FACULDADE ILAPEO

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Patient's oral health-related quality of life and clinician assessment after treatment with Platform-Switching Grand-Morse Connection Implants.

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Orientador: Prof. Dr.Rubens Moreno de Freitas

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Dedicatoria

A mis amados Martín y Felipe, cada día al lado de ellos es un regalo que Dios me dio, sus risas, sus miradas fueron motor para estudiar aún mas y ser un mejor profesional, este trabajo es fruto de la inspiración que ellos me dan al llenar mi vida de risas y lecciones.

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Sumário

1. Articulo científico

Artigo de acordo com as normas da Faculdade ILAPEO

PATIENT'S ORAL HEALTH-RELATED QUALITY OF LIFE AND CLINICIAN ASSESSMENT AFTER TREATMENT WITH PLATFORM-SWITCHING GRAND-MORSE CONNECTION IMPLANTS.

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RESUMO

A troca de plataforma é um conceito que pode aumentar a sobrevivência e o sucesso do implante e, consequentemente, a satisfação e a qualidade de vida do paciente. Hoje em dia, a melhoria da qualidade de vida do paciente é considerada quando se analisa o sucesso do tratamento com implantes. Desta forma, este estudo teve como objetivo avaliar a qualidade de vida relacionada à saúde bucal do paciente após o tratamento com implantes e a satisfação do médico com o implante Neodent® platform-switching GM Helix. Cento e cinquenta e quatro implantes foram colocados em 34 pacientes. O pilar e o protocolo de carga foram selecionados de acordo com as necessidades de cada paciente e as instruções do fabricante. Os pacientes foram reavaliados 6, 12, 24 e 36 meses após a colocação do implante. As taxas cumulativas de sobrevivência e sucesso do implante foram calculadas. A qualidade de vida relacionada à saúde bucal do paciente foi avaliada por meio da ferramenta OHIP-14 durante o período de avaliação do paciente. Após a colocação do implante, o médico avaliou sua satisfação com o sistema de implante e procedimento realizado. Foi realizada análise estatística descritiva. Os dados das consultas de acompanhamento de 36 meses (T36) estavam disponíveis para 29 pacientes e 149 implantes. Foi observada uma taxa cumulativa de sucesso do implante de 97,3% (IC 95%: 93,3 - 99,3%) e uma taxa cumulativa de sobrevivência do implante de 98,7% (IC 95%: 95,2% - 99,8%). A pontuação média do OHIP-14 (Oral Health Impact Profile Questionnaire) pré-tratamento foi de 12,6 ± 6,9 no momento da triagem. Trinta e seis meses após a instalação do implante, diminuiu para 0,7 ± 1,8, aumentando dramaticamente a satisfação do paciente. A satisfação do clínico foi alta com o torque final do implante (9,3 ± 1,0), a adequação do implante às necessidades do paciente (9,7 ± 0,6) e o tempo necessário para preparar o leito e inserir o implante (9,8 ± 0,5), destacando-se a confiabilidade e facilidade de uso do implante GM Helix de plataforma de comutação Neodent®. Concluindo, este estudo demonstrou que a qualidade de vida relacionada à saúde bucal dos pacientes melhorou três anos após a colocação do implante, com uma melhora considerável já seis meses após o procedimento. Além disso, o médico ficou satisfeito com o desempenho do sistema de implante. Por fim, este estudo demonstrou o excelente desempenho do implante GM Helix®, que apresentou altas taxas de sobrevivência e sucesso

Palavras-chave: Implante dentário; Troca de plataforma; Conexão Grand-Morse; Qualidade de vida.

ABSTRACT

Platform-switching is a concept that can increase the implant's survival and success and, consequently, the patient's satisfaction and quality of life. Nowadays, the improvement of a patient's quality of life is considered when analyzing the success of implant treatment. In this way, this study aimed to assess the patient's oral health-related quality of life after implant treatment and clinician satisfaction with the Neodent® platform-switching GM Helix implant. One hundred and fifty-four implants were placed in 34 patients. The abutment and loading protocol were selected according to each patient's needs and the manufacturer's instructions. Patients were re-evaluated 6, 12, 24, and 36 months after implant placement. Implant cumulative survival and success rates were calculated. The patient's oral health-related quality of life was evaluated through the OHIP-14 tool during the patient's evaluation time. After implant placement, the clinician assessed his/her satisfaction with the implant system and procedure performed. A descriptive statistical analysis was conducted. Data from the 36-month follow-up visits (T36) was available for 29 patients and 149 implants. A cumulative implant success rate of 97.3% (95% CI: 93.3 - 99.3%) and a cumulative implant survival rate of 98.7% (95% CI: 95.2% - 99.8%) were observed. The mean pre-treatment OHIP-14 (Oral Health Impact Profile Questionnaire) score was 12.6 ± 6.9 at the time of screening. Thirty-six months after implant installation, it decreased to 0.7 ± 1.8, dramatically increasing patient satisfaction. The clinician satisfaction was high with the final torque of the implant (9.3 ± 1.0), the implant suitability for the patient's needs (9.7 ± 0.6), and the time taken to prepare the bed and insert the implant (9.8 ± 0.5), highlighting the reliability and ease of use of the Neodent® platform-switching GM Helix implant. In conclusion, this study demonstrated that the patients' oral health-related quality of life improved three years after implant placement, with a considerable improvement already six months after the procedure. In addition, the clinician was satisfied with the implant system's performance. Finally, this study demonstrated the excellent performance of the GM Helix® Implant, which presented high survival and success rates.

Keywords: Dental implant; Platform-Switching; Grand-Morse connection; Quality of life.

INTRODUCTION

Since the discovery of implant osseointegration in the 1950s, the dental implant has evolved and is now considered the primary treatment choice for partial and total edentulous patients[1]. Dental implants enhanced the scope of dentistry's treatment, and nowadays, they are considered a reliable and predictable treatment with high survival rates in different clinical conditions.

Factors such as biocompatibility, implant surface treatment, implant design, bone quality, and surgical techniques can influence implant survival and success. Thus, the industry has worked on several implant design modifications to achieve high survival rates. The platform-switching concept is one of these modifications[2].

The concept of a platform-switched implant consists of an abutment diameter narrower than the implant diameter, favoring biomechanical behavior where the mechanical stress is no

longer concentrated in the implant cervical bone. Additionally, the infiltration of inflammatory cells stays away from the marginal bone, promoting the protection of the underlying bone[3]. The implant body can influence the insertion torque and the primary stability[4]. In this way, both characteristics can affect the implant's survival and success and, consequently, the patient's satisfaction and quality of life.

At the end of the implant system development, the main objective is to restore the patient's masticatory function and quality of life. The patient expects an esthetic solution, as they do not comprehend the complications associated with the procedure. In this way, the patient's perceptions and psychological parameters have become part of the implant treatment success[5]. Nowadays, one tool to evaluate oral health-related quality of life is the OHIP-14.

Finally, clinician satisfaction is essential for the implant system chosen since factors such as final insertion torque and time for bone bed preparation are important for the clinician, even the treatment results. Thus, this study aimed to assess the patient's oral health-related quality of life and clinician satisfaction with the Neodent® platform-switching GM Helix implant.

MATERIAL AND METHODS

The study protocol was submitted and approved by the Ethical Committee of the Positivo University (Curitiba, Brazil; opinion n°. 3.070.126). The investigation was conducted according to the revised principles of the Helsinki Declaration and ISO 14155. Written informed consent was obtained from each enrolled patient. The study was registered in the Clinical Trials database under the number NCT03812276.

Study population

The sample size calculation was performed based on the primary endpoint, implant success (including survival). Assuming an implant success rate of 96.6% (α = 5%) in 3 years after installation[6–8], the sample size required for an accurate 95% Clopper-Pearson Confidence Interval (CI) was 119 implants. Estimating a rate of 3.5 implants per patient and a "worst case" drop-out rate of 20%, a minimum sample size of 151 implants (estimated 43 patients) was considered sufficient to allow a descriptive analysis of clinical outcome data up to 36 months after implant placement.

This observational study involved 34 patients (53.3% females and 46.7% males; mean age 49±12 years), in whom 154 implants were placed. The sample was selected prospectively and consisted of patients over the age of 18 who required one or more dental implants and who were assessed as suitable for the placement of Neodent® Helix GM implants (Curitiba, Brazil) at the participating study centers (ILAPEO, Curitiba, Brazil; Positivo University, Curitiba, Brazil).

Only contraindications to the device, according to the IFU, were applied as exclusion criteria. Patients who show signs of allergy or hypersensitivity to the chemical components of the implant material were not included. In addition, implant placement in the presence of an acute infectious or inflammatory process, inadequate bone volume or quality, serious medical problems such as bone metabolism disorders, blood coagulation disorders, inadequate healing, inadequate oral hygiene, incomplete jaw growth, uncooperative and unmotivated patient, drug or alcohol abuse, psychoses, prolonged functional disorders that resist any drug treatment, xerostomia, weakened immune system, diseases that require the regular use of steroids, uncontrolled endocrine diseases, and pregnancy were considered factors for patient exclusion.

The first patient was enrolled in the study on February 14, 2019. The study started on November 26, 2018, and ended on May 31, 2023. The last patient completed the study on January 12, 2023.

Surgical procedures

Helix GM Acqua implants (Neodent®, Curitiba, Brazil) were placed under local anesthesia (4% Articaine with 1:100,000 epinephrine) and with adequate bone bed preparation according to the manufacturer's recommendations. It should be noted that in this study, all patients received the same brand and implant model. The patients were also given post-operative and oral hygiene orientations.

At the end of this stage, the suture was performed, and an X-ray was taken (baseline). Patients were instructed to return between 7 and 14 days after surgery to remove the sutures.

The abutment and loading protocol (delayed or immediate) were selected according to each patient's needs and the manufacturer's instructions (IFU). Immediate loading was applied at the surgeon's discretion when primary stability reached at least 32 N.cm and the patient presented physiological occlusion.

All definitive crowns were cemented or screwed over the abutment. The clinician was responsible for choosing the abutment that better fits the patient´s case. After the prosthesis installation, a radiographic examination was performed to confirm the adaptation of the prosthetic work. Patients were re-evaluated 6, 12, 24, and 36 months after implant placement.

Outcomes

Implant survival and success

Survival was considered when the implant was present and functioning in the oral cavity during the follow-up visit. A failure was defined as a mobile implant outside the oral cavity or planned for removal.

Success was evaluated according to Buser[9,10] considering the factors below:

1) Absence of persisting subjective discomfort such as pain, foreign body perception, and or dysesthesia.

2) Absence of recurrent peri-implant infection with suppuration (an infection was termed recurrent when observed at two or more follow-up visits after treatment with systemic antibiotics).

3) Absence of implant mobility on manual palpation.

4) Absence of any continuous peri-implant radiolucency.

Clinician satisfaction

Clinician satisfaction was assessed using a questionnaire and a visual analog scale (VAS) in the form of a 10 cm horizontal line, where 0 (left end) indicates minimum satisfaction and 10 (right end) indicates maximum satisfaction. The clinicians were instructed to mark the best position to represent their general satisfaction with patient treatment. The score was measured in centimeters from the left end of the line to the marked point.

After implant placement, the clinician evaluated his/her satisfaction with the final placement torque achieved, the suitability of the implant for the particular patient condition, and the time taken for the implant bed preparation and implant insertion procedures.

Patient Satisfaction

The Portuguese translation of the OHIP-14 questionnaire was used to assess Oral Health-Related Quality of life (OHRQoL)[11,12], as a measure of patient satisfaction with treatment. Patients were asked how frequently they had experienced the problems assessed by the questionnaire in the preceding six months.

The OHIP measures individuals' attitudes toward the social impact of oral disorders on their well-being. The questionnaire comprises seven dimensions. The seven dimensions of the questionnaire include limitation of function, pain, psychological discomfort, physical and psychological disability, social disability, and handicap. The patient's response was to be

recorded as one of the five categories, i.e., never (0), hardly ever (1), occasionally (2), fairly often (3), and very often (4).

Statistics

The statistical analysis was done using SPSS Statistics software (Armonk, NY: IBM Corp), version 23. Quantitative variables were described by mean, standard deviation, median, quartiles, minimum, and maximum. For qualitative variables, absolute and relative frequencies were provided.

For this study, a specific analysis set, the full analysis set (FAS), was carried out. The FAS consisted of all study implants for which there has been at least one follow-up after implant installation. The primary analysis was carried out using the intention-to-treat principle with the FAS.

Survival and success rates were calculated by dividing the number of events (survival or success) by the total number of implants/prostheses evaluated. In addition, Kaplan-Meier stratified analyses were used to assess the association between survival and success with i) risk factors, ii) type of loading, and iii) complications, using these qualitative variables as grouping factors.

RESULTS

Two of the 34 patients registered at the two study centers could not be analyzed. These patients consented to participate in the study but did not meet the inclusion/exclusion criteria at the screening visit or receive a study implant. These patients were classified as "not analyzable" and excluded from the statistical analysis.

According to the FAS principle, efficacy analysis was possible in 29 patients who received 149 implants. Two patients with implants did not have follow-up data after implant installation, so efficacy could not be assessed in these two cases.

Of the thirty-four enrolled patients, eight had one or more relevant clinical conditions: infection at the dental apex (n=1); heart disease (n=1); hypertension/controlled hypertension (n=5); depression (n=1); pre-diabetes (n=1); hyperthyroidism (n=1). Seven patients (20.6%) were ex-smokers, and five (14.7%) were smokers.

Regarding dental history, most patients had 1 to 8 missing teeth (44.8%), followed by 9 to 18 (31.0%), 19 to 27 (17.2%), and 27 to 32 missing teeth (6.9%). Regarding oral hygiene, 42.1% of the patients were assessed as having "good" oral hygiene during their visits.

Data from the 36-month follow-up visits (T36) was available for 29 patients and 149 implants. A Kaplan-Meier survival analysis was carried out to assess the success rate and survival of the implants, considering all the events that occurred throughout the study. In total, four implants (from 3 patients) were considered "unsuccessful" (three at visit T6 and one at visit T24), leading to a cumulative implant success rate of 97.3% (95% CI: 93.3 - 99.3%). In total, two implants (from 2 patients) were considered "lost" (both at visit T6), leading to a cumulative implant survival rate of 98.7% (95% CI: 95.2% - 99.8%). No implants were considered "lost" or "unsuccessful" at visits T12 and T36 after placement.

Thirty-four provisional prostheses and 71 final prostheses were installed. Of the 71 prostheses installed, 40 (56.3%) were multi-unit, and 31 (43,7%) were single-unit. Most multi-unit prostheses had two elements (22), and the full arches represented ten prostheses in total.

The mean pre-treatment OHIP-14 (Oral Health Impact Profile Questionnaire) score was 12.6 ± 6.9 at the time of screening. At 36 months after implant installation, it decreased to 0.7 ± 1.8, showing a remarkable increase in patient satisfaction over time (Figure 1).

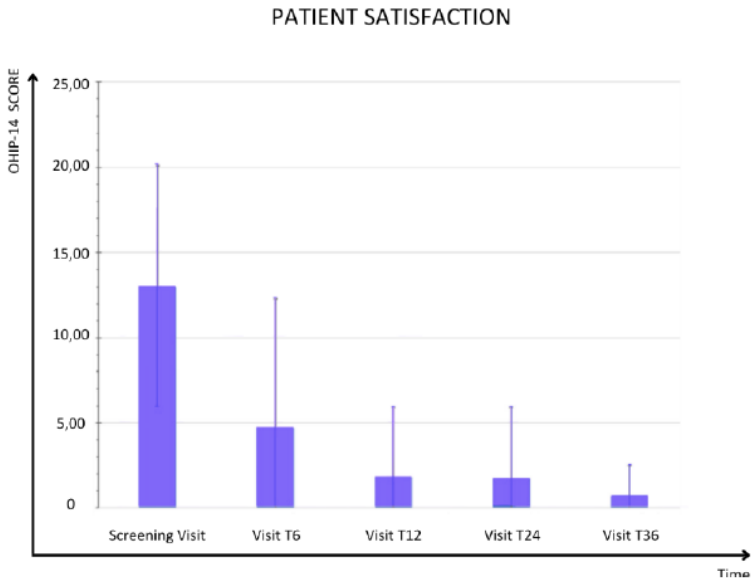

Figure 1 - The average score on the OHIP-14 questionnaire over time for patient satisfaction.

According to the mean VAS scores, clinician satisfaction was high with the final torque of the implant (9.3 ± 1.0), the implant suitability for the patient's needs (9.7 ± 0.6), and the time taken to prepare the bed and insert the implant (9.8 ± 0.5).

DISCUSSION

High implant survival and success rates were observed in this study. Beschnidt et al.[13] found a platform-switching implant survival rate of 98.6% and an overall implant success rate of 98% in 5 years of follow-up. This is similar to the implant survival and success rates observed in this study (98.7% and 97.3%, respectively). When a Cone Morse platform-switching implant was followed up for four years, a cumulative survival rate of 97.9% was observed, corroborating this study's findings[14].

Clinician satisfaction measured by the 10 cm visual analog scale (VAS) was high regarding final torque, the suitability of the implant to the patient's needs, and the time taken to prepare the bed and insert the implant. Clinician satisfaction for final torque had a slightly lower mean score than the other topics assessed for clinical satisfaction. This may be explained by one situation reported related to the high insertion torque encountered when using the drill

sequence recommended by the manufacturer. However, previous animal studies have shown that implants with high insertion torque did not induce bone necrosis or implant failure[15]. Furthermore, another study concluded that insertion torques between 55 and 70 N.cm are not detrimental to osseointegration[16]. Additionally, clinician satisfaction is essential to understand the suitability of the implant system in daily practice.

Patient satisfaction, as measured by the OHIP-14 total score, improved from 12.6 (± 6.9) at the screening visit to 0.7 (± 1.8) after 36 months. This means the patients' average oral health-related quality of life considerably increased after treatment. Studies in the literature using the OHIP-14 instrument have also reported an improvement in oral health-related quality of life after three years of follow-up of implant-supported rehabilitation[17]. The results showed a reduction from the initial 22.1 ± 13.8 to 1.9 ± 3.1 at three years after rehabilitation with implant-supported fixed complete dentures[18].

This evident increase in the quality of life can be associated with most patients having more than nine missing teeth. Multiple missing teeth have more impact on the patient's quality of life. Studies assessing the patient's quality of life after rehabilitation of one missing tooth found an OHIP-14 punctuation of 28.2[19]. In another study assessing full-arch rehabilitation, the OHIP-14 punctuation was 4.6 post-treatment[20]. Another interesting situation is that the quality of life increased considerably six months after implant installation, and this can be explained because, by the end of 6 months, most of the patients had already received the prosthesis.

One limitation of the study is that it took place during the pandemic period, which may have affected the follow-up of patients during intermediate visits. However, the final period of the study, the 36-month visits, took place after the end of the pandemic, which did not jeopardize the primary endpoint of the study. It would be interesting to perform more studies evaluating other aspects of the Neodent GM Helix® Implant treatment.

CONCLUSION

This study demonstrated that the patients' oral health-related quality of life improved three years after implant placement, with a considerable improvement already six months after the procedure. In addition, the clinician was satisfied with the implant system's performance. Finally, this study demonstrated the excellent performance of the Neodent GM Helix® Implant, which presented high survival and success rates.

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2. Certificados