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DEBORA REIS DIAS

Effect of the surgical treatment of peri-implantitis: an 8 to 10-year follow-up cohort study

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Dissertação apresentada ao Programa de Pós-Graduação em Odontologia Integrada da Universidade Estadual de Maringá como parte dos requisitos para obtenção do título de Mestre em Odontologia Integrada.

Orientador: Prof. Dr. Maurício Guimarães Araújo

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Efeito do tratamento cirúrgico da peri-implantite: um estudo de coorte de 8 a 10 anos de acompanhamento

RESUMO

Objetivo: Avaliar os efeitos do tratamento cirúrgico da peri-implantite à longo prazo. O objetivo secundário foi avaliar indicadores de risco para a falha do tratamento.

Material e métodos: Pacientes diagnosticados com peri-implantite e tratados por cirurgia de acesso e limpeza mecânica da superfície do implante foram incluídos no estudo. Os indivíduos foram reavaliados após 2 meses (resposta a curto prazo), mantidos em terapia de manutenção rigorosa por 2 anos e encaminhados para seus dentistas de referência para manutenção individual. Oito a dez anos após, os pacientes foram reavaliados. O sucesso do tratamento foi definido como ausência de profundidade de sondagem ≥ 5 mm com concomitante sangramento/supuração e perda óssea ≥ 0,5 mm. Uma análise multinível foi realizada para determinar os indicadores de risco para a falha do tratamento (recorrência da doença + perda do implante).

Resultados: Entre os 45 pacientes com 76 implantes incluídos, 47,4% dos implantes apresentaram sucesso no tratamento, 13,2% não retornaram, 19,7% tiveram recorrência de peri-implantite e 19,7% dos implantes foram perdidos ou removidos. Uma resposta negativa em curto prazo (OR 2,3; IC 95% 1,7 – 2,9) e níveo ósseo reduzido inicialmente (OR 2,4; 95%CI 1,7–3,2), após 1 (OR 2,3; 95%CI 1,7–3) e 2 anos em terapia de suporte (OR 2,2; 95%CI 1,7–3) foram identificados como indicadores de risco para a falha do tratamento.

Conclusão: A cirurgia de acesso demonstra ser capaz de tratar com sucesso a maioria dos implantes, porém a recorrência da doença e perda do implante são frequentemente observados. Implantes com resposta ao tratamento em curto prazo negativa, assim como nível ósseo marginal reduzido indicam risco para a falha do tratamento.

Palavras-chave: sucesso; peri-implantite; tratamento cirúrgico.

Effect of the surgical treatment of peri-implantitis: an 8 to 10-year follow-up cohort study

ABSTRACT

Objectives: To assess the long-term effects of the surgical treatment of peri-implantitis. A secondary objective was to evaluate the risk indicators for treatment failure.

Material and methods: Patients diagnosed with peri-implantitis and treated by access flap surgery and mechanical cleaning of the implant surface were included in the study. All subjects were re-evaluated after 2 months (short-term), enrolled in a strict maintenance program for 2 years and forwarded to their referring dentists for individual maintenance. Eight to ten years later, the patients were re-evaluated. Treatment success was defined as absence of probing depths ≥ 5mm with concomitant bleeding/suppuration and bone loss ≥ 0.5mm. A multilevel analysis was performed to determine risk for treatment failure (disease recurrence + implant loss).

Results: Of 45 patients and 76 implants included, at 8-10 years, 47.4% of implants had a successful treatment outcome, 13.2% were lost to follow-up, 19.7% had recurrence of peri-implantitis and 19.7% were lost or removed. A negative short-term response for the initial treatment (OR 2.4; 95%CI 1.2–4.5) and a reduced marginal bone level at baseline (OR 2.4; 95%CI 1.7–3.2), 1 year (OR 2.3; 95%CI 1.7–3) and 2 years (OR 2.2; 95%CI 1.7–3) were identified as risk indicators for treatment failure.

Conclusion: Access flap surgery demonstrates to be able to treat successfully most of the implants, but disease recurrence and implant loss are frequently observed. Implants with a short-term negative response to the treatment, as well as reduced marginal bone level indicate risk for treatment failure.

Keywords: success; peri-implantitis; surgical treatment.

SUMMARY

LITERATURE REVIEW

Introduction

According to the last World Workshop on the Classification of Periodontal and Peri-implant Diseases and Conditions (2017), peri-implantitis was defined as a pathological condition occurring in tissues around dental implants, characterized by inflammation in the peri-implant connective tissue and progressive loss of supporting bone (Berglundh et al., 2018; Schwarz et al., 2018). The progression of peri-implantitis lesions may lead to implant loss (Derks et al., 2016). Peri-implantitis is also a highly prevalent oral disease within the population (Derks et al., 2016; Matarazzo et al., 2018). Recent cross-sectional studies applying the new criteria definition for daily practice, showed that in Brazil it occurred in 24.8% subjects and 8.5% implants (Botelho, 2020) while in the USA in 15% subjects and 9% implants (Shimshuk et al., 2020).

The primary etiologic factor of peri-implant diseases is the accumulation of dental biofilm around implant surfaces (Ericsson et al., 1992; Pontoriero et al., 1994; Renvert & Polyzois 2018). Thus, the primary goal of the peri-implantitis treatment is the biofilm removal and control in order to achieve resolution of the peri-implant infection and halt of further bone loss (Heitz-Mayfield & Mombelli 2014; Renvert & Polyzois 2018). The surgical treatment of peri-implantitis lesions has been frequently proposed in the literature due to the complex characteristics of the implant surface and topography (Heitz-Mayfield & Lang, 2010; Renvert & Polyzois 2018; Karlsson et al., 2019; Khoury et al., 2019). Such treatment includes mainly raising a mucosal flap to access the implant surface for proper cleaning with mechanical devices and chemical agents. Resective and regenerative surgical techniques may also be used as adjunctive to the anti-infective therapy (Roccuzzo et al., 2018; Khoury et al., 2019).

Studies reporting long-term outcomes following the surgical treatment of peri-implantitis have increased over the past decade (Schwarz et al., 2017; Heitz-Mayfield et al., 2018; Carcuac et al., 2020; Roccuzzo et al., 2020; Serino et al., 2021). The literature review below describes the available research on long-term outcomes following the surgical treatment of peri-implantitis.

A bibliographic search was conducted in MEDLINE-PubMed to identify the current evidence supporting the present literature review. The PICOS methodology (Tacconelli 2010) was used with the following MeSH terms:

PICOS	Definition	MeSH terms
P (Patient or population)	Patients diagnosed and treatment surgically for peri-implantitis	peri-implantitis
I (Intervention)	Surgical treatment of peri-implantitis with a minimum follow-up of 3 years	surgical treatment OR peri-implant surgery OR therapy
C (Comparison)	There is no gold standard treatment protocol to be compared.	-
O (Outcomes)	Success rates, implant loss for any reason, recurrence of the disease, long-term outcomes	survival OR success OR recurrence OR long-term
S (Study design)	Systematic reviews, randomized controlled clinical trials, prospective or retrospective studies and case series	clinical

Resulting in: (((peri-implantitis) AND (((surgical treatment) OR (peri-implant surgery)) OR (therapy))) AND (((((survival) OR (success)) OR (recurrence)) OR (long-term)) AND (clinical)

Then, a filter was applied for articles first published between January 2010 to January 2021. The inclusion criteria were clinical studies of any design with at least 10 implants followed for > 3 years. Exclusion criteria were studies not published in English; in vitro or animal designs; lack of information and previous investigations in the same patient population (the longest follow-up was chosen). A total of 382 studies were identified in MEDLINE, of which 10 were included in this literature review. Three more studies were selected from hand searching screening. The primary outcome was implant survival and treatment success/failure (defined by each author). Clinical and radiographic outcomes, such as, marginal bone level (MBL); probing depth (PD); bleeding on probing

(BOP); suppuration (SUP) and plaque index (PI - different criteria) associated with the primary outcomes were also recorded.

LONGITUDINAL STUDIES

Eleven longitudinal studies were included in the present literature review. Detailed data collected from each study are shown in Table 1.

Access surgery

Two articles reported access flap surgery as treatment choice for peri-implantitis with a 5-year follow-up (Heitz-Mayfield et al., 2018; Isehed et al., 2018). The mean survival rate reported by the 2 papers was 82.9% (80-85.8%) and treatment failure, 34.8% (25-44.5%), i.e., recurrence of the disease or implant loss. Heitz-Mayfield et al. (2018) found that, individually, bone loss and the full-mouth bleeding score before treatment as well as PI and BOP at the 3-year follow-up increased the likelihood of a failure treatment outcome. Isehed et al. (2018) compared the effect of adjunctive EMD (test) to the open flap debridement (control) in sites diagnosed with peri-implantitis presenting an angular peri-implant bone defect ≥ 3mm. A positive association of the use of EMD with longer implant survival was observed. Shorter survival outcomes were associated with PD and BOP (1-year follow-up), number of cigarettes smoked (1- and 3-year follow-ups), SUP (3-year follow-up) and measures of MBL (3- and 5-year follow-ups).

Resective surgery

Four studies reported the long-term outcomes of resective surgery. Of those, one study performed a modified implantoplasty therapy (Bianchini et al., 2019), two studies were aiming at pocket reduction (Carcuac et al., 2020 and Berglundh et al., 2018) and one also performed corrections in the bone architecture (Serino et al., 2021). The mean survival rate observed in the studies was 86% (79.3-96%) and 37.8% treatment failure (13-65.2%). The presence of residual pockets was frequently associated with recurrence of the disease in two studies (Serino et al., 2021; Carcuac et al., 2020). Besides, these same studies

showed that reduced MBL before (Serino et al., 2021) or at 1 year after surgery (Carcuac et al., 2020) as well as implants with modified surfaces presented an increased risk for the progression of peri-implantitis.

Regenerative surgery

Four articles reported the long-term outcomes following regenerative surgery. Roccuzzo et al. (2020) treated single intrabony crater-like defects (Class II) by means of a deproteinized bovine bone mineral with 10% collagen (DBBMC), while La Monaca et al. (2018) associated mineralized dehydrated bone allograft with a collagen membrane and Ross-Jansaker et al. (2014) compared the use of a bone substitute with or without a resorbable membrane in sites with horizontal bone loss and evidence of a vertical crater-like defect. Parma-Benfenati et al. (2020) combined different resorbable and non-resorbable GBR materials. The studies reported a mean implant survival rate of 88.2% (67-100%) and 29.8% treatment failure (2.2-46%).

Resective/regenerative surgery

One study with a 7-year follow-up, that associated resective and regenerative therapies in sites with combined intrabony and supracrestal bone defects, was included (Schwarz et al., 2017). Implantoplasty was performed at the buccal and supracrestally exposed implant parts, while the intrabony defect was filled with anorganic bovine bone and covered by a collagen membrane. No implants were lost, resulting in 100% implant survival, but 12.5% presented pus formation and progressive bone loss.

Table 1. Longitudinal studies.

Author (year), Country*	Study design	Follow-up	P/i (n)	Objective	Pre-intervention	Intervention	Maintenance	Success criteria	Data/statistical analysis	Success rates	Regression analysis	Author's conclusion
Access surgery												
Heitz-Mayfield et al., 2018, Australia	P	5y	24/36	To evaluate clinical outcomes of SPIT following surgical treatment of peri-implantitis	FMP + NSD implant sites + OHI	Access surgery + mechanical debridement + surface decontamination with sterile saline + gauze AMX and MTR	Semestral; FMD + OHI	SUC: Implant survival + No PD ≥5 mm with BOP/SUP + No further BL	P and I level; Wilcoxon test; OR + 95% CI; Multivariate logistic regression	SUC 53% REC 14% LTF 22% LOSS 11%	Only individual analysis: Implant level - MBL before treatment; FMBS before treatment; 3-year PI; 3-year BOP	Peri-implant conditions established following peri-implantitis surgery were maintained after 5 years in the majority of patients and implants.
Isehed et al., 2018, Sweden	RCT	5y	25/25	To assess the clinical and radiographic outcomes 3 and 5y after the surgical treatment of peri-implantitis per se or in combination with an EMD	OHI + FMD	Access surgery + mechanical debridement + surface decontamination with sterile saline (control group) + EMD (test group)	1 year: Trimestral Then based on individual needs	SURV	Partial least square regression - variables associated with SURV (months)	SURV 85% EMD 75% control REC/LOSS 31% EMD 58% control	Longer SURV: +BL change and EMD Shorter SURV: BOP + PD at 1 year; cigarettes at 1 and 3 years, SUP at 3 years and BL at 3 and 5 years	Five years after the surgical treatment of peri-implantitis, 80% of the implants survived. Adjunctive EMD was positively associated with SURV, indicating that EMD might postpone LOSS.
Resective surgery												
Serino et al., 2021, Sweden	R	10y	22/55	To report a follow-up of patients following the surgical treatment of peri-implantitis and to identify possible risk indicators for the progression of disease during SPiT.	OHI + FMD + hygiene access evaluation	Surgery aiming at pocket reduction + mechanical debridement + correction of the bony architecture + surface decontamination with 0.12% CHX CLI	Semestral; Motivation + OHI + FMD + CHX irrigation	Absence of PD ≥ 5mm + BOP/SUP + MBL ≥ 2mm	Wilcoxon rank sum, Chi-square, multilevel analysis using a GEE, OR	At 6m – 45.5% - healthy, 54.5% - persisting peri-implantitis 10y – 84% healthy were stable; 66.6% of the treated were stable; 29% showed disease progression and 11 were extracted.	Clinical BL before treatment, modified surface, residual PD at 3/4 sites associated with progression of the disease	Residual pockets were a frequent finding at implants with substantial BL before treatment. Presence of PD around the entire circumference of the implants resulted as a risk indicator for further disease progression. The probability of progression of peri-implant disease increased with increased observation time.

Carcuac et al., 2020, Sweden	P	5y	73/ 130	To assess the risk for disease recurrence following surgical therapy of peri-implantitis. To evaluate predictors for the 5-year outcomes	NR	Surgery aiming at pocket reduction+ mechanical debridement + implant surface decontamination with different protocols	1 year: Trimestral. Then, annual - based on individual needs	REC/progression between years 1 and 5: MBL >1.0 mm; surgical retreatment; implant removal/loss.	Multiple logistic regression	REC 44%: 47% LOSS 23% surgically retreated 30% further BL >1 mm - not retreated/removed	Increased odds for REC: Residual PD ≥6 at 1 year MBL at 1 year Modified surface	Implants with residual deep PD, reduced BL, or modified surfaces following surgical therapy of peri-implantitis present with increased risk for recurrence/progression.
Berglundh et al., 2018, Sweden	R	2-11y 4.5 ± 2.1	50/ 95	To assess long-term clinical and radiological outcomes of surgical treatment of peri-implantitis	OHI + FMD + NSD implants + prophylaxis ATB – AMX to patients SUP+ following FMD, 3 days prior to surgery	Surgery aiming at pocket reduction + mechanical debridement + implant surface decontamination with saline	4-month intervals - motivation + OHI + FMD	SUC: PD ≤ 5 mm, BOP-BL ≤ 0.5 mm at the latest follow-up.	Multilevel regression model	SUC 30.4% patients 34.8% implants	Probability of no further BL - 77% for the absence of BOP and 83% for PD ≤ 5 mm at follow-up, combined 78%	Surgical treatment of peri-implantitis was effective in the long-term; Better at implants with non-modified than with modified surfaces, and preservation of MBL was consistent with healthy peri-implant tissue conditions.
Bianchini et al., 2019, Brazil	P/R	2-6y 3.4 ± 1.5	23/ 32	To evaluate radiographically and clinically the disease resolution and MBL stability rates of peri-implantitis cases treated through a combined RES-IPP therapy in a moderate to long-term period	NR	Open flap elevation + mechanical debridement + IPP + surface decontamination with CA (20%)	Semestral ; plaque control program	Disease resolution (DR): absence of BL changes + BOP Implant failure (IF): mobility, fracture, or progressive MBL > 70% implant´s length.	MBL percentage Fisher's Exact test	DR/SUC: 83% (patient) and 87% (implant level). IF: 13% (implant level) MBL stability in 87% implants 10.7% BOP+ implants	No association between implant failure and patient characteristics	IPP treated cases showed high DR% and MBL stability over a moderate to long-term period.
Regenerative surgery												
Roccuzzo et al., 2020, Italy	P	10y	14/ 14	To evaluate the 10-year outcomes of a REG surgical treatment of single peri-implantitis intrabony defects, by means of ABB with 10% collagen	FMD + NSD implants + OHI	Open flap debridement + EDTA 24% + CHX 1% gel + saline over the impl surf + ABB with 10% collagen to fill the intrabony defect + CTG if there was insufficient KM + ATB (AMX+CLA)	Individualized; motivation + OHI + FMD + reduction in modifiable risks CIST	SUC: PD ≤5 mm, absence of BOP/SUP, and no further BL	Descriptive; Kaplan-Meier survival analysis	SUC 35% Partial res 19% LTF 19% LOSS 27%	NR	REG + SPiT was able to maintain in function the majority of SLA implants, but many of TPS implants were removed. Therefore, the decision to treat implants affected by peri-implantitis should be based on several factors, including surface characteristics.

La Monaca et al., 2018, Italy	P	5y	34/ 34	To evaluate the 5-year clinical and radiographic outcomes following REG therapy of peri-implantitis lesions using MDBA and CM in the non-submerged mode of wound healing	FMD + NSD implants + OHI	Open flap debridement + chemical decontamination using hydrogen peroxide (3%), CHX (0.2%), and a tetracycline hydrochloride solution + bone defect filling with MDBA and CM + ATB (AMX+CLA and MTR)	1 year: Trimestral. Then, semestral - motivation + OHI + FMD	Primary outcome: absence of MBL ≥1.0 mm (2x the *SD* of the measurement error) after surgery compared to the baseline Composite outcome: absence of MBL ≥1.0 mm; absence of PD ≥5 mm; and absence of BOP/SUP	Binomial logistic regression	Primary SUC 77% Composite SUC 59% LOSS 0	Primary - no significant predictor variable Composite - function time of implant	REG using MDBA + CM resulted in clinical improvement and radiographic defect filling at a 1-year follow-up. Thereafter the implants showed a progressive decrease in the bone filling of the defects and > mean PD. At 5-year follow-up, no LOSS and no BL was found in 77% of treated implants, and the absence of PD ≥5 mm + no BOP/SUP in 58.82% of sites.
Ross-Jansaker et al., 2014, Sweden	P	5y	25/ 45	To compare two REG surgical treatments for peri-implantitis over 5 years	FMD + NSD implants + OHI	Open flap debridement + chemical decontamination using hydrogen peroxide (3%), and saline + bone substitute (control) and resorbable membrane (test) + ATB (AMX and MTN)	Trimestral: motivation + OHI + FMD as necessary	REC - BL ≥1.0 mm + BOP SUC: ≥ 25% bone fill ≥25% bone fill + probing depth ≤5 mm ≥25% bone fill + probing depth ≤5 mm + BOP≤1	T-test, paired t-test, Mann-Whitney.	SUC ≥ 25% bone fill 66.7% ≥25% bone fill + PD ≤5 62.2% ≥25% bone fill + PD ≤5 + BOP≤1 51.1% REC 2.2% LTF 34% LOSS 0 Patient level no change BL - 40%	SUC unrelated to baseline PD	Clinical improvements and defect fill obtained at 1 year after surgical treatment with a bone substitute and membrane or with bone substitute alone remained stable between 1 and 5 years in cases on maintenance care. The use of a resorbable membrane in combination with a bone substitute did not add to the predictability or extent of bone fill.
Parma-Benfenati et al., 2020, Italy	R	2-21y 6.9	45/ 57	To evaluate the long-term clinical and radiologic outcomes of submerged and non-submerged GBR for peri-implantitis lesions	FMD + NSD implants + OHI	Different techniques of bone defect debridement + implant surface decontamination + GBR materials + ATB (AMX+CLA)	Individualized	Disease resolution (DR): implant survival + absence PD ≥ 5 mm with BOP/SUP + no further BL. DR - failure - LOSS	Kruskal-Wallis, Pearson's Correlation	SUC 70.2% FAILURE 15.8% LOSS 14.0% All implants that failed or were lost during the observation period had modified surfaces.	NR	Under TPiS, GBR was effective in the treatment of moderate to advanced peri-implantitis for the majority of the treated implants. Complete resolution of peri-implantitis, defined as the absence of BOP and deep PD at all sites, is not easy to achieve.
Resective/Regenerative surgery												

Schwarz et al., 2017, Germany	RCT	7y	15/ 15	To assess the long-term outcomes (>4 years) following combined surgical RES/REG therapy of advanced peri-implantitis lesions using two surface decontamination methods	FMD, NSD	Open flap debridement + IPP at buccally and supracrestally exposed implant parts + decontamination of the intrabony surface: (i) Er:YAG laser (ERL) or (ii) plastic curettes + cotton pellets + sterile saline + ABB and CM + ATB	Annual; OHI + FMD	REC: SUP and progressive BL	Descriptive analysis	REC: 12.5% LTF: 40.1% BOP reduction - CPS: 90 ± 12% versus ERL: 87 ± 18% CAL gain - CPS: 2.8 ± 1.9 mm vs ERL: 2.1 ± 2.5 mm	NR	Combined surgical RES/REG therapy of advanced peri-implantitis was effective on the long-term, but not influenced by the initial method of surface decontamination.

*Country of the first author.
Study design: P – prospective; RCT – randomized controlled trial; R – retrospective.
P/i (n) - patients/implants
Objective: ABB – anorganic bovine bone (Bio-Oss); CM – collagen membrane (Bio-Gide); EMD – enamel matrix derivate; GBR – guided bone regeneration; IPP – implantoplasty; MBL – marginal bone level; MDBA: mineralized dehydrated bone allograft (Puros); REG – regenerative; RES - resective; SPIT – supportive peri-implant therapy.
Pre-intervention: AMX – amoxicillin; ATB – systemic antibiotics; FMD – full-mouth debridement; NSD – non-surgical debridement; NR – not reported; OHI – oral hygiene instruction; SUP – suppuration.
Intervention: AMX+CLA – amoxicillin and clavulanic acid; CA – citric acid; CLI – clindamycin; CHX – chlorhexidine; CTG - connective tissue graft; EDTA - ethylenediamine tetra-acetate; KM – keratinized mucosa; MTR – metronidazole.
Maintenance: CIST – cumulative interceptive supportive therapy.
Success criteria: BL - bone loss; BOP - bleeding on probing; DR: disease resolution; PD - peri-implant probing depth; REC – recurrence; SD – standard deviation; SUC – success; SURV – implant survival.
Data/statistical analysis: GEE – generalized estimating equation; OR + 95% CI – Odds ratio and 95% confidence interval.
Success rates: CAL - clinical attachment level; CPS - cotton pellets and plastic curettes; ERL - Er:YAG laser; IF – implant failure; LTF – lost to follow-up; LOSS – implant loss.
Regression analysis: FMBS – full mouth bleeding score; PI – plaque index.

SYSTEMATIC REVIEWS

Two systematic reviews reporting long-term clinical outcomes following the treatment of peri-implantitis were selected. Detailed data are shown in Table 2.

Roccuzzo et al. (2018) reported the clinical outcomes of implants treated for peri-implantitis who subsequently received supportive care for at least 3 years from 13 studies. The primary outcome of the SR was implant survival rates and, according to the studies, it was 81.73%–100% at 3 years, 74.09%–100% at 4 years, 76.03%–100% at 5 years and 69.63%–98.72% at 7 years for both non-surgical and surgical approaches. As secondary outcome, the treatment success was reported by five studies with different definitions. Successfully rates at implant level ranged from 34% to 57% at 3 years, 71% to 75% at 5 years and 7% to 41% at 7 years across studies. It is noteworthy that studies with strict definition generally reported lower success figures, but studies with less strict definitions did not necessarily achieve better outcomes. In general, anti-infective treatment protocols with or without a reconstructive approach resulted in clinical improvements for the majority of patients and implants. However, some studies also documented the need for additional interventions (such as connective tissue grafting, surgical intervention, systemic antibiotics) to achieve the desired outcome or manage disease recurrence.

Di Gianfilippo et al. (2020) reported the long-term clinical and radiographic outcomes following the surgical treatment of peri-implantitis using different approaches. Thirteen studies were divided into three groups: (i) access flap, (ii) resective and (iii) regenerative treatment. It was observed that all treatment modalities were successful in achieving favorable biological outcomes after therapy, however, more favorable bone gain was noted with regenerative therapies.

In short, both SRs reported a large heterogeneity among studies regarding diagnostic criteria, peri-implantitis treatment protocols including the pretreatment phase, surgical approach (access, regenerative, resective, combination), implant surface decontamination method, biomaterials used, adjunctive treatment, peri-operative antimicrobials, and success definitions.

Table 2. Systematic review.

Author (year), Country*	Journal	Nº of articles included	Objective	Variables	Results	Conclusion
Roccuzzo et al., 2018, Italy	Clinical Oral Implants Research	18 qualitative and 13 quantitative studies.	To report the clinical outcomes for patients with implants treated for peri-implantitis who subsequently received supportive care for at least 3 years.	Primary outcome: SURV at the patient and implant level. Secondary outcomes: SUC, REC and LOSS at the patient and implant level	Peri-implantitis treatment protocols differed across all categories: pretreatment phase; surgical approach (RES, REG, combination); implant surface decontamination method; biomaterials used; adjunctive treatment; and peri-operative antimicrobials. SURV was 81.73%–100% at 3 years, 74.09%–100% at 4 years, 76.03%–100% at 5 years and 69.63%–98.72% at 7 years. Definitions for SUC were reported by five studies and varied markedly. SUC ranged from 34% to 57% (at 3 years), 71% to 75% (at 5 years) and 7% to 41% (at 7 years) across studies at implant level. Anti-infective treatment protocols aimed at implant surface decontamination with or without REG using bone graft/substitutes resulted in clinical improvements for the majority of patients and implants. Some studies documented the need for additional interventions (CTG, surgical intervention, systemic antimicrobials) to achieve the desired outcome or manage REC.	Peri-implantitis can be successfully treated in patients adhering to a SPiT which involves professional biofilm removal at implants and teeth. High SURV rates can be achieved in the medium to long term. Implant surface may influence the treatment outcomes. Some implants in some patients may require retreatment, adjunctive therapies or implant removal.
Di Gianfilippo et al., 2020, USA	Applied Sciences	13 studies	To report on the long-term clinical and radiological outcomes after treatment of peri-implantitis with different surgical approaches.	Studies were clustered into three groups based on the surgical approach used to treat peri-implantitis: (i) flap access, (ii) RES and (iii) REG. Probing depth (PD) increase, radiographic bone gain and implant survival at last follow-up were considered the primary outcomes of the study.	Large heterogeneity existed among studies for diagnostic criteria and decontamination modalities. All treatment modalities were successful in achieving favorable biological outcomes after therapy. More favorable bone gain was noted with REG, despite successful outcomes for PD reduction and SURV rate being achieved in all treatment modalities.	Surgical treatment of peri-implantitis following flap, resective or regenerative approaches improved peri-implant probing depth and survival rate three to seven years after surgical treatment of peri-implantitis. REG induced more favorable radiographic bone gain and biological outcomes.

CTG: connective tissue graft, LOSS: implant loss, PD: probing depth, REC: recurrence of the peri-implantitis, REG: regenerative therapy, RES: resective therapy, SPiT: supportive peri-implant therapy; SUC: success; SURV: survival.

Conclusion

Regardless of the large heterogeneity in the literature for different parameters such as the diagnosis of peri-implantitis, classification of bone defects, pre-surgical and various surgical approaches, studies have demonstrated that, in general, the surgical treatment of peri-implantitis is effective for a long term in a given percentage of the population. The recurrence of the disease or implant loss, however, are common findings (mean of the 11 longitudinal studies: 30.6%, range from 2.2-65.2%) and achieving predictable outcomes is a challenge. Moreover, the investigation of possible risk factors for treatment success/failure is increasing in the current literature. Marginal bone level, residual pockets, and presence of bleeding/suppuration on probing have been identified as possible predictors, however, evidence on the effect of time and thresholds for treatment decision are still limited.

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Effect of the surgical treatment of peri-implantitis: an 8 to 10-year follow-up cohort study

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Effect of the surgical treatment of peri-implantitis: an 8 to 10-year follow-up cohort study

ABSTRACT

Objectives: To assess the long-term effects of the surgical treatment of peri-implantitis. A secondary objective was to evaluate the risk indicators for treatment failure.

Material and methods: Patients diagnosed with peri-implantitis and treated by access flap surgery and mechanical cleaning of the implant surface were included in the study. All subjects were re-evaluated after 2 months (short-term), enrolled in a strict maintenance program for 2 years and forwarded to their referring dentists for individual maintenance. Eight to ten years later, the patients were re-evaluated. Treatment success was defined as absence of probing depths ≥ 5mm with concomitant bleeding/suppuration and bone loss ≥ 0.5mm. A multilevel analysis was performed to determine risk for treatment failure (disease recurrence + implant loss).

Results: Of 45 patients and 76 implants included, at 8-10 years, 47.4% of implants had a successful treatment outcome, 13.2% were lost to follow-up, 19.7% had recurrence of peri-implantitis and 19.7% were lost or removed. A negative short-term response for the initial treatment (OR 2.4; 95%CI 1.2–4.5) and a reduced marginal bone level at baseline (OR 2.4; 95%CI 1.7–3.2), 1 year (OR 2.3; 95%CI 1.7–3) and 2 years (OR 2.2; 95%CI 1.7–3) were identified as risk indicators for treatment failure.

Conclusion: Access flap surgery demonstrates to be able to treat successfully most of the implants, but disease recurrence and implant loss are frequently observed. Implants with a short-term negative response to the treatment, as well as reduced marginal bone level indicate risk for treatment failure.

Keywords: success; peri-implantitis; surgical treatment.

INTRODUCTION

Peri-implantitis is a plaque-associated pathology occurring in tissues around dental implants, marked by inflammation of the peri-implant mucosa and progressive loss of supporting bone (Berglundh, et al., 2018; Schwarz, Derks, Monje, Wang, 2018). According to the definition of the latest EFP-APP World Workshop, recent studies have shown that peri-implantitis affects about 15% subjects and 9% implants (Matarazzo, Sabóia-Gomes, Alves, de Oliveira, Araújo, 2018; Vignoletti, Di Domenico, Di Martino, Montero, de Sanctis, 2019; Shimshuk, Weinstein, Daubert, 2020). Due to its high prevalence, different treatment alternatives have been proposed, including non-surgical and surgical anti-infective approaches, resective and regenerative therapies (Renvert & Polyzois 2018; Roccuzzo, Layton, Roccuzzo, Heitz-Mayfield, 2018). These approaches aim at the resolution of the infection in peri-implant tissues and the prevention of further bone loss. However, achieving predictable outcomes after the treatment is challenging and, so far, there is no gold-standard therapy.

Different case definitions of the disease, success criteria and hence clinical outcomes have been reported in the literature. In a short-term evaluation, Máximo, et al. (2009) surgically treated implants diagnosed with peri-implantitis and reported that 25% of the implants still presented signs of inflammation (probing depth ≥ 5mm with concomitant bleeding on probing or suppuration) at the 3-month assessment. Long-term surgical studies (Berglundh, Wennström, Lindhe, 2018; Carcuac, Derks, Abrahamsson, Wennström, Berglundh, 2020; Heitz-Mayfield, et al., 2018; Roccuzzo, Fierravanti, Pittoni, Dalmasso, Roccuzzo, 2020; Serino, Wada, Mameno, Renvert, 2021; Schwarz, John, Schmucker, Sahm, Becker, 2017) also have shown a high percentage of implants with disease recurrence/progression or even implant loss, varying from 16% to 65%. A predictable response to the treatment was, therefore, not observed at both short and long-term follow-ups. It appears that the clinical decision on whether implants should be removed or treated should be based not only on the implant clinical and radiographic parameters but also on several patient-related elements (Roccuzzo et al., 2020). Understanding possible risk indicators for treatment success or failure seems to be important in order to achieve predictable outcomes.

History of periodontitis, poor plaque control and no regular maintenance care are well established in the literature as risk factors for the onset of the disease (Costa, et al., 2012; Schwarz, et al., 2018; Hu, Lang, Ong, Lim, Tan, 2020; Heitz-Mayfield, Heitz, Lang, 2020). There are, however, few studies reporting risk indicators influencing the clinical outcomes following the surgical treatment. A short-term study (Koldsland et al., 2017), in which patients were treated with resective therapy and followed for 6 months, observed that implants with suppuration prior to intervention and bone loss exceeding 7 mm were more likely to present negative outcomes. Carcuac et al. (2020) assessed risk factors for the recurrence or progression of the disease 5 years following resective therapy. The authors reported that residual probing depth ≥ 6 mm after surgical therapy and reduced marginal bone level at 1 year increased the odds for disease recurrence/progression.

Thus, the aim of this cohort study was to assess the long-term effect of the surgical treatment of peri-implantitis. As secondary objective, short and long-term risk indicators for treatment failure were evaluated.

MATERIAL AND METHODS

Study design and population

The present study was conducted with patients treated for peri-implantitis in a university setting in Brazil. Ethics approval was obtained by the Institutional Review Board for Research Conducted with Human Beings at the State University of Maringá, Brazil (CAAE nº 79246317.0.0000.0104). This study was conducted in accordance with the Helsinki declaration and the manuscript preparation followed the STROBE guidelines (von Elm, et al., 2007).

Patients diagnosed and treated for peri-implantitis by a Periodontist at the Dental Clinic of the State University of Maringá, Brazil, from January 2010 to December 2012 were followed. These patients fulfilled the following criteria:

Inclusion criteria:

- At least one implant diagnosed with peri-implantitis, defined as: probing depth (PD) ≥ 5 mm, bleeding on probing (BOP) and/or

suppuration (SUP) and marginal bone level (MBL) ≥ 2 mm from the implant shoulder;

- Treatment of peri-implantitis lesions by access flap surgery;
- Enrollment in a maintenance program.

Exclusion criteria:

- Recurrence of peri-implantitis during the maintenance program requiring resective or regenerative treatment;
- Incomplete clinical and radiographic records.

Eligible patients received explanations on the objectives of the study and were requested to sign a written informed consent. Clinical and radiographic examinations were performed from July 2018 to October 2020 following the same protocol since 2010. Figure 1 shows the study outline.

Treatment protocol and supportive therapy

Individuals evaluated and diagnosed with peri-implantitis at 2010 (baseline) underwent a pre-surgical phase consisting of oral hygiene instruction, supra/sub-gingival scaling as required, and prophylaxis. Non-surgical debridement was performed at all implants before the surgical phase. Subsequently, the peri-implantitis sites were treated between 2010 to 2012 as follows: after local anesthesia (2% mepivacaine with 1:100,000 epinephrine), intrasulcular incisions were performed to create a horizontal flap extending beyond the adjacent teeth and/or implants. Buccal and lingual full-thickness flaps were elevated. Granulation tissue was removed to expose the implant threads and bone defect. The implant surface was scaled with Teflon curettes (Hu-Friedy, Rio de Janeiro, RJ, Brazil) to remove biofilm and calculus followed by irrigation with sterile saline. Jets of bicarbonate (Jet Sonic, Gnatus, Ribeirão Preto, SP, Brazil) were used to decontaminate implant surface. The flap was repositioned in its original position and stabilized with interrupted sutures, which were removed after 10 days. Analgesics were prescribed to all subjects, and they were instructed to rinse with a 0.12% chlorhexidine mouthwash twice a day for 7 days. Subjects returned to the clinic 2 months (T0) after the surgical procedure and their short-term response to the treatment was assessed. A positive response was considered at implants

presenting no PD ≥ 5 mm with concomitant BOP/SUP. Patients with a negative response received additional therapy and were only included in maintenance therapy when positive outcomes were achieved. All individuals were kept in a strict trimestral supportive peri-implant therapy (SPiT) for 2 years. Each recall visit consisted of medical history update, clinical monitoring, OHI reinforcement, oral prophylaxis and supra/submucosal biofilm removal in the implant sites with BOP. A complete clinical and radiographic examination was performed at 1 (T1) and 2 years (T2) in SPiT. Thereafter, maintenance care was provided by the referring clinician according to individual needs.

Clinical and radiographic examinations

At the 8 to 10-year examination (T9), the following clinical parameters were evaluated at six sites of all implants and teeth (mesiobuccal, buccal, distobuccal, mesiolingual, lingual, distolingual) using a millimeter North Carolina periodontal probe (PCPUNC-BR 15; Hu-Friedy, Rio de Janeiro, RJ, Brazil):

- Plaque index (PI): presence or absence of supragingival plaque as the probe traverses the margin of the peri-implant mucosa or gingival sulcus.
- Probing depth (PD): measured as the distance in millimeters from the mucosal (or gingival) margin to the bottom of the sulcus/pocket.
- Clinical attachment level (CAL): measured as the distance in millimeters from the cementoenamel junction or implant shoulder to the bottom of the sulcus/pocket.
- Bleeding on probing (BOP – Lang, Joss, Orsanic, Gusberti, Siegrist, 1986): presence or absence of bleeding up to 30 seconds after a gentle probing.
- Mucosal recession (MR): determined as the difference in millimeters between CAL and PD.

In addition, implant and patient-related information were recorded: implant connection, prosthetic characteristics (type, retention), full mouth plaque score (FMPS), full mouth bleeding score (FMBS) and demographic data, such as age, gender, number of implants and history of periodontitis (Papapanou et al., 2018).

All clinical evaluations were performed by the same examiner (FM) at baseline, T0, T1, T2 and T9, who was previously calibrated according to the method proposed by Araújo et al. (2003).

Periapical radiographs acquired at baseline, T1 and T2 used an intraoral dental E-Speed film (Eastman Kodak®, Rochester, USA) and X-ray positioner (Indusbello, Londrina, PR, Brazil) according to the parallelism technique. Subsequently, these radiographs were digitized with the aid of a film and slide scanner (Nikon® CoolScan IV ED, Tokyo, Japan). At T9, digital periapical radiographs were acquired with an intra oral sensor (RVG 5200, Carestream Dental LLC, Atlanta, GA, USA) and X-ray positioner (Indusbello, Londrina, PR, Brazil) according to the same technique. The implant sites were centralized in all acquirements to avoid distortion. All resulting images were analyzed by a blind examiner for patient's diagnosis using a computer software (Image J®, National Institutes of Health, Maryland, USA), calibrated to the known implant diameter. Marginal bone level (MBL) was defined as the distance in millimeters between the implant shoulder and the most coronal bone-to-implant contact measured at both mesial and distal sites. Bone loss was calculated by subtracting the values obtained at T9 from T2. A threshold of 0.5 mm was considered error measurement. The higher value was used to determine treatment success. All radiographic measurements were performed by the same examiner (DRD) previously calibrated according to the method proposed by Peñnarrocha, Palomar, Sanchis, Guarinos, Balaguer (2004). To determine intraobserver reproducibility, 30 randomly chosen implants were measured twice within a minimum of 24-hour interval. The intraclass correlation coefficient was 0.96.

Subsequently, all patients received OHI reinforcement, oral prophylaxis, and supra/submucosal biofilm removal in the implant sites by means of scalers, if necessary. Implants diagnosed with peri-implantitis recurrence were referred for treatment.

Outcomes

The primary outcome of the present study was the success rate of the peri-implantitis surgical treatment calculated at both implant and patient level at T9.

Treatment success was defined as absence of PD ≥ 5 mm with concomitant BOP/SUP and bone loss ≥ 0.5 mm. Failure cases were divided into disease recurrence and implant loss. The worst implant was considered for patient classification. Secondary outcomes included success rates at T1 and T2, implant survival (its presence regardless of the health of the surrounding tissues) and an evaluation of the association between clinical signs of inflammation (such as bleeding on probing, probing depth) or bone loss progression with treatment failure.

Data analysis

Descriptive data was expressed as mean values or percentages and standard deviation (SD). Clinical and radiographic changes through time were analyzed with Friedman and Dunn's post hoc tests since the data set was not normally distributed (Shapiro-Wilk test). To evaluate the implant survival rates following treatment, a Kaplan–Meier analysis (single group) was performed.

Patients/implants were divided according to success criteria at T9 into 3 groups: Success, Recurrence and Implant loss. Differences between the groups were analyzed with Chi-Square, Kruskal-Wallis and Dunn's post hoc tests (Shapiro-Wilk test – non-parametric data set).

The treatment outcome at T9 was also dichotomized into success [0] vs. failure [1] to identify risk indicators for treatment failure at implant level. Odds ratio and 95% confidence intervals (CI) were calculated individually. Then, a linear mixed model (multilevel model) for clustered longitudinal data was used to investigate whether covariates [PI, PD, biggest PD, BOP, MBL, implant region, type of supported-prosthesis, implant short-term response, patient's age, gender, number of implants, number of implants diagnosed with peri-implantitis, history of periodontal disease, FMPS, FMBS, patient short-term response and patient failure] measured at each level of the hierarchy had an impact on the dependent variable (treatment failure). Outliers were removed for better estimation and model performance. Final models for the peri-implant event were established by the regressive elimination (Wald) of insignificant variables.

Statistical analyses were conducted with Sigma Plot (Systat Software Inc, San Jose, CA) and R statistical software, version 4.0.2 Team (R Foundation for Statistical Computing, Vienna, Austria) using NLME package with the level of significance established at 5% ($p < 0.05$).

RESULTS

Baseline demographic data are shown in Table 1. A total of 45 patients and 76 implants that underwent surgical treatment for peri-implantitis and were kept in maintenance care were included in the present study. Thirty patients (66.6%) had a history of periodontitis. Thirty-six implants (47.4%) were located in the posterior mandible. All implants had a modified surface, and the majority were external hexagon (88.1%) supporting a screw-retained (90.1%) single-crown (52.6%) or fixed-dental prosthesis (39.5%). In the last examination (T9), 31 patients (mean age of 58±10 years) with 51 implants (in function for 12±2 years) were assessed. Five patients with 10 implants failed to return to follow-up and 9 patients with 15 implants experienced implant loss. After the surgery, all individuals were re-evaluated at the 2-month time interval (Table 2). Approximately 67% of patients and 74% of implants presented a positive response to the first intervention, consequently, about 26% of the cases failed and needed a second surgical procedure. Of those, 53% and 45% of patients and implants, respectively, still presented a negative response after the second surgical treatment.

Clinical and radiographic parameters of all implants across different time points (baseline, T0, T1, T2 and T9) are described in Table 3. The percentage of sites with dental plaque increased from baseline (17±30%) to T0 (19±32%), T1 (22±33%), T2 (29±32%) and T9 (69±32%, $p<0.05$). Peri-implant mean PD decreased from baseline (4.3±1.1mm) to T0 (3.2±0.8mm, $p<0.05$) and remained stable at T1 (3.2±1mm), T2 (3.3±1.2mm) and T9 (3.7±1.4mm). Means of the deepest PD registered at each implant decreased from baseline (6.1±1.2mm) to T0 (4.3±1.1mm, $p<0.05$), were stable at T1 (4.2±1.3mm) and T2 (4.6±1.5mm) but increased at T9 (5.1±1.7mm). There were significant differences between baseline, T1 and T9. The percentage of sites with BOP decreased from baseline (82±26%) to T0 (48±34% - $p<0.05$) and T1 (47±33%) but increased at T2

(55±32%) and T9 (70±30% - $p<0.05$). The mean MR increased from baseline (0.2±0.4mm) to T0 (0.4±0.7mm, $p<0.05$) and T1 (0.5±0.7mm) and remained stable at T2 (0.3±0.5mm) and T9 (0.3±0.6mm). Mean MBL was stable across all study observations (3.5±1.5mm at baseline, 3.6±1.5mm at T1, 3.6±1.4mm at T2 and 3.5±1.4mm at T9). In a nutshell, at 2 months after treatment, the post-hoc test showed a significant reduction in mean PD, mean deepest PD and percentage of sites with BOP but an increase in mean MR ($p<0.05$). At the 1 and 2-year follow-ups under strict periodontal maintenance, clinical and radiographic variables did not show any changes compared to 2 months ($p<0.05$). At 8-10 years, the experimental sites presented significantly increased PI, deepest PD and BOP ($p<0.05$).

Successful treatment outcomes, defined as absence of PD ≥ 5 mm with concomitant BOP/SUP and MBL ≥ 0.5 mm, at implant and patient levels are described in Table 4 and Fig. 2a,b. At T1, a successful treatment was observed in 63 implants (82.9%) and 37 patients (82.2%), while 10 implants (13.2%) and 5 patients (11.1%) experienced disease recurrence and 3 implants (3.9%) of 3 patients (6.7%) were lost. At T2, 1 patient (2%) with 1 implant (1.3%) failed to show-up at the follow-up examination. The success rate decreased to 73.7% and 66.7% at implant and patient levels, respectively. Recurrence of the disease was found in 15 implants (19.7%) and 10 patients (22.2%). Implant loss was observed in 4 implants (5.3%) and 4 patients (8.9%). At T9, 4 patients with 9 implants failed to take part in the follow-up examination. Twenty patients (44.4%) and 36 implants (47.4%) exhibited a successful outcome. Fifteen implants (19.7%) and 11 (24.4%) patients were diagnosed with disease recurrence and 11 additional implants belonging to 9 patients were lost, resulting in 19.7% implant loss at implant level and 20% at patient level. At T9, implant survival was calculated in 67% of the implants (Fig. 3).

Patients and implants were divided into 3 groups (Success [S], Recurrence [R] and Implant loss [IL]) according to its success outcome obtained at T9. Clinical and radiographic parameters were compared between the 3 groups, aiming to identify risk indicators for treatment failure (Fig. 4a-e; Table S1). Individuals and implants lost to follow-up or experiencing implant loss at T1 or T2 were excluded from the analysis.

It was observed that the mean PI increased over time. The S group exhibited lower PI values at T0, T1, T2 and T9 (17±28%, 19±29%, 20±26% and 68±30%, respectively) than R (T0: 23±36%, T1: 30±36%, T2: 36±40%, T9: 70±40%) and IL groups (T0: 26±42%, T1: 23±33%, T2: 40±33%). There were no significant differences between the 3 groups at all the time-points.

The percentage of sites with BOP at T0 was similar between the 3 groups (S: 47±32%, R: 55±40%, IL: 56±34%). At T1 and T2, BOP increased in the IL group (T1: 61±28%, T2: 79±23%) while it decreased/remained stable in S (T1: 46±32%, T2: 50±32%) and R groups (T1: 42±34%, T2: 53±29%). The post-hoc test showed significant differences between the S and IL groups at T2. At T9, high percentages of BOP were observed in both R (79±25%) and S groups (66±31%), with no significant differences.

Mean PD was similar between R (3.5±0.7mm) and IL groups (3.5±0.7mm) at T0, with lower values in the S group (3±0.7mm). At T1 and T2, PD was higher in the IL group (T1: 3.7±1mm, T2: 4.4±1.7mm) followed by R (T1: 3.3±0.8mm, T2: 3.5±0.8mm) and S (T1: 3±1.1mm, T2: 3.1±1.1mm). At T9, PD was higher in R (5.2±1.4mm) than S group (3.1±0.7mm). There were statistically significant lower results in the S group than IL at T1 or R group at T9.

At all examinations, the mean deepest PD was higher in the IL group (T0: 5±1.1mm, T1: 4.8±1.3mm, T2: 5.9±1.9mm), followed by R (T0: 4.4±1mm, T1: 4.4±1.5mm, T2: 5.1±1mm, T9: 7.1±1.5mm) and S (T0: 4±0.9mm, T1: 4±1.3mm, T2: 4.2±1.4mm, T9: 4.3±1mm). There were statistically significant differences between S and R/IL at T2, and S and R at T9.

The mean MBL values were higher in both IL (T0: 4.4±1.2mm, T1: 4.8±1.9mm, T2: 5.2±1.6mm) and R groups (T0: 3.6±1.2mm, T1: 3.8±1.2mm, T2: 3.9±1.2mm, T9: 4.9±1.4mm) than S (T0: 2.8±1.1mm, T1: 3.1±1mm, T2: 2.9±1.1mm, T9: 2.9±1.1mm) at all time points. There were statistically significant differences between IL/R groups and S at T0, T2 and T9. At T1, only the difference between S and IL was significant.

In short, the post-hoc tests indicated significant differences between the Success group and Implant loss regarding the percentage of BOP (T2), mean PD (T1), deepest PD (T2), and MBL (all time points). Differences between Recurrence and Success were only observed in the mean PD (T9), deepest PD

(T2 and T9) and MBL (T0, T1, T2 and T9). There were, however, no significant differences between Recurrence and Implant loss groups for all variables.

Table S2 shows the previous peri-implant diagnosis of each group at short-term evaluation, T1 and T2. Within the implants that ended the study in the Success group, 19.4% presented a negative short-term response, 8.3% and 8.6% were diagnosed with disease recurrence at T1 and T2, respectively. In the Recurrence group, 26.7% presented a negative short-term response and, 13.3% showed early signs of recurrence at T1 and 26.7% at T2. Within the Implant loss group, 45.5% showed a negative short-term response to the surgical treatment, 36.4% were diagnosed with disease recurrence at T1 and 63.4% at T2. The percentages of success/disease recurrence within the 3 groups at T2 were statistically significant ($p<0.001$).

Table 5 shows the individual odds ratio and 95% CI for treatment success or failure outcomes. The odds of having a treatment failure were 4.9 times (95% CI 1.1 - 20.7) higher when MBL ≥ 4.5mm at baseline, 5 times (95% CI 1.35 - 18.4) when MBL ≥ 4.5mm at 1 year and 6.2 (95% CI 1.8 - 20.9) at 2 years. The likelihood of having a treatment failure outcome was 3 times (95% CI 1.02 - 8.8) higher in implants presenting residual PD ≥ 5mm at 2 months and 5.9 times (95% CI 1.9 - 17.7) at 2 years.

The final model results from the multilevel analysis evaluating associated risk indicators for treatment failure are described in Table 6. After controlling for the effects of MBL at baseline, T1 and T2, and a short-term negative response, the results suggested a positive effect of both parameters in function on treatment failure significant at 5%. The odds of having a treatment failure outcome were 2.4 times (95% CI 1.7 – 3.2) higher to each millimeter MBL increased at baseline, 2.3 times (95% CI 1.7 – 3) at T1 and 2.2 times (95% CI 1.7 – 3) at T2. A short-term negative response increased 2.4 times (95% CI 1.2 - 4.5) the odds of having a treatment failure outcome.

DISCUSSION

The present study assessed the long-term effect of surgical treatment of peri-implantitis. The results showed that 8-10 years after treatment, 47% of the

implants exhibited successful treatment outcomes, while treatment failure was observed in 39%. Furthermore, the multilevel analysis demonstrated that a negative short-term response to the initial treatment and reduced marginal bone level at baseline, T1 or T2 were risk indicators for treatment failure.

The definition of a successful treatment outcome was, in the present study, absence of PD ≥ 5 mm with concomitant BOP/SUP and MBL ≥ 0.5mm. Previous studies have reported a plethora of different success criteria including a combination of clinical signs of inflammation and progressive bone loss. Heitz-Mayfield et al. (2018) and Parma-Benfenatti et al. (2020) considered (i) implant survival, (ii) absence of PD ≥5 mm with BOP/SUP, and (iii) no further bone loss. Carcuac et al. (2020) and Serino et al. (2021) used higher bone loss thresholds (1 and 2mm, respectively) while a stricter criterion (PD ≤ 5 mm, absence of BOP/SUP, and no further bone loss) was implemented by Roccuzzo et al. (2020). Indeed, a recent systematic review (Roccuzzo et al., 2018) showed that there is no consensus regarding the success criteria used for determining a successful outcome following surgical treatment of peri-implantitis. Thus, the comparison of success rates between several studies and surgical treatment is difficult and limited.

At the short-term assessment (2-month interval), the majority of the implants presented a positive response to the treatment (absence of PD ≥ 5mm + BOP/SUP), however, 26% failed to respond and needed a second surgical intervention. These findings are in agreement with a previous short-term follow-up study (Máximo et al., 2009). The authors reported that at the 3-month assessment, out of 20 implants treated (access flap surgery, Teflon curettes and abrasive sodium carbonate air-powder), 25% exhibited PD ≥ 5 mm associated with BOP/SUP. Serino et al. (2021) evaluated the effect of resective surgical treatment (pocket reduction) of peri-implantitis lesions. After 6 months of healing, a higher frequency of treatment failure was observed, 35% of the implants. The findings from the studies above indicate that treatment of peri-implantitis lesions following one single surgical intervention is not predictable.

In the current study, failure outcomes at the 8–10-year evaluation period were a common observation, 20% of the implants presented recurrence of peri-implantitis and additional 20% were lost. This finding is not in agreement with

Heitz-Mayfield et al. (2018) who associated the surgical treatment with the administration of systemic antibiotics and reported, after 5 years, a lower treatment failure rate (25%), 14% disease recurrence and 11% implant loss. Previous investigations using also surgical approaches to treat peri-implantitis lesions presented, however, similar failure rates to the present study (Carcuac et al., 2020; Roccuzzo et al., 2020). Carcuac et al. (2020) evaluated after 5 years the effect of resective surgery (pocket elimination). Treatment failure was defined as MBL >1.0 mm, need of surgical retreatment or implant removal/loss. The study reported a 44% failure rate. In the 10-year follow-up study performed by Roccuzzo et al. (2020), the treatment was a combination of open flap debridement, mechanical and chemical cleaning of the implant surface and graft with a bone substitute. In addition, connective tissue graft was performed if needed and systemic antibiotics were prescribed. The authors observed a high failure rate (46%), 19% disease recurrence/partial and 27% implant loss. It is suggested that the currently available surgical approaches to treat peri-implantitis failed to prevent, to a certain extent, disease recurrence or implant loss.

A significant effect of disease severity on the final treatment outcomes was observed in the individual analysis. A marginal bone level ≥ 4.5mm at baseline, 1- and 2-year time intervals, as well as implants presenting residual PD ≥ 5mm at 2-month and 2-year time intervals were associated with treatment failure. These findings are in agreement with previous studies (De Waal et al., 2016; Karlsson et al., 2018) in which the amount of disease severity before treatment appeared to be reflected in the final outcomes. These observations corroborate in part with data from Heitz-Mayfield et al. (2018) who reported a negative association between treatment success and baseline MBL, 3-year implant plaque and BOP. Thus, larger amounts of bone loss and deeper probing depths may represent a clinical challenge for obtaining a proper access for biofilm removal due to the corresponding increase in the number of threads not covered by bone (Heitz-Mayfield & Lang, 2010; De Waal et al., 2016; Renvert & Polyzois, 2018).

The multilevel model also indicated an impact of disease severity on treatment outcomes. Two parameters influencing failure outcomes were observed in the combined analysis: MBL and short-term response. To each millimeter MBL increased at baseline, the odds of having a treatment failure were

2.4 times higher. Similar results were obtained at T1 (OR 2.3) and T2 (OR 2.2). The short-term negative response (PD ≥ 5mm + BOP/SUP) increased 2.4 times the odds of treatment failure. These findings corroborate with data reported in a recent study (Carcuac et al., 2020) that observed greater odds for recurrence/progression 5 years following pocket reduction surgery at implants with a residual PPD ≥ 6 mm at 1-year follow-up (OR 7.4). This study also correlated the radiographic bone level at 1-year with the odds for further deterioration (OR 1.4). Thus, according to these findings mentioned above, it may be suggested that implant removal should be considered when implants presenting reduced marginal bone level fail to respond successfully to the first surgical intervention.

Antibiotics were not combined with the access flap surgery in this long-term follow-up study, unlike some previous reports (Heitz-Mayfield, et al., 2018; Serino, et al., 2021). The success outcomes and failure rates, however, were no different from those studies. This finding is in agreement with a randomized clinical trial, in which the adjunctive effect of antibiotics was not observed after 1 year of follow-up (Carcuac, et al., 2017). Thus, antibiotics do not appear to be pivotal in the context of the treatment of peri-implantitis lesions.

The present study presents some limitations. The patients were kept in supportive care performed by a Periodontist at the University dental clinic for the first 2 years that included motivation, plaque control and mechanical debridement (if necessary) each 3-month interval. Later, the patients returned to their referring clinicians and, therefore, a control of the quality and frequency of the supportive care could not be performed. The importance of SPiT in the primary prevention of peri-implant diseases and to prevent recurrence following active treatment is well established in the literature (Schwarz et al., 2018; Heitz-Mayfield et al., 2018; Roccuzzo et al., 2018).

CONCLUSION

This current study indicated successful treatment outcomes 8-10 years following access flap surgery. Disease recurrence and implant loss were frequently

observed. Implants with a short-term negative response to the treatment, as well as a reduced marginal bone level were considered in risk for treatment failure.

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TABLES

Table 1. Baseline demographic data.

Number of patients	**45**
Age (years; mean ± SD)	50.4 ± 10
Gender, n (%)	
Females	22 (48.9%)
Males	23 (51.1%)
History of periodontitis (yes/no)	30/15
Number of implants with peri-implantitis	**76**
Time of loading (years/mean ± SD)	2.8 ± 1.7
Implant location, %	
Maxilla (anterior/posterior)	51.3% (22/17)
Mandible (anterior/posterior)	48.7% (1/36)
Implant supported-prosthesis, n	
External hexagon/Conical connection/Internal hexagon	67/5/4
Screwed/Cemented	69/7
Single crown/Fixed-dental prosthesis/Full-arch	40/30/6

Table 2. Number (%) of implants and patients presenting a short-term positive (absence of PD ≥ 5 + BOP) or negative response following the first and second interventions.

Implant	1st intervention N = 76		2nd intervention N = 20	
	Number	%	Number	%
Positive Response	56	**73.7**	11	**55.0**
Negative Response	20	**26.3**	9	**45.0**
Patient	1st intervention N = 45		2nd intervention N = 15	
	Number	%	Number	%
Positive Response	30	**66.7**	7	**46.7**
Negative Response	15	**33.3**	8	**53.3**

Table 3. Mean (SD) clinical and radiographic description of the implants before (baseline), at 2 months (T0), 1 (T1), 2 (T2) and 8 to 10 years (T9) after treatment.

	Baseline n = 76	After treatment			
		T0 n = 76	T1 n = 73	T2 n = 71	T9 n = 51
PI (%)	17 ± 30[a]	19 ± 32[a]	22 ± 33[a]	29 ± 32[a]	69 ± 32[b]
PD (mm)	4.3 ± 1.1[a]	3.2 ± 0.8[b]	3.2 ± 1[b]	3.3 ± 1.2[b]	3.7 ± 1.4[b]
Deepest PD (mm)	6.1 ± 1.2[a]	4.3 ± 1.1[bc]	4.2 ± 1.3[b]	4.6 ± 1.5[bc]	5.1 ± 1.7[c]
BOP (%)	82 ± 26[a]	48 ± 34[b]	47 ± 33[b]	55 ± 32[bc]	70 ± 30[c]
MR (mm)	0.2 ± 0.4[a]	0.4 ± 0.7[b]	0.5 ± 0.7[bc]	0.3 ± 0.5	0.3 ± 0.6
MBL (mm)	3.5 ± 1.5	-	3.6 ± 1.5	3.6 ± 1.4	3.5 ± 1.4

- Different letters mean statistically significant differences over time. Friedman test with Dunn's post-hoc test.

Table 4. Success rates at implant and patient level expressed in number and percentage at T1, T2 and T9.

Implant level	T1		T2		T9	
n = 76	n	**%**	n	**%**	n	**%**
Success	63	**82.9**	56	**73.7**	36	**47.4**
Lost to follow-up	0	**0.0**	1	**1.3**	10	**13.2**
Recurrence	10	**13.2**	15	**19.7**	15	**19.7**
Implant loss	3	**3.9**	4	**5.3**	15	**19.7**
Patient level	T1		T2		T9	
n = 45	n	**%**	n	**%**	n	**%**
Success	37	**82.2**	30	**66.7**	20	**44.4**
Lost to follow-up	0	**0**	1	**2**	5	**11**
Recurrence	5	**11.1**	10	**22.2**	11	**24.4**
Implant loss	3	**6.7**	4	**8.9**	9	**20**

Table 5. Individual odds ratios and 95% CI associated with a failure outcome.

Time	Parameter	Odds ratio	95% CI	*p*-value
Baseline	MBL ≥ 4.5mm	4.8889	(1.1515, 20.7562)	0.0315
2 months	PD ≥ 5mm	3.0000	(1.0217, 8.8084)	0.0456
1 year	MBL ≥ 4.5mm	5.0000	(1.3550, 18.4504)	0.0157
2 years	MBL ≥ 4.5mm	6.2000	(1.8343, 20.9563)	0.0033
	PD ≥ 5mm	5.8500	(1.9336, 17.6985)	0.0018

Table 6. Multilevel analysis with treatment failure at implant level (0: success; 1: failure) as the dependent variable.

Parameters	Odds ratio	SD	95% CI	*p*-value
$MBL_{baseline}$ (mm)	2.3861	0.1567	(1.7551, 3.2441)	< 0.0001
MBL_{T1} (mm)	2.2618	0.1459	(1.6991, 3.0108)	< 0.0001
MBL_{T2} (mm)	2.2502	0.1429	(1.7007, 2.9774)	< 0.0001
SHORT (negative)	2.3646	0.3286	(1.2417, 4.5018)	0.0088

Supplementary tables

Table S1. Mean (SD) clinical and radiographic parameters of the implants divided according to success criteria at T9: Group 1 - Success; 2 - Recurrence; 3 - Implant loss.

T9 n = 62	Success (n=36)				Recurrence (n=15)				Implant loss (n=11)			
	T0	T1	T2	T9	T0	T1	T2	T9	T0	T1	T2	T9
PI (%)	17 ± 28	19 ± 29	20 ± 26	68 ± 30	23 ± 36	30 ± 36	36 ± 40	70 ± 40	26 ± 42	23 ± 33	40 ± 33	-
BOP (%)	47 ± 32	46 ± 32	50 ± 32[a]	66 ± 31	55 ± 40	42 ± 34	53 ± 29	79 ± 25	56 ± 34	61 ± 28	79 ± 23[b]	-
PD (mm)	3 ± 0.7	3 ± 1.1[a]	3.1 ± 1.1	3.1 ± 0.7[a]	3.5 ± 0.7	3.3 ± 0.8	3.5 ± 0.8	5.2 ± 1.4[b]	3.5 ± 0.7	3.7 ± 1[b]	4.4 ± 1.7	-
Deepest PD (mm)	4 ± 0.9	4 ± 1.3	4.2 ± 1.4[a]	4.3 ± 1[a]	4.4 ± 1	4.4 ± 1.5	5.1 ± 1[b]	7.1 ± 1.5[b]	5 ± 1.1	4.8 ± 1.3	5.9 ± 1.9[b]	-
MBL (mm)	2.8 ± 1.1[a]	3.1 ± 1[a]	2.9 ± 1.1[a]	2.9 ± 1[a]	3.6 ± 1.2[b]	3.8 ± 1.2	3.9 ± 1.2[b]	4.9 ± 1.4[b]	4.4 ± 1.2[b]	4.8 ± 1.9[b]	5.2 ± 1.6[b]	-

Different letters mean statistically significant differences between the groups at the same time point. Kruskal-Wallis test with Dunn's post-hoc test.

Table S2. Previous negative outcomes: Short-term response and disease recurrence at 1 and 2 years of the implants divided according to success criteria at T9.

Time	Success	Recurrence	Implant loss
Short-term negative response	19.4%	26.7%	45.5%
Disease recurrence at 1 year	8.3%	13.3%	36.4%
Disease recurrence at 2 years	8.6%*	26.7%*	63.6%*

*Statistically significant differences between the 3 groups. Chi-Square test.

FIGURES:

Figure 1. Study outline. All patients screened and diagnosed with peri-implantitis at 2010 (baseline) were treated by open access debridement and mechanical cleaning of the implant surface. A re-evaluation was performed after 2 months (T0 - short-term response). Then, patients were kept in a strict SPiT protocol for 2 years (T1 and T2) and forwarded to their referring clinicians. Individuals were re-evaluated between 2018-2020, after 8-10 years (T9) following the surgical treatment of peri-implantitis.

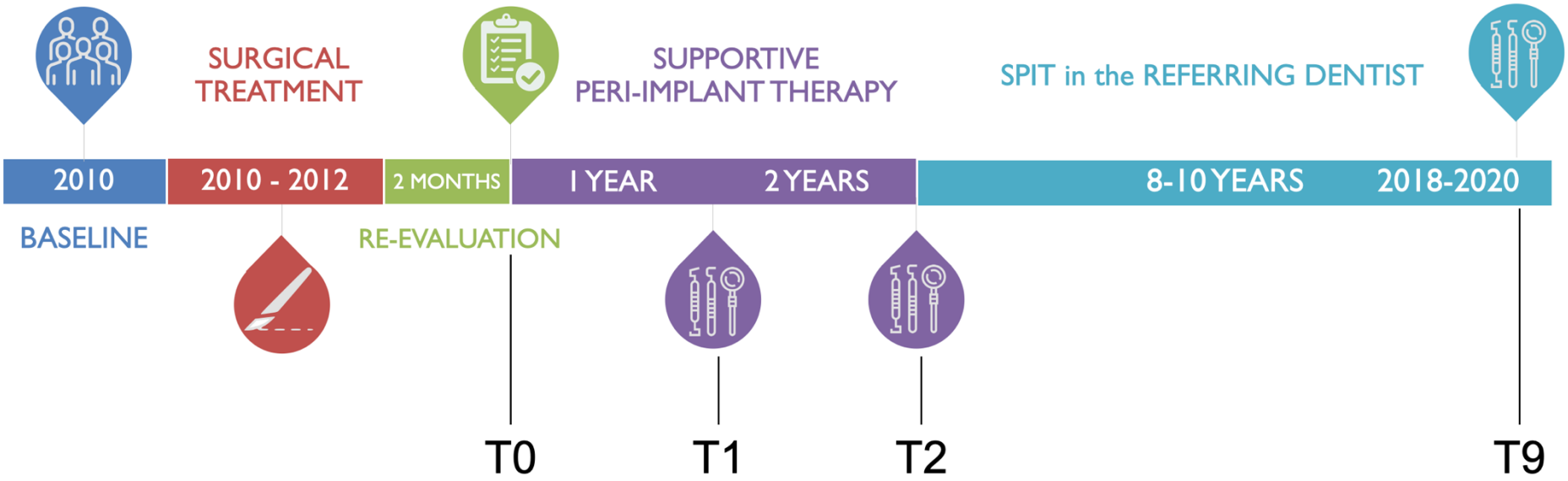


Figure 2. Success rates (%) at implant (a) and patient (b) level at 1, 2 and 8-10 years after treatment.

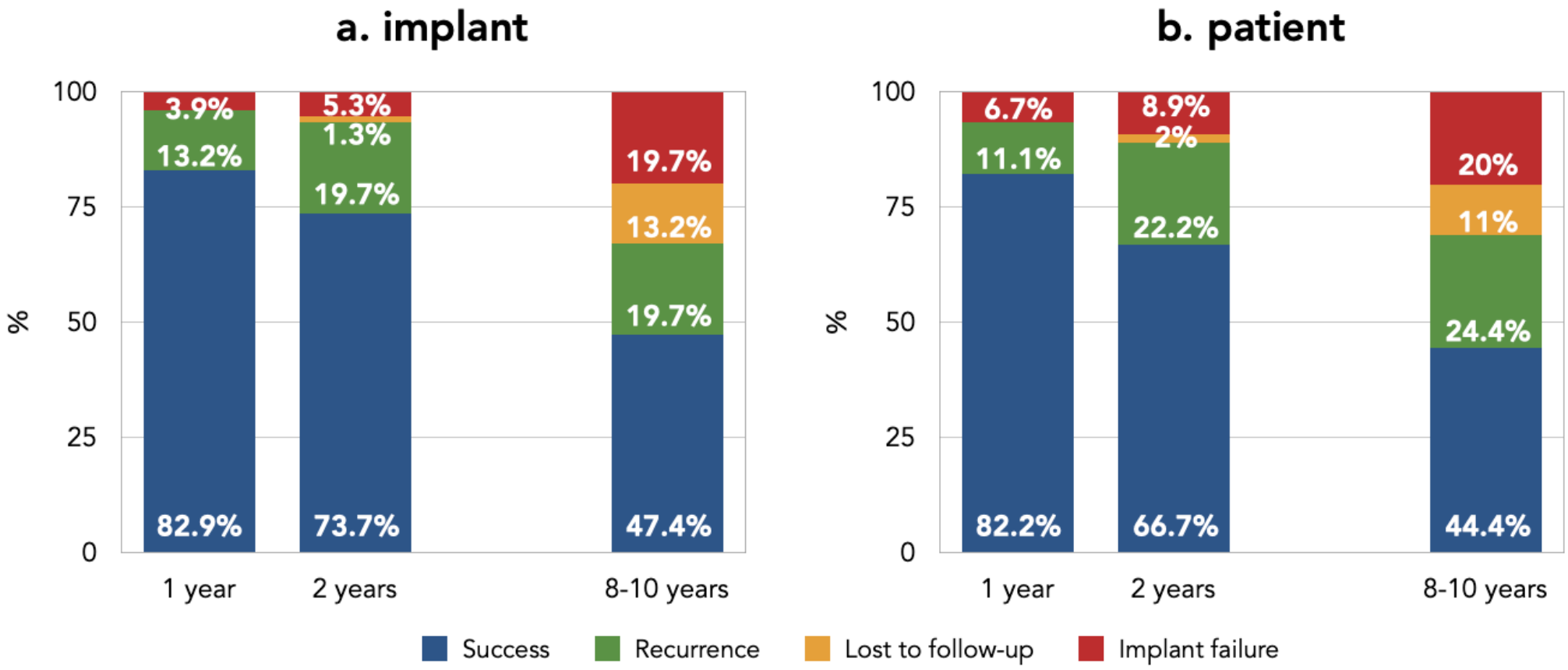


Figure 3. Kaplan-Meier estimate of the survival rate of the implants as a function of time.

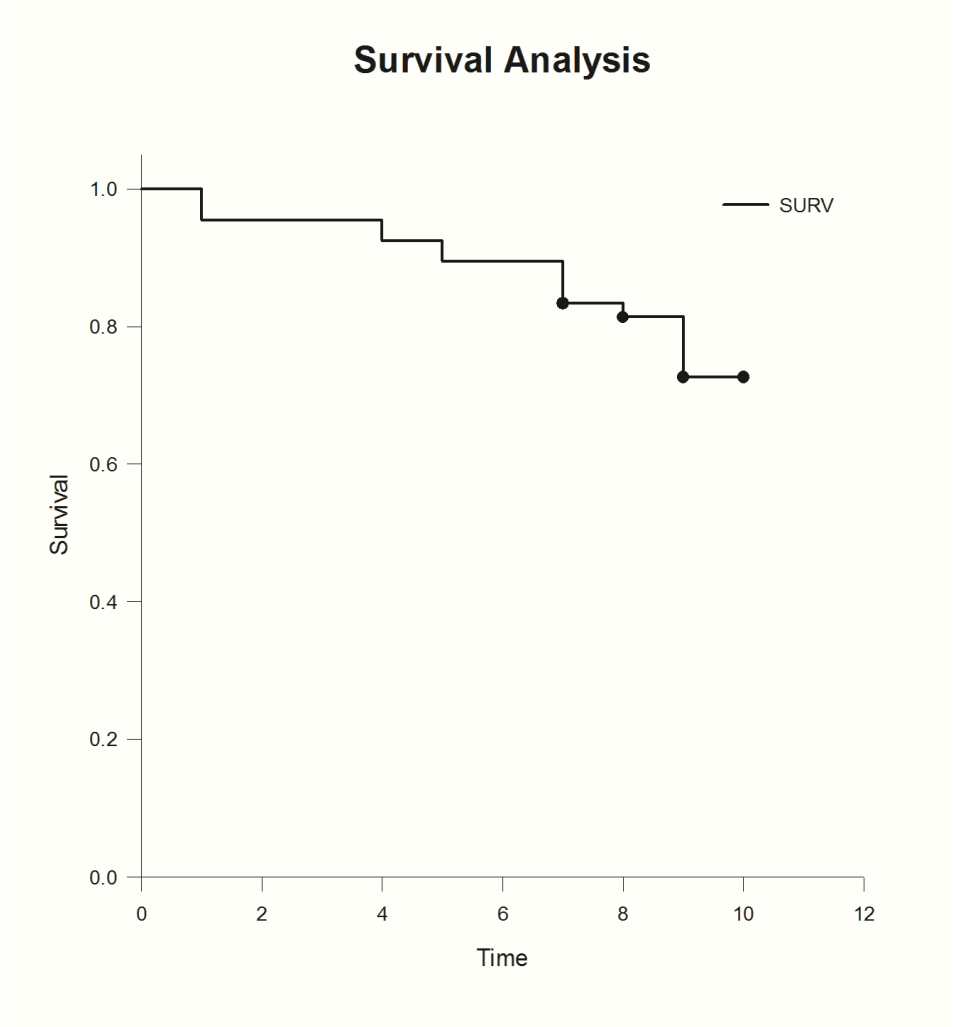
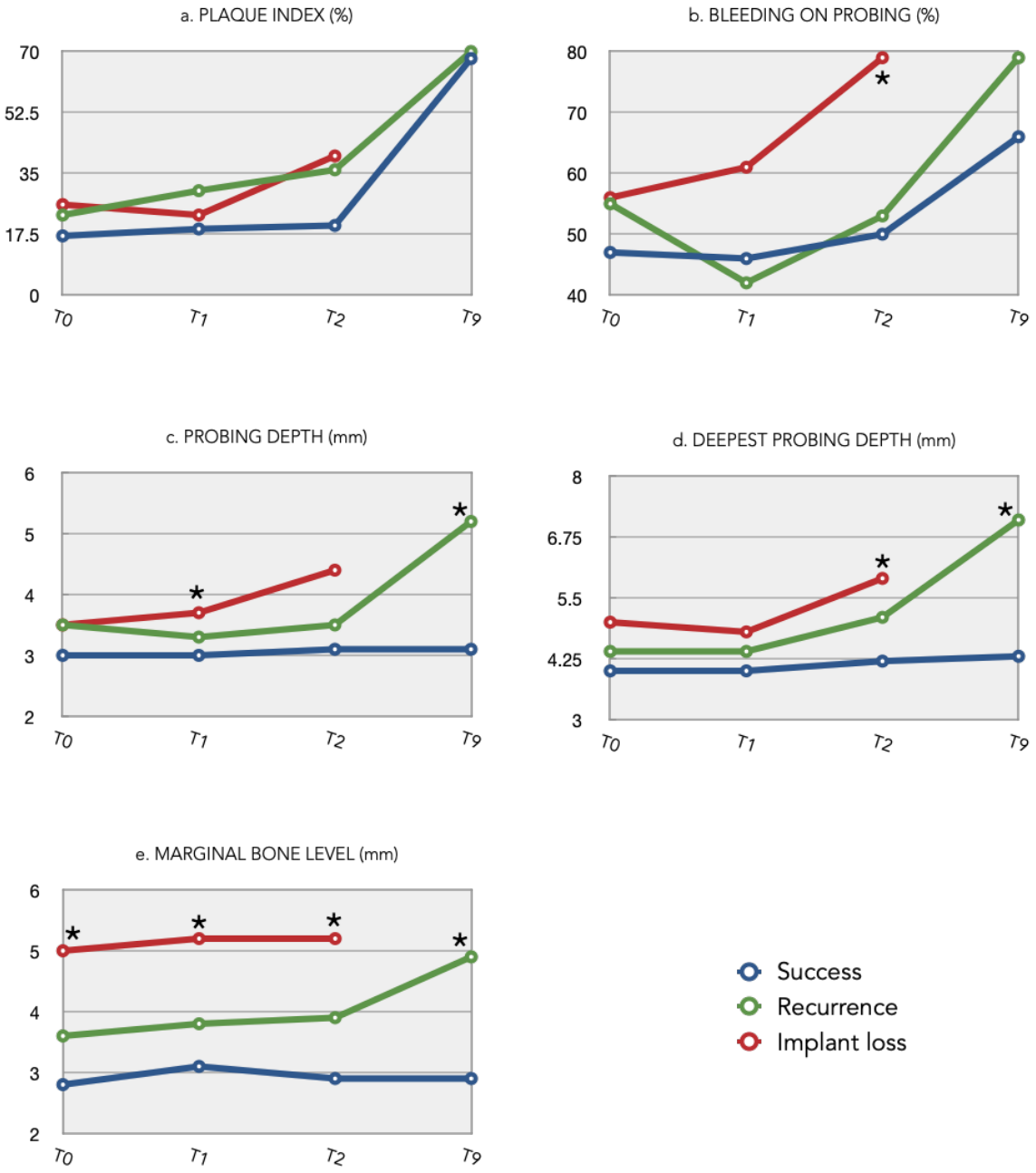


Figure 4. Clinical and radiographic parameters divided into 3 groups according to success criteria at T9: Success, Recurrence and Implant loss. (a) Plaque index; (b) Bleeding on probing; (c) Probing depth; (d) Deepest probing depth; (f) Marginal bone level.



• Statistically significant differences between the groups. Kruskal-Wallis test.

APPENDIX

Clinical Oral Implants Research Guidelines

Author Guidelines

The study specific criteria were selected. Full-text guideline is available at:
https://onlinelibrary.wiley.com/page/journal/16000501/homepage/forauthors.html

Clinical Oral Implants Research conveys scientific progress in the field of implant dentistry and its related areas to clinicians, teachers and researchers concerned with the application of this information for the benefit of patients in need of oral implants. The journal addresses itself to clinicians, general practitioners, periodontists, oral and maxillofacial surgeons and prosthodontists, as well as to teachers, academicians and scholars involved in the education of professionals and in the scientific promotion of the field of implant dentistry.

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    - data availability statement
    - funding statement
    - conflict of interest disclosure
    - ethics approval statement
    - patient consent statement
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If you are invited to revise your manuscript after peer review, the journal will also request the revised manuscript to be formatted according to journal requirements as described below.

Parts of the Manuscript

The manuscript should be submitted in separate files: main text file; figures.

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iv. The author's institutional affiliations where the work was conducted, with a footnote for the author's present address if different from where the work was conducted;

v. Acknowledgments;

vi. Author contributions: Please provide a statement listing the contributions made by each of the authors. Example: A.S. and K.J. conceived the ideas; K.J. and R.L.M. collected the data; R.L.M. and P.A.K. analysed the data; and A.S. and K.J. led the writing. Please refer to the journal's Authorship policy in the **Editorial Policies and Ethical Considerations section** for details on author listing eligibility;
vii. Abstract, MeSH term keywords and word count;
viii. Main text;
ix. References;
x. Tables (each table complete with title and footnotes);
xi. Figure legends;
xii. Appendices (if relevant).
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The main text should include Introduction, Material and Methods, Results and Discussion.

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- Clinical trial registration number and name of the trial register should be included in the Materials and Methods at the submission stage.
- Authors who have completed the ARRIVE guidelines, STROBE or CONSORT checklist should include as the last sentence in the Methods section a sentence stating compliance with the appropriate guidelines/checklist.
- **Results:** Present your results in a logical sequence in the text, tables, and illustrations. Do not repeat in the text all data in the tables and illustrations. The important observations should be emphasised.
- **Discussion:** Summarise the findings without repeating in detail the data given in the Results section. Relate your observations to other relevant studies and point out the implications of the findings and their limitations. Cite other relevant studies.

References

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References should be prepared according to the Publication Manual of the American Psychological Association (6th edition). This means in text citations should follow the author-date method whereby the author's last name and the year of publication for the source should appear in the text, for example, (Jones, 1998). The complete reference list should appear alphabetically by name at the end of the paper.

A sample of the most common entries in reference lists appears below. Please note that a DOI should be provided for all references where available. For more information about APA referencing style, please refer to the **APA FAQ**. Please note that for journal articles, issue numbers are not included unless each issue in the volume begins with page one.

Journal article

Beers, S. R. , & De Bellis, M. D. (2002). Neuropsychological function in children with maltreatment-related posttraumatic stress disorder. The American Journal of Psychiatry, 159, 483–486. doi:**10.1176/appi.ajp.159.3.483**

Book edition

Bradley-Johnson, S. (1994). Psychoeducational assessment of students who are visually impaired or blind: Infancy through high school (2nd ed.). Austin, TX: Pro-ed.

Internet Document

Norton, R. (2006, November 4). How to train a cat to operate a light switch [Video file]. Retrieved from **http://www.youtube.com/watch?v=Vja83KLQXZs**

In-text citations

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If your source has three, four, or five authors, include all names in the first in-text citation along with the date. In the following in text citations, only include the first author's name and follow it with et al.

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2nd and any other subsequent citations: (Gilley, et al.)

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Tables should be self-contained and complement, not duplicate, information contained in the text. They should be supplied as editable files, not pasted as images. Legends should be concise but comprehensive – the table, legend, and footnotes must be understandable without reference to the text. All abbreviations must be defined in footnotes. Footnote symbols: †, ‡, §, ¶, should be used (in that order) and *, **, *** should be reserved for P-values. Statistical measures such as SD or SEM should be identified in the headings.

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Legends should be concise but comprehensive – the figure and its legend must be understandable without reference to the text. Include definitions of any symbols used and define/explain all abbreviations and units of measurement.

Figures

All figures should clarify the text and their number should be kept to a minimum. Details must be large enough to retain their clarity after reduction in size. Micrographs should be designed to be reproduced without reduction, and they should be dressed directly on the micrograph with a linear size scale, arrows, and other designators as needed. Each figure should have a legend.

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- If your study is a randomized clinical trial, you will need to fill in all sections of the CONSORT Checklist. If your study is not a randomized trial, not all sections of the checklist might apply to your manuscript, in which case you simply fill in N/A.
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a sentence stating compliance with the appropriate guidelines/checklist. Checklists should be included in the submission material under “Supplementary Files for Review”.

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	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	23 24
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	25
Objectives	3	State specific objectives, including any prespecified hypotheses	26
Methods			
Study design	4	Present key elements of study design early in the paper	26
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	26
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	26-27
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	28-29
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	28-29
Bias	9	Describe any efforts to address potential sources of bias	28-29
Study size	10	Explain how the study size was arrived at	-
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	30
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	30-31
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	31
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	31
Outcome data	15*	Report numbers of outcome events or summary measures over time	31-32

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	32-33
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	34
Discussion			
Key results	18	Summarise key results with reference to study objectives	34-35
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	37
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	34-38
Generalisability	21	Discuss the generalisability (external validity) of the study results	34-38
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	-

*Give information separately for exposed and unexposed groups.

Note: Information on the STROBE Initiative is available at http://www.strobe-statement.org.

Institutional Review Board for Research Conducted with Human Beings approval

UNIVERSIDADE ESTADUAL DE MARINGÁ

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: PREVALÊNCIA DA DOENÇA PERI-IMPLANTAR. EFICIÊNCIA DA TERAPIA COM IMPLANTES ANALISADA EM UMA POPULAÇÃO BRASILEIRA REABILITADA COM IMPLANTES NACIONAIS E IMPORTADOS.

Pesquisador: FLAVIA MATARAZZO

Área Temática:

Versão: 1

CAAE: 79246317.0.0000.0104

Instituição Proponente: CCS - Centro de Ciências da Saúde

Patrocinador Principal: Fundação Araucária

DADOS DO PARECER

Número do Parecer: 2.403.505

Apresentação do Projeto:

Trata-se de projeto de pesquisa proposto por pesquisador vinculado à Universidade Estadual de Maringá.

Objetivo da Pesquisa:

O objetivo do presente estudo será determinar a prevalência, a extensão e a severidade da doença peri-implantar na população brasileira reabilitada proteticamente com implantes.

Avaliação dos Riscos e Benefícios:

Avalia-se que os possíveis riscos a que estarão submetidos os sujeitos da pesquisa serão suportados pelos benefícios apontados.

Comentários e Considerações sobre a Pesquisa:

Para esse estudo transversal, indivíduos reabilitados com próteses suportadas por implantes, nacionais e importados, na Clínica Odontológica da Universidade Estadual de Maringá (COD-UEM) serão chamados para avaliação dos seus implantes dentários. Implantes de diferentes marcas comerciais, em função mastigatória há pelo menos 1 ano, serão examinados clínica e radiograficamente. Todos os participantes serão informados sobre os objetivos do estudo, seus riscos e benefícios, incluindo os tipos de medições clínicas e terapias realizadas conforme necessidade. Os indivíduos que concordarem em participar assinarão um Termo de Consentimento

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UF: PR **Município:** MARINGA
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Livre e Esclarecido, responderão a um questionário de saúde/anamnese e, quando necessário, receberão terapia peri-implantar, estando de acordo com as diretrizes e normas do Conselho Nacional de Saúde. Avaliação clínica: As mensurações clínicas serão realizadas em 6 sítios (mesiovestibular, vestibular, distovestibular, mesiolingual, lingual, distolingual), em todos os dentes (exceto terceiros molares) e implantes, utilizando-se sonda periodontal milimetrada Carolina do Norte PCPUNC-BR 15 (HuFriedy do Brasil, Rio de Janeiro, RJ, Brasil). Os parâmetros clínicos avaliados serão: índice de placa (presença/ausência), índice gengival (presença/ausência), profundidade de sondagem (PS, mm), nível clínico de inserção (NCI, mm), sangramento à sondagem (SS, presença/ausência) e supuração (presença/ausência). Avaliação radiográfica:Exames radiográficos periapicais serão realizados em todos os implantes para a verificação de alterações ósseas marginais em sítios interproximais. As imagens obtidas serão avaliadas com auxílio do programa de domínio público Imaje J (Wayne Rasband, National Institutes of Health, USA). A distância entre o ombro do implante e o primeiro ponto de contato ossoimplante nas posições mesial e distal serão medidas e a perda óssea peri-implantar será obtida através do cálculo da média aritmética destes dois valores.Calibração do examinador: A avaliação clínica será realizada por um examinador previamente treinado e calibrado (FM) pelo método de erro padrão da medida e erro médio percentual (GURSKY et al., 2005). A medida radiográfica de perda óssea será realizada por um único examinador devidamente calibrado. Para determinar o erro intra-observador, e permitir sua calibração, a perda óssea ao redor de 40 implantes será medida. Cada medida será realizada duas vezes em dois dias consecutivos, com um intervalo de 24 h, como preconizado por Penärrocha et al.

Considerações sobre os Termos de apresentação obrigatória:

Apresenta Folha de Rosto devidamente preenchida e assinada pelo responsável institucional. O cronograma de execução é compatível com a proposta enviada. Descreve gastos sob a responsabilidade do pesquisador. O Termo de Consentimento Livre e Esclarecido contempla as garantias mínimas preconizadas. Apresenta as autorizações necessárias.

Conclusões ou Pendências e Lista de Inadequações:

O Comitê Permanente de Ética em Pesquisa Envolvendo Seres Humanos da Universidade Estadual de Maringá é de parecer favorável à aprovação do protocolo de pesquisa apresentado.

Considerações Finais a critério do CEP:

Face ao exposto e considerando a normativa ética vigente, este Comitê se manifesta pela aprovação do protocolo de pesquisa em tela.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_990243.pdf	18/10/2017 17:47:17		Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	18/10/2017 17:47:01	FLAVIA MATARAZZO	Aceito
Declaração de Instituição e Infraestrutura	Autorizacao_para_uso_da_clinica.pdf	16/10/2017 16:12:50	FLAVIA MATARAZZO	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_FA.pdf	16/10/2017 16:04:52	FLAVIA MATARAZZO	Aceito
Folha de Rosto	Folha_de_rosto_assinada.pdf	16/10/2017 16:02:05	FLAVIA MATARAZZO	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

MARINGA, 28 de Novembro de 2017

Assinado por:
Ricardo Cesar Gardiolo
(Coordenador)