Immediate Nonsubmerged Custom Root Analog Implants: A Prospective Pilot Clinical Study

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Purpose: *To evaluate the feasibility of a commercially available immediate root analog implant system Replicate (Natural Dental Implants).* ***Materials and Methods:*** *Five consecutive patients in need of an implant in the premolar region were recruited for this pilot study. Following clinical examination, a cone beam computed tomography scan was made and the dental impressions digitized. On the basis of the superimposition of these datasets, a three-dimensional (3D) envelope was created for the selected tooth. Subsequently, the tooth root at the prospective implant site was segmented to create a 3D surface, and the obtained mesh data were used as the basis for designing a single-piece root analog implant within the 3D envelope. The designed root analog implant was fabricated using a five-axis computer-aided manufacturing machine. The root analog implants were inserted following flapless minimally invasive root extraction. Following 3 months of uninterrupted healing, definitive restorations were fabricated. Peri-implant clinical and radiographic measurements were obtained up to 12 months follow-up.* ***Results:*** *All patients functioned well following 12 months of functional loading. Within one patient, one of the two root analog implants failed early. Peri-implant clinical and radiographic measurements demonstrated a stable situation after 12 months of functional loading.* ***Conclusion:*** *A novel digital approach for immediately restoring single teeth using root analog implants was introduced. In the future, long-term evaluation of the root analog implant technique is necessary to evaluate the success and survival of implants that were inserted using this technique.* Int J Oral Maxillofac Implants 2018;33:e37–e44. doi: 10.11607/jomi.6048

Keywords: *CAD/CAM, CBCT, custom implants, digital dentistry, 3D planning*

Combining the technologies of cone beam computed tomography (CBCT), computer-aided design (CAD), and computer-aided manufacturing (CAM) allows for new developments in the field of implant dentistry. One application of these advancements is to produce a customized dental root analog implant as an alternative to the traditional threaded, straight or tapered, standard implant systems.[1–3] The root analog implant is preoperatively custom designed based on the CBCT and CAD data to fit into the socket of a soon-to-be-extracted tooth. This implant would have similar dimensions to the original root and would be congruent with the root socket. Anticipated benefits include uncomplicated immediate implant placement, decreased number of surgeries, and increased patient comfort.[1–5] Moreover, mimicking root features might result in a higher esthetic outcome. A few studies describing various techniques of creating and placing custom root analog implants have been noted in the literature.[1–5] However, to date, clinical data regarding the root analog implant technique remain limited. The aim of the present pilot clinical investigation was to evaluate the feasibility of a commercially available root analog implant system Replicate (Natural Dental Implants).

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MATERIALS AND METHODS

Study Design and Participants

The study was designed as a nonrandomized, noncontrolled prospective pilot case series. Patients were consecutively recruited from referrals to the specialist

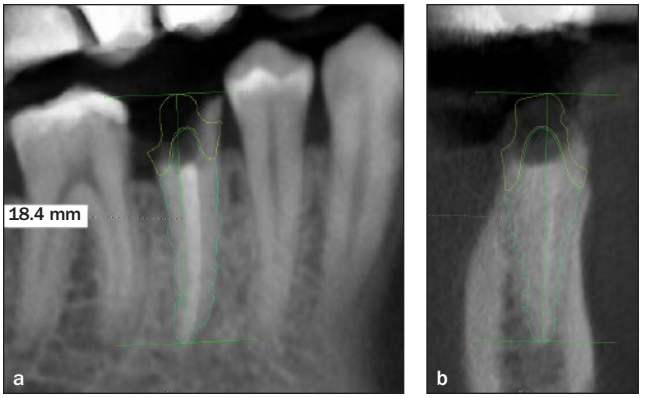


Fig 1 *(a)* Sagittal and *(b)* frontal view incorporating possible root analog implant design for patient no. 4.

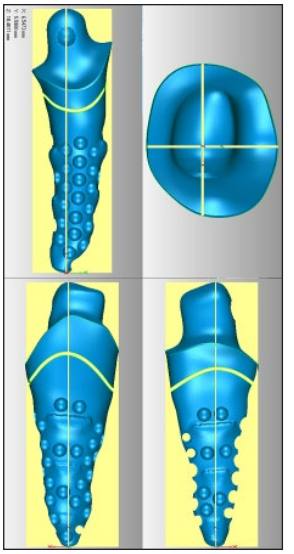


Fig 2 *(Right)* Final root analog implant CAD design for patient no. 4 consisting of root/implant portion and abutment portion.

outpatient clinic of the Implantology department at the Academic Centre for Dentistry Amsterdam (ACTA), VU University of Amsterdam, Amsterdam, The Netherlands. Information concerning the purpose of this study was presented to all patients, and informed consent was obtained from all participants. One patient functioned as a test case, to determine and resolve any procedural difficulties. The authors subsequently analyzed prospectively the next five consecutive root analog implant procedures that were performed with this technique.

The following inclusion criteria were implemented:

- Patients in need of a single premolar replacement with the root still in situ who could be considered good candidates for immediate implant insertion
- Minimum of 1.5 mm of bone circumferentially as measured on the CBCT scan
- Absence of periapical granuloma
- Good oral hygiene (Plaque Index < 25%)
- Able to sign informed consent

The following exclusion criteria were implemented:

- General contraindications to implant surgery including recent infarct (< 6 months) and uncontrolled diabetes mellitus
- Heavy smokers > 15 cigarettes/day
- Periodontal pocket depth > 5 mm
- Presence of significant dehiscence of large bony defects impeding immediate replacement
- History of drugs or alcohol abuse

The indication for implantation in cases no. 2 and 4 was deep caries lesions. In cases no. 1, 3, and 5, the indications for implantation were vertical root fractures.

This study was performed in accordance with the guidelines of the authors' institution and followed the Declaration of Helsinki on medical protocol and ethics. The study protocol was reviewed as a pilot study and accordingly approved by the ACTA institutional ethical review board.

Data Acquisition and CAD/CAM Process

Patients were scanned with the three-dimensional (3D) Accuitomo 170 CBCT system (Accuitomo 170, 90 kVp, 5 mA, 30.8 seconds, 8 × 8 cm field of view [FoV]), Morita). The scan position was with the occlusal plane parallel to the floor following the manufacturer's recommendations. The isotropic voxel size and slice interval were 0.08 mm. The CBCT scan volumes were exported in DICOM 3 format.

Two-stage putty and wash technique impressions (Panasil, Kettenbach) and bite registrations (Futar D, Kettenbach) were taken from the patients. The impressions were poured in type IV stone (FUJIROCK EP, GC) to create master models. High-resolution optical scanning technology was used to scan and digitize the stone casts and bite registrations and stored as Standardized Triangulation Language (STL) files. The DICOM 3 files and surface STL data were imported specialized proprietary analysis software (Replicate, Natural Dental Implants). On the basis of the superimposition of these datasets, a 3D envelope was created for the selected tooth representing the extension of the root, alveolar bone, marginal bone level, gingival margins, adjacent and antagonist dental structures, and anatomical structures (Fig 1).

Subsequently, within this 3D envelope, CAD designs of the root analog implant were made consisting of a root/implant portion and an abutment portion (Figs 1 and 2). CAD designs were additionally made for

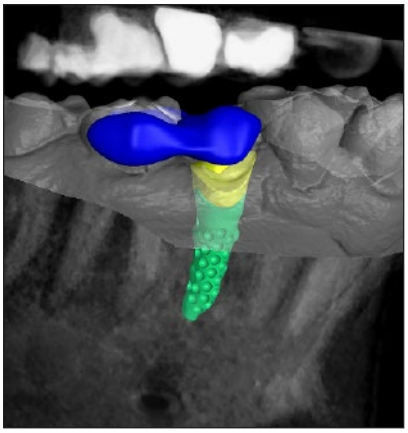
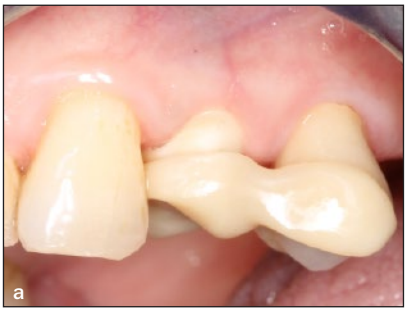


Fig 3 Root analog implant design and provisional cantilevered fixed partial denture within the 3D envelope of patient no. 4.



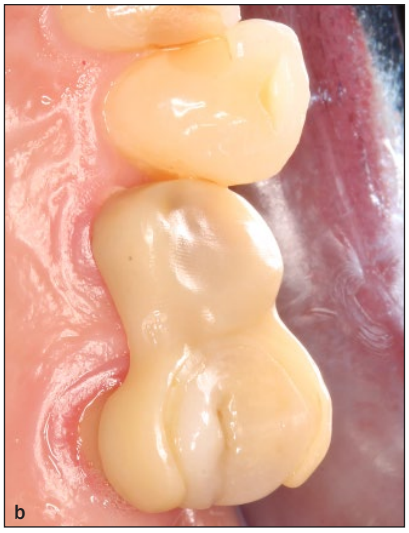


Fig 4 Protective provisional cantilevered fixed partial denture for patient no. 1 after 3 months postoperatively. *(a, above)* Buccal view and *(b, right)* palatal view.

a root analog implant try-in and provisional cantilevered fixed partial denture (Fig 3).

CAD data were transferred to a five-axis rapid manufacturing CAM machine with an effective resolution of 10 µm to mill the titanium root from a solid medical grade 4 titanium (ISO 5832-2) workpiece, and to mill the ceramic parts (root analog implant try-in, abutment portion of the root analog implant, and provisional cantilevered fixed partial denture) from presintered white body blanks of tooth-colored yttria-stabilized tetragonal zirconia (Y-TZP) material (ISO 13356). Subsequently, the zirconia parts were fired into sintered solid dense objects. The ceramic abutment portion and the titanium root portion were then fused together with a biocompatible glass solder to create a one-piece implant. Finally, the titanium root portion was sandblasted with medical-grade zirconia grit (ISO 13356) and acid-etched. The zirconia abutment portion remained a machined smooth surface. The Replicate root analog implants were then delivered in sterile packaging.

Surgical and Prosthetic Procedure

All patients were treated according to the same treatment protocol, and implants were placed using the same surgical technique by one operator (D.A.M.). Under local anesthetics (Septanest SP, Septodont), the respective teeth were carefully flapless extracted to reduce risk of fracturing the bone and roots and to avoid any alterations to the shape of the socket. Alveolar surface decontamination and debridement were performed mechanically using curettes and excavators and chemically by meticulous irrigation with sterile saline (2 × 12 mL). Subsequently, the zirconia root analog implant try-ins were positioned into their respective sockets and visually checked for misfits. In all cases, the zirconia try-in seemed well incorporated to the alveolar socket, and there was no need for mucosal or osseous corrections. The root analog implants were then implanted into their corresponding sockets, and with finger pressure and the gentle use of a hammer and a mallet, good primary stability of the root analog implant was achieved and checked by palpation and percussion. In one patient (patient no. 5), it was necessary to suture the ruptured interproximal papilla with nonresorbable monofilament (GORE-TEX, W. L. Gore & Associates). Finally, one patient (no. 1) received a provisional cantilevered cemented fixed partial denture as a protective measure against occlusal loading (Fig 4). The winged extensions of the protective fixed partial denture were cemented to neighboring tooth with a resin-based cement (RelyX, 3M ESPE). Occlusion was checked, and necessary adjustments were performed. On the basis of the operator opinion (D.A.M.), the consecutive patients did not receive the provisional cantilevered fixed partial denture.

All patients received systemic antibiotics (amoxicillin 500 mg T.I.D.) starting 1 hour prior to surgery and following 7 days after surgery. If necessary, analgesic drugs (acetaminophen 500 mg) were administered during the first postoperative days. Throughout 2 weeks postoperatively, patients rinsed with chlorhexidine 0.12% twice a day. One week postoperatively, all patients were seen for maintenance care. Oral hygiene methods were reinforced or reinstructed, and sutures were removed in one patient (no. 5). After 3 months of uninterrupted healing, the protective fixed partial denture was removed, and definitive impressions with a polyether material (Impregum, 3M ESPE) were taken for the definitive restoration. The restorations were ceramic built on a zirconia core and were semi-permanently cemented with Durelon (3M ESPE). No soft tissue management was applied in this study group.

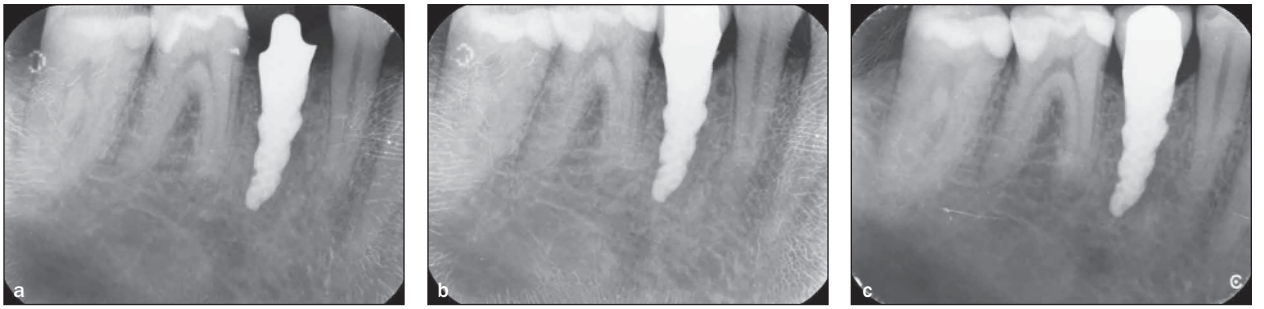


Fig 5 Radiographic evaluation of patient no. 4: *(a)* directly after root analog implant insertion, *(b)* after definitive restoration, and *(c)* 12 months after functional loading.

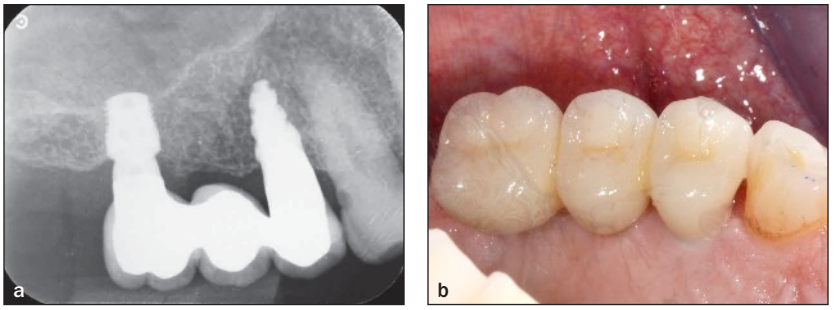


Fig 6 *(a)* 12 months postoperative radiograph and *(b)* clinical palatal view of patient no. 5.

Clinical and Radiographic Evaluation

Clinical evaluation of the placed implants was performed following definitive restoration placement and 12 months after functional loading. The following parameters were included: probing pocket depth measurement at six sites per implant if the depth was more than 5 mm, and bleeding on probing was checked generally, but was not noted when the general appearance was healthy.

Radiographic evaluations were performed within the following time points: directly after implant insertion, after definitive restoration placement, and 12 months after functional loading (Fig 5). Digital intraoral radiographs (Carestream 7200, Carestream Dental) of the respective implant sites were obtained using the paralleling long cone technique with an aiming device (film-focus distance 30 cm; Xact X-ray). The radiographs were anonymized and organized in random order for analysis. Radiographic bone levels were measured as an average of the mesial and distal aspect from a hypothetical bone position (margin of the glass-fused abutment-titanium joint) to the first bone-to-implant contact. With the known dimensions of the root analog implant, the radiographic distance was recalculated using ImageJ software (National Institutes of Health) to the physiologic extent of the bone level. After 12 months of functional loading, another CBCT scan was made to evaluate the peri-implant bone condition. Patients were scanned with the exact same scan settings as with the first CBCT scan. On the basis of this CBCT scan, the absence and presence of buccal bone were analyzed.

Descriptive statistics were applied to calculate the mean and standard deviation (SD) of the evaluation parameters. No statistical interference testing was performed between the evaluation parameters due to the lack of statistical power.

RESULTS

Initially, six patients were enrolled in this study protocol. However, one patient was lost to follow-up after implant placement due to unknown reasons. The data of this patient are not represented. There were no intraoperative complications noted during the surgeries. In patient no. 5, the root analog implant for the right second premolar showed mobility and symptoms of peri-implant infection after 4 weeks postoperatively. It was decided to remove the root analog implant at the position of the right second premolar, and simultaneously, a short implant at the position of the right first molar was inserted (Alpha-Bio 5 × 6 mm, Alpha-Bio). For this patient, a three-unit fixed partial denture was fabricated to fit the root analog implant (position of the right first premolar) and conventional implant (Fig 6).

At the 12-month postrestoration evaluation, all remaining implants were successful with satisfactory esthetic results. The mean bone levels around the root analog implants immediately after implant insertion (0.59 mm [SD: 0.52]), directly after restoration (–0.36 mm [SD: 1.20]), and 12 months postfunction (–0.31 mm [SD: 0.90]) appear to be stable with

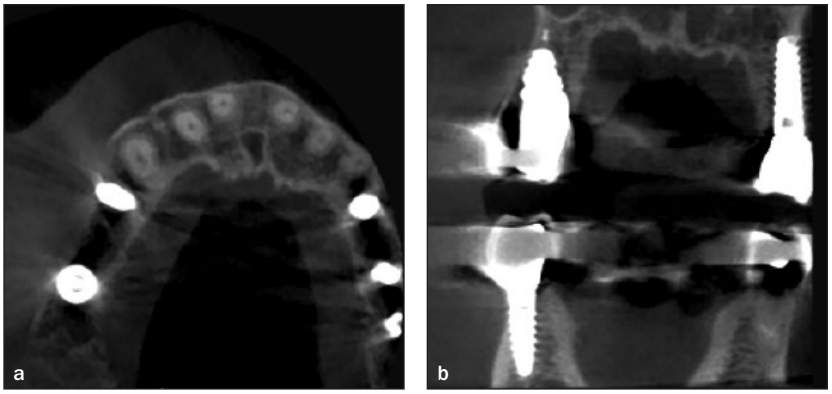


Fig 7 12 months postfunction CBCT scan of patient no. 5 showing the presence of circumferential bone around root analog implant at position of the maxillary first premolar in *(a)* transversal view and *(b)* frontal view.

Table 1 Summarized Clinical Evaluation Parameters

Patient no.	Sex	Age (y)	Target position	Indication for removal/ implantation	MBL after insertion of root analog implant (mm)	MBL after definitive restoration (mm)	MBL after 12 months function (mm)	Presence of buccal bone after 12 months function
1	F	66	Maxillary left first premolar	Fracture	0.26	1.22	1.17	No
2	M	57	Maxillary right first premolar	Caries	1.47	0.46	–0.27	Yes
3	F	69	Maxillary right first premolar	Fracture	0.58	–1.84	–1.20	No
4	M	44	Maxillary right second premolar	Caries	0.15	–0.85	–0.82	Yes
5	M	56	Maxillary right first premolar (and maxillary right second premolar)	Fracture	0.47	–0.79	–0.45	Yes
Mean (SD)					0.59 (0.52)	–0.36 (1.20)	–0.31 (0.90)	

MBL = marginal bone level.

no evident changes in bone level. Analysis of the 12 months postfunction CBCT scan showed two patients (no. 1 and no. 3) with an absence of buccal bone around the root analog implants. In patients no. 2, 4, and 5, the CBCT scans showed the presence of circumferential bone around the root analog implants after 12 months in function (Fig 7).

Probing pocket depth measurements showed no probing depths deeper than 5 mm and a generally healthy mucosal appearance.

All case characteristics and measurement of the evaluation parameters are noted in Table 1.

DISCUSSION

This study shows that preoperatively creating a root analog implant with the Replicate system allows for immediate individual implant placement. With the combined use of CBCT 3D data and high-end CAD/CAM technology, it was possible to manufacture a root analog implant with sufficient precision. As has been previously noted in the literature, there are a multitude of factors influencing the accuracy of 3D surface models generated from the CBCT data. These include clinical factors, such as bone density and stable patient position during the CBCT scan, and technical factors, such as CBCT device settings (kVp, mA, scan FOV, and voxel size) and segmentation accuracy. The CAD/CAM process may result in overestimation or underestimation of the root analog implant, and this needs to be taken into consideration when planning this method of implant surgery. Depending on the amount of undersizing, the root analog implant could exhibit a loose fitting, resulting in a lack of primary stability and subsequent implant failure. Inserting an

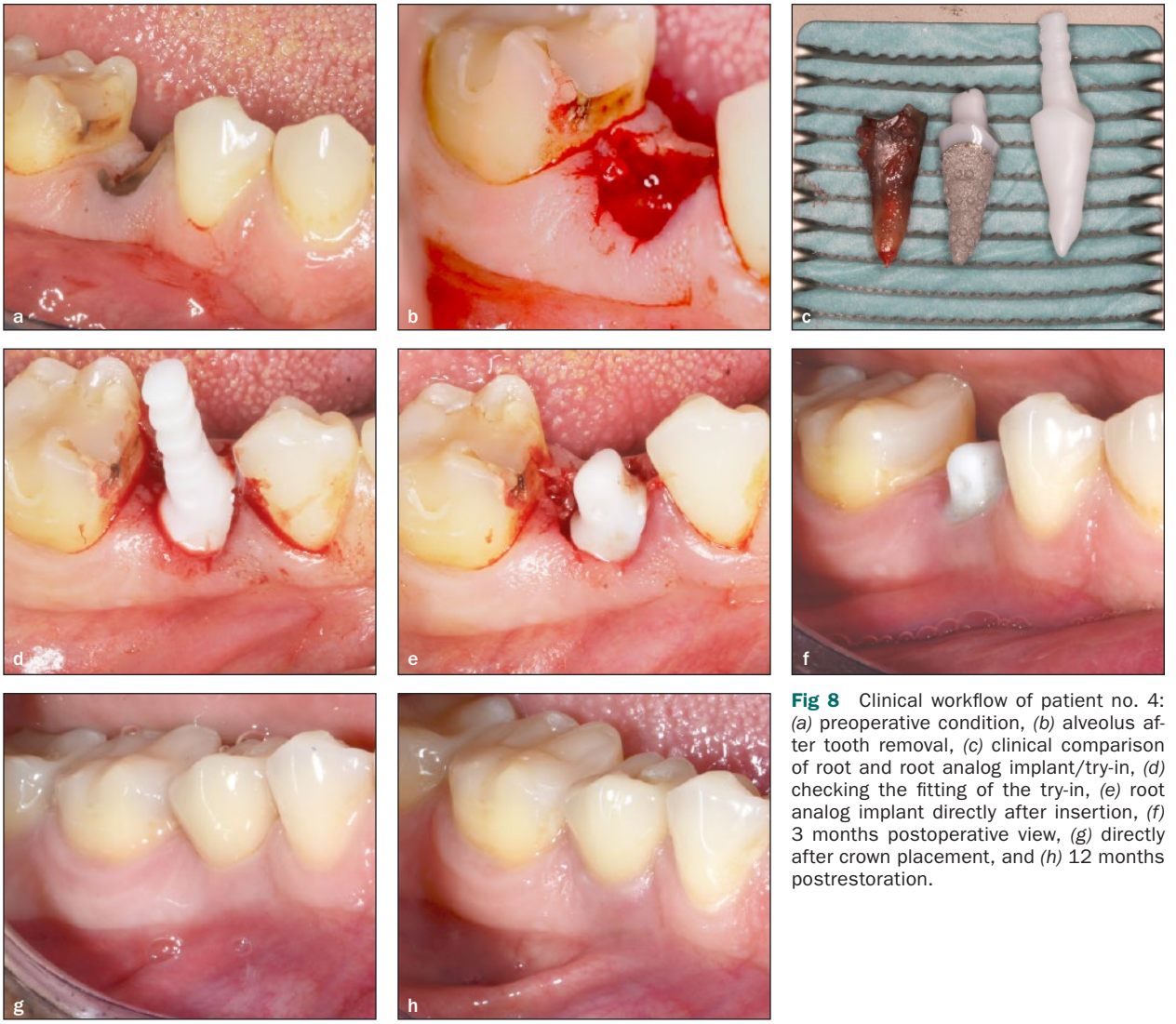


Fig 8 Clinical workflow of patient no. 4: *(a)* preoperative condition, *(b)* alveolus after tooth removal, *(c)* clinical comparison of root and root analog implant/try-in, *(d)* checking the fitting of the try-in, *(e)* root analog implant directly after insertion, *(f)* 3 months postoperative view, *(g)* directly after crown placement, and *(h)* 12 months postrestoration.

oversized root analog implant into its respective extraction socket may lead to bone fracture and overpressurized bony walls inducing bone resorption.[6] Therefore, it is crucial to first assess the fit of the root analog implant in the extraction socket using a mock root analog implant such as the Replicate system including a root analog implant try-in (Figs 8c and 8d). In the five study patients, the root analog implant try-ins were well incorporated within their respective sockets and appeared to show a high degree of congruence.

Primary stability is of critical importance for successful osseointegration of the root analog implant, especially since the root analog implants are one-piece implants with no option for submerged healing. To accomplish a certain amount of primary stability, the Replicate system designs standard-sized protruding bulbs on the mesial and distal aspects of the root analog implants. With available technology, it is very feasible to individually design targeted press-fit root analog implants with individually designed micro-porosities. However, current knowledge on the effect of bone growth and biomechanics with patient-specific designs on root analog implant size, shape, and press-fit distribution is limited. Also, knowledge on the long-term effects on electrochemical corrosion, mechanical stability, and of custom-shaped implants is nonexistent. It must be emphasized that for custom-medical devices, such as dental implants, the EU regulations are limited and that safeguards are under the manufacturer's diligence.

As seen in this study, five of the six root analog implants were successful after 12 months in function.

The root analog implants were inserted in one surgical session through an easy minimally invasive approach. None of the cases required any additional adjustments to the alveolar bone or drilling. In patient no. 5, the root analog implant at the position of the right second premolar was lost due to a possible multitude of factors. One plausible explanation is that the root of the right second premolar, owing to its history of apical resection surgery, resulted in a relatively short root analog implant with insufficient primary stability (Fig 9). Since the root analog implant approach relies on a press-fit mechanism to obtain primary stability, it is currently uncontrollable to measure the amount of obtained primary stability when inserting the root analog implant. Therefore, the threshold for sufficient primary stability relies mostly on the surgeon's intuition.

The Replicate root analog implants are accompanied with a preoperatively fabricated cantilevered fixed partial denture (to be attached to a neighboring tooth) as a protective measure against premature loading during the early stages of osseointegration (Fig 9). However, from a clinical point of view, the authors believe this provisional cantilevered fixed partial denture will not contribute to more favorable survival or success of the root analog implant because of its cantilevered design and the necessity to apply adhesive chemicals (resin bonding, primer, and composite cement) near the wound area to attach the fixed partial denture. The application of the provisional cantilevered fixed partial denture was hence discarded for patients no. 2, 3, 4, and 5. Furthermore, it should be underlined that this study does not have the statistical power to rule out the biologic effects of variability in geometry of the root analog implant with or without the use of the provisional cantilevered fixed partial denture.

A significant finding in this study was the absence of buccal bone at the 12 months postoperative CBCT follow-up, suggesting advanced bone loss not corroborated by clinical measurements of peri-implant probing. These contradictory findings could be explained by the CBCT image suffering from scatter, beam hardening, and beam "extinction" artefacts in the presence of metal objects such as dental implants caused by the complete absorption of the x-ray beam so that no information can reach the detector to reconstruct the images.[7,8] In a histologically controlled study regarding the accuracy of CBCT in assessing peri-implant buccal bone, the radiographic and histologic findings had poor correlation, and CBCT was deemed inaccurate for depicting peri-implant bone.[9]

To summarize, the authors believe the future of implant dentistry will include customization of implants and digitalized approaches. Nevertheless, possible disadvantages should also be considered. For the fabrication of a root analog implant, a preoperative CBCT scan is made of the selected tooth. The use of ionizing radiation should be justifiable for each specific patient and should be limited. Therefore, the authors made selective CBCT scans focused on the respective tooth with the smallest FOV possible. Radiation load was kept as minimal as possible. The selective CBCT scan not only enables the fabrication of the root analog implant, but also allows the surgeon to carefully plan the extraction of the tooth with consideration of the available surrounding bone and anatomical parameters. It facilitates a shorter and easier surgical procedure, which in turn could minimize the chance of complications. Moreover, in immediate implant cases, a preoperative CBCT scan is standard protocol. The authors therefore believe this limited amount of additional ionizing radiation is appropriate.

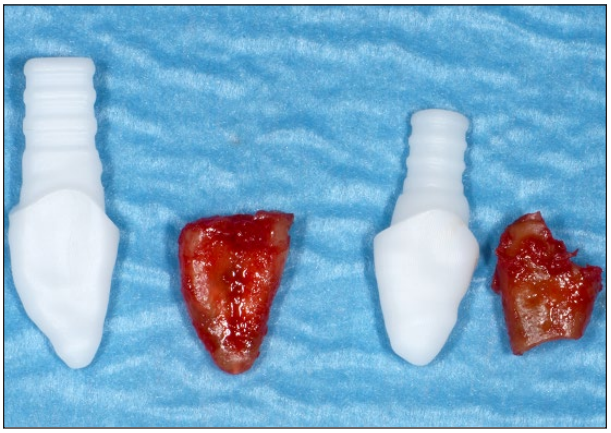


Fig 9 The root analog implant try-ins versus their respective original roots of patient no 5. *(left)* Maxillary first premolar and *(right)* maxillary second premolar.

CONCLUSIONS

This study aimed to evaluate the root analog implant technique with the Replicate system. Therefore, the technical and clinical characteristics of the procedure were reported. In the future, long-term evaluation of the root analog implant technique is necessary to evaluate the success and survival of implants that were inserted using this technique.

ACKNOWLEDGMENTS

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