FACULDADE ILAPEO

Kleryo Antonilo Santos Camara

Retrospective cohort study of 4,783 morse tapered hybrid macrogeometry dental implants: implant and prosthesis survival rate analysis

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Tese apresentada a Faculdade ILAPEO como parte dos requisitos para obtenção de título de Doutor em Odontologia

Orientadora: Profa. Dra. Tatiana Miranda Deliberador

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Presidente da Banca Orientadora: Profa. Dra. Tatiana Miranda Deliberador

BANCA EXAMINADORA

Prof. Dr. Sergio Rocha Bernardes
Profa. Dra. Ivete Aparecida de Mattias Sartori
Prof. Dr. Carlos Araújo
Prof. Dr. Erton Miyasawa

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Dedicatória

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VENCEMOS!

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1. Artigo científico 1

Artigo de acordo com as normas da Faculdade ILAPEO.

RETROSPECTIVE COHORT STUDY OF 4,783 MORSE TAPERED HYBRID MACROGEOMETRY DENTAL IMPLANTS: SURVIVAL RATE ANALYSIS.

Kleryo Antonilo Santos Câmara[1]
Alexandre Negretto[1]
Geninho Thomé[2]
Sergio Rocha Bernardes[2]
Tatiana Miranda Deliberador[2]

[1] **DDS, PhD Student in Dentistry at Ilapeo College, Curitiba, Brazil**
[2] **DDS, MsC, PhD, Professor at Ilapeo College, Curitiba, Brazil**

RESUMO

Objetivo: Este estudo retrospectivo teve como objetivo avaliar o índice de sobrevivência de implantes macrogeométrico híbridos em distintos perfis de pacientes e condições clínicas.

Métodos: Um total de 1215 prontuários clínicos de pacientes com pelo menos um implante Helix instalado na Faculdade ILAPEO (Curitiba, Brasil) foram avaliados de 2018 a 2024. A coleta de dados foi realizada de 2021 a 2024. Parâmetros relacionados aos pacientes, implantes e características cirúrgicas foram coletados: idade, sexo, presença de comorbidades, hábitos de tabagismo, higiene oral, radioterapia prévia de cabeça/pescoço e presença de bruxismo e apertamento, comprimento e diâmetro do implante, interface protética, procedimento de enxerto ósseo, procedimento de enxerto de tecido mole, tipo de osso, torque de inserção, cirurgia com retalho ou sem retalho, cirurgia guiada, região de instalação do implante, eventos adversos e sobrevivência do implante. Estatísticas descritivas resumidas foram estimadas para todos os parâmetros. A taxa de sobrevida foi estimada dividindo-se o número de eventos pelo número total de implantes avaliados. As associações entre as variáveis dependentes "sobrevida do implante" e as características do paciente, do procedimento e do implante foram avaliadas pelos testes qui-quadrado ou de Fisher.

Resultados: Um total de 4783 implantes GM Helix foram instalados em 1215 pacientes com idade média de 57,17 ± 12,09 anos (variando de 24 a 93 anos). A condição médica mais frequente nos pacientes foi diabetes, hipertensão, disfunção da tireoide, uso de esteroides (corticoides), limitações psicológicas e bruxismo e apertamento. Os pacientes foram acompanhados por um período médio de 29,54 ± 18,95 meses (variando de 0 a 81,70 meses). Cento e cinquenta e um implantes foram perdidos devido à falta de osseointegração, resultando em uma taxa de sobrevivência do implante de 96,83%. Eventos adversos foram relatados em 389 (8,13%) implantes. Hipertensão, hábitos de fumar, procedimento de enxerto ósseo, tipo de osso, torque de inserção, região de instalação na mandíbula e ocorrência de eventos adversos foram associados à perda do implante.

Conclusão: O tratamento com o implante macrogeométrico híbrido é uma opção previsível para pacientes desdentados totais ou parciais com saúde comprometida e diferentes condições clínicas. A taxa de sobrevivência do implante foi de 96,83% em até 6,8 anos de acompanhamento. Foi relatada uma baixa taxa de complicações de 8,13%, e a maioria dos eventos foi leve e com possibilidade de tratamento.

Palavras-chave: Implantes dentários; Estudo Clínico; Complicações; Taxa de sobrevida.

ABSTRACT

Objective: This retrospective study aimed to evaluate the mid-term safety and performance of a hybrid macrogeometry dental implant in different patient profiles and clinical conditions.

Methods: A total of 1215 patients were chosen from clinical records of patients with at least one Helix implant (Neodent, Curitiba, Brazil) inserted at ILAPEO College (Curitiba, Brazil) from 2018 to 2024. The data collection was performed from 2021 to 2024. Parameters related to patients, implants, and surgical characteristics were collected: age, gender, presence of comorbidities, smoking habits, oral hygiene, previous head/neck radiotherapy, and bruxism and clenching presence, implant length and diameter, prosthetic interface, bone graft procedure, tissue graft procedure, bone type, insertion torque, flap or flapless surgery, guided surgery, region of implant placement, adverse events, and implant survival. Descriptive summary statistics were estimated for all parameters. Survival rate was estimated by dividing the number of events by the total number of implants evaluated. The associations between the dependent variables "implant survival" and patient, procedure and implant characteristics were evaluated by chi-square or Fisher tests.

Results: A total of 4783 GM Helix implants were placed in 1215 patients with a mean age of 57.17 ± 12.09 years (ranging from 24 to 93 years). The most frequent patient's medical condition was diabetes, hypertension, thyroid dysfunction, use of steroids (corticoids), psychological limitations, and bruxism and clenching. Patients were followed for a mean period of 29.54 ± 18.95 months (varying from 0 to 81.70). One hundred and fifty-one implants were lost due to lack of osseointegration, resulting in an implant survival rate of 96.83%. Adverse events were reported in 389 (8.13%) implants. Hypertension disease, smoking habits, bone graft procedure, bone type, insertion torque, region of placement on the mandible, and adverse event occurrence were associated with implant loss.

Conclusion: Treatment using a hybrid macrogeometry dental implant is a predictable option for total or partial edentulous patients with compromised health and different clinical conditions. The implant survival rate was 96.83% up to 6.8 years of follow-up. A low complication rate of 8.13% occurred, and most events were mild and with management possibility.

Keywords: Dental implants; Clinical study; Complications; Survival rate.

INTRODUCTION

Since Branemark discovered titanium osseointegration in the 1969s, dental implants have become the primary treatment for totally or partially edentulous patients with various clinical conditions. With decades of use, dental implants present high survival rates from 91.69% to 100% in up to 20 years of follow-up(1–4). To enhance the predictability of implant

treatment in challenging clinical conditions, the manufacturers invested in developing different implant surfaces, macrogeometries, and prosthetic interfaces(5).

The first implant macrogeometry was cylindrical, introduced by Branemark with long-term survival and success(6). However, macrogeometry evolved, and tapered implants emerged to enhance primary stability, mainly in poor-quality bone. The implant survival of both implants is comparable(7,8). To potentiate the advantages of cylindrical and tapered implants, hybrid microgeometry was developed with a coronal cylindrical and tapered apical part (9).

In addition to the evolution of macrogeometry, manufacturers have paid attention to the implant-abutment interface. The implant-abutment connection is the most critical part of the implant system because it must resist maximum masticatory forces and bacterial infiltration(10). Different prosthetic connections are available and evolved from external hexagon (HE) to grand morse (GM), which is an evolution of cone morse (CM). The conical connection seems to lead to lower bone loss; however, implant survival is comparable between conical and non-conical connections(10).

This way, optimizing macrogeometry and implant-abutment connection can lead to a more reliable implant in many clinical conditions, even challenging ones. To the author's knowledge, there is no mid-term clinical study evaluating a GM Hybrid Implant. We expected to find a high implant survival rate and no serious adverse event. Thus, this retrospective study aimed to evaluate the survival rate of hybrid macrogeometric implants in different patient profiles and clinical conditions.

MATERIALS AND METHODS

Study design and data collection

This study was approved by Ilapeo College ethical committee (process number: 6.792.960). The manuscript was prepared according to the Strengthening Reporting of

Observational Studies (STROBE) in Epidemiology(11). The data were retrospectively collected from clinical records of patients with at least one Helix implant (Neodent, Curitiba, Brazil) inserted at ILAPEO College (Curitiba, Brazil) from 2018 to 2024. All patients rehabilitated with Helix implant at Ilapeo until the date of this study were included in this sample. The data collection was performed from 2021 to 2024. Patients rehabilitated with at least one Helix Implant (Neodent, Curitiba, Brazil) were included. No exclusion criteria were applied.

Two trained operators retrieved the following parameters from patients' files:

- Patient-related: age, gender, presence of comorbidities, smoking habits, oral hygiene, previous head/neck radiotherapy, and bruxism and clenching presence.
- Implant- and surgical procedure-related: implant length and diameter, prosthetic interface, bone graft procedure, tissue graft procedure, bone type, insertion torque, flap or flapless surgery, guided surgery, region of implant placement, adverse events, and implant survival.

Multiple operators, students and attendants, performed all surgical procedures. However, the clinic's standard procedures were applied to all patients. Post-operative instructions, appropriate medication prescriptions, and scheduled follow-up appointments were given after implant placement.

Data analysis

All analyses were performed using Jamovi software version 2.6.19 (The jamovi project, 2023). Descriptive summary statistics were estimated for all parameters. Quantitative parameters were described by mean, standard deviation, minimum, and maximum. For qualitative variables, frequencies were given. Survival rate was estimated by dividing the number of events by the total number of implants evaluated.

The association between the dependent variables "implant survival" and patient, procedure and implant characteristics were evaluated by chi-square or Fisher tests. Missing data concerning a specific parameter was not included in association analyses. The significance level for all tests was $p<0.05$.

RESULTS

Population characteristics

The sample consisted of 1215 patients, of whom 740 (60.91%) were women and 475 (39.09%) were men, with a mean age of 57.17 ± 12.09 years (ranging from 24 to 93 years). The most frequent patient's medical condition was controlled or uncontrolled diabetes (99; 8.14%), controlled or uncontrolled hypertension (346; 28.48%), controlled or uncontrolled thyroid dysfunction (101; 8.32%), use of steroids (corticoids) (73; 6.01%), psychological limitations (78; 6.42%), and self-reported bruxism and clenching (71; 5.84%). Presence of weak immunological system (5; 0.41%), coagulation disorders (24; 1.97%), unsuitable soft tissue capacity (16; 1.32%), periodontitis (13; 1.07%), previously head/neck radiotherapy (3; 0.24%), and poor oral hygiene (7; 0.57%) were presented in lower quantity. Table 1 describes the patient's characteristics.

Table 1 – Descriptive analysis of the patient's characteristics at the patient level (n=1215)

Variable		**N**	**%**
Presence of a weak immunological system?	Yes	5	0.41
	Not informed	1210	99.59
Diabetes	Yes, controlled diabetes	67	5.51
	Yes, uncontrolled diabetes	2	0.16
	Yes, not informed if controlled	30	2.47
	No	1092	89.88
	Not informed	24	1.98
Hypertension	Yes, controlled hypertension	286	23.54
	Yes, uncontrolled hypertension	7	0.58
	Yes, not informed if controlled	53	4.36

	No	840	69.13
	Not informed	29	2.39
Thyroid disfunction	Yes, controlled thyroid dysfunction	90	7.41
	Yes, not informed if controlled	11	0.91
	No	5	0.41
	Not informed	1109	91.27
Coagulation disorders (hemophilia, low platelet count)	Yes	23	1.89
	Yes, low platelet count	1	0.08
	No, but had bleeding problems in the past	2	0.16
	No	548	45.10
	Not informed	641	52.77
Unsuitable soft tissue capacity?	Yes	16	1.32
	No	553	45.51
	Not informed	646	53.17
Periodontitis	Yes, and treated	13	1.07
	Not informed	1202	98.93
Use of steroids (corticoids)	Yes	73	6.01
	No	1094	90.04
	Not informed	48	3.95
Previously head/neck radiotherapy	Yes, more than 5 years	1	0.08
	Yes, date no informed	2	0.16
	No	1162	95.64
	Not informed	50	4.12
Psychological limitations?	Yes	78	6.42
	No	1104	90.86
	Not informed	33	2.72
Presence of poor oral hygiene?	Yes and treated	2	0.16
	Yes	5	0.41
	No	5	0.41
	Not informed	1203	99.02
Bruxism and clenching	Yes	66	5.43
	Yes, use occlusal splint	4	0.33
	Yes, but do not use occlusal splint	1	0.08
	No	37	3.05
	Not informed	1107	91.11
Presence of other diseases?	Yes	506	41.65
	No	706	58.10
	Not informed	3	0.25
Smoking	Yes	56	4.61
	Yes, less than 10 cigarettes/day	50	4.12
	Yes, more than 10 cigarettes/day	36	2.96
	Former smoker	2	0.16
	No	1019	83.87

	Not informed	52	4.28

Procedure and implant characteristics

Regarding the surgical procedure (Table 2), 1295 (27.08%) implants received bone grafts. Most bone graft procedures (927; 19.38%) occurred in conjunction with implant placement. The tissue graft procedure was performed 809 (16.91%) times, and the majority (420; 8.99%) in conjunction with implant placement.

Forty-six (0.96%) implants were placed in bone type I, 215 (4.50%) in bone type II, 232 (4.85%) in bone type III, 44 (0.92%) in bone type IV, and 4246 (88.77%) not informed. Most implants were placed with an insertion torque between 32-60 N.cm (3212; 67.18%). Nine (0.19%) implants were placed through flapless surgery and 44 (0.92%) open flap. Guided surgery was used in 474 (9.91%) implants.

The main region of implant placement on the maxilla was premolar (823; 17.21%), followed by molar (702; 14.68%), incisor (530; 11.08%), full arch (218; 4.56%), canine (174; 3.64%), and not informed (9; 0.19%). On the other hand, the main region of implant placement on the mandible was molar (1120; 23.42%), followed by full arch (607; 12.69%), premolar (461; 9.64%), incisor (113; 2.36%), canine (29; 0.61%), not informed (3;0.06%), and symphysis (1; 0.02%).

Table 2 - Descriptive analysis of surgical procedure variables at implant level (n=4783)

Variable		**N**	**%**
Bone graft procedure	Yes	1295	27.08
	No	3487	72.90
	Not informed	1	0.02
Type of graft procedure	Autogenous	32	0.67
	Synthetic	1	0.02
	Xenogenous	1256	26.26
	Not informed	6	0.13
	Not applicable	3488	72.92

Time between bone graft and implant placement	In conjunction with implant placement	927	19.38
	1-4 months	15	0.31
	5-6 months	10	0.21
	7-12 months	156	3.26
	More than 1 year	186	3.89
	Not informed	2	0.04
	Not applicable	3487	72.91
Tissue graft procedure	Yes	809	16.91
	No	3973	83.07
	Not informed	1	0.02
Time between tissue graft and implant placement	In conjunction with implant placement	430	8.99
	1-4 months	31	0.65
	5-6 months	19	0.40
	7-12 months	155	3.24
	More than 1 year	174	3.64
	Not informed	1	0.02
	Not applicable	3973	83.06
Bone type	I	46	0.96
	II	215	4.50
	III	232	4.85
	IV	44	0.92
	Not informed	4246	88.77
Insertion torque (N.cm)	<= 10	80	1.67
	>10 and <32	572	11.96
	32-60	3213	67.18
	>60	245	5.12
	No torque	1	0.02
	Not informed	672	14.05
Flapless of open flap surgery	Flapless	9	0.19
	Open flap	44	0.92
	Not informed	4730	98.89
Guided surgery	Yes	474	9.91
	No	4309	90.09
Region of implant placement on maxilla	Incisor	530	11.08
	Canine	174	3.64
	Premolar	823	17.21
	Molar	702	14.68
	Full arch	218	4.56
	Not informed	9	0.19
	Not applicable	2327	48.64
Region of implant placement on mandible	Incisor	113	2.36
	Canine	29	0.61
	Premolar	461	9.64
	Molar	1120	23.42
	Symphysis	1	0.02

	Full arch	607	12.69
	Not informed	3	0.06
	Not applicable	2449	51.20

A total of 4783 Helix implants (Neodent, Curitiba, Brazil) were placed. Their length ranged from 8 to 18 mm, and their diameters from 3.5 mm to 7 mm. Almost all implants were Acqua except for one (0.02%) Neoporos. All the implants were Grand Morse. Patients were followed for a mean period of 29.54 ± 18.95 months (varying from 0 to 81.70). The "not informed" and "not applicable" answers were excluded from calculating the implant survival rate, resulting in 4777 implants with implant loss information. Thus, one hundred and fifty-one implants were lost due to lack of osseointegration, resulting in an implant survival rate of 96.83%.

Adverse events were reported in 389 (8.13%) implants. Table 3 describes all adverse events observed.

Table 3 – Description of adverse events data at implant level.

Variable		**N**	**%**
Adverse event type	Alteration to soft tissue	1	0.27
	Alveolitis	1	0.27
	ATM pain	4	1.05
	Bleeding	1	0.27
	Bone exposure	6	1.58
	Bone fracture	1	0.27
	Bone loss	4	1.06
	Bone spicule	6	1.58
	Chronic pain	18	4.77
	Chronic pain and abutment loosening	1	0.27
	Contamination	34	9.01
	Dehiscence	6	1.59
	Expelling graft material	4	1.06
	Exposed threads	2	0.53
	Fenestration	5	1.33
	Fistula	6	1.58
	Fracture of implant screw	3	0.8
	Abutment fracture	6	1.58

	Hyperplasia	4	1.06
	Implant fell in the sinus	3	0.8
	Infection	3	0.8
	Inflammation	5	1.33
	Abutment loosening	5	1.33
	Healing abutment loosening	2	0.53
	Loss of abutment and prosthetic component	1	0.27
	Loss of bone edge	55	14.58
	Loss of bone edge and oedema	1	0.27
	Healing loss	1	0.27
	Molding material between implants	2	0.53
	Mucosal lesion	3	0.8
	Necrosis due to tissue graft	1	0.27
	Edema	12	3.17
	Edema and inflammation	2	0.53
	Oral sinus communication	9	2.39
	Other	11	2.92
	Pain	55	14.58
	Pain and bone exposure	2	0.53
	Pain and fistulae	1	0.27
	Pain and edema	20	5.3
	Pain and suppuration	8	2.12
	Paresthesia	42	11.14
	Paresthesia and dehiscence	1	0.27
	Paresthesia and oedema	2	0.53
	Peri-implant injury	1	0.27
	Peri-implant mucositis	1	0.27
	Root drilling of 43	1	0.27
	Sensibility	3	0.8
	Sensibility and pain	1	0.27
	Suppuration	6	1.58
	Suppuration and edema	1	0.27
	Touching the adjacent tooth	1	0.27
	Ulcer	1	0.27
	Not informed	1	0.27

Association between patient, procedure, and implant characteristics with implant loss

Table 4 presents the frequency of patients' characteristics variables according to implant loss. Only hypertension disease and smoking habits were associated with implant loss.

Table 4 - Frequency of variables referring to patients' characteristics according to implant loss.

Variables		Did implant loss happened?				
		No		Yes		
		N	lin%	N	lin%	p-value*
Age	<60	620	91.40	58	8.60	0.561
	≥60	485	90.50	51	9.50	
Gender	Female	669	90.40	71	9.60	0.348
	Male	436	92.00	38	8.00	
Diabetes	Yes, controlled diabetes	57	85.10	10	14.90	0.362
	Yes, uncontrolled diabetes	2	100.00	0	0.00	
	Yes, not informed if controlled	28	93.30	2	6.70	
	No	996	91.30	95	8.70	
Hypertension	Yes, controlled hypertension	252	88.40	33	11.60	0.021
	Yes, uncontrolled hypertension	5	71.40	2	28.60	
	Yes, not informed if controlled	52	98.10	1	1.90	
	No	769	91.50	71	8.50	
Thyroid disfunction	Yes, controlled thyroid dysfunction	82	91.10	8	8.90	1.000
	Yes, not informed if controlled	10	90.90	1	9.10	
	No	5	100.00	0	0.00	
Coagulation disorders (hemophilia, low platelet count)	Yes	22	95.70	1	4.30	0.224
	Yes, low platelet count	1	100.00	0	0.00	
	No, but had bleeding problems in the past	1	50.00	1	50.00	
	No	500	91.40	47	8.60	
Unsuitable soft tissue capacity?	Yes	16	100.00	0	0.00	0.384
	No	503	91.10	49	8.90	
Use of steroids (corticoids)	Yes	69	94.50	4	5.50	0.287
	No	993	90.90	100	9.10	
Previously head/neck radiotherapy	Yes, more than 5 years	0	0.00	1	100.00	0.096
	Yes, date no informed	2	100.00	0	0.00	
	No	1059	91.20	102	8.80	
Psychological limitations?	Yes	71	91.00	7	9.00	0.979
	No	1005	91.10	98	8.90	
Presence of poor oral hygiene?	Yes and treated	2	100.00	0	0.00	1.000
	Yes	4	80.00	1	20.00	
	No	4	80.00	1	20.00	
Bruxism and clenching	Yes	60	90.90	6	9.10	0.722
	Yes, use occlusal splint	4	100.00	0	0.00	
	Yes, but do not use occlusal splint	1	100.00	0	0.00	

	No	32	86.50	5	13.50	
Presence of other diseases?	Yes	489	96.80	16	3.20	0.927
	No	682	96.70	23	3.30	
Smoking	Yes	50	89.30	6	10.70	0.009
	Yes, less than 10 cigarettes/day	38	76.00	12	24.00	
	Yes, more than 10 cigarettes/day	34	94.40	2	5.60	
	Former smoker	2	100.00	0	0.00	
	No	937	92.00	81	8.00	

*Chi-Squared test and Fisher test when at least one expected count was less than 5; N = number of observations; lin% = relative frequency (line).

A statistically significant association was found between implant loss and bone graft procedure, bone type, insertion torque, region of placement on the mandible, and adverse event occurrence. Table 5 describes these associations. No association between implant characteristics and implant loss was found.

Table 5 - Frequency of variables referring to surgical procedure characteristics according to implant loss.

Variables		**Did implant loss happened?**				
		No		**Yes**		
		N	**lin%**	**N**	**lin%**	**p-value***
Bone graft procedure	Yes	1239	95.90	53	4.10	0.024
	No	3386	97.20	98	2.80	
Type of graft procedure	Autogenous	32	100.00	0	0.00	0.654
	Synthetic	1	100.00	0	0.00	
	Xenogenous	1200	95.80	53	4.20	
Time between bone graft and implant placement	In conjunction with implant placement	881	95.30	43	4.70	0.479
	1-4 months	14	93.30	1	6.70	
	5-6 months	10	100.00	0	0.00	
	7-12 months	152	97.40	4	2.60	
	More than 1 year	181	97.30	5	2.70	
Use of Neodent graft screw	Yes	68	94.40	4	5.60	0.290
	No	4557	96.90	147	3.10	
Tissue graft procedure	Yes	776	95.90	33	4.10	0.102
	No	3849	97.00	118	3.00	
Time between tissue graft and implant placement	In conjunction with implant placement	405	94.20	25	5.80	0.151
	1-4 months	30	96.80	1	3.20	
	5-6 months	19	100.00	0	0.00	

	7-12 months	152	98.10	3	1.90	
	More than 1 year	170	97.70	4	2.30	
Bone type	I	46	100.00	0	0.00	0.028
	II	206	95.80	9	4.20	
	III	231	99.60	1	0.40	
	IV	43	97.70	1	2.30	
Insertion torque (N.cm)	<= 10	73	91.30	7	8.80	0.004
	>10 and <32	551	96.30	21	3.70	
	32-60	3130	97.40	82	2.60	
	>60	243	99.20	2	0.80	
	No torque	1	100.00	0	0.00	
Flapless of open flap surgery	Flapless	8	88.90	1	11.10	0.170
	Open flap	44	100.00	0	0.00	
Guided surgery	Yes	464	97.90	10	2.10	0.168
	No	4162	96.70	141	3.30	
Region of placement on maxilla	Incisor	521	98.30	9	1.70	0.188
	Canine	166	96.00	7	4.00	
	Premolar	799	97.40	21	2.60	
	Molar	675	96.20	27	3.80	
	Full arch	211	96.80	7	3.20	
Region of placement on mandible	Incisor	111	98.20	2	1.80	<.001
	Canine	29	100.00	0	0.00	
	Premolar	435	94.60	25	5.40	
	Molar	1071	95.70	48	4.30	
	Symphysis	1	100.00	0	0.00	
	Full arch	605	99.70	2	0.30	
Any adverse event occurred?	Yes	291	75.00	97	25.00	<.001
	No	4335	98.80	54	1.20	

*Chi-Squared test and Fisher test when at least one expected count was less than 5; N = number of observations; lin% = relative frequency (line).

DISCUSSION

Implant-supported prostheses are a good choice for treating totally or partially edentulous patients. Indeed, this study found a high implant survival rate (96.83%) in a follow-up period of up to 6.8 years, showing that GM Helix implants are also a reliable option for patients with comorbidity and different clinical conditions.

Choosing implants is crucial to clinical outcomes, osseointegration, stability, and long-term success. The two main implant macrogeometries in the market are cylindrical and tapered, and depending on the bone quality, one macrogeometry achieves better primary stability than the other. The tapered implant is indicated for low bone density or, in recent extraction

sockets(12). Due to the combination of tapered and cylindrical shapes, hybrid macrogeometry can be used for all bone types, facilitating clinician practice. Indeed, this study proves that this hybrid implant has high implant survival and is safe in all bone types and for different clinical conditions.

The survival rate of cylindrical and tapered implants has been extensively studied. Studies observed survival rates between 81% and 98.7% in up to 10 years of follow-up for these macrogeometries(13–16). One study evaluated a hybrid implant with a similar design to the Helix implant and observed a survival rate of 92% to 98.6% in 1-year follow-up when subjected to different loading and insertion protocols(9). These survival rates are similar to our findings. However, our study highlights some important topics. The survival rate found in our study was evaluated in a high quantity of implants, which is difficult to find in the literature. In addition, the implants were placed in a diverse population with different clinical conditions and by multiple clinicians, including non-experienced, and even in this scenario, the survival rate was high. Only one macrogeometry was evaluated in a high quantity, reinforcing the good survival rate of this macrogeometry.

Health-compromised patients are a challenge. It is crucial to identify potential risk factors associated with implant failure and evaluate if it is possible to manage them. The association analysis of patient characteristics and implant loss in this study showed an association between hypertension and tobacco use. Smoking as a risk factor for implant failure has been extensively discussed, and there is a controversy in the literature. Some studies reported that smoking alone could not be considered a risk factor, while other authors showed higher risks of implant failure in smokers(17–20). Hypertension was also associated with implant loss. However, a few studies evaluating this influence and a systematic review found no association between hypertension and dental implant failure(21).

The implant loss was also associated with bone graft procedures. This association has been studied, and studies revealed that implant survival rates are comparable between graft and non-grafted areas(22,23). However, systemic health, smoking status, and oral hygiene can influence survival in graft and non-graft areas, and these influences may explain the association found in this study.

The current knowledge of implant survival in different bone types can explain the association between bone type and implant loss found in our study. The bone is classified according to bone density, and it is well established that bone density can interfere with implant stability and osseointegration. Low-density bone is related to insufficient bone-to-implant contact, leading to low stability(24). Additionally, low-quality bones have lower vascularization and reduced ability to repair, which can interfere with the osseointegration process. Studies have shown that the implant survival rates are lower when bone quality decreases(25–26). As bone type is related to implant stability, higher insertion torques are achieved in higher-density bone. Since the bone type was associated with implant loss, insertion torque was also associated.

The region of implant placement on the mandible may affect implant survival due to anatomical and biomechanical differences. Implants placed in the posterior region are more susceptible to greater forces and stress during mastication, which can lead to complications(27). Additionally, with the presence of anatomical landmarks and difficulty in achieving primary stability due to bone quality, the anterior mandible is a challenging region(28)All these factors can lead to higher rates of implant failure, which corroborates the association found in our study.

Many studies describe changes in design as one factor improving implant stability(29). Indeed, the hybrid implant was designed to achieve high insertion torques and allow immediate loading. More than 70% of the implants evaluated in this study achieved insertion torques

higher than 32 N.com, allowing immediate loading. This result reinforces the use of this hybrid macrogeometry implant for immediate loading.

Since this study is retrospective, missing data could result from poor registration quality or variables not considered registered in advance. In both cases, the origin of missing information can lead to information bias. Analyses of the correlation between patient characteristics and parameters of interest may also minimize confounding bias. Additionally, missing or not informed data were removed from the statistical analysis not to compromise the results. Another limitation inherent to retrospective design is the lack of information due to the clinician not reporting adequately in the patient file, leading to a conclusion different from the real scenario. In this way, variables with low information must be evaluated with caution.

CONCLUSION

Treatment using a hybrid macrogeometry dental implant is a predictable option for total or partial edentulous patients with compromised health and different clinical conditions. The implant survival rate was 96.83% up to 6.8 years of follow-up. A low complication rate of 8.13% occurred, and most events were mild and with management possibility.

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2. Artigo científico 2

Artigo de acordo com as normas da Faculdade ILAPEO.

FINAL PROSTHESIS SURVIVAL AND COMPLICATION RATES OF PROSTHESES SUPPORTED BY A GRAND MORSE IMPLANT: A RETROSPECTIVE STUDY

Kleryo Antonilo Santos Câmara[1]
Alexandre Negretto[1]
Ivete Aparecida de Mattias Sartori[2]
Geninho Thomé[2]
Sergio Rocha Bernardes[2]
Tatiana Miranda Deliberador[2]

[1] **DDS, PhD Student in Dentistry at Ilapeo College, Curitiba, Brazil**
[2] **DDS, MsC, PhD, Professor at Ilapeo College, Curitiba, Brazil**

RESUMO

Objetivo: Este estudo retrospectivo teve como objetivo avaliar a sobrevivência da prótese final a médio prazo e as taxas de complicações de próteses suportadas por implante cone morse.

Métodos: Um total de 1215 prontuários clínicos de pacientes com pelo menos um implante Helix (Neodent, Curitiba, Brasil) instalado na Faculdade ILAPEO (Curitiba, Brasil) de 2018 a 2024. A coleta de dados foi realizada de 2021 a 2024. Parâmetros relacionados aos pacientes, implantes e características da prótese foram coletados: idade, sexo, presença de comorbidades, hábitos de tabagismo, higiene oral, radioterapia prévia de cabeça/pescoço e presença de bruxismo e apertamento, comprimento e diâmetro do implante, interface protética, uso de prótese temporária, tipo de prótese, retenção da prótese final, complicações da prótese e sobrevivência da prótese. Estatísticas descritivas resumidas foram estimadas para todos os parâmetros. A taxa de sobrevida foi estimada dividindo-se o número de eventos pelo número total de próteses avaliadas. As associações entre as variáveis dependentes "sobrevida da prótese" e as características do paciente e da prótese foram avaliadas pelos testes qui-quadrado ou de Fisher.

Resultados: Um total de 4783 implantes Helix GM foram instalados em 1215 pacientes com idade média de 57,17 ± 12,09 anos (variando de 24 a 93 anos). A condição médica mais frequente dos pacientes foi diabetes, hipertensão, disfunção tireoidiana, uso de esteroides (corticoides), limitações psicológicas e bruxismo e apertamento. 1719 próteses foram instaladas. Destas 1719 próteses, 1021 eram unitárias, 380 de arco total, 317 múltiplas e 1 tipo não informado. Em relação à retenção final da prótese, 569 foram parafusadas, 304 cimentadas e 788 não foram informadas. Pelo menos 955 próteses temporárias foram utilizadas. As próteses foram acompanhadas por um período médio de 17,49 ± 19,15 meses (variando de 0 a 81,57 meses). Trinta e uma próteses foram perdidas, resultando em uma taxa de sobrevivência da prótese de 97,68%. Complicações foram relatadas em 132 (7,68%) próteses. Hipertensão e ocorrência de complicações foram associadas à falha da prótese.

Conclusão: As próteses implantossuportadas por implantes morse taper Helix® são uma boa opção para o tratamento de pacientes total ou parcialmente desdentados. A taxa de sobrevida da prótese foi de 97,68% em até 6,8 anos de acompanhamento. A taxa de complicações foi baixa, de 7,68%, sendo fratura e afrouxamento da prótese as complicações mais comuns..

Palavras-chave: Prótese Dentária Fixada por Implante; Complicações; Falha de Restauração Dentária.

ABSTRACT

Objective: This retrospective study aimed to assess the mid-term final prosthesis survival and complication rates of prostheses supported by a grand morse implant.

Methods: A total of 1215 patients were chosen from clinical records of patients with at least one Helix implant (Neodent, Curitiba, Brazil) inserted at ILAPEO College (Curitiba, Brazil) from 2018 to 2024. The data collection was performed from 2021 to 2024. Parameters related to patients, implants, and prosthesis characteristics were collected: age, gender, presence of comorbidities, smoking habits, oral hygiene, previous head/neck radiotherapy, and bruxism and clenching presence, implant length and diameter, prosthetic interface, use of temporary prosthesis, prosthesis type, final prosthesis retention, prothesis complications, and prosthesis survival. Descriptive summary statistics were estimated for all parameters. Survival rate was estimated by dividing the number of events by the total number of implants evaluated. The associations between the dependent variables “implant survival” and patient and prosthesis characteristics were evaluated by chi-square or Fisher tests.

Results: A total of 4783 GM Helix implants were placed in 1215 patients with a mean age of 57.17 ± 12.09 years (ranging from 24 to 93 years). The most frequent patient’s medical condition was diabetes, hypertension, thyroid dysfunction, use of steroids (corticoids), psychological limitations, and bruxism and clenching. 1719 prosthesis were installed. From these 1719 prostheses, 1021 were single-unit, 380 full arch, 317 multi-unit, and 1 type not informed. Regarding final prosthesis retention, 569 were screwed, 304 cemented and 788 were not informed. At least 955 temporary prosthesis was used. Prostheses were followed for a mean period of 17.49 ± 19.15 months (varying from 0 to 81.57 months). Thirty-one prostheses were lost resulting in a prosthesis survival rate of 97,68%. Complications were reported in 132 (7,68%) prostheses. Hypertension disease and complication occurrence were associated with prosthesis failure.

Conclusion: Cone-morse Helix Implant-supported prostheses are a good choice for treating totally or partially edentulous patients. The prosthesis survival rate was 97.68% up to 6.8 years of follow-up. A low complication rate of 7.68% occurred, with prosthesis fracture and loosening being the most common complications..

Keywords: Dental Prosthesis, Implant-Supported; Complications; Dental Restoration Failure.

INTRODUCTION

Muco-supported and implant-supported prostheses are the two options for treating edentulous patients. Due to muco-supported prostheses’ limitations and the high predictability and long-term success of implant-supported prostheses, their use has been increasing independently if they are to replace a single or multiple tooth(1). Despite the high predictability, treatment success can be affected by routine complications and prosthesis failure(2).

Survival rates cannot be the only factor defining treatment success, as survival rates mean prostheses used during a determined follow-up time without considering complications that can occur during their lifetime. Complication rates are a critical factor influencing general treatment success(3). Additionally, patients with prosthesis complications tend to be more dissatisfied, impacting the treatment success(1).

Prosthesis complications can be defined as technical or mechanical. Technical complications are related to the laboratory-manufactured parts, such as prosthesis fracture or chipping of the veneering material. On the other hand, the mechanical complications are more related to the pre-manufactured part, implants and abutments, and prosthetic fixation screw or abutment loosening and fracture of abutment are examples of mechanical complications(4).

This way, evaluating the prosthesis survival and complication rates is important to understanding the treatment success. We expected to find high prosthesis survival and complication rates equivalent to those already observed in the literature. Thus, this retrospective study aimed to assess the mid-term final prosthesis survival and complication rates of prostheses supported by a grand morse implant.

MATERIALS AND METHODS

Study design and data collection

This study was approved by Ilapeo College ethical committee (process number: 6.792.960). The manuscript was prepared according to the Strengthening Reporting of Observational Studies (STROBE) in Epidemiology(5). The data were retrospectively collected from clinical records of patients with at least one Helix implant (Neodent, Curitiba, Brazil) inserted at ILAPEO College (Curitiba, Brazil) from 2018 to 2024. All patients rehabilitated with Helix implant at Ilapeo until the date of this study were included in this sample. The data

collection was performed from 2021 to 2024. Patients rehabilitated with at least one Helix Implant (Neodent, Curitiba, Brazil) were included. No exclusion criteria were applied.

Two trained operators retrieved the following parameters from patients' files::

- Patient-related: age, gender, presence of comorbidities, smoking habits, oral hygiene, previous head/neck radiotherapy, and bruxism and clenching presence.
- Implant- and prosthesis-related: implant length and diameter, prosthetic interface, use of temporary prosthesis, prosthesis type, final prosthesis retention, prosthesis complications, and prosthesis survival.

Multiple operators, students and attendants, performed all surgical procedures and prostheses installation. However, the clinic's standard procedures were applied to all patients. Post-operative instructions, appropriate medication prescriptions, and scheduled follow-up appointments were given after implant placement.

Data analysis

All analyses were performed using Jamovi software version 2.6.19 (The jamovi project, 2023). Descriptive summary statistics were estimated for all parameters. Quantitative parameters were described by mean, standard deviation, minimum, and maximum. For qualitative variables, frequencies were given. Survival rate was estimated by dividing the number of events by the total number of prostheses evaluated.

The association between the dependent variables "prosthesis survival" and patient, and prosthesis characteristics were evaluated by chi-square or Fisher tests. Missing data concerning a specific parameter was not included in association analyses. The significance level for all tests was $p<0.05$.

RESULTS

Population characteristics

The sample consisted of 1215 patients, of whom 740 (60.91%) were women and 475 (39.09%) were men, with a mean age of 57.17 ± 12.09 years (ranging from 24 to 93 years). The most frequent patient's medical condition was controlled or uncontrolled diabetes (99; 8.14%), controlled or uncontrolled hypertension (346; 28.48%), controlled or uncontrolled thyroid dysfunction (101; 8.32%), use of steroids (corticoids) (73; 6.01%), psychological limitations (78; 6.42%), and self-reported bruxism and clenching (71; 5.84%). Presence of weak immunological system (5; 0.41%), coagulation disorders (24; 1.97%), unsuitable soft tissue capacity (16; 1.32%), periodontitis (13; 1.07%), previously head/neck radiotherapy (3; 0.24%), and poor oral hygiene (7; 0.57%) were presented in lower quantity. Table 1 describes the patient's characteristics.

Table 2 – Descriptive analysis of the patient's characteristics at the patient level (n=1215)

Variable		**N**	**%**
Presence of a weak immunological system?	Yes	5	0.41
	Not informed	1210	99.59
Diabetes	Yes, controlled diabetes	67	5.51
	Yes, uncontrolled diabetes	2	0.16
	Yes, not informed if controlled	30	2.47
	No	1092	89.88
	Not informed	24	1.98
Hypertension	Yes, controlled hypertension	286	23.54
	Yes, uncontrolled hypertension	7	0.58
	Yes, not informed if controlled	53	4.36
	No	840	69.13
	Not informed	29	2.39
Thyroid disfunction	Yes, controlled thyroid dysfunction	90	7.41
	Yes, not informed if controlled	11	0.91
	No	5	0.41
	Not informed	1109	91.27
Coagulation disorders (hemophilia, low platelet count)	Yes	23	1.89
	Yes, low platelet count	1	0.08
	No, but had bleeding problems in the past	2	0.16
	No	548	45.10
	Not informed	641	52.77
Unsuitable soft tissue capacity?	Yes	16	1.32

	No	553	45.51
	Not informed	646	53.17
Periodontitis	Yes, and treated	13	1.07
	Not informed	1202	98.93
Use of steroids (corticoids)	Yes	73	6.01
	No	1094	90.04
	Not informed	48	3.95
Previously head/neck radiotherapy	Yes, more than 5 years	1	0.08
	Yes, date no informed	2	0.16
	No	1162	95.64
	Not informed	50	4.12
Psychological limitations?	Yes	78	6.42
	No	1104	90.86
	Not informed	33	2.72
Presence of poor oral hygiene?	Yes and treated	2	0.16
	Yes	5	0.41
	No	5	0.41
	Not informed	1203	99.02
Bruxism and clenching	Yes	66	5.43
	Yes, use occlusal splint	4	0.33
	Yes, but do not use occlusal splint	1	0.08
	No	37	3.05
	Not informed	1107	91.11
Presence of other diseases?	Yes	506	41.65
	No	706	58.10
	Not informed	3	0.25
Smoking	Yes	56	4.61
	Yes, less than 10 cigarettes/day	50	4.12
	Yes, more than 10 cigarettes/day	36	2.96
	Former smoker	2	0.16
	No	1019	83.87
	Not informed	52	4.28

Implant and prosthesis characteristics

A total of 4783 Helix implants were placed. Their length ranged from 8 to 18 mm, and their diameters from 3.5 mm to 7 mm. Almost all implants were Acqua except for one (0.02%) Neoporos. All the implants were Grand Morse. Implants were followed for a mean period of 29.54 ± 18.95 months (varying from 0 to 81.70).

Excluding the “not informed” and “not applicable answers”, 1719 prostheses were installed. From these 1719 prostheses, 1021 (59.39%) were single-unit, 380 (22.11) full arch, and 317 (18.44%) multi-unit. Regarding final prosthesis retention, 569 (33.10%) were screwed and 304 (17.68%) cemented. At least 955 (55.55%) temporary prosthesis was used. Table 2 describes the prosthesis variable.

Table 2 - Descriptive analysis of prosthesis variables at prosthesis level (n=1719)

Variable		**N**	**%**
Use of temporary prosthesis	Yes	955	55.55
	No	642	37.35
	Not informed	122	7.1
Type of prosthesis	Single-unit	1021	59.39
	Multi-unit	317	18.44
	Full arch	380	22.11
	Not informed	1	0.06
Final prosthesis retention	Cemented	304	17.68
	Screwed	569	33.10
	Not informed	788	45.85
	Not applicable	58	3.37
Was the final prosthesis lost?	Yes	31	1.80
	No	1306	75.97
	Not informed	20	1.16
	Not applicable	362	21.07

Excluding the “not applicable” and “not informed data,” the mean time for final prosthesis installation was 10.90 ± 12.80 months (varying from 0 to 67.60), and the mean loading time was 4.84 ± 9.70 months (varying from 0 to 62.40).

The “not informed” and “not applicable” answers were excluded from calculating the prosthesis survival rate, resulting in 1337 prosthesis with prosthesis loss information. Thirty-one prostheses were lost; thus, the prosthesis survival rate was 97.68% (1306/1337) in a mean prosthesis follow-up of 17.49 ± 19.15 months (varying from 0 to 81.57 months).

One hundred thirty-two (7.68%) final prosthesis presented complications. Table 3 describes all final prosthesis complications.

Table 3 – Description of final prosthesis complication data at the prosthesis level.

Variable		N	%
Final prosthesis complication?	Yes	132	7.68
	No	1205	70.10
	Not informed	20	1.16
	Not applicable	362	21.06
If yes, which complications?	Aesthetic problems	8	0.47
	Bad touchpoint with 46	1	0.06
	Bar without passivity and fracture of prosthesis	1	0.06
	Dehiscence	1	0.06
	Food accumulation	1	0.06
	Fracture of prosthesis	71	4.12
	Fracture of prosthetic screw	1	0.06
	Loosening of abutment	1	0.06
	Loosening of prosthesis	23	1.33
	Loosening of prosthesis and abutment	2	0.12
	Loosening of prothesis and fracture of prosthesis	1	0.06
	Loosening of prosthesis and loss of the screws	1	0.06
	Loosening of prosthesis and nuisance	1	0.06
	Loss of a prosthetic component	4	0.23
	Loss of a prosthetic component (44), fracture (42 and 43)	1	0.06
	Loss of a prosthetic component and fracture of prosthesis	2	0.12
	Loss of a prosthetic screw and loosening of prosthesis	1	0.06
	Nuisance	1	0.06
	Patient can’t sanitize	2	0.12
	Sore gum	1	0.06
	The bar did not adapt to the component of implant 4	1	0.06
	Not informed	23	1.33
	Not applicable	1570	91.32

Association between patient and prosthesis characteristics with prosthesis loss

Only an association between hypertension disease and prosthesis loss was observed. Table 4 shows the frequency of variables referring to the patients' characteristics according to prosthesis loss.

Table 4 - Frequency of variables referring to patients' characteristics according to prosthesis loss.

Variables		**Did prosthesis loss happened?**				
		No		**Yes**		
		N	**lin%**	**N**	**lin%**	**p-value***
Age	<60	460	97.00	14	3.00	0.803
	≥60	418	96.80	14	3.20	
Gender	Female	540	97.50	14	2.50	0.219
	Male	338	96.00	14	4.00	
Diabetes	Yes, controlled diabetes	57	98.30	1	1.70	1.000
	Yes, uncontrolled diabetes	1	100.00	0	0.00	
	Yes, not informed if controlled	24	100.00	0	0.00	
	No	778	96.80	26	3.20	
Hypertension	Yes, controlled hypertension	216	97.70	5	2.30	0.038
	Yes, uncontrolled hypertension	3	75.00	1	25.00	
	Yes, not informed if controlled	34	91.90	3	8.10	
	No	602	97.10	18	2.90	
Thyroid disfunction	Yes, controlled thyroid dysfunction	65	100.00	0	0.00	0.198
	Yes, not informed if controlled	10	90.90	1	9.10	
	No	5	100.00	0	0.00	
Coagulation disorders (hemophilia, low platelet count)	Yes	16	94.10	1	5.90	0.522
	Yes, low platelet count	1	100.00	0	0.00	
	No, but had bleeding problems in the past	1	100.00	0	0.00	
	No	420	96.30	16	3.70	
Unsuitable soft tissue capacity?	Yes	10	90.90	1	9.10	0.347
	No	425	96.40	16	3.60	
Use of steroids (corticoids)	Yes	54	98.20	1	1.80	1.000
	No	791	97.10	24	2.90	

Previously head/neck radiotherapy	Yes, more than 5 years	1	100.00	0	0.00	1.000
	Yes, date no informed	2	100.00	0	0.00	
	No	839	97.10	25	2.90	
Psychological limitations?	Yes	56	98.20	1	1.80	1.000
	No	799	97.00	25	3.00	
Presence of poor oral hygiene?	Yes and treated	1	100.00	0	0.00	1.000
	Yes	3	100.00	0	0.00	
	No	3	100.00	0	0.00	
Bruxism and clenching	Yes	56	90.30	6	9.70	0.416
	Yes, use occlusal splint	4	100.00	0	0.00	
	Yes, but do not use occlusal splint	1	100.00	0	0.00	
	No	25	100.00	0	0.00	
Presence of other diseases?	Yes	375	96.90	12	3.10	0.996
	No	501	96.90	16	3.10	
Smoking	Yes	41	97.60	1	2.40	1.000
	Yes, less than 10 cigarettes/day	37	97.40	1	2.60	
	Yes, more than 10 cigarettes/day	20	100.00	0	0.00	
	Former smoker	2	100.00	0	0.00	
	No	744	97.00	23	3.700	

*Chi-Squared test and Fisher test when at least one expected count was less than 5; N = number of observations; lin% = relative frequency (line).

Only final prosthesis complications among the prosthesis characteristics were associated with prosthesis loss. Table 5 describes the frequency of variables referring to prosthesis characteristics according to prosthesis loss.

Table 5 - Frequency of variables referring to prosthesis characteristics according to prosthesis loss.

Variables		**Did implant loss happened?**				
		No		**Yes**		
		N	**lin%**	**N**	**lin%**	**p-value***
Use of temporary prosthesis	Yes	587	98.20	11	1.80	0.320
	No	616	97.30	17	2.70	
Type of prosthesis	Single-unit	732	97.90	16	2.10	0.323
	Multi-unit	213	98.60	3	1.40	
	Full arch	361	96.80	12	3.20	
Final prosthesis retention	Cemented	283	96.30	11	3.70	0.492
	Screwed	541	97.10	16	2.90	
Final prosthesis complication?	Yes	110	83.30	22	16.70	<.001
	No	1196	99.30	9	0.70	

*Chi-Squared test and Fisher test when at least one expected count was less than 5; N = number of observations; lin% = relative frequency (line).

DISCUSSION

GM Helix Implant-supported prostheses are a good choice for treating totally or partially edentulous patients. Indeed, this study found a high prosthesis survival rate (97.68%) in a mean follow-up of 17.49 ± 19.15 months, showing that fixed implant-supported prostheses are a reliable option for partial or total edentulism treatment.

According to a systematic review, the 5-year rate of prosthesis survival ranged from 93.5% to 97.1% over the decades(3). Our study's final prosthesis survival rate was 97.68%, with a mean follow-up of 17.49 ± 19.15 months and up to 6.8 years. A recent meta-analysis of metal-ceramic multi-unit found a prosthesis survival of 98.7% in 5 years of follow-up. In the same 5 years of follow-up, the zirconia-ceramic multi-unit prosthesis presented a lower survival rate of 93%(6). Another study observed a high cumulative prosthesis survival rate of >95% regardless of type of retention(2).

In our study, 132 patients experienced any prosthesis complication, leading to a complication rate of 7.68%. This rate is lower than the observed in the literature for different prosthesis types(2,7). The most common complication was prosthesis fracture (4.12%), followed by prosthesis loosening (1.33%). These findings agree with other studies indicating fracture and loosening of artificial teeth as the most common complications with implant-supported crowns(7,8). Additionally, the most frequent prosthesis type in this study was single-unit, and prosthesis fracture and loosening were reported to be common technical complications in single-unit prosthesis(4).

Prosthesis complications can be influenced by sex, arch, opposing dentition, occlusal pattern, bruxism, poor health, metal framework design, and teeth and veneering material(7). Some studies have related bruxism with prosthesis complications(9,10). However, our study

did not find an association between bruxism and prosthesis failure. The diagnosis of bruxism is controversial and could influence this study's results.

According to the literature data, no prosthesis has yet been proven free of complications, and factors such as planning, prosthetic design, and execution can be related to catastrophic complications(11). The position of implants should be defined according to the prosthetic plan since implant malposition increases the risk of biomechanical complications with abutments and prosthesis(4,12). Thus, prosthetic planning is crucial to enhancing treatment success.

We observed an association between hypertension and prosthesis failure. To the author’s knowledge, no study in the literature evaluated this association. Another study from our group with this same sample showed an association between hypertension and implant loss, and prosthesis failure could be a consequence of this implant loss. In this way, as this association was observed with implant loss, the same association was observed for prosthesis failure without an etiological explanation related to the prosthesis.

Another association with prosthesis failure found in this study was complication occurrence. The fracture as the most common complication can explain this observation since the protocol to repair this condition is range from minor polishing adjustment of the restoration in minor cases to complete replacement(12). And when necessary to replace, the prosthesis is considered failed.

Since this study is retrospective, missing data could result from poor registration quality or variables not considered registered in advance. In both cases, the origin of missing information can lead to information bias and underestimation of prosthesis survival and complication rates. Analyses of the correlation between patient characteristics and parameters of interest may also minimize confounding bias. Additionally, missing or not informed data were removed from the statistical analysis not to compromise the results. Another limitation inherent to retrospective design is the lack of information due to the clinician not reporting

adequately in the patient file, leading to a conclusion different from the real scenario. In this way, variables with low information must be evaluated with caution.

CONCLUSION

GM Helix Implant-supported prostheses are a good choice for treating totally or partially edentulous patients. The prosthesis survival rate was 97.68% up to 6.8 years of follow-up. A low complication rate of 7.68% occurred, with prosthesis fracture and loosening being the most common complications.

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