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Clinical and radiographic performance of late placed and early loaded dental implants with a conditioned hydrophilic surface in posterior mandible sites: A prospective case series with an 8.5- to 9.5-year follow-up

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Abstract

Objective: To assess the clinical outcomes by means of implant and prosthetic survival of late placed and early loaded implants with a hydrophilic, moderately rough surface for partially edentulous patients after a follow-up of 8.5 to 9.5 years.

Materials and methods: A prospective case series study involving 15 patients with single, late placed and early loaded implants in the posterior mandible was performed. Clinical and radiographical parameters, including biological and technical complications and patient satisfaction, were assessed.

Results: From an initial sample of 15 patients, 12 were included. A total of 16 implants were observed. After a mean follow-up of 9 years and 7 months (SD ± 3.8 months), implant success and survival rate were 100%. The prosthetic survival rate was 100%, and the prosthetic success rate was 93.8% since a major chipping was observed. No biological complications were observed, and the mean modified plaque index was 0.03 (SD ± 0.09) with a mean probing pocket depth of 2.95 mm (SD ± 0.09). A mean marginal bone level (MBL) of 0.04 mm (SD ± 0.88) and a mean VAS of 9.42 (SD ± 0.90) for patient satisfaction were recorded.

Conclusion: Late placed and early loaded implants with a moderately rough endoseal surface are a reliable option for rehabilitating partially edentulous patients. An implant survival rate of 100% and a prosthodontic success rate of 93.8% were observed. Patient satisfaction scores were high and peri-implant hard and soft tissues remained healthy. The study findings should be carefully interpreted because of the small sample.

KEYWORDS
dental implant, early loading, hydrophilic implant surface, implant crowns, late implant placement

Summary box

What is known

Early-loaded implants are a well-established reliable treatment option for the rehabilitation of partially edentulous patients; however, there is a lack of evidence for successful long-term outcomes of implants with hydrophilic, moderately rough surface.

What this study adds

This prospective case series study does provide long-term data on the reliability of implants with hydrophilic, moderately rough surface implants late placed and loaded after 21 days of healing, revealing high implant success rate, stable MBL, patient satisfaction, and healthy peri-implant health.

1 | INTRODUCTION

Implant-supported fixed dental prostheses (FDP) are considered a reliable and safe treatment option after tooth loss with high, mid-, and long-term success rates.[1,2] For patients qualifying for dental implant placement, bone formation and a predictable bone-to-implant contact at the hydrophilic, moderately rough implant surface are crucial for successful osseointegration.[3] In addition to adequate bone formation, good marginal bone level (MBL) maintenance and a healthy peri-implant mucosa with proper hygiene recall compliance are key factors to guarantee a favorable long-term prognosis.[4,5] In the past, implant therapy often required extended periods of 6–12 months before the final restoration was delivered due to less effective implant surfaces exhibiting a rather hydrophobic and smooth implant surface.[3,6] However, over the previous two decades, there has been an increased demand for shorter treatment times by patients and clinicians alike.[3,6] To address this issue, additive and subtractive implant surface modifications were developed to improve the osteointegration process.[6–8]

Although roughness and moderately rough surfaces show improvements in the quantity and speed of direct bone apposition during the healing process relative to smooth surfaces,[9,10] it has been reported that additive, moderately rough implant surface topography presents greater bone-to-implant contact relative to rough topography.[9] One of the most frequently investigated subtractive surface modifications is sandblasting with large particles, followed by acid etching in a bath of HCl/H_2SO_4.[10,11] Although SLA surfaces have been reported as the standard moderately rough surface due to their excellent long-term clinical outcomes,[10,12,13] not all the rough surfaces presented the same results.[14] For example, modifications such as titanium plasma-sprayed (TPS) surfaces showed higher failure rates.[8] Considering these limitations, further chemical modifications were developed[15] to achieve faster and improved bone healing during the initial implant treatment steps, such as increasing the surface energy of hydrophilic implants, leading to enhanced protein adhesion and osteoblast maturation.[16,17] In this sense, using these surfaces may be compatible with immediate or early loading scenarios.[3,12] Among others, a hydrophilic surface (INICELL, Thommen Medical) has been reported as a reliable option in previous studies.[18,19] This surface is based on an intraoperative chemical conditioning of a sandblasted and thermally acid-etched surface to achieve superhydrophilic surface properties using a dedicated device (APLI-QUIQ) with 0.05 M NaOH solution (pH 12.4).[20,21] This process preserves the implant structure and topography while significantly increasing its surface energy and wettability.[22]

Although early loading of implant reconstructions and implants with hydrophilic surfaces has previously been evaluated, there is a lack of evidence for successful long-term outcomes (i.e., longer than 5 years) for implants with hydrophilic, moderately rough surface implants late placed and loaded after 21 days of healing.

Therefore, the present prospective case series study aimed to evaluate the clinical performance and patient satisfaction of late placed and early loaded implants with a hydrophilic, moderately rough surface for partially edentulous mandibles after a follow-up of 8.5–9.5 years. The null hypothesis was that no significant difference would be found regarding clinical performance and patient satisfaction in comparison with previous study follow-up.

2 | MATERIALS AND METHODS

2.1 | Study design and patients

A prospective observational single-center study, registered in clinicaltrials.gov (Identifier: NCT06138392), and approved by the Cantonal Ethics Committee (KEK-Nr.2020-00782) following the Declaration of Helsinki of ethical principles for medical research involving human subjects was conducted at the Department of Reconstructive Dentistry and Gerodontology at the University of Bern. The manuscript was organized according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[23] The previous results of this prospective study were reported after 6-month and 3-year follow-up visits.[21,22] Patients were contacted and invited to attend a clinical re-examination. Written informed consent was obtained from all patients after an explanation of the study's objectives and a discussion of arising questions. The original eligibility criteria were as follows:

- Inclusion criteria:
  - Individuals between the ages of 18 and 75 years (inclusive).
  - Partially edentulous patients with missing teeth in the posterior mandible (positions 34–37 and 44–47) and a healed site at least 4 months after tooth extraction.
  - Patients with physical status 1 or 2 according to the American Society of Anesthesiologists Classification System.
  - Inadequate native bone quality and quantity to place implants with a diameter of ≥4.0 mm.
  - Removable prosthesis or complete dentures in the antagonizing dentition.
- Exclusion criteria:
  - Patients with compromised general health contraindicating surgical intervention.
  - Presence of conditions requiring chronic routine prophylactic or prolonged use of antibiotics.
  - Heavy smokers (exceeding 10 cigarettes/day or equivalent) and chewing tobacco users.
  - Pregnancy or childbearing potential with a positive urine pregnancy test.
  - Insufficient oral hygiene, untreated periodontitis (any residual pockets >4 mm), or persistent intra-oral infection.
  - Mucosal diseases such as erosive lichen planus.
  - Patients with severe bruxism or clenching habits.
  - Unwillingness to participate in the study.
- Local exclusion criteria:
  - Patients with augmented bone at the implant site.
  - Pathologic processes at the implant site.
  - Insufficient primary stability (ISQ <70) of at least one implant during the surgery.

2.2 | Surgical and reconstructive phase

The present study evaluated screw-shaped titanium self-tapping dental implants with a super hydrophilic endosseal surface (sandblasted and thermal acid etched) and a 1 mm machined collar (ELEMENT RC INICELL, Thommen Medical). The implants were placed after a minimum 4-month healing period (late placement protocol)[24] following dental extraction, verifying that sufficient bone width of ≥5.5 mm (including simultaneous or staged horizontal bone augmenting procedures) and 2 mm of keratinized mucosa were present before implant placement. Implant surgeries were performed by two independent and calibrated oral surgeons placing the implants according to a standard single-stage procedure (non-submerged) under local anesthesia. Preoperative antibiotic prophylaxis based on amoxicillin combined with clavulanic acid (2 g Aziclav; Spirig HealthCare AG, Egerkingen, Switzerland) was administered 2 h before the surgeries.

The implants were placed following a standardized and calibrated surgical protocol, preparing the implant bed according to the manufacturer's instructions. Immediately before implant placement, the implant surface hydrophilization was performed by a conditioning procedure following the manufacturer's guidelines and including implant wetting with a 0.05 M NaOH solution, pH 12.4 using a dedicated applicator (APLIQUIQ; Thommen Medical AG).[22] Once the surgical bed was prepared, the microroughened implant surface border was placed slightly subcrestally (∼0.5–1.0 mm). The implant stability was assessed through ISQ measurement (Osstell, Gothenburg, Sweden). Before flap closure, a screw-retained impression coping was connected to the implant. After visually checking its fit, the coping was bonded to the surgical stent with a resin material (GC Pattern Resin LS; GC Corporation) to transfer the implant position to an initial study model using an altered cast technique. Next, a provisional screw-retained reconstruction was fabricated. Individualized bite blocks were generated, and standardized radiographs were taken after connecting the healing abutment and closing the wound. Standard postoperative instructions were given for 2 weeks (rinse with 0.12% chlorhexidine mouthwash for 1 min, three times daily).[25] After 21 days of healing, 3 ISQ measurements were performed; once values of ≥70 were obtained, screw-retained provisional acrylic reconstructions with a prefabricated titanium abutment were inserted and torqued to 15 N cm, with at least one occlusal contact to the opposing dentition tested with the use of Shimstock occlusion foil (Coltene/Whaledent, Langenau, Germany), following a late early loading protocol. All implants were loaded following an early loading protocol[24] upon satisfying the following criteria:

- ISQ ≥70 (mean of 3 measurements)
- Absence of implant mobility
- Soft tissue conditions which did not preclude or render proceeding with placement of the provisional restoration unadvisable
- Absence of pain or severe discomfort on palpation of the soft tissue and implant during removal of the healing cap or mobility testing.

The provisional reconstructions were replaced at the 6-month follow-up with a final screw-retained reconstruction was delivered.

2.3 | Clinical evaluation

The previous follow-up examinations were performed at baseline (day 0), upon occlusal loading (day 21), and at 1, 3, 6, 12, and 36 months. The present 120-month follow-up was assessed by a calibrated and independent clinician (M.F.) from September 2020 to September 2021, who was not involved in any of the previous treatments. The appointments included a clinical and radiographic examination, digital photographs, and a patient satisfaction questionnaire.

The present study assessed implant and prosthetic survival rates within the included patients. Survival was classified as the continued presence of both the implant and reconstruction during the re-examination appointment. Implant success was classified as the absence of persisting subjective discomfort such as pain, foreign body perception and or dysesthesia (i.e., painful sensation), lack of recurrent peri-implant infection with suppuration, absence of implant mobility on manual palpation, and absence of any continuous peri-implant

radiolucency. Prosthetic success was defined as the absence of technical complications without needing any reconstruction repair. A visual exploration of each implant and reconstruction was performed with 2.5× magnification loupes (Swiss loupes) to detect any biological and technical complications following the definitions reported at the 4th Consensus Conference of the International Team for Implantology.[26]

During the clinical follow-up appointments, peri-implant health was evaluated based on the parameters reported by Berglundh et al. using a modified plaque index (mPI),[27] modified sulcus bleeding index (mSBI),[28] and probing pocket depth (PPD). All parameters were evaluated mesially, distally, buccally, and orally relative to the implant site using a periodontal probe (HH12 periodontal probe, Deppler SA). The peri-implant health was evaluated according to the recommendations described by Herrera et al.[29] The average mean values were included for downstream statistical analysis. In addition, a visual inspection of the mucosa was performed for signs of food impaction and the presence of fistulae trauma and discolorations. Patient satisfaction was evaluated using a visual analogue scale (VAS).

2.4 | Radiological evaluation

To assess MBL and implant-crown fit, a standardized digital periapical radiograph was taken at implant placement, upon loading (after 21 days), and at the scheduled follow-up visits (1, 3, 6, 12, 36, and 120 months). For this purpose, individualized film holders (Extension Cone Paralleling, Dentsply Rinn) with a polymethyl methacrylate resin index (GC Pattern Resin, LS GS Corporation) were used during examinations. The MBL evaluation consisted of mesial and distal crestal MBL measurements as the distances between the implant shoulders and the marginal bone level, with the implant axis and the first bone-to-implant contacts as landmarks. Once the radiograph was taken, an independent and calibrated examiner (P.M-M.) performed a radiological linear evaluation using ImageJ's image analysis software (ImageJ, National Institutes of Health, version J64). The examiner calibration was performed using random blinded radiographs under the supervision of a senior investigator (M.F.).

2.5 | Study outcomes

The primary outcome of this study was to evaluate the implant/prosthetic survival and success after 10 years of function. Secondary study outcomes included peri-implant health, radiological, and patient satisfaction evaluation.

2.6 | Statistical analysis

A descriptive analysis of continuous variables (mean, standard deviation, range, median, and quartiles) and categorical factors (absolute and relative percentages) was performed. In addition, a non-parametric Brunner–Langer model for longitudinal data was conducted to study parameter changes over time. An ANOVA type-test statistic (ATS) was used to estimate primary effects with a temporal component. Multiple comparisons between time points were adjusted using Bonferroni's criteria. The significance threshold used for analysis was set at 5% ($\alpha = 0.05$). The statistical analysis software SPSS was used to perform all analyses (SPSS v25.0; IBM, Armonk, NY, USA). An ATS test reached power at 79.3% to detect a medium effect size ($f = 0.25$) at differences in one parameter over time as significant with confidence at 95%.

3 | RESULTS

In this study, 12 patients from the initial cohort of 15 were included (Table 1). The other three patients were contacted, but they could not attend the clinical evaluation. Further information regarding patient eligibility has already been published.[21,22]

3.1 | Clinical evaluation

The implants were in service for a mean time of 9 years and 7 months (SD ± 3.8 months, min: 8 years and 6 months, max: 9.5 years and 6 months, Figures 1 and 2). At the present follow-up, all 16 implants remained functional and presented no complications; therefore, implant survival and success rates were 100%. Regarding the prosthetic restorations, all restorations were still in place and functional, resulting in a 100% prosthetic survival rate. Nevertheless, one major chipping event was observed after 110 months in a 6.0–9.5 mm implant, and the issue was resolved with a new restoration. Therefore, the prosthetic success rate was 93.8% (Figure 3).

No biological complications were observed. The mean mPI was 0.03 (SD ± 0.09) and the mean PPD was 2.95 mm (SD ± 0.09). These values were significantly smaller than the earlier observation points ($p < 0.001$). The mean mSBI was 0.31 (SD ± 0.30) and was statistically significant relative to the 6-month value ($p < 0.020$). Finally, no fistulas, trauma, discoloration, or food impaction were reported.

3.2 | Radiographical evaluation

Mean MBL reached its maximum value in 3–6 months, showing a reduction after that.

At the 12-months follow-up, the mean MBL was 0.99 mm (SD ± 0.48), with a median of 0.91 mm. The results of the radiographic measurements between the implant shoulder and bone crest at the present follow-up showed a mean MBL of 0.04 mm (SD ± 0.88), with a median of 0.14 mm (IQR: −0.80 0.78), which was significantly lower than the 6-month measurement ($p = 0.002$). The changes in MBL are illustrated in Figure 4.

TABLE 1 Demographic data of the patients and implant reconstructions.

Patients			
Total		12	
Gender			
Male		7	
Female		5	
Age			
Range		40–75 years	
Mean		60.3 years (SD ± 11.95)	
Implants			
Total		16	
Patient number	Implant position	Implant width/length	Type of restoration
1	36	5.0–8.0	Titanium abutment-lithium disilicate
	45	4.5–8.0	
	46	4.5–8.0	
2	46	6.0–11.5	Metal-ceramic
3	46	6.0–9.5	Metal-ceramic
4	36	4.5–8.0	Metal-ceramic
5	46	6.0–9.5	Metal-ceramic
6	36	6.0–8.0	Metal-ceramic
7	36	4.5–9.5	Metal-ceramic
8	36	4.5–8.0	Metal-ceramic
	46	4.5–8.0	Metal-ceramic
9	45	4.5–9.5	Metal-ceramic
10	34	4.5–9.5	Metal-ceramic
	36	6.5–8	Metal-ceramic
11	46	4–11.5	Metal-ceramic
12	46	4–11.5	Metal-ceramic

3.3 | Patient satisfaction

Patient satisfaction remained constant since the 6-month assessment and showed no statistically significant changes across longitudinal observation points ($p = 0.868$). The mean VAS value at this follow-up was 9.42 (SD ± 0.90), with a median of 10 (IQR: 9–10; Figure 5).

4 | DISCUSSION

The present study aimed to prospectively report long-term outcomes of late-placed and early-loaded (21 days after placement)[24] implants with an intraoperatively conditioned, hydrophilic, moderately rough surface in posterior sites for partially mandibular edentulous patients using clinical performance and patient satisfaction. All implants were clinically stable after a mean duration of 9 years and 7 months in function, showing this treatment option to be safe and reliable. The present study is, to the authors' knowledge, the most extended follow-up period of this specific implant surface reported to date. The included implants presented a survival and success rate of 100% with stable and healthy peri-implant tissues. These findings agree with similar studies included in a recent systematic review on INICELL (Thommen) hydrophilic implant surfaces, reporting survival rates of 94.6%–100.0%.[19]

Over the past two decades, moderately rough implant surfaces have been established as a safe and successful option and are currently considered the gold standard surface due to their capability to accelerate the process of osseointegration.[12,13] In addition, hydrophilic surfaces have proven that chemical changes in the surface energy may lead to faster bone healing.[15–19] The findings of this study confirm that dental implants with hydrophilic surfaces show favorable stability and healthy peri-implant conditions in the long term.

Considering the assessed biological parameters, the plaque index evaluation showed good outcomes with a progressive reduction from 3 months post-loading. At the present evaluation, only two sites in different patients showed a positive value in the plaque evaluation. In addition, the bleeding index reached its maximum value at 6 months, showing a reduction after that visit. The median bleeding index was 0.25 (IQR: 0.00–0.50), significantly lower than the 6-month measurement. PPD also reached its maximum value at 6 months and showed a reduction afterward. This report considers the obtained values favorable, since the median PPD was 2.75 mm (IQR: 2.50–3.13),

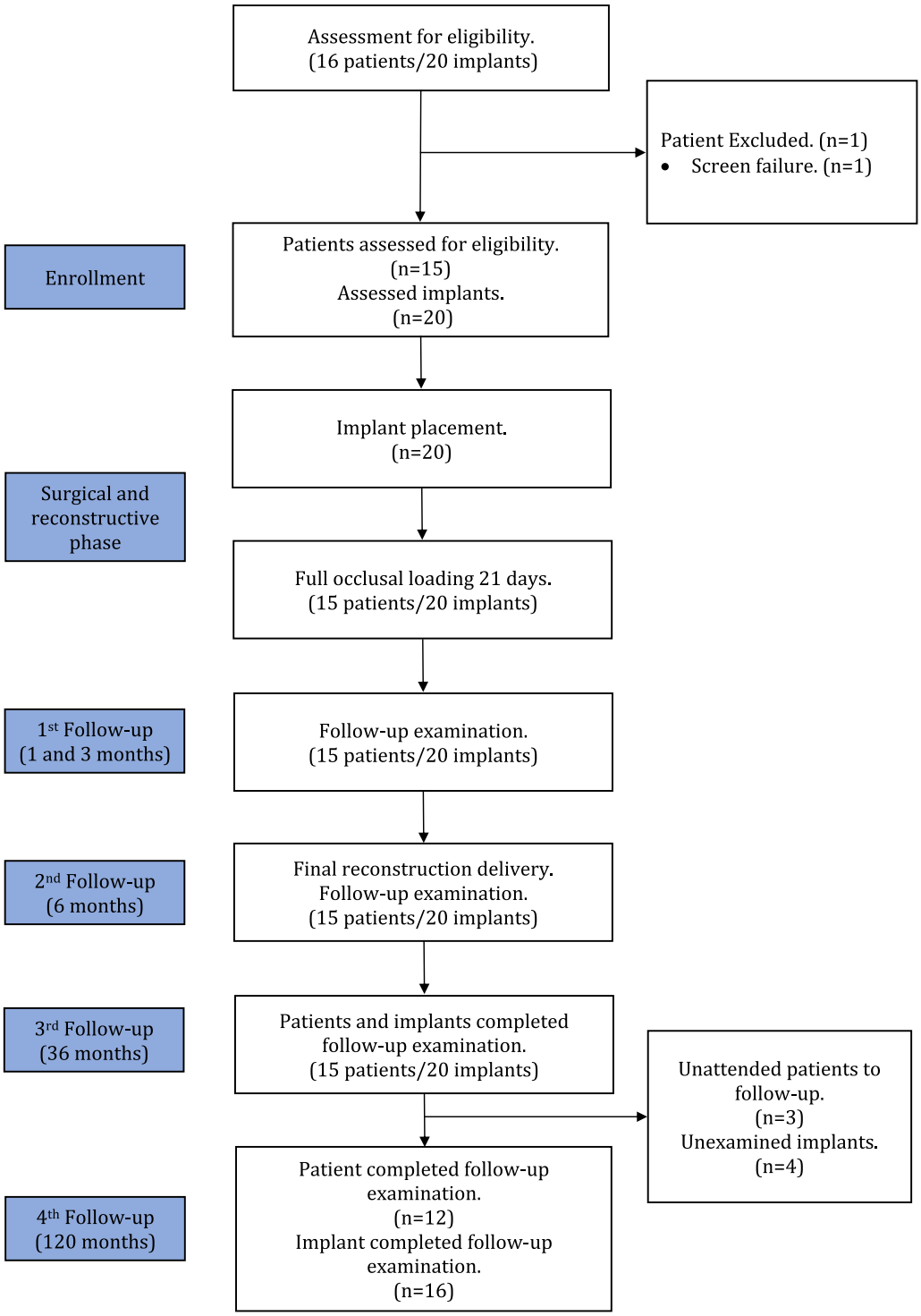


FIGURE 1 Flowchart of the study design and follow-up process.

significantly lower than at any other timepoint. One possible explanation for such favorable results may be that patients followed the recommended systematic supportive implant therapy, demonstrating the effectiveness of this protocol, as no signs of peri-implant disease were reported over a 10-year follow-up period. These results are in agreement with similar long-term studies.[30–35]

The maintenance of the MBL is essential to ensure stable and favorable peri-implant soft and hard tissues. Notably, the implants were placed 0.5–1 mm below the crestal bone level, and the implant design had a machined neck height of 1 mm.[21,22] In this sense, some non-pathological marginal bone loss was to be expected due to initial remodeling during the osseointegration process, in which bone-

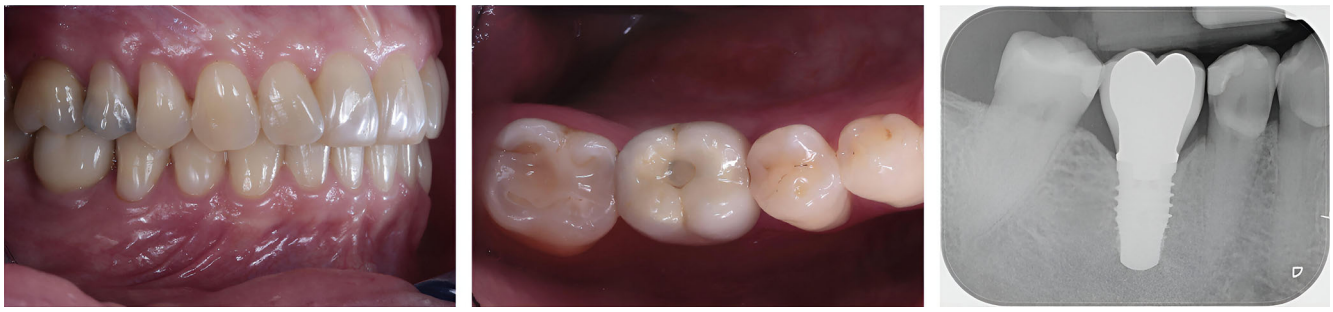


FIGURE 2 Clinical situation of patient number 9; porcelain fused to metal screw-retained implant crown showing clinical and radiological stable conditions.

FIGURE 3 A major chipping in one restoration was observed; a new implant restoration was manufactured to resolve the issue.

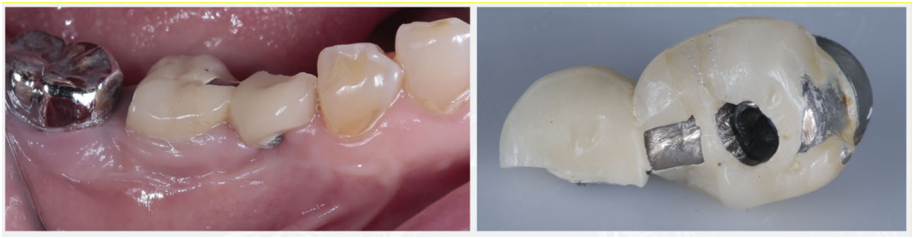
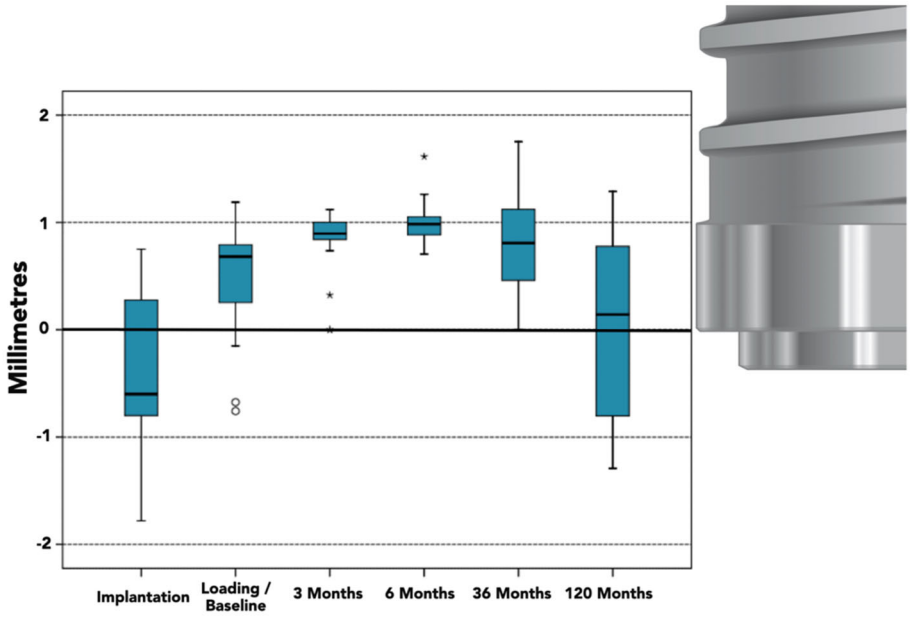


FIGURE 4 Boxplot showing radiographic MBL changes across follow-up time points.



to-implant contact was always within the mentioned limits, as previously reported.[31–34] The mean MBL reached its maximum value at 3–6 months in the present cohort, showing a subsequent reduction with a marginal bone loss of 0.76 mm after 36 months.[21] Finally, at the last follow-up (9 years and 7 months), the median marginal bone loss was 0.14 mm (IQR: −0.80 0.78), significantly lower than the 6-month and 36-month measurements. Considering the present marginal bone level evaluation, the reported results are similar to those observed in studies on hydrophilic implant surfaces. Nevertheless, most studies evaluated MBL in the short and medium terms (at 6, 12, or 24 months).[19,34]

Considering technical complications, it should be mentioned that a polishable minor chipping was reported in the previous 3-year follow-up study.[21] The present follow-up reported one major chipping after 110 months, which required the fabrication of a new reconstruction. This study observed fewer technical complications than expected from the data of systematic reviews on technical complications of fixed implant-supported reconstructions, which report an incidence of 2.9%–25.5% chipping of the veneering ceramic of metal-ceramic reconstructions after 5 years[1,36,37] a prosthetic survival rate of 89.4% after 10 years of function.[38]

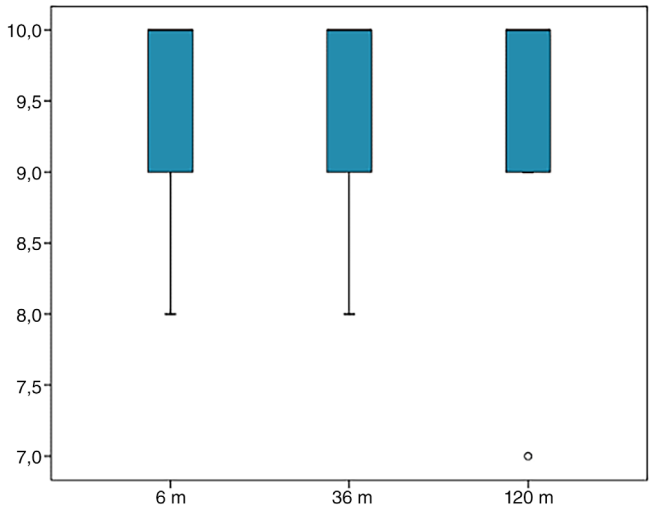


FIGURE 5 Boxplot of patient satisfaction (VAS-value). The median level of satisfaction was 10 (IQR: 9–10) at the present follow-up.

Considering the reconstructive phase, the presented workflow can be regarded as predictable due to the favorable reported outcomes. It can be adapted to current digital workflow trends, allowing the final reconstruction to be manufactured faster and more economically affordable.[39]

The median level of patient satisfaction was 10 points (IQR: 9–10) at the 10-year follow-up visit, showing stable values since the 6-month follow-up.[22]. Similar studies also reported high patient satisfaction with implant restorations in partially dentated arches.[40–42]

Considering the strengths and limitations of this study, despite its relatively small sample, the reported long-term data can provide valuable information regarding the use of dental implants with intraoperatively conditioned hydrophilic surfaces in an early loading scenario. The presented outcomes should be carefully considered since the limited sample may not guarantee that the reported cohort is sufficiently representative. In addition, being a single-arm study, the lack of a control or comparison group with late loading and machined or rough surface implants limits the interpretation of the reported data. Therefore, further randomized clinical trials with larger populations are needed to confirm the results of this study.

5 | CONCLUSION

Early-loaded implants with a moderately rough endosseal hydrophilic surface are a reliable option for rehabilitating the posterior mandible in partially edentulous patients after 9 years of function. An implant survival rate of 100% and a prosthodontic success rate of 93.8% were observed. Patient satisfaction scores were high and peri-implant hard and soft tissues remained healthy. The study findings should be carefully interpreted because of the small study sample.

AUTHOR CONTRIBUTIONS

Pedro Molinero-Mourelle was involved in the analysis and collection of data, article draft, writing and critical revision of the manuscript, and approved the final version of the manuscript. Martin Schimmel was involved in the concept and design of the study, critical revision of the manuscript, and approved the final version. Fiona Alena Forrer was involved in the concept and design of the study and approved the final version of the manuscript. Stefan Paul Hicklin was involved in the concept and design of the study, data analysis, critical revision of the manuscript, and approved the final version. Clemens Raabe was involved in the article draft, writing and critical revision of the manuscript, and approved the final version of the manuscript. Vivianne Chappuis was involved in the concept and design of the study and approved the final version of the manuscript. Manrique Fonseca was involved in the data collection, analyzed and interpreted data, drafted the article, and approved the final version of the manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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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