Andrew Sotirios Melenikiotis

Avaliação da Qualidade Óssea e do Nível Ósseo ao Redor sw Implantes Cone Morse e Plataforma Switch Instalados em Áreas com Diferentes Densidades Ósseas e Submetidos à Carga Imediata : estudo clínico de um ano.

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

Orientador: Prof. Dr. Geninho Thomé
Co-orientadora: Profa. Dra. Ana Cláudia M. M. Toyofuku

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Dedicatória

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Sumário

1. Artigo científico 1

Artigo de acordo com as normas da Faculdade ILAPEO, para futura publicação no periódico **Journal of Periodontal and Implant Science**

INFLUENCE OF BONE QUALITY ON SUCCESS AND BONE LEVEL CHANGES AROUND PLATFORM-SWITCHED MORSE TAPER CONNECTION IMPLANTS SUPPORTING FIXED PARTIAL PROSTHESES: ONE-YEAR PROSPECTIVE CLINICAL STUDY

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RESUMO

Objetivo: Este estudo teve como objetivo avaliar a influência da qualidade óssea e a remodelaçnao do tecido ósseo ao redor de implantes Cone Morse com *platform switching* submetidos à carga imediata com próteses parciais fixas, no período de um ano.

Material e métodos: Quarenta e nove implantes Cone Morse e plataforma switch com superfícies hidrofílicas foram instalados em 12 pacientes (6 homens e 6 mulheres; idade média 44,67 ± 3,49 anos) sendo que vinte e sete destes, em osso tipo I/II e 22 em osso tipo III/IV. Pacientes encaminhados a uma Faculdade de Odontologia com necessidade de reabilitação parcial fixa implanto-suportada entre fevereiro e julho de 2019 foram incluídos neste estudo. A qualidade óssea foi avaliada por cirurgiões experientes de acordo com sua percepção de resistência durante a preparação do local do implante e confirmada na radiografia periapical. A avaliaçnao da remodelação do tecido ósseo peri-implantar foi realizada por radiografias periapicais obtidas em diferentes momentos : imediatamente após a colocação do implante (T0), 6 meses (T6) e um ano (T12) após a cirurgia. Todas as medições foram feitas por um único operador treinado.

Resultados: As taxas de sobrevivência e sucesso do implante foram de 100% para ambos os tipos de osso um ano após a cirurgia. Não foram encontradas diferenças estatisticamente significativas em relação às alterações do nível ósseo entre os grupos em nenhum dos períodos de observação. A perda

óssea média em T12 para o grupo osso tipo I/II foi de 0,93± 0,46mm e 1,00±0,58mm para o grupo osso tipo III/IV, sem diferença estatisticamente significante.
Conclusões: Dentro dos limites do prsente estudo, os resultados sugerem que os implantes de conexão Cone Morse e plataforma switch com superfície hidrofílica suportando próteses parciais fixas alcançaram altas taxas de sucesso e excelente manutenção do nível ósseo marginal em tipos de osso de baixa e alta qualidade, sem demonstrar diferenças estatísticas significativas, um ano após a cirurgia.
Palavras chave : Prótese e Implantes; Qualidade óssea; Nível ósseo; Cone Morse

ABSTRACT

Purpose: This study aimed to evaluate the influence of bone quality and bone tissue remodeling around Morse Taper implants with platform switching subjected to immediate loading with fixed partial dentures, over a period of one year.
Material and methods: Forty-nine Morse Taper implants and switch platforms with hydrophilic surfaces were installed in 12 patients (6 men and 6 women; mean age 44.67 ± 3.49 years), twenty-seven of which were in type I /II bone and 22 in type III/IV bone. Patients referred to a Faculty of Dentistry in need of implant-supported fixed partial rehabilitation between February and July 2019 were included in this study. Bone quality was assessed by experienced surgeons according to their perception of density during implant site preparation and confirmed on periapical radiography. Peri-implant bone tissue remodeling was accessed by periapical radiographs obtained at different times: immediately after implant placement (T0), 6 months (T6) and one year (T12) after surgery. All measurements were made by a single trained operator.
Results: Survival and implant success rates were 100% for both bone types one year after surgery. No statistically significant differences were found in relation to changes in bone level between the groups in any of the observation periods. The mean bone loss at T12 for the type I/II bone group was 0.93±0.46mm and 1.00±0.58mm for the type III/IV bone group, with no statistically significant differences.
Conclusions: Within the limits of the present study, the results suggest that Morse Taper connection implants and switch platform with hydrophilic surface supporting fixed partial dentures achieved high success rates and excellent maintenance of the marginal bone level in low and high quality bone types , without demonstrating significant statistical differences, one year after surgery.
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Keywords: Prostheses and Implants; Bone quality;Bone level; Success; Morse Taper.

INTRODUCTION

Implant-supported protheses are a well-established procedure to replace missing teeth, and implant materials and designs are continuously developed in order to improve their efficiency[1]. One of the factors that could directly influence implant survival and success is marginal bone loss, which could lead in the last instance to implant loss[2].

Several risk factors have been associated with marginal bone loss[3,4] including patient-related aspects such as smoking habits, periodontal disease, diabetes and oral hygiene[5,6]. In addition to that, surgery-related factors such as site preparation, loading protocol, grafting

procedure, occlusal schemes[7,8], as well as implant-related factors such as implant shape and the design of abutment-implant connection[9,10] may also play a role.

The prosthetic concept of using an abutment with a diameter smaller than the of the implant shoulder is called platform-switching, and has been associated with prevention and reduction of crestal bone loss, when compared to conventional restorative procedure[11]. Also, a systematic review has shown that the amount of marginal bone resorption is inversely related to the extent of the implant-abutment mismatch[12].

Another factor that has been associated with bone loss and implant failure is bone quality. It has been reported that local bone density has great influence on implant primary stability, and thereby, affects implant success[13]. Moreover, long-term implant success rates have been reported to be higher in mandible than in maxilla, and the main reason for that is believed to be better quantity and quality of bone in mandible. Bone type IV has been also associated with greater implant failure[14].

When treating partially edentulous regions, fixed partial prostheses have the advantage over multiple single crowns in allowing better distribution and transmission of masticatory forces to implants and adjacent bone, especially in challenging regions for rehabilitation using implants[15,16]. On the other hand, they have the disadvantage that implant failure, as well as bone loss, may compromise the prosthetic rehabilitation success as a whole.

Therefore, the aim of this study was to assess the influence of bone quality on success and bone level changes around morse taper implants with platform switching supporting fixed partial prostheses, within one year after placement.

MATERIAL AND METHODS

Patient selection

The present prospective study was approved by the local ethics committee (approval number: 3.070.126) and was conducted in accordance with the principles embodied in the Helsinki Declaration of 1975, as revised in 2013, for biomedical research involving human subjects. Patients who were referred to Dental College (Curitiba, Brazil) in need of implant-supported fixed partial rehabilitation attended to between February and July of 2019 were evaluated and 49 patients who met the following inclusion criteria were enrolled: over the age of 18 and having the absence of teeth with space to install 2 or more implants. Exclusion criteria were any contraindication for implant surgery such as titanium allergy or hypersensitivity, presence of acute infection, unsuitable bone volume or quality, undergoing biphophonate treatement, immunosuppressed, patients receiving therapeutic radiation in the head and neck, tabacco users, incomplete jawbone growth and pregnancy. Written consent was given by all patients.

Study design

To start off with, Cone Beam Computed Tomography (CBCT), panoramic and periapical radiography exams, and photographs were obtained for diagnostic and planning purposes. Implant dimensions were selected as to be inserted at a 2-mm subcrestal position and presenting at least 1 mm of buccal and lingual bone availability around them. A minimum distance of 1.5 mm from the implant shoulder to adjacent teeth and of 3mm between two adjacent implant shoulders was planned.

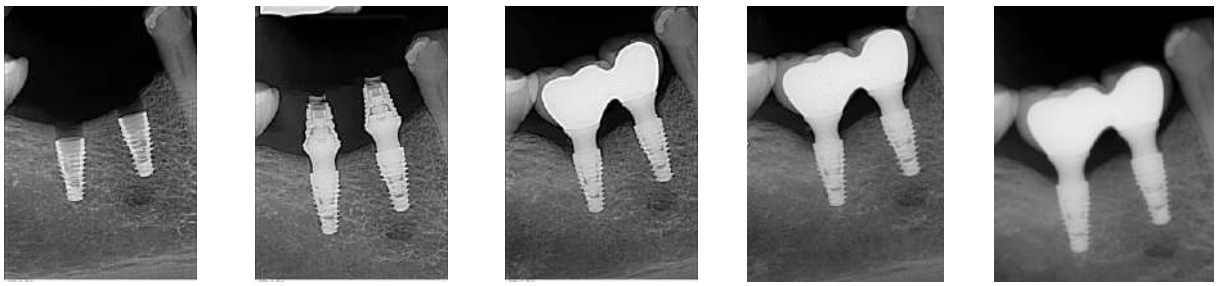
All patients were treated by means of placement of hydrophilic tapered implants (Helix Acqua GM, Neodent, Curitiba, Brazil) with a platform-switched Morse taper prosthetic interface, made with commercially pure titanium Grade 4 (ASTM F67). The main feature of

the implant is a hybrid thread design, being conical on the apex and cylindrical on the coronal portion.

Surgical and Prosthetic Proceduers

All implants were placed under local anesthesia and following the drill sequence as indicated by the manufacturer, as well as according to each site, bone type, along with profuse irrigation. Grafting procedures were performed on three implants to repair bone defects in the esthetic zone, using Cerabone ™ . Immediate loading protocol was applied when the minimum insertion torque (32 N.cm) was achieved for all implants supporting the same prosthesis. GM mini and micro conical abutments (Neodent, Curitiba, Brazil) and partial fixed provisional acrylic prostheses were installed within the first day. After the soft tissue healing period, these were replaced by splinted metal-ceramic prostheses, and the occlusion checked at all periods of the study.

Digital periapical x-rays were obtained (Heliodent Plus, Dentsply Sirona, USA), using the parallelism radiography technique to standardize the images, at all visits: screening, immediately after placement (T0), 6 months after surgery (T6) and one year after surgery (T12). Surgeries and prosthetic procedures were performed by two experienced clinicians. (Figure 1)



(a) (b) (c) (d) (e)

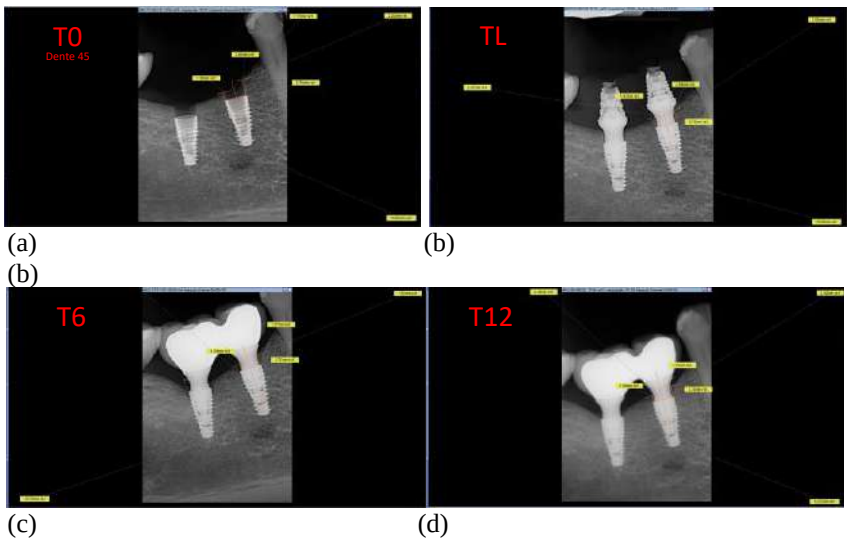
Figure 1: placement of implants T0 (a), immediate loading (b), definite crown placement after 3 months (c), 6 months after surgery T6 (d), one year after surgery T12 (e).

Bone quality was surgically assessed by the surgeons according to their perception of resistance during implant site preparation and confirmed on periapical radiography, as described by Lekholm and Zarb[17]. Thereby, for radiographic and statistical analysis, implants

were divided in two groups, according to the bone quality of placement site: bone type I/II and bone type III/IV.

Radiographic measurements and Clinical evaluation

The digital periapical radiographs obtained were evaluated by a trained operator using Sidexis XG version 2.6 software (Sirona, Bensheim, Germany). (Figure 2) Artificial lines were drawn to help the marginal bone level measurement. Vertical lines – parallel to long axis of the implant – and a horizontal line – which was drawn at the interface implant platform and prosthetic connection – were used as a reference for the linear measurement of vertical bone height on both the mesial and distal surfaces of each implant. Regarding implants with bone level below the implant platform, the measurement was performed from the most apical point of bone in contact with the implant (towards the implant shoulder), to a horizontal line in the implant platform. In case of bone level above the implant, the measurement was performed from the highest point of the alveolar crest to the horizontal line in the implant platform. Mesial and distal values were used to obtain the mean bone level.



(a) (b)
(b)
(c) (d)

Figure 2: Radiographic measurements T0 (a), immediate loading (b), definite crown placement after 3 months (c), 6 months after surgery T6 (d), one year after surgery T12 (e).

After a 15-day interval of the first measurements, one-third of the radiographs were randomly selected and revaluated. The random error was calculated according to Dahlberg's

formula ($Se^2 = \sum d^2/2n$) resulting in a value of 0.02mm, and the systematic error was calculated with dependent t tests, at $P< 0.207$.

Implant survival rate was calculated for each group and defined as no loss of the implant. Moreover, implant success was evaluated according to Buser et al.[18], regarding absence of persistent pain, recurrent infection, mobility and radiolucency, as well as the possibility of restoration. Prosthetic survival and success were also evaluated, considering if the prostheses was in place irrespective of its condition (survival) and if it remained unchanged and did not need laboratory repair (success) during the follow-up[19].

Statistical Analysis

For intergroup comparability analyses, the Mann-Whitney test was used for age comparison whereas for all other comparations (gender, final insertion torque, performance of grafting procedures, presence of systematic diseases, site status and loading protocol), the Chi-square and Chi-square continuity correction tests were used. The Chi-square continuity correction was applied when one or more expected cell counts in the cross-tabulation were less than 5.

Regarding bone level and bone loss comparison between the groups, first, the normality and equality of variances were checked by Shapiro-Wilk's test and Levene's test, respectively. For the samples with normal distribution and common variance, the Student's T-Test was used. For normal distributions with different variances, the Welch's T-Test was used whereas if the distributions were not normal, the Mann-Whitney test was applied.

All statistical analyses were performed at 0.05 significance level using JASP free software (JASP version 0.14.1)[20].

RESULTS

Twelve patients (6 male and 6 female), with a mean age of 44.67 ± 3.49 years, consented to participate in this study and had 51 implants inserted. One implant was lost before loading and, since the adjacent implant turned out to receive a single-unit prosthesis, both had to be excluded from the sample. Therefore, the final study sample comprised 49 implants, inserted to support 20 fixed partial prostheses. Twenty-seven implants were evaluated as presenting bone type I/II and 22 implants bone type III/IV.

No complications were observed for any of the study implants, thus, implant survival and success rates were 100% for both groups, after 1 year. Prosthesis survival and success rates were also 100% for the two groups.

Intergroup comparability is shown in Table 1. Only the distribution of site healing status was statistically different between groups. Bone type III/IV group had implants inserted on healed (77.3%) as well as on post-extraction (22.7%) sites whereas bone type I/II group had only in healed sites.

Bone level measurements at the different stages are described in table 2. Bone type III/IV group presented higher mean bone levels at T0 (2.38 mm ± 0.71), T6 (1.51 mm ± 0.78) and T12 (1.38 mm ± 0.83), than Bone type I/II group (1.83 mm ± 0.78; 0.93 mm ± 0.86; 0.90 mm ± 0.89, respectively). The difference was statistically significant in all evaluation periods (T0, p=0.001; T6, p=0.004; T12 ,p=0.019).

Nevertheless, no statistically significant differences concerning mean bone loss level changes were found between groups at any of the observational periods, with a mean bone loss of 0.93±0.46 mm for bone type I/II group and of 1.00±0.58 mm for bone type III/IV group, at T12. (Table 3).

DISCUSSION

Bone loss and implant success depends on several factors related to patient and implant parameters as well as surgical and prosthetic procedures[4,21]. The reported success rates of hydrophilic implants as well as the obtained by the present study are high, usually ranging from 94.2% to 100%[22,23,24]. In addition to that, the hydrophilic surface has been reported to improve stability during early healing period and to provide faster osseointegration by accelerating osteogenesis[25].

Among the factors involved in early implant failure, bone quality and quantity have been reported as determinant aspects[2]. Good bone quality has also been related as prerequisite for primary stability achievement, whereas marginal bone loss is considered to be one of the indicators of treatment success[26]. However, the impact of bone quality on marginal bone loss around platform-switching hybrid implant remains unclear.

In the present study, parameters that could influence the bone loss such as age, gender, final torque, augmentation procedure, presence of systemic diseases and loading protocol were comparable between groups, with the exception of site healing status. It has been shown that implants placed in healed sites tend to present less bone loss and are more likely to be successful[27], therefore, the insertion of implants in healed sites could be an advantage for poor quality bones. Since study group Bone type III/IV included 22.7% of immediate implants, whereas Bone type I/II group included only implants placed in healed sites, the difference observed regarding implant site status distribution is not expected to have influenced the present results.

The intergroup compatibility with respect to final insertion torque and the possibility of immediate loading is another important factor to be highlighted. These results indicate that the hybrid design of the study implant allows achieving excellent primary stability in all bone types.

Although the intergroup comparison with respect to mean bone level showed statistically significant differences in all observational periods, it should be observed that implants on both groups were placed, on average, in a position close to 2-mm subcrestal, as planned. At T6 and T12 implants still presented a mean subcrestal position of approximately 1 mm in group I/II and 1.5mm in group III/IV.

Nonetheless, no statistically significant difference between groups was observed for bone level changes. Mean bone loss found for type I/II group was 0.93±0.46 mm and 1.00± 0.58 mm for type III/IV group, during the first year. Corroborating with other authors who have shown that mean bone resorption during the first year can range from 0.4 to 1.5 mm[28,29]. Previous studies have found no significant differences between different bone qualities regarding bone level changes, however, bone loss was observed to decrease by increasing bone quality in the long-term[30].

Some authors have evaluated peri-implant bone loss regarding different prosthetic connections. A systematic review has reported that greater loss was found around implants with external connections, followed by those with internal ones. Conical connections seemed to exhibit lower values of bone loss[31]. The same was reported in another study, with higher mean values of bone level changes around external hexagon implants in follow-up period of 5 years[32]. Therefore, implants with conical connections, as the ones used in the present study, are expected to present less bone loss.

Hybrid tapered implants have been reported as being suitable for all bone types, in single-unit, partial or full arch rehabilitations and under immediate or conventional loading protocol. It has been suggested that by allowing trabecular bone compaction in the middle and cervical portions, it leads to better outcomes regardless of the bone quality[22]. Therefore, the present study corroborates with these results, showing that hybrid implants have adequate

performance regardless of bone quality, since no significant differences were observed regarding bone loss between groups.

The platform switching characteristic of the implants, have also been reported to reduce bone loss[33,34,35]. A study that compared bone remodeling platform switching and platform matching implants, showed that the ones presenting this concept showed less bone loss after 1 year. The loss, however, was greater (mean bone loss 1.48 mm)[36] than the observed in the present study (mean bone loss 0.9mm and 1.0mm) for the same time period.

Only one implant system was used in this study in order to avoid imposing other possible influencing factors as implant design, material, and surgical procedures. Thus, these results cannot be extrapolated to others implant systems. To the authors knowledge, this is the first study evaluating the influence of bone quality on implant success and bone level changes around platform-switching hybrid implants. Further studies should be considered to assess whether the observed results are also shown when the study implants are used to support single and full-arch rehabilitation.

CONCLUSIONS

Within the limits of the present study, the results suggest that Morse Taper connection implants and switch platform with hydrophilic surface supporting fixed partial dentures achieved high success rates and excellent maintenance of the marginal bone level in low and high quality bone types , without demonstrating significant statistical differences, one year after surgery. Thus, this study reinforces that platform-switched Morse Taper connection implants with hydrophilic surfaces are a suitable choice to support fixed partial rehabilitation independent of patient bone quality.

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standard tapered implant design after immediate loading. A 3-year multicentre randomised controlled trial. Eur J Oral Implantol. 2012;5:123–36.

Table 1. Intergroup comparability.

Parameters		Bone type I/II (n=27)		Bone Type III/IV (n=22)		P value
		Mean ± S.D		Mean ± S.D		
Mean age (years)[1]		42.2 ± 6.2		48.1 ± 14.2		0.127
		N	**%**	**N**	**%**	
Gender[2]	**Female**	13	48.1%	14	63.6%	0.278
	Male	14	51.9%	8	36.4%	
Final Torque[3]	**< 35 N.cm**	3	11.1%	6	27.3%	0.279
	35 to 60 N.cm	24	88.9%	16	72.7%	
Bone graft[3]	**Yes**	0	00.0%	3	13.6%	0.167
	No	27	100.0%	19	86.4%	
Presence of controlled systemic disease[3]	**Yes**	0	00.0%	2	9.1%	0.382
	No	27	100.0%	20	90.9%	
Site Healing Status[3]	**Healed**	27	100.0%	17	77.3%	0.032*
	Post-extraction	0	00.0%	5	22.7%	
Loading protocol[2]	**Immediate**	5	18.5%	9	40.9%	0.084
	Delayed	22	81.5%	13	59.1%	

Note: [1]Mann-Whitney, [2]Chi-square and, [3]Chi-square continuity correction tests were performed

*p < 0.05 is considered significant.

Table 2. Intergroup comparison for mean marginal bone level at T0, T6 and T12.

Time	Bone quality	n	Bone level (mm) Mean ± SD	S.E. mean	IQR	p-value
T0[1]	**I/II**	27	**1.82 ± 0.78**	0.150	0.495	0.001*
	III/IV	22	**2.38 ± 0.71**	0.150	0.954	
T6[1]	**I/II**	27	**0.93 ± 0.86**	0.166	0.618	0.004*
	III/IV	22	**1.51 ± 0.78**	0.167	0.646	
T12[1]	**I/II**	27	**0.90 ± 0.89**	0.171	0.550	0.019*
	III/IV	22	**1.38 ± 0.83**	0.177	0.714	

Note: [1]Mann-Whitney test was performed.

*p < 0.05 is considered significant.

Table 3. Intergroup comparison on mean bone loss at the different time periods.

Time period	Bone quality	n	Bone loss (mm) Mean ± SD	S.E. mean	IQR	p-value
T0-T6[1]	**I/II**	27	**0.89 ± 0.45**	0.087	0.737	0.901
	III/IV	22	**0.88 ± 0.54**	0.115	0.841	
T6-T12[2]	**I/II**	27	**0.04 ± 0.10**	0.019	0.080	0.082
	III/IV	22	**0.13 ± 0.22**	0.046	0.206	
T0-T12[1]	**I/II**	27	**0.93 ± 0.46**	0.088	0.725	0.628
	III/IV	22	**1.00 ± 0.58**	0.124	0.904	

Note: [1]Student's T-Test and [2]Welch's T-Test were performed. SD: Standard deviation; S.E. mean: Standard error of the mean.

*$p < 0.05$ is considered significant.

APÊNDICE

1) TERMO DE CONSENTIMENTO INFORMADO

- Li, ou foi lido para mim, e entendi as informações ao paciente e o termo de consentimento datado de 04 de outubro de 2018, versão 1.
- O cirurgião-dentista responsável ou a equipe do estudo conversaram comigo sobre este estudo, tive a oportunidade de fazer perguntas e obter respostas satisfatórias a elas.
- Tive tempo suficiente para considerar as informações fornecidas e pedir orientação, se necessário.
- Estou ciente e concordo que os representantes do patrocinador, as autoridades reguladoras e os representantes do comitê de ética tenham acesso direto aos meus registros médicos/odontológicos para o estudo clínico, conforme necessário, conforme descrito acima.
- Concordo em seguir as instruções do cirurgião-dentista responsável.
- Entendo que minha participação neste estudo é voluntária e que estou completamente livre para me recusar a participar ou retirar-me deste estudo a qualquer momento, sem penalidades e sem mudar de forma alguma a qualidade do atendimento que recebo.
- Fui informado sobre o propósito, procedimentos, possíveis benefícios e riscos deste estudo.
- Entendo que não estou renunciando a nenhum dos meus direitos legais como resultado da assinatura deste termo de consentimento.
- Eu promovo livremente meu consentimento em participar deste estudo.
- Fui informado de que uma via datada e assinada deste formulário ficará comigo e outra com o pesquisador responsável.

- *I have read, or it has been read to me, and I understood the subject information and consent form dated 04-October-2018, version 1.*
- *The study dentist or personnel have talked to me about this study and I have had the opportunity to ask questions and have had satisfactory responses to them.*
- *I have had sufficient time to consider the information provided and to ask for advice if necessary.*
- *I am aware of and agree that the sponsor representatives, regulatory authorities and ethics committee representatives will be granted direct access to my medical/dental records for the clinical study, as necessary, as described above.*
- *I agree to follow the instructions from the study dentist.*
- *I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without any penalties and without changing in any way the quality of care that I receive.*
- *I have been informed about this study's purpose, procedures, possible benefits and risks.*
- *I understand that I am not waiving any of my legal rights as a result of signing this consent form.*
- *I freely consent to participate in this study.*
- *I have been told that a dated and signed copy of this form will remain with me and another with the responsible investigator.*

Nome por extenso do Participante

Assinatura do Participante ou Representante Legal | Data

DECLARAÇÃO DO PESQUISADOR

Eu atesto que o indivíduo que forneceu o consentimento teve tempo suficiente para considerar essa informação, teve a oportunidade de fazer perguntas e concordou voluntariamente em participar deste estudo. Confirmo que o indivíduo não foi coagido a dar consentimento e voluntariamente concordou em participar deste estudo.

Assinatura do Pesquisador Principal ou Representante | Data

2) Questionário OHIP-14 / *OHIP-14 Questionnaire* (T6)

Data / *Date:*	/ / d d m m m y y	
Sujeito / *Subject:*	First, Middle, Last Initials	Subject Number

Nos últimos 6 meses, com que frequência você apresentou os seguintes problemas: ***In the last 6 months, how frequent have you experienced the following problems:***	0 Nunca *Never*	1 Raramente *Hardly Ever*	2 Ás Vezes *Occasionally*	3 Repetida-mente *Fairly Often*	4 Sempre *Very Often*	Peso *Weight*	Pontos *Score*
Você teve problemas para falar alguma palavra por causa de problemas com seus dentes, boca ou próteses? *Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?*						0.51	
Você sentiu que o sabor dos alimentos tem piorado por causa de problemas com seus dentes, boca ou próteses? *Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?*						0.49	
Você sentiu dores em sua boca? *Have you had painful aching in your mouth?*						0.34	
Você se sentiu desconfortável ao comer algum alimento por causa de problemas com seus dentes, boca ou próteses? *Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?*						0.66	
Você ficou preocupado(a) por causa de seus dentes, boca ou próteses? *Have you been self-conscious because of your teeth, mouth or dentures?*						0.45	
Você se sentiu estressado(a) por causa de problemas com seus dentes, boca ou próteses? *Have you felt tense because of problems with your teeth, mouth or dentures?*						0.55	

Sua alimentacão ficou prejudicada por causa de problemas com seus dentes, boca ou próteses? *Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?*						0.52	
Você teve que parar suas refeições por causa de problemas com seus dentes, boca ou próteses? *Have you had to interrupt meals because of problems with your teeth, mouth or dentures?*						0.48	
Você encontrou dificuldade para relaxar por causa de problemas com seus dentes, boca ou próteses? *Have you found it difficult to relax because of problems with your teeth, disability mouth or dentures?*						0.6	
Você se sentiu envergonhado(a) por causa de problemas com seus dentes, boca ou próteses? *Have you been a bit embarrassed of problems with your teeth, mouth or dentures?*						0.4	
Você ficou irritada com outras pessoas por causa de problemas com seus dentes, boca ou próteses? *Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?*						0.62	
Você ˆ teve dificuldade para realizar suas atividades diárias por causa de problemas com seus dentes, boca ou próteses? *Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?*						0.38	
Você sentiu que a vida, em geral, ficou pior por causa de problemas com seus dentes, boca ou próteses? *Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?*						0.59	
Você ficou totalmente incapaz de fazer suas atividades diárias por causa de problemas com seus dentes, boca ou próteses? *Have you been totally unable to function because of problems with your teeth, mouth or dentures?*						0.41	

ANEXO

UNIVERSIDADE POSITIVO - UNICENP

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Estudo Prospectivo Observacional de Dispositivos Implantáveis da linha GM da Neodent

Pesquisador: RUBENS MORENO DE FREITAS

Área Temática:

Versão: 1

CAAE: 03673918.9.1001.0093

Instituição Proponente: INSTITUTO LATINO AMERICANO DE PESQUISA E ENSINO ODONTOLOGICO -

Patrocinador Principal: JJGC INDUSTRIA E COMERCIO DE MATERIAIS DENTARIOS S.A

DADOS DO PARECER

Número do Parecer: 3.070.126

Apresentação do Projeto:

Estudo prospectivo, longitudinal, observacional, do tipo coorte. Os dispositivos serão utilizados conforme rotina padrão de prática diária, de acordo
com todas as indicações especificadas pelo fabricante na IFU (instruções de uso).

Objetivo da Pesquisa:

O objetivo do estudo é coletar, prospectivamente, dados clínicos para confirmar a segurança em longo prazo e o desempenho clínico dos implantes Neodent Helix GM Acqua e componentes da linha GM no ambiente da prática odontológica diária, por meio das taxas de sucesso e sobrevivência desses dispositivos.

Objetivo Secundário:

A partir dos dados coletados, o estudo objetiva identificar efeitos colaterais previamente desconhecidos e monitorar os efeitos colaterais e contraindicações
conhecidos e presentes na IFU (instruções de uso), monitorar e analisar os riscos emergentes com base em evidências factuais, assegurar a continuidade da aceitação da relação risco-benefício, e identificar possíveis utilizações indevidas sistemáticas do dispositivo, com o intuito de verificar se o uso pretendido está adequado para todos os produtos Neodent que entram em contato com o paciente e estão envolvidos no procedimento.

Endereço: Rua Profº Pedro Viriato Parigot de Souza nº 5300
Bairro: Campo Comprido **CEP:** 81.280-300
UF: PR **Município:** CURITIBA
Telefone: (41)3317-3260 **Fax:** (41)3317-3030 **E-mail:** cep@up.edu.br

Avaliação dos Riscos e Benefícios:

Riscos:

Os riscos e efeitos adversos esperados associados à participação no estudo são aqueles inerentes aos procedimentos de anestesia local e ao procedimento cirúrgico. A instalação de implantes assim como qualquer outro procedimento cirúrgico pode causar leve desconforto e edema localizado. Sintomas mais persistentes podem ocorrer como: dor crônica relacionada com o implante dentário, parestesia permanente, disestesia,

perda de rebordo ósseo maxilar/mandibular, infecção localizada ou sistêmica, fístula oroantral ou oro-nasal, dano irreversível aos dentes adjacentes, fraturas do implante, maxilar, osso ou prótese, problemas protéticos, lesão dos nervos, esfoliação, hiperplasia.Nenhum dos riscos mencionados está especificamente associado com o dispositivo de estudo mas estão relacionados ao tratamento com implantes

dentários em geral.

Estes riscos serão minimizados por meio de anamnese criteriosa das condições de saúde do participante da pesquisa antes da cirurgia.

Adicionalmente, serão passadas recomendações aos pacientes antes a após a cirurgia, as quais serão realizadas em ambiente apropriado, com materiais selecionados e instrumentais esterilizados. Será realizado controle constante da higienização oral e da cicatrização dos implantes. Caso haja perda de implantes, será realizado procedimento padrão que inclui um período de espera e instalação de novo implante.

O presente estudo clínico foi projetado para envolver o mínimo possível de dor, desconforto, medo e qualquer outro risco previsto para os indivíduos.

Os efeitos adversos do dispositivo, deficiências do dispositivo e o grau de desconforto do paciente serão monitorados constantemente e reportados aopatrocinador.

Benefícios:

Os benefícios clínicos esperados com a terapia envolvem melhoria da saúde bucal por meio do reestabelecimento das funções afetadas pela perda dos dentes, tais como mastigação e estética do sorriso. Adicionalmente, os dados coletados podem oferecer benefícios potenciais para futuros pacientes, uma vez que fornecem evidências clínicas para apoiar o estado de desempenho e a segurança do dispositivo.

Comentários e Considerações sobre a Pesquisa:

Pesquisa de relevância que visa coletar dados clínicos para confirmar a segurança a longo prazo dos implantes Neident helix GM aqua e seus componentes.

UNIVERSIDADE POSITIVO - UNICENP

Continuação do Parecer: 3.070.126

Considerações sobre os Termos de apresentação obrigatória:

Foram apresentados

Conclusões ou Pendências e Lista de Inadequações:

recomendo a sua aprovação

Considerações Finais a critério do CEP:

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1222550.pdf	27/11/2018 15:38:16		Aceito
Outros	Carta_Resposta.pdf	27/11/2018 10:55:36	WALESKA TROVISCO CALDAS FURQUIM	Aceito
Declaração de Instituição e Infraestrutura	Carta_Anuencia_ReitorUP.pdf	27/11/2018 10:52:12	WALESKA TROVISCO CALDAS FURQUIM	Aceito
Projeto Detalhado / Brochura Investigador	ProjetoDePesquisa.pdf	26/11/2018 10:29:23	WALESKA TROVISCO CALDAS FURQUIM	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	23/11/2018 15:36:45	WALESKA TROVISCO CALDAS FURQUIM	Aceito
Declaração de Instituição e Infraestrutura	Carta_Anuencia_DiretorCienciasSaudeUP.pdf	23/11/2018 15:33:56	WALESKA TROVISCO CALDAS FURQUIM	Aceito
Declaração de Instituição e Infraestrutura	Carta_Anuencia_CoordOdontoUP.pdf	23/11/2018 15:33:15	WALESKA TROVISCO CALDAS FURQUIM	Aceito
Declaração de Instituição e Infraestrutura	Carta_Anuencia_ILAPEO.pdf	20/11/2018 16:19:53	WALESKA TROVISCO CALDAS FURQUIM	Aceito
Cronograma	Cronograma.pdf	19/11/2018 09:35:00	WALESKA TROVISCO CALDAS FURQUIM	Aceito
Folha de Rosto	folhaDeRosto.pdf	18/10/2018 09:40:23	WALESKA TROVISCO CALDAS	Aceito
Orçamento	OrcamentoDetalhado.pdf	16/10/2018 09:57:37	WALESKA TROVISCO CALDAS	Aceito

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UNIVERSIDADE POSITIVO - UNICENP

Continuação do Parecer: 3.070.126

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

CURITIBA, 10 de Dezembro de 2018

Assinado por:
Wellington Menyrval Zaitter
(Coordenador(a))

Endereço: Rua Profº Pedro Viriato Parigot de Souza nº 5300
Bairro: Campo Comprido **CEP:** 81.280-300
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2. Artigo científico 2

Artigo publicado de acordo com a referencia abaixo:

Melenikiotis AS, Vianna CP, Caldas W, Trojan LC, de Freitas RM. Using the Digital Flow to Increase Efficiency in Complex Partial Rehabilitation with Dental Implants. Case Rep Dent. 2022 Feb 9;2022:7525837.

Using the Digital Flow to Increase Efficiency in Complex Partial Rehabilitation with Dental Implants

Andrew Sotirios Melenikiotis ,[1]
Camila Pereira Vianna ,[2]
Waleska Caldas ,[3]
Larissa Carvalho Trojan ,[4]
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[5]Ilapeo College, Curitiba, Brazil

RESUMO

Assunto. Este relato apresenta um caso clínico em que a tecnologia CAD-CAM foi aplicada para otimizar uma complexa reabilitação parcial com próteses implantossuportadas de um paciente com diversos problemas funcionais e estéticos.

Apresentação do caso. Paciente de 40 anos com várias queixas devido à ausência de múltiplos dentes e grande insatisfação com sua saúde bucal foi encaminhado a uma Faculdade de Odontologia (Curitiba, Brasil). Foi planejada cirurgia guiada de 11 implantes. Foi aplicado fluxo digital e protocolo de carga imediata. A paciente foi acompanhada por 2 anos apresentando boa evolução clínica e radiográfica.

Conclusões. O fluxo digital trouxe agilidade e precisão na colocação dos implantes, a provisionalização imediata somada à satisfação na fase provisória, e a tecnologia CAD/CAM proporcionou previsibilidade e conforto para a entrega das restaurações definitivas.

Palavras-chave: Próteses e implantes; Carga imediata; Fluxo digital.

ABSTRACT

Background. This report presents a clinical case in which the CAD-CAM technology was applied to optimize a complex partial rehabilitation with implant-supported prostheses of a patient with several functional and aesthetic issues.

Case presentation. A 40-year-old patient with several complaints due to the absence of multiple teeth and great dissatisfaction regarding his oral health was referred to a Dental College (Curitiba, Brazil). Guided surgery of 11 implants was planned. Digital flow and immediate loading protocol were applied. The patient was followed up for 2 years presenting good clinical and radiographic outcomes.
Conclusions. The digital flow brought agility and precision to implant placement, immediate provisionalization added to satisfaction in the provisional phase, and CAD/CAM technology provided predictability and comfort to deliver the definite restorations.

Keywords: Prostheses and implants; Immediate loading; Digital flow.

INTRODUCTION

Computer-aided design and manufacturing (CAD-CAM) was developed in the 1960s and first applied in automotive industries. Later, it started to be used in dentistry, increasing digital flow popularity in dental offices every year, contributing to the preliminary stages of dental implant treatment such as diagnosis and planning, and the actual surgical and prosthetics procedures [1]. Among the advantages of its use are reduced time and production costs, high-quality restorations due to consistent precision, and reproducible results [2].

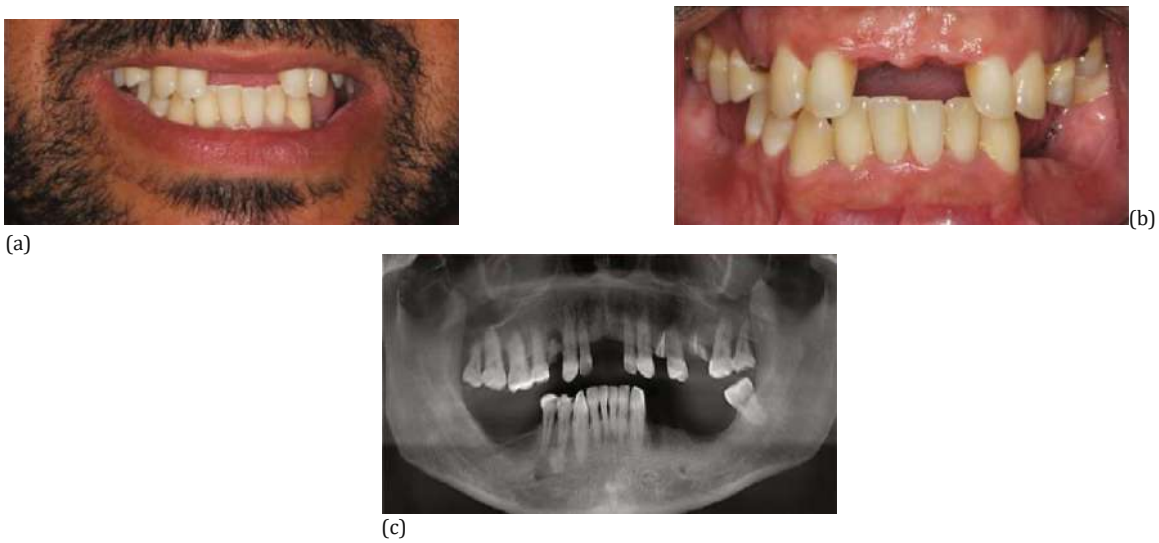
The integration of this technology with rapid prototyping methods made surgical guide fabrication possible, and its use for dental implant placement is referred to as guided implant surgery [3]. Guided surgeries allow predictability in the relationship between planned restorations and the underlying bony anatomy, providing the placement of mul-

tiple dental implants, according to surrounding anatomy and principles of ideal implant positioning and spacing. Thereby, this technology is especially beneficial in situations of multiple units or full arch immediate rehabilitation, with or without extractions [4].

The aim of this report is to present a clinical case in which the CAD-CAM technology was applied to optimize a complex partial rehabilitation with implant-supported prostheses of a patient with the absence of multiple teeth and several functional and aesthetic issues.

CASE PRESENTATION

A 40-year-old patient in good general health was referred to a Dental College (Curitiba, Brazil) with chief complaints of difficulty in eating/chewing due to the absence of multiple teeth, altered speech due to use of a removable provisional partial prosthesis with palatal extension, and low self- esteem due to dissatisfaction with smile's aesthetics and bad breath. After careful anamnesis and clinical and radiographic evaluation, it was also possible to diagnose the loss of teeth 11 due to caries and failed endodontic and restorative treatments (Figure 1). Verbal explanations of treatment options like a removable partial denture, conventional nonguided implant surgery, and rehabilitation with dental implants using the guided surgery technique were given, and the latter was the patient's choice due to enhanced comfort and reduced surgery time and morbidity. The patient gave written consent, and ethics approval was not necessary for this study.



(a) (b) (c)

Figure 1: Patient's initial photos (a, b) and panoramic radiography (c) showing the absence of several elements in both arches.

2.1. Case Planning. Superior and inferior impressions were taken and later digitized with a lab TRIOS scanner and the STL files, together with the DICOM files of a full mouth CBCT, and were uploaded to Neodent website for guided surgery planning. These were processed in Dental

Wings program of coDiagnostix software (Chemnitz, Germany) by a third party, who virtually planned the case according to instructions given by the oral surgeon (Figure 2). Once this plan was reviewed and approved by the oral surgeon, the surgical guide was fabricated with a 3D printer (Rapid Shape GmbH, Heimsheim, Germany).

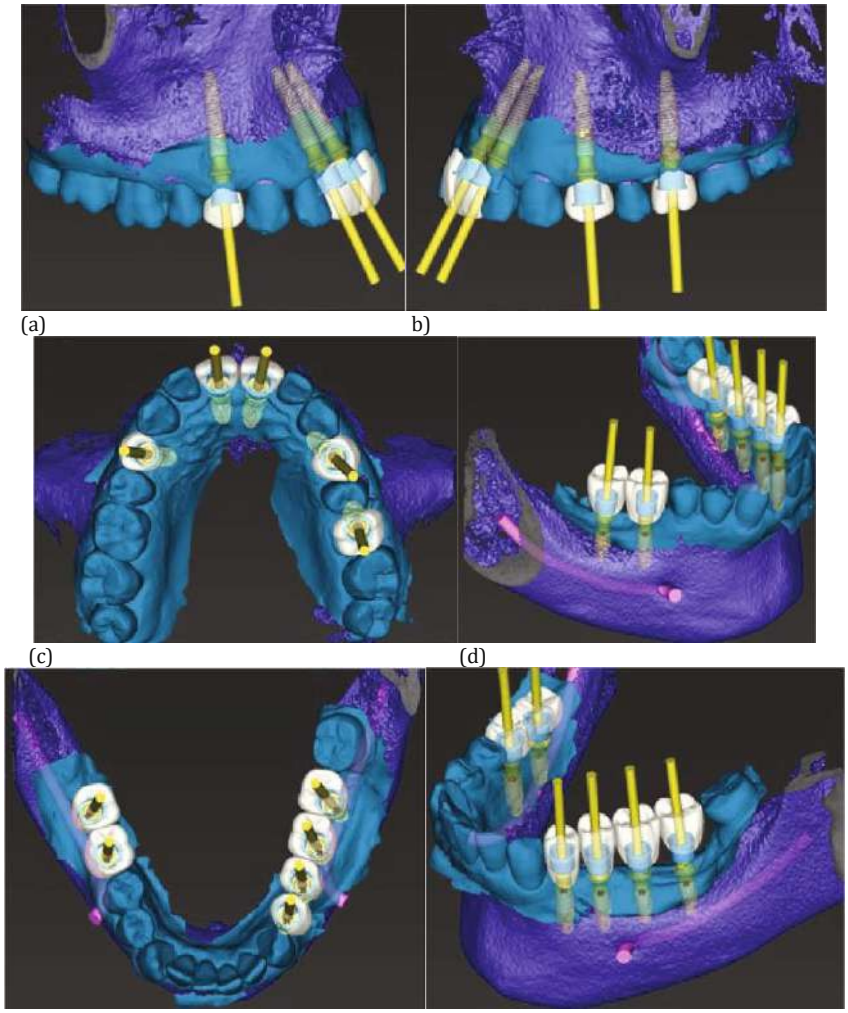


Figure 2: Virtual planning of maxillary (a)–(c) and mandibular (d)–(f) implants position considering the planned prosthesis rehabilitation.

2.2. Surgical and Prosthetic Procedures. The patient was medicated and prepared for surgery, and after local anesthesia, the residual roots of teeth 14, 24, and 26 were carefully extracted with minimally invasive techniques, after which the tooth-supported surgical guide was installed (Figure 3 (a)), verifying a perfect fitting through the inspection windows. To increase the stability of the guide, stabilizing pins were screwed through the sleeves into the implant

connection with the specific Guided Surgery Surgical kit for Helix GM implants (Neodent, Curitiba, Brazil), and each bed was prepared following the sequence recommended by the manufacturer for bone type III, with the compensated drills through the corresponding drill guide and sleeve, whereas the drills have laser markings, the depth is controlled visually, and the implant drivers are fabricated with stoppers (Figure 3(b)). Once those touch the sleeve, they indicate that the implant has reached its planned position, which for this case was 2mm subcrestal for all implants. Hydrophilic Morse cone tapered with 3.75mm of diameter implants (Helix GMAcquaimplants, Neodent) and lengths between 8 and 13 mm were inserted in the sequence #14, 24,11,12,and 26. Once concluded, the stabilizing pins were removed as was the surgical guide, showing very little bleeding. The torque was measured with the torque wrench, and since all presented torques above 32N/cm, indicating ideal primary stability for immediate loading, definitive screw-retained abutments were selected for each position, by means of measuring the transgingival height, with the aid of the GM height measurer and the abutment selection kit, and installed according to the specifications and torques recommended by the manufacturer (Neodent, Curitiba, Brazil). After this, and as previously planned, a technique for connective tissue graft in # 14 and xenograft fill was performed. Following the same steps as with the upper arch, implants in positions #35, 36, 37, 46, and 47 were placed using the surgical guide.

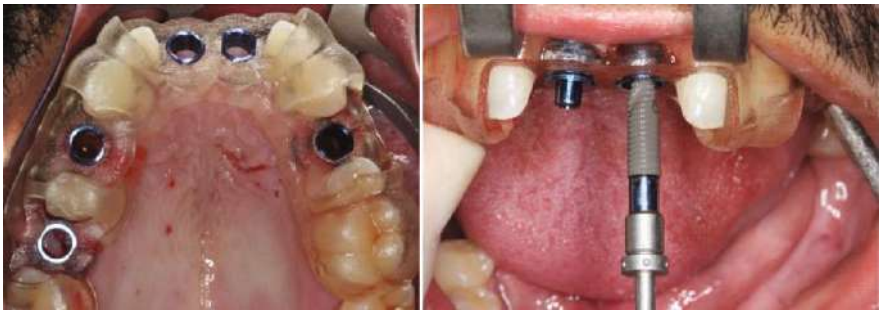
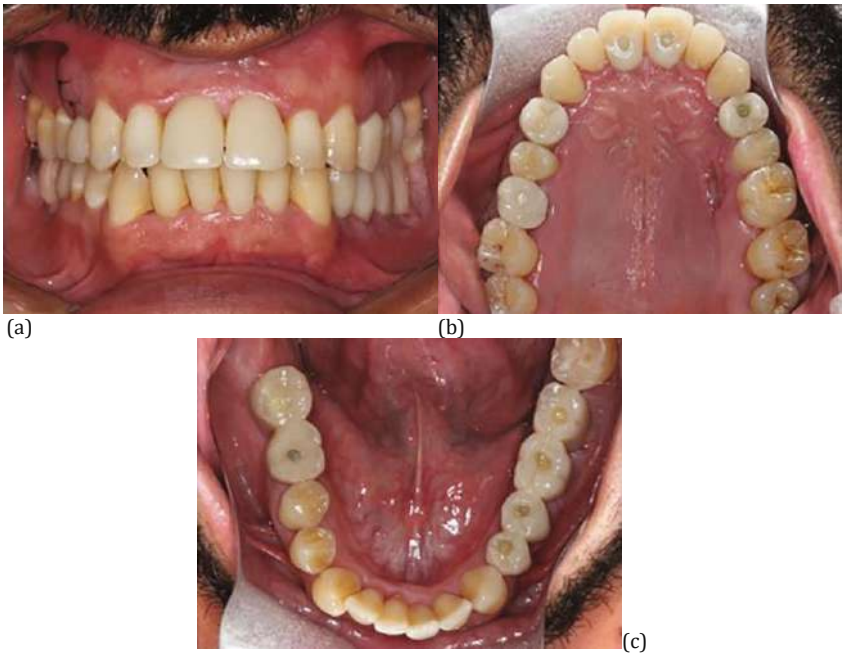


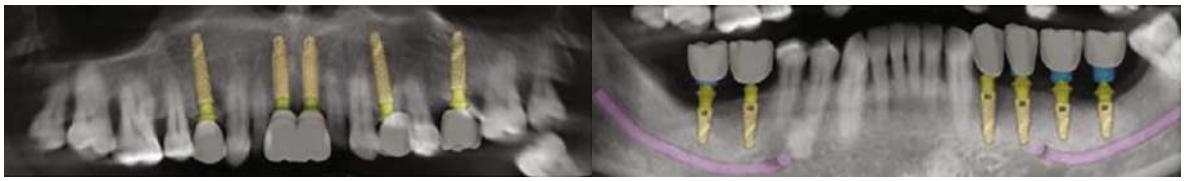
Figure 3: Tooth-supported surgery guide positioned in maxilla (a). Implant driver with stopper that indicates when the implant reaches the planned position (b).

In order to follow the one abutment-one time philosophy [5] and since a compatible digital impression coping (scan body) was not available at the time, the abutment impression copings were inserted for a conventional impression of both arches with addition silicone material (Kulzer, Hanau, Germany). Then, with the bite registration, it was sent to the lab for fabrication of the temporary crowns and bridges. The patient returned the following day to install the temporary acrylic restorations. The maxillary prostheses were single crowns, either screw-retained or with the click abutment for temps, and the mandibular ones were screw-retained multiunit acrylic prostheses (Figures 4 and 5).

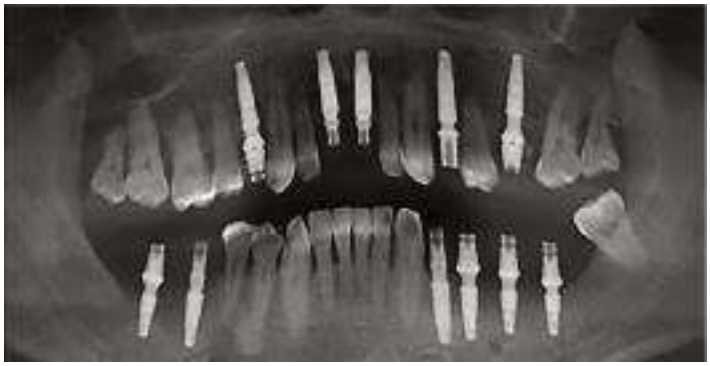


(a) (b) (c)

Figure 4: Clinical aspects at the time of immediate loading. Frontal view in occlusion (a), maxillary (b), and mandibular (c) occlusal view of acrylic resin temporary crowns.



a) (b)



(c)

Figure 5: Virtual planning of implants and abutments (a, b) and immediate loading panoramic radiography (c).

Three months thereafter, clinical and radiographic evaluation of the implants, abutments, and temporary prosthesis revealed adequate regeneration of peri-implant bone and soft tissues and, thus, the procedures for the confection of the final metal-ceramic restorations were followed through. Since the scan body for the GM conical abutment was not yet available, the GM conical abutments were replaced for GM Titanium Bases in positions # 14 and 26, to allow obtaining digital impressions. The scan bodies were inserted, and an intraoral scan was performed. Next, the metal coping try-in was conducted with radiographic verification, registration with red pattern resin (GC America, Alsip, USA), and repositioning of the temporaries. The metal copings were correctly positioned on the hybrid analogs in the printed models, with the resin registration and sent to the lab for porcelain build-up. After crowns try-in to adjust contact points and occlusal contacts, they were cemented onto the Tibases and then were installed (Figure 6).

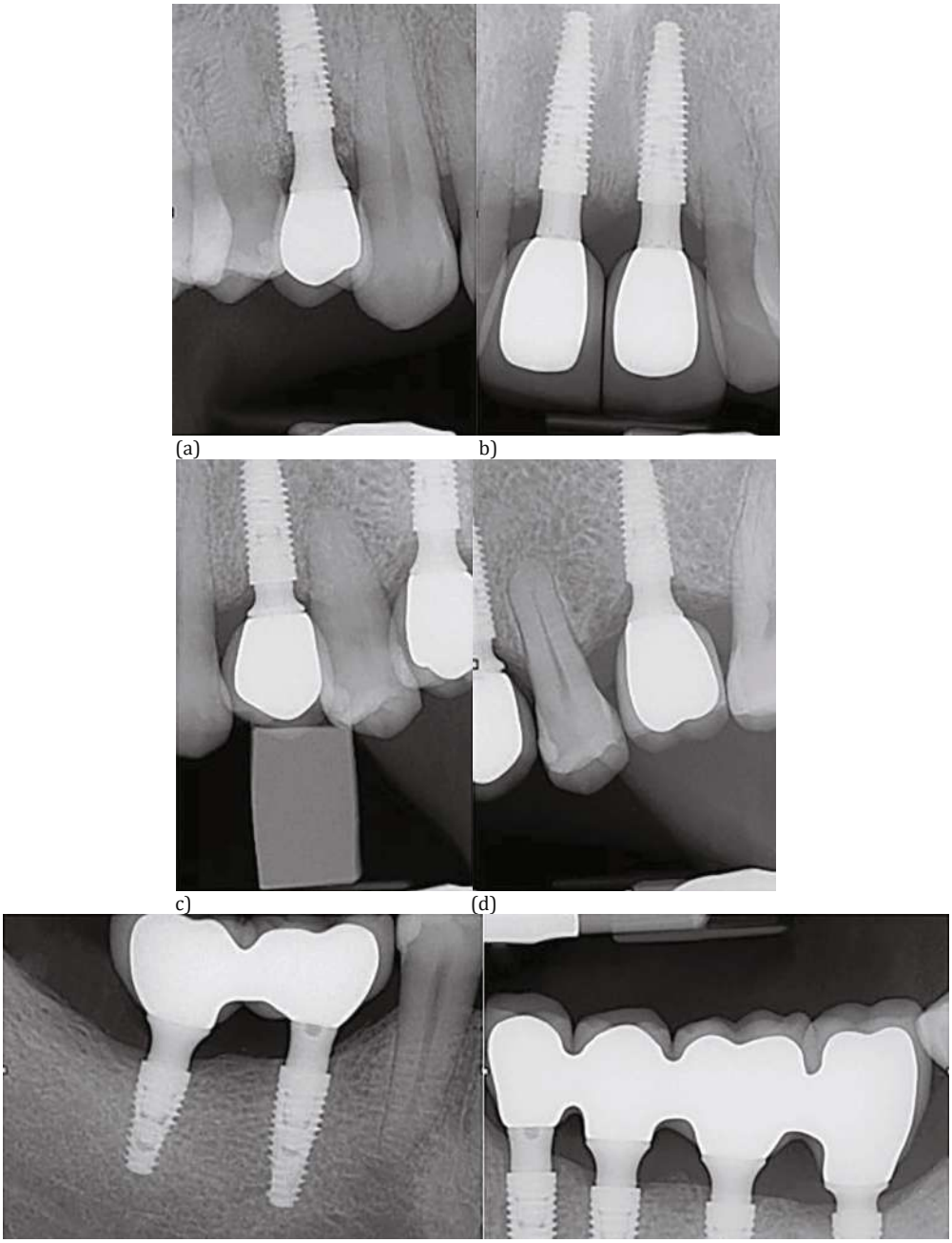


Figure 6: Periapical X-rays after maxillary (a)–(d) and mandibular (e, f) definitive prosthesis installation.

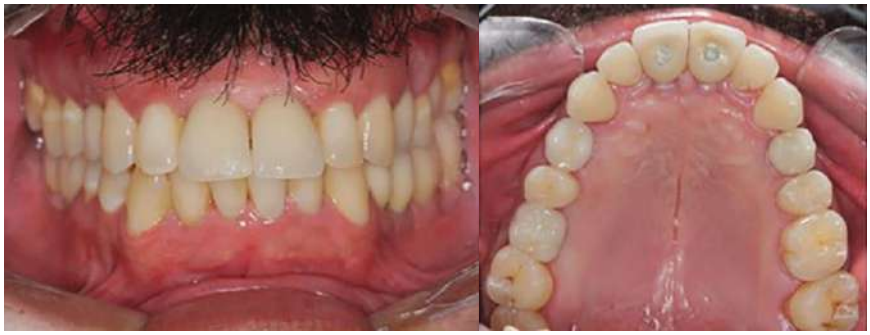
The Portuguese translation of OHIP–14 (Oral Health Impact Profile) questionnaire [6, 7] was used to evaluate the quality of life related to oral health, as a measure of patient satisfaction during the treatment. The patient was asked before treatment, and after 6, 12, and 24 months

post- surgery, how often, in the prior 6 months, he presented the problems evaluated by the questionnaire.

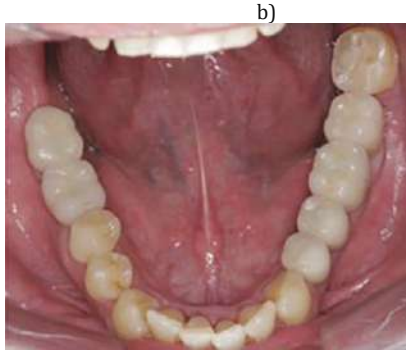
2.3. Clinical Follow-Up and Outcomes. The advantage of conducting the presented treatment using the guided sur- gery technique was mainly the ideal positioning of the implants, according to what was virtually planned, through evaluation of the virtual wax-up and available bone volume. Second, the ease and speed for site preparation and insertion of multiple implants, which, in conventional open-flap surgery, would have probably taken up to 4 sessions. Also, by having the virtual planning on the computer, communication with the patient by means of understanding the treatment plan was optimized, and the fascination factor by an innovative technology was decisive for this patient. During the surgery, the flapless technique resulted in little bleeding, the patient reported no postsur- gical pain, and no edema was evidenced the days after, as well as other adverse events.

Regarding patient's satisfaction, at the screening visit, the subject reported to have had fairly often trouble pronounc- ing words and discomfort to eat. Besides that, life was considered less satisfied by him. Self-consciousness, tenseness, unsatisfactory diet, and embarrassment were reported by him to happen very often due to his teeth problems. Occasionally, the patient has had painful aching in his mouth, according to the questionnaire. Therefore, OHIP-14 score was 14.9, showing how unsatisfied the patient was with his oral health. However, after 6 months of treatment start, OHIP-14 decreased to 0, revealing great satisfaction, which remained at the 2 years follow-up visit.

Also, good aesthetic outcomes remained 24 months after surgery, and soft tissue was clinically healthy (Figure 7). Moreover, no significant bone loss was observed at periapical X-rays, and thereby, all implants were considered as successful (Figure 8).

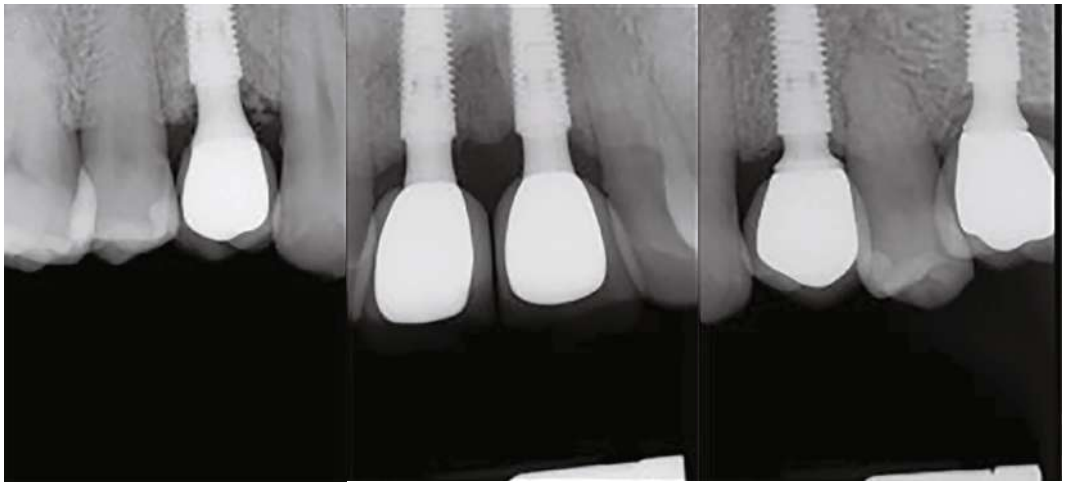


(a) b)

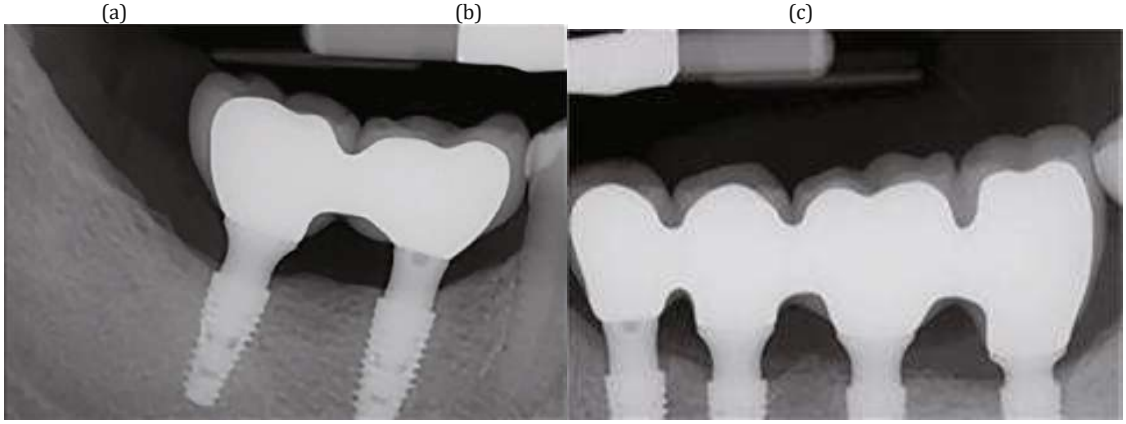


(c)

Figure 7: Clinical aspects at 2 years follow-up visit. Frontal view in occlusion (a), maxillary (b), and mandibular (c) occlusal photos.



(a) (b) (c)



(d) (e)

Figure 8: Periapical X-rays of maxillary (a)–(c) and mandibular (d, e) implants at the 24 months follow-up visit.

DISCUSSION

The use of virtual planning and digital workflow has shown to improve preoperative planning and patients' comprehension of the proposed procedures, in addition to increased predictability and reduced surgical morbidity [3]. Moreover, the CAD/CAM technology makes a possible complex rehabilitation, like the one presented, to be completed with fewer appointments by anticipating surgical challenges and pro- viding high quality restorations with consistent precision [1]. Also, regarding digital flow time-efficiency, it has been demonstrated that the entire clinical and laboratory process for single-unit crown production can take 16% less time than conventional prosthetic flow [8] Fewer clinical adjustments in digitally produced crowns have also been reported [2] and since these usually demand some time, digital flow can be very helpful, especially in complex cases with several prostheses to be installed.

Even though the present case was a guided surgery, surgeon's experience with conventional open flap free-hand surgeries, as well as passing through a good learning curve in the guided technique, was fundamental for the adequate management of the treatment. The understanding of the various steps and that errors in each step can accumulate and lead to the lack of precision of the final implant posi- tioning, compared to the virtual planning, needs to be considered. First, careful image acquisition and reconstruction of CBCT and scanning, as well as segmentation and super-positioning of these images in the planning software, are performed. Then, adequate virtual wax-up, positioning of implants in relation to the wax-up, and choosing sleeves, followed by the design of the surgical guide, were also performed. After that, the virtual planning should be meticulously reviewed by the surgeon for approval. It is also important to assure careful maintenance of the 3D printer and correct printing and insertion of sleeves in the surgical guide, especially for these not to get loosen during the surgical procedure. Finally,

previous disinfection/sterilization of the surgical guide without causing deformation should be made, and the perfect fit of the tooth supported surgical guide should be verified through the inspection windows.

In comparison to conventional open-flap free-hand surgery, other advantages include, during surgery, less bleeding, greater precision, and absence of suture; in the postoperative, less edema and pain, and consequently fewer medications leading to greater patient comfort and satisfaction; and in the healing process, since the periosteum is not displaced, maintaining the blood supply, there is less bone and soft tissue, leading to an excellent prognosis and predictability [9], whereas some authors have shown that flapless surgery resulted in less crestal bone loss than when flaps are elevated [10]; other studies have reported that there was no statistically difference in bone loss between different techniques [11].

Flapless surgery has some drawbacks reported in the literature as the real condition of the underlying bone cannot be observed due to gingival tissue not being raised, which could lead to unwanted perforations and fenestration [12]. Another disadvantage that has been discussed is the potential for thermal damage due to reduced access for external irrigation [10]. However, even in the absence of flap, limited vision, and access to the bone bed, none of the aforementioned events occurred in the present case.

Finally, at the screening visit, the patient's OHIP-14 score was very high, revealing that his oral problems had a significant impact on function and social well-being, as reported in the literature [13]. However, after surgery, and being maintained for the 2 years of follow-up, the patient's great satisfaction showed how the implant-supported reha- bilitation improved his quality of life.

CONCLUSION

With the use of technology and the digital flow, the prosthet- ically driven virtual planning for the correct 3D positioning of the implants provided the surgeon with a clear under- standing of the outcome of this complex case with multiple implants in both arches, whereas the images generated an efficient communication with the patient. The guided surgery technique for implant placement, combined with the immediate loading concept with immediate provisionaliza- tion, brought agility and great comfort to both the patient and the professional. The intra-oral scanning for digital impression and CAD/CAM technology for design and fabri- cation of the definite restorations contributed to greater effi- ciency in re-establishing function and aesthetics to this oral rehabilitation case. A learning curve is necessary to under- stand all the steps involved in the digital flow.

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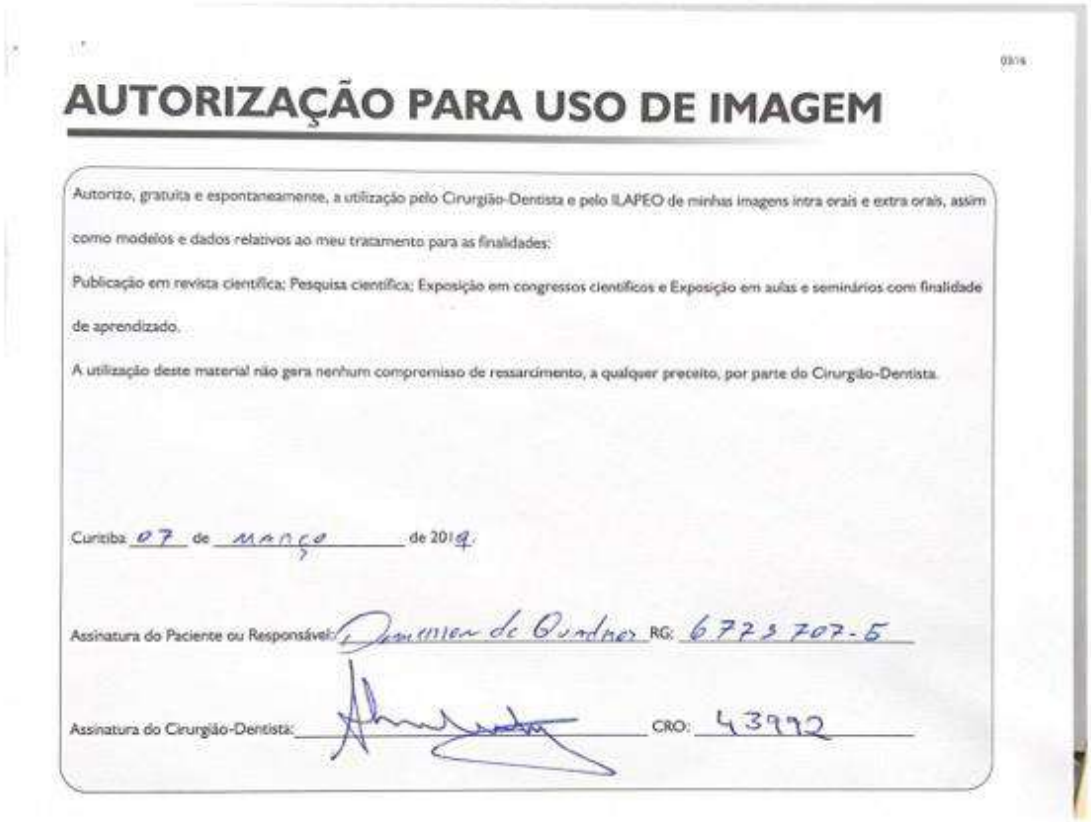
ANEXO



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Curitiba 07 de março de 2019.

Assinatura do Paciente ou Responsável: [illegible] RG: 6723707-5

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