

# Clinical and radiographic performance of self-locking conical connection implants in the posterior mandible: Five-year results of a two-centre prospective study

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## Abstract

**Objective:** This prospective study aims to assess the 5-year clinical performance of implants with internal conical connection and platform-switched abutments in the posterior mandible.

**Material and Methods:** Healthy adults missing at least two teeth in the posterior mandible and with a natural tooth mesial to the implant site received two or three adjacent implants. After a transmucosal healing period single crown restorations were cemented on platform-switched abutments. Changes in marginal bone levels were investigated in standardized periapical radiographs from surgery and loading (baseline) to 60-months post-loading.

**Results:** Twenty-four patients received 52 implants. Bone remodelling took place between surgery and loading (mean:-0.5, SD:±0.4 mm). From loading to 60 months, there was a mean bone change of 0.27 (SD:±0.47 mm) which stabilized 24 months after prosthesis delivery (mean:0.2, SD:±0.46 mm). 71.7% of all implants presented bone preservation at 60 months irrespective of the initial insertion depth. Two implants were lost after 5 years and the success rate was 95.1%. Patient enquiry revealed high satisfaction.

**Conclusion:** Internal conical connection implants with platform-switched abutments presented a high success rate and preservation of marginal bone levels at the implant shoulder after 5 years of loading.

## KEYWORDS

bone level, bone remodelling, conical connection implants, dental implant, outcome, platform switch

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## 1 | INTRODUCTION

The use of dental implants is established as a reliable treatment option for partially or fully edentulous patients for more than a decade (Pjetursson et al., 2012; Rasmusson et al., 2005). Since the first insertion of osseointegrated titanium implants by Brånemark in 1965, the basic principles associated with the treatment have evolved on many aspects, currently aiming at long-term functional oral rehabilitation (Brånemark et al., 1975). Apart from more long-term survival rates following an uneventful healing period, more sophisticated models for the definition of implant success have been described (Albrektsson et al., 1986; Buser et al., 1990; Misch et al., 2008; Smith & Zarb, 1989). For instance, Buser defined implant success utilizing the following criteria: implant in situ, absence of persisting pain or discomfort, absence of signs that point at peri-implantitis, for example suppuration, bleeding on probing, radiolucency or implant mobility (Buser et al., 1990).

The preservation of the peri-implant marginal bone is also universally recognized as a crucial feature conditioning long-term stability and favouring soft tissue maintenance (Albrektsson et al., 1986; Sanz et al., 2015). However, numerous factors have been identified with potential to influence bone remodelling and with impact on the overlying soft tissue.

On one hand there are patient-related factors influencing marginal bone preservation which include habits (smoking, bruxism), metabolic conditions (diabetes, osteoporosis), medication with potential to affect bone metabolism (corticosteroids, antiresorptive drugs, vitamin D), history of periodontitis or unfavourable IL-immunotype, the amount and density of bone at the implant site and the mucosal biotype (Chrcanovic et al., 2014; Clementini et al., 2014; Dereka et al., 2012; Linkevicius et al., 2009).

On the other hand, there are device- and technique-related factors deemed to modify the marginal bone levels. For instance, the implants used for rehabilitation promote different outcomes according to the surface treatment, body and neck geometry (Messias et al., 2018), type of threading and abutment connection among others. Likewise, the surgical technique for the insertion of the implants highly influences marginal bone resorption since it is responsible not only for the three-dimensional positioning of the implant, namely buccal-lingual positioning, implant-to-implant and implant-to-teeth distance and insertion depth, but also for the resulting surgical trauma (Romanos et al., 2019).

After implant insertion, another factor determining marginal bone resorption is the establishment of the peri-implant biological width that follows the connection of transmucosal abutments (Broggini et al., 2006; Kim et al., 2005), and the consecutive bacterial colonization of the peri-implant sulcus (Furst et al., 2007). The subsequent phase of functional loading sets a specific mechanical and microbiologic interaction at the abutment-implant interface. Loading induces micromovements of the abutment (Messias et al., 2017; Rack et al., 2010) which disrupts the stability of the peri-implant soft tissue that has completed integration (Passos et al., 2013), and creates a microgap between the implant

and the abutment that causes a micropumping effect that leads to leakage of bacteria and their toxic by-products to the implant body (Lazzara & Porter, 2006) and the peri-implant space. The morphology of the implant-abutment interface seems to be intimately related to the magnitude of the micromovements and, consequently, to the size of the microgap and extent of bacterial leakage. Several systematic reviews (Caricasulo et al., 2018; Goiato et al., 2015; Palacios-Garzon et al., 2018) have addressed the biological efficiency of different implant-abutment connections, generally pointing to higher stability and sealing capacity of implants with internal connections, as opposed to external connections (Mishra et al., 2017). In particular, conical or morse taper connections (Goiato et al., 2015; Tsuruta et al., 2018) are described as the most efficient in terms of seal and mechanical stability of the connection. The reviews also suggest that morse taper connections are associated with lower peri-implant bone resorption but unanimously express reservations regarding that outcome since it is mainly validated by *in vitro* studies and clinical studies with potential risks of bias and follow-ups inferior to 5 years (Caricasulo et al., 2018; Palacios-Garzon et al., 2018).

Therefore, the present study focused on the long-term documentation of the radiographic and clinical performance of a 2-piece bone level implant with internal conical connection on the rehabilitation of posterior mandibular edentulism to fill the gap of missing clinical data.

## 2 | MATERIAL AND METHODS

### 2.1 | Study design & settings

The present study is a multicentre prospective observational study designed to document the clinical and radiological performance of CONELOG® SCREWLINE implants. The study was performed in the outpatient facilities of the Dentistry Department of the Faculty of Medicine of the University of Coimbra [Portugal] and of the Department of Oral and Maxillofacial Surgery of the Johannes Gutenberg-University in Mainz [Germany]. Ethical approvals were obtained from both local institutional review boards (Coimbra:12-CE-2011; Mainz:837.030.11). The study followed the Declaration of Helsinki. The recruitment period extended from May 2011 to February 2012 and each participant was followed for 60 months. The study report used the observational clinical trials STROBE guidelines (Vandenbroucke et al., 2014), a part of the EQUATOR Network. All patients gave written informed consent in advance of study participation.

### 2.2 | Participants

Healthy adults missing two or more adjacent teeth in the posterior mandible and with a natural tooth mesial to the edentulous region were eligible to participate in the study. The opposing dentition had

to be natural teeth or fixed crowns and bridges, whereas free-end situations were allowed. Exclusion criteria included uncontrolled metabolic or systemic diseases and intake of drugs with known interaction on bone metabolism (e.g., corticosteroids, bisphosphonates, calcium), as well as medical history of irradiation or chemotherapy. Cigarette consumption was limited to a maximum of 10 per day. All patients were screened for absence of acute mucosal inflammation or other signs of periodontitis and patients had to present with adequate oral hygiene habits. Furthermore, patients with signs of bruxism or severe craniomandibular disorder were excluded. Mental disorders, alcohol or other drug intake that may avert principle understanding of study participation, hygiene instruction or with influence on manual capability led also to exclusion. During surgery or loading phase a lack of primary or secondary stability, or a mispositioning of the implant with impossibility of a reasonable prosthetic rehabilitation were excluding criteria. None of the patients who underwent surgery had to be excluded before loading.

## 2.3 | Implants

Two to three adjacent CONELOG® SCREWLINE implants (CAMLOG Biotechnologies, Basel, CH) were placed in the selected sites with a diameter of 3.8 or 4.3 mm and a length of 11 or 13 mm.

The implants present an internal conical connection with 7.5° taper and inherent mismatch between the abutment and the implant platform of 0.4 mm for the 3.8 diameter implants and 0.65 mm for the 4.3 diameter implants. Healing abutments, impression posts and definitive abutments were inserted following manufacturer instructions. All products used in this study were registered and commercially available.

## 2.4 | Surgery

All patients were submitted to surgery in an ambulatory setting with the use of local anaesthesia for the installation of two or three consecutive implants in the posterior mandible. Pre-surgical oral antibiotic prophylaxis was left at the discretion of the standard of care of each centre. After preparation of a full thickness mucosal flap the implants were placed at bone level with a minimum distance to the neighbouring teeth of at least 1.5 mm and 3 mm between two implants. No bone augmentation or regeneration techniques nor bone substitute materials were allowed. Primary stability was assessed manually with the torque wrench. The transmucosal healing period was supported by platformed switched healing abutments. A series of clinical photographs was taken intra- and postoperatively. Standardized periapical radiographs were performed immediately post-surgery. A soft diet was recommended, and oral hygiene instructions were enhanced by the use of chlorhexidine-digluconate 0.12% (3 times per day) until sutures were removed.

## 2.5 | Prosthetic treatment

Impressions were taken after a 6 weeks healing period in class I-III bone and 12 weeks in class IV bone (Cochran et al., 2004) according to the indications of the manufacturer. Two to three weeks after the impression the definite restoration was delivered using CONELOG® Esthomic® abutments retained with 20 Ncm torque. Ceramo-metal and ceramo-ceramic single crowns were cemented with the margin 1–2 mm subgingival. Loading of the implants served as a baseline for the upcoming measurements.

## 2.6 | Primary study objective

The primary study objective was the evaluation of the marginal bone levels at the mesial and distal sites of each implant as recorded by standardized x-rays at the time of implant insertion, rehabilitation delivery and then annually until 60 months. To ensure a comparable and orthogonal alignment of the X-ray tube over the observation period, an individually adapted tube holder was fabricated for each patient at the initial examination, which was oriented to the natural dentition by occlusal fixation with silicone bite impression. Two independent observers blinded to the clinical data of the patients measured marginal bone levels as the linear distance between the implant shoulder and the first visible bone contact—distance-implant-bone (DIB)—using the open source software ImageJ 1.44p (Schneider et al., 2012).

## 2.7 | Secondary study objectives

Secondary study objectives were the annual determination of implant survival and implant success as defined by (Buser et al., 2002). The observation period ranged from insertion to 5 years after loading. In addition to the implants, the performance of the restorative components was also included in the evaluation. Specifically, apart from type and frequency of adverse events, a simple patient satisfaction rating was recorded using a questionnaire. Furthermore, the plaque index (PI) and sulcus bleeding index (SBI) at the accessible buccal, lingual distal and mesial sites of each implant were measured annually for the detection of peri-implantitis according to the criteria described by Mombelli (Mombelli et al., 1987). In both indices, the implant received the worst score measured at the four sites. Pocket probing depth (PPD) was measured at the same sites, and the four values were averaged into a single value per implant.

## 2.8 | Statistical methods

Due to the non-interventional nature of the study, with observation of a single cohort, no power or sample size calculation was carried out. Descriptive statistics were reported for demographic and baseline data. Means and standard deviations were calculated for

continuous variables, absolute and relative frequencies for categorical variables.

Mesial and distal DIB values were considered, as well as the average of both measurements. Proximal sides of the implants were classified according to the radiographic crestal positioning of the shoulder obtained in the surgery. Implant sides with negative DIB were placed below the crest and categorized as subcrestal. Implants with DIB values ranging from 0 to 0.1 mm ( $\varnothing$  3.8 mm implant) or 0.2 mm ( $\varnothing$  4.3 mm implant) were classified as epicrestal. Implants with DIB values superior to 0.1 or 0.2 mm were classified as supra-crestal. The variation of DIB over time was assessed using a mixed-effects model analysis assuming auto-regressive covariance matrix for the repeated measures and considering both random intercepts and slopes. Centre and insertion level were established as fixed effects whereas the clustering of implants within each patient was established as the random effect.

Bone level changes (BLC) were calculated as the difference in DIB measurements between two consecutive appointments: surgery to load, load to 1 year, 1 year to 2 years and so on until 5 years. Additionally, a functional BLC was calculated from load to 1 and 5-year follow-up. Differences in BLC between insertion depth categories were assessed with one-way ANOVA and post hoc Tukey correction.

Survival analysis was applied to calculate implant success and survival rate. All statistical analysis was performed using the IBM SPSS Statistics 24 (IBM Corp.) with significance level set to  $\alpha = 0.05$ .

### 3 | RESULTS

#### 3.1 | Participants and implant data

Between May 2011 and February 2012 the two centres evenly recruited 24 patients, 14 males and 10 females with a mean age of 48.9 years ( $SD: \pm 13.8$ ), who received a total of 52 implants. Two thirds of the patients were non-smokers, four patients were former smokers for a reasonable number of years and four patients reported smoking less than 10 cigarettes per day. Only 3 patients reported drug intake for hypertension control and lipid metabolism. The general health score of the patient cohort was good to very good (ASA 1:  $n = 21$ , ASA 2:  $n = 3$ ).

A total of 7 patients (14 implants) did not complete the follow-up period of 5 years: one patient withdrew consent prior to the 12-month visit (2 implants), two patients (4 implants) passed away before the 48-month visit and four patients (8 implants) were lost to follow-up (not possible to contact after several attempts at different times of the day). The flow diagram is presented in Figure 1.

The characteristics of participants and of the CONELOG® SCREWLINE implants (CAMLOG Biotechnologies) at baseline and end of follow-up are detailed in table 1.

All implants achieved primary stability and were submitted to transgingival healing using wide body platform-switching healing abutments in 49 cases and cylindrical platform-switching healing abutments in 3 cases. After the predefined healing period, the

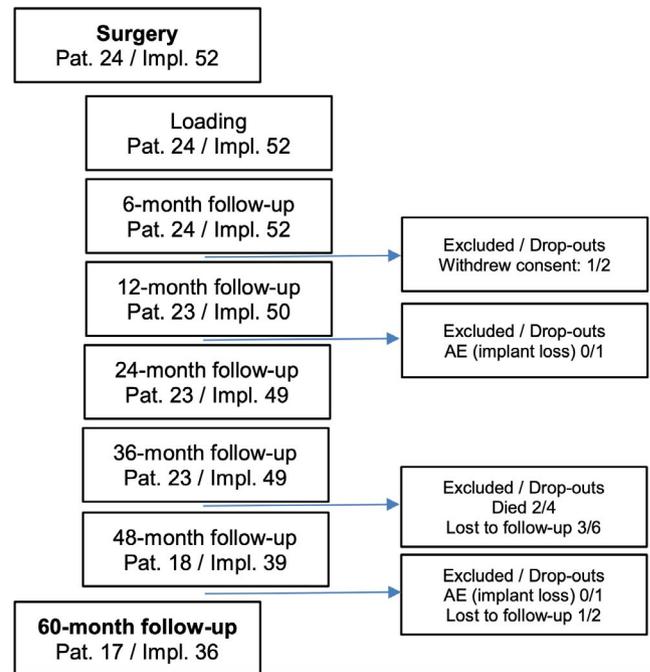


FIGURE 1 Study flow-diagram

implants were rehabilitated with single crowns cemented over prosthetic abutments that were fastened to the implants with a 20 Ncm torque. The cement used was Fuji I ( $n = 24$ ), Temp Bond ( $n = 21$ ), Ketac Cem ( $n = 4$ ) and Harvard ( $n = 3$ ). Most restorations were porcelain-fused-to-metal crowns ( $n = 46$ ) and six were all-ceramic ( $n = 6$ ). The mean crown to implant ratio was 0.73 ( $SD: \pm 0.18$  mm). A representative case of the treatment provided and the corresponding follow-ups is presented in Figure 2.

#### 3.2 | Bone level analysis

All patients were submitted to radiographic control of the implants in all appointments, however, radiographs were not available for one patient (2 implants) at loading and 6-month visits due to pregnancy, for one patient (2 implants) at the 1-year visit, for 2 patients at the 2-year visit (5 implants) and 2 patients (4 implants) at the 3-year visit. Marginal bone level changes (BLC) over the course of the study are summarized in table 2 and detailed according to the crestal positioning of the implant shoulder in table 3. From loading to study completion, there was, on average 0.27 mm ( $SD: \pm 0.47$ ) bone level change.

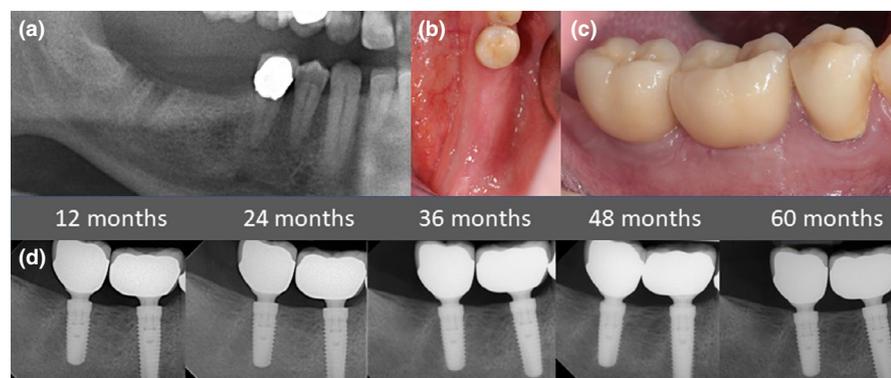
All other radiographic controls were available and considered for analysis of mesial and distal DIB values over time, which are represented in Figure 3.

The graphics reveal post-surgical bone remodelling in all three groups, sub-, epi- and supra-crestal. Within the mixed-model context, implant insertion depth exerted a statistically significant influence on this remodelling event ( $F(2,537.8) = 3.65$ ,  $p = .027$ ) with the subcrestal implants presenting approximately 0.35 mm higher bone loss than epi- and supra-crestal implants in

**TABLE 1** Demographic and clinical parameters of the study population and implanted sites at baseline and 60-month follow-up. % within column

Characteristics (N)		Surgery	60 months
		24	17
Mean age (SD) (years)		48.9 (13.8)	46.4 (12.1)
Gender	male/female	14/10	10/7
Use of tobacco	never/former smoker/<10 cigarettes/day	16/4/4	10/4/3
Quadrants randomized	2 adjacent implants	20	13
	3 adjacent implants	4	4
Implants (n)	TOTAL	52	36 <sup>a</sup>
	Centre 1	28	16
	Centre 2	24	20
Diameter; n implants (%)	∅ 3.8 mm	28 (53.8)	20 (55.5) <sup>a</sup>
	∅ 4.30 mm	24 (46.2)	17 (44.5) <sup>a</sup>
Bone quality; n implants (%)	Type I	6 (11.5)	4 (11.1)
	Type II	19 (36.5)	15 (41.7) <sup>a</sup>
	Type III	21 (40.4)	14 (38.9)
	Type IV	6 (11.5)	3 (8.3)
Oral Hygiene; n patients (%)	Excellent	0 (0.0)	4 (23.5)
	Good	23 (95.8)	9 (52.9)
	Fair	1 (4.2)	3 (17.6)
	Poor	0 (0.0)	1 (6.0)

<sup>a</sup>Number does not consider two implants (∅ 3.8 mm = 1; ∅ 4.3 mm = 1) that were lost in a patient that originally received 3 implants in type II bone and completed the study.

**FIGURE 2** Clinical example with the initial orthopantomography (a), the clinical view intraoperatively (b) and the prosthetic rehabilitation after 60 months (c). In D the bone levels as presented annually

	Surgery-load	Load-12 M	12-60 M	Load-60 M
N (implants)	50	46	35	35
BLC	-0.5 ± 0.40	0.12 ± 0.42	0.13 ± 0.26	0.27 ± 0.47

**TABLE 2** Changes in radiographic crestal bone level between follow-up appointments for mesial and distal implant sides and averaged for each implant

Note: Mean variation and standard deviation in millimetres.

that period (see table 3). After loading, a loss of bone is observed until 24 months. From this point onwards, the bone level is stabilized at the level of the implant shoulder (subcrestal implants) or keeps improving up to 0–0.5 mm distance from the shoulder (epi- and supracrestal implants) and no differences can be found

between DIB values of the three groups ( $p > .05$ )—model detailed in supplementary material.

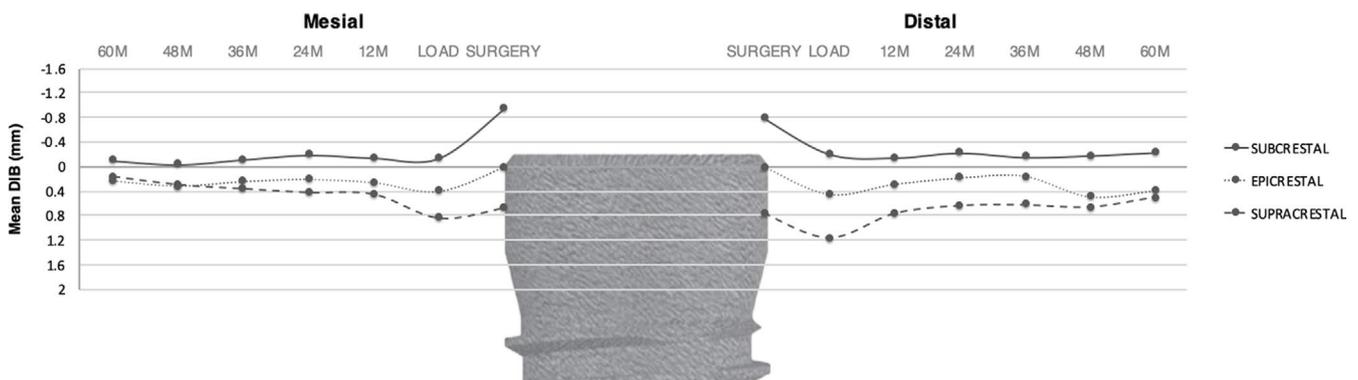
This trend is confirmed by the graphic representation of the median values of each group from loading to the end of the study (Figure 4).

**TABLE 3** Implant insertion level at surgery and bone level changes between succeeding evaluation periods

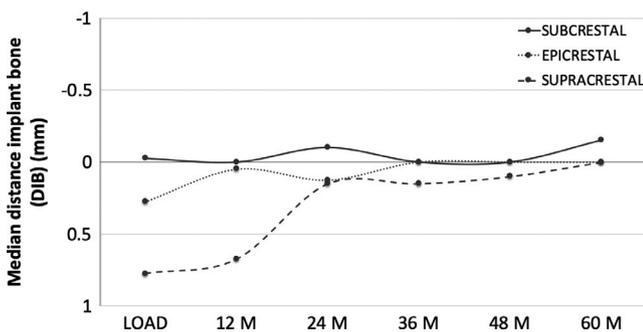
		DIB surgery		BLC surgery-load		BLC load-12 M		BLC 12-60 M	
		N	(Mean ± SD)	N	(Mean ± SD)	N	(Mean ± SD)	N	(Mean ± SD)
Mesial	Subcrestal	22	-0.94 ± 0.54	20	-0.82 ± 0.49 <sup>a</sup>	19	0.00 ± 0.47	16	0.12 ± 0.26
	Epicrestal	20	0.02 ± 0.05	20	-0.40 ± 0.45	20	0.15 ± 0.46	13	0.12 ± 0.21
	Supracrestal	10	0.68 ± 0.26	10	-0.17 ± 0.32	7	0.40 ± 0.29	6	0.23 ± 0.35
					<i>p</i> < .01		<i>p</i> = .127		<i>p</i> = .665
Distal	Subcrestal	16	-0.79 ± 0.39	16	-0.58 ± 0.49	16	-0.06 ± 0.47	15	0.02 ± 0.18
	Epicrestal	22	0.01 ± 0.03	21	-0.45 ± 0.38	20	0.14 ± 0.46	12	0.08 ± 0.25
	Supracrestal	14	0.76 ± 0.37	13	-0.38 ± 0.48	10	0.32 ± 0.55	8	0.35 ± 0.59
					<i>p</i> = .467		<i>p</i> = .149		<i>p</i> = .091
Mean	Subcrestal	23	-0.68 ± 0.29	22	-0.70 ± 0.33 <sup>a</sup>	22	0.06 ± 0.41	20	0.09 ± 0.16
	Epicrestal	15	0.01 ± 0.03	14	-0.34 ± 0.40	13	0.07 ± 0.49	6	0.05 ± 0.21
	Supracrestal	14	0.56 ± 0.25	14	-0.34 ± 0.44	11	0.29 ± 0.29	9	0.26 ± 0.42
					<i>p</i> = .005		<i>p</i> = .303		<i>p</i> = .188

Note: Classification according to mesial and distal DIB measurements at surgery for the respective implant side or according to the averaged mesial and distal measurements of DIB for mean values per implant. *p* values for One-way ANOVA. Post hoc analysis using Tukey correction.  $\alpha = 0.05$ .

<sup>a</sup>Statistically different from implants placed epicrestal and the implants placed supracrestal



**FIGURE 3** Mean DIB (mm) for mesial and distal implant sites according to the insertion depth for all periods of evaluation



**FIGURE 4** Median DIB in millimetres for the three groups from loading onwards. Notice the stabilization around the implant shoulder regardless of the initial insertion depth

From loading to 60 months, the relative frequency of implants with no change in bone levels or positive bone level change kept relatively stable compared to the 12-month data (69.5% versus 71.1%, respectively), as represented in Figure 5. No statistically significant

differences were found between bone level changes of  $\varnothing$  3.8 mm and  $\varnothing$  4.3 mm implants (*p* = .53).

### 3.3 | Implant success and complications

Up to 60-months post-loading, two implants were lost within the same patient with a survival rate of 95.4%

After 5 years of loading and according to the success criteria of absence of complaints, peri-implantitis, mobility and radiolucency (Buser et al., 2002) the success rate was 95.1%.

One patient experienced chipping of porcelain at distal crown at 36-month post-loading. Four months later, the crown was cemented again. One year later, bone loss (mesial -2.9 mm; distal -2.3 mm) without suppuration was observed and was related to overload of the implant. The occlusion was corrected with the new crown and 1 year later, no further bone loss nor other complications were reported. These values are considered in the bone level analysis (Figure 3).

The single technical adverse event noticed occurred during the insertion of the definite rehabilitation with fracture of the prosthetic screw inside of the implant connection. The event was successfully solved, and the final restoration placed after repeating the prosthetic procedures.

### 3.4 | Soft tissue health

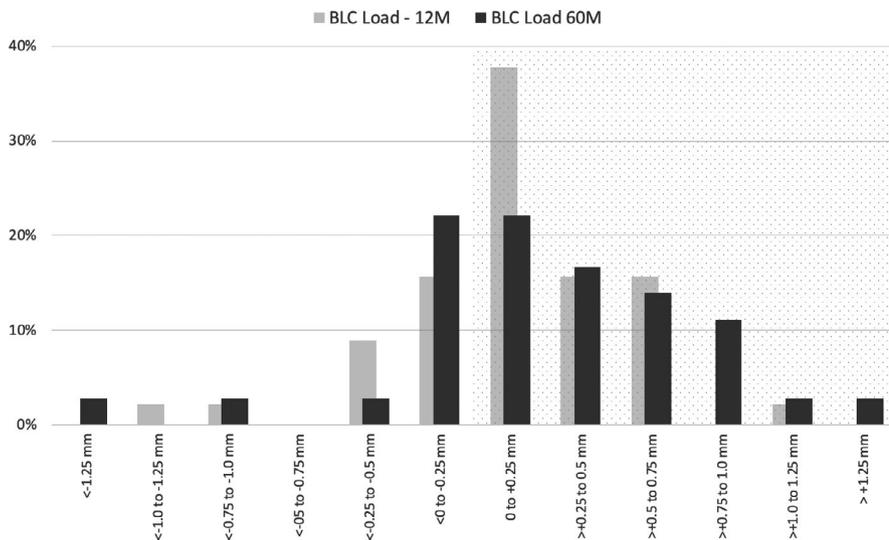
All patients presented very good compliance regarding oral health with 44.4% and 55.6% of the patients presenting no plaque or a minimal amount of plaque detected using a probe at 60 months, respectively, as expressed in table 4—scores 0 and 1. Similarly, 47.2% of the implants presented no bleeding when a periodontal probe was passed along the gingival margin and 50% presented an isolated visible bleeding spot. We found no significant differences of the modified plaque index (PI) distributions (Friedman-Test: Chi-Quadrat = 6.316,  $p = .277$ ,  $n = 33$ ) and likewise no significant differences of the sulcus bleeding index distributions (Friedman-Test: Chi-Quadrat = 6.067,  $p = .300$ ,  $n = 33$ ) between time points. The mean probing depth was <3 mm at all examinations.

### 3.5 | Patient satisfaction

At loading 58% of the patients reported being ‘very satisfied’ with the implant restoration regarding the criteria: comfort, appearance, ability to chew, ability to taste and general satisfaction. At 5-year post-loading, the percentage increased to 77%–88% of the patients being ‘very satisfied’ with the implant restoration.

## 4 | DISCUSSION

The present study followed the market introduction in 2011 of a new two-piece implant with conical connection, the CONELOG® implant system, and targeted the absence of long-term clinical data on conical connections. The study addressed the clinical performance of CONELOG® SCREWLINE implants rehabilitated with single cemented crowns in the posterior mandible and the primary objective comprised the evaluation of marginal bone level changes over the course of 5 years. Secondary objectives included the documentation of implant survival, clinical parameters, nature and frequency of adverse events, as well as the performance of the restorative components and patient satisfaction. This paper complements the previously



**FIGURE 5** Distribution of bone level changes from loading to 12 and 60 months by categories. Negative values represent bone loss and positive values represent bone preservation above the implant shoulder. From loading to 60-months postop more than 69% of the implants had a positive variation of bone (shaded area of the graphic)

	N	PI	SBI	PPD
		0/1/2/3 (%)	0/1/2/3 (%)	Mean ± SD
Loading	52	59.6/30.8/9.6/ -	69.2/30.8/ - / -	2.01 ± 0.83 -
12-months	50	64.0/36.0/ - / -	54.0/44.0/2.0/ -	2.29 ± 0.63
24-months	49	57.1/42.9/ - / -	51.0/49.0/ - / -	2.04 ± 0.54
36-months	45	55.6/44.4/ - / -	57.8/40.0/2.2/ -	2.08 ± 0.61
48-months	37	43.2/48.7/8.1/ -	54.1/32.4/13.5/ -	2.13 ± 0.70
60-months	36	44.4/55.6/ - / -	47.2/50.0/2.8/ -	1.97 ± 0.74

**TABLE 4** Summary of the measurement of the clinical parameters

Note: Relative frequencies of the scores attributed to the implants (PI, SBI). Mean (±SD) pocket probing depth, in millimetres.

published work (Moergel et al., 2016) with the final data at 5 years. The results indicate that despite the initial bone remodelling events, the Conelog implant system presents on average a  $0.27 \pm 0.47$  mm bone level change after loading until 5 years of follow-up. This positive change in peri-implant bone promotes, at long-term, the stabilization of marginal bone at the level of the implant shoulder, regardless of the initial insertion depth—sub-, epi- or supracrestal.

These findings are in line with those of a recent systematic review (Pellicer-Chover et al., 2019), which did not find better outcomes between epicrestal and subcrestal implant placement. Interestingly, in the present study, the supracrestal positioning of any part of the implant shoulder, mainly due to anatomical constrictions of the posterior mandible, did not compromise the long-term radiographic outcome. In fact, these implants sites present the lowest post-surgical bone remodelling and, at 5 years, present a median DIB of 0.0 mm, which means that at least 50% of the cases recover to the level of the implant shoulder or even more, similarly to the epicrestal and subcrestal groups.

This extraordinary behaviour of the implants regardless of the insertion depth could be attributable to the Morse taper connection with integrated platform-switching, which not only presents high stability in terms of micromovements (Goiato et al., 2015; Tsuruta et al., 2018) but also presents the lowest microleakage (Mishra et al., 2017) at the implant-abutment interface. The location of the implant-abutment interface and the associated microgap have been considered as contributing factors for peri-implant marginal bone resorption. Lazzara and Porter in 2006 postulated that in platform-switched implants the biological width formation takes place in a more horizontal fashion, thus, offering more surface area for mucosal attachment and sealing, which contributed for lower marginal bone resorption (Lazzara & Porter, 2006).

Some authors found that besides the diameter of the restorative components, the apicocoronal position of the implants (e.g., supracrestal, crestal or subcrestal) also affects the vertical marginal bone loss. For instance, (Veis et al., 2010) observed greater marginal bone loss in two-piece implants with platform-switched abutments placed at crestal levels than in the implants placed supracrestal or subcrestal levels. The marginal bone loss was significantly lower in the group of implants placed subcrestal. Other studies point to minimal bone resorption around platform-switching implants placed in a subcrestal position (Koutouzis et al., 2011; Weng et al., 2008). Using the same implant system, (Schwarz et al., 2015) found in an animal model different patterns of post-insertion resorption for different crestal insertion depths, that is, epi-, sub- or supracrestal. In the present study, the subgroup analysis of slightly supracrestally, crestally and slightly subcrestally inserted implants found a similar pattern for the initial remodelling, but no statistically nor clinically relevant deviation between the groups with equal gain of bone after 60 months.

The results of the present observational study with positive bone level from loading to 60 months of follow-up are in line with those of the randomized controlled clinical trial (RCT) published by (Messias et al., 2019), who reported, for a similar period, positive bone level with values of 0.19 mm on average for platform-switched implants with a butt joint connection (Tube-in-tube™), but slightly surpass them. Since the present study was conducted under the same

conditions as the mentioned trial, with similar inclusion and exclusion criteria, it is possible to assume that part of the positive post-loading bone level development is attributable to the platform-switching feature but another important part is attributable to the Morse taper implant-abutment connection of the implant system used.

In fact, the implant system used in the present study respects the minimal discrepancy of 0.4 mm between implant and prosthetic component suggested by the systematic reviews and meta-analysis of (Annibaldi et al., 2012; Atieh et al., 2010) for a clinically relevant impact on the marginal bone. The implants within the present study respected this aspect with an integrated platform switch of 0.4 mm with implants of 3.8 mm in diameter and 0.65 mm within the 4.3 mm diameter implant.

The present study also found marginal bone establishment being a highly time dependent biological process with 0.5 mm bone loss from surgery to begin of the loading phase after 12 weeks but followed by recovery and stabilization in the years thereafter. Using the same implants, (Cacaci et al., 2019) determined exactly the same post-surgical bone remodelling and post-loading stabilization. These results further contribute for the characterization of the bone level changes around conical connection implants and, from a practitioner point of view, ensure the needed long-term stability and predictability that determine the success of implant therapy. This is further corroborated by the survival rate of 95.4% after 5 years of loading, a result that slightly outruns that of another long-term cohort study on Morse tapered platform-switched implants (Cassetta et al., 2016).

Limitations of the present study are mainly related to the strict inclusion criteria, with focus on healthy non-smokers featuring excellent oral hygiene habits and compliance. From a statistical point of view major limitations are the single cohort design without option for establishing a control group (platform switch is an integral part of the implant type), the missing sample size calculation and a 29% of loss to follow-up. However, it is important to mention that this observational study followed the same design conditions of the abovementioned RCT, allowing direct comparisons. Additionally, it is possible to confirm that no major deviations occurred in the study population from baseline to the end of follow-up (table 1), which significantly reduces the risk of attrition bias due to the large number of loss to follow-up patients.

A technical limitation might be attributed to measurement of the bone level changes by a two-dimensional method. The authors respect that bone remodelling takes place in a three-dimensional space around the implant. On the other hand, the possibilities to detect bone level changes in all three dimensions are still limited. Conebeam tomography was not available as a routine examination method at start of the study and the elevated radiation exposure would have caused ethical criticism. Consequently, a radiological method, well established in dental routine assessment of periodontal bone level changes, was used to assess peri-implant bone remodelling. Furthermore, this approach allowed direct comparison with other studies of equal intention and design. Possible deviations by misangulation of the radiation path were controlled by using an individualized tube holder with bite impressions in a silicone base.

On the contrary, the major strength of this study relies on the long-term follow-up (5 years) of an implant system with conical connection,

filling the literature gap previously identified. For this reason, we believe that the present results are generalizable to other clinical situations of posterior bounded edentulous gaps planned to receive fixed restorations, as long as there is enough bone volume to install dental implants without resorting to bone regeneration procedures.

In conclusion, the present observational study demonstrated successful functional, clinical and radiographic outcomes of implants with internal conical connection used in the posterior mandible. After 5 years of loading, these implants presented stable marginal bone at the level of the implant shoulder, independent of the initial crestal positioning.

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## CONFLICT OF INTEREST

The authors declare that they have no conflict of interests related to this study. This study was funded by an unrestricted grant of the Oral Reconstruction Foundation, Basel, Switzerland. Prof. F. Guerra is a member of the Oral Reconstruction Foundation Board.

## AUTHOR CONTRIBUTIONS

**Maximilian Moergel:** Investigation (equal); Visualization (equal); Writing-original draft (equal); Writing-review & editing (equal). **Salomão Rocha:** Formal analysis (equal); Investigation (equal); Validation (equal); Writing-original draft (equal). **Ana Messias:** Data curation (equal); Formal analysis (equal); Investigation (equal); Methodology (equal); Writing-original draft (equal); Writing-review & editing (equal). **Pedro Nicolau:** Formal analysis (equal); Investigation (equal); Writing-original draft (equal); Writing-review & editing (equal). **Fernando Guerra:** Conceptualization (equal); Funding acquisition (equal); Investigation (equal); Methodology (equal); Project administration (equal); Resources (equal); Supervision (equal); Writing-original draft (equal); Writing-review & editing (equal). **Wilfried Wagner:** Conceptualization (equal); Formal analysis (equal); Investigation (equal); Methodology (equal); Project administration (equal); Resources (equal); Supervision (equal); Validation (equal); Writing-original draft (equal); Writing-review & editing (equal).

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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