FACULDADE ILAPEO

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The Long-Term Survival and Success of Grand Morse-Connection Implants: a 36-month follow-up

CURITIBA
2024

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Dissertação apresentada a Faculdade ILAPEO como parte dos requisitos para obtenção de título de Mestre em Odontologia com área de concentração em implantodontia.

Orientador: Prof. Dr.Rubens Moreno de Freitas

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Aprovada em: 17-12-2024

Sumário

1. Artigo científico 1

Artigo de acordo com as normas da Faculdade ILAPEO.

THE LONG-TERM SURVIVAL AND SUCCESS OF GRAND MORSE-CONNECTION IMPLANTS: A 36-MONTH FOLLOW-UP

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RESUMO

A evolução das plataformas protéticas é uma tentação para melhorar a distribuição da força oclusal levando a um melhor desempenho do sistema de implantes. Este estudo teve como objetivo avaliar a sobrevivência e o sucesso em um acompanhamento de 3 anos de reabilitação de pacientes com implantes dentários com interface protética Grand Morse. 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. Todas as coroas definitivas foram cimentadas ou parafusadas sobre o pilar e o clínico foi responsável pela escolha do pilar. 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 análise estatística foi realizada ao nível do implante. $P \leq 0,05$ foi considerado como indicador de significância estatística. Os dados das consultas de acompanhamento de 36 meses (T36) estavam disponíveis para 29 pacientes e 149 implantes. No total, 4 implantes (de 3 pacientes) foram considerados "sem sucesso" (três na visita T6 e um na visita T24), levando a uma taxa cumulativa de sucesso do implante de 97,3% (IC 95%: 93,3 - 99,3%). No total, 2 implantes (de 2 pacientes) foram considerados "perdidos" (ambos na visita T6), levando a uma taxa cumulativa de sobrevivência do implante de 98,7% (IC 95%: 95,2% - 99,8%). Nenhum implante foi considerado "perdido" ou "malsucedido" nas visitas T12 e T36 após a colocação. Foram observadas complicações técnicas como fratura de próteses, perda/falha de pilares, perda de retenção de cimento da prótese, fratura de parafusos protéticos, fratura de pilares, afrouxamento de parafusos protéticos e afrouxamento de pilares. Os resultados deste estudo confirmam a segurança e o bom desempenho clínico dos implantes Grand Morse Helix em 3 anos de acompanhamento.

Palavras-chave: Cone Morse; Taxa de Sobrevivência; Pilares Dentários; Implantes Dentários; Projeto de pilar de implante dentário; Grande Morse.

ABSTRACT

The evolution of prosthetic platforms is a temptation to improve occlusal force distribution leading to a better implant system performance. This study aimed to evaluate the survival and success in a 3-year

follow-up of patients´ rehabilitation using dental implants with a Grand Morse prosthetic interface. 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. All definitive crowns were cemented or screwed over the abutment and the clinician was responsible for choosing the abutment. Patients were re-evaluated 6, 12, 24, and 36 months after implant placement. Implant cumulative survival and success rates were calculated. The statistical analysis was conducted at the implant level. $P \leq .05$ was considered as an indicator of statistical significance. Data from the 36-month follow-up visits (T36) was available for 29 patients and 149 implants. In total, 4 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, 2 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. Technical complications such as prostheses fracture, abutment loss/failure, loss of prosthesis cement retention, prosthetic screws fracture, abutments fracture, prosthetic screw loosening, and abutment loosening were observed. This study's results confirm the safety and good clinical performance of the Grand Morse Helix implants in 3 years of follow-up.

Keywords: Morse Taper; Survival Rate; Dental Abutments; Dental Implants; Dental Implant-Abutment Design; Grand Morse.

INTRODUCTION

Dental implants become the best treatment to rehabilitate partial or complete edentulous patients. Different factors can influence the long-term success of implant treatment. In addition to biological aspects and clinician experience, the design and type of implant system can affect implant survival and success. The influence occurs through biomechanical aspects, sealing the micro gaps that facilitate bacterial adhesion, and peri-implant tissue remodeling[1].

Implant systems have been changing to improve performance and allow more predictable and stable rehabilitation. The variety of prosthetic platforms is a temptation to improve occlusal force distribution, and these platforms have evolved from External Hexagon to Cone Morse[2].

Grand Morse prosthetic platform is an evolution of Cone Morse. Due to its tapered interface, the design of Grand Morse implants favors the maintenance of a natural emergency profile. This result is expected since it allows the application of concepts that prove peri-implant tissue conservation.

In the long-term, few biological complications have been reported for tapered interface implants and are observed in 1.4%[3] to 10%[4] of the implant-supported restorations. The most

commonly reported biological complication is peri-implantitis[3–5], which is frequently observed in active smoking patients[4] and has been associated with 21% of failed implants[3]. A rate of approximately 1% or less of peri-implant mucositis has been reported[3,6]. Additionally, Morse Tapper connections have shown less peri-implant bone loss compared to External hexagon connections[7].

To the authors' knowledge, few studies in the literature show the long-term survival and success of Grand Morse-Connection implants. Thus, this study aimed to evaluate the survival and success in a 3-year follow-up of patients´ rehabilitation using dental implants with a Grand Morse prosthetic interface, an evolution of the Cone Morse interface.

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[8–10], 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-operatory and oral hygiene orientations.

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

The prosthetic component 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 fits better for 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

Survival was considered when the implant was present and functioning in the oral cavity at the time of the follow-up visit. A failure was defined as an implant that was mobile, outside the oral cavity, or planned for removal.

Success was evaluated according to Buser[11,12] 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.

Prosthetic survival and success were also evaluated. Prosthetic survival was assessed as the prosthesis remaining in situ at each follow-up, irrespective of its condition. On the other

hand, success was defined as the prosthesis that remained unchanged and did not require any intervention during the entire observational period.

Additional data were also collected, such as demographics, bone augmentation procedures, bone site characteristics, oral hygiene, and occurrence of complications.

Statistics

The statistical analysis was carried out 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.

Two different analysis sets were carried out for this study. The safety analysis set (SAS) consisted of all study patients who received at least one study implant. The SAS population was the basis for the safety analysis. The full analysis set (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.

The significance level for all tests is $p<0.05$.

RESULTS

Of the 34 patients registered at the two study centers, 2 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. Safety could be analyzed in 32 of the 34 patients.

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.

From 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.

The average diameter of the implants placed was 3.81 ± 0.28 mm (range 3.5 to 5.0 mm), and the average length was 10.5 ± 1.9 mm (range 8 to 18 mm). The average final insertion torque was 47.7 ± 14.5 N.cm (range 10 to 60 N.cm). Table 1 describes data collected at the implant placement visit.

Table 1 – Descriptive analysis of the variables collected at implant placement visit at the implant level

Variables		**N**	**%**
Implant localization	Maxilla	58	38.9%
	Mandible	81	54.4%
Bone quality	Type I	33	22.1%
	Type II	57	38.3%
	Type III	51	34.2%
	Type IV	8	5.4%
Bone graft	Yes, xenogene	5	3.35%
	No	144	96.6%
Collagen membrane	Yes	1	0.67%
	No	148	99.32%
Soft tissue transplantation	Yes	1	0.67%
	No	148	99.32%

Complications were observed during the study. Local edema, pain, fever, and infection at the implant site with suppuration and inflammation occurred in 6 patients. Regarding technical complications, prostheses fracture, abutment loss/failure, loss of prosthesis cement retention, prosthetic screws fracture, abutments fracture, prosthetic screw loosening, and abutment loosening were observed.

In 82.8% of cases, the provisional or definitive prosthesis was installed one week after surgery. Five of the 29 patients (17.2%) had their prostheses installed immediately after surgery. At the implant loading visit, GM Mini Abutments (Neodent, Curitiba, Brazil) were inserted in 68.8% of the loaded implants (n=99/144). However, GM Micro Conical Abutments (Neodent, Curitiba, Brazil), GM Universal Abutments (Neodent, Curitiba, Brazil), GM Exact Titanium Base (Neodent, Curitiba, Brazil), and Pro PEEK GM Abutment (Neodent, Curitiba, Brazil) were also used.

The average time to final prosthesis (time interval between the final prosthesis and the implant placement visit) was 149 ± 88 days, ranging from 12 days to 354 days. Thirty-four provisional prostheses and 71 final prostheses were installed. Only 20 final prostheses over the course of the visits were considered "unsuccessful", leading to a cumulative prosthesis success rate of 71.8%. However, for the 36-month analysis, only 9 final prostheses were unsuccessful, leading to a final success rate of 87.7%. In total, 5 prostheses (from 3 patients) were considered "lost", leading to a cumulative prosthesis survival rate of 93.0%.

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, 4 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, 2 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.

DISCUSSION

Thirty-four patients from two study centers were enrolled in this study. Thirty-two of these patients (154 implants) received one or more study implants and were available for safety evaluation. Efficacy (performance of the medical devices) could be analyzed in 29 patients (149 implants) according to the Full Analysis Set (FAS). The follow-up period was 36 months after implant installation.

Implants were placed in patients with health conditions that could interfere with the success of the procedure, such as depression (psychosis), acute infectious process, uncontrolled endocrine disease, insufficient oral hygiene, and smoking[13]. However, none of these patients had lost implants, showing the performance of these implants even in compromised patients.

During the 36-month period, some complications were reported. None of these complications were serious, the majority being related to the abutment or prosthetic screw loosening and fracture of the prosthesis, abutment, or screw. Although good success rates for dental implants are a clinical reality, it is common to find a high incidence of mechanical complications, such as loosening of the abutment and occlusal screw[14,15].

The implant survival rate was 98.7% (95% CI: 93.3 - 99.3%), which is higher than the survival rate of implants with Morse Cone connection of approximately 92.0% in up to a mean of 40 months of follow-up found by Casseta et al[16]. The success rate of the Grand Morse implants was 97.3% (95% CI: 92.2% to 99.4%), similar to the success rate of 97.4% expected for implants with Morse Cone connection for the same evaluation period[17].

The prosthetic success rate over 3 years after implant placement, estimated by Kaplan-Meier survival analysis based on 154 implants from the FAS dataset, was 73.8%. For the 36-

month analysis, only 9 prostheses were unsuccessful, leading to the final success rate of 87.3%. Barter et al., 2012[18], obtained a prosthesis success rate of 81.8% with only 2 years of follow-up. Some of these prostheses had frequent complications, i.e. recurring at more than one visit. The most common complications were loosening of the abutment or prosthetic screw (41.0%), followed by fracture of the prosthesis, abutment, or screw (16.6%). According to a recent study and the results of a systematic review involving 85 studies on implant-supported fixed dental prostheses, the most common technical complications are prosthesis fracture, abutment or screw loosening, and loss of retention[19,20].

The prosthesis survival rate was 93,0%, as estimated by Kaplan-Meier survival analysis. This scenario is similar to that found in other studies in the literature for 3-year follow-up, with rates also close to 90.0%[21]. The analysis of the prosthesis's survival rate did not consider 4 prostheses "lost" by the same patient, as the loss was due to a fall suffered by the patient in which the prosthesis fractured and was not related to the device studied.

A limitation of the study is the fact 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.

CONCLUSION

The results of this final analysis 36 months after the first patient underwent surgery to install the implants confirm the safety and good clinical performance of the Grand Morse Helix implants and Grand Morse abutments within their indications for use. The implant survival and success rates were 98.7% and 97.3%, respectively, in 36 months of follow-up.

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