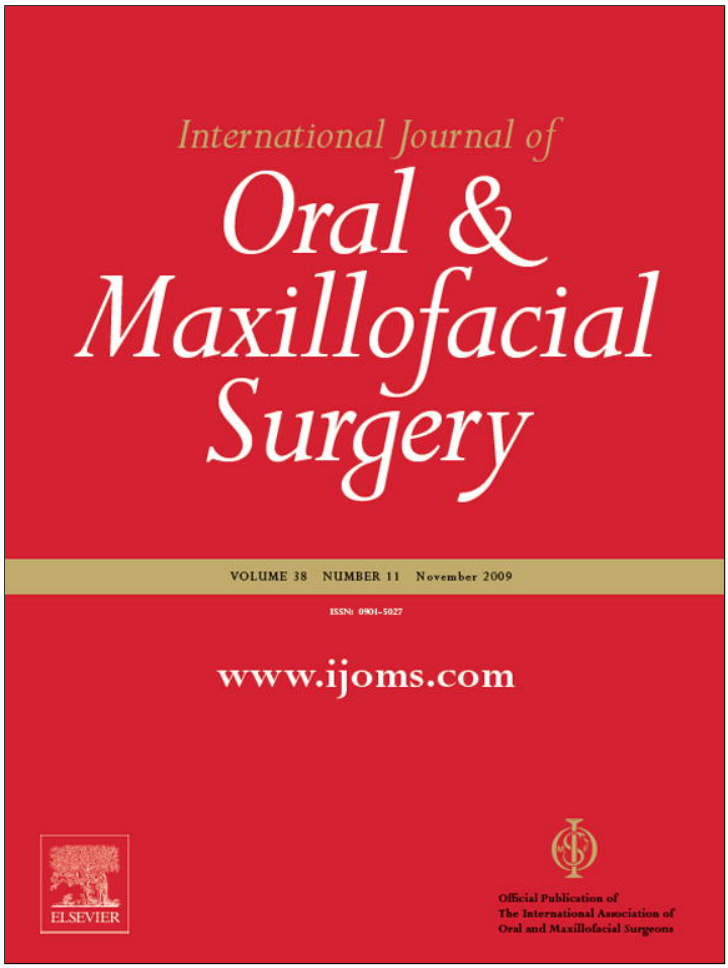

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Immediate, non-submerged, root-analogue zirconia implants placed into single-rooted extraction sockets: 2-year follow-up of a clinical study

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Abstract. This study evaluated non-submerged, root-analogue zirconia implants with two different surfaces for immediate single-rooted tooth replacement in 18 patients. After tooth extraction the root was laser scanned and one-piece root analogue zirconia dental implants with one of two different surfaces were manufactured. In group A ($n = 6$) the implant surface was roughened by sandblasting only, in group B ($n = 12$) additional macroretentions limited to the interdental space, to avoid fracture of the thin buccal cortex, were designed prior to laser scanning. Implants were placed in the socket 1–8 days after extraction by tapping and restored with a composite crown 3–5 months later. Implant survival, level of marginal bone and adverse soft tissue changes were recorded. No complications occurred during the healing period. In group A, all implants were lost within 2 months, with an unaltered extraction socket. In group B, overall survival rate was 92% for implants that were functional for 1–33 months. Excellent aesthetic and functional results were achieved with the composite crown with minimal bone resorption and soft tissue recession. Significant modifications, such as macroretentions seem to indicate that primary stability and excellent osseointegration of immediate root-analogue zirconia implants can be achieved, while preventing unaesthetic bone resorption.

Keywords: zirconia; dental implant; root-analogue; immediate; single stage.

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Dental implants are a common treatment for replacing missing teeth, with long-term success rates of 90–100% at 10 year follow-up.[21] Originally, a healing period of 6–9 months was recommended before implant insertion (late implant placement). Earlier placement of implants after 2–3 months has been proposed (delayed implant placement) and immediate implantation within a few days of tooth extraction is performed clinically in highly selected cases.[22] Results with shorter intervals between extraction and implantation are comparable to late implant placement. The advantages of immediate implant placement are the decrease in the treatment time for the patient, the reduction in the number of surgical interventions leading to an improved quality of life and cost reduction. Alveolar bone resorption and soft

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tissue regression are avoided or significantly reduced, due to early, albeit limited, functional load.

One problem associated with immediate implant placement using conventional screw- or cylinder-type implants is their incongruence with the extraction socket necessitating the use of a barrier membrane and/or bone augmentation to prevent down growth of connective tissue or epithelium in between the implant and the socket.[5]

The concept of replacing teeth with custom-made root analogue implants is not new. The oldest evidence of a dental implant dates back to around 550 BC.[1,3] In ancient times, wood, metal, shell or stone were carved and shaped to form the root for the implant.[2] The first literature reference to a modern style implant came in 1809 when Maggiolo described a tooth root-shaped implant made out of 18-carat gold.[4] In 1969 the use of a tooth replica implant was reported, however the autopolymerized and heat-processed polymethacrylate utilized to fabricate the tooth analogue was encapsulated by soft tissue rather than osseointegrated.[7] Meanwhile placement of dental implants had become an everyday treatment option for dental patients missing teeth. All implant systems involve screw-type threaded implants or cylindrical implants with no resemblance to the native root.

Hodosh et al. were the first to tackle the problem of incongruence by employing a novel approach using custom-made root analogue implants placed into the extraction socket.[7] By adapting the root to the extraction socket instead of adapting the bone to a preformed standardized implant they reduced the bone and soft tissue trauma.

Lundgren et al. reintroduced the idea of root analogue implants in 1992.[14] Instead of using polymers, titanium was utilized in an experimental model of immediate implant placement leading to bony integration in 88%. A good fit between implant and the host bed has been described as an important factor for implant success.[8,21,22] For that reason Kohal et al. further refined the approach of root analogue titanium implants by widening the coronal aspect of the implant to compensate for the lost periodontium and to obtain a good congruence between implant and extraction socket. In several instances the implant insertion led to fractures of the thin buccal wall of the alveolar bone.[5,9]

Experimental studies in monkeys gave favourable results with clear evidence of osseointegration and clinical stability.[9,10] The ensuing clinical trial by Kohal et al. resulted in a 100% primary stability at insertion and 1 month follow-up. Owing to the high failure rate of 97% over the short follow-up period of 12 months this implant system was not been recommended for clinical use.[12]

The goal of the present study was to evaluate a novel approach to root-analogue dental implants. Zirconia was used for its excellent biocompatibility, improved esthetic results by preventing dark discoloration of the gum and the display of titanium roots in case of gum recession, compressive strength, bending forces, fracture toughness and high electrical resistance. Microretentions were added to the entire root surface. Owing to the high failure rate, the initial trial was limited to 6 patients and a second series of root identical implants with significant modifications were started. The first modification was the addition of macroretentions, strictly limited to the interdental space, in order to get beyond primary stability and improve osseointegration. The second was to reduce the diameter of the implant next to the thin cortical bone to avoid fracture and pressure-induced bone loss. The third was to choose a single-stage implantation, resulting in immediate, albeit limited, functional load via the crown stump to prevent bone resorption.

Material and methods

18 patients were included in this prospective study. The 6 patients in group A received root identical replicas with the implant surface roughened by sandblasting only. In the 12 patients in group B the root was modified by adding macroretentions, strictly limited to the interdental space, and by reducing the buccal and lingual face by approximately 0.1–0.2 mm, preventing fractures of the thin cortical bone layer at insertion. The inclusion criteria were: patients with a single tooth gap; with uncompromised periodontal ligaments in the anterior or premolar region; informed consent; and willingness to adhere to the protocol. Indications for tooth extraction included root caries, vertical or horizontal root fracture, endodontic lesions, and unsuccessful root canal treatment. Patients with dehiscence of the crestal bone as determined by clinical examination and with tooth extraction necessitating surgical intervention leading to contusion of the bone were excluded from the study. Chronic apical paradontitis was not an exclusion criterion, but in these cases the area of infection was removed.

The compromised tooth was carefully extracted under local anaesthesia (Ultracain DS forte, Aventis), avoiding damage to the socket and soft tissue. The extraction socket was cleaned meticulously by means of curettage and an iodoform soaked cotton gaze was placed in the socket. This minimal invasive, flapless approach was chosen to avoid trauma to the hard and soft tissue avoiding swelling and bruising. The root was laser scanned and, in group B, macroretentions were designed according to the study protocol, strictly limited to the interdental space, and the buccal and lingual face was reduced by 0.1–0.2 mm. A crown stump was designed for later connection to the crown. The root was then milled from a medical-grade zirconia block (more exactly yttria stabilized tetragonal zirconia polycrystal), the surface roughened by sandblasting and sintered for 8 h to achieve the desired mechanical properties. The implant was cleaned in an ultrasonic bath containing 96% ethanol for 10 min, packaged and steam-sterilized. 1–8 days after extraction the iodoform cotton gauze was removed, and the alveolar socket curetted and flushed with sterile physiologic saline solution. The custom-made individualized implant was placed in the socket under finger pressure and gently tapped into place with a hammer and a mallet. Primary stability was achieved in all instances as checked by palpation and percussion. Patients received postoperative analgesics (Parkemed 500 mg, Pfizer) on demand. They were instructed to chew predominantly on the contralateral side and to avoid hard food for 8 weeks on the implant side. Clinical parameters, such as implant stability, bleeding on probing, mucosal margin position, variation of gingival level, and variation of papilla position, were ascertained at baseline and after 1 week, 1 month, 2 months and thereafter every 6 months post intervention. The clinical situation was also photo-documented at the same time points. Radiographic assessments using Scanora X-ray images were made at baseline and every 12 months after implant placement. Bone level measurement by radiographic examination was limited because the implant is radiopaque. The success of the dental implants was defined, according to the criteria suggested for determination of success with reference to clinical and X-ray control parameters by Jahn and Buser. Survival of dental implants was computed using the Kaplan–Meier method. Data

were analyzed descriptively for patient age and quoted as mean values ± SD.

Results

6 patients (4 women; 2 men), aged 27–60 years (mean age 40 ± 8) were enrolled in group A. 6 root identical zirconia replicas with a surface roughened only by sandblasting were inserted in fresh extraction sockets within 1–4 days after tooth extraction. Primary implant stability was achieved in all patients and no complications, such as swelling, inflammation, bleeding and pain, were observed during the follow-up period. Implant survival is shown in Fig. 1. 5 implants were lost within 26–128 days (62 ± 40 mean ± SD), with an unaltered extraction socket compared with the clinical situation immediately after initial tooth extraction. Implants loosened and were lost suddenly without prior pain or infection. In one case, the patient underwent an orthodontic treatment. The implant, which was clinically functioning without a crown, was removed easily on day 239 with little resistance, indicating loose adherence. None of the implants were restored with a crown, because of the early loss. Owing to the inferior results, based on the lack of osseointegration, patient enrolment was stopped after only 6 patients.

Significant modifications were devised, as detailed above, and study group B was started, consisting of 12 consecutive patients (4 women; 8 men), aged 27–65 years (mean 45 ± 12 yeas). In 4 patients, chronic apical paradontitis was noticed. All patients received a dental implant within 1–8 days after tooth extraction. Primary stability was achieved in all patients. On day 18, 1 patient said that he sensed the implant, without reporting any pain, after he had chewed hard food with it. The implant, which was in a left maxillary premolar position, sounded dull on percussion without visible movement. The implant was left in place and after an observational period with no changes in the clinical situation, it was removed on day 624 to clear the way for a definitive solution. As in group A, the extraction socket appeared unaltered compared with the clinical situation immediately after initial tooth extraction. There was no infection, no noticeable bone resorption and no soft tissue retraction (Fig. 2). Although the implant was left in place for 624 days, the implant failure was recorded to have happened on day 18, when the lack of osseointegration was indicated by sounding dull on percussion.

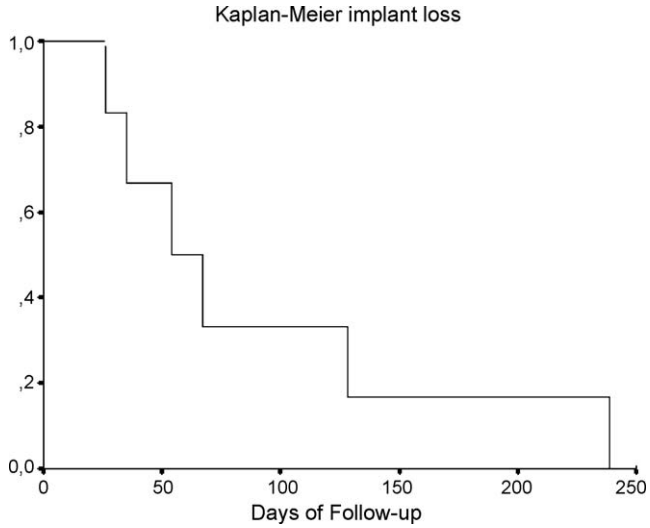

Fig. 1. Kaplan–Meier estimate of implant loss in group A patients with sandblasted, root identical zirconia replicas.

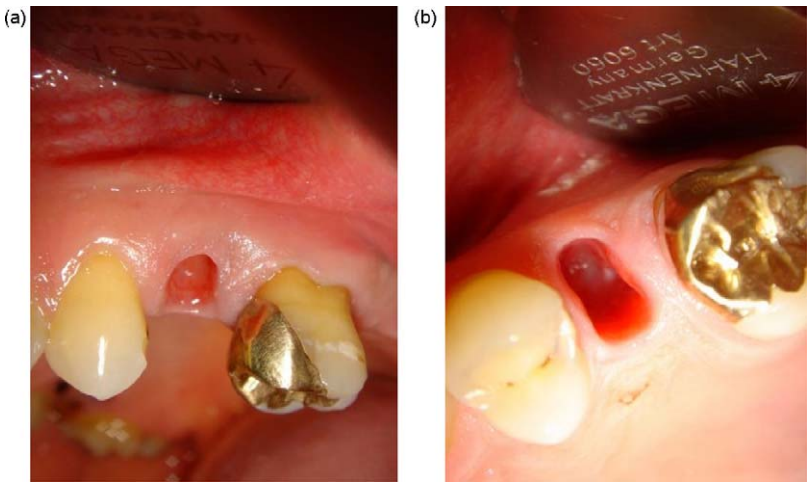

Fig. 2. (a, b) Two views of the preserved extraction socket at the time of implant loss (root analogue implant with macroretentions) 624 days after insertion.

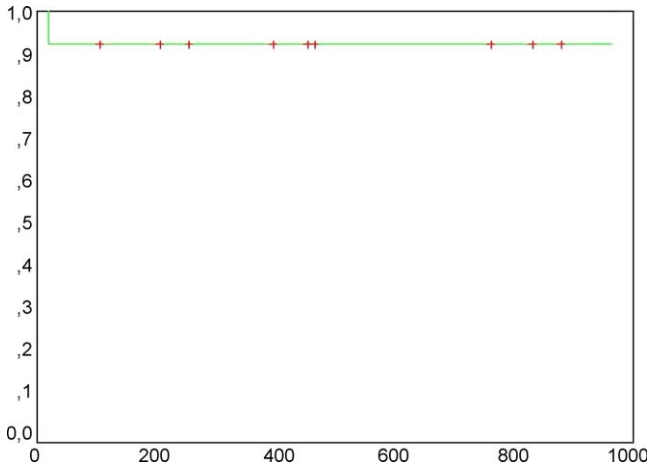

Fig. 3. Kaplan–Meier estimate of implant loss in group B patients with sandblasted, root-analogue zirconia implants modified with macroretentions in the interdental space and diameter reduction next to the cortical bone.

Implant survival as computed according to the Kaplan–Meier method is depicted in Fig. 3. All 11 remaining implants healed uneventfully with no complications, giving an overall success rate of 92%.

After 3–13 months a composite crown was cemented in place. Patients were followed for 6–34 months (18 ± 10, mean $\pm$ SD). At the latest follow-up, 11 implants were assessed as stable and successful and no complications were detected. Each follow-up revealed a clinically healthy marginal area and no swelling or pain was reported. Soft tissue retraction ranged from 0–1.5 mm (0.5 ± 0.7, mean $\pm$ SD) within the first year and remained stable thereafter. Many implants (58%) had no observed soft tissue retraction and maintained an aesthetic gingival architecture. Probing depths ranged from 1 to 4 mm. Clinically, the mucosa around the implants seemed free of inflammation with the sulcus bleeding index averaging 0.24. There was no wound infection, no signs of periodontitis, and no implant mobility/dislocation. No implants were lost during the functional loading period and none of the patients needed treatment in the follow-up period. Fig. 4 shows the situation before extraction, during insertion, before crown reconstruction, and at 15 months follow-up. Radiological examination revealed uncomplicated healing of the lesions in patients with chronic apical paradontitis, without antibiotic treatment (Fig. 5).

Discussion

This report describes two novel approaches to dental root replacement in humans and evaluates the use of root analogue zirconia implants prospectively in 18 patients. Since all implants were lost in group A, enrolment was stopped after only 6 patients. Significant modifications, including macroretentions limited to the interdental space and diameter reduction next to the cortical bone, were devised and led to a highly successful intermediate term implant rate in the following trial in 12 patients.[17]

Zirconia, which emerged as an alternative material to titanium for dental implant fabrication, was used to achieve better aesthetic results and because of its superior mechanical and chemical properties. It has a high flexural strength, good hardness, and its biocompatibility as a dental implant that osseointegrates to the same extent as titanium implants has been demonstrated in several animal investigations.[6,11,13,15,16,18,19,20] Rough surface topography has been shown to enhance

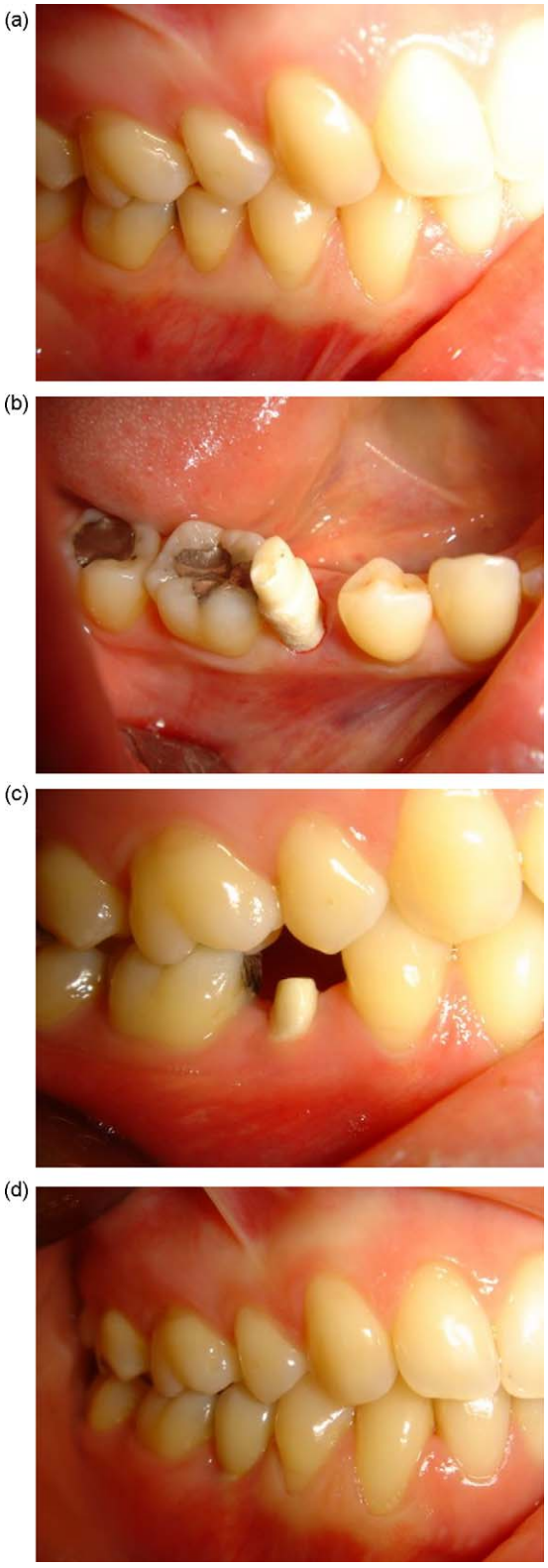

Fig. 4. (a) Before tooth extraxtion. (b) Implant placement; tooth replacement with crown at 2 year follow-up. (c) 2 months after implant placement, before crown reconstruction. (d) At 15 months follow-up, soft tissue retraction of 1 mm.

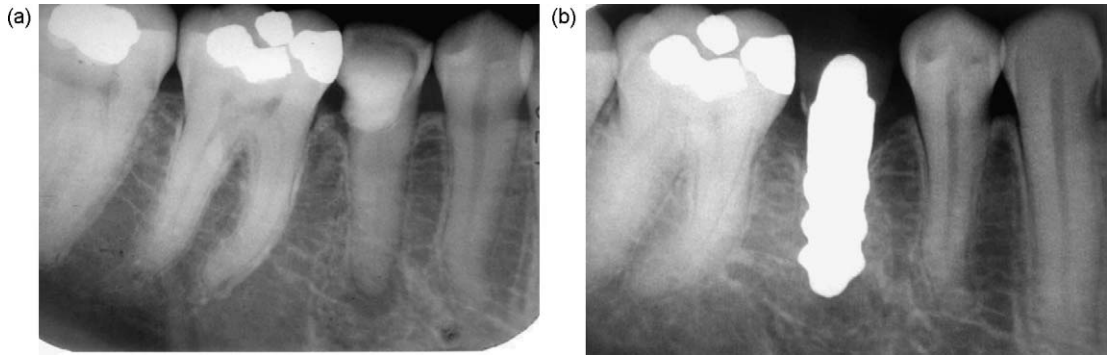

Fig. 5. (a) X-ray before extraction. (b) X-ray at 15 months follow-up with the zirconia implant and crown in situ.

bone integration. In the initial study, root identical replicas with a surface roughened by sandblasting were inserted. Kohal et al. tested loaded, custom-made, sandblasted zirconia implants with metal crowns in the maxillae of 12 monkeys.[10] All implants achieved and maintained stability, and no mechanical problems were reported. In contrast, in the present human trial all implants failed, despite being exposed to partial load. This indicates that a root identical design with microretentions only does not allow for osseointegration in the clinical situation. A perfect implant fit with no retentions leads to excellent primary stability, but it might be responsible for the intermediate term failure, because of the subsequent uniform pressure-induced resorption on the entire alveolar surface, resulting in a loosened interlock between the implant and in-growth bone. This prohibits secondary stability of a conical, root-analogue implant. For that reason the authors chose a novel approach. A cross-section of the jaws shows that there is only sufficient room for enlargements and retentions in the interdental space, whereas the thin buccal and lingual layers do not allow for any enlargement of implants in this area. The authors manufactured root-analogue implants with macroretentions in the interdental space, an implant diameter reduction of 0.1–0.2 mm next to the buccal cortical bone. The surface was roughened by sandblasting to increase the surface area, aiding bone cell attachment. A single-stage implant approach with a crown stump was chosen, since it leads to an early, albeit reduced, functional load, allowing for osseointegration while preventing the unaesthetic early bone resorption observed with submerged implants.

There are several advantages to the approach described in the current study: The topography of the implants is similar to that of the root of the extracted tooth, which eliminates the need for conventionally used bone drills and other traumatic procedures required for preparing for implantation. Zirconia is highly biocompatible, has the mechanical properties required for a good dental implant and is aesthetically pleasing. It could replace titanium for visible dental repairs. Immediate implantation of a root analogue replica allows instantaneous support of soft tissue and limited functional load, resulting in perfect socket preservation in the instance of implant failure with minimal bone loss. This allows the dentist to start the implant strategy from the beginning in cases of implant failure.

The present clinical trial indicate that by introducing significant modifications, such as macroretentions and implant diameter reduction next to the cortical bone, primary stability and excellent osseointegration of immediate root-analogue zirconium implants can be achieved, while preventing unaesthetic bone resorption. The macroretentions have to be limited to the interdental space to avoid fracture of the thin buccal cortex. This novel approach could form an alternative method for replacing teeth immediately after extraction. The preliminary results of human trials with multi-rooted teeth indicate that this method might be applied to all teeth. This successful clinical study warrants further clinical research in well-controlled trials to evaluate the long-term success rate of root analogue zirconia implants.

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