

Clinical Study with Gradually Anodized Implants Restored with Two-Piece Anodized Abutments – 1-Year Results

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Introduction

Surface chemistry and topography of the implant-abutment complex play a key role in implant osseointegration and proper adhesion of the soft tissue to the restoration.¹ To optimize tissue integration at every level, novel anodized implant and abutment surfaces were developed. The implant surface has a gradual change in topography designed to promote early osseointegration and support stable marginal bone, while the new surface at the tissue-level base promotes undisturbed mucointegration.² This study aims to evaluate the clinical performance of these new implant and abutment surfaces after 3 years of function.

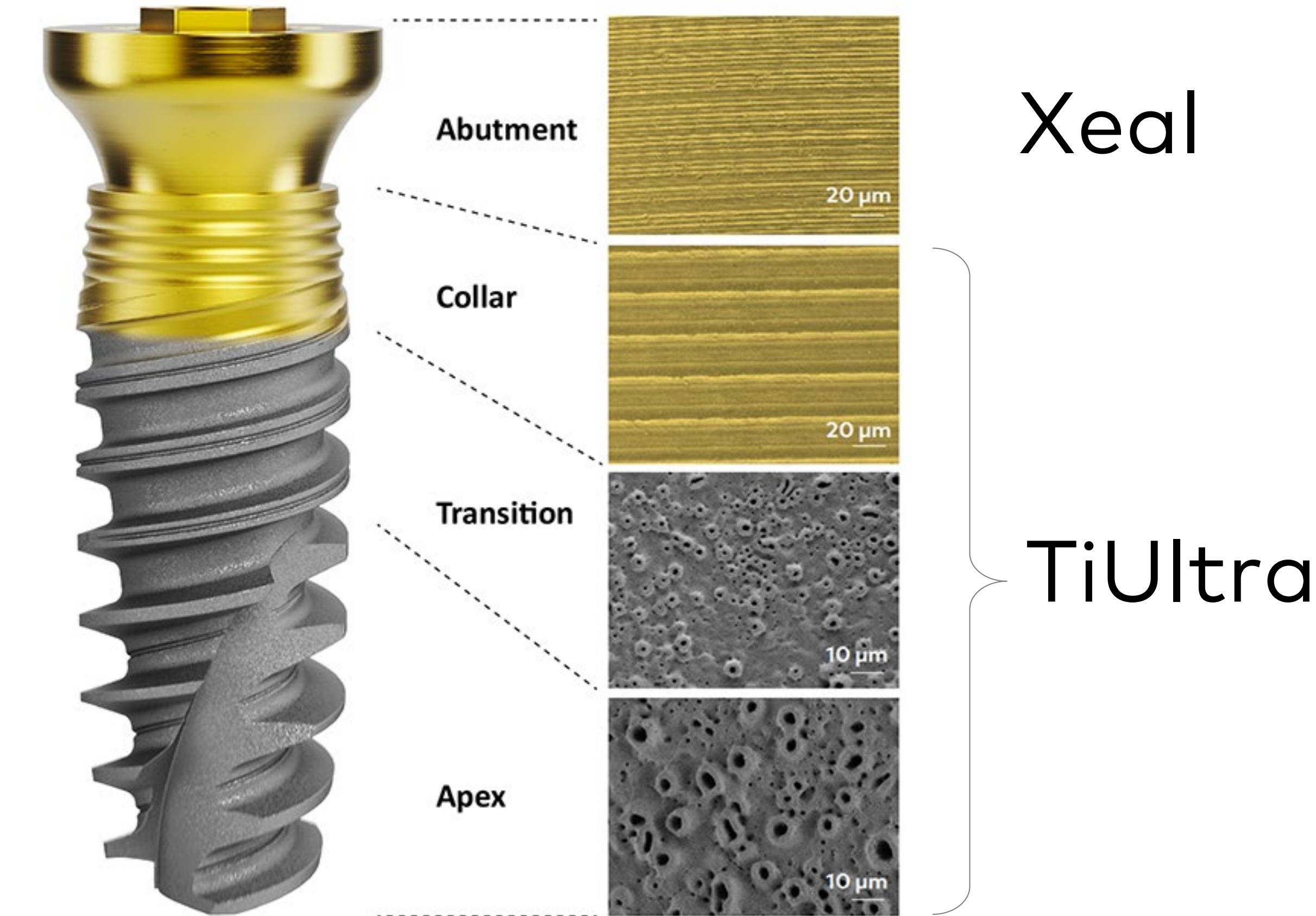


Figure 1. Implant system with the newly engineered TiUltra and Xeal surfaces (left) and low magnification SEM images of the surfaces at indicated regions (right).

Materials and methods

This prospective, open single-center study enrolled patients requiring **one single tooth** replacement in the premolar or molar area in either jaw. Variable thread tapered implants with gradual anodized surface (NobelActive TiUltra; Nobel Biocare AB, Göteborg, Sweden) were placed in healed sites, and an abutment base with anodized surface (On1 Xeal, Nobel Biocare AB) was immediately attached to the implant and connected to a healing cap. Digital impressions were taken on the day of surgery, while the final prosthesis was placed 4 months later. The outcome measures in this interim analysis include implant survival and success, marginal bone remodeling, and soft tissue health assessments by 1-year follow-up. Data analysis was performed with SPSS v25 (IBM, Armonk, USA).

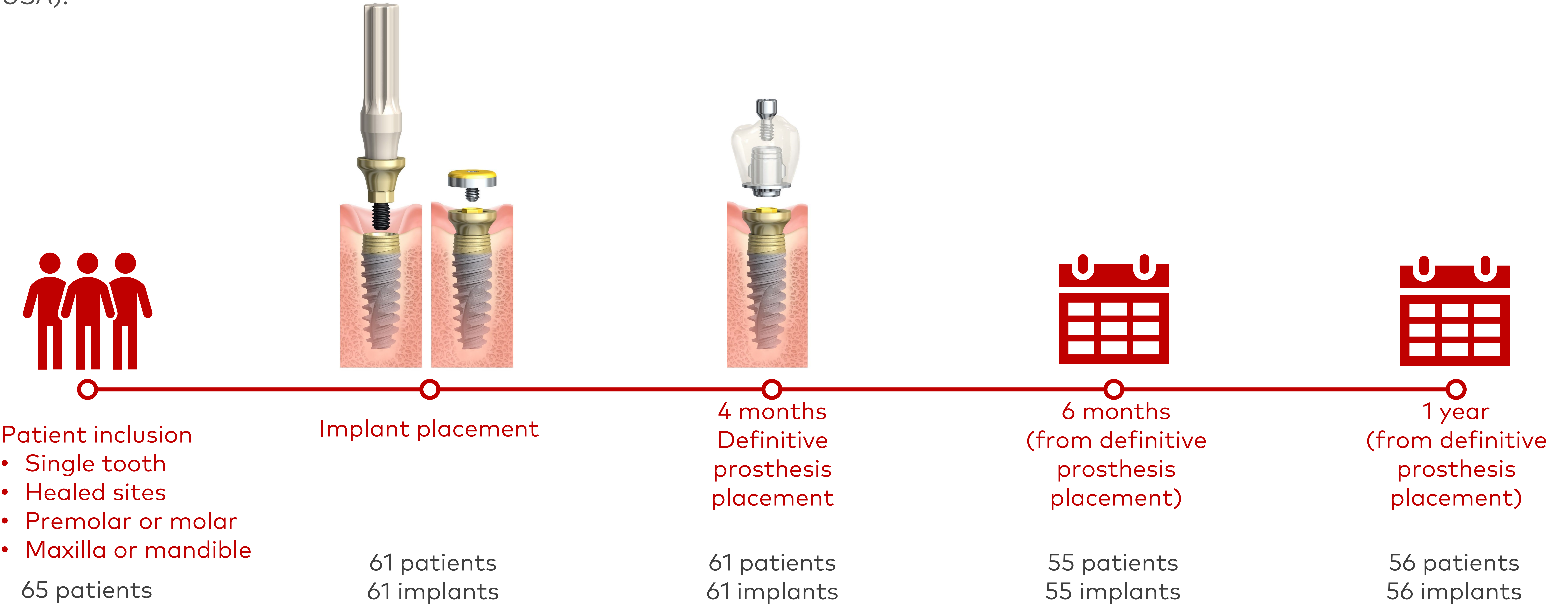


Figure 2. Study flow-chart with the number of patients and implants available at each visit.

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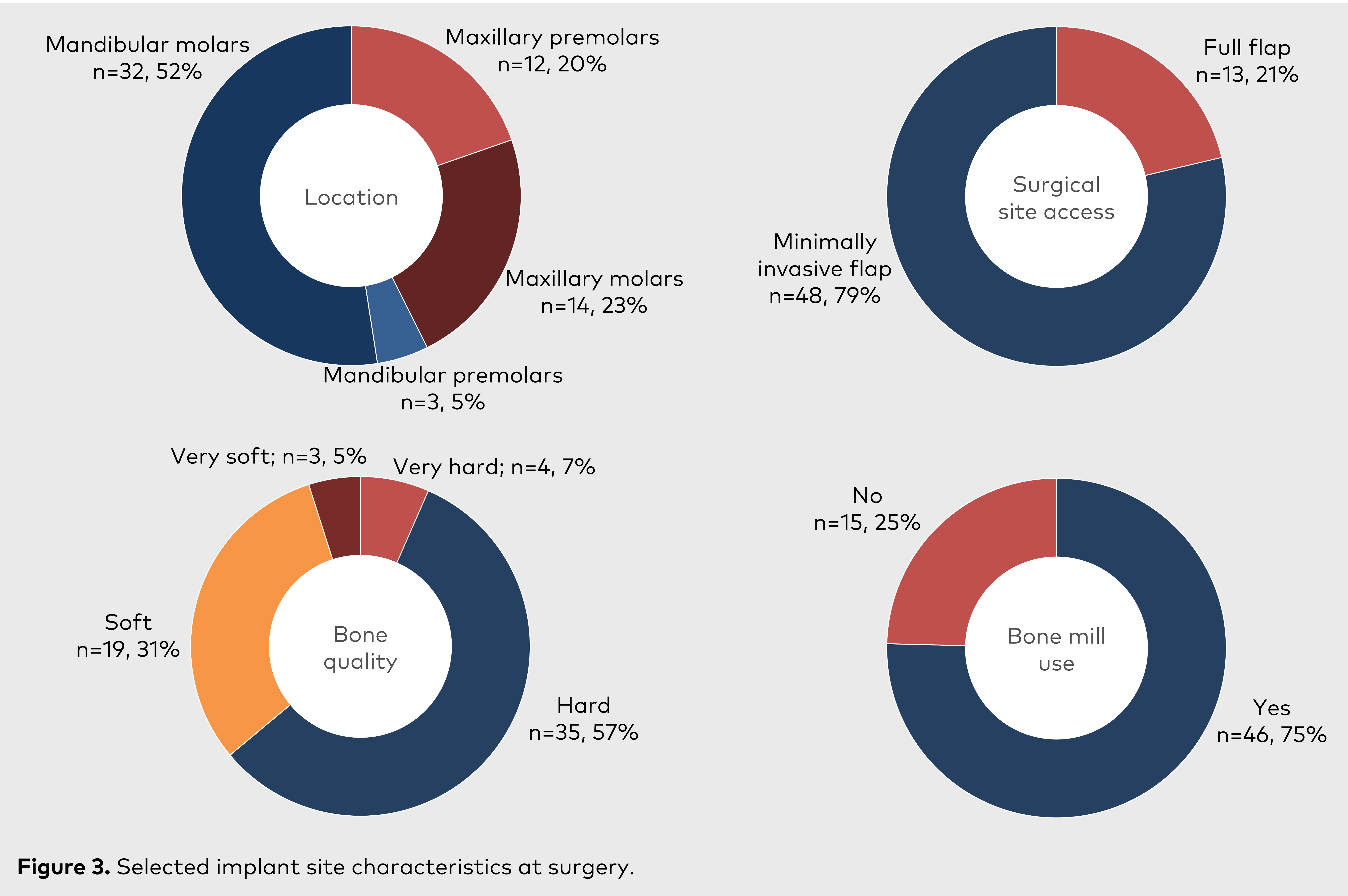
Results: Baseline characteristics

The study included 61 patients, who received 61 implants. Baseline characteristics of the patient population are listed in Table 1.

Table 1. Baseline patient characteristics (n=61 patients)

Patient characteristics		n (%)
Gender	Female	30 (49.2%)
	Male	31 (50.8%)
Age (mean ±SD; range) (in years)		51.4 ±12.6 (28-85)
Smoking status	Current smoker	13 (21.3%)
	Former smoker	18 (29.5%)
	Never smoker	30 (49.2%)
Relevant medical history	Parafunctional tendencies	8 (13.1%)
	History of periodontitis	6 (9.8%)

- Surgical characteristics:
- Mean implant insertion torque was 58.2 ±12.5 Ncm (n=61).
 - Soft tissue grafting was performed at one site.
 - Selected surgical site characteristics are shown in Figure 3.



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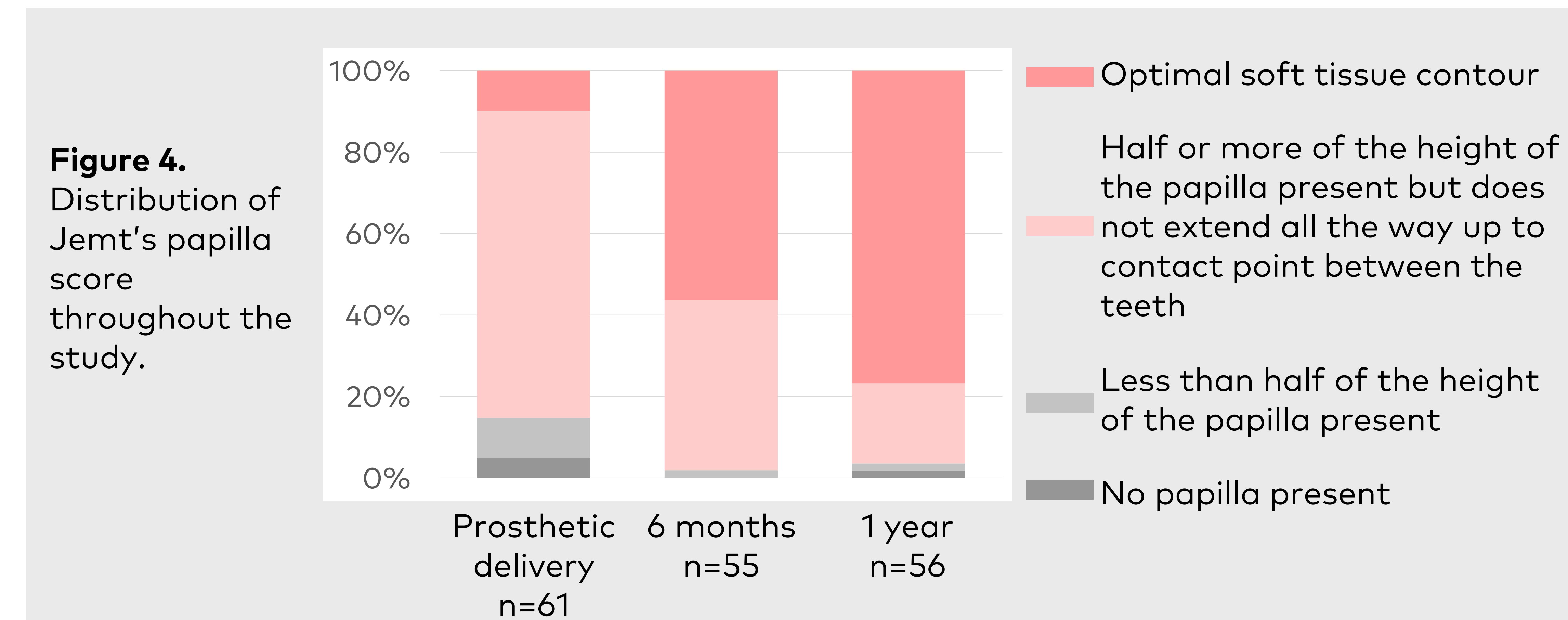
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Results: Final prosthesis delivery

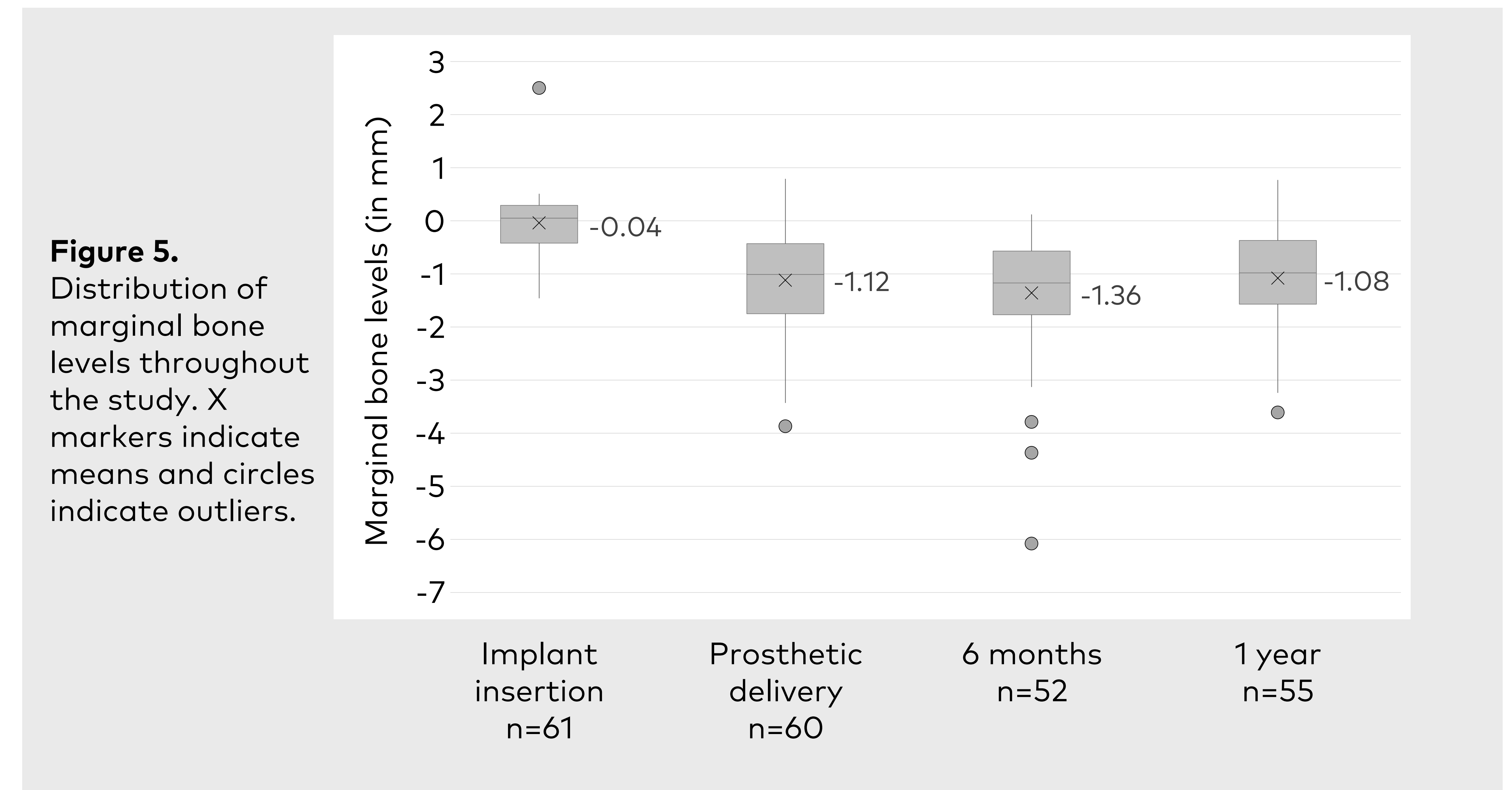
- The prosthetic delivery visit took place on average 4.0 ± 2.0 months after implant insertion.
- The clinical screw had to be retightened at 17 implants.
- Most of the final prostheses (70.5%) were NobelProcera full contour or cutback crowns.

Results: Outcome measures

- The cumulative implant survival and success rates at 1 year were 96.5% and 96.7%, respectively.
- **Excellent soft tissue response:**
 - Increased keratinized mucosa presence and keratinized mucosa height (from 3.7 ± 0.9 mm at implant insertion to 4.0 ± 1.0 mm at 1 year).
 - Continuous improvement in modified bleeding and gingival indices and Jemt's papilla score throughout the follow-up (Figure 4).
 - Mild plaque accumulation, with 98.2% sites showing no plaque or plaque only detectable by running a probe across the marginal surface of the restoration at 1 year.



- **Stable marginal bone levels** of $+0.04 \pm 0.76$ mm from prosthetic delivery to the 1-year follow-up (n=54) after the expected remodeling following implant insertion (Figure 5).



- **Improved oral-related quality of life**, with the OHIP-14 score decrease from 1.1 at pre-treatment to 0.1 at prosthetic delivery and 0.0 at the 1-year follow-up.
- **Very high patient satisfaction** with function and esthetics, with mean scores of ≥ 9.7 , on a scale from 0 to 10, at all follow-up visits.
- **Excellent ease-of-use ratings** of ≥ 8.9 on a scale of 0 to 10.
- **High clinician's confidence in the system** of 9.0 on a scale of 0 to 10.

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Sample clinical case

Figure 6. Clinical views (top row) and peri-apical radiographs (bottom row) at indicated time points. A 43-year-old female patient, non-smoker, reported with a missing first molar tooth in the mandible (FDI position 36). Surgical access was provided with a minimally invasive flap and the implant recipient site was evaluated as dense bone with moderate residual ridge resorption. A 4.3-mm wide and 10-mm long NobelActive TiUltra implant was placed with the final insertion torque of 45 Ncm. Following the digital impression, a 1.75-mm high On1 base Xeal and a 1.5-mm high On1 healing cap were placed on top of the implant. The final prosthesis was delivered 6.7 months later and consisted of an On1 universal abutment and a NobelProcera full contour zirconia crown. Note the improvement of soft tissue health throughout the follow-up and marginal bone level stability following the initial remodeling.



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Sample clinical case: Patient with history of periodontal disease and peri-implantitis

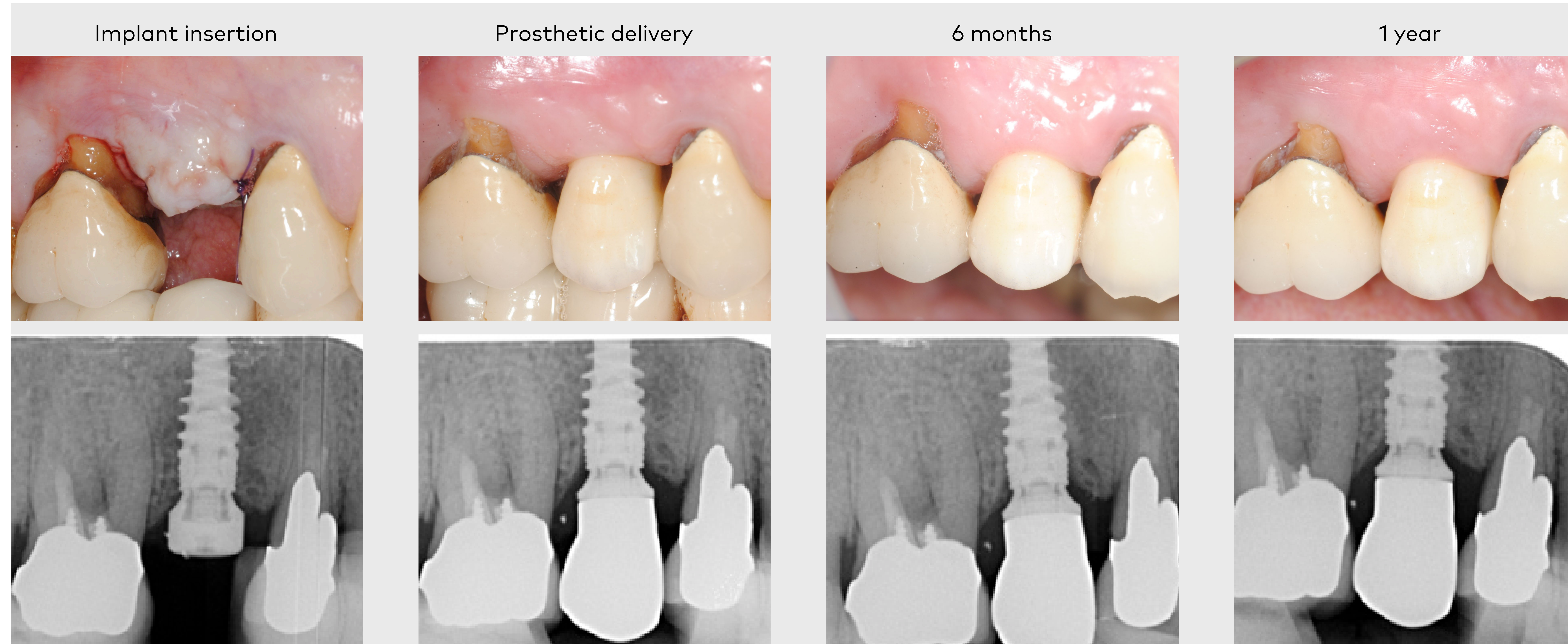


Figure 7. Clinical views (top row) and peri-apical radiographs (bottom row) at indicated time points. A 69-year-old female patient, smoker (5 or less cigarettes per day), with poor oral hygiene and history of periodontitis and peri-implantitis, reported with a missing second premolar tooth in the maxilla (FDI position 15). Implant recipient site was evaluated as soft bone with moderate residual ridge resorption. A 4.3-mm wide and 11.5-mm long NobelActive TiUltra implant was placed with the final insertion torque of 63 Ncm. Following the digital impression, a 1.75-mm high On1 base Xeal and a 2.5-mm high On1 healing cap were placed on top of the implant. The final prosthesis was delivered 4.4 months later and consisted of an On1 universal abutment and a NobelProcera cut back zirconia crown. Note the excellent marginal bone response and the soft tissue gain.

Conclusions

Within the limitations of the short follow-up, **high implant survival** combined with **excellent soft tissue health** and **stable marginal bone levels** following the initial remodeling post-insertion indicate that the novel anodized surfaces TiUltra at implants and Xeal at abutments are **safe and promote excellent peri-implant tissue response**.

References

1. On implant surfaces: a review of current knowledge and opinions. A Wennerberg, T Albrektsson. Int J Oral Maxillofac Implants. 2010;25:63-74.
2. Rational design and in vitro characterization of novel dental implant and abutment surfaces for balancing clinical and biological needs. V Milleret, P S Lienemann, A Gasser, S Bauer, M Ehrbar, A Wennerberg. Clin Implant Dent Relat Res. 2019 Mar;21 Suppl 1:15-24.

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