Thamires Diuquele da Silva

Avaliação clínica retrospectiva de próteses sobre implante com pilares UCLA calcináveis

Retrospective clinical evaluation of implant-supported prosthesis with UCLA castable abutments

Dissertação apresentada à Faculdade de Odontologia da Universidade de Uberlândia, para obtenção do Título de Mestre em Odontologia na Área de Clínica Odontológica Integrada.

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SUMÁRIO

RESUMO/PALAVRAS-CHAVE	1
ABSTRACT/KEYWORDS	2
1 INTRODUÇÃO E REFERENCIAL TEÓRICO	3
2 CAPÍTULO 1	6
REFERÊNCIAS	27
ANEXO	28

RESUMO

Estudos clínicos sobre condições protéticas e periodontais de reabilitações com próteses parciais fixas implanto-suportadas com pilar UCLA são necessários. O objetivo deste estudo foi avaliar próteses parciais fixas posteriores esplintadas sobre implantes hexágono externo (HE), com pilares UCLA totalmente calcináveis, com pelo menos 4 anos em função. A força máxima de mordida (FMM), a satisfação do paciente, o impacto da saúde bucal na qualidade de vida (OHIP-14) e a perda óssea marginal por radiografia foram avaliados. O exame clínico foi realizado verificando as condições da prótese, oclusão, tecidos periimplantares e condições do implante. A análise estatística foi realizada por meio do teste t de Student, a correlação não paramétrica de Spearman e o teste de Kaplan-Meier (=0,05). **Trinta e cinco próteses foram avaliadas em 23 pacientes (11 homens** e 12 mulheres, 41 a 90 anos) com um total de 85 implantes HE e acompanhamento de 4 a 10 anos. Os homens apresentaram valores de FMM significativamente mais elevados do que as mulheres (P=0,008). Os dados do OHIP-14 variaram de 0 a 6,64 pontos. Considerando a perda óssea marginal (média=2,3mm) e anos de prótese em função, não foi observada correlação (r=0,19, P=0,27). Durante o exame clínico, 8 parafusos soltos e 2 fraturados foram encontrados. O ponto de contato estava ausente em 22 coroas. A placa estava presente em 69 coroas. Dois implantes apresentaram perda da osseointegração e foram substituídos antes da colocação da prótese. Correlação positiva foi encontrada entre a largura da mucosa queratinizada e mucosite (r=0,313, P=0,003). A sobrevida de Kaplan-Meier estimada para próteses parciais mostrou 98,8% de sobrevida de próteses e 100% de sobrevida de implantes. Próteses posteriores esplintadas com pilares UCLA totalmente calcináveis parafusados em implantes HE são uma opção de tratamento adequada quando bem indicadas, com prevenção de hábitos parafuncionais, além de considerar a manutenção de boa higiene bucal e oclusão favorável ao longo dos anos.

PALAVRAS-CHAVE: implantes dentários, prótese parcial fixa, hexágono externo, desaperto de parafuso, pilar UCLA calcinável.

ABSTRACT

Clinical studies regarding prosthetic and periodontal conditions of rehabilitations with implant-supported fixed partial prostheses with UCLA abutment are needed. The aim of this study was to evaluate splinted posterior fixed partial prostheses on external hexagon (EH) implants, with UCLA totally castable abutments, after at least 4 years in function. The maximum bite force (MBF), patient satisfaction, the oral health impact in quality of life (OHIP-14) and marginal bone loss by radiography were evaluated. The clinical exam was performed by checking the prosthesis conditions, occlusion, periimplant tissues and implant conditions. Statistical analysis was made with Student t-test, Spearman nonparametric correlation and Kaplan–Meier estimator (=.05). Thirty-five prostheses were evaluated in 23 patients (11 men and 12 women, 41 to 90 years) with a total of 85 EH implants and follow-up of 4 to 10 years. Men presented significantly higher MBF values than women (*P*=.008). The data of OHIP-14 ranged from 0 to 6.64 points. Considering marginal bone loss (mean=2.3mm) and years of prosthesis in function, no correlation was observed (r=0.19, *P*=.27). During the clinical examination, 8 loosened and 2 fractured screws were found. The contact point was absent in 22 crowns. The plaque was present in 69 crowns. Two implants presented loss of osseointegration and were replaced before prosthesis placement. A positive correlation was found between width of keratinized mucosa and mucositis (r=0.313, *P*=.003). The estimated Kaplan-Meier survival rate for partial prosthesis showed 98.8% prosthesis survival and 100% implant survival. Splinted posterior prostheses with UCLA totally castable abutments screwed on EH implants are a suitable treatment option when well indicated, with prevention of parafunctional habits, besides considering the maintenance of good oral hygiene and a favorable occlusion over the years.

KEYWORDS: dental implants, fixed partial dentures, external hexagon, screw loosening, UCLA castable abutments.

1. INTRODUÇÃO E REFERENCIAL TEÓRICO

O sistema de implantes Brånemark foi introduzido na América do Norte em 1980 para reabilitações de pacientes edêntulos totais (Lewis et al., 1992). Esta reabilitação foi chamada de protocolo devido a uma série de passos cirúrgicos e protéticos a serem executados até a instalação da prótese (Brånemark & Albrektsson, 1985). A prótese fixada por parafusos foi classificada como prótese segmentada pois utilizavam-**se pilares padronizados chamados "Standard", os quais apresentavam cinta** padrão de 3 mm, fato aceitável pelo padrão de reabsorção dos pacientes edêntulos totais chamados de inválidos orais. Após o sucesso desta reabilitação para arcos totais era evidente que pacientes parcialmente desdentados poderiam ser beneficiados com a técnica, porém pelo padrão de reabsorção mínima decorrente da perda de poucos dentes, o uso destes pilares tornou-se difícil ou impossível, devido à limitação de espaço interoclusal e exigência estética do paciente não satisfeito com a exposição da cinta metálica localizada supragengival.

Por esta razão, os pilares foram modificados com o tempo apresentando uma variação de altura de cinta metálica e da conicidade (EstethiCone, MirusCone) (Binon, 2000). Apesar disso, os pilares com reduzidas dimensões ainda apresentavam limitações em espaços interoclusais reduzidos e/ou em locais que existia a ausência de altura gengival na vestibular, que prejudicaria a estética. Desta forma, o conceito de restauração parafusada diretamente no implante, prótese não segmentada, foi desenvolvido em 1988, por Lewis e colaboradores, sem utilizar pilares em titânio. Para isso cilindros plásticos calcináveis, denominado pilar UCLA, foram desenvolvidos para serem aparafusados no interior do implante da mesma forma que os parafusos dos pilares convencionais. Estes cilindros são utilizados como matriz de enceramento e fundição, o que permite uma configuração especial na sua porção cervical para a aplicação da cerâmica. Nestes casos a adaptação das próteses eram obtidas manualmente pelo protético, apresentando limitação apesar da técnica orientada pelos desenvolvedores (Byrne et al., 1998).

O UCLA originalmente foi desenvolvido para próteses fixas múltiplas apresentando a área interna de assentamento da prótese circular, sem um hexágono para

se encaixar no hexágono do implante, classificado com rotacional (Lewis et al., 1988). Com a porção interna lisa do UCLA, os autores recomendaram que a parte interna do pilar também fosse encerada criando o mecanismo antirrotacional, necessário para próteses unitárias (Mito et al., 1989). Devido à sua vasta aplicabilidade, baixo custo e fácil manuseio, este pilar é ainda amplamente utilizado para reabilitar casos de perdas totais, parciais e unitárias (Neves et al., 2016).

Apesar das altas taxas de sucesso da osseointegração, falhas com restaurações sobre implante estão normalmente relacionadas com o afrouxamento do parafuso, sendo assim uma complicação técnica comum que se não resolvida pode evoluir para fratura do parafuso de fixação da prótese, fratura do implante, como também para a quebra da hemostasia peri-implantar (Renouard & Rangert, 2008; Quirynen et al., 1994). O afrouxamento acontece por adaptação inadequada da prótese, seja por moldagem incorreta do posicionamento do implante, limitação técnica do laboratório e/ou sobrecarga oclusal (Delben et al., 2014). Para solucionar a limitação técnica da adaptação do pilar após fundição em laboratório, as empresas iniciaram a confecção de UCLAs com base pré-fabricada de metal para otimizar a adaptação e a estabilidade da reabilitação fixada diretamente no implante. Os pilares UCLA com base pré-fabricada para sobrefundição apresentam superfícies regulares e melhor manutenção do torque do que os cilindros calcináveis em que a adaptação é feita manualmente no laboratório após fundição (Kano et al., 2006; Bhering et al., 2013). Apesar desta opção, um estudo clínico randomizado demonstrou que não houve diferença significativa entre pilares tipo UCLA calcinável ou com cinta metálica pré-fabricada, quanto ao desaperto do parafuso de pilar (Bhering et al., 2013).

Além do sucesso mecânico da prótese, a relação do tecido ósseo com o implante também é alvo de investigação e é considerado sucesso quando os implantes osseointegrados apresentarem imóveis, ao exame radiográfico não mostrar nenhuma evidência de radiolucidez e se a perda óssea vertical for menor que 1,5 mm no primeiro ano e 0,2 mm em cada ano seguinte em função. Além disso, devem apresentar ausência de dor ou de parestesia e neuropatias, como também integridade do canal mandibular (Albrektsson et al., 1986). Contudo, os implantes analisados por esses critérios deverão obter 85% de sucesso após cinco anos e 80% de sucesso após dez anos em função. Assim, estudos longitudinais com avaliação clínica e radiográfica podem dar

informações relevantes para pautar a prática odontológica diária. Além destes fatores, é importante que haja satisfação por parte do paciente, em relação à estabilidade, conforto e duração do trabalho.

Tendo em vista o grande número de cirurgiões-dentistas que utilizaram e ainda utilizam este tipo de prótese não segmentada, é de extrema importância estudar seu comportamento clínico a longo prazo para assim orientar melhor quanto às indicações, taxas de sucesso e sobrevivência, podendo definir protocolos para evitar possíveis falhas. Desta forma, pretende-se avaliar o comportamento clínico das próteses parciais fixas posteriores sobre implantes hexágono externo (HE), com pilares UCLA totalmente calcináveis, com pelo menos 4 anos em função.

2. CAPÍTULO 1

Retrospective clinical evaluation of implant-supported prosthesis with UCLA castable abutments

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ABSTRACT

Statement of problem. Clinical studies regarding prosthetic and periodontal conditions of implant-supported fixed partial prostheses with UCLA abutment are needed. **Purpose.** The aim of this study was to evaluate splinted posterior fixed partial prostheses on external hexagon (EH) implants, with UCLA totally castable abutments, after at least 4 years in function.

Material and methods. The maximum bite force (MBF), patient satisfaction, oral health impact profile questionnaire (OHIP-14) and marginal bone loss by radiography were evaluated. The clinical exam was performed by checking the prosthesis conditions, occlusion, periimplant tissues and implant conditions. Student t-test, Spearman nonparametric correlation and Kaplan–Meier estimator were used (=.05).

Results. Thirty-five prostheses were evaluated in 23 patients (11 men and 12 women, 41 to 90 years) with a total of 85 EH implants and follow-up of 4 to 10 years. Men presented significantly higher MBF values than women (*P*=.008). The data of OHIP-14 ranged from 0 to 6.64 points. Considering marginal bone loss (mean=2.3mm) and years of prosthesis in function, no correlation was observed (r=0.19, *P*=.27). During the clinical examination, 8 loosened and 2 fractured screws were found. The contact point was absent in 22 crowns. The plaque was present in 69 crowns. Two implants presented loss of osseointegration and were replaced before prosthesis placement. A positive correlation was found between width of keratinized mucosa and mucositis (r=0.313, *P*=.003). The estimated Kaplan-Meier survival rate for partial prosthesis showed 98.8% prosthesis survival rates and 100% implant survival.

Conclusions. Splinted posterior prostheses with UCLA totally castable abutments screwed on EH implants are a suitable treatment option when well indicated, with prevention of parafunctional habits, besides considering the maintenance of good oral hygiene and a favorable occlusion over the years.

Clinical Implications

Clinicians should perform more frequent assessments for the maintenance of good oral hygiene and favorable occlusion of patients rehabilitated with implant-supported fixed partial prostheses with UCLA abutment.

INTRODUCTION

Oral rehabilitation with osseointegrated implants is the main choice to reestablish the masticatory function and aesthetic of partial edentulous patients (Naert et al., 2002a; Naert et al., 2002b; Goiato et al., 2011). Initially, the standard abutments developed by Brånemark System were used to rehabilitate completely and partially edentulous patients (Lekholm et al., 1994). Although standard abutments were routinely used at the past years, several improvements in the original treatment concept were necessary for partial prosthesis, as conical abutments with different sizes of metal base (Binon, 2000). To solve problems related to superficial implants that compromise esthetics, without adequate prosthetic space available and insufficient interproximal distance, the abutment UCLA (Universal Cast to Long Abutment) was developed (Lewis et al., 1988; Lewis et al., 1992).

The UCLA abutments can be totally castable or present premachined metal base, and after casting they are screwed directly to the implant platform. Screwed implant-supported prostheses are reversible, facilitating removal for component replacement, ceramic repair or prosthesis cleaning, besides presenting predictability of retention by the mechanical action of the torque on the abutment screw (Shadid & Sadaqa, 2012). However, problems such as screw loosening or fracture, bone loss around the implant, mucositis or peri-implantitis, may occur when it is not indicated to use UCLA abutments, or the prosthesis was not correctly planned or made (Gracis et al., 2012; Kreissl et al., 2007; Montero et al., 2012).

Implants with the external hexagon (EH) connection when associated with the UCLA abutment have demonstrated high rates of screw loosening and fractures, since only the abutment screw is responsible for maintaining the stability of the connection at the implant-abutment interface (Gracis et al., 2012; Camargos et al., 2012; Pessoa et al., 2010; Montero et al., 2012). In this regard, loosening abutment screws is more frequent in prostheses retained with titanium screws than with gold or surface-treated screws (Camargos et al., 2012), which decrease the coefficient of friction between the threads and increase the preload of the screwed joint (Martin et al., 2001; Tan & Nicholls, 2001; Siamos et al., 2002). To reduce complications, the use of splinted prosthesis with two or more adjacent implants, increases the success rate of the rehabilitation using UCLA

components because of better stress distribution during the application of masticatory loads (Rangert et al., 1995; Mendonça et al., 2014).

Due to the high temperatures required for the fabrication of metal-ceramic / all ceramic prostheses, it was reported higher misfit in UCLA totally castable abutments subjected to ceramic firing cycles than in pre-machined abutments (Byrne et al., 1998). This vertical misfit promotes plaque accumulation and stress concentration in the abutment screw (Barbosa et al., 2007). In addition, other conditions may also increase the stress on this screw, such as distorted impression of the actual implant positioning, wrong component planning, and occlusal overloading (Byrne et al., 1998).

Several experimental studies evaluating different aspects of UCLA rehabilitation can be found in the literature, but few clinical studies report the performance of posterior partial prostheses with UCLA, on the longitudinal success of rehabilitation (Kreissl et al., 2007; Montero et al., 2012). It is important to assess partial prosthetic rehabilitations with UCLA abutment to report biological responses and prosthetic performance with incidence of most common technical problems. Therefore, the aim of this study was to evaluate splinted posterior fixed partial prostheses on EH implants, with UCLA totally castable abutments, after at least 4 years in function, and to verify the possible factors influencing the survival and success rates of these rehabilitations. The null hypothesis was that no complications were presented at rehabilitation with splinted posterior fixed partial prostheses on external hexagon (EH) implants, with UCLA totally castable abutments.

MATERIAL AND METHODS

This retrospective cohort study was carried out in patients rehabilitated between 2007 and 2014 at the private clinic INPES (Institute of Education in Research and Health) in Uberlandia-MG, Brazil. This study was approved by the Ethics Committee of the Federal University of Uberlandia (CAAE 63911616.9.0000.5152). Patients who agreed to participate in the study, signed the Free and Informed Consent Term, after receiving explanations about each step of the procedures to be performed.

Inclusion criteria were: patient in good general health, implants installed *AD MODUM* Brånemark (Brånemark & Albrektsson, 1985), splinted posterior fixed partial prosthesis with UCLA abutment over 2, 3 or 4 external hexagon implants (SIN, São

Paulo, SP, Brazil), at least 4 years in function. Exclusion criteria were: patients who did not present data in clinical records, patients with local or systemic diseases that compromised clinical analysis.

The patients were selected at the private clinic INPES based on the analysis of dental records. After that the inclusion and exclusion criteria were analyzed, and the patients were called for the clinical evaluations considering USPHS criteria, radiographic analysis, patient satisfaction and maximum bite force.

Clinical evaluations

All clinical exams were performed by the same professional and the results recorded by the assistant.

The clinical parameters evaluated were:

Prosthetic complications: The metal-ceramic implant-supported prosthesis were examined using a modified United States Public Health Service (USPHS) criteria (Table 1) (Cvar & Ryge, 2005; Sailer et al., 2018). The following findings were recorded: framework fracture, chipping or fracture of the veneering ceramic, occlusal wear of the veneering ceramic, marginal fit and anatomical shape of the prosthesis. All parameters were rated Alfa (A) in case of no complications, Bravo (B) in case of minor complications, Charlie (C) if the complications were major and Delta (D) if new reconstruction was needed. Also, screw loosening or fracture and the number of times the patient needed care for the resolution of complications after the installation of the prostheses was recorded.

Occlusal evaluation: the following findings were recorded: 1- favorable; 2- class III of Angle (Angle, 1899); 3- class II of Angle (1899); 4- crossbite; 5- top bite; 6- open bite; 7- absence of anterior guide; 8- premature contact; 9- absence of interproximal contact point; 10- parafunctional habits; 11- unfavorable occlusal table; 12- absence of posterior stability by the absence of antagonist; 13- overjet (Gross, 2008).

Biological evaluation of peri-implant tissues:

- Periimplant plaque index: plaque adhering to the abutments for each implant, quantified according to the scale: 1 = absence of plaque in the gingival area; 2 = presence of plaque (Silness & Löe, 1964).

- Width of keratinized mucosa: after drying the mucosa lightly, the keratinized mucosa was measured with a periodontal probe and measured according to scale: 1 = without keratinized mucosa; 2 = 1 mm or less; 3 = between 1 and 2 mm; and 4 = greater than 2 mm of keratinized mucosa (Löe & Silness, 1963).

- Probing depth (PD): the four regions were measured in millimeters with a periodontal probe in each implant: mesial, distal, buccal and lingual (Esposito et al., 1998).

- Marginal bleeding index: observed after passing a periodontal probe around the marginal gingiva adjacent to the implant. It was evaluated according to the scale: 0 = no bleeding; 1 = spot bleeding; 2 = linear bleeding and 3 = spontaneous bleeding (Mombelli et al., 1987).

- Implant conditions: 1 = implant in function; 2 = implant in function, but with mobility; 3 = missing implant; 4 = buried implant; 5 = loss of osseointegration (repeat implant) (Smith et al., 1989).

- Implant pain or discomfort: 1 = no pain; 2 = 1 implant with pain; 3 = 2 implants with pain and 4 = 3 implants with pain (Esposito et al., 1998).

- Mucositis: 1= absence of mucositis; 2= presence of mucositis.

Radiographic analysis

Marginal bone loss was evaluated in digital periapical radiographs of the areas involved using radiographic positioner to maintain the parallelism and the same digital apparatus (Schick CDR Elite, Schick Technologies, EUA). To compensate for possible blurring at the implant threads and to guarantee the quality of the radiographic image to evaluate bone loss, the method suggested by Schropp et al. (2012) was used. All images were sent to a computer and evaluated in an image processing software (ImageJ, US National Institutes of Health, Bethesda, USA) to evaluate marginal fit and measurement of vertical bone loss. The software was calibrated on each radiography using the known measurement of the diameter of the implant platform. Measurements of mesial and distal vertical bone loss were performed parallel to the long axis of the implant, with a resolution of 0.01 mm, and the means of each prosthesis were obtained. It was considered that all implants were installed *AD MODUM* Brånemark (Brånemark & Albrektsson, 1985), placement of the implant at the bone crest level, and the reference

points were the upper margin of the implant platform and the first bone-implant contact. All measurements were performed by the same investigator.

Patient satisfaction

Each patient was asked to assign a score of 0 to 10, based on their satisfaction with the treatment received, 10 fully satisfied and 0 absolutely dissatisfied. Also, the patient should explain the score assigned.

OHIP-14

The 14 item Oral Health Impact Profile questionnaire (OHIP-14) was used to determine the impact of oral problems on quality of life and self-perceived oral health of patients after treatment. The patient perceptions through the answers corresponded to codes of a Likert scale model: 0 = "never", 1 = "hardly ever", 2 = "occasionally", 3 = "fairly often" and 4 = "very often" (Slade, 1997). The following specific weight of each question was multiplied by the answer (0 to 4): 1- 0.51, 2- 0.49, 3- 0.34, 4- 0.66, 5-0.45, 6-0.55, 7- 0.52, 8- 0.48, 9- 0.60, 10- 0.40, 11- 0.62, 12- 0.38, 13- 0.59, 14- 0.41. The sum of the scores can be recorded between 0 and 28 points. The lowest scores represented a higher satisfactory individual's perception on oral health-related quality of life (OHRQoL).

Maximum Bite Force Test

The maximum bite force (MBF) was performed using a gnathodynamometer (digital dynamometer, IDDK model, Kratos, Bauru, SP, Brazil) measured in the first molar region. During the test, patients remained seated in a chair with their feet flat on the floor and their head parallel to the horizontal plane. The patient was oriented to bite at its maximum force and then release, repeating this by 25 times divided into 5 sets of 5 bites on each side, and the force evaluated in Newtons (N). The first set of 5 bites was excluded for patient adaptation with the test, thus obtaining 4 sets with 5 bites, where the sum of all data was performed, and the mean obtained for each side.

Statistical analysis

Survival and success probabilities was estimated with the Kaplan-Meier estimator. Descriptive statistics was used to present data of all analyzed parameters.

Values of maximum bite force were logarithmically transformed to improve normality. Student t-test was used to compare sex and sides.

The Spearman nonparametric correlation between marginal bone loss, mucositis, width of keratinized mucosa, plaque, screw loosening, interproximal contact point, occlusion and parafunctional habits was calculated for each implant.

All statistical analyses were performed using SPSS 20.0 (SPSS for Windows 20.0 Statistical Package, Chicago, IL, USA) with statistical significance at =.05.

RESULTS

The patients were selected based on the dental records. Ninety patients were selected and called for clinical evaluation. After setting the appointments, 26 patients were evaluated and 3 were excluded because they did not meet the inclusion criteria.

Thirty-five prostheses were evaluated in 23 patients (11 men and 12 women, 41 to 90 years, mean= 61 years) with a total of 85 external hexagon implants and follow-up of 4 to 10 years (Table 2). Patients were rehabilitated with 2-, 3- or 4-unit implant-supported fixed partial prothesis. In this research, 21 prostheses with 2 implants, 13 prostheses with 3 implants and 1 prosthesis with 4 implants were evaluated.

The estimated Kaplan-Meier survival rate for partial prosthesis was 98.8%, 97.6% of the implants survived before the prosthesis and 100% of the implants survived after the prosthesis. The implant success was 80% considering probing depth and marginal bleeding.

Clinical evaluations

The Modified United States Public Health Service (USPHS) criteria results are presented in Table 3. During the clinical examination, 8 loosened and 2 fractured screws were found. Also, the contact point was absent in 22 crowns (Table 4).

The plaque was present in 69 crowns and only 16 crowns were absent from plaque. The keratinized mucosa in 41 crowns was considered thin or absent. At the

mucosa around 20 implants was found mucositis. The depth of probing in 6 implants was between 3 and 5mm. Spot bleeding was found in 33 implants, linear bleeding in 15 implants and spontaneous bleeding in 3 implants. Before prosthesis placement, two implants lost osseointegration and were replaced. No pain or discomfort was found at the implants.

A positive correlation was found between width of keratinized mucosa and mucositis (r=0.313, *P*=.003). There was no correlation between marginal bone loss, plaque index or screw loosening with any of the following parameters: width of keratinized mucosa, mucositis, contact point, parafunctional habits or occlusion. A positive correlation was found between contact point and occlusion (r=0.677, *P*<.001), and parafunctional habits and occlusion (r=0.465, *P*<.001).

Radiographic analysis

The mean values of marginal bone loss of each prosthesis are presented in Table 5. The overall mean marginal bone loss was 2.3mm, with a mean implant bone loss ranging from 1.1 to 5.8mm. Considering marginal bone loss and years of prosthesis in function, no correlation was observed (r=0.19, *P*=.27) (Figure 1).

Patient satisfaction

Based on a 10-point scale, the mean value of patient satisfaction with evaluated prosthesis was 9 (±2.2). Twenty patients were very satisfied with the implant treatment received and 3 reported difficulty to maintain hygiene.

OHIP-14

The data of OHIP-14 ranged from 0 to 6.64 points, with 14 patients with 0-point value and 9 patients with values between 0.34 and 6.64 points.

Maximum Bite Force Test

The mean values of MBF are presented in Table 6 and were from 50.3N to 417.2N, with 4 patients with mean values below 100N. Men presented significantly

higher MBF values than women (*P*=.008). In all patients there was a stronger side, but without significant differences (women *P*=.80, men *P*=.68) (Table 6).

DISCUSSION

The null hypothesis was rejected because complications were found at rehabilitation with splinted posterior fixed partial prostheses on external hexagon (EH) implants, with UCLA totally castable abutments. Partial fixed prostheses over implants showed 98.8% prosthesis survival rates, 100% implant survival but 80% implant success, when considering probing depth and marginal bleeding, up to 10 years in function. The different types of implants and prostheses can influence these rates over the years (Naert et al., 2002a; Naert et al., 2002b; Krennmair et al., 2002; Berglundh et al., 2002, Brägger et al., 2005; Papaspyridakos et al., 2012). This retrospective clinical research was proposed because few studies have assessed fixed partial prostheses with UCLA abutments more than 5 years in function (Pjetursson et al., 2004; Kreissl et al., 2007; Montero et al., 2012).

In the present research, the screw loosening was found in 9.4% of the crowns evaluated, as shown in Table 6. The two fractured screws were of the same prosthesis in which the patient had parafunctional habits and absence of contact point. The screw loosening or fracture can cause extra chair-side time and patient dissatisfaction (Kreissl et al., 2007), and is the most frequent complication reported, since only the abutment screw is responsible for maintaining the stability of the connection at the implant-abutment interface (Gracis et al., 2012; Camargos et al., 2012). The effectiveness of the prostheses made with UCLA is related to the technique of making the prosthesis, the planning of the implant installation position and the maintenance of a favorable occlusion. Error in impression of the implant real positioning, component planning error, and occlusal overload may lead to loosening or fracture of the abutment screw within the implant, which is a complex resolution problem (Byrne et al., 1998).

The reversibility of screwed prostheses makes it possible to remove the prosthesis when maintenance is necessary, and the predictability of screw retention is another advantage that, by means of torque, maintains the abutment adapted to the implant platform, requiring no subgingival cement removal (Goiato et al., 2011). One of the components indicated for screwed prostheses is the UCLA abutment. However, the

correct indication is one of those responsible for maintaining the harmony of the biomechanical system. Oral rehabilitations with superficial implants that compromise esthetics, diminished prosthetic space, with an interocclusal space of at least 4.5 mm, and insufficient interproximal distance may present satisfactory results when rehabilitated with UCLA (Lewis et al., 1988).

The success of a treatment should consider the patient's perception with its result. The oral health impact profile questionnaire (OHIP-14) was developed with the aim of providing a measure of self-reported physical and psychological dysfunction and discomfort attributed to oral health status in quality of life (Slade, 1997; Paul et al., 2018). In the present study, the scores obtained were closer to 0, with a total mean of 0.86 points, whereas one patient had physical pain and psychological discomfort, with a score of 6.64. Additionally, patient satisfaction with the treatment should be considered for the success results. The mean value of 9 based on a 10-point scale showed that the patients were very satisfied with the treatment. Three patients reported difficulty to maintain hygiene.

Vertical misfit between abutment and implant promotes bacterial leakage and increases screw stress, causing screw loosening or fracture, which may lead to fracture of the implant if the problem is not solved (Tagger Green et al., 2002). Larger mismatches are found on UCLA abutments that are castable and subjected to ceramic firing cycles than on premachined abutments, which remain intact after the casting process (Byrne et al., 1998). However, the steps of waxing, embedding and casting may induce distortions in the final rehabilitation, without affecting the premachined metal base, increasing imprecision and prosthetic complications (de França et al., 2017). In this research was found vertical misfit radiographically between abutment and implant in one crown, which can be solved with separation of the abutment infrastructure and welding procedure.

The implant should be evaluated for its success only after being placed under functional load. Implants that present changes in the mucosa, but the surrounding bone does not present changes should not be included as a failure, only as a complication (Smith & Zarb, 1989). The indices evaluated in this study, referring to the peri-implant tissues, showed that plaque was presented in 69 crowns. This may be related to the difficulty of sanitizing splinted prostheses.

The maintenance of a favorable occlusion is another important factor to avoid mechanical complications with the prostheses. The absence of contact point and occlusal wear can generate overload, as well as the parafunctional habits of tightening and teeth grinding and absence of teeth on the opposite side and can result in the loosening or fracture of screws, more frequent in the first year of function (Nedir et al., 2006). Table 3 showed the maximum bite force results, with significant difference between men and women. The absence of contact points was registered in 22 crowns, which can be explained by the physiological movement of the teeth while the implants remain in the place of installation (das Neves et al., 2012). Besides that, a positive correlation was found between contact point and occlusion, and parafunctional habits and occlusion ($P<.001$).

In splinted prostheses, 3 contiguous implants are more favorable compared to 2 implants. The formation of a polygon instead of a straight line provides greater stability and raises the success rate of the rehabilitation due to the stress distribution on the screws of the splinted prosthesis during the application of masticatory loads (Rangert et al., 1995; Mendonça et al, 2014).

Loosened screws lead to the movement of the components and biofilm accumulation at the implant-abutment interface, which can cause mucositis and consequently peri-implantitis with bone loss (Berglundh et al., 2018). The marginal bone loss around implants is attributed to microorganisms and biomechanical overload (Salcetti et al., 1997; Engel et al., 2001). Implants that are in the process of failure present progressive bone loss, peri-implant infection and implant without mobility. Radiographs should be used to evaluate bone loss but should be associated with clinical exams for diagnosis (Esposito et al., 1998; Pessoa et al., 2017). The greatest bone losses were found in implants rehabilitated for more than 7 years and presented unfavorable occlusion. Table 4 presented the mean bone loss, which showed a mean above 3mm in 15.7% of the implants.

Increased probing depth may be related to peri-implant mucosal inflammation, and not necessarily to bone loss. The use of UCLA abutments in implants with peri-implant sulcus depth greater than 2mm is not indicated. The patients did not present pain or discomfort in the implants when the clinical evaluation was performed. Only

one patient with 2 implants presented loss of osseointegration and it had already been replaced before the prosthesis was installed.

The limitation of this research was that not all patients were evaluated and may impact the results. The location of the implant, maxilla or mandible, can be an important variable in the success of the rehabilitation, due to the difference in bone quality. Although the frequency of implant fractures is low, treatment planning should be directed at preventing occlusal overload and subsequent loosening screw or fracture, indicating the use of occlusal splint in patients with parafunctional habits. It is also suggested the prosthesis accuracy, to ensure the passive fit on the implants, adequate torque on the screws, reduction in size of the crowns, flattened cusps, centralized occlusal contacts on the implants and correct number, diameter and length of the implants to rehabilitate partial edentulous patients.

CONCLUSIONS

Within the limitations of this study, the following conclusions were drawn:

1. Splinted posterior fixed partial prostheses with UCLA totally castable abutments screwed on EH implants are a suitable treatment option when well indicated.
2. Loosening or fracturing of retaining screw should be resolved in the shortest time to avoid inconvenience to the patient and biofilm accumulation at the implant-abutment interface, which can cause mucositis and bone loss.
3. The maintenance of good oral hygiene and a favorable occlusion over the years and the prevention of parafunctional habits may influence the survival and success rates of these rehabilitations.

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REFERENCES

1. Naert I, Koutsikakis G, Duyck J, Quirynen M, Jacobs R, van Steenberghe D. Biologic outcome of implant-supported restorations in the treatment of partial edentulism. Part I: a longitudinal clinical evaluation. Clin Oral Implants Res 2002;13:381-9. https://doi.org/10.1034/j.1600-0501.2002.130406.x
2. Naert I, Koutsikakis G, Quirynen M, Duyck J, van Steenberghe D, Jacobs R. Biologic outcome of implant-supported restorations in the treatment of partial edentulism. Part 2: a longitudinal radiographic study. Clin Oral Implants Res 2002;13:390-5. https://doi.org/10.1034/j.1600-0501.2002.130407.x
3. Goiato MC, Pesqueira AA, dos Santos DM, Haddad MF, Moreno A, Bannwart LC. Oral rehabilitation with implantations: association of fixed partial prosthesis, UCLA system, and EsthetiCone. J Craniofac Surg. 2011 Jan;22(1):155-8. https://doi.org/10.1097/SCS.0b013e3181f6f9ea
4. Lekholm U, van Steenberghe D, Herrmann I, Bolender C, Folmer T, Gunne J, et al. Osseointegrated implants in the treatment of partially edentulous jaws. A prospective 5-year multicenter study. Int J Oral Maxillofac Implants 1994;9:627–635.
5. Binon PP. Implants and components: entering the new millennium. Int J Oral Maxillofac Implants 2000;15(1):76-94.
6. Lewis S, Beumer J, Hornburg W, Moy P. The "UCLA" abutment. Int J Oral Maxillofac Implants 1988;3(3):183-9.
7. Lewis SG, Llamas D, Avera S. The UCLA abutment: a four year review. J Prosthet Dent 1992;67:509-515. https://doi.org/10.1016/0022-3913(92)90082-L
8. Shadid R, Sadaqa N. A comparison between screw- and cement-retained implant prostheses. A literature review. J Oral Implantol. 2012 Jun;38(3):298-307. https://doi.org/10.1563/AAID-JOI-D-10-00146
9. Gracis S, Michalakis K, Vigolo P, Vult von Steyern P, Zwahlen M, Sailer I. Internal vs. external connections for abutments/reconstructions: a systematic review. Clin Oral Implants Res. 2012 Oct;23 Suppl 6:202-16. https://doi.org/10.1111/j.1600-0501.2012.02556.x
10. Kreissl ME, Gerds T, Muche R, Heydecke G, Strub JR. Technical complications of implant-supported fixed partial dentures in partially edentulous cases after an average observation period of 5 years. Clin Oral Implants Res. 2007 Dec;18(6):720-6. https://doi.org/10.1111/j.1600-0501.2007.01414.x

11. Montero J, Manzano G, Beltrán D, Lynch CD, Suárez-García MJ, Castillo-Oyagüe R. Clinical evaluation of the incidence of prosthetic complications in implant crowns constructed with UCLA castable abutments. A cohort follow-up study. J Dent. 2012 Dec;40(12):1081-9. https://doi.org/10.1016/j.jdent.2012.09.001
12. Camargos GV, Prado CJ, Neves FD, Sartori IAM. Clinical Outcomes of Single Dental Implants with External Connections: Results After 2 to 13 Years. The International Journal of Oral & Maxillofacial Implants 935- 44, 27, 4, 2012.
13. Pessoa RS, Muraru L, Júnior EM, Vaz LG, Sloten JV, Duyck J, Jaecques SV. Influence of implant connection type on the biomechanical environment of immediately placed implants - CT-based nonlinear, three-dimensional finite element analysis. Clin Implant Dent Relat Res. 2010 Sep;12(3):219-34. https://doi.org/10.1111/j.1708-8208.2009.00155.x
14. Martin WC, Woody RD, Miller BH, Miller AW. Implant abutment screw rotations and preloads for four di erent screw materials and surfaces. J Prosthet Dent 2001;86:24-32. https://doi.org/10.1067/mpr.2001.116230
15. Tan KB, Nicholls JI. Implant-abutment screw joint preload of 7 hex-top abutment systems. Int J Oral Maxillofac Implants 2001;16:367–377.
16. Siamos G, Winkler S, Boberick KG. Relationship between implant preload and screw loosening on implant-supported prostheses. J Oral Implantol 2002;28:67– 73. https://doi.org/10.1563/1548-1336(2002)028<0067:TRBIPA>2.3.CO;2
17. Rangert B, Krogh PH, Langer B, Van Roekel N. Bending overload and implant fracture: a retrospective clinical analysis. Int J Oral Maxillofac Implants 1995;10:326-34.
18. Mendonça JA, Francischone CE, Senna PM, Matos de Oliveira AE, Sotto-Maior BS. A retrospective evaluation of the survival rates of splinted and non-splinted short dental implants in posterior partially edentulous jaws. J Periodontol. 2014;85(6):787-94.
19. Byrne D, Houston F, Cleary R, Claffey N. The fit of cast and premachined implant abutments. J Prosthet Dent. 1998;80:184–192. https://doi.org/10.1016/S0022-3913(98)70108-8
20. Barbosa GA, Simamoto Júnior PC, Fernandes Neto AJ, de Mattos Mda G, Neves FD. Prosthetic laboratory influence on the vertical misfit at the implant/UCLA abutment interface. Braz Dent J. 2007;18(2):139-43. https://doi.org/10.1590/S0103-64402007000200010

21. Brånemark PI, Albrektsson T. Tissue integrated prostheses. Osseointegration in clinical dentistry. Chicago: Quintessence books; 1985.
22. Cvar JF, Ryge G. Reprint of criteria for the clinical evaluation of dental restorative materials. 1971. Clin Oral Investig. 2005 Dec;9(4):215-32. https://doi.org/10.1007/s00784-005-0018-z
23. Sailer I, Balmer M, Hüsler J, Hämmerle CHF, Känel S, Thoma DS. 10-year randomized trial (RCT) of zirconia-ceramic and metal-ceramic fixed dental prostheses. J Dent. 2018 May 25. [Epub ahead of print]. https://doi.org/10.1016/j.jdent.2018.05.015
24. Angle EH. Classification of malocclusion. Dental Cosmos. 1899.
25. Gross MD. Occlusion in implant dentistry. A review of the literature of prosthetic determinants and current concepts. Aust Dent J. 2008 Jun;53 Suppl 1:S60-8. https://doi.org/10.1111/j.1834-7819.2008.00043.x
26. Silness J, Löe H. Periodontal disease in pregnancy II. Correlation between oral hygiene and periodontal condition. Acta odontologica scandinavica, v. 22, n. 1, p. 121-135, 1964. https://doi.org/10.3109/00016356408993968
27. Löe H, Silness J. Periodontal Disease in Pregnancy. I. Prevalence and Severity. Acta Odontol Scand 1963;21:533-51. https://doi.org/10.3109/00016356309011240
28. Esposito M, Hirsch JM, Lekholm U, Thomsen P. Biological factors contributing to failures of osseointegrated oral implants. (II). Etiopathogenesis. Eur J Oral Sci 1998;106(3):721-64. https://doi.org/10.1046/j.0909-8836..t01-6-.x
29. Mombelli A, Van Oosten MAC, Schürch E, Lang NP. The microbiota associated with successful or failing osseointegrated titanium implants. Oral Microbiol Immunol 1987;2:145-51. https://doi.org/10.1111/j.1399-302X.1987.tb00298.x
30. Smith D, Zarb GA. Criteria for success of osseointegrated endosseous implants. J Prosthet Dent 1989;62(5)567-72. https://doi.org/10.1016/0022-3913(89)90081-4
31. Schropp L, Stavropoulos A, Spin-Neto R, Wenzel A. Evaluation of the RB-RB/LB-LB mnemonic rule for recording optimally projected intraoral images of dental implants: an in vitro study. Dentomaxillofac Radiol 2012; 41:298–304. https://doi.org/10.1259/dmfr/20861598
32. Slade GD. Derivation and validation of a shortform oral health impact profile. Community Dent Oral Epidemiol 1997; 25:284-90. https://doi.org/10.1111/j.1600-0528.1997.tb00941.x

33. Krennmair G, Schmidinger S, Waldenberger O. Single-tooth replacement with the Frialit-2 system: a retrospective clinical analysis of 146 implants. Int J Oral Maxillofac Implants. 2002 Jan-Feb;17(1):78-85

34. Berglundh T, Persson L, Klinge B. A systematic review of the incidence of biological and technical complications in implant dentistry reported in prospective longitudinal studies of at least 5 years. J Clin Periodontol. 2002;29 Suppl 3:197-212. https://doi.org/10.1034/j.1600-051X.29.s3.12.x

35. Brägger U, Karoussis I, Persson R, Pjetursson B, Salvi G, Lang N. Technical and biological complications/failures with single crowns and fixed partial dentures on implants: a 10-year prospective cohort study. Clin Oral Implants Res. 2005;16(3):326-34. https://doi.org/10.1111/j.1600-0501.2005.01105.x

36. Papaspyridakos P, Chen CJ, Chuang SK, Weber HP, Gallucci GO. A systematic review of biologic and technical complications with fixed implant rehabilitations for edentulous patients. Int J Oral Maxillofac Implants. 2012;27(1):102-10.

37. 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 at least 5 years. Clin Oral Implants Res. 2004;15(6):625-42. https://doi.org/10.1111/j.1600-0501.2004.01117.x

38. Paul SA, Simon SS, Kumar S, Chacko RK. Assessing perceptions of oral health related quality of life in dental implant patients. Experience of a tertiary care center in India. J Oral Biol Craniofac Res. 2018 May-Aug;8(2):74-77. https://doi.org/10.1016/j.jobcr.2018.05.003

39. Tagger Green N, Machtei EE, Horwitz J, Peled M. Fracture of dental implants: literature review and report of a case. Implant Dent 2002;11:137-43. https://doi.org/10.1097/00008505-200204000-00014

40. de França DG, Morais MH, das Neves FD, Carreiro AF, Barbosa GA. Precision Fit of Screw-Retained Implant-Supported Fixed Dental Prostheses Fabricated by CAD/CAM, Copy-Milling, and Conventional Methods. Int J Oral Maxillofac Implants. 2017;32(3):507–513. https://doi.org/10.11607/jomi.5023

41. Smith DE, Zarb GA. Criteria for success of osseointegrated endosseous implants. J Prosthet Dent. 1989;62(5):567-72. https://doi.org/10.1016/0022-3913(89)90081-4

42. Nedir R, Bischof M, Szmukler-Moncler S, Belser UC, Samson J. Prosthetic complications with dental implants: from an up-to-8-year experience in private practice. Int J Oral Maxillofac Implants. 2006;21(6):919-28.

43. das Neves FD, Coró V, da Silva Neto JP, de Mattias Sartori IA, do Prado RA. Implant-supported prosthesis misalignment related to the dental arch: a 14-year clinical follow-up. J Oral Implantol. 2012 Aug;38(4):399-404 . https://doi.org/10.1563/AAID-JOI-D-10-00100

44. Berglundh T, Armitage G, Araujo MG, Avila-Ortiz G, Blanco J, Camargo PM, Chen S, Cochran D, Derks J, Figuero E, Hämmerle CHF, Heitz-Mayfield LJA, Huynh-Ba G, Iacono V, Koo KT, Lambert F, McCauley L, Quirynen M, Renvert S, Salvi GE, Schwarz F, Tarnow D, Tomasi C, Wang HL, Zitzmann N. Peri-implant diseases and conditions: Consensus report of workgroup 4 of the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions. J Periodontol. 2018;89 Suppl 1:S313-S318. https://doi.org/10.1002/JPER.17-0739

45. Salcetti JM, Moriarty JD, Cooper LF, Smith FW, Collins JG, Socransky SS, Offenbacher S. The clinical, microbial, and host response characteristics of the failing implant. Int J Oral Maxillofac Implants. 1997 Jan-Feb;12(1):32-42.

46. Engel E, Gomez-Roman G, Axmann-Krcmar D. Effect of occlusal wear on bone loss and Periotest value of dental implants. Int J Prosthodont 2001;14:444-50.

47. Pessoa RS, Sousa RM, Pereira LM, Neves FD, Bezerra FJ, Jaecques SV, Sloten JV, Quirynen M, Teughels W, Spin-Neto R. Bone Remodeling Around Implants with External Hexagon and Morse-Taper Connections: A Randomized, Controlled, Split-Mouth, Clinical Trial. Clin Implant Dent Relat Res. 2017 Feb;19(1):97-110. https://doi.org/10.1111/cid.12437

Table 1 – The modified United States Public Health Service (USPHS) criteria.

USPHS	Alfa (A)	Bravo (B)	Charlie (C)	Delta (D)
Framework fracture	No fracture of framework			Fracture of framework
Veneering fracture	No fracture	Chipping, but polishing is possible	Chipping down to the framework	New reconstruction is needed
Occlusal wear	No occlusal wear on reconstruction or on opposite teeth	Occlusal wear on reconstruction or on opposite teeth is < 2 mm	Occlusal wear on reconstruction or on opposite teeth is > 2 mm	New reconstruction is needed
Marginal fit	No probe catch	Slight probe catch, but no gap at the implant-abutment interface	Gap at the implant-abutment interface	New reconstruction is needed
Anatomical shape	Ideal anatomical shape; good proximal contact	Slightly over or under contoured, weak proximal contact	Highly over or under contoured, open proximal contact	New reconstruction is needed

Table 2 – Distribution of Implants (n=85) and prostheses (n=35).

	Mandible			Maxilla		
Prostheses	32			3		
Implant Dimensions	Molar	Premolar	Canine	Molar	Premolar	Canine
4.1 x 8.5mm	9	3	0	0	0	0
4.1 x 10mm	13	8	0	1	0	0
4.1 x 11.5mm	21	8	0	0	1	0
4.1 x 13mm	6	5	1	2	3	1
5.0 x 7mm	1	0	0	0	0	0
5.0 x 8.5mm	2	0	0	0	0	0
Total	52	24	1	3	4	1

Table 3 – The Modified United States Public Health Service (USPHS) criteria results for each implant-supported crown (%)

USPHS	Alfa (A)	Bravo (B)	Charlie (C)	Delta (D)
Framework fracture	85 (100%)	-	-	-
Veneering fracture	85 (100%)	-	-	-
Occlusal wear	75 (88.2%)	10(11.8%)	-	-
Marginal fit	84 (98.8%)	-	-	1 (1.2%)
Anatomical shape	83 (97.6%)	2(2.4%)	-	-

Table 4 – Prosthetic data and complications (n=85).

Prosthetic data and complications		Incidence
Years of function	4 – 6 years	22(25.9%)
	7 – 10 years	63(74.1%)
Type of antagonist	Natural	57 (67%)
	Prosthetic	25(29.4%)
	Absent	3(3.6%)
Abutment	UCLA	85 (100%)
	Mini-conical	84(98.8%)
Occlusion	Absence of interproximal contact	22(25.8%)
	Parafunctional habits	18(21.2%)
Screw loosening		8(9.4%)
Screw fracture		2(2.4%)
Needed care after function		20(23.5%)

Table 5 – Patient data (n=23) and marginal bone loss (MBL) (mm) of each prosthesis (n=35).

Patient	Sex	Age	Number of Implants	Years in Function	MBL
1	Female	74	2	9	1.23
			3	9	1.34
2	Male	56	2	8	2.90
3	Female	64	2	4	1.92
			2	4	1.10
4	Male	43	2	9	2.69
5	Female	59	2	8	1.91
6	Male	60	3	9	1.74
7	Male	64	3	7	1.72
			2	7	1.86
8	Female	74	2	7	1.55
9	Male	41	2	6	2.24
			2	6	1.91
10	Male	51	3	8	2.06
			2	8	2.81
11	Female	57	2	7	4.99
			2	7	2.15
12	Female	79	3	7	1.98
			3	7	4.05
13	Female	55	3	10	2.94
			3	10	2.49
14	Female	57	2	6	2.12
			2	7	2.03
			3	7	2.00
15	Male	52	3	7	1.63
16	Male	63	2	4	1.42
			2	4	1.67
17	Female	58	3	7	3.52

			2	7	3.51
18	Female	64	3	8	1.99
19	Male	64	4	6	1.90
20	Male	90	2	8	3.80
21	Male	50	2	6	3.49
22	Female	65	3	7	1.47
23	Female	53	2	4	2.17

Table 6 – Maximum Bite Force – mean and standard deviation (sd) of right and left sides.

MBF	Mean right side	Mean left side	sd	*P* value
Women	140.8	148.3	71.1	0.80
Men	241.5	222.6	90.3	0.68

Student T test (=.05)

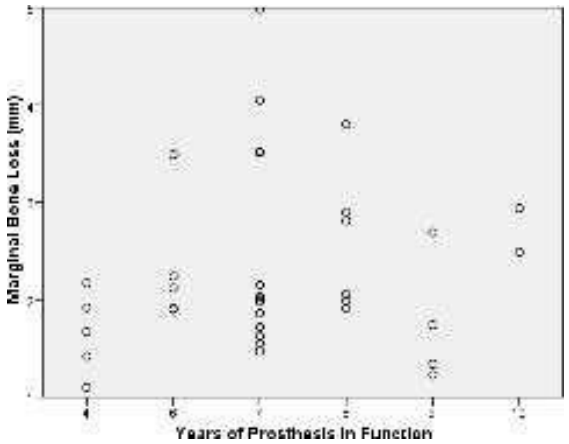

Figure 1 – Marginal bone loss (mm) of each prosthesis (n=35).

REFERÊNCIAS

1. Mito RS, Lewis S, Beumer J, Perri G, Mov PK. The UCLA implant study. J Calif Dent Assoc 1989;17(3):12-7.
2. Neves FD, Barbosa GAS, Bernardes SR. Fundamentos da Prótese sobre Implantes. Rio de Janeiro: Elsevier, 2016. 392 p.
3. Renouard F, Rangert B. Fatores de Risco em Implantodontia: Análise clínica simplificada para um tratamento previsível. 2ª ed. São Paulo: Quintessence, 2008. 193p.
4. Quirynen M, Bollen CM, Eyssen H, van Steenberghe D. Microbial penetration along the implant components of the Brånemark system. An in vitro study. Clin Oral Implants Res. 1994;5(4):239-44. https://doi.org/10.1034/j.1600-0501.1994.050407.x
5. Delben JA, Barão VA, Dos Santos PH, Assunção WG. Influence of abutment type and esthetic veneering on preload maintenance of abutment screw of implant-supported crowns. J Prosthodont. 2014;23:134-9. https://doi.org/10.1111/jopr.12065
6. Kano SC, Binon P, Bonfante G, Curtis DA. Effect of casting procedures on screw loosening in UCLA-type abutments. J Prosthodont 2006;15(2):77-81. https://doi.org/10.1111/j.1532-849X.2006.00078.x
7. Bhering CL, Takahashi JM, Luthi LF, Henriques GE, Consani RS, Mesquita MF. Influence of the casting technique and dynamic loading on screw detorque and misfit of single unit implant-supported prostheses. Acta Odontol Scand 2013;71:404-9. https://doi.org/10.3109/00016357.2012.690528
8. Albrektsson T, Zarb G, Worthington P, Eriksson AR. The long-term efficacy of currently used dental implants: a review and proposed criteria of success. Int J Oral Maxillofac Implants 1986;1(1):11-25.

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Taxas de sucesso e sobrevivência de próteses confeccionadas com o pilar do tipo UCLA sobre implantes hexágono externo

Pesquisador: Leticia Resende Davi

Área Temática:

Versão: 1

CAAE: 63911616.9.0000.5152

Instituição Proponente: FACULDADE DE ODONTOLOGIA

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.919.442

Apresentação do Projeto:

Conforme apresenta o protocolo: Trata-se de um estudo clínico observacional retrospectivo no qual participarão 46 pacientes usuários de próteses confeccionadas com o pilar do tipo UCLA sobre implantes hexágono externo (HE). Os participantes serão divididos em dois grupos: próteses unitárias e próteses múltiplas, instaladas no mínimo há 24 meses. No estudo serão avaliadas as taxas de sucesso e sobrevivência das próteses.

Os participantes serão recrutados entre os pacientes do Instituto de Ensino e Pesquisa em Saúde (INPES). Inicialmente uma pesquisadora da equipe fará contato telefônico com pacientes atendidos no INPES convidando-os a participar da pesquisa. Após os esclarecimentos sobre objetivos e procedimentos da pesquisa, os interessados em participar irão à clínica e assinarão o TCLE.

Será realizada avaliação clínica e radiográfica para ambos os grupos, para avaliar as condições das próteses, dos tecidos peri-implantares e mensurar as perdas ósseas em torno do implante.

A hipótese é de que após a avaliação das próteses unitárias e múltiplas não será encontrado desaperto de parafuso ou perda óssea marginal em torno dos implantes.

Após esta avaliação os dados serão submetidos inicialmente ao teste de normalidade e homogeneidade de variância. As taxas de falha das restaurações serão calculadas por meio da análise de sobrevivência, usando o método Kaplan-Meier. Adicionalmente, será realizada a análise

de Regressão de Cox para avaliar todas as variáveis de sobrevivência das restaurações (=0,05).
Desfecho Primário: 1- Avaliação quanto ao sucesso e à sobrevida da prótese; 2- Substituição da mesma sem nenhum custo, caso seja necessário; 3- Manutenção e limpeza das próteses.
Desfecho Secundário: Auxiliar na elaboração de um protocolo que irá definir, entre outros, a elaboração de uma técnica para definição de quais pilares utilizar, qual técnica a ser utilizada, o tempo de sobrevivência das próteses, a melhor indicação e planejamentos, aumentando assim as expectativas de sobrevivência do tratamento para o paciente.

Objetivo da Pesquisa:
Primário: Avaliar clinicamente e radiograficamente as próteses confeccionadas sobre implantes hexágono externo utilizando pilar tipo UCLA.

Secundários: 1- Avaliar retrospectivamente a taxa de sucesso e de sobrevivência de próteses confeccionadas sobre implantes hexágono externo utilizando pilar tipo UCLA, com tempo mínimo de acompanhamento de 24 meses; 2- Categorizar retrospectivamente o tipo de restauração (unitária ou múltipla), quanto ao gênero (masculino e feminino) e quanto às falhas (desadaptação entre pilar e implante; desaperto ou fratura de parafuso; fratura do material restaurador; perda óssea; perda de implante por fatores biológicos e mecânicos); 3- Avaliar o desempenho clínico da prótese em relação às falhas; 4- Buscar correlação entre o tipo de falha e o tipo de prótese (unitária ou múltipla).

Avaliação dos Riscos e Benefícios:
Segundo os pesquisadores:

RISCOS: riscos mínimos aos participantes: 1- Exposição do participante da pesquisa: para evitar tal risco os pesquisadores identificarão os participantes por meio de números, dificultando a identificação da pessoa; 2- Exposição aos feixes de radiação nas radiografias periapicais: Para amenizar os efeitos da radiação, será utilizado radiografia digital. Os participantes serão expostos a um nível mínimo de radiação e protegidos com avental de chumbo com protetor da glândula tireóide. Os pesquisadores destacam que essas radiografias já seriam realizadas no controle convencional destes trabalhos não sendo, assim, específicas para a pesquisa.

BENEFÍCIOS: 1- acadêmicos, indiretos para os participantes: Tendo em vista o grande número de cirurgiões -dentistas que utilizaram e ainda utilizam este componente, e que em alguns casos clínicos a única solução é utilizar o pilar tipo UCLA, é importante estudar seu comportamento

clínico a longo prazo para orientar melhor quanto a suas indicações, taxas de sucesso e sobrevivência, e assim definir protocolos para evitar possíveis falhas; 2- Diretos: os pacientes receberão a manutenção e limpeza das próteses, que também serão avaliadas com relação ao sucesso e sobrevivência. Caso seja necessário, a prótese será substituída sem nenhum custo para o participante.

Comentários e Considerações sobre a Pesquisa:

1- O projeto está elaborado de forma clara e objetiva. Apresenta embasamento teórico e justificativa para sua realização.

2- Apresenta os seguintes critérios de:

a) Inclusão = Paciente maior de 18 anos, boa saúde geral, não possuir qualquer contraindicação para a realização de tratamento odontológico, não apresentar xerostomia ou fazer uso de medicamento que reduza o fluxo salivar, apresentar boa higiene bucal (Índice de Placa Visível 33%), ter pelo menos uma prótese instalada sobre implante hexágono externo com o pilar tipo UCLA com no mínimo 24 meses de instalação da prótese.

b) Exclusão = Pacientes com oclusão desfavorável e/ou hábitos parafuncionais, gestantes e impossibilitados de comparecer às consultas.

3- Apresenta o Modelo de Ficha para coleta de dados que inclui: a) levantamento de informações do prontuário sobre o paciente (como idade e gênero) e sobre a prótese (como Tipo de restauração; material da prótese e outros); b) Avaliação da Coroa; c) Avaliação Periodontal; d) Critérios para avaliação da coroa; e) Questionário de Satisfação do Paciente. Além disso, apresenta os critérios para avaliação clínica das próteses, avaliação radiográfica e periodontal.

4- Apresenta o TCLE que está redigido de forma clara, tendo também a informação sobre ressarcimento de despesas de deslocamento.

5- Inclui o cálculo amostral, esclarecendo assim o número de participantes.

6- Justifica a escolha do local para realização da coleta de dados no INPES da seguinte forma: " ... ele possui um grande número de pacientes por ser um centro de pesquisa e uma escola de pós-graduação na área de implante e prótese sobre implante."

7- Descreve a metodologia que será utilizada para a análise dos dados.

Considerações sobre os Termos de apresentação obrigatória:

Foram apresentados todos os Termos, inclusive a solicitação para realização da coleta de dados e a autorização do INPES, que também assina a Declaração de Instituição coparticipante.

Recomendações:

1- Mesmo tendo sido afirmado no projeto e no Termo de Consentimento Livre e Esclarecido que despesas com deslocamento serão ressarcidas pelos pesquisadores, incluir no Orçamento uma previsão dessas despesas.

2- Caso o participante possua radiografias recentes que possam ser utilizadas no estudo, as mesmas deverão ser utilizadas, evitando assim que o participante seja exposto a radiação de forma desnecessária.

Conclusões ou Pendências e Lista de Inadequações:
Os pesquisadores deverão se atentar e atender as recomendações citadas no campo acima.

De acordo com as atribuições definidas na Resolução CNS 466/12, o CEP manifesta-se pela aprovação do protocolo de pesquisa proposto.
O protocolo não apresenta problemas de ética nas condutas de pesquisa com seres humanos, nos limites da redação e da metodologia apresentadas.

Considerações Finais a critério do CEP:
Data para entrega de Relatório Final ao CEP/UFU: Fevereiro de 2018.

OBS.: O CEP/UFU LEMBRA QUE QUALQUER MUDANÇA NO PROTOCOLO DEVE SER INFORMADA IMEDIATAMENTE AO CEP PARA FINS DE ANÁLISE E APROVAÇÃO DA MESMA.

O CEP/UFU lembra que:
a- segundo a Resolução 466/12, o pesquisador deverá arquivar por 5 anos o relatório da pesquisa e os Termos de Consentimento Livre e Esclarecido, assinados pelo sujeito de pesquisa.
b- poderá, por escolha aleatória, visitar o pesquisador para conferência do relatório e documentação pertinente ao projeto.
c- a aprovação do protocolo de pesquisa pelo CEP/UFU dá-se em decorrência do atendimento a Resolução CNS 466/12, não implicando na qualidade científica do mesmo.

Orientações ao pesquisador :
• O sujeito da pesquisa tem a liberdade de recusar-se a participar ou de retirar seu consentimento em qualquer fase da pesquisa, sem penalização alguma e sem prejuízo ao seu cuidado (Res. CNS 466/12) e deve receber uma via original do Termo de Consentimento Livre e Esclarecido, na íntegra, por ele assinado.

• O pesquisador deve desenvolver a pesquisa conforme delineada no protocolo aprovado e descontinuar o estudo somente após análise das razões da descontinuidade pelo CEP que o aprovou (Res. CNS 466/12), aguardando seu parecer, exceto quando perceber risco ou dano não previsto ao sujeito participante ou quando constatar a superioridade de regime oferecido a um dos grupos da pesquisa que requeiram ação imediata.

• O CEP deve ser informado de todos os efeitos adversos ou fatos relevantes que alterem o curso normal do estudo (Res. CNS 466/12). É papel de o pesquisador assegurar medidas imediatas adequadas frente a evento adverso grave ocorrido (mesmo que tenha sido em outro centro) e enviar notificação ao CEP e à Agência Nacional de Vigilância Sanitária **–** ANVISA **–** junto com seu posicionamento.

• Eventuais modificações ou emendas ao protocolo devem ser apresentadas ao CEP de forma clara e sucinta, identificando a parte do protocolo a ser modificada e suas justificativas. Em caso de projetos do Grupo I ou II apresentados anteriormente à ANVISA, o pesquisador ou patrocinador deve enviá-las também à mesma, junto com o parecer aprobatório do CEP, para serem juntadas ao protocolo inicial (Res.251/97, item III.2.e).

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BASICAS_DO_PROJETO_769131.pdf	19/01/2017 18:55:54		Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_com_beneficios.doc	19/01/2017 18:54:51	Thamires Diuquele da Silva	Aceito
Projeto Detalhado / Brochura Investigador	6_Projeto_Orientador_Final.docx	19/01/2017 18:14:19	Thamires Diuquele da Silva	Aceito
Outros	8_Curriculo_Lattes_Pesquisadores.docx	04/11/2016 22:25:06	Leticia Resende Davi	Aceito
Outros	7_Modelo_coleta_de_dados_sem_id.docx	04/11/2016 22:21:05	Leticia Resende Davi	Aceito
Outros	2_Carimbo_Autorizacao_Coleta.pdf	04/11/2016 22:19:59	Leticia Resende Davi	Aceito
Declaração de Instituição e Infraestrutura	1_Carimbo_Declaracao_Instituicao_Co_Participante.pdf	04/11/2016 22:19:12	Leticia Resende Davi	Aceito
Declaração de Pesquisadores	5_Termo_de_Compromisso_Equipe_Executora.pdf	11/10/2016 15:52:30	Leticia Resende Davi	Aceito

Outros	3_Solicitacao_do_pesquisador_para_a_instituicao.pdf	11/10/2016 15:41:51	Leticia Resende Davi	Aceito
Folha de Rosto	0_Folha_de_Rosto.pdf	11/10/2016 15:37:31	Leticia Resende Davi	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

UBERLANDIA, 14 de Fevereiro de 2017

Assinado por:
Sandra Terezinha de Farias Furtado
(Coordenador)