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ORIGINAL ARTICLE

Implant survival/success and peri-implant outcomes of titanium-zirconium mini implants for mandibular overdentures: Results from a 1-year randomized clinical trial

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Abstract

Objective: To report the 1-year implant survival/success and peri-implant outcomes of mandibular overdentures retained by four titanium-zirconium mini implants (Straumann® Mini Implant System), and to assess how surgery and loading protocols influence these outcomes.

Materials and Methods: A 2×2 factorial randomized clinical trial (RCT) tested the combined effects of two loading protocols (immediate or delayed) and two surgical approaches (flapless or flapped) on the success/survival of the mini implants, and peri-implant parameters (plaque, bleeding, sulcus depth, gingival position, and marginal bone loss). Outcomes were assessed up to 1-year after loading, and generalized estimating equations (GEEs) were used to analyze longitudinal and within-patient clustered data.

Results: Two hundred and ninety-six implants were placed in 74 patients. The implant survival/success rates after 1 year were 100%, and no major biological complications were observed. After 1-year, descriptive data suggest no noticeable changes in plaque scores, whilst a reduction in bleeding scores at the 6-month and 1-year follow-ups compared to baseline. Good longitudinal stability was observed for the probing depth and gingival margin height measures. Overall mean marginal bone loss was 0.68 (±0.68) mm after 3 months and 0.89 (±0.75) mm after 1-year. The flapless protocol showed better results on soft tissue stability and health but a slightly higher risk for marginal bone loss.

Conclusion: The results of this RCT suggest that mandibular overdentures retained by this novel mini implant system represent a safe and predictable treatment option as confirmed by implant survival/success and peri-implant outcomes, even when flapless surgery and immediate loading protocols are adopted.

KEYWORDS
clinical assessment, clinical research, clinical trials, dental implant, diagnosis, edentulous patient

1 | INTRODUCTION

Although the two-implant mandibular overdenture has been recommended as the standard implant treatment option for the edentulous patient (Feine et al., 2002), there are several other overdenture designs concerning the type, number, and distribution of fixtures and retention mechanisms (Prasad et al., 2022). A more conservative and suitable alternative is using one-piece implants with reduced diameters (mini implants). Mini implants have been used successfully, as reported by several clinical studies (Klein et al., 2014; Schiegnitz & Al-Nawas, 2018).

Mini implants are narrow-diameter implants (<2.5 mm) recommended for the support of definitive complete mandibular overdentures or support of interim prostheses, both fixed and removable (Jung et al., 2018; Schiegnitz & Al-Nawas, 2018). Mini implants have been used for overdenture treatment to provide less traumatic surgical protocols in limited-width alveolar ridges, especially for older patients for whom complex surgical procedures could preclude treatment with implants (Mundt et al., 2015).

Most commercially available one-piece mini implants for overdentures are conventional length, tapered, self-threaded, composed of biocompatible titanium materials, with a rough sandblasted surface and unsplinted ball-o'ring attachments. However, more recently, a novel mini implant system for overdentures with improved properties has been developed (Straumann® Mini Implant System, Institut Straumann AG) as a 2.4-mm one-piece, apically tapered implant body design made of a high-strength titanium-zirconium alloy (Roxolid®) and a sandblasted, large grit, acid-etched implant surface (SLA®). This mini implant has a prosthetic connection coated with an amorphous diamond-like carbon (ADLC) surface that attaches to a female PEEK matrix insert incorporated into a titanium housing (Straumann® Optiloc® Retentive System, Institut Straumann AG) (Yilmaz et al., 2020).

A previous study (Leles et al., 2022) reported the safety and comparative effectiveness of combining early or immediate loading protocols with flapped or flapless surgical techniques. These findings suggested that the surgical and loading protocols may affect post-operative symptoms and short-term patient-perceived outcomes. However, surgical and loading protocol combinations may not affect implant survival and success when implant bed preparation and soft tissue are appropriately managed and sufficient primary stability is achieved for immediate loading (Leles et al., 2022; Leles et al., 2023).

Nevertheless, there is still a need for clinical studies documenting the long-term results of potential technical and biological complications of mini implants. Although previous studies suggest that mini implants are associated with high survival rates (Schiegnitz & Al-Nawas, 2018) and stable peri-implant bone and soft tissue conditions over a mid-term follow-up (Enkling et al., 2020), there is limited information derived from well-designed clinical trials with larger samples. In addition, there is no data on the novel titanium-zirconium mini implants regarding implant survival and success and other clinical outcomes, such as peri-implant soft tissue health and hygiene status, marginal bone level, and probing depth.

Therefore, this study aimed to report the 1-year implant survival/success and peri-implant outcomes of patients treated with mandibular overdentures retained by four titanium-zirconium mini implants in a randomized controlled clinical trial (RCT). The secondary aim was to assess the influence of implant loading protocol using immediate or delayed protocols and the surgical approach using flapped or flapless techniques on peri-implant outcomes.

2 | MATERIALS AND METHODS

2.1 | Study design, sampling and randomization

This report was produced according to the CONSORT Guideline extension for reporting multi-arm parallel-group randomized trials (Juszczak et al., 2019). This study evaluated implant survival/success and peri-implant outcomes from patients participating in an RCT aiming to assess the effect of different surgical and loading protocols on treatment outcomes of mandibular overdentures retained by four titanium-zirconium mini implants. The study was conducted at the School of Dentistry of the Federal University of Goias, Brazil. The local Ethical Research Committee approved the main study protocol, and the trial was registered at the ClinicalTrial.gov database before patient recruitment (NCT04760457).

A detailed description of all stages of the study has been previously published elsewhere (Leles et al., 2022; Leles et al., 2023). A summary of the methods concerning patient selection, surgery planning, and surgical procedures, as well as the peri-implant assessments and study outcomes, is described as follows.

This RCT had a 2×2 factorial design with two loading protocols—immediate (IL) or delayed/6-week (DL), and two surgical approaches—flapless (FLS) or flapped (FPS). This factorial design resulted in four treatment combinations: IL/FLS, IL/FPS, DL/FLS, and DL/FPS. The sample size calculation estimated 74 participants (18 participants per group) based on the effect of the interventions on short-term post-surgical outcomes (Leles et al., 2022).

For inclusion in the study, eligible participants had no medical contraindications for implant surgery, sufficient bone height in the interforaminal area for implants of a minimal length of 10 mm, and a ridge width of at least 5.4 mm for implant insertion. Exclusion criteria comprised non-compliant participants, those who did not agree to be randomly allocated into the treatment groups, or with signs of

untreated temporomandibular disorders or uncontrolled systemic or oral conditions requiring additional treatments.

Recruited patients were randomized to the study groups using a computer-based random number generator and stratified according to gender. This study used block randomization and concealed allocation of the assigned surgery protocols (flapped or flapless) and loading protocols (immediate or delayed). To avoid selection bias and ensure adequate allocation concealment, the assignment of the surgery protocol was concealed in opaque sealed envelopes, and only disclosed immediately before administration of local anesthesia, assignment of loading protocol was only revealed after completion of the surgical procedures.

Deviations from the randomized protocol occurred when a patient was assigned to the flapless group but the surgeon needed to raise a flap during the surgery. Similarly, when a patient was assigned to the immediate loading group, and at least one of the mini implants did not achieve the minimum 35 Ncm torque for immediate loading, the patient was then assigned to the delayed loading protocol. Then, to prevent unequal group sizes due to deviation from the randomized protocol, the allocation ratio in the following block was adjusted to minimize unbalanced treatment regimens delivered.

2.2 | Mini-implant surgery procedures

Cone-beam computed tomography (CBCT) images of the anterior mandible were used for surgical planning using coDiagnostiX™ 10.5 software (Dental Wings GmbH). The most distal implants were planned at least 7 mm anterior to the mental foramen, and the four implants were equally distributed, with a minimum 5 mm distance between implants. Implant length (10, 12, or 14 mm) was selected according to bone availability and morphology.

The Straumann® Mini Implant System and the Optiloc® Retentive System (Institut Straumann AG) were used in this clinical trial. All surgeries were performed by a single surgeon (JLRL). For the implant placement, surgical access was performed according to the assigned surgical protocol. Drilling procedures were performed according to the recommended protocol for different bone types, using the 1.6 mm needle drill and the 2.2 mm BLT Pilot Drill at a maximum speed of 800 rpm. The drilling protocol was slightly modified according to specific features of the implant bone site. The mini implants were inserted to achieve a minimum of 35 Ncm final insertion torque, independent of the randomized implant loading protocol (immediate or delayed) (Leles et al., 2023). In the case of a patient assigned to the immediate loading group and any mini-implants not achieving the minimum 35 Ncm torque, delayed loading was performed. For the delayed loading cases, a 6-week healing period was adopted. A chairside modification of the mandibular denture into an overdenture was performed to incorporate intraorally the matrix housings in the denture using self-curing PMMA resin.

2.3 | Outcomes

Peri-implant outcomes were assessed at 3-, 6-month, and 1-year follow-ups after loading. Outcomes included implant survival and success, clinical outcomes (plaque accumulation, bleeding on probing, and gingival height), and radiographic outcomes (marginal bone loss and other radiographic findings).

In general terms, implant "success" is denoted if it meets the success criteria, while "survival" means the implant is still in the mouth (Buser et al., 2012). Therefore, clinical examination and periapical radiographs were used to assess treatment success-to-failure criteria. The following signs and symptoms were evaluated: (1) Pain—evidence of pain under vertical or horizontal forces; (2) Mobility—evidence of rigid fixation of the implant and absence of observed clinical mobility under vertical or horizontal forces; (3) Crestal bone loss—changes in the measurements of the position of the first implant-bone contact, assessed with periapical radiograph; (4) Probing depth—measurement of sulcus depths around the implants; (5) Peri-implant disease—absence of bleeding, exudate, or abscess around the implant; (6) Radiographic findings—radiolucency near the implants or any abnormal aspect, assessed in a panoramic radiograph.

Then, the ICOI Pisa Implant Quality of Health criteria (Misch et al., 2008) were applied to categorize cases (at the implant level) into implant success, implant survival, and implant failure, according to the following description (Misch et al., 2008):

I—Success: no pain upon palpation, percussion, or function; no clinical implant mobility; less than 2.0 mm of marginal bone loss; no history of exudate;

II—Satisfactory survival: no pain or tenderness upon palpation, percussion, or function; no observable mobility; marginal bone loss between 2 and 4 mm;

III—Compromised survival: although the implant is still surviving, there is a slight to moderate peri-implantitis and compromised peri-implant health status; no pain in function and no mobility; marginal bone loss >4 mm since implant placement, but bone loss less than 50% around the implant; probing depths increased from baseline up to one-half of the length of the implant, often accompanied with bleeding on probing; exudate episodes (if any) may have lasted more than 2 weeks;

IV—Failure: pain on palpation, percussion or function, horizontal and/or vertical mobility, uncontrolled progressive bone loss, uncontrolled exudate, or more than 50% bone loss around the implant; the implant may still be in the mouth or removed.

For assessment of plaque accumulation around the mini implant, each implant was individually evaluated with the naked eye and later with the periodontal probe around the attachment. Plaque index was scored using the following criteria (Mombelli et al., 1987): Score 0—no detection of plaque; Score 1—plaque only recognized by running probe across the smooth marginal surface of implant; Score 2—plaque seen by naked eye; Score 3—abundance of soft matter.

Bleeding on probing was a criterion to diagnose gingival inflammation, scored initially as present or absent. In addition, the Modified Sulcus Bleeding Index (Mombelli et al., 1987) was used according to scoring criteria: Score 0—no bleeding when the probe is passed along the gingival margin; Score 1—isolated bleeding, spots present; Score 2—blood forms a confluent red line on margins; Score 3—heavy or profuse bleeding.

Peri-implant probing depth was measured with a millimeter periodontal probe (Colorvue, Hu-Friedy® UNC 12) in four sites (buccal, lingual, mesial, and distal) around each mini implant by measuring the distance between the soft tissue margin and bottom of the probeable pocket. In addition, the height (in millimeters) of the gingival margin level was measured in the follow-up visits, considering the vertical distance from the top of the prosthetic abutment to the gingival margin. This measure was subtracted from the known height of the Optiloc®—2.35 mm (i.e., the carbon-coated part) to assess the gingival margin position compared to the abutment platform level. A negative value meant that the gingival margin was apically positioned to the Optiloc® platform.

The peri-implant marginal bone level (MBL) was assessed on digital periapical radiographs at the 3-month and 1-year follow-up visits after implant loading. The periapical radiographs were standardized using the paralleling extension-cone technique. The peri-implant bone level was measured using the Cliniview™ software (Cliniview™, Instrumentarium Company). The vertical distance (in millimeters) from the mini implant shoulder to the first bone-to-implant contact was used to measure the marginal bone level at the mesial and the distal aspects of the mini implants. Changes in MBL were calculated by subtracting follow-up visit MBL values from the baseline measurements (3-month level). In addition, horizontal MBL changes were obtained by measuring the distance from the implant to the crestal bone aspect in the peri-implant region.

Figure 1 shows the mini implant dimensions and summarizes the main clinical peri-implant features assessed in this study.

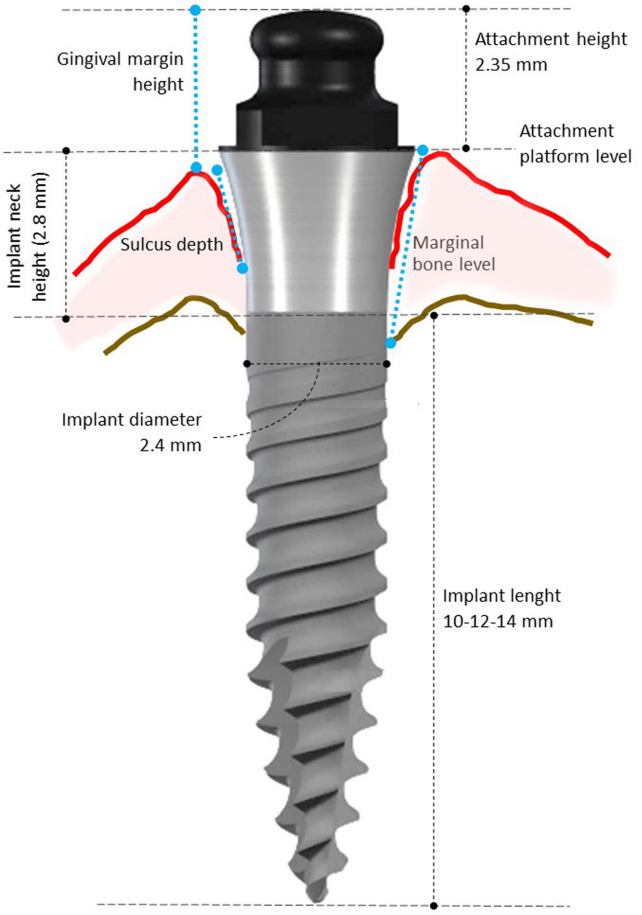

FIGURE 1 Mini implant dimensions and peri-implant measurements.

2.4 | Independent variables

The delivered surgical and loading protocols, bone density at the implant site region, anatomical bone ridge features, gingival thickness, and the width of the keratinized mucosa around the mini implants were tested as predictive variables for adverse peri-implant outcomes. In addition, the effects of age, gender, and smoking habit were also assessed.

Bone density was categorized using the Lekholm and Zarb classification (Lekholm & Zarb, 1985) as: Type I—large homogenous cortical bone; type II—thick cortical layer surrounding a dense medullar bone; type III—thin cortical layer surrounding a dense medullar bone; type IV—thin cortical layer surrounding a sparse medullar bone. The edentulous ridge form at each implant site was assessed in preoperatory tomographic sections using the following classification (Cawood & Howell, 1988): Class III—well-rounded ridge form, adequate in height and width; Class IV—knife-edge ridge form, adequate in height and inadequate in width; Class V—flat ridge form, inadequate in height and width; Class VI—depressed ridge form, with some basalar loss evident.

During the implant placement surgery, after local anesthesia, the gingival thickness was evaluated using a transgingival needle probing with a sterile disposable anesthetic needle (Kloukos et al., 2018). Measurements were performed by perpendicularly inserting the needle mounted in the soft tissue with a silicone stopper at the crestal level of each implant site until the alveolar bone was reached. Then, the gingival thickness was measured to the nearest millimeter with a millimeter ruler. The width of the keratinized mucosa was also measured in millimeters from the buccal to the lingual soft tissue margin to the mucogingival junction of each implant site. Differences in color, texture, and mobility of the keratinized and alveolar mucosa were used to identify the mucogingival junction.

2.5 | Data analysis

All statistical analyses were performed using the IBM-SPSS 24.0 software. Descriptive analysis of demographic, clinical baseline features, and clinic-radiographic outcomes included absolute and

relative frequencies and mean (standard deviation) for numerical variables.

Both the descriptive analyses and the regression models were firstly based on a per-protocol analysis, in order to identify a treatment effect which would occur under optimal conditions, or "as assigned" to the intervention groups considering the deviations from the randomized protocols. Further, an intention-to-treat analysis was also performed for the regression models, considering the respective treatment group they have been assigned to at randomization ("as randomized"), independently from the provided surgical and loading protocols.

Multiple regression analyses were performed using generalized estimating equations (GEEs) which is an extension of generalized linear models (GLMs) for modeling longitudinal or clustered data. GEE was used due to the analysis of repeated measurements (longitudinal data) or correlated observations due to the clustered data related to the multiple number of implants per subject, as well as the paired measurements of the marginal one level at the mesial and distal faces of the implant. Models were specified for a binary response (binary logistic); therefore, outcome measures were dichotomized to express a favorable or unfavorable response to the clinical parameter. The marginal bone level was tested as a numerical dependent variable. The $p < .20$ cut-off value was considered in each step of selecting independent variables for entry in the model. Then, the $p < .05$ value was used to remove independent variables in the final multiple regression models. Regression parameters were expressed as odds ratio (OR) (and their 95% confidence intervals) and p-values. The significance of the model effects was tested using Wald chi-square statistics, considering a .05 level of significance.

3 | RESULTS

Seventy-four patients were included in this study and received four mini implant mandibular overdenture treatment (296 mini implants) between April and November 2021. The 1-year follow-up period was completed in December 2022. The majority of patients included ($n = 48$) were female (64.9%), and the mean age at the time of surgery was 64.1 years (SD = 8.0). The main characteristics of the patients and implant site features are described in Table 1. In addition, Figure 2 shows a typical aspect of the clinical presentation of the surgical and prosthodontic stages of the treatment using the flapped and flapless protocols.

The complete patient flowchart is detailed in Figure 3. Concerning the combination of surgery and loading protocols, and considering the randomization process and deviations from protocol, the following group frequencies were achieved: Immediate/Flapless—$n = 17$ (23.0%); Immediate/Flapped—$n = 18$ (24.3%); Delayed/Flapless—$n = 20$ (27.0%); and Delayed/Flapped—$n = 19$ (25.7%). During the follow-up, three patients did not attend the 3-month follow-up, two did not attend the 6-month follow-up, and one did not attend the 1-year follow-up. Only one patient did not attend any follow-up visit (loss to follow-up) and was excluded from the

TABLE 1 Main characteristics of the patients/cases ($n = 74$) and implants ($n = 296$).

Categories	*n* (%)
Age (years)	
<65 years	41 (55.4)
65–75 years	26 (35.1)
>75 years	7 (9.5)
Sex	
Male	26 (35.1)
Female	48 (64.9)
Smoking	
Yes—currently	15 (20.3)
Former smoker	21 (28.4)
No	38 (51.3)
Diabetes	
Yes	13 (17.6)
No	61 (82.4)
Bone type[a]	
I	96 (32.4)
II	161 (54.4)
III	39 (13.2)
Ridge form[b]	
Class 3 (well-rounded)	171 (57.8)
Class 4 (knife-edge)	78 (26.4)
Class 5 (flat)	19 (6.4)
Class 6 (depressed)	28 (9.5)
Implant length	
10 mm	82 (27.7)
12 mm	136 (45.9)
14 mm	78 (26.4)
Ridge osteotomy ($n = 37$ cases)[c]	
Yes	12 (32.4)
No	25 (67.6)
Surgery protocol	
Flapped	37 (50.0)
Flapless	37 (50.0)
Loading protocol	
Delayed	39 (52.7)
Immediate	35 (47.3)
Gingival thickness (Missing data = 4)	
≤3 mm	199 (69.1)
>3 mm	89 (30.9)
Keratinized mucosa width (mm) (Missing data = 4)	
<5 mm	72 (24.7)
5–10 mm	182 (62.3)
>10 mm	38 (13.0)
Implant outcomes (Missing data = 4)	
Success	292 (100)
Satisfactory survival	0
Compromised survival	0
Failure	0

[a]Lekholm & Zarb classification.

[b]Cadwood & Howell classification (REF).

[c]Only for flapped surgeries.

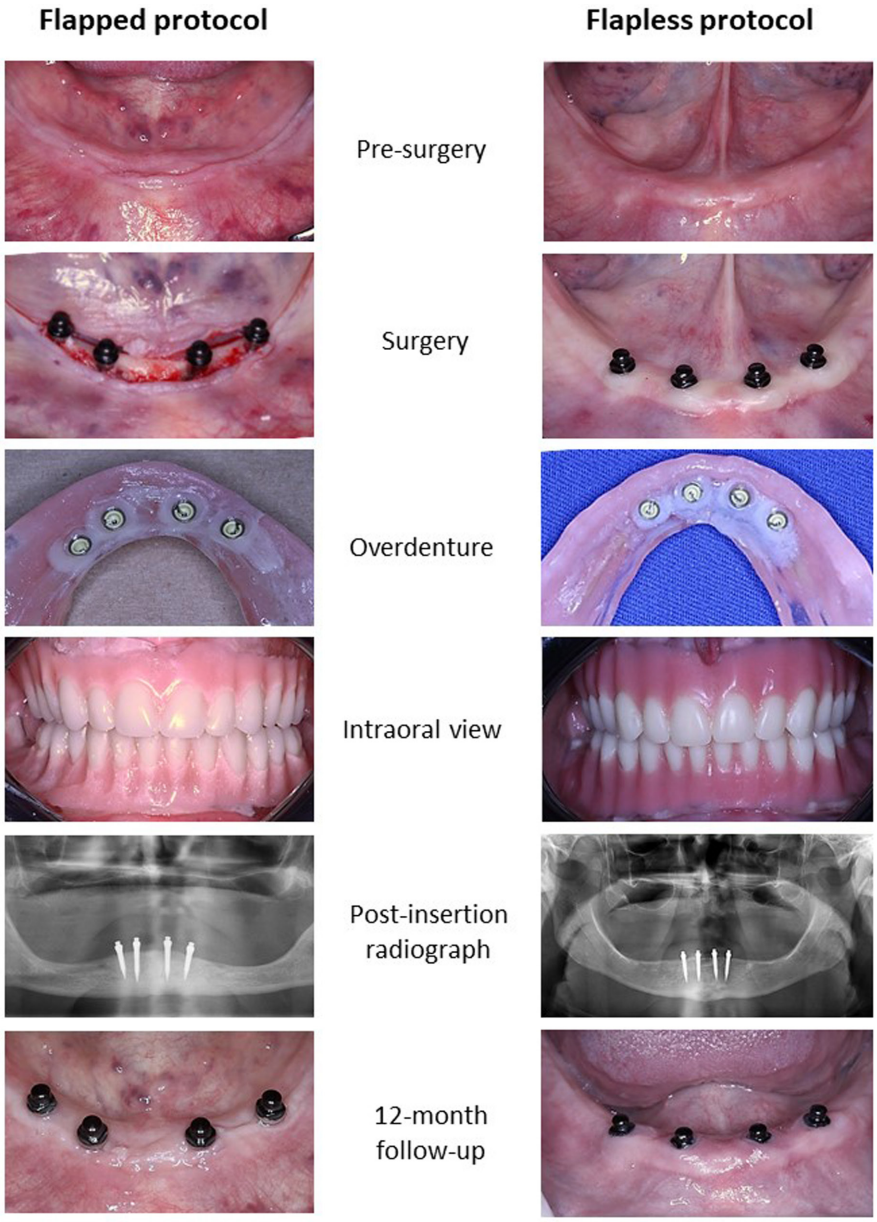

FIGURE 2 Clinical and radiographic aspects of treatments using the flapped (left) and flapless (right) protocols.

longitudinal data analysis. The other two patients with incomplete data were included for data analyses.

Per-protocol analyses were subsequently performed, aiming to estimate the effect of treatment as delivered or as received by the patient. The outcomes related to the implant treatment success-to-failure criteria are also described in Table 1. No implant failures were observed during the 1-year follow-up (100% survival rate), no major biological complications, such as abnormal marginal bone loss or probing depth, and no additional signs or symptoms related to the mini implants were observed. No signs of implant failure or compromised survival occurred throughout the 1-year follow-up.

Assessment of post-insertion panoramic radiographs revealed no abnormal radiolucency around any of the implants. However, an uncommon finding detected in post-insertion radiographs was the occurrence of incidental implant tip fractures, observed in five implants of five patients (1.7% at the implant level). Nevertheless, no clinically relevant issues associated with implant tip fractures were observed in further follow-up exams.

Table 2 shows the measurements of all peri-implant outcomes throughout the study. Plaque and bleeding scores assessed around the implants are represented in Figure 4. Descriptive data suggest no noticeable changes in plaque score were observed at the 6-month and 1-year follow-ups compared to the initial assessment. However, a substantial and progressive reduction in the bleeding score was observed at the 6- and 12-month follow-ups compared to baseline. The number of implants showing bleeding on probing reduced from 61.3% at the 3-month follow-up to 50.3% and 32.3% after 6 month and 1 year follow-ups, respectively.

Concerning changes in peri-implant soft tissue measures, good stability was observed for the probing depth and gingival margin height measures. A slight increase in sulcus depth and minor apical

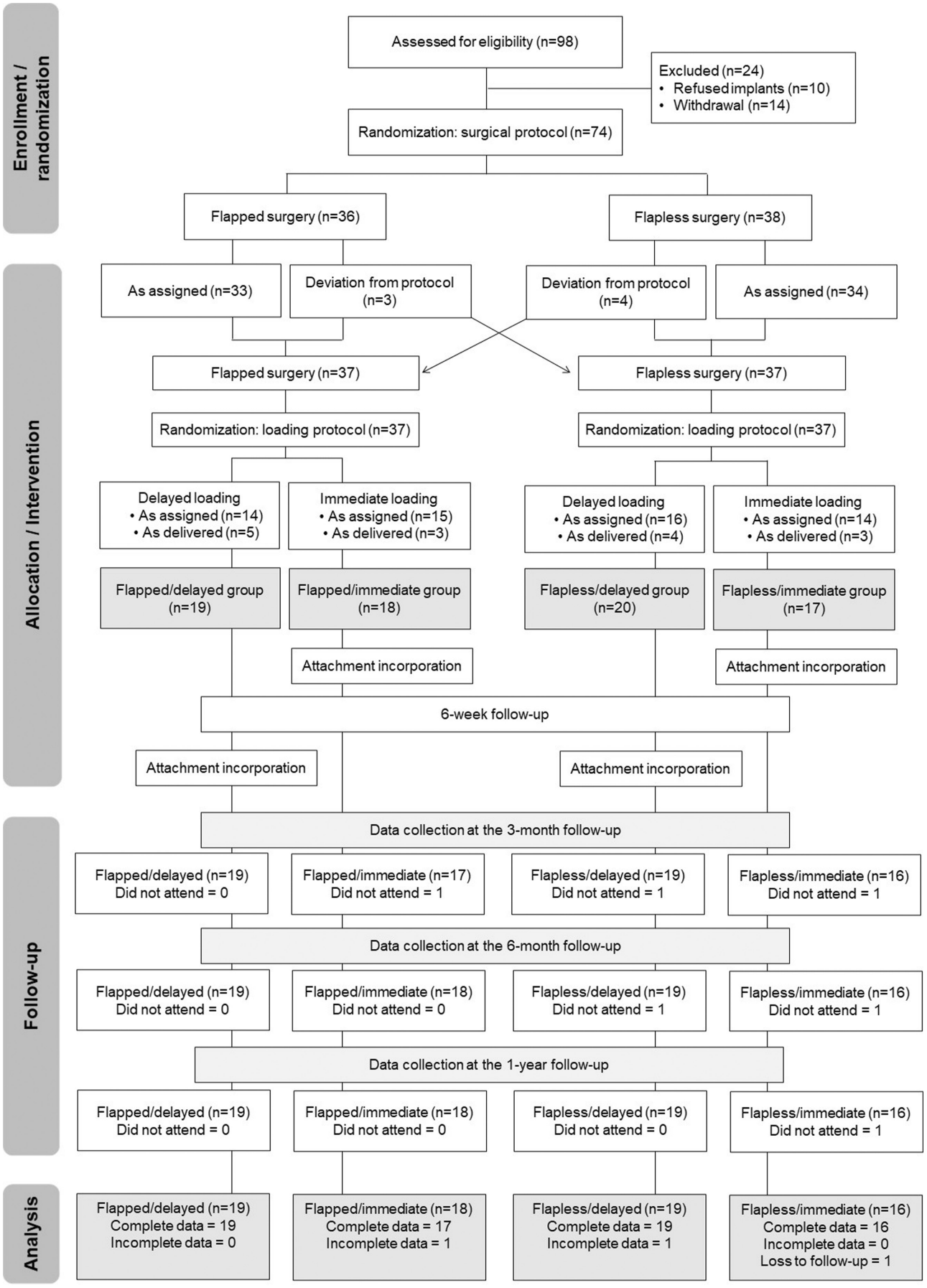

FIGURE 3 Patient flowchart throughout the study.

migration of the gingival margin were also detected. A complete exposure of the Optiloc® abutment was observed in 68.8% and 81.3% of the mini implants at the 3- and 12-month follow-ups, respectively (Table 2).

Measures of peri-implant marginal bone levels illustrated that the mean distances from the mini implant platform were around 3 mm (Table 2). When all measurements were considered, an increase in the mean distance (marginal bone loss) due to bone remodeling

TABLE 2 Clinical and radiograph peri-implant parameters measured at the implant level. Measurements are expressed as means and 95% confidence intervals, except for the frequency of bleeding on probing and level of abutment gingival coverage.

Parameters	3 months	6 months	12 months	Δ6–3months	Δ12–3months
Plaque index	1.19 (1.07–1.32)	1.14 (1.02–1.26)	1.11 (1.01–1.21)	−0.05 (−1.18–0.08)	−0.04 (−1.18–0.11)
Bleeding index	0.84 (0.75–0.93)	0.64 (0.56–0.73)	0.42 (0.34–0.50)	−0.18 (−0.28 – −0.07)	−0.39 (−0.50 – −0.28)
Bleeding on probing – *n* (%)	174 (61.3)	147 (50.3)	93 (32.3)	−27 (−11.0)	−81 (−29.0)
Probing depth (mm)					
Buccal	2.34 (2.26–2.44)	2.33 (2.25–2.42)	2.81 (2.71–2.91)	0.00 (−0.10–0.10)	0.46 (0.35–0.57)
Lingual	2.33 (2.25–2.42)	2.17 (2.09–2.24)	2.40 (2.32–2.48)	−0.16 (−0.26 – −0.07)	0.07 (−0.03–0.17)
Mesial	2.59 (2.49–2.69)	2.60 (2.50–2.71)	2.98 (2.89–3.07)	0.02 (−0.09–0.14)	0.40 (0.29–0.51)
Distal	2.67 (2.57–2.76)	2.64 (2.55–2.74)	3.02 (2.92–3.11)	−0.01 (−0.11–0.10)	0.36 (0.24–0.48)
Gingival margin position (mm) - in relation to the abutment platform					
Buccal	0.15 (0.04–0.27)	0.25 (0.16–0.34)	0.16 (0.06–0.25)	−0.09 (−0.17–0.00)	0.02 (−0.07–0.10)
Lingual	−0.01 (−0.13–0.11)	−0.07 (−0.16–0.16)	−0.21 (−0.30 – −0.12)	0.07 (−0.03–0.17)	0.22 (0.11–0.33)
Mesial	0.19 (0.09–0.29)	0.20 (0.12–0.29)	0.08 (−0.01–0.16)	−0.01 (−0.08–0.06)	0.13 (0.05–0.21)
Distal	0.24 (0.15–0.34)	0.24 (0.16–0.33)	0.15 (0.07–0.24)	0.00 (−0.07–0.07)	0.11 (0.03–0.19)
Level of abutment coverage—*n* (%)					
0	179 (68.8)	213 (72.9)	231 (81.3)	+34 (+4.1)	+52 (+12.5)
<1 mm	71 (27.4)	74 (25.4)	51 (17.9)	+3 (−2.0)	−20 (−9.5)
≥1 mm	10 (3.8)	5 (1.7)	2 (0.7)	−5 (−2.1)	−8 (−3.1)

				Marginal bone loss (mm)	
	Immediate	3-month	12-month	Δ3-month	Δ12-month
Marginal bone level (mm)					
Lateral left (33)					
Mesial	2.37 (2.17–2.55)	3.01 (2.77–3.19)	3.19 (3.18–3.39)	0.64 (0.48–0.80)	0.82 (0.63–1.01)
Distal	2.44 (2.26–2.59)	2.97 (2.76–3.14)	3.17 (2.96–3.36)	0.53 (0.37–0.69)	0.73 (0.54–0.92)
Central left (31)					
Mesial	2.60 (2.40–2.80)	3.34 (3.17–3.51)	3.52 (3.34–3.70)	0.74 (0.55–0.92)	0.92 (0.75–1.10)
Distal	2.50 (2.31–2.68)	3.15 (2.97–3.34)	3.38 (3.20–3.56)	0.66 (0.48–0.83)	0.88 (0.69–1.08)
Central right (41)					
Mesial	2.64 (2.42–2.87)	3.35 (3.14–3.57)	3.64 (3.44–3.84)	0.71 (0.54–0.88)	1.00 (0.80–1.20)
Distal	2.60 (2.39–2.81)	3.44 (3.22–3.66)	3.67 (3.46–3.87)	0.85 (0.67–1.02)	1.07 (0.88–1.26)
Lateral right (43)					
Mesial	2.40 (2.18–2.61)	2.96 (2.73–3.19)	3.08 (2.83–3.34)	0.57 (0.40–0.74)	0.69 (0.49–0.89)
Distal	2.49 (2.81–2.69)	3.07 (2.84–3.29)	3.27 (3.02–3.51)	0.58 (0.42–0.74)	0.78 (0.60–0.96)
Lateral implants (33/43)					
Mesial	2.38 (2.19–2.57)	2.99 (2.78–3.20)	3.14 (2.92–3.36)	0.61 (0.45–0.77)	0.76 (0.57–0.95)
Distal	2.46 (2.29–2.63)	3.01 (2.82–3.20)	3.22 (3.01–3.43)	0.55 (0.41–0.69)	0.75 (0.57–0.93)
Central implants (31/41)					
Mesial	2.62 (2.43–2.81)	3.35 (3.17–3.53)	3.58 (3.40–3.76)	0.72 (0.56–0.88)	0.96 (0.79–1.13)
Distal	2.54 (2.36–2.72)	3.29 (3.10–3.48)	3.52 (3.34–3.70)	0.74 (0.58–0.90)	0.98 (0.80–1.16)
All measurements	2.54 (2.45–2.62)	3.22 (3.14–3.31)	3.43 (3.34–3.52)	0.68 (0.61–0.75)	0.89 (0.82–0.97)

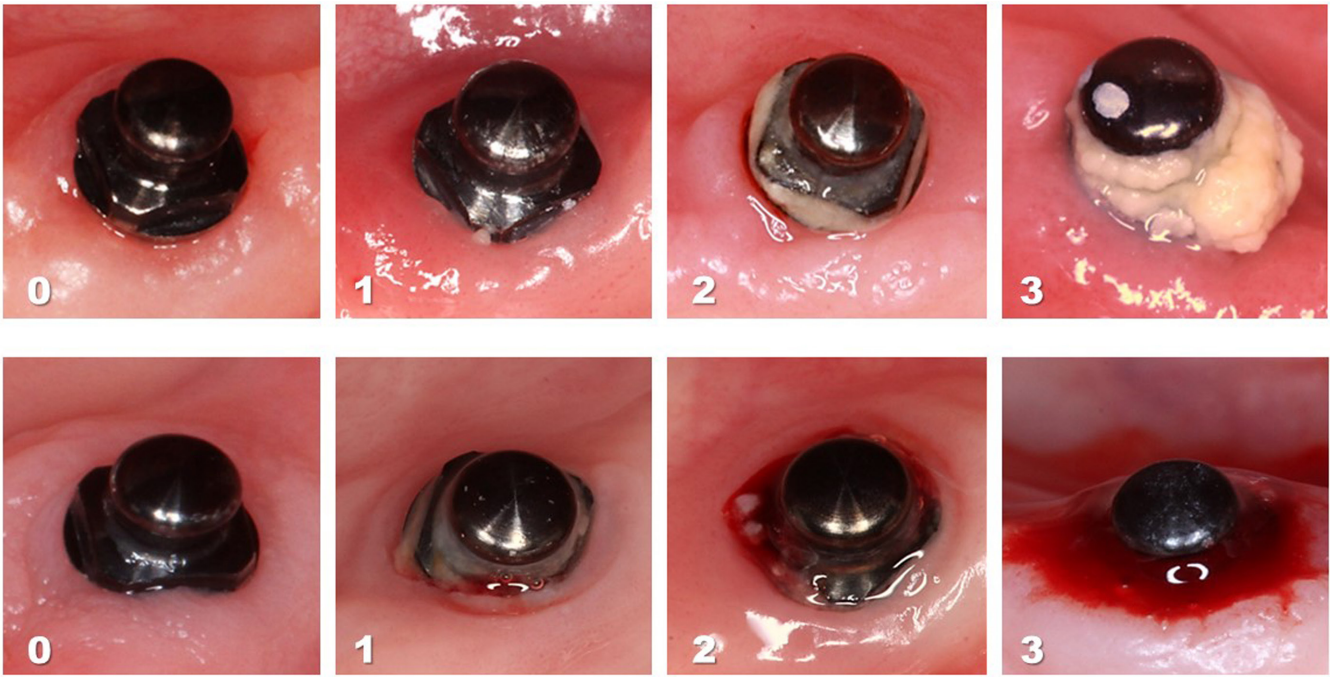

FIGURE 4 Plaque (upper) and bleeding (lower) indexes. Plaque index was scored as: Score 0—no detection of plaque; Score 1—plaque only recognized by running probe across the smooth marginal surface of implant; Score 2—plaque seen by naked eye; Score 3 – abundance of soft matter. The modified sulcus bleeding index was escored as: 0—no bleeding when the probe is passed along the gingival margin; Score 1—isolated bleeding, spots present; Score 2—blood forms a confluent red line on margins; Score 3—heavy or profuse bleeding.

was observed after 3 months (mean = 0.68; 95% CI = 0.61–0.75), and after 12 months (mean = 0.89; 95% CI = 0.82–0.97). Overall, mean marginal bone loss were within acceptable limits around 1 mm after 1 year.

The effects of clinical parameters (independent variables) were tested for each primary peri-implant outcome, as detailed in Table 3. A lower risk of bleeding was observed in the follow-up visits until the 1-year follow-up (OR = 0.27; $p < .001$), for the flapless protocol (OR = 0.49; $p = .009$), higher gingival thickness (OR = 0.34; $p = .030$), and a higher risk for the lateral implants (OR = 1.32; $p = .016$). Similarly, the risk for abutment covering was significantly reduced after 1-year (OR = 0.39; $p < .001$) and for the flapless protocol (OR = 0.23; $p < .001$). The risk for increased marginal bone loss after 1-year (OR = 2.35; $p < .001$), was higher for the flapless protocol (OR = 1.29; $p = .042$) and width of the keratinized mucosa ≤3 mm (OR = 1.20; $p = .021$), and lower for the lateral implants (OR = 0.74; $p < .001$).

At the 1-year follow-up, the lingual aspect of the mini implants was more likely to exhibit gingival recession (OR = 0.75; 95% CI = 0.68–0.83; $p < .001$), with more shallow sulcus depths (OR = 0.82; 95% CI = 0.75–0.89; $p < .001$). Furthermore, unadjusted and adjusted regression models showed no significant effects for the age of the patients, loading protocol, bone type classification, bone ridge form, and gingival thickness on the peri-implant outcomes.

Along with the per-protocol analyses, multiple regression models were also constructed using an intention-to-treat approach regarding the group allocation provided by the randomization process. Only minor changes were observed in the final multiple regression models using the intention-to-treat approach for regression analysis (Table S1). A significant effect at the 12-month follow-up was observed on the reduction of the risk for bleeding on probing (OR = 0.30; 95% CI = 0.19–0.47; $p < .001$) and abutment covering probing (OR = 0.38; 95% CI = 0.25–0.59; $p < .001$), and increased marginal bone loss probing (OR = 2.35; 95% CI = 2.07–2.66; $p < .001$). Lower bleeding on probing (OR = 0.53; 95% CI = 0.31–0.91; $p = .022$) and abutment covering (OR = 0.23; 95% CI = 0.12–0.46; $p < .001$) were associated with the flapless protocol. However, the effect of the flapless protocol did not affect the marginal bone loss (OR = 1.23; 95% CI = 0.97–1.57; $p = .089$).

4 | DISCUSSION

This RCT assessed the 1-year peri-implant outcomes of titanium-zirconium mini implants for mandibular overdentures, as influenced by different surgical and loading protocols. Overall results revealed 100% survival/success rates, and only minor changes in soft and hard tissues around the implants, independent from the clinical protocols used. Therefore, these findings confirm the safety and predictability of this novel mini implant system in a four-implant treatment protocol for the edentulous mandible, corroborating previous favorable results of a study focused on short-term post-surgical outcomes (Leles et al., 2022).

Narrow-diameter Ti-Zr implants were introduced to offer superior mechanical strength compared with grade IV titanium, thus reducing the risk of fracture (Ho et al., 2008), with satisfactory

TABLE 3 Regression parameter estimates for the multiple regression models using a per-protocol approach, assessing the effect of clinical predictors on changes in the marginal bone level (MBL), bleeding on probing, and gingival margin height.

		Bleeding on probing		Abutment covering		Marginal bone level (mm)[a]	
Independent variables	**Categories**	**OR (95% CI)**	***p*-value**	**OR (95% CI)**	***p*-value**	**OR (95% CI)**	***p*-value**
(Intercept)	–	2.64 (1.48–4.71)	.001	1.23 (0.72–2.08)	.442	11.4 (9.74–13.4)	<.001
Follow-up (months)	12-month	0.27 (0.16–0.43)	<.001	0.39 (0.26–0.60)	<.001	2.35 (2.07–2.66)	<.001
	6-month	0.58 (0.41–0.83)	.002	0.60 (0.45–0.79)	<.001		
	3-month	Reference		Reference		1.91 (1.70–2.15)	<.001
	Immediate					Reference	
Surgical protocol	Flapless	0.49 (0.29–0.84)	.009	0.23 (0.11–0.48)	<.001	1.29 (1.01–1.65)	.042
	Flapped	Reference		Reference		Reference	
Gingival thickness	>10 mm	0.34 (0.13–0.90)	.030				
	5–10 mm	0.78 (0.47–1.32)	.357				
	<5 mm	Reference					
Keratinized mucosa width	≤3 mm					1.20 (1.03–1.40)	.021
	>3 mm					Reference	
Implant position	Lateral	1.32 (1.05–1.65)	.016			0.74 (0.66–0.82)	<.001
	Central	Reference				Reference	

[a]OR >1 means increased distance between the implant platform and the marginal bone level (marginal bone loss).

osseointegration properties (Al-Nawas et al., 2012). In addition, the monolithic structure of one-piece mini-implants also avoids the risk of bacterial microleakage at the abutment-implant interface, which improves the maintenance of bone levels around implants in the long term (do Nascimento et al., 2012). It was also reported that one-piece mini implants show lower levels of biomechanical stress compared to two-piece mini-implants (Trang et al., 2022).

Previous studies report survival rates of mini implants for overdentures ranging from 86.9% to 100% (Park et al., 2017). Although the survival rate of mini implants has been considered inferior to that of standard diameter implants (de Souza et al., 2015), it has been suggested that mini implant overdentures may equally effective and more cost-effective than overdentures on two standard-sized implants (Della Vecchia et al., 2018). In this study, none of the implants failed after 1 year, and the high survival and success rates corroborate the highly satisfactory clinical performance of the titanium-zirconium mini implant system. Moreover, the SLA® surface may also allow improved cellular adhesion, proliferation, and osteoblastic differentiation, thus contributing to osseointegration (Yin et al., 2019).

It was observed that the surgical and loading protocols did not influence implant survival/success rates, thus favoring the use of a more straightforward procedure using flapless surgery and immediate loading (Leles et al., 2022). This is an interesting finding with clinical relevance since this therapeutic approach, with lower post-surgical morbidity, can improve implant treatment acceptance due to less post-operative discomfort and generally shorter treatment times. It has been advocated for years that single-stage implant placement, with immediate loading and flapless surgery can provide success rates as high as those of conventional two-stage surgical techniques when proper procedures are performed in patients with satisfactory bone quality and quantity, and adequate keratinized tissue width (Hahn, 2000).

Concerning peri-implant outcomes, a previous study (Enkling et al., 2020) assessed the marginal bone changes in a 5-year prospective cohort of mandibular overdentures retained by four one-piece mini implants (MDI®, condent GmbH) with o'ring attachments. The authors concluded that it was a predictable treatment option, providing stable peri-implant bone and soft tissue conditions. Overall mean marginal bone changes were −0.73 (±0.67) mm after 12 months and −1.18 (±0.79) mm after 5 years (Enkling et al., 2020), which fall within clinically acceptable limits. A systematic review (Lemos et al., 2017) reported acceptable marginal bone loss around mini implants retaining mandibular overdentures, usually below 1.5 mm (Lemos et al., 2017), and a clinical trial comparing mini implants and conventional diameter implants showed that the

former presented higher marginal bone resorption (Aunmeungtong et al., 2017). Furthermore, concerning the slight higher risk of marginal bone loss associated with the flapless protocol in our study, it could be considered that it is due to the higher imprecision of the surgical procedure, especially during bone drilling, when the flapless approach has the disadvantage of not accurately determining the bone volume and best osteotomy at the crestal bone level (Sculean et al., 2014).

Enkling et al. found no major biological complications or marked changes concerning plaque accumulation, bleeding on probing, keratinized mucosa, and probing depth in a 5-year follow-up of one-piece mini dental implants (Enkling et al., 2020). Similar findings were reported by Tomasi et al. (2013), who found a mean plaque score of 20%, a mean bleeding on probing of 30%, and a mean probing depth of 2.3 mm at the 12-month follow-up. A systematic review suggested that mini implants have a lower risk of plaque accumulation than standard-diameter implants (Borges et al., 2022). Nevertheless, since plaque accumulation around implants is highly influenced by the patient's ability to maintain proper oral hygiene (Corbella et al., 2011), patients with poor oral cleaning and brushing skills were submitted to prophylaxis for plaque and calculus removal, as well as reinforcement of oral hygiene measures.

The bleeding index was significantly reduced after follow-up visits, probably due to the effect of the attention given to daily hygiene, since the bleeding index would reveal a safer and more reliable marker of oral hygiene over the months, while the plaque index may be influenced shortly before of a follow-up consultation (Büttel et al., 2012). Since the formation of the biological width and maturation of the barrier function around transmucosal implants requires 6–8 weeks of healing (Sculean et al., 2014), at the 3-month follow-up (baseline assessment) it is expected that the signs of inflammation may not be related to the surgical procedures. This is the reason why the 3-month follow-up was considered as the reference time point for assessment of changes in peri-implant soft tissues. In addition, the differences in favor of the flapless group concerning bleeding and gingival position may be justified by the fact that the flapless approach has, at least in the short-term, advantages over flap surgery, provided that the diameter of the soft tissue punch is below that of the transmucosal portion of the implant (Sculean et al., 2014).

Concerning the final position of the gingival margin in relation to the abutment platform, it was observed that some implants had undesired coverage of the abutment platform lower than 1 mm in 17.9% of the mini implants at the 1-year follow-up, and ≥1 mm in 3.8% and 0.7% of the mini implants at the 3-month and 1-year follow-ups, respectively. There was a limiting factor that this study protocol listed a specific commercial brand of mini implants with a unique neck height of 2.8 mm. However, other neck heights are now commercially available as part of the mini implant system (3.8 and 4.8 mm heights). Using different neck heights would be helpful to prevent abutment covering by the marginal gingiva in cases with greater gingival thickness and management of soft tissues in flapped surgeries. Therefore, different abutment neck heights should be considered during surgery planning.

Another relevant finding in post-surgical radiographic control was the occurrence of implant tip fractures in five mini implants, which were identified as incidental findings in follow-up panoramic radiographs. There is evidence that the implant diameter lower than 3.75 mm is associated with a higher incidence of implant fracture (Tabrizi et al., 2017), and tapered or conical implants seem to generate higher crestal stress than cylindrical implants of similar dimensions (Holmgren et al., 1998). Therefore, due to their narrow diameter and sharp apical taper, mini implants may be exposed to a higher fracture risk than standard implants. In addition, since adequate torque had to be achieved during insertion, and extreme insertion torque values may occur in high-density bone sites, there is a risk of reaching high torque values that exceed the implant body fracture resistance (Leles et al., 2023). Moreover, anatomical factors may also increase the risk of apical fracture during insertion, which demands the identification of potentially dangerous areas predisposing to implant breakage that may affect optimal insertion torque and implant stability. Although the observed tip fractures occurred in a very small number of cases and did not result in any detrimental clinical outcomes, it deserves further investigation in order to identify risk factors and measures to prevent this minor surgical complication.

For data analysis, this study used a per-protocol approach complemented by intention-to-treat method. Although some cases deviated from the assigned study protocols, analyses according to the intention-to-treat principle aimed to preserve the original randomization and avoid potential bias due to the exclusion of patients. Conversely, the per-protocol analysis was adopted as the primary data analysis to identify the treatment effect which would occur under optimal conditions, since data are analyzed only for those patients who completely adhered to the treatment protocol. This means that the patients reached the study endpoints without dropping out and complete all key assessments at all study visits, showing good treatment adherence. Complete analysis and especially per-protocol analysis represent results in the ideal situation in which patients take treatment as advised and for the duration advised. Nevertheless, the intention-to-treat approach was also performed in the regression analyses and no major changes in the interpretation of findings were observed.

Due to restrictions for performing the flapless surgery and loading the mini implants immediately, changes in the randomized protocols occurred, and consequent adjustment in the allocation ratio was needed. This decision to include the patients with deviated protocols was based on the fact that excluding patients from the analysis often results in biased estimates of treatment effects in randomized trials. To avoid potential attrition bias, it should be ensured low dropout rates, and high compliance rates and minimize missing outcome data (Nüesch et al., 2009). Another problem was that the deviations from protocol always occurred in only one direction (flap instead of flapless, delayed instead of immediate loading), thus creating unbalanced group sizes at the end of the study. Changing the allocation ratio in the following

randomization block was considered the most suitable solution to minimize this problem. Moreover, the rationale for changes in the allocation ratio was based on the adoption of an adaptive randomization design. Pre-planned changes that an adaptive design permit include (but are not limited to) changing the allocation ratio of patients to trial arms (Pallmann et al., 2018), in which alterations in the randomization schedule is allowed depending upon the varied or unequal probabilities of treatment assignment of patients already in the trial, using a scheme of permuted blocks to adjust treatment assignment probabilities (treatment-adaptive randomization) (Mahajan & Gupta, 2010).

Finally, inferences from this study should be considered within the limitation of the study's timeframe. Although the 1-year results regarding implant survival and stability of the hard and soft peri-implant tissues show promising results on treatment success, longer follow-up periods are needed. In addition, overall treatment effectiveness may consider patient-centered outcomes and long-term prosthodontic success. Studies focused on the applicability of this mini implant system in typical settings of care, in a real-world perspective, would also complement the findings of this controlled clinical trial.

5 | CONCLUSION

Within the limits of this randomized clinical trial, results suggest that the four-implant protocol for mandibular overdentures, using this novel titanium-zirconium mini implant system, represents a safe and predictable treatment option concerning implant survival and peri-implant outcomes, even when flapless surgery and immediate loading are adopted.

AUTHOR CONTRIBUTIONS

- Thalita Fernandes Fleury Curado: Data collection and investigation, data analysis and interpretation, original draft preparation, project administration.
- Jésio Rodrigues Silva: Data collection and investigation, data analysis and interpretation, original draft preparation.
- Lays Noleto Nascimento: Data collection and investigation, data analysis and interpretation, original draft preparation.
- José Luiz Rodrigues Leles: Conceptualization, methodology, investigation, draft writing, review & editing.
- Martin Schimmel: Data analysis and interpretation, original draft writing, review and editing, funding acquisition.
- Gerald McKenna: Data analysis and interpretation, original draft writing, review and editing, funding acquisition.
- Cláudio Rodrigues Leles: Conceptualization, methodology, statistics, original draft writing, review & editing, funding acquisition, project administration.

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CONFLICT OF INTEREST STATEMENT

Cláudio R. Leles, Martin Schimmel, and Gerald McKenna are the recipients of other funding from Institut Straumann AG and the ITI. The other authors do not report any conflict of interest related to the present study.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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