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Immediate versus delayed implant placement of novel fully tapered tissue-level implants – A retrospective multicenter clinical study

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Abstract

Objectives: To compare the clinical and radiological outcomes of novel fully tapered tissue-level implants in immediate implant placement (type 1) versus late implant placement (type 4) for the first time.

Materials and Methods: For this clinical study, 318 fully tapered tissue-level implants in 65 patients were inserted immediately ($n=68$ implants) or late ($n=250$ implants) in two different centers. Implant survival and success rates and marginal bone levels were analyzed.

Results: After a mean follow-up of 12.0 ± 5 months, implant survival rates were 97.8% for all implants. No statistically significant difference in implant survival rates between type 1 and type 4 could be detected (98.5% vs 97.6%, HR 0.70, 95%-CI 0.084–5.81). Neither for implant length (HR 0.53, 95%-CI 0.055–5.08) nor for implant width (HR 0.27, CI 0.028–2.55), a significant influence on implant survival could be detected. Type of used biomaterial for filling the gap and immediate loading showed no effect on implant survival. Mean marginal bone loss was 0.02 ± 0.05 mm for type 1 and 0.04 ± 0.1 for type 4.

Conclusions: Within the limitations of this retrospective study and the short follow-up, the results demonstrated comparable high survival and success rates and stable marginal bone levels for type 1 and type 4 placement of this novel tissue-level implant (no clinical trial registration as retrospective study design).

KEYWORDS
biomaterial, fully tapered tissue-level implants, immediate type 1 and late implant placement type 4, implant survival

The data from this study are part of the dissertation work submitted to Johannes Gutenberg University, Mainz as part of doctoral thesis of Leila Raahimi.

1 | INTRODUCTION

Dental implants are an established and safe treatment option to restore single edentulous space and partially or completely edentulous jaws even in medically compromised patients (Al Najam et al., 2021; Duong et al., 2022; Duttenhoefer et al., 2019; Jung et al., 2021; Roccuzzo et al., 2022; Schiegnitz, Müller, et al., 2021; Wagner et al., 2022). In the past years, dental implants have undergone a lot of modifications and improvements concerning its material and treatment concept. The treatment concepts are differentiated regarding the time of implant insertion (immediate (type 1), early (type 2 and 3), late implantation (type 4)), and the time of loading (immediate, early, conventional) (Gallucci et al., 2018). In the case of immediate implant placement (IIP), the implant is placed directly in the fresh socket on the same day of tooth extraction (type 1). Early-type implant placement with soft tissue healing (type 2) is performed 4–8 weeks after extraction, and early-type implant placement with partial bone healing is performed 12–16 weeks after extraction (type 3). In the case of late implant placement, implant placement is performed after complete bone healing (type 4).

The concept of IIP has gained importance in recent years for both the patient and the treating surgeon (Huynh-Ba et al., 2018). This concept brings on the one side many advantages, especially the support of the preservation of the surrounding soft and hard tissues. In addition, IIP involves a reduced treatment time and fewer surgical procedures. In esthetically demanding regions such as the anterior region, direct restorations with a temporary implant crown are possible after IIP (De Angelis et al., 2021; Fujita et al., 2021; Groenendijk et al., 2021). On the other side, IIP is a challenging therapy option from a surgical point of view. The osteotomy is usually performed apical of the alveolus in order to be able to install an implant with sufficient primary stability (Cosyn et al., 2019). Therefore, it can be critical to achieve an optimal three-dimensional implant position. If the osteotomies follow the long axis of the original tooth, it could result in implants too buccally positioned and angulated. Such a buccal implant position is one of the main causes of midfacial recession and marginal bone loss (Chen & Buser, 2009; Cosyn et al., 2019). Therefore, several criteria must be met for successful immediate implant placement. According to the ITI consensus, these criteria include a thick gingival phenotype (morphotype B: thick attached gingiva), an intact vestibular bone wall (with a minimum thickness of 1 mm), and inflammation-free hard and soft tissue conditions (Morton et al., 2018). Last, the practitioner should have sufficient clinical expertise. If only one of these conditions is not fulfilled or if local or systemic complications such as poor compliance or diabetes mellitus are present, delayed or late implant placement should be considered.

There are three concepts regarding the loading time of the dental implant (Gallucci et al., 2018). A distinction is made between immediate, early, and conventional loading. In case of immediate loading, the dental implant is functionally loaded within the first week after implant placement. In early loading, the implant is restored between 1 week and 2 months after insertion. In conventional loading, the implant should heal for at least 2 months without connection to any prosthetic restorations.

Regarding the implant design, there are bone and tissue-level implants differentiated (Schiegnitz, Kämmerer, et al., 2021). Implants with a rough surface up to the implant shoulder are called bone-level implants. Tissue-level implants (also called hybrid-design implants) have a machined (smooth) neck/shoulder and a roughened surface in the body area. This hybrid design keeps the implant–abutment junction above the alveolar crest and there is evidence that this hybrid design is less prone to periimplantitis (Derks et al., 2016).

To our best knowledge, studies on fully tapered tissue-level implants and immediate treatment protocols are missing so far. Therefore, the aim of this study was to compare for the first time the clinical survival and success rates of fully tapered tissue-level implants in type 1 and type 4 protocols. The null hypothesis was that immediately and late inserted fully tapered tissue-level implants have a comparable clinical outcome. Primary outcome was implant survival. Secondary outcomes were marginal bone levels and implant success rates.

2 | MATERIALS AND METHODS

2.1 | Study design

In this multicenter clinical study, the clinical and radiological outcome of all fully tapered, self-cutting tissue-level implants (Straumann® TLX, Straumann, Basel, Switzerland; Figure 1), inserted in the Department of Oral and Maxillofacial Surgery of the University Medical Centre Mainz, Germany (study center 1, surgeons ES, KS, and BA) and in the Private Praxis Dr. Adriano Azaripour, Germany (study center 2, surgeon AA) between May 2020 and December 2021, were evaluated retrospectively. No implant was excluded that was inserted in the investigated time period. Ethical approval was obtained from the ethical committee of Rhineland-Palatinate, Germany (Registration number: 2022–16,442, Landesärztekammer Rheinland-Pfalz). The study was conducted in accordance with the Helsinki Declaration of 1975 as revised in 2000 and the study is in compliance with the STROBE guidelines. All implants were inserted by experienced surgeons in the Department of Oral and Maxillofacial Surgery of the University Medical Centre Mainz, Germany, and in the Private Praxis Dr. Adriano Azaripour, Germany.

2.2 | Patient selection

The inclusion criteria of the present study were as follows:

1. Patients receiving one or more fully tapered tissue-level implants (TLX, Straumann, Basel, Switzerland) in one of the both study centers between May 2020 and December 2021.
2. Implants were inserted immediately directly in the fresh socket on the same day of tooth extraction (type 1) or after complete bone healing (type 4) according to (Gallucci et al., 2018).

FIGURE 1 The investigated fully tapered, self-cutting tissue-level implant (Straumann® TLX, Straumann, Basel, Switzerland).

3. Patient age ≥ 18 years.

There were no exclusion criteria defined in the present study.

2.3 | Surgical procedure and outcome assessment

The implants were inserted according to the protocol of the manufacturer. Please see Figures 2 and 3 for clinical examples for type 1 and type 4 placement. Decision criteria for immediate implant insertion were an intact facial bone wall with a thick wall phenotype (>1 mm), a thick gingival biotype, an absence of acute purulent infection in the extraction site, and a sufficient bone volume apically and palatally of the extracted root to allow a correct 3D implant positioning with good primary stability (Buser et al., 2017). Adequate implant primary stability is required when attempting to conduct an immediate loading. Therefore, implant insertion torque (IT) was judged by the surgeon intraoperatively. If the insertion torques were <35 Ncm, no immediate loading was conducted. For filling the gap in IIP, different bone substitute materials were used: deproteinized bovine bone mineral with 10% collagen (Bio-Oss® Collagen, Geistlich, Switzerland; XenoFlex®, Straumann, Basel, Switzerland), cortico-cancellous allograft bone substitute (Puros® Cortico-Cancellous, particle size: 0.25- to 1-mm Zimmer dental, Palm Beach Garden, FL, USA; maxGraft® granules, botiss biomaterials, Berlin, Germany) and/or autologous bone particles. For bone augmentation procedures guided bone regeneration using the above-mentioned bone substitutes and a collagen membrane was used (Bio-Gide®, Geistlich, Switzerland).

2.4 | Prosthetic phase

In case of immediate loading, provisional temporary crowns were fabricated through a fully digital approach (Smile in a Box®, Institut Straumann AG, Switzerland) or were fabricated chair side. Final restorations were finished 4 months after surgery.

2.5 | Supportive peri-implant care

Following the completion of the surgical and prosthetic procedures, the patients were informed about how to carry out self-performed infection control procedures in detail. Depending on the design of the prosthetic restoration, different types of toothbrushes and/or floss were shown to properly clean the implant and adjacent parts of the prosthesis.

2.6 | Clinical/radiographic examination at follow-up

A clinical follow-up examination was performed after 3, 6, 12, and 18 months. Radiography via orthopantomogram or intraoral radiographs was done at the time of examination. The up-to-date and clinical follow-up radiograph were matched to analyze the distance from the implant–abutment periphery to the apex of the implant as described before (Schiegnitz et al., 2016; Schiegnitz, Kämmerer, et al., 2021; Schiegnitz, Müller, et al., 2021). The implant length was used in every X-ray as a reference to calibrate for the correct distance. Success rates according to Albrektsson et al. (1986) were analyzed. These criteria were in accordance with implant's survival time or time to loss, mobility of the implant, peri-implant radiographic translucency, bone loss, signs of

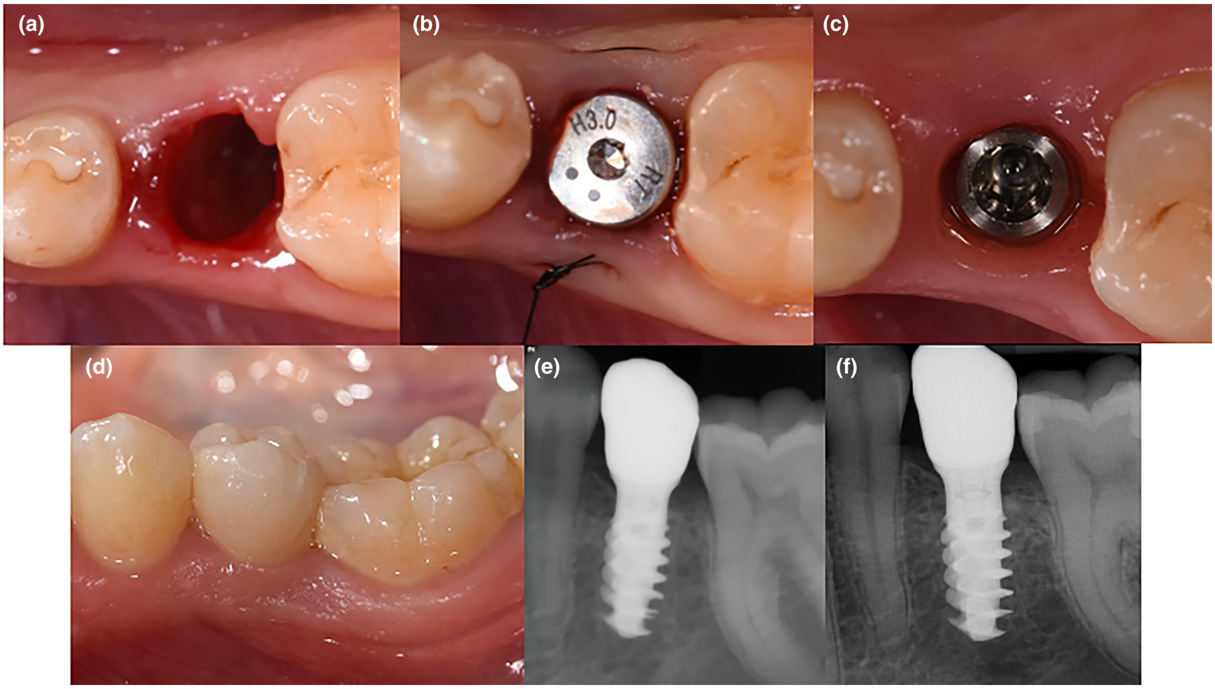

FIGURE 2 Clinical example of IIP type 1. (a) Clinical situation after tooth extraction, (b) Immediate Implant Placement of fully tapered tissue-level implant, (c) Emergence Profile after 8 weeks, (d) Final restoration, (e) intraoral radiograph after 6-month follow-up, (f) intraoral radiograph after 12-month follow-up.

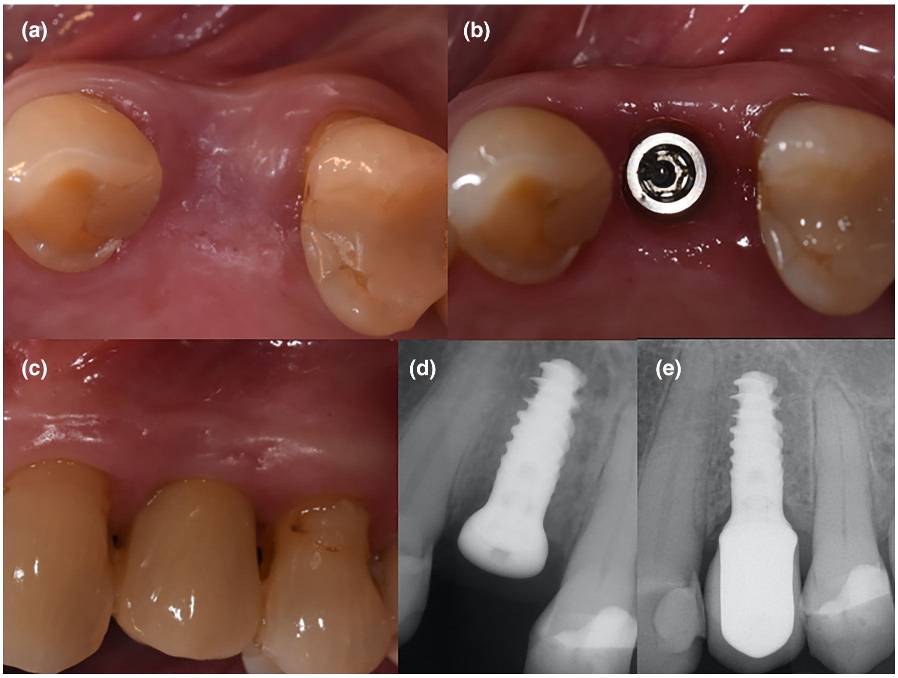

FIGURE 3 Clinical example of late implant placement type 4. (a) Clinical situation before implant placement, (b) Emergence Profile 8 weeks after Delayed Implant placement, (c) Final restoration, (d) post-operative intraoral radiograph, (e) intraoral radiograph after 12-month follow-up.

infection/inflammation, and lesions of the anatomical structures. All implants with <0.2 mm vertical bone loss and less than 12-month follow-up were regarded as a success.

2.7 | Data analysis

Implant-related data were calculated for the statistical analysis. The nature of this study was descriptive and exploratory. Survival rates and hazard ratios were presented with confidence intervals. No p-values were indicated for implant survival to emphasize the descriptive nature of this study. No adjustment to multiple testing was performed. The Kaplan–Meier survival function was used for the description of survival rates. To analyze the statistical difference between treatment groups with respect to implant survival, a log-rank test was used. We fitted a cox model, allowing for clustering due to multiple implants per patient and we report 95% Wald robust confidence limits. The proportional hazards assumption for the Cox model was not assessed due to the small event numbers. Marginal bone loss was calculated by an independent samples t-test of Satterthwaite, applied to average bone loss per person. The analyses were conducted using SPSS version 20.0 (IBM, USA).

3 | RESULTS

3.1 | Study data

A total of 165 patients with 318 fully tapered tissue-level implants were included in our study (study center 1 with 100 patients and 212 implants and study center 2 with 65 patients and 106 implants). Mean age was 59 ± 16 years (range 18–86 years). Ninety-six patients were female and 69 patients were male. In the investigated period, 68 implants (21.4%) were immediately placed and 250 implants (78.6%) were inserted lately. Twenty-four implants (7.5%) were short implants (≤6 mm) and 294 implants (92.5%) were standard-length implants (>6 mm). Two hundred and nine implants (66%) were implants with a diameter 3.75 mm, 109 implants (34%) were implants with a diameter >3.75 mm. The patient and implant-related data correlated to type 1 and type 4 placement are displayed in Table 1.

3.2 | Survival rates

Mean follow-up for all included patients was 12.0 ± 5 months (range 1–25 months). During follow-up, seven implants in six patients failed, indicating a survival proportion of 97.8%. Five of these failures were early implant failures with missing osseointegration during the first 3 months. Two failures in one patient were late failures due to periimplantitis after 14 months. For the type 1 group, mean follow-up was 11.1 ± 5 months and during the follow-up, one immediate implant failed, indicating a survival proportion of 98.5%. For the type 4 group, mean follow-up was 12.2 ± 6 months and during the follow-up, six late implants failed. This meant a survival proportion of 97.6%. Cumulative 5-year survival rate for type 1 was 98.5% and 98.4% for type 4. The difference between survival rates of type 1 and type 4 did not differ (Figure 4). The fitted Cox model was inconclusive with the point estimate favoring the type 1 group but with a wide confidence interval (hazard ratio (HR) 0.70; 95%-confidence interval 0.084 to 5.81). Taking the different follow-up times into consideration, the survival rate for implants with a follow-up from 0 to 6 months was 94.9%, with a follow-up from 7 to 12 months was 99.1%, and with a follow-up >12 months was 98.4%.

Short fully tapered tissue-level implants (6 mm length) showed a comparable implant survival rate to standard length implants (>6 mm length; 95.8% vs 98%; Figure 5). The fitted Cox model was inconclusive with the point estimate favoring the long implant group (HR 0.53, 95%-CI 0.055 to 5.08). In addition, implant width (3.75 mm vs > 3.75 mm) had no influence on implant survival (97.1% vs 99.1%). The fitted Cox model point estimate favored the width implant group providing a hazard ratio (HR) of 0.27 (95%-CI 0.028 to 2.55). The type of used biomaterial (deproteinized bovine bone mineral with 10% collagen vs cortico-cancellous allograft bone substitute vs autologous bone particles) for filling the gap in type 1 had no influence on implant survival of the immediate inserted implants. We refrained from fitting a Cox model due to small number of events (*n* = 1). Eighteen of the 68 immediate inserted implants were immediately loaded (Type 1A according to Gallucci et al. (2018)). In these immediately loaded immediately placed implants no implant failure occurred, indicating an implant survival of 100%. In the conventionally loaded immediately placed implants (Type 1C according to Gallucci et al. (2018)) one implant failure was seen, indicating an implant survival of 98%. We refrained from fitting a Cox model due to small number of events (*n* = 1).

TABLE 1 Patient and implant-related data.

	Immediate implant placement	Late implant placement
Patient and implant numbers	50 patients with 68 implants	115 patients with 250 implants
Gender	25 females and 25 males	71 females and 44 males
Age	59.9 ± 17 (24–84)	59.2 ± 15 (18–86)
Region of implant insertion	Anterior maxilla: 10 implants Posterior maxilla: 19 implants Anterior mandible: 5 implants Posterior mandible: 34 implants	Anterior maxilla: 26 implants Posterior maxilla: 89 implants Anterior mandible: 24 implants Posterior mandible: 111 implants
Implant lengths	6 mm: 1 implant 8 mm: 23 implants 10 mm: 20 implants 12 mm: 23 implants 14 mm: 1 implant	6 mm: 23 implants 8 mm: 95 implants 10 mm: 98 implants 12 mm: 32 implants 14 mm: 2 implants
Implant widths	3.75 mm: 47 implants 4.5 mm: 21 implants	3.75 mm: 162 implants 4.5 mm: 87 implants 5.0 mm: 1 implant

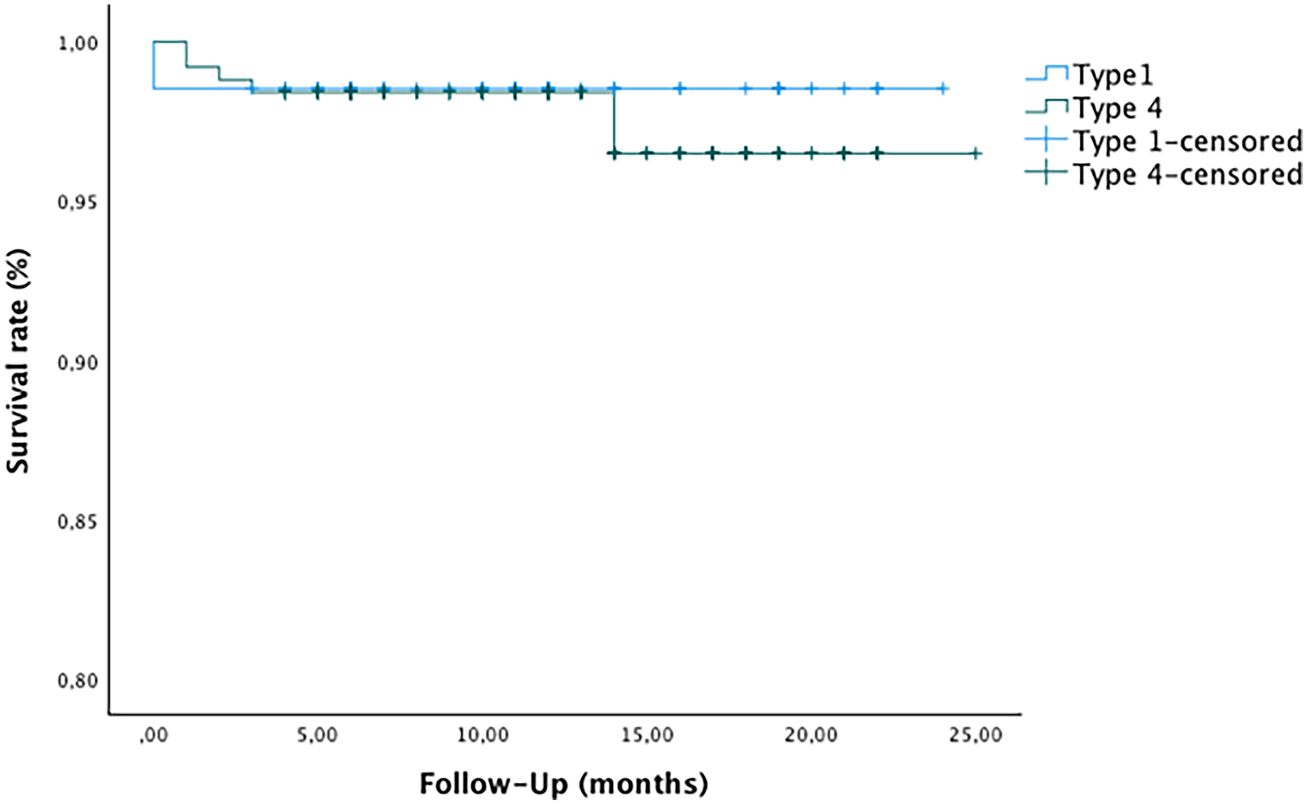

FIGURE 4 Cumulative survival rate according to Kaplan–Meier for type 1 and type 4 placement.

3.3 | Marginal bone levels and success rates

The mean marginal bone loss for all included fully tapered tissue-level implants that were available for 6-month follow-up (n=157) was 0.03±0,1 mm (range: 0–0.69 mm; mesial mean bone loss: 0.02±0.09 mm, distal mean bone loss: 0.04±0.13 mm). For the type 1 group, mean bone loss was 0.02±0.05 mm (mesial mean bone loss: 0±0 mm, distal mean bone loss: 0.03±0.1 mm). In the type 4 group, a mean bone loss of 0.04±0.1 mm (mesial mean bone loss: 0.03±0.1 mm, distal mean bone loss: 0.05±0.1 mm) was analyzed. These results indicated a comparable mean marginal bone loss between the type 1 and type 4 groups (p=.108). Application of the success criteria of Albrektsson et al. (1986) indicated a 98.5% implant success rate for the type 1 group and a 97.6% implant success rate for the type 4 group.

4 | DISCUSSION

The main objective of this clinical study was to compare IIP (type 1) to late placement (type 4) of a novel fully tapered, self-cutting tissue-level implants in terms of implant survival and success and radiographic bone levels. Our results showed that immediately and late placed fully tapered tissue-level implants showed comparable implant survival and success rates after a mean follow-up of 12 months.

In our study, a fully tapered, self-cutting tissue-level implant was used. To our best knowledge, there are so far no clinical studies published on this specific implant type. In a study, in minipigs, the osseointegration and crestal bone level maintenance of this implant type was compared to a clinically established parallel-walled tissue-level implant (El Chaar et al., 2021). The results showed that histometrically derived bone-to-implant contact was comparable between the two implant designs. Maximum insertion torque values were distinctly higher for the fully tapered tissue-level compared to the parallel-walled tissue-level implant, qualifying the fully tapered tissue-level implant as a promising candidate for immediate placement in bone of limited quality.

Regarding tissue-level implants used in immediate treatment concepts, we could only identify studies with parallel-walled tissue-level implants. A prospective multicenter study investigated immediate and early-loaded parallel-walled tissue-level implants (Ganeles et al., 2008). The results showed that four implants failed in the immediate loading group and six in the early loading group, giving comparable implant survival rates of 98 and 97%, respectively. In a randomized clinical trial, 116 parallel-walled tissue-level implants were immediately inserted with or without a subepithelial connective tissue graft (Bianchi & Sanfilippo, 2004). The 9-year cumulative survival rate was 100% for both groups. Comparative statistical analysis of soft and hard tissue peri-implant parameters demonstrated better results in the group with the combined treatment during every single 3-year analysis. The group with the

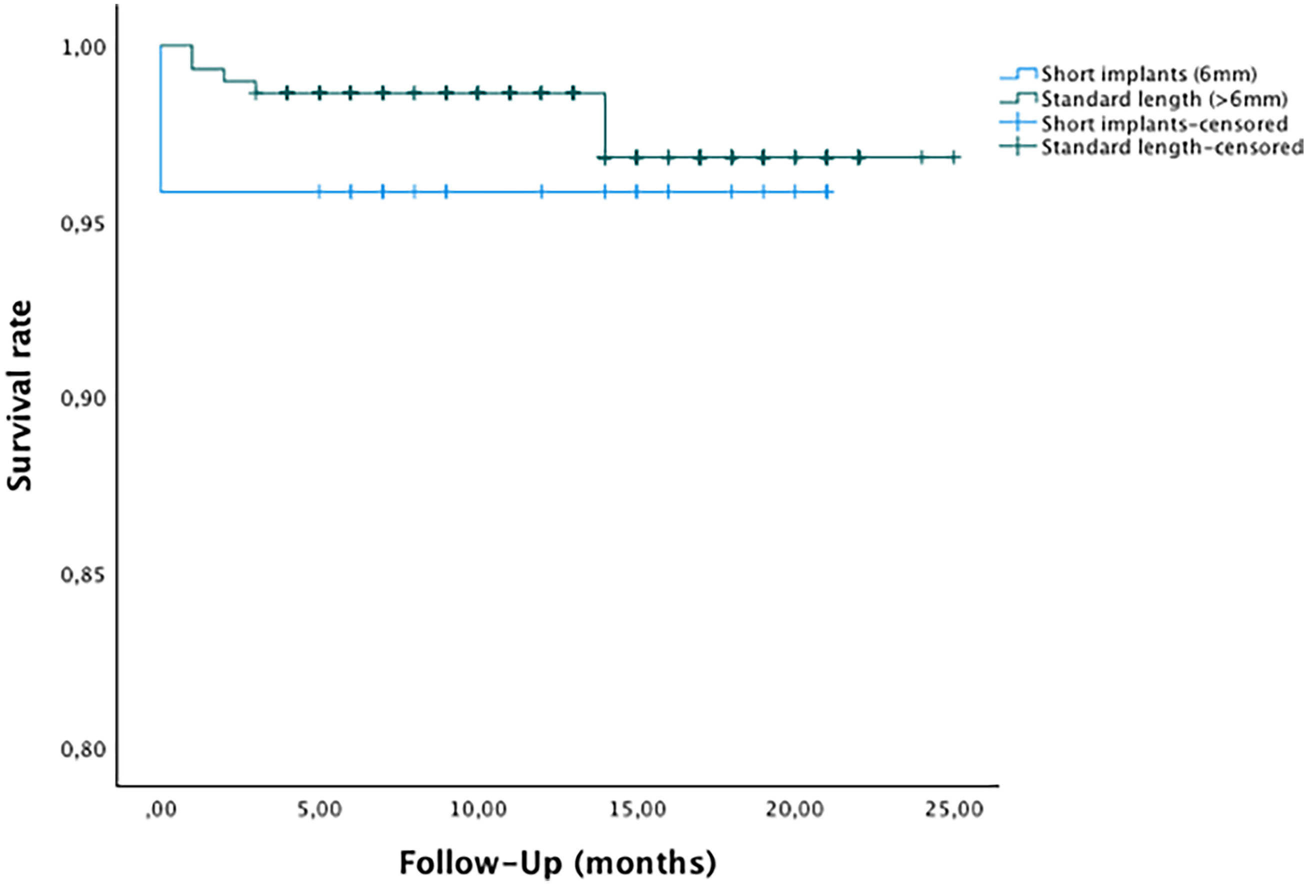

FIGURE 5 Cumulative survival rate according to Kaplan–Meier for short and standard-length implants.

combined treatment also indicated very good results in terms of aesthetic parameters.

Independently of the implant design, several systematic reviews investigated the clinical and radiological outcome of immediate placement and loading protocols. Cosyn et al. examined the difference of immediate implant placement to delayed single implant placement (≥3 months post-extraction) in terms of implant survival (primary outcome), surgical, clinical, aesthetic, radiographic, and patient-reported outcomes (secondary outcomes) (Cosyn et al., 2019). Meta-analysis showed significantly lower implant survival for immediate implant placement (94.9%) as compared to delayed placement (98.9%) (RR 0.96, 95% CI [0.93; 0.99], $p = .02$). All failures were early implant failures. In addition, the results indicated similar probing depth and aesthetic outcomes as assessed by the pink aesthetic score. Soft tissue recessions were underreported and results on marginal bone loss were conflicting and with high bias.

Gallucci et al. analyzed in their systematic review of the Sixth ITI Consensus Conference the clinical outcome of fixed implant prostheses treated with different combinations of implant placement and loading protocols in partially edentulous patients (Gallucci et al., 2018). The weighted cumulative survival rate of each type of placement and loading protocol was 98.4% for immediate placement + immediate restoration/loading, 98.2% for immediate placement + early loading, 96.0% for immediate placement + conventional loading, 97.9% for late placement + immediate restoration/loading, 98.3% for late placement + early loading, and 97.7% for late placement + conventional loading. The criteria for selection of specific placement/loading protocols were as follows in the included studies: an adequate bone height and width for implant placement was a prerequisite for inclusion in most studies. The specific criteria of what is seen as adequate varied and were not always well reported. Adequate bone quality was another criterion in six studies. No signs of periodontal disease or infection at the apex were mandatory in eight studies. In nine studies adequate width of keratinized tissue and in three studies, a thick phenotype at the implant site were prerequisites. Ragucci et al. investigated systematically the clinical outcomes of immediate implants placed in molar areas (Ragucci et al., 2020). The weighted mean survival rate of 1.106 immediate implants after 1 year of follow-up was 96.6%, and the success rate was 93.3%. Marginal bone loss was 1.29 ± 0.24 mm. When grafting the gap, implant survival was higher compared to non-grafting. The loading protocol had a significant influence on survival rates. Immediately loaded implants showed a lower survival rate than delayed loading protocols. Meta-analysis of four studies indicated a weighted mean difference of 0.31 mm ± 0.8 more marginal bone loss at immediate implant placement versus implants in healed sites ($p < .001$). A recent meta-analysis investigated differences between immediate and delayed placement in terms of survival rate and success rate, radiographic marginal bone levels, height/thickness of buccal wall, peri-implant mucosal margin position, aesthetics outcomes, and patient-reported outcomes (Garcia-Sanchez et al., 2022). Immediate implants had a high survival rate (97%) and presented high PES scores (range 10.36–11.25). Meta-analyses did not show any significant difference in implant survival between immediate and delayed implants, but it did for bone levels and PES scores at 1-year post-loading, favoring the immediate group. However, immediate implants presented threefold early complications and twofold delayed complications.

In our study, the gap between the implant surface and alveolar socket was filled with autologous bone, collagenated xenogenic bone substitute, or allogenic bone, depending on the patient's wish after informed consent. The chosen material had no influence on implant survival rates. Seyssens et al. investigated the effect of grafting the gap on hard and soft tissue changes following a single immediate implant placement (Seyssens et al., 2022). Meta-analysis indicated 0.59 mm (95% CI [0.41; 0.78], $p < .001$) or 54% less horizontal buccal bone resorption following IIP + socket grafting when compared to IIP alone. In addition, significantly less apical migration of the mid-facial soft tissue level was seen when immediate implants were inserted with socket grafting. Meta-analysis also indicated that less distal papillary recession was found when socket grafting was done, while mesial papillae appeared not significantly affected by socket grafting. Vertical buccal bone changes were also not significantly influenced by socket grafting.

The present study has a retrospective design and includes, therefore, the risk of selection bias and confounding. This study design has less validity than randomized prospective clinical trials. For radiographic analysis, the up-to-date and post-operative radiograph were matched to analyze the distance from the implant–abutment periphery to the apex of the implant as described before (Schiegnitz et al., 2016; Schiegnitz, Kämmerer, et al., 2021; Schiegnitz, Müller, et al., 2021). With limitations, this procedure showed reliable results for this purpose (Kullman et al., 2007; Zechner et al., 2003). In addition, the range of our follow-up was high with 1–25 months and the implants included show a mismatching distribution between the immediate and delayed implants that might directly impact the result. Therefore, the conclusions that can be drawn from this retrospective study are limited.

5 | CONCLUSION

The results demonstrated comparable high survival and success rates and stable marginal bone levels for IIP and DIP of this novel fully tapered, self-cutting tissue-level implant. However, it should be kept in mind that due to the retrospective character of this study, clinical conclusions are limited.

AUTHOR CONTRIBUTIONS

Schiegnitz E, Sagheb K, Azaripour A, Al-Nawas B: conceptualization, writing – review and editing, methodology, data curation, investigation, surgery, and visualization. König J: conceptualization, writing – review and editing, methodology, data analysis. Raahimi L: writing – review and editing, data acquisition.

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CONFLICT OF INTEREST STATEMENT

Eik Schiegnitz reports lectures, personal fees, and/or grants from Dentsply, Geistlich, Medartis, Septodont, and Straumann outside the submitted work. Keyvan Sagheb reports lectures, personal fees, and/or grants from Dentsply, Geistlich, and Straumann outside the submitted work. Leila Raahimi declares that she has no conflict of interest. Jochem König declares that he has no conflict of interest. Adriano Azaripour reports lectures, personal fees, and/or grants from Bego, Medartis, Thommen Medical, Straumann, and Geistlich outside the submitted work. Bilal Al-Nawas reports lectures, personal fees, and/or grants from Camlog, Dentsply, Geistlich, Medartis, Straumann, and Zimmer outside the submitted work.

DATA AVAILABILITY STATEMENT

Data available on request from the authors.

ETHICS STATEMENT

Ethical approval was obtained from the ethical committee of Rhineland-Palatinate, Germany (Registration number: 2022–16,442, Landesärztekammer Rheinland-Pfalz).

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