Immediate, non-submerged, root-analogue direct laser metal sintering (DLMS) implants: a 1-year prospective study on 15 patients

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Abstract This study evaluated the 1-year survival and success rate of root-analogue direct laser metal sintering (DLMS) implants, placed into the extraction sockets of 15 patients. DLMS is a technology which allows solids with complex geometry to be fabricated by annealing metal powder microparticles in a focused laser beam, according to a computer-generated three-dimensional (3D) model; the fabrication process involves the laser-induced fusion of titanium microparticles, in order to build, layer-by-layer, the desired object. Cone-beam computed tomography (CBCT) acquisition and 3D image conversion, combined with the DLMS process, allow the fabrication of custom-made, root-analogue implants (RAIs). CBCT images of 15 non-restorable premolars (eight maxilla; seven mandible) were acquired and transformed into 3D models: from these, custom-made, root-analogue DLMS implants with integral abutment were fabricated. Immediately after tooth extraction, the RAIs were placed in the sockets and restored with a single crown. One year after implant placement, clinical and radiographic parameters were assessed: success criteria included absence of pain, suppuration, and exudation; absence of implant mobility and absence of continuous peri-implant radiolucency; distance between the implant shoulder and the first visible bone-to-implant contact <1.5 mm from initial surgery; and absence of prosthetic complications. At the 1-year follow-up, no implants were lost, for a survival rate of 100 %. All implants were stable, with no signs of infection. The good conditions of the peri-implant tissues were confirmed by the radiographic examination, with a mean DIB of 0.7 mm (±0.2). The possibility of fabricating custom-made, RAI DLMS implants opens new interesting horizons for immediate placement of dental implants.

Keywords Immediate implants · Primary stability · Custom-made · Root-analogue implant (RAI) · Direct laser metal sintering (DLMS)

Introduction

The prosthetic rehabilitation of partially and totally edentulous patients with endosseous dental implants has become a common practice, with excellent long-term success rates [1, 2]. In the last decades, implant dentistry has evolved toward simplification of clinical procedures and shortened treatment times, with such developments as immediate implant placement [3, 4]. Immediate implants are implants inserted immediately after surgical extraction of the teeth to be replaced. The major advantages of immediate implant placement are the decrease in treatment time with fewer surgical interventions, leading to overall cost
reduction and an improvement in the patients’ psychological outlook for treatment; it has also been suggested that the ideal orientation of the implant, preservation of the bone at the extraction site and maintenance of ideal soft tissue contours, and esthetics may be achieved [3, 4]. Primary stability following implant placement is needed: when micromotion occurs, stem cells in the osseous wound differentiate to fibroblasts and form scar tissue around the implant, thus inhibiting osseointegration [5]. In a fresh extraction socket, however, it can be difficult to achieve primary implant stability. In addition, after implant installation, a gap may occur in the marginal part of the recipient site, necessitating the use of a barrier membrane and/or bone augmentation to prevent downgrowth of connective tissue or epithelium in between the implant and the socket [3, 4]. The surgical requirements for immediate implantation include extraction with the least trauma possible and careful preservation of the alveolar socket walls; conventionally, primary stability has been achieved by placing implants exceeding the alveolar apex by 3–5 mm, or by inserting high diameter implants in surgically enlarged sockets, together with grafting and/or regenerative procedures around primarily stabilized implant [3, 4, 6–8]. However, immediate post-extraction implant placement deals with one major problem: the incongruity between the socket wall and the endosseous implant shape. Following tooth extraction, in fact, a socket often presents dimensions that may be considerably greater than the diameter of a conventional, screw- or cylinder-type implant [3, 4]. This problem could be rectified by employing a novel approach, using custom-made root-analogue implants (RAIs) placed into the extraction sockets, adapting the root to the socket instead of adapting the bone to a preformed standardized implant; such an implant would fit into the extraction socket due to its congruence with it [6–8]. Several studies describing techniques of fabricating and placing custom-made RAI have been noted in the literature [9–16]. This approach could have advantages, such as uncomplicated immediate implant placement, eliminating the need for conventionally used bone drills and other traumatic procedures required for preparing for implantation, with increased patient comfort; moreover, mimicking root features might result in higher esthetic outcome [9–16]. However, a significant shortcoming with previously reported techniques is that the process entails laser scanning or machine copying of an extracted root with placement of the subsequently created RAI at a second surgery [9–16]. It would seem more efficient to obtain a root replica prior to tooth extraction, thus allowing for immediate implant placement, negating the need for a subsequent surgery. In the last few years, rapid prototyping (RP) has been widely used in many biomedical applications [17]. RP is a strategy to directly fabricate physical objects with defined structure and shape on the basis of virtual three-dimensional (3D) data [17–19]. Combined with the introduction of cone-beam computed tomography (CBCT) scanning techniques and computer-aided design (CAD) approaches, RP technologies, such as direct laser metal sintering (DLMS), can be used as tools to directly produce custom-made RAI in a biocompatible titanium alloy [17–19]. DLMS is a time-saving and costless metal-forming procedure in which a high-power laser beam is focused on a metal powder bed and programmed to fuse particles according to a CAD file, thus generating a thin metal layer. Apposition of subsequent layers gives shape to a desired 3D form with the need of minimal post-processing requirements [17–21]. With DLMS, it is possible to fabricate titanium dental implants directly from CAD models [22–24]. Recently, a novel approach to fabricate a custom-made titanium RAI has been proposed [6–8]. With the combined use of CBCT 3D data and high-end DLMS technology, it was possible to manufacture a RAI with sufficient precision [6–8]. In two different clinical reports, a custom-made, root-analogue DLMS implant was placed into an extraction socket [7, 8]. A perfect congruence between implant and extraction socket was obtained; after 1 year of follow-up, the custom-made implants showed a perfect functional and esthetic integration [7, 8]. However, the evidence emerging from these first clinical reports had to be confirmed by a prospective study on a larger sample of patients. The aim of the present study was to evaluate the survival and success rate of custom-made, root-analogue DLMS implants on a larger sample of patients, with 1-year of follow-up.

Materials and methods

Patient selection

Between January 2009 and June 2011, all patients referred to the Dental Clinic, University of Varese, and to a private practice were considered for inclusion in this study. The inclusion criteria were patients with a fractured/non-restorable premolar in the maxilla/mandible, uncompromised periodontal ligaments, informed consent, and willingness to adhere to the protocol. Indications for tooth extraction included root caries, vertical/horizontal root fracture, endodontic lesion, and unsuccessful root canal treatment (Fig. 1a–b). Patients with dehiscence/fenestration of the crestal bone as determined by clinical and radiographic examination and with tooth extraction necessitating surgical intervention leading to compromise of the alveolar socket walls were excluded from this study. Additional exclusion criteria consisted of poor oral hygiene, active periodontal infections, uncontrolled diabetes, bruxism, and smoking habit. Chronic apical periodontitis was not an exclusion criterion,
but in these cases, the area of infection had to be removed. The study protocol was explained to each subject, and a signed informed consent was obtained. The study was performed according to the principles outlined in the World’s Medical Association’s Declaration of Helsinki on experimentation involving human subjects, as revised in 2008, and it was approved by the Local Ethics Committee for Human Studies.

CBCT scan and preoperative CAD work-up

Computer tomographic datasets of the fractured teeth were acquired using a modern CBCT scanner (CS9300R, Carestream, Rochester, NY, USA). CBCT datasets were transferred to a specific 3D reconstruction software (MimicsR, Materialise, Leuven, Belgium). With this software, it was possible to construct a 3D projection of the maxilla/mandible and the residual roots, simulating a “virtual” extraction of the roots. The virtual roots were isolated as stereolithographic (STL) files and transferred to proprietary, reverse engineering software (Leader ImplantsR, Milan, Italy). The roots were smoothed in order to obtain a regular surface. The STL files were returned to the 3D reconstruction software again (MimicsR, Materialise, Leuven, Belgium) to test the congruence between the roots and the alveolar sockets. Then, the files were transferred to Pro/Engineering CAD 3D software (PTC GroupR, Needham, MA, USA) where the prosthetic conical abutments were designed, and a reduction of the diameter (0.1–0.3 mm) of the implant neck next to the thin vestibular cortical bone was made. After that, with the aid of another 3D image reconstruction software (MagicsR, Materialise, Leuven, Belgium), copies of the final STL file (virtual root plus abutment) were prepared, with sequential percentage dimensional increments, in order to provide the surgeon with at least three different STL files representing different size increments (0, 5, and 10 %) of the same object (to avoid potential distortions or errors related to the 3D projection steps). All these three STL copies with increments (0, 5, and 10 %) were used to manufacture the RAIs using the DLMS technique.

Implant fabrication

DLMS technology (Leader ImplantsR, Milan, Italy) was used to fabricate the custom-made RAI (Silvetti-Combe Technique) with integral abutment, directly from the STL files [7, 8]. Three RAIs (representing 0, 5, and 10 % increments of the same object) were fabricated for each clinical case. The implants were made of Ti-6Al-4V alloy powder, with a particle size of 25–45 μm as the basic material. Processing was carried out in an argon atmosphere using a powerful ytterbium (Yb) fiber laser system (Eos Laser SystemsR, Munich, Germany) with the capacity to build a volume up to 250×250×215 mm using a wavelength of 1,054 nm with a continuous power of 200 W, at a scanning rate of 7 m/s. The size of the laser spot was 0.1 mm. To remove residual particles from the manufacturing process, the implants were sonicated for 5 min in distilled water at 25 °C, immersed in NaOH (20 g/L) and hydrogen peroxide (20 g/L) at 80 °C for 30 min, and then further sonicated for 5 min in distilled water. Acid etching was carried out by immersion of the sample in a mixture of 50 % oxalic acid and 50 % maleic acid at 80 °C for 45 min, followed by washing for 5 min in distilled water in a sonic bath. The surface topography of the DLMS implants had no clear orientation. The DLMS provided an implant surface with a roughness surface with the mean (SD) of the absolute values of all profile points, the root mean square of the values of all points, and the average value of the absolute heights of the five highest peaks and the depths of the five deepest valleys of 66.8 (6.6)μm, 77.6 (11.1)μm, and 358.3 (101.9)μm, respectively. Finally, the implants were packaged in custom-made disposable packaging fabricated with the aid of a specific software (Pro/Engineering CAD 3D®, PTC, Needham, MA, USA).

Surgical and prosthetic procedure

Two weeks before surgery, all patients underwent presurgical treatment including case presentation, professional tooth cleaning, and instruction in oral hygiene measures. A 0.12 % chlorhexidine mouthwash (ChlorexidineR, OralB,
(EnantyumR, Menarini, Bologna, Italy), as postoperative analgesic. Antibiotic therapy with amoxicillin + clavulanic acid (AugmentinR, GlaxoSmithKline Beecham, Brentford, UK), 1 g two times a day, was also administered and maintained for 6 days. Detailed instructions about oral hygiene were given, with mouth rinses with 0.12 % chlorhexidine (ChlorexidineR, OralB, Boston, MA, USA) administered for 7 days. The patients were seen on a weekly basis during the first 4 weeks. At the first control visit, 7 days after the surgery, sutures were removed. The provisional restorations were maintained in situ for 3 months, after which the definitive restorations, which were cemented metal–ceramic single crowns, were placed.

Clinical, radiographic, and prosthetic evaluation

The following clinical parameters were investigated after 1 year of functional loading for each implant: presence/absence of pain, suppuration or exudation, and presence/absence of implant mobility, tested manually using the handles of two dental mirrors [25]. Intraoral periapical radiographs were taken of each implant, using an alignment system with a rigid film-object X-ray source coupled to a beam-aiming device to achieve reproducible exposure geometry [25]. Customized positioners, made of polyvinyl siloxane and combined with an alignment system with a rigid film-object X-ray source coupled to a beam-aiming device, were used for precise repositioning and stabilization of the radiographic template. Radiographs were taken at the baseline (immediately after implant insertion) and at the 1-year follow-up session, and two different radiographic parameters were evaluated: presence/absence of continuous peri-implant radiolucencies and distance between the implant shoulder and the first visible bone contact (DIB) in millimeters, measured with the
aim of an ocular grid [25]. With the latter value, crestal bone level changes at 1 year were registered as modifications in the distance from the implant shoulder to the bone level on the mesial and distal implant side. To correct dimensional distortion, the apparent dimension of each implant was measured on the radiograph and then compared with the real implant length. Finally, at the 1-year follow-up session, prosthesis function was tested. Static and dynamic occlusion was evaluated, using standard occluding papers [25]. Careful attention was dedicated to the analysis of any potential prosthetic complications.

Implant survival and success criteria

The evaluation of implant survival and implant success was performed according to the following clinical and radiographic parameters. Implants were divided into two categories: survived and failed implants. A survived implant was classified as such when it was still functional at the end of the study, after 1 year of functional loading. Implant losses were categorized as failures. Implants presenting pain on function, suppuration, or clinical mobility were removed and categorized as failures [26]. The conditions for which implant removal could be indicated included failure of osseointegration or infection, recurrent peri-implantitis, or implant loss caused by mechanical overload. To achieve implant success, the following clinical and radiographic success criteria had to be fulfilled: absence of pain on function; absence of suppuration or exudation; absence of clinically detectable implant mobility; absence of continuous peri-implant radiolucency; DIB <1.5 mm from initial surgery; and absence of prosthetic complications [26].

Results

Fifteen patients (eight males, seven females; aged between 39 and 55 years, average 45.5) were selected for this study. Each patient received a custom-made, root-analogue DLMS implant (Fig. 5a–b). The reasons for the extraction of natural teeth were summarized in Table 1. The distribution of the implants was summarized in Table 2. At the first control visit, 7 days after the surgery, a clinically healthy marginal area was present in all patients, and no postoperative pain or swelling was reported (Fig. 6). There was no bleeding or wound infection. After 2 weeks, the peri-implant tissues showed a good marginal adaptation. After 3–4 weeks, the peri-implant tissues were stable and in optimal conditions. At the end of the study, 1 year after placement, no implants were lost, for an overall survival rate of 100 %. All implants were stable, with no signs of infection such as pain or suppuration. The good conditions of the peri-implant tissues were confirmed by the radiographic examination, with unchanged peri-implant marginal bone level and no peri-implant radiolucency. The 1-year mean DIB was 0.7±0.2 mm (median, 0.7; 95 % CI 0.6–0.8). The radiographic profile of the implant–crown complex was very similar to that of natural teeth. No prosthetic complications occurred. The prosthetic restoration showed good functional and esthetic integration (Fig. 7a–b–c).

Discussion

The concept of replacing teeth with custom-made RAI is not new. The oldest evidence of a dental implant dates back to around 600 BC. While excavating Mayan burial sites in Honduras in 1931, archaeologists found a fragment of mandible of Mayan origin. This mandible, which was considered to be that of a young woman, had three tooth-shaped pieces of shell placed into the sockets of three missing lower incisors. In ancient times, wood, metal, shell, and stone were carved and shaped to form the root for the implant. In 1969, Hodosh et al. used a custom-made RAI placed into the extraction socket, reducing bone and soft tissue trauma [9]. Autopolymerized and heat-processed polymethacrylate was utilized to fabricate the RAI. The extracted tooth was invested in plaster and the resulting mold was packed with the polymer and heat processed; the replica of the extracted tooth was then placed into the extraction socket [9]. Unfortunately, the polymethacrylate tooth analogue was encapsulated by soft tissue rather than osseointegrated [9]. Lundgren et al. reintroduced the idea of RAI in 1992 [10]. Instead of using polymers, commercially pure titanium was utilized in an experimental model of immediate implant

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<th>Table 1</th>
<th>Indications for tooth extraction</th>
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<tr>
<td>Root caries</td>
<td>7 (46.6 %)</td>
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<tr>
<td>Vertical/horizontal root fracture</td>
<td>5 (33.3 %)</td>
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<tr>
<td>Endodontic lesion</td>
<td>2 (13.3 %)</td>
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<tr>
<td>Unsuccessful root canal treatment</td>
<td>1 (6.6 %)</td>
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placement, leading to bony integration in 88% [10]. The authors concluded that this system osseointegrated with a high degree of predictability and the quality of bone-to-implant contact was high enough to function well. In fact, they placed their implants in the lower premolar area where a thicker buccal and lingual alveolar wall can be anticipated and less bone resorption after trauma might occur [10]. In another animal experiment, Kohal et al. tried to refine the approach of titanium RAI 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 [11]. Unfortunately, some of the implants were too large to fit precisely into the respective extraction sockets; in several instances, the implant insertion led to fractures of the thin buccal wall of the alveolar bone [11]. These bone fractures and the exerted pressure of the implants onto the bone appeared to induce bone resorption and its replacement by soft connective tissue [11].

A subsequent clinical trial by the same authors resulted in a 100% primary stability at insertion and 1 month follow-up, but with a high disappointing failure rate of 48% at 9-month follow-up [12]. A possible explanation is that all implants were placed in the upper anterior jaw, where cortical bone covering the root is very thin with no or few blood vessels and prone to fracture; a perfect fit of the implant leads initially to excellent primary stability; however, it might be responsible for the intermediate time esthetic failure because of the subsequent uniform pressure-induced resorption simultaneously involving the entire alveolar surface. Moreover, the problems encountered were due to the nature of the scanning laser and the milling unit of this first generation of RAI. The relatively wide focusing area of the laser was not adjusted to the small animal roots and their irregularities, and the milling unit was not able to process all the structures of the tooth root [11, 12]. Also, the utilized carbide burs were too coarse for such small specimens contributing to the confronting problems. The amount of osseointegration may depend on the precision of the fabrication of the RAI [11, 12]. Owing to this disappointing high failure rate, the use of these titanium RAI was not recommended for clinical use [12].

More recently, zirconia-based RAI was introduced [13–15]. In a clinical report by Pirker et al., the immediate placement of a root-analogue non-submerged zirconia implant with macro-retention in the interdental space and a diameter reduction of 0.1 to 0.3 mm next to the buccal cortical bone yielded excellent functional and esthetic results, with no clinically noticeable bone resorption or soft tissue recession at 2-year follow-up [13]. The surface of the RAI was roughened by sand blasting to increase the surface area aiding bone cell attachment; the macroretentions were limited to the interdental space to avoid fracture of the thin buccal cortex. These results were confirmed in more recent clinical studies demonstrating that the presence of macroretentions limited to the interdental space can improve primary implant stability and finally osseointegration, and the reduction of the diameter of the implant next to the thin cortical bone is important to avoid fracture and pressure-induced bone loss [14, 15]. In the last few years, the application of digital technology in dentistry has become increasingly widespread with the introduction of CBCT scan technology, and considerable progress has been made in the development of computer-aided design/computer-aided manufacturing (CAD/CAM) techniques, including DLMS [17–21].

DLMS is a CAD/CAM method, creating patterns using thermal fusing (sintering) of powdered titanium. In DLMS, the digital representation of an object is mathematically sliced into a number of thin layers. The object is then created by scanning a laser beam and selectively fusing (melting or sintering) patterns into sequentially deposited layers of powder. Each patterned layer of powder is also fused to its underlying layer and corresponds to a cross section of the object as determined from the mathematical slicing operation [17–21]. The revolutionary precision of these techniques, by which it is possible to join very thin sections (from 0.02 to 0.06 mm) together, allows the fabrication of geometries with a high degree of complexity: it can be used to fabricate 3D structures with complex features.
such as overhangs and undercuts [17–21]. Nowadays, patient-specific reconstruction strategies can be easily developed: modern CBCT acquisition and 3D image conversion, combined with the DLMS process, allow the fabrication of custom-made, RAI, perfect copies of the radicular units we need to replace [6–8, 17–21]. In our present study, custom-made, titanium RAIs with a preoperatively designed abutment were fabricated with the DLMS technique and placed into the extraction sockets of 15 consecutive patients. The fabrication of a custom-made RAI with the DLMS technique presents some potential advantages. The RAIs were fabricated in an argon atmosphere using a powerful, high-precision Yb fiber laser system, with the capacity to build a volume up to 250×250×215 mm using a wavelength of 1,054 nm with a continuous power of 200 W, at a scanning rate of 7 m/s. The size of the laser spot was 0.1 mm. The RAIs were then placed into the sockets under finger pressure and subsequent gentle tapping with a hammer and a mallet to achieve the primary stability. A perfect congruence between implant and extraction socket was obtained, with a diameter reduction of 0.1 to 0.3 mm next to the buccal cortical bone. At the 1-year follow-up examination, all implants were in function (100 % survival), showing a good functional and esthetic integration. The technique described in the present study has limits. In fact, when atraumatic extraction cannot be performed, or bony walls of the socket are fractured, the placement of RAI should be avoided, and standard, commercially available implants/fixtures should be installed. In addition, the presence of curved and divergent roots may represent another potential limitation of the RAI technique; in fact, this anatomical situation may render the placement of RAI difficult. However, the elasticity of alveolar bone may limit, at least to some extent, the negative impact of divergent root anatomy/curved roots, when RAIs are placed [8, 15]. The direct laser metal forming (DLMF) technique allows the fabrication of functionally graded titanium implants, with a relatively high porosity at the surface and a high density in the core [17–24]. This kind of modulation may allow better load adaptation, avoiding stress shielding and pressure-induced bone loss. In addition, DLMF technique allows the fabrication of a porous structure with controlled porosity, pore interconnection, size, shape, and distribution, which are requirements for rapid bone ingrowth [17–24]. In fact, with DLMF, it is possible to control the porosity of each layer and consequently of the 3D model by changing the processing parameters, which include the diameter of the focused laser beam, power rating of the laser, scanning speed, average particle size of the starting material powder, layer thickness, track overlap, and process atmospheric conditions [17–19]. It has been demonstrated that porous surfaces can promote better and faster bone apposition, being more osteoconductive than smooth surfaces [22, 23]. Osseointegration is favored by porous implants that improve fixation by creating a mechanical interlock via the growth of bone into the porous structure [17–23]. Improved fixation can be achieved by bone ingrowth into and through a porous matrix of metal, bonding the implant to the bone. Finally, body fluid transport through the porous scaffold matrix is possible, which can trigger bone ingrowth, if substantial open pore interconnectivity is established. The DLMF surface geometry, rich in interconnecting pores and cavities, may represent an ideal environment for osteogenic phenotype expression [17–23]. The shape cells are forced to adopt within the 3D microstructure of pores and cavities may be responsible of creating mechanical stresses that modulate osteogenic phenotype expression [27].
Conclusions

The introduction of DLMS may signal the start of a new revolutionary era for implant dentistry. This novel approach of custom-made, RAI immediately following extraction is minimally invasive, respects the underlying anatomy, and is time and cost saving with good esthetic results, leading to an increased patient acceptance. Moreover, since the information on the abutment design is digital, the definitive prosthetic temporary crown can be made with the CAD/CAM technology. In the future, instead of solid body RAIs, 3D cage root analogues could also be fabricated. The fabrication of DLMS RAI could form an alternative method for replacing teeth immediately after extraction. Further long-term studies, however, are needed with a larger sample of patients to evaluate the benefits of this technique.

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