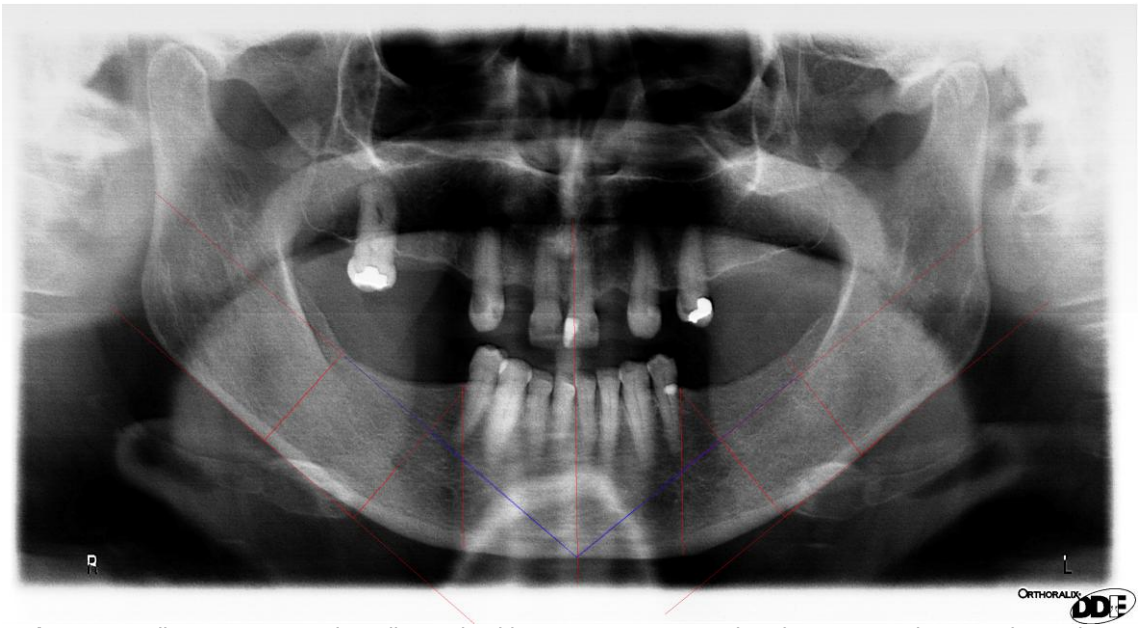


Figure 6: Follow-up panoramic radiograph with measurements on the abutment teeth, premolar region and molar region at both quadrants

C. Oral Health-Related Quality of Life:

The degree of well-being provided by the removable dentures was assessed with a prosthetic quality of life (PQL) questionnaire adapted and validated by Montero, Bravo and López-Valverde [34] to partial denture wearers. The questionnaire consisted of 11 items addressing the prosthetic fit, the chewing capability and the sensation of foreign body in mouth, aesthetics, impact on communication, realism and unnoticeability of the prosthesis, facility to perform hygiene, food impaction, functional comfort and self-confidence **(Supplementary Material 3)**. A 12th item was added to ascertain the self-conscience of the individual to the modification of the oral health status over the former year. The PQL questionnaire was designed to be self-completed intuitively as the responses to the items were expressed in a Likert-scale format (from 1 to 5), with a coding proportional to the degree of impact. The total score was the mean of the different item scores.

3. Data Analysis:

Statistical analysis was performed using IBM SPSS Version 20.0. Descriptive statistics were recorded as frequencies for the nominal and ordinal variables and as mean ± standard deviation for scale variables. Associations between nominal or ordinal variables were performed by crosstabulation and the Qui-square test for association. Spearman correlation was used to establish associations between ordinal and scale variables. Vertical bone level changes were determined with the paired samples t-test. A multiple regression using a stepwise approach was conducted to build a model to predict annual vertical bone loss in the edentulous areas. Significance level was set to 5%.

RESULTS

1. Description of Sample:

Sixty patients with a mean age of 57.7 ± 10.9 years and wearing mandibular removable partial dentures for 4.4 ± 2.3 years, ranging from three months to eight years, were considered for observation. Gender distribution is represented in **Table III.**

Table III: Frequency of male and female patients and descriptive statistics of age and time of denture wear. N(%) - Number of patients (relative frequency); Age - Mean ± Standard deviation; Denture time in use – Mean time in use ± Standard deviation

	N (%)	Age	Time of Denture Wear
Male	16 (26.7%)	66.1 ± 8.28	5.20 ± 2.36
Female	44 (73.3%)	54.61 ± 10.16	4.09 ± 2.27

2. Follow-up Prosthodontic Procedure:

A. Clinical Evaluation:

Oral and prosthesis hygiene assessment revealed similar distribution for both sexes and is summarized in **Table IV**. Patients with less than 20% of dental and/or prosthetic surfaces covered with plaque were considered to have good hygiene, patients presenting 20-60% surfaces with plaque received the satisfactory score and the remaining, presenting more than 60% plaque, were considered to have poor hygiene.

Table IV: Frequency of classifications attributed to the variables oral hygiene and prosthesis hygiene. N (%)

	Poor	Satisfactory	Good
Oral Hygiene	28 (46.7%)	28 (46.7%)	4 (6.7%)
Prosthesis Hygiene	15 (25.1%)	33 (55%)	12 (20%)

Nineteen patients (6 males; 13 females) were diagnosed with prosthetic stomatitis. Even though no association was established between prosthesis hygiene and the presence of prosthetic stomatitis, there is a statistically significant association between the last and oral hygiene: $X^2(2)=8.34$, $p=0.02$. Patients with poor oral hygiene present higher proportion of prosthetic stomatitis cases while patients with satisfactory

and good oral hygiene present higher percentages of cases free from candidosis. No different risk is attributable to either gender: $X^2(1)=0.34$, $p=0.55$.

Qualitative assessment of retromolar pads and buccal shelves are summarized in **Tables V** and **VI**. Small retromolar pad are associated to mobility while medium and large retromolar pad were predominantly adhered X^2 (2) = 23.705, $p<0.01$. Mobility is in association with small buccal shelves X^2 (2) = 43.60, $p<0.01$. Consequently, underlying tissues were classified as bad in 56.7% of cases, medium in 25.0 of patients and good in the remaining. In 73.3% of cases, keratinized mucosa was not found.

Table V: Qualitative assessment of retromolar pad. N(%)

		Dimension		
		Small	**Medium**	**Large**
Mobility	**Yes**	28 (23.3%)	6 (5.0%)	0 (0%)
	No	29 (24.2%)	46 (38.3%)	11(9.2%)

Table VI: Qualitative assessment of buccal shelves. N(%)

		Dimension		
		Small	**Medium**	**Large**
Mobility	**Yes**	71 (59.2%)	15 (12.5%)	2 (1.7%)
	No	6 (5.0%)	16(13.3%)	10(8.3%)

The periodontal analysis of abutment teeth revealed a mean loss of clinical attachment level of 3.46 ± 1.34mm. Despite being weak, Spearman's correlation found a statistically significant association between patients with worse ridge support quality presented higher loss of clinical attachment level (CAL) of the abutment teeth ($R=-0.197$, $p=0.031$).

Abutment teeth were evaluated for failure considering the periodontal condition, caries and fractures. No teeth were lost due to periodontal problems. Thirty-three abutment teeth presented caries or fractures and were recorded as failures (27.5% of the total of the abutment teeth). Nevertheless, in only 3 cases the tooth lost viability thus compromising the prosthetic rehabilitation. The distribution of the problems reported for the abutment teeth is described in **Table VII**.

Table VII: Evaluation of the abutment teeth at the follow-up appointment considering the initial condition N(%)

		Evaluation at follow-up			Total
		OK	**Caries**	**Fracture**	
Abutment tooth condition	**Higid**	45 (37.5%)	14 (11.7%)	3 (2.5%)	62 (51.7%)
	Composite resin restoration	32 (26.7%)	14 (11.7%)	1 (0.8%)	47 (39.2%)
	Amalgam	5 (4.2%)	1 (0.8%)	0 (0.0%)	6 (5.0%)
	Metalo-ceramic crown	5 (4.2%)	0 (0.0%)	0 (0.0%)	5 (4.2%)
Total		87 (72.5%)	29 (24.2%)	4 (3.3%)	120 (100%)

No statistically significant association was established between the condition of the abutment tooth at the time of prosthesis placement and the evaluation at the follow-up appointment: X^2 (6) = 3.765, p=0.708.

B. Prosthetic Evaluation:

In our study, only the teeth that serve as a support for a clasp or for an attachment were considered to be 'abutment teeth'. Other teeth, serving as a support for an isolated (or indirect) occlusal rest or for a major connector (lingual plate) were not recorded as abutment teeth. Considering this, 58 of RPDs evaluated were supported by 116 (96.7%) natural teeth with no intracoronary retention and the remaining 2 prosthesis were supported by 4 abutment crowns. Of the total of abutment teeth, 53.9% were higid. The second premolar was the most frequent abutment tooth with a relative frequency of 50%, corresponding to 60 teeth. Canines represented 20.8% of the abutment teeth (25) and the first pre-molar 29.2% (35). One RPD did not present retentive clasp for the abutment teeth, corresponding to one of the prosthesis supported by abutment crowns. A total of 118 retentive clasps were recorded for the other prosthesis, 91.5% (108) of which promoted suprabulge retention and 8.5% (10) promoted infrabulge retention. The distribution of the types of direct retainers found is summarized in **Table VIII**. Only in 7.6 % of the cases, the retention elements presented the reciprocal clasp. In 63.3% of the cases (38 patients), the mandibular arch was symmetrical, thus also was the distribution of the direct retainers, meaning that those

prosthesis received the same type of direct retainers in the 3º and 4º quadrants. The mean number of indirect retainers per prosthesis was 4.17 ±1.80, going up to 6. Generally there is great distribution of loads across the remaining teeth trough the indirect retainers, as 74.6% of the prosthesis present 4 or more indirect retainers. Lingual bar was the most prevalent major connector (86.4%). Lingual plate and double lingual bar presented low relative frequencies (5.1 and 8.5%, respectively). Mean major connector thickness found for both the lingual bar and the inferior part of double bar was 3.264± 0.443 mm. These connectors are usually 2.52 ± 1.21mm away from gingival margins, and respect a larger distance to the lingual frenum (4.54 ± 1.61mm).

Table VIII: Distribution of the types of direct retainers per abutment teeth. N(%)

	Canine	**First Pre-Molar**	**Second Pre-Molar**	**Absolute Frequency (%)**
Simple Circlet Clasp	10 (8.5%)	0 (0%)	2 (1.7%)	**12 (10.2%)**
Reverse Circlet Clasp	9 (7.6%)	34 (28.8%)	53 (44.9%)	**96 (81.3%)**
T- Clasp	4 (3.4%)	1 (0.8%)	5 (4.3%)	**10 (8.5%)**
Absolute Frequency (%)	**23 (19.5%)**	**35 (29.6%)**	**60 (50.9%)**	**100%**

The major connector was considered deformed when passive insertion wasn't possible or occurred with compression or ulcers of the support areas of the lingual mucosa of dentate areas, or presented misfit superior to 2mm. Deformity was attributed to 14 major connectors (23.3%). A statistically significant association was established between type of connector and the presence of deformity (χ^2 (2)= 6.15, p=0.046), which was only observed for lingual bars. Minor connector deformity was classified accordingly and was observed in 9 prostheses (15%). Loss of retention of direct retainers occurred in 50.8% of the evaluated cases. Thirteen direct retainers (10.8%) presented either fracture or deformation of the flexible tip of the clasp. Denture base fracture was identified in 3 prostheses (5%).

C. Residual Ridge Resorption Assessment:

The vertical residual ridge heights are summarized in **Table IX.** For the abutment tooth, there was a statistical significant decrease in vertical height of 0.55 mm as assessed by the paired samples T-test: t(83)= -2.34, p=0.02. Despite the decrease of 0.32mm in vertical height measured for the premolar area, no statistical significant difference was found: t(29)= -1.10, p=0.282. In molar region, decrease of 0.42 mm in vertical measurements was verified: t(78)= -4.38; p<0.001. No statistically significant differences were found for vertical bone loss between men and women at both the molar measurement site and the abutment: mean difference of -0.023mm, 95% CI [-0.49; 0.45], t(77)=-0.096, p=0.74 and mean difference of -0.018mm, 95% IC [-1.04; 1.01], t(82)=-0.035, p=0.972, respectively.

Table IX: Vertical residual ridge heights on abutment teeth, premolar and molar regions and mean differences (mm)

	Abutment Tooth	Premolar	Molar
Initial	16.70 ± 2.27	14.76 ± 2.95	11.79±2.22
Follow-up	16.17 ± 2.78	14.44 ± 2.71	11.37±2.34
Mean Difference Confidence Interval	**-0.55 ± 2.06 ***	**-0.32 ± 1.62 ***	**-0.42 ± 0.86 ***
	[-0.97; -0.08]	**[-0.93; 0.28]**	**[-0.62; -0.23]**

A linear regression model was established in order to predict the mean annual bone loss in the molar area, considering the predictors time of denture wear, retromolar pad mobility and buccal shelves extension **(Table X)**. The model was statistically significant (R=0.436, p<0.001). The bone height loss can be predicted by: -1.014 + 0.498*(buccal shelves extension) + 0.493*(retromolar pad tissue) – 0.424*(quality of residual ridge).

Table X: Linear regression model in molar area

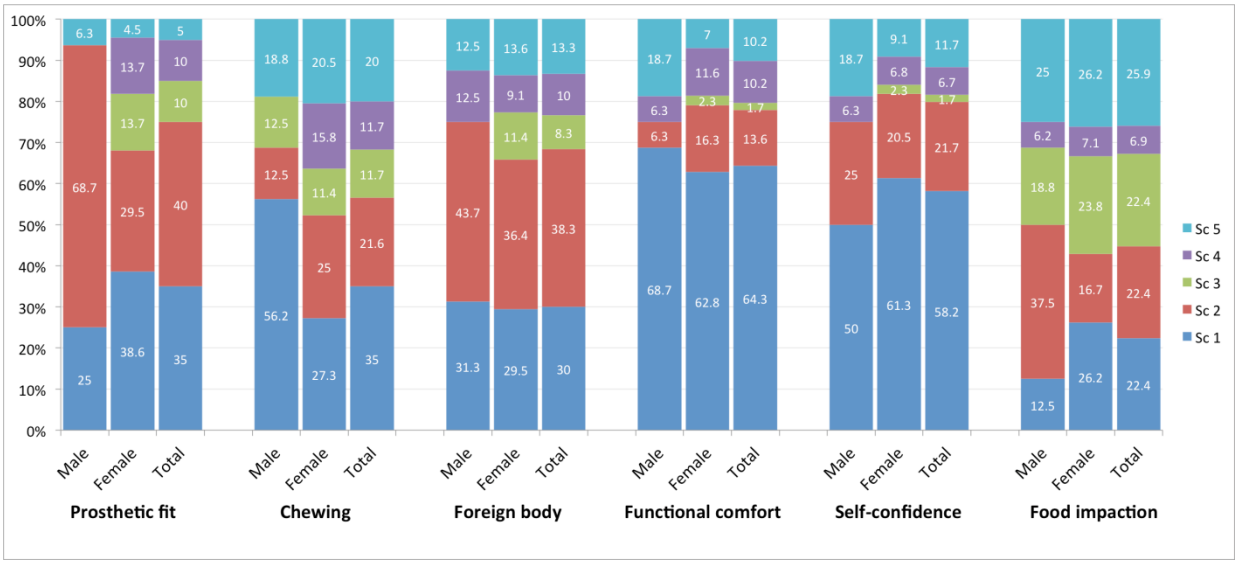
Model	Unstandardized Coeficients		Standardized Coeficients	t	Sig.
	B	Std. Error	Beta		
Constant	-1.014	0.319		**-3.179**	**0.02**
Buccal Shelves Extension	0.498	0.175	0.379	**2.846**	**0.006**
Retromolar Pad Tissue	0.493	0.232	-0.277	**2.128**	**0.037**
Quality of Residual Ridge	-0.424	0.162	-0.361	**-2.615**	**0.011**
Time of Denture Wear	-0.037	0.041	-0.906	**-0.907**	**0.367**

No correlation was established between any of the variables assessed in the retrospective clinical study and the bone loss in the abutment tooth area.

D. Oral Health Related Quality of Life:

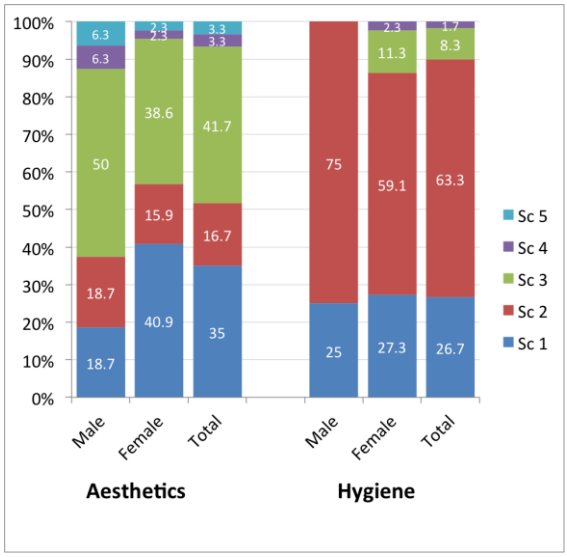
According to the authors [34], the questions addressed in this indicator of quality of life of wearers of removable dentures comprise three latent dimensions that evaluate the impact on physical, psychological and social well-being. Physical well-being consists of questions 1, 2, 3, 9, 10 and 11, which assess prosthetic fit, chewing capability, foreign body sensation, food impactation, functional comfort and self-confidence while wearing the RPD. The psychological dimension is composed of only two questions (4 and 8) assessing aesthetics and the facility of hygiene of the prosthesis. Questions 5, 6 and 7, focusing on communication capabilities, realism of prosthesis and unnoticeability, appraise the social dimension. Relative frequencies of the answers to the questions addressing each dimension are plotted in Graphics A, B and C, considering gender and total distribution. For all questions, no statistically significant differences were found between males and females.

1. Physical Dimension:



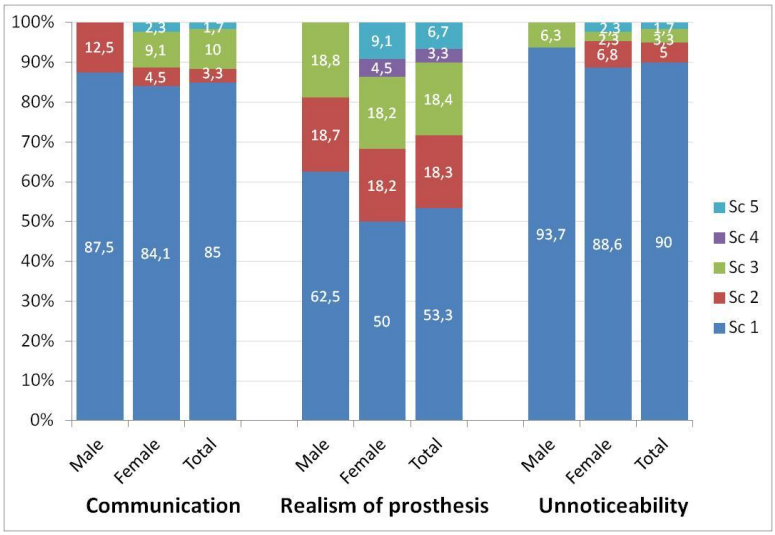
Graphic A: Relative frequencies of the scores obtained in physical dimension questions.

2. Psychological Dimension:



Graphic B: Relative frequencies of the scores obtained in psychological dimension questions

3. Social Dimension:



Graphic C: Relative frequencies of the scores obtained in social dimension questions

Global satisfaction was assessed by calculating of the mean score of the individual scores associated to the first 11 questions and presented a mean value of 1.97± 0.72, ranging from 1 to 4.18. The 12th question, assessing the self-conscience of the oral health status, revealed that 83.3% of the patients considered that their oral health had improved a little during the passing year. Only 5% of the patients felt that their oral health had worsened a lot during the same period.

Figure 7/8: Potential space for food impaction between denture base and residual ridge

DISCUSSION

Removable prostheses have long been considered a suitable and conservative alternative for the rehabilitation of partially edentulous patients, particularly for those situations that require implant installation to allow for a fixed rehabilitation, such as Kennedy Class I edentulism. Even though several studies evaluate the clinical performance of removable partial dentures in general, the literature is sparse on the evaluation of the long-term success of distal extension conventional removable dentures thus direct comparison of our results with published data is possible only to a limited extent. Nevertheless, dimension and mean age of our sample are similar to previous retrospective studies focusing specifically on conventional mandibular removable partial dentures [26, 30].

Despite being the least invasive approach for the rehabilitation of edentulous spaces, placement of a prosthesis in the oral cavity results in alterations of the environmental conditions [35]. Some authors have reported an increase in *Candida albicans* levels and subsequent infection by this yeast [36] and the enhancement of plaque formation over teeth in contact with RPDs due to the restriction of the self-cleaning action of the buccal mucosa and tongue (Chamrawy *et al.* cited in [13])[35]. The implementation of meticulous hygiene of both the oral cavity and denture, associated to regular recall appointments, is therefore essential for the sustainability of the rehabilitation and abutment teeth [10, 13, 37]. The patients that attended the recall appointment presented poor (46.7%) or satisfactory oral hygiene (46.7%) and satisfactory prosthetic hygiene (55%) and could be the justification for the high frequency of *Candida* colonization under the prosthesis, reported as prosthetic stomatitis in 19 patients. Our results (32% frequency of prosthetic stomatitis) are in accordance to the systematic review of Emami and colleagues, who found a prevalence of prosthetic stomatitis in partial RDP wearers ranging from 1.1% to 36.7% [38], and go further by determining a positive association between poor oral hygiene and prosthetic stomatitis.

The poor hygiene indices and the lack of regular recall appointments provided to the patients rehabilitated at the Area of Dentistry of the Faculty of Medicine could also be the related to problems of the abutment teeth recorded in 27.5% of the cases. Despite the high frequency of recurring caries or fractures found in the RPD wearers, abutment failure with tooth loss and consequent need for replacement of the prosthetic rehabilitation occurred only in 2 cases (three teeth), which is favorable when compared

to other studies, such as Schmitt *et al.*, Rehmann *et al.*, Jorge *et al.*, Piwowarczyk *et al*. and Wagner *et al.* [17, 25, 28-30].

The absence of abutment failure due to periodontal problems could be attributable to the direct retainer. This choice is important in the design of every RPD because the direct retainers are responsible for the transmission of loads acting on the saddles to the abutment teeth but assumes particular importance in distal extension RPDs [39]. In these cases of tooth-mucous support, the different resilience of the abutment teeth and tissues underlying the saddle generates harmful rotational forces with fulcrum in the root, leading to mobility increase and loss of clinical attachment level. Even though Mizuuchi *et al.* report that the type of direct retainer does not affect the directional movements of the abutments, other authors claim that is fundamental to ensure the transmission of loads vertically to the main axis of the tooth, which is not possible with all clasp designs [5]. The literature recommends the use of direct retainers with mesial rests adjacent to reduce the magnitude of the movements [5] and to produce the least torque on the abutment teeth [37]. For these reasons, the use of conventional circumferential clasps is inadvisable, particularly on premolars, while the typical RPI (with mesial rest seat and buccal I-bar) retainer design is recommended for teeth with reduced periodontal support for the breakage of harmful forces and protective role [37]. Pellizer *et al*. reported also that a T-Clasp type had the most favorable stress distribution to the underlying tissues for any configuration of residual ridge [39]. The reverse circlet clasp found in 81.3% of the cases examined in this study seems to promote the same protective role on non-periodontally compromised teeth, as no increased mobility or clinical attachment loss was found for the abutments, allowing for a convenient mesial rest seat with minimal tooth preparation.

In spite of the biomechanical stability provided by the reverse circlet clasp, a very large number of retainers with loss of retention were found, which could be in part attributable to this retainer. Loss of retention was registered for 50.8% of the retainers and even though no statistically significant association could be established to the reverse circlet clasp, this rate is much higher than those reported by Rehmann *et al.* or Wagner *et al.* (18.1%) [25, 30] who make use of different retainers. The reverse circlet clasp allows the use of undercuts adjacent to edentulous spaces but covers extensive tooth surface, probably inducing higher fatigue of the retentive arm and favoring the reduction of flexibility and subsequent loss of retention. Notwithstanding this, the

mentioned authors pointed clasp activation as the second or third main reason for RPD repair after base relining, respectively [25, 30].

In order to improve the maintenance of retention and stability of the direct retainers applied on premolar abutments of distal-extention RPDs, Shifman *et al.* proposed a modification of the circumferential clasp that comprises a mesial rest, lingual bracing arm, distal guiding plate and a buccal bracing/retentive arm. Contrarily to the usual designs, the mesial rest is connected to the proximal plate through a lingual bracing arm [40]. The guiding plate added to the clasp assembly not only enhances retention, but also reduces the fatigue of the clasp during insertion and removal of the RPD without compromising the torque-releasing effect. This also obviates the need for a separate minor connector contributing for the reduction of food impaction and clearance of subgingival areas, thus decreasing food impaction and improving both hygiene and patient comfort.

In fact, food impaction was the major cause of dissatisfaction of RPD wearers assessed in the present study, with more than 50% of the patients referring frequent or invariable food accumulation under the prosthesis. This is in part due to the absence of retentive elements distal to the saddle, which is the main contributor for the rotational movements of the RPD around a virtual axis that connects the two abutments, and subsequent weak capability to resist to desinsertion forces, but also due to the absence of guiding planes in the abutment teeth. The preparation of distal guiding planes, either associated or not with proximal plates, would improve retention and reduce undercuts between the acrylic base of the prosthesis and the abutment tooth, clearly visible in figures 7 and 8, and improve patient satisfaction, as mentioned by Shifman *et al* [40]. Nonetheless, other authors [41] mention that the significance of guiding planes cannot be readily assessed regarding periodontal health of the abutments and food impaction, as concluded by of the London International Prosthodontic Symposium of 1982, to justify a less extensive preparation of the tooth.

Other RPD design-related issue that was found to be associated with the perceived prosthetic fit and functional comfort mentioned by the patients aside to the responses to the questionnaire was the major connector. The literature refers the lingual bar as the most widespread connector for mandibular prosthesis, used in 72.5% of the cases [27] because of the small volume and unobtrusiveness, and should be the preferred design unless additional advantages could be obtained from another connector [42]. Similarly, the lingual bar was the most prevalent major connector found

in this retrospective study (86.4%). However, a high rate of deformation was associated to this type of connector, present in 23.3% of the cases despite being inconsequential and not preventing the use of the RPD. The deformation of this component could be attributable to some lack of rigidity found in many cases, as expressed by the mean occluso-gingival width of 3.28±0.45mm, inferior to that mentioned as ideal in the literature of 4 to 6mm [42]. In the particular case of tooth-tissue-supported rehabilitations, ensuring rigidity is mandatory so that the partial denture functions as one unit, providing cross arch stabilization and counteracting the tissue-ward movements of the lingual bar under load of the distal saddles. Flexing connectors do not distribute equally functional loads to the abutment teeth and mucosa and are exposed to bending moments. Eventually, the continuous load of the saddles and flexing of the major connector induces fatigue of the material, passing the elastic deformation limit of the chrome-cobalt and inducing plastic deformation. This means that in order to guarantee less cases of deformation it would be advisable to either increase the occluso-gingival width of the lingual bars to the preconized values or to adopt another design for the major connector. For instance, lingual plates provide additional stability in cases of extensive distal saddles and/or severe vertical resorption of the ridges, despite being associated to more food impaction and difficult hygiene. Some authors as Vanzeveren *et al.* [27] or Frank *et al.* [21] report the use of this connector more frequently than the 5.1% of cases found in our study with no failures of the metal framework.

Failures regarding denture base fracture presented low frequency (5%) and were in accordance with other studies, such as Jorge *et al.* [17] or Vanzeveren *et al.* [27]. Necessity for relining is also a frequent need for intervention in what concerns to the denture base and occurs subsequent to vertical bone loss in the edentulous areas under the saddles. In order to quantify the bone loss that occurs under the saddles between RPD insertion and the follow-up appointment, vertical measurements were performed in three points (abutment tooth, pre-molar and molar regions) of each hemi-mandible in the two moments. Because of the lack of landmark identifying the premolar and molar areas in the edentulous sites, the measurements were performed at the locations obtained for the distal faces of the first premolar and molar from the analysis of dentate subjects [14, 31-33].

A statistically significant decrease in vertical height measurements was found between initial and follow-up radiographs for the abutment teeth and molar region. In

the pre-molar region there was equally a reduction in vertical bone height but not statistically significant probably due to the reduced number of measurements obtained in this area consequence of the frequent presence of an abutment tooth. Up to our knowledge, no other studies compare initial and follow-up bone heights. Some studies compare vertical bone measurements in dentate and edentulous subjects, with higher decrease found for edentulous subjects [31, 33] and a trend to be more evident from anterior to posterior, which has been attributed to higher bone resorption in response to the loss of teeth and denture wear [31]. However, we were unable to find a correlation between the time of denture wear and the extent of bone resorption. In the molar area, factors as the quality of ridge support, the tissue of the retromolar pad and the extension of the buccal shelves seem to be determining more important in residual ridge resorption. This also contradicts Cagner *et al.*, who reported the time of denture wear as being determinant influence after the assessment of edentulous patients [14]. Quality of residual ridge support seems to be associated to different resorption rates, as mentioned by Wictorin *et al.* cit. in [43] who found increased residual ridge resorption for large alveolar processes. This could mean that high rounded ridges retain some alveolar bone whilst the others are comprised exclusively of basal bone with slower remodeling, which is also in accordance to the predictive model for vertical bone loss presented in this work.

Residual ridge support becomes more important as the distance from the abutment increases and will depend on the several factors [7]. The described ideal mandibular residual ridge consists of cortical bone that covering relatively dense cancellous bone with a broad rounded crest with high vertical slopes, and over lined by firm, dense, fibrous connective tissue. Unfortunately this ideal is seldom found and the conditions of the mandibular residual ridge prevent the crest from being a primary stress-bearing region [7]. Thus, the denture-supporting area of the RPD should be designed to be as large as possible within the non-movable mucosa so that there are less occlusal forces distributed over the alveolar ridge [44]. The buccal shelf region seems to be better suited for a primary stress-bearing role [7] and apparently contributes for the lowering of bone resorption with the larger areas associated to the less resorption. The retromolar pad is also considered a primary stress-bearing area in distal extension removable partial dentures. We verified that the character of their covering tissues can be determining in residual ridge resorption, regardless of the size of the retromolar pad. Our predictive model states the superiority of keratinized tissues,

which are normally adhered, reducing the range of movements and instability of the denture base, contributing for lower bone resorption.

The success of the prosthodontic treatment cannot be exclusively assessed clinically. Patient perceptions about the rehabilitation are important and must be considered. Then, in our retrospective study, we included a prosthetic quality of life questionnaire, specifically developed and validated for patients wearers of partial removable dentures [34]. This questionnaire supports the notion that the PQL is multidimensional, grouping 11 questions in three categories (physical; psychological and social well-being). Kimura's OHRQoL also considered this multidimensionality in two major groups: "oral health condition" (16 questions) and "psychological health condition" (12 questions), assessed in pre and post treatment periods [45]. The retrospective nature of our study limits the assessment of the impact of the rehabilitation in the daily life of patients as no comparison between pre and post treatment can be performed. More, some of the questions of this questionnaire were considered somehow inappropriate for mandibular distal extension RPD wearers. The items aesthetics, realism of prosthesis and unnoticeability are not applicable and could induce patients to answer based upon their upper denture or natural anterior teeth, introducing a bias. Additionally, during the filling of the surveys, we identified interpretation difficulties and complaints about the extent for many patients despite the plainness of the questions. This could be related to the generally low educational level of the population studied and could represent another limitation of the questionnaire. A reformulation of the questionnaire redirecting it for the particular case of distal extension RPD wearers would be most suitable to specifically address patient satisfaction.

CONCLUSION

Prosthetic design is fundamental for the long-term success of rehabilitations with distal extension removable partial dentures. Denture base must be extended to the primary stress-bearing areas, namely retromolar pad and buccal shelves. These seem to contribute to the prevention of residual ridge resorption in the molar region. Lingual bars seem to be associated to higher rates of deformation of the major connector. Despite the high rate of retention loss, the reverse circlet clasp contributes to the periodontal stability of the abutment teeth. Food impaction is the most frequent complaint of distal extension RPD wearers. Nevertheless, the level of satisfaction with the prosthetic rehabilitation remains high.

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SUPPLEMENTARY MATERIALS:

List of Figures, Tables and Graphics:

I. Figures:

- **Figure 1:** Intra-oral image of patient rehabilitated with distal extension removable partial dentures
- **Figure 2:** Mandibular residual ridge
- **Figure 3 and 4:** Distal extension removable partial denture with lingual plate as major connector
- **Figure 5:** Initial panoramic radiograph with measurements on the abutment teeth and molar region at both quadrants. Premolar region as only measured on 4th quadrant
- **Figure 6:** Follow-up panoramic radiograph with measurements on the abutment teeth, premolar region and molar region at both quadrants
- **Figure 7 and 8:** Potential space for food impaction between denture base and residual ridge

II. Tables:

- **Table I:** Summary of the studies evaluating the clinical performance of distal extension removable partial dentures. Data on number of patients/prosthesis, mean age, follow-up time, intervention, retention, failure rate, abutment teeth loss and prosthetic failure
- **Table II:** Inclusion and exclusion criteria
- **Table III:** Frequency of male and female patients and descriptive statistics of age and time of denture wear. N(%) - Number of patients (relative frequency); Age - Mean ± Standard deviation; Denture time in use – Mean time in use ± Standard deviation
- **Table IV:** Frequency of classifications attributed to the variables oral hygiene and prosthesis hygiene. Absolute frequency (relative frequency)
- **Table V:** Qualitative assessment of retromolar pad N(%)
- **Table VI:** Qualitative assessment of buccal shelves N(%)
- **Table VII:** Evaluation of the abutment teeth at the follow-up appointment considering the initial condition N(%)
- **Table VIII:** Distribution of the types of direct retainers per abutment teeth N(%)
- **Table IX:** Vertical residual ridge heights on abutment teeth, premolar and molar regions and mean differences (mm)
- **Table X:** Linear regression model in molar area

III. Graphics:

- **Graphic A:** Relative frequencies of the scores obtained in physical dimension questions.
- **Graphic B:** Relative frequencies of the scores obtained in psychological dimension questions
- **Graphic C:** Relative frequencies of the scores obtained in social dimension question

Supplementary Material 1 – Informed Consent:

From: **Comissão de Ética (FMUC)** comissaoetica@fmed.uc.pt
Subject: Envio parecer CE_Proc. CE-036/2013_Ana Lúcia de Pereira Neves Messias
Date: 25 Jul 2013 15:24
To: analuciamessias@gmail.com
Cc: Comissão de Ética (FMUC) comissaoetica@fmed.uc.pt

Exma. Senhora

Dra. Ana Lúcia de Pereira Neves Messias

Cumpre-nos informar que o projecto de investigação apresentado por V. Exa. no âmbito do Programa Doutoral em Ciências da Saúde, com o título *"Estudo clínico e numérico das modificações de classes I e II de Kennedy com recurso a implantes endósseos na região mandibular posterior"*, mereceu o parecer da Comissão de Ética da FMUC que a seguir se transcreve: " *Parecer favorável com a recomendação de se utilizar texto de consentimento informado com cabeçalho institucional".*

Na presente data segue para o Conselho Científico da FMUC para aprovação do tema e de orientação científica. Para futuras informações, é favor contactar o STAG – CC através do e-mail ccientifico@fmed.uc.pt.

Cordiais cumprimentos.

Grata Bazarra Campos
Universidade de Coimbra • Faculdade de Medicina •
STAG – Secretariado Executivo
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TEXTO DE INFORMAÇÃO AO DOENTE

Está convidado a participar num estudo clínico retrospetivo. Este formulário serve para o ajudar a decidir sobre a sua participação neste estudo. Por favor leia atentamente o formulário e não hesite em colocar qualquer dúvida que tenha ao Médico Dentista que o acompanha.

Título do estudo: E*studo clínico e numérico das modificações de classes I e II de Kennedy com recurso a implantes endósseos na região mandibular posterior*

Duração do estudo: Vinte e quatro meses desde a consulta de controlo do tratamento protético.

Investigadores: Coordenador geral do estudo – Prof. Doutor Pedro Miguel Gomes Nicolau

Investigador principal – Ana Messias (Médica Dentista, aluna de doutoramento da FMUC)

Local: Este é um estudo retrospetivo realizado no âmbito do Programa Doutoral em Ciências da Saúde da Faculdade de Medicina da Universidade de Coimbra que pretende avaliar a estabilidade de tratamentos protéticos removíveis e determinar o índice de satisfação global dos pacientes. Todas as intervenções terão lugar no Departamento de Medicina Dentária da Faculdade de Medicina da Universidade de Coimbra, localizado no Bloco de Celas dos HUC (Hospitais da Universidade de Coimbra), sito na Av. Dr. Bissaya Barreto em Coimbra.

Enquadramento:

A perda dos dentes posteriores é responsável por mais de 72% dos casos de edentulismo (falta de dentes) parcial. O edentulismo posterior, denominado Classe I ou II de Kennedy consoante seja bilateral ou unilateral respetivamente, pode resultar em perda de estabilidade neuromuscular da mandíbula, redução de eficiência mastigatória, perda de dimensão vertical de oclusão e atrição (desgaste) dos dentes anteriores.

As opções de reabilitação de desdentados parciais posteriores incluem próteses fixas convencionais ou implanto-suportadas e próteses parciais removíveis (PPR). Situações de ordem médica, de saúde oral ou de ordem económica podem impossibilitar a realização de reabilitações fixas. Nestes casos considera-se a elaboração de uma PPR esquelética que, não sendo a solução ideal, apresentam boa relação custo-benefício para o paciente.

As PPR esqueléticas de extensão distal livre permitem o restabelecimento da dimensão vertical de oclusão e recuperam, ainda que com algumas limitações, as funções mastigatória e fonética. Porém estas próteses retidas em dentes e suportadas tanto por dentes quanto mucosa alveolar (tecido que recobre as zonas desdentadas), denominadas de próteses dento-muco-suportadas, estão sujeitas a movimentos torsionais e de desinserção provocados por forças que se geram durante os períodos funcionais. As diferentes capacidades de resistência às forças mastigatórias do ligamento periodontal dos dentes de suporte e dos tecidos moles que recobrem as zonas desdentadas levam a um afundamento da base da prótese em direção à crista óssea subjacente, resultando em compressão da mucosa com desconforto do paciente e reabsorção óssea progressiva. Esta perda de volume do rebordo

obriga a sucessivos rebasamentos das selas (zonas onde a prótese substitui os dentes perdidos) e piora o prognóstico da reabilitação. Os dentes de suporte também são lesados com os movimentos de rotação da prótese.

Apesar de ser do conhecimento geral que a fraca estabilidade e retenção inerentes às próteses parciais removíveis geram perdas ósseas nas selas distais e dentes de suporte, até hoje não foi feita uma quantificação destas perdas nem foi estabelecida a completa compreensão das forças e movimentos exercidos por uma PPR de sela distal livre.

Desta forma, o objetivo deste estudo passa pela avaliação clínica de pacientes Classe I e II de Kennedy mandibular reabilitados com próteses parciais removíveis esqueléticas desde 2006 na Área de Medicina Dentária da Faculdade de Medicina da Universidade de Coimbra, determinando a qualidade dos tratamentos e sua estabilidade ao longo dos anos mediante a realização de um exame intra-oral e de um registo de satisfação dos mesmos. Adicionalmente, o estudo pretende avaliar os níveis ósseos dos dentes-pilar e das selas distais através de técnicas de sobreposição radiográfica. Por último, mas não menos importante o estudo visa a determinação dos micromovimentos dos dentes-pilar das próteses quando as selas distais estão em carga.

Descrição dos procedimentos:

Em primeiro lugar o paciente fará o preenchimento do questionário de satisfação que usa uma escala visual como medida de quantificação. O médico dentista, na consulta, irá proceder a um exame intra-oral para determinar as condições oral e periodontal, e avaliar a adaptação e capacidades de função (fonética e mastigatória) do paciente com a sua reabilitação. Seguidamente será feita a medição dos micromovimentos dos dentes-pilar com recurso ao método de correlação de imagem digital tridimensional (CID 3D). Este método (CID 3D) consiste numa técnica ótica de medição, sem contacto, que consegue determinar o contorno tridimensional da superfície de um objeto e seguir o campo de micromovimentos dessa superfície numa sequência de imagens. Por fim, será feito um controlo radiográfico de todos os elementos orais através da realização de uma radiografia digital panorâmica, que permitirá determinar os níveis ósseos.

Quais são os riscos dos procedimentos?

Os procedimentos de determinação das condições intra-orais e periodontais, bem como a técnica radiográfica apresentada, são utilizados há anos de uma forma eficaz e segura, pelo que não existem riscos associados a este estudo. O método de correlação de imagem digital tridimensional não está amplamente divulgado mas baseia-se em princípios óticos perfeitamente validados e seguros. Assim, sendo este um estudo sem riscos, não haverá, para os participantes compensações nem médicas nem financeiras.

Quais são os benefícios para os participantes do estudo?

A participação neste estudo oferece-lhe a possibilidade de receber tratamento periodontal e de manutenção adequados à sua reabilitação protética e ao seu estado de saúde oral. Além dos benefícios clínicos na preservação da sua reabilitação oral protética, a sua generosa contribuição

permitirá determinar qual o melhor tratamento de forma a que futuros doentes possam beneficiar dele.

O que será feito dos meus dados pessoais?

Não será divulgada qualquer informação que possa revelar a sua identidade. Informação sensível será lidada com extrema discrição. Os seus dados pessoais só serão acessíveis aos investigadores e se necessário às autoridades responsáveis pela auditoria/monitorização dos dados.

Resultados agregados de todos os participantes no estudo serão publicados em revistas científicas internacionais e apresentados em conferências científicas para informar a sociedade dos resultados do estudo sem revelar a identidade dos participantes.

Quem poderei contactar se tiver alguma dúvida?

O Médico Dentista responsável pelo estudo pode providenciar todas as explicações que entender necessárias sobre a sua participação. No caso de surgir alguma complicação, por favor contacte-o imediatamente.

Contactos da Drª. Ana Messias:

- analuciamessias@gmail.com

- telefones do Departamento de Medicina Dentária – 239484183 ou 239400578.

O que sucede se decidir não participar no estudo ou se mudar de opinião durante o decorrer do estudo?

A PARTICIPAÇÃO NESTE ESTUDO É INTEIRAMENTE VOLUNTÁRIA E PODERÁ RECUSAR EM PARTICIPAR SEM QUE A QUALIDADE DO TRATAMENTO QUE RECEBER FIQUE COMPROMETIDA. Depois de assinar este consentimento informado, poderá decidir retirar-se do estudo sem providenciar uma justificação ou clarificação.

O que me é exigido?

É importante que se apresente a todas as consultas de forma a que possamos controlar regularmente a sua saúde e fazer todas as medições programadas. Não serão requisitados mais nenhum exame ou consulta adicional e todos os controlos e exames serão exatamente os mesmos que qualquer outro doente deveria ter recebido.

Declaração de interesses dos investigadores.

O presente estudo é patrocinado pela Fundação para a Ciência e Tecnologia através de uma bolsa de doutoramento atribuída ao Investigador Principal (referência SFRH / BD / 82442 / 2011, financiada pelo POPH - QREN - Tipologia 4.1 - Formação Avançada, comparticipado pelo Fundo Social Europeu e por

fundos nacionais do Ministério da Educação e Ciência). Os investigadores deste centro declaram a ausência de conflitos de interesse neste estudo.

TERMO DE CONSENTIMENTO INFORMADO E ESCLARECIDO

Eu compreendi o conteúdo deste formulário e tive a possibilidade de colocar qualquer questão, portanto dou o meu consentimento informado para participar neste estudo e autorizo o acesso aos meus dados pessoais exclusivamente aos investigadores e às autoridades responsáveis pela auditoria/monitorização.

Nome do doente (letras maiúsculas):_____

_____

Data e assinatura do doente: ___/____/_____ _____

_____

Nome do investigador principal (letras maiúsculas):_____

_____

Data e assinatura do investigador principal: ___/_____/_____ _____

_____

Nome da testemunha (letras maiúsculas):_____

_____

Data e assinatura da testemunha: ___/_____/_____ _____

_____

Supplementary Material 2 - Clinical Evaluation Form:

Patient Identification Name: Age: Process:				
Stage	**Item**		**Options**	**Code**
A. General Health Issues	1. Morbidities		-	
	2. Medication		-	
	3. Feeding Habits		-	
B. Oral Health Issues	1. Oral hygiene		Poor Satisfactory Good	**1** **2** **3**
	2. Prosthetic stomatitis		Yes No	**1** **2**
	3. General periodontal condition		Periodontogram	
	4. Prosthesis hygiene		Poor Satisfactory Good	**1** **2** **3**
C. Edentulous Area	1. Saddle length		3ºQ (mm) 4ºQ(mm)	
	2. Quality of ridge support		Bad Medium Good	**1** **2** **3**
	3. Primary stress-bearing area - Retromolar Pad	a. Dimension	Small Medium Large	**1** **2** **3**
		b. Mobility	Mobile Adhered	**1** **2**
		c. Tissue	Oral mucosa Keratinized mucosa	**1** **2**
	3. Primary stress-bearing area – Buccal shelves	a. Dimension	Small Medium Large	**1** **2** **3**
		b. Mobility	Mobile Adhered	**1** **2**
		c. Tissue	Oral mucosa Keratinized mucosa	**1** **2**
	4. Soft tissue variables Lingual Frenum	Dist. Frenum-Conector	(mm)	
		Conector Tickness	(mm)	
		Dist. Connector-Gingival margin	(mm)	
	5. Character of the mucoperiosteum		Oral mucosa Keratinized mucosa	**1** **2**
D. Abutment Tooth	1. Gingival recession		Periodontogram	
	2. Probing depth		Periodontogram	
	3. Clinical attachment level		Periodontogram	
	4. Tooth condition		Ok Carie Fracture	**1** **2** **3**
	5. Endodontic condition		TER Necrosis/Pulpitis Vital	**1** **2** **3**
	6. Restoration		No Composite resin Amalgam	**1** **2** **3**
	7. Intracoronal direct retainer		No Precision attachment	**1** **2**

			Semiprecision attachment	**3**
	8. Extracoronal direct retainer		No Attachment Retentive clasp	**1** **2** **3**
	9. Retentive clasp		Suprabulge Infrabulge	**1** **2**
	10. Reciprocal clasp		Yes No	**1** **2**
	11. Oclusal rest seat		Mesial Distal Cingulum No	**1** **2** **3** **4**
	12. Guiding plane		Yes No	**1** **2**
E. Removable Prosthesis	1. Major connector		Lingual bar Lingual plate Double lingual bar Labial bar	**1** **2** **3** **4**
	2. Oclusal rests		Number	
	3. Direct retainers	3rd Quadrant	Simple circlet clasp Reverse circlet clasp Embrasure clasp – double Ackers clasp T-clasp Modified T-clasp I-clasp Not applicable	**1** **2** **3** **4** **5** **6** **7**
		4th Quadrant	Simple circlet clasp Reverse Circlet clasp Embrasure clasp – double Ackers clasp T-clasp Modified T-clasp I-clasp Not applicable	**1** **2** **3** **4** **5** **6** **7**
	4. Direct retainers symmetry		Yes No	**1** **2**
	5.Indirect retainers		Number	**1** **2**
	6. Indirect retainers symmetry		Yes No	**1** **2**
	7. Deformity of major connector		Yes No	**1** **2**
	8. Deformity of minor connector		Yes No	**1** **2**
	9. Loss of retention of direct retainers		Yes No	**1** **2**
	10. Deformity of direct retainers		Yes No	**1** **2**
	11. Denture base fracture		Yes No	**1** **2**

Supplementary Material 3 - Prosthetic Quality of Life Questionnaire:

1.	**O que pensa do ajuste da sua prótese superior/inferior?**	
a)	Muito bom	**1**
b)	Bom	**2**
c)	Aceitável	**3**
d)	Mau	**4**
e)	Muito mau	**5**
2.	**Precisa de ter cuidado com o que come ou bebe devido à qualidade das suas próteses?**	
a)	Não, nunca	**1**
b)	Sim, mas muito ocasionalmente	**2**
c)	Sim, por vezes	**3**
d)	Sim, quase sempre que bebo ou como	**4**
e)	Não consigo comer com as próteses na minha boca	**5**
3.	**Sente que a prótese é um corpo estranho na sua boca ou parece que está integrada na boca?**	
a)	Completamente integrada, como se fosse parte de mim	**1**
b)	Adaptei-me à prótese e não noto a sua presença	**2**
c)	Não pareço ser capaz de me adaptar à prótese apesar de a usar sempre.	**3**
d)	Não me adapto à prótese e raramente a uso	**4**
e)	Nunca uso a prótese porque não suporto a sensação	**5**
4.	**Pensa que a prótese alterou o aspeto do seu sorriso?**	
a)	Sim, muito	**1**
b)	Sim, ligeiramente	**2**
c)	Está mais ou menos semelhante	**3**
d)	Penso que está pior	**4**
e)	Está bastante pior	**5**

5.	**Evita falar com outras pessoas por causa da prótese?**	
a)	Nunca	**1**
b)	Raramente	**2**
c)	Por vezes	**3**
d)	Frequentemente	**4**
e)	Sempre	**5**
6.	**Pensa que as outras pessoas percebem que você está a usar uma prótese?**	
a)	Nunca	**1**
b)	Raramente	**2**
c)	Por vezes	**3**
d)	Frequentemente	**4**
e)	Sempre	**5**
7.	**Tenta esconder o facto de estar a usar uma prótese?**	
a)	Nunca	**1**
b)	Raramente	**2**
c)	Por vezes	**3**
d)	Frequentemente	**4**
e)	Sempre	**5**
8.	**Pensa que prestar cuidados de higiene à sua prótese é fácil?**	
a)	Muito fácil	**1**
b)	Fácil	**2**
c)	Nem fácil nem difícil	**3**
d)	Difícil	**4**
e)	Muito difícil	**5**
9.	**Sente impactação de comida como consequência da sua prótese?**	
a)	Nunca	**1**
b)	Raramente	**2**
c)	Por vezes	**3**
d)	Frequentemente	**4**
e)	Sempre	**5**

10. Sente-se à vontade com a sua prótese no que diz respeito às funções habituais da sua boca: comer, falar, sorrir?

a)	Sinto-me completamente à vontade	**1**
b)	Sinto-me relativamente à vontade	**2**
c)	Não me sinto muito mal	**3**
d)	Sinto-me um pouco desconfortável	**4**
e)	Sinto-me muito desconfortável	**5**

11. A sua prótese fá-lo sentir auto-confiante no dia-a-dia?

a)	Sim, sinto-me muito confiante	**1**
b)	Sim, sinto-me relativamente confiante	**2**
c)	Nem uma nem outra opções	**3**
d)	Nem sempre coloco a prótese porque não me sinto confiante a usá-la	**4**
e)	Raramente a coloco porque nunca me sinto confiante quando a estou a usar	**5**

12. Considera que, no último ano, a sua saúde dentária:

a)	Piorou bastante	**1**
b)	Piorou um pouco	**2**
c)	Permaneceu estável	**3**
d)	Melhorou um pouco	**4**
e)	Melhorou bastante	**5**