# A Multicenter Cohort Study on 301 Tissue-Level Implants: Cumulative Implant Survival Rate and Marginal Bone Level Change up to 4.5 Years

Doriane Chacun, DDS, PhD<sup>1,2</sup>/Laurent Laforest, MD, PhD<sup>1</sup>/Carole Langlois-Jacques, MSc<sup>3,4</sup>/ Michel Dard, DDS, PhD<sup>5</sup>/Kerstin Gritsch, DDS, PhD<sup>1,2</sup>/Brigitte Grosgogeat, DDS, PhD<sup>1,2</sup>

Purpose: To retrospectively determine the cumulative survival rate (CSR) and marginal bone level change (ΔMBL) around novel hybrid design tissue-level (TL) dental implants that support multiple-screw-retained restorations. Materials and Methods: Implant CSRs were analyzed at the implant and patient level using Kaplan-Meier estimates. AMBL was measured by comparing the periapical loading and follow-up visit radiographs using an improved standardized digital methodology based on image gray levels. AMBL outcomes were subject to linear mixed regression to identify potential risk factors. *Results:* A total of 301 TL implants in 69 patients with an average age of  $62.6 \pm 11.7$  years (range: 36 to 87 years) at the time of implant placement were considered for the analysis. All 301 implants were successfully restored and loaded. The 54-month CSRs at the implant and patient levels were 98.9% (95% CI: 96.7 to 99.6) and 95.3% (95% CI: 86.1 to 98.5), respectively.  $\Delta$ MBL after a mean follow-up of 22 ± 10.7 months after loading was 0.00 ± 0.57 mm. None of the implant sites showed marginal bone loss exceeding 1.5 mm. Multivariate regression analysis revealed a significant association between  $\Delta$ MBL and the loading protocol (P = .027) but not between  $\Delta$ MBL and age or transgingival height. Conclusions: The high CSRs and stable peri-implant marginal bone levels support the use of recent TL implants, which have a hybrid design inherited from the bone-level implant-abutment connection, as a suitable treatment option for restoring partially or fully edentulous patients with a good mid-term prognosis. These results should be complemented by further prospective studies in a real-world multicenter private practice setup that represents the daily realities of implant treatment. Int J Oral Maxillofac Implants 2024;39:224-234. doi: 10.11607/jomi.10141

*Keywords:* dental implants, retrospective study, cumulative survival rate, marginal bone level, real-world evidence, hybrid design

Dental implants represent a well-established modality for the treatment of edentulism. Hard and soft tissue integration of dental implants can be considered key factors for the long-term clinical outcome of implant therapy.<sup>1</sup> The analysis of implant survival and the factors affecting it (eg, patient, surgical, and prosthetic-related characteristics) is imperative for the rational evolution of implant therapy and the associated implant designs and treatment workflows.<sup>2–5</sup> Among the various clinical parameters, marginal bone stability

d'Odontologie, Université de Lyon, Lyon, France.

<sup>2</sup>Services de Parodontologie et de Recherche Clinique, Pôle

Correspondence to: Brigitte Grosgogeat, brigitte.grosgogeat@univ-lyon1.fr

Submitted June 29, 2022; accepted July 18, 2023. ©2024 by Quintessence Publishing Co Inc. has evolved as a key indicator of implant survival and success.<sup>6,7</sup>

Modern dental implants have evolved from two major categories: bone-level (BL) and tissue-level (TL) implants.<sup>8</sup> Compared to the traditionally submerged healing BL implants, TL implants heal transgingivally and offer an alternative treatment method that requires fewer surgical interventions and less chair time for the patient.9 TL implants have been clinically documented as equivalent to BL implants in terms of osseointegration and long-term survival.<sup>10,11</sup> Further, the potentially lower prosthetic flexibility of TL implants may be compensated for by its advantages in better preserving marginal bone levels, which has been attributed to the absence of surgical re-entry and the avoidance of microgaps as a potential source for bacterial colonization, as well as reduced micromechanical movements at the bone level.<sup>12–14</sup>

The macrodesign of the cervical implant region is another important factor that contributes to periimplant marginal bone stability. Platform switching has been shown to effectively improve the stability of marginal bone levels around BL implants.<sup>15</sup> Also, the mean marginal vertical and horizontal bone loss

<sup>&</sup>lt;sup>1</sup>Laboratoire des Multimatériaux et Interfaces, Faculté

d'Odontologie, Hospices Civils de Lyon, Lyon, France.

<sup>&</sup>lt;sup>3</sup>Service de Biostatistique et Bioinformatique, Pôle de Santé

Publique, Hospices Civils de Lyon, Lyon, France.

<sup>&</sup>lt;sup>4</sup>Université de Lyon, Lyon, Villeurbanne, France.

<sup>&</sup>lt;sup>5</sup>Columbia University, College of Dental Medicine, Section of Oral, Diagnostic and Rehabilitation Sciences, New York, NY, USA.

**Fig 1** (*a*) Illustration of a conventional platform-switched abutment connection on a BL implant. (*b*) Illustration of a conventional TL implant design. (*c*) Schematic representation of study device—ie, hybrid design TL implants with three transgingival platform heights.



around platform-switched abutments was reported to be lower than platform-matched abutments after 3<sup>16</sup> and 5 years<sup>17</sup> of functional loading. Similar results could be expected from tissue-level implants that present a platform-switched design. However, the investigation of this specific feature for TL implants remained, to the best of our knowledge, undocumented.

The first mention of hybrid design regarding dental implants in the literature goes back to 1993, when Tarnow<sup>18</sup> referred to surface characteristics of implants that had a machined neck in the coronal part and a plasma-sprayed surface on the apical part to better induce osseointegration and prevent peri-implantitis. This study proposed to extend this concept to a TL implant with macroscopic design features inherited from BL implants.

A defining characteristic of this hybrid design consists of a marked change in diameter at the crestal level, similar to the platform-switched implant-abutment junction found in conical connection BL implants<sup>19</sup> (Fig 1). However, the long-term impact of this modification on marginal bone stability and implant survival has not been documented so far.<sup>20</sup> Therefore, this retrospective multicenter cohort study aimed to analyze this novel TL hybrid implant design's survival rate and marginal bone level stability in an in-practice real-world setting.

## **MATERIALS AND METHODS**

The primary and secondary objectives of this study were to analyze the cumulative implant survival rate (CSR) of novel hybrid design TL implants at different time points and the marginal bone level change ( $\Delta$ MBL) at  $\geq$  1 year postloading. In addition, technical complications and causes of implant failure were analyzed. Age, loading protocol, and transgingival implant height were studied as possible risk factors for marginal bone change.

#### **Study Design**

This retrospective study analyzed records from a cohort of patients treated with multiple screw-retained restorations who received implant treatment with commercially available REG and PX Axiom Tissue Level implants (Anthogyr, Straumann; see Fig 1c). Axiom implants consist of standard surgical grade titanium alloy (Ti-6Al-4V ELI) and a biphasic calcium phosphate surface manufactured via particle-blasting with a mixture of hydroxyapatite and tricalcium phosphate followed by nitric acid treatment.

This study was conducted according to the French regulation for health data studies under CNIL MR-004 guidance<sup>21</sup> and adhered to the STROBE guidelines for cohort studies.<sup>22</sup> It was approved by the Institutional Review Board and Ethics Committee in Lyon (Scientific and Ethical Committee of Hospices Civils de Lyon; CNIL approval number 22\_5731).

#### Data Collection

This study considered 389 consecutive implant treatment records of 90 patients, including multi-implantbased restorations, from 23 private practices performed by 23 experienced implant surgeons from 2015 to 2018. Patient records that lacked completed follow-ups since implant placement were excluded, which reduced the number of implants and patients considered for analysis in the cohort to 301 and 69, respectively. No specific exclusion criteria were applied regarding implant placement or loading protocols.

 $\Delta$ MBL of an implant subcohort that had at least a completed 1-year postloading radiographic follow-up (range: 12 ± 1 months) was analyzed as described below. The selection process for this subcohort analysis is schematically depicted in Fig 2 and was based on the availability of baseline and follow-up radiographs with sufficient quality for analysis.

The following nominal and categorical factors were recorded:

- Patient-related factors: sex, age, smoking habits, and history of periodontal disease
- Recipient site-related factors: placement and loading protocols



Fig 2 Election process for the subcohort of patient records used for  $\Delta MBL$  analysis.

- Implant-related factors: position, thread design, length, diameter, platform diameter, transgingival platform height
- Prosthetic design-related factors: type, material
- Type of prosthetic complications
- Implant survival rate

The CSR was determined using Kaplan-Meier analysis and defined the time to implant failure as the time interval between implant placement and failure. The implants were considered failed if they presented signs and symptoms that led to implant removal or were put to sleep (ie, were left in place and either were unloaded or no longer participated in prosthetic support) due to the lack of osseointegration or mechanical failure.<sup>23</sup>

# Marginal Bone Level Change: Radiographic Assessment

 $\Delta$ MBL was defined as the difference between radiographic marginal bone levels at the most recent followup and the time of loading (baseline) and was assessed by two independent treatment-blinded, calibrated examiners (D.C. and F.P.). The  $\Delta$ MBL in milimeters measured by the two examiners was averaged and used for the statistical analysis. Examiner calibration was performed using periapical radiographs excluded from the final evaluation. The intraclass correlation coefficients (Lin coefficient of concordance) were 0.93 (36 measures) and 0.95 (36 measures) for each respective examiner. The interclass correlation coefficient (Lin coefficient of concordance) was 0.84 between the two examiners (36 measures).

As this restrospective study was multicentric, the angulation errors and radiograph capturing techniques

Fig 3 Methodology of measurement of marginal bone level using periapical radiographs. (a) Areas used to select reference gray profiles of bone at the mesial and distal aspects of the implant, excluding anatomically intrinsic radiolucent structures, eg, extraction sites. (b) Dimensions of the endosseous part of the implant used for dimensional image calibration. (c) Assessment of marginal bone level at the mesial and distal aspects using the step between the transgingival platform and the endosseous implant body as reference landmark.

and protocols were not standardized. To address this, a specific methodology was employed to maximize measurement reliability.

Digital periapical radiographs (> 300 dpi) were evaluated using ImageJ (NIH). Radiographs with insufficient resolution or with motion blur were excluded.

 $\Delta$ MBL assessment followed the routines and definitions previously described by Weber and Buser.<sup>24</sup> In brief, individual vertical marginal bone levels were averaged from measurements on mesial and distal aspects using the distance between the most coronal bone to implant contact relative to the implant platform (Fig 3). Radiographs were calibrated using the implant length or, in cases of partial radiographs that did not display the entire implant, the dimensions of the transgingival platform.

To improve measurement validity of the nonstandardized images, originally reported routines were modified by using digital image gray level profiles to reduce the level of bias in coronal bone level identification. Reference gray level profiles for osseous structures were determined in regions of interest located at least three implant threads apically to the implant platform, equidistant from possible neighboring implants, and under exclusion of possible anatomical radiolucent structures like extraction sockets (see Fig 3). The minimum derived gray level profile of osseous structures was selected as the reference value to determine the individual vertical marginal bone levels.

As a result of the applied selection process, 45 pairs of radiographs from four practitioners with a mean resolution higher than 1040 dpi were available. The final interclass correlation coefficients (Lin coefficient of concordance) between the two examiners (D.C. and F.P.) for

			Patient level % (n),	Implant level % (n),
actor type	Factor	Characteristics	n = 69	n = 301
	Sex	Male	44.9 (31)	46.2 (139)
	Jex	Female	55.1 (38)	53.8 (162)
		≥ 60	59.4 (41)	66.1 (199)
	Age (y)	< 60	39.1 (27)	31.9 (96)
		Unknown	1.5 (1)	2.0 (6)
atient factors		No	79.7 (55)	79.1 (238)
	Tobacco use/smoking	Yes	17.4 (12)	18.9 (57)
		Unknown	2.9 (2)	2.0 (6)
	History of pariodoptal	No	59.4 (41)	53.2 (160)
	History of periodontal disease	Yes	36.2 (25)	40.5 (122)
		Unknown	4.4 (3)	6.3 (19)
	Implantation	Delayed implantation	N/A	62.5 (188)
ecipient site	inplantation	Immediate implantation	N/A	37.5 (113)
actors	Loading	Conventional loading	N/A	36.2 (109)
	Loading	Immediate loading	N/A	63.8 (192)
		Anterior maxilla	N/A	24.2 (73)
	Position	Posterior maxilla	N/A	28.6 (86)
		Anterior mandible	N/A	10.3 (31)
		Posterior mandible	N/A	36.9 (111)
	Thread design	REG	N/A	38.5 (116)
	iniead design	PX	N/A	61.5 (185)
		Short: < 10 mm	N/A	14.0 (42)
	Length	Conventional: ≥ 10 mm	N/A	80.7 (243)
nplant factors		Missing	N/A	5.3 (16)
		Narrow: 3.4 mm	N/A	36.9 (111)
	Diameter	Conventional: 4 or 4.6 or 5.2 mm	N/A	57.8 (174)
		Missing	N/A	5.3 (16)
	Distance discussion	4	N/A	21.3 (64)
	Platform diameter	4.8	N/A	78.7 (237)
		1.5	N/A	14.6 (44)
	Platform height	2.5	N/A	66.1 (199)
		3.5	N/A	19.3 (58)
	Fixed multiple	Partial	56.5 (39)	39.9 (120)
	prosthesis	Full-arch	43.5 (30)	60.1 (181)
		CoCr	31.9 (22)	31.6 (95)
osthesis		Ті	36.2 (25)	42.5 (128)
	Material	Zi	23.2 (16)	15.9 (48)
		Polymer	4.3 (3)	4.7 (14)
		Missing	4.3 (3)	5.3 (16)

N/A: not applicable.

the 45 analyzed implants (90 measurements) was 1 for the gray level profiles and 0.85 for the  $\Delta$ MBL.

#### Data and Statistical Analysis

Descriptive characteristics were reported as means, standard deviations, and frequencies (percent). CSRs were determined using Kaplan-Meier analysis and reported using 95% CIs.

The association of  $\Delta$ MBL values and risk factors was analyzed by applying linear mixed univariate and multivariate regression models, considering the age of the patient (< 60 years old vs > 60 years old), transgingival height (1.5 mm vs 2.5 and 3.5 mm), and loading protocols (immediate vs conventional) as fixed effects, and the patient as a random effect. Due to the limited sample size, robust *P* values were additionally estimated using a bootstrap approach. The model assumptions (constant variance and normality of residuals) were verified.

All analyses were performed in R v4.0.2 or SAS software v9.4. A two-sided *P* value < .05 was considered statistically significant.

## RESULTS

#### **Patient and Implant Cohort Characteristics**

The descriptive characteristics of the cohort at implant and patient levels are summarized in Table 1. A total of 301 TL implants in 69 patients with an average age

Table 2         Mechanical and Technical Complications Reported on Patient and Prosthesis Levels						
Complication	Patient-based events	Prosthesis-based events				
Total complications	15 / 59 (25.4%)	16 / 72 (22.2%)				
Screw loosening	10 / 15 (66.6%)	11 / 16 (68.8%)				
Ceramic chipping	1 / 15 (6.6%)	1 / 16 (6.3%)				
New prosthesis	1 / 15 (6.6%)	1 / 16 (6.3%)				
Screw access cover lost	1 / 15 (6.6%)	1 / 16 (6.3%)				
Resin repair	1 / 15 (6.6%)	1 / 16 (6.3%)				
Fractured prosthesis	1 / 15 (6.6%)	1 / 16 (6.3%)				

#### Table 3 Kaplan-Meier Survival Probabilities at the Implant and Patient Levels

	Survival probability % (95% CI)				
Time (mo)	Implant level	Patient level			
2.2	99.7 (97.5–100.0)	98.5 (89.6–99.8)			
3	99.3 (97.2–99.8)	96.9 (88.2–99.2)			
3.5	98.9 (96.7–99.6)	95.3 (86.1–98.5)			
54	98.9 (96.7–99.6)	95.3 (86.1–98.5)			

Table 4 Characteristics of Failed Implants											
Failed implant	Position (FDI system)		Diameter (mm)	Length (mm)	Platform diameter (mm)	length	Implantation	Loading	Prosthesis	Removal time after implant placement (mo)	Cause of failure reported
1	25	РХ	3.4	12	4.8	2.5	Delayed	Immediate	Full-arch	2.2	Non-osseointegration
2	13	РХ	3.4	14	4.8	2.5	Delayed	Conventional	Partial	3	Abscess
3	36	РХ	4	8	4.8	3.5	Delayed	Conventional	Full-arch	3.5	Non-osseointegration

of  $62.6 \pm 11.7$  years (range: 36 to 87 years) at the time of implant placement were considered in the analysis. All 301 implants were successfully restored and loaded. Of these, 159 implants (52.8%) were placed in the maxilla and 142 implants (47.2%) were placed in the mandible, while 104 (34.6%) and 197 (65.4%) implants were placed in the anterior and posterior regions, respectively. Furthermore, 17.4% (12) of patients carrying 18.9% (57) of implants were smokers, and 36.2% (25) of patients affecting 40.5% (122) of implants displayed a documented history of periodontal disease.

At the prosthetic level, 85 prosthetic restorations or 1.2 prostheses per patient were delivered, with 53 patients (76.8%) receiving 1 prosthesis and 16 patients (23.2%) receiving 2 prostheses. 42.4% (36) of the delivered prostheses were full-arch prostheses, comprising 60.1% of implants in the cohort. Of the 85 prosthetic records, 13 did not report the prosthetic follow-up, reducing the number of patients and prostheses considered for the descriptive analysis at the prosthetic level to 59 and 72, respectively. Mechanical and technical prosthetic complications are summarized in Table 2 and are reported for an average follow-up time of 22.6  $\pm$  12.8 months postdelivery. The most frequent technical complication observed was screw loosening in 10 patients and 11 prostheses. The remaining technical complications occurred in 5 patients.

#### Implant Survival Rate

CSR analysis considered 301 implants in 69 patients with an average follow-up period of  $22.7 \pm 14.0$  months after implant placement. The longest follow-up period was 54.4 months. 78.8% of the placed implants had a follow-up period of at least 1 year.

The Kaplan-Meier tables and survival plots are displayed in Table 3 and Fig 4. The CSR at 54 months was 98.9% (95% CI: 96.7 to 99.6) at the implant level and 95.3% (95% CI: 86.1 to 98.5) at the patient level. A total of three implants failed over the entire follow-up period. All failures were recorded within the first 3.5 months after implant placement. The characteristics of the failed implants are reported in Table 4 and were recorded

Fig 4 (a) Kaplan-Meier survival curves at implant level (n = 301) and the corresponding number of implants at risk. (b) Kaplan-Meier survival curves at patient level (n = 69) and the corresponding number of patients at risk.



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			Patient level % (n) for $\Delta$ MBL, n = 16	Implant level % (n) for $\Delta$ MBL, n = 45	
	C	Male	56.25 (9)	57.8 (26)	
	Sex	Female	43.75 (7)	42.2 (19)	
		≥ 60	43.75 (7)	51.1 (23)	
	Age (y)	< 60	56.25 (9)	48.9 (22)	
		Unknown	0.0 (0)	0.0 (0)	
Patient factors		No	81.25 (13)	80.0 (36)	
	Tobacco use/smoking	Yes	18.75 (3)	20.0 (9)	
		Unknown	0.0 (0)	0.0 (0)	
		No	68.75 (11)	68.9 (31)	
	History of periodontal disease	Yes	31.25 (5)	31.1 (14)	
		Unknown	0.0 (0)	0.0 (0)	
	luce le station	Delayed implantation	N/A	53.3 (24)	
Recipient site	Implantation	Immediate implantation	N/A	46.7 (21)	
actors		Conventional loading	N/A	42.2 (19)	
	Loading	Immediate loading	N/A	57.8 (26)	
		Anterior maxilla	N/A	26.7 (12)	
		Posterior maxilla	N/A	35.5 (16)	
	Position	Anterior mandible	N/A	8.9 (4)	
		Posterior mandible	N/A	28.9 (13)	
		REG	N/A	57.8 (26)	
	Thread design	PX	N/A	42.2 (19)	
		Short: < 10 mm	N/A	20.0 (9)	
	Length	Conventional: ≥ 10 mm	N/A	80.0 (36)	
mplant factors		Missing	N/A	0.0 (0)	
		Narrow: 3.4 mm	N/A	28.9 (13)	
	Diameter	Conventional: 4, 4.6, or 5.2 mm	N/A	71.1 (32)	
		Missing	N/A	0.0 (0)	
		4	N/A	44.4 (20)	
	Platform diameter	4.8	N/A	55.6 (25)	
		1.5	N/A	17.8 (8)	
	Platform length	2.5	N/A	77.8 (35)	
		3.5	N/A	4.4 (2)	
	Fixed multiple presthesis	Partial	75 (12)	55.6 (25)	
	Fixed multiple prosthesis	Full-arch	25 (4)	44.4 (20)	
		CrCo	31.25 (5)	37.8 (17)	
Prosthesis		Ti	6.25 (1)	4.4 (2)	
	Material	Zi	62.5 (10)	57.8 (26)	
		Polymer	0.0 (0)	0.0 (0)	
		Missing	0.0 (0)	0.0 (0)	

N/A = not applicable.



Fig 5 Distribution of the marginal bone level change (mm) over the 45 implants in the  $\Delta$ MBL subcohort.



Fig 6 Box plot diagram of  $\Delta$ MBL per analyzed time interval subcohort. Horizontal bars designate medians. Boxes represent the second and third quartiles, and upper and lower whiskers designate the first and fourth quartiles, demarking minimum and maximum values, respectively.

Table 6         Associations Between Risk Factors and ΔMBL									
	Univaria	ate (n = 45)		Multivariate (n = 45)					
	ΔMBL (mm)	Р	P value bootstrap	ΔMBL (mm)	Р	<i>P</i> value bootstrap			
Age group (60 vs $\geq$ 60)	0.21 (-0.13 to 0.55)	.174	.212	0.33 (-0.14 to 0.80)	.164	.082			
Loading (immediate vs conventional)	-0.21 (-0.55 to 0.13)	.358	.225	-0.47 (-0.95 to 0.01)	.054	.027			
Transgingival height (1.5 vs 2.5 and 3.5 mm)	-0.01 (-0.46 to 0.45)	.641	.976	-0.18 (-0.63 to 0.28)	.446	.223			

in one male and two female patients (range: 66 to 75 years). Two of the patients experiencing implant loss were smokers and displayed a history of periodontitis.

#### ΔMBL

 $\Delta$ MBL was analyzed on a cohort of 45 implants and 16 patients and reported for an average follow-up time of 24.1 ± 11.1 months postplacement and 22 ± 10.7 months postloading. The descriptive characteristics of the cohort are reported in Table 5. Specifically, treatments of this cohort were provided by four clinicians and with an average loading time of 2.2 ± 2.5 months postplacement.

The average  $\Delta$ MBL was 0.00  $\pm$  0.57 mm, with a distribution displayed in Fig 5. Corresponding values after 11 to 12 months (12  $\pm$  0.6), 13 to 24 months (21.2  $\pm$  2.8), and > 24 months (32.9  $\pm$  8.4) postloading were 0.03  $\pm$  0.62 mm (18 implants), 0.16  $\pm$  0.56 mm (10 implants), and -0.14  $\pm$  0.52 mm (17 implants), respectively (Fig 6).

Individual univariate models did not reveal any significant association between  $\Delta$ MBL and age (P = .212), loading (P = .225), or transgingival height (P = .976).

Multivariate regression analysis did reveal a significant association between  $\Delta$ MBL and the loading protocol (*P* = .027), but not between  $\Delta$ MBL and age (*P* = .082) or transgingival height (*P* = .223) (Table 6). Specifically, immediately loaded implants displayed on average a 0.47 mm negative difference in  $\Delta$ MBL compared to conventionally loaded implants.

Associations were derived by mixed multivariate regression models with the age of the patient, transgingival height, and loading protocol as a fixed effects, and the patient as random effect.

#### DISCUSSION

The current study documented the clinical performance of a hybrid TL implant that displayed a specific platformswitched design at the crestal level of the implant. This implant design was expected to support crestal bone stability and implant survival. The retrospective analysis of patient records reported herein found a 54-month cumulative survival rate of 98.9% for the analyzed average follow-up of 20.7 months. A radiographically stable marginal bone level was measured after an average follow-up of 24.1 months postloading.

Considering the limited average follow-up time of 20.7 months, the 54-month CSRs of 98.9% at the implant level and 95.3% at the patient level observed herein are in good agreement and comparable to other studies on TL implants: 5 year-CSRs of 98.76% and 98.13% at implant and patient levels, respectively, for Kim et al<sup>11</sup>; a 5 year-CSR of 97.9% and a survival rate of 99.4% between 4 to 5 years at the implant level for Buser et al<sup>25</sup>; and a survival rate of 99% at 3 years at the implant level for French et al.<sup>26</sup> The three failed implants were lost early after implant placement, and no implant fracture was reported.

Furthermore, despite this study's limited observation time and sample size, the fact that the observed ΔMBL was close to 0 mm suggests that the transgingival implant design has a positive effect on marginal bone levels. Overall, the observed values were consistent with other retrospective studies reporting on the ability of TL implants to support crestal bone stability. Specifically, Kumar et al<sup>8</sup> reported a  $\Delta$ MBL derived from panoramic radiographs of  $-0.61 \pm 1.13$  mm and -0.93 $\pm$  0.42 mm at 1 (79 implants) and 3 years (43 implants) after implant placement, respectively. Wallner et al<sup>27</sup> reported a  $\Delta$ MBL of -0.15 ± 0.53 mm on periapical radiographs for 20 implants after a mean follow-up time of 4.9 years, and Kang et al<sup>28</sup> reported a  $\Delta$ MBL between  $-0.05 \pm 0.17$  mm after 1 year (1,585 implants) and -0.17± 0.45 mm after 9 years (198 implants), as derived from periapical and panoramic radiographs analysis. Finally, in a prospective cohort study, Bornstein et al<sup>29</sup> reported an average change of 0.15 mm observed between 3 months and 5 years after early loading. Despite the obvious limitation brought by the reduced AMBL cohort size as a result of the selection process, the final sample size of 45 remains in the same order of magnitude as these previous works.

In agreement with other reports, the most prominent mechanical or technical complication observed herein was screw loosening.<sup>30</sup> The restriction to screwretained restorations as the sole connection type analyzed within this study was particularly relevant to the outcomes, as factors like cement pollution, subgingival platform positioning, and compromised access for maintenance that may negatively impact  $\Delta$ MBLs and implant survival when applying alternative connection types could be excluded for the analyzed cohort.<sup>31</sup>

The current study further suggested a negative impact on  $\Delta$ MBL after immediate loading compared to delayed loading protocols, with the immediately loaded implants showing an average of 0.47 mm less bone gain or more bone loss compared to conventionally loaded counterparts. These results contrasted with recent systematic reviews by Suarez et al<sup>32</sup> and Sommer et al,<sup>33</sup> who have failed to identify a systematic effect of the timing of restoration on marginal bone level<sup>32</sup> and reported a significantly higher marginal bone loss for conventional loading protocols compared to immediate, immediate nonocclusal, early loadings 1 year after implant placement.<sup>33</sup>

Also, the current study failed to show an effect of age or transgingival height on  $\Delta$ MBL, which is contrary to previous preliminary results studying the same implant type.<sup>20</sup> These differences may be attributed to the radiographic assessment methodology used and different baseline settings for the studies. Specifically, Fillion et al<sup>20</sup> assessed marginal bone levels during a period of 2 to 6 months after implant placement, while this study reported on the  $\Delta$ MBL after significantly longer periods by using the time of loading as the baseline timepoint. Therefore, the results presented here may better represent the possible postloading physiological changes of marginal bone levels around this specific implant type after being put into function.

A further important aspect of this study was the use of an improved methodology for  $\Delta$ MBL assessment, which was based on strictly selected periapical radiographs with sufficient resolution. Specifically, the ΔMBL analysis was based on 45 implants placed by four implantology specialists as part of partial to full-arch prosthetic restorations. In contrast to traditional methods, the applied methodology determined the first bone contact based on software digital radiographic gray level profiles. This addressed a major source of error related to the capability to distinguish neighboring gray levels via visual observation (law of simultaneous contrast<sup>34</sup>). Compared to the original methodology introduced by Weber et al,<sup>24</sup> the presented methodology used standardized calibrated gray level profiles and was, unlike human visual evaluation, not biased by intrinsic

differences between individual radiographs, like the visual acuity, lighting, and magnification. Further, the applied method compensated for the angulation error of the radiographic images or the absence of bone walls as much as possible by identifying the presence of four bone walls based on calibrated radiographic gray level values. Finally, substantial efforts were put into the calibration of the examiners to prepare for the radiographic assessment, and future research may address the robustness of the presented methodology towards angular variations during the radiography.

Finally, although the methodology for measuring  $\Delta$ MBL on two-dimensional images has certain known limitations,<sup>35</sup> the high radiographic resolution and the absence of artifacts on periapical radiographs, unlike three-dimensional CBCT or CT measurements, confirm its usefulness as a technique of choice. Future improvements in the methodology may automate the evaluation process or apply machine learning algorithms to analyze the bone level around implants more quickly and easily, as demonstrated in similar applications around teeth.<sup>36</sup>

Another important aspect of the presented study was related to retrospectively analyzing the patient records of real-world routine treatment outcomes, which differs from the standardized set-up encountered in long-term or large retrospective cohort studies traditionally reported in the scientific literature.<sup>11,25,37,38</sup> French et al<sup>39</sup> recently re-emphasized the importance of these real-world implantology data to document the "real life" performance of dental implants over time. Although retrospective designs may be classically limited in determining the direct cause and effect relationship between treatment outcomes and interventions, they may be well suited to determine the event rates in conventional dental implant therapies. This retrospective multicenter cohort study collected patient records from 23 private practices and analyzed real-world data, overcoming potential biases of more controlled setups.<sup>40</sup>

One of the limitations of the presented study of  $\Delta$ MBL may be related to the small number of implants. This number only allowed for consideration of the impact of age, transgingival height, and loading procedure as potential risk factors as part of the univariate and multivariate analysis, while immediate implantation<sup>41</sup> (representing 46.7 % of the cases herein), additional bone surgery,<sup>42</sup> or the angulation of abutments<sup>30</sup> may represent other potentially interesting characteristics reported to impact  $\Delta$ MBL. Prospective studies with large samples and long-term observational periods may complement the presented real-world retrospective data.

#### CONCLUSIONS

The high cumulative survival rates and stable marginal peri-implant bone levels found in the current study support recent TL implants with a hybrid design as a suitable treatment option for restoring partially or fully edentulous patients, with a good mid-term prognosis. The retrospective design and the small sample size for the evaluation of the  $\Delta$ MBL outcome reported herein should be complemented by future prospective studies, ideally in a multicentric real-world setup.

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