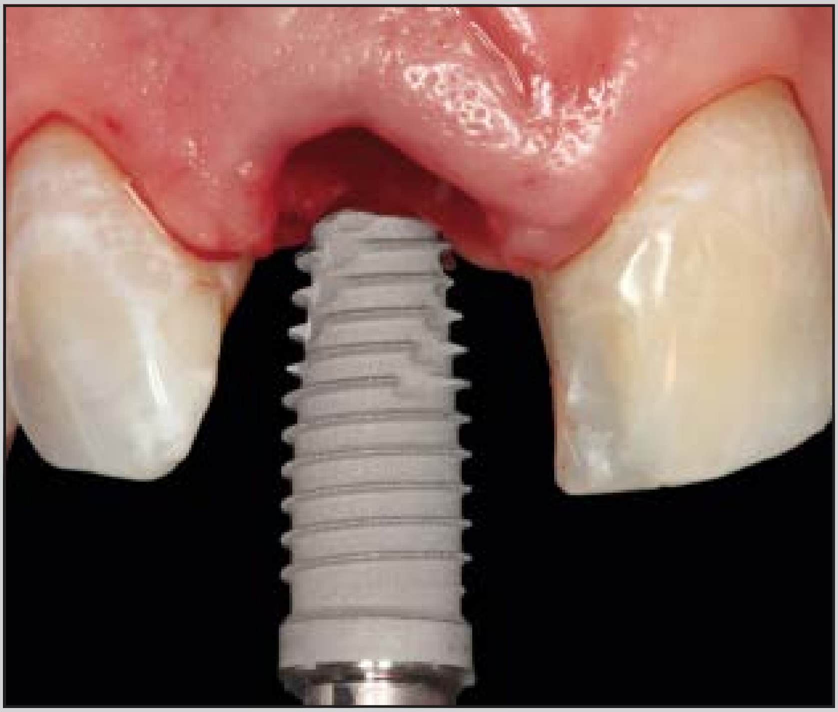
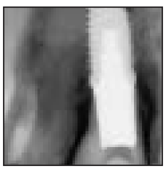


A Prospective Evaluation of a Novel Implant Designed for Immediate Loading



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This prospective study evaluated the survival rate of immediately loaded anatomically tapered implants with a dual acid-etched, microtextured surface. Patients in a private practice were recruited for placement of 3i T3 tapered implants in single, multiple, and full-arch applications in the mandible and maxilla, in both fresh extraction and healed placement sites. Ninety patients were treated, and 240 implants were placed and immediately loaded: 124 in the maxilla and 116 in the mandible. One hundred twelve definitive prostheses were delivered between 4 and 6 months after implant placement. Over the course of 2 to 12 months of follow-up (mean: 4.8 months), five implants failed in the maxilla and no implants failed in the mandible, a survival rate of 96% for the maxilla and 100% for the mandible. The cumulative survival rate was 98%. (Int J Periodontics Restorative Dent 2014;34(suppl):s43–s49. doi: 10.11607/prd.2130)

Placement of dental implants in a two-stage protocol to treat partially and completely edentulous patients has been predictably successful.[1,2] The biologic rationale behind the two-stage approach, which submerges the implants for a 3- to 4-month healing period in the mandible and 6 to 8 months in the maxilla,[3,4] is to avoid implant micromovement that could create fibroencapsulation of the implant-bone interface during the healing period.[5] For many years, this approach was considered mandatory to prevent infection and epithelial downgrowth.[6]

However, the protocol has several negative aspects,[7] and the alternative of early or immediate occlusal loading has been introduced as a way to reduce treatment time and increase patient comfort.[8,9] The main requirement to enable such early/immediate loading is primary stability.[10,11] Insertion torque values have been used for clinically assessing implant primary stability.[12,13] It has been suggested that by increasing the insertion torque, implant primary stability can be improved and the risk of micromovement reduced.[14–16]

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A minimum of 32 Ncm of torque has been suggested for loading implants early or immediately,[17] but no consensus has been reached regarding optimal and/or maximum recommended insertion torque values. Some studies have suggested that high insertion torque can compress the peri-implant bone, disturb the microcirculation, and lead to osteocyte necrosis and bone resorption.[18] Other studies, however, have found no statistical difference in marginal bone resorption and implant success rates for implants inserted with low insertion torque (30 to 50 Ncm) and those inserted with high (> 70 Ncm) insertion torque values,[19,20] even for values up to 176 Ncm.[19,21]

The aim of the present study was to evaluate the cumulative survival rate of immediately loaded anatomically tapered implants with a dual acid-etched, microtextured surface.

Method and materials

From January to December 2013, patients in a private dental practice in Catania, Italy, who were at least 19 years of age and in need of single-tooth, partial, or full-arch implant restoration, both mandibular and maxillary, were invited to participate in the study. The selection criteria included patients who had adequate bone height to accommodate implants, along with sufficient interarch space to allow for the placement of anatomically sized crowns. An insertion torque of more than 50 Ncm had to be achieved for at least one of the implants. Patients could be smokers or nonsmokers, and both immediate and delayed extraction sites were included.

Patients with systemic disorders that contraindicated surgical treatment were excluded, as were those with severe maxillomandibular discrepancies, parafunctional habits, or active pathology of the adjacent teeth. All study participants provided written informed consent.

All patients were given complete intraoral examinations, and computed tomography (CT) scans were obtained. Bone quality was categorized as one of four types according to Lekholm and Zarb.[22] Study casts were mounted on an articulator and diagnostic wax-ups were made. A surgical template was fabricated for each patient.

Three to 4 days before surgery, patients were prepared with an oral hygiene session and instructed to use a 20% chlorhexidine rinse three times a day for 14 days. Twenty-four hours before surgery, antibiotic prophylaxis was started (amoxicillin 1 g twice a day for 6 days). Local infiltration was induced with articaine 4% with adrenaline (1:100,000 Ubistesin, 3M ESPE) in the vestibular and lingual area and on the incision line with adrenaline 1:50,000. In healed sites, a midcrestal incision was made, and a full-thickness mucoperiosteal flap was raised to expose the crestal bone and increase the amount of the vestibular band of keratinized tissue. In all immediate extraction sites, and where the alveolar crest was wider than 6 mm and an adequate band of keratinized tissue was present, a flapless approach was preferred. For every case in which a tooth needed to be extracted and replaced, an implant was placed immediately after the extraction.

Osteotomies were performed according to the manufacturer's protocol for types 1 and 2 bone. To improve implant primary stability in types 3 and 4 bone, the osteotomies were underprepared. In the maxillary arch, underpreparation was achieved by using osteotomes. In the mandibular arch, it was achieved by using a final drill of the same diameter as the implant but one size shorter than the actual implant length. For type 4 mandibular bone, it was achieved by using a final drill of the same length as the implant but one size narrower than the actual implant diameter. The final implant seating was obtained with a calibrated torque hand ratchet.

Provisional abutments (PreFormance Temporary Cylinders, Biomet 3i) were selected. Platform switching was carried out for all 5-mm-diameter implants; for the 4-mm-diameter implants, the platform-switch was already incorporated into the design.

The cylinders were inserted, and the abutment screw was torqued to 10 Ncm using a torque driver. In each case, the screw-retained provisional prosthesis was inserted and luted to the cylinders using a light-cured composite resin (Tetric-Flow, Ivoclar Vivadent). The occlusion was adjusted, and

Fig 1 *The patient was a 37-year-old man who presented with pain upon occluding on the maxillary right central incisor.*

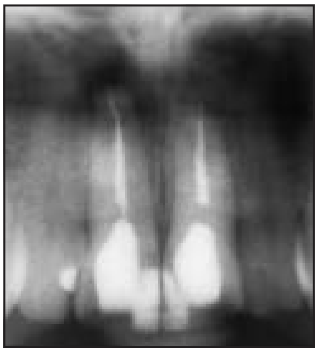


Fig 2 *Radiographic examination revealed a periapical lesion, subsequent to prior root canal therapy. The alveolus was intact, and the periodontium was healthy.*

Fig 3 *Cross-sectional CT scan showing the lesion and the thin buccal and palatal walls.*

Fig 4 *The tooth was extracted using root-tip elevators, extraction forceps, and gentle rotation to avoid damaging the socket walls. The mesiodistal diameter of the coronal third of the root measured 5.35 mm.*

Fig 5 *A palatally oriented osteotomy was prepared, and a 5-mm-diameter by 13-mm-long 3i T3 tapered implant was placed.*

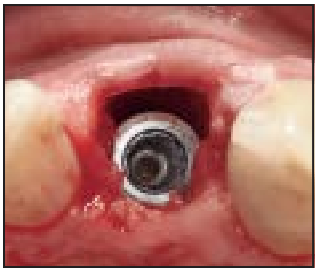


Fig 6 *The buccal gap can be seen in this occlusal view, immediately after implant placement.*

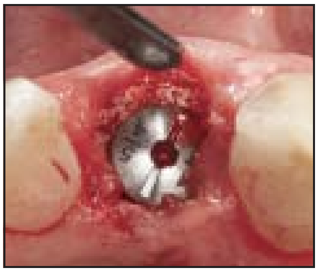
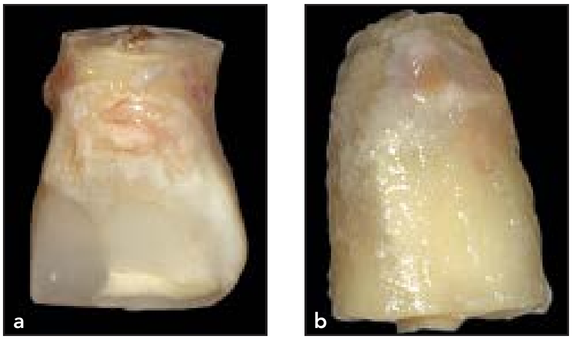


Fig 7 *A healing abutment was placed to act as a mold for bone augmentation material and to prevent it from entering the internal connection of the implant. The gap was filled with 50% autogenous bone (to provide growth factors and osteoprogenitor cells) and 50% Endobon Xenograft Granules (Biomet 3i) to provide space maintenance and a scaffold for new bone.*

the provisional prosthesis was removed, refined, polished, and then reinserted and torqued to 10 Ncm for the final seating. An acrylic resin provisional prosthesis was used in all areas except the immediate single-tooth maxillary central incisor sites. For these sites, the crowns of the extracted natural teeth were adapted to serve as provisional prostheses. Implants placed in completely edentulous arches or partially edentulous posterior sites were immediately functionally loaded, whereas those placed in single-tooth or anterior partially edentulous sites were given provisional prostheses that were left just out of occlusion (nonfunctionally loaded).

In all cases where a flap was raised, interrupted resorbable sutures (Vicryl Rapide Polyglactin, Ethicon) were used. Patients were instructed to maintain a liquid diet for the first week. After 4 to 6 months, a final impression was made using a custom tray, pick-up coping, and low-viscosity polyether impression material (Impregum Penta, 3M ESPE). Gold UCLA definitive abutments were connected to all implants. Definitive restorations were all screw-retained with abutments torqued to 20 Ncm using a calibrated torque driver. Figures 1 to 12 illustrate the common treatment for one of the study's patients.



Figs 8a and 8b *The extracted tooth was sectioned 2 mm apical to the cementoenamel junction.*

Fig 9 (left) *After placing the PreFormance Temporary Cylinder into the implant, securing it with an abutment screw, and luting the hollowed-out crown to it with light-cured composite resin, the cylinder-crown assembly was removed, voids were filled extraorally, and the provisional crown was completed and polished.*

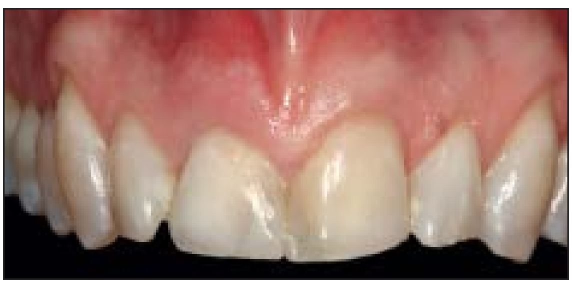


Fig 10 (left) *Five days after placement of the provisional restoration, the gingival margin had migrated coronally. This was desirable to obtain ideal soft tissue contours.*

Fig 11 *Six months after extraction, immediate implant placement, and provisional restoration, the lithium disilicate definitive crown was fabricated and delivered, supported by a UCLA screw-retained abutment. It is seen here at the 1.5-year follow-up appointment. By this point, the gingival margin had migrated apically to match the height of the contralateral central incisor.*

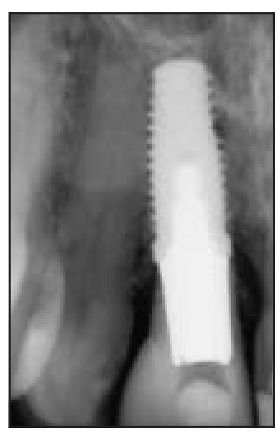


Fig 12 *The 1.5-year postoperative periapical radiograph shows excellent preservation of the bone level. Graft particles can be seen embedded in the soft tissue, a benefit for maintaining soft tissue contours.*

Results

The study population included 90 patients: 41 men and 49 women. Thirty-nine patients required single-tooth restorations, 61 were partially edentulous, and 12 required full-arch treatment. Table 1 shows the patient distribution by age.

The study patients received a total of 240 immediately loaded implants that were restored with 112 definitive restorations. One-hundred sixty-four implants were placed in completely edentulous arches or partially edentulous posterior sites and immediately functionally loaded, while 76 were placed in single-tooth or anterior partially edentulous sites and given provisional prostheses that were left just out of occlusion. One hundred twenty-four implants were placed in the maxilla and 116 in the mandible. Insertion torque values are shown in Table 2. Figures 13 and 14 show implant distribution by site, size, and type.

One hundred thirty-two implants were inserted in healed bone, and 108 were placed in immediate extraction sites. All implants placed immediately in extraction sites were 5 mm in diameter to provide better adaptation to the alveolus. Table 3 displays implant distribution by type of bone.

The mean follow-up period was 4.8 months (range: 2 to 12 months) during which five implants failed in the maxilla and none failed in the mandible, resulting in a cumulative

Table 1 Patient distribution by age	
Age	**Patients (n)**
18–30	4
31–50	25
51–70	56
> 70	5
Total	90

Table 2 Implant distribution by insertion torque	
Insertion torque (Ncm)	**Implants (n)**
> 90	64
70–90	89
50– < 70	63
< 50	24
Total	240

Table 3 Bone conditions	
Bone quality	**Implants (n)**
Extraction socket	108
Type 1	21
Type 2	49
Type 3	45
Type 4	17
Total	240

survival rate of 98%. The survival rate was 96% for the maxilla and 100% for the mandible. The five implants that failed were all placed in partially edentulous patients. Furthermore, all were placed in type 4 maxillary bone, and one of the implants had an insertion torque lower than 50 Ncm.

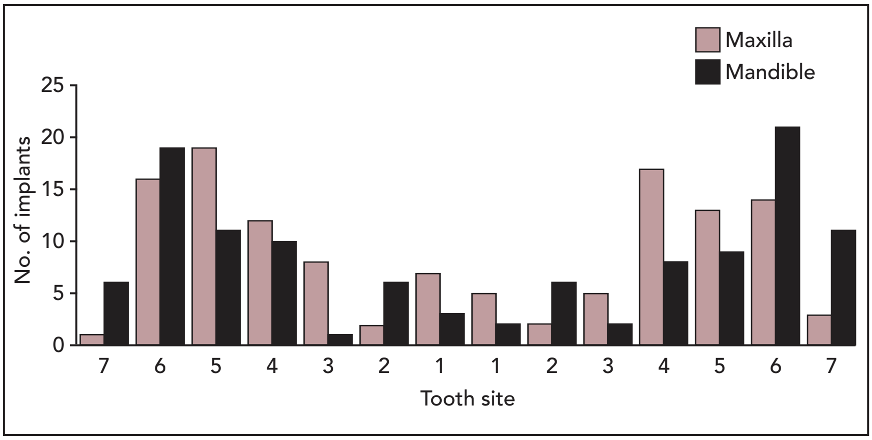


Fig 13 *Implant distribution by site.*

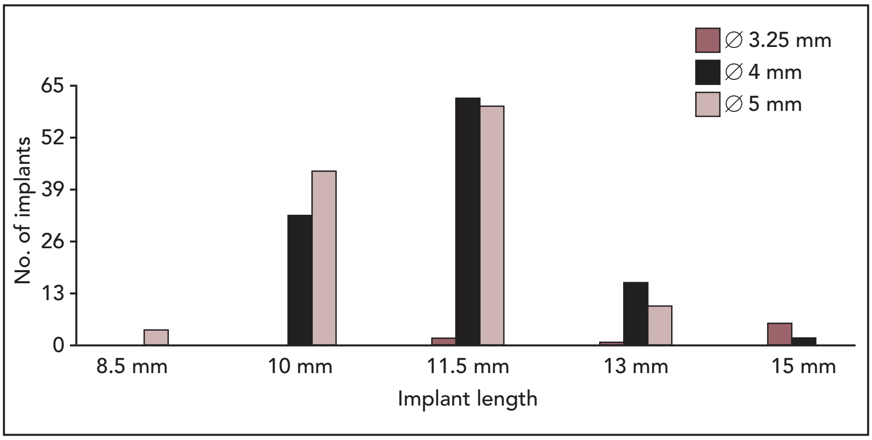


Fig 14 *Implant distribution by size.*

Discussion

Immediate loading of dental implants presents a means of reducing treatment time while decreasing patients' physiologic, psychologic, and sociologic discomfort. This protocol can reduce the incidence of bone atrophy and has the main advantage of immediately replacing missing teeth or teeth that need to be extracted, while avoiding the need for unilateral mastication or removable partial dentures.[23] The use of implant-supported restorations has been shown to lead to a significant improvement in patients' lives, allowing them to avoid the disadvantages of removable dentures.[24]

High success rates for immediately loaded implants in human models were documented in 1986, when a cumulative success rate of 88% was reported for 1,739 implants.[25] Subsequent studies of immediately loaded implants have reported similar or higher cumulative success rates.[26,27]

The high success rates that have been documented for full-arch restorations are probably related to the cross-arch stabilization that plays an important role in reducing implant micromovement.[27]

However, comparable success rates can be obtained in partially edentulous patients, for whom the splinting of implants placed in a straight line represents a way of reducing lateral forces.[28,29] The importance of vertical and lateral force distribution as a requisite for optimizing the healing of loaded implants has been demonstrated. The implant number and arrangement and the stiffness of the fixed prosthesis are all essential for effectively distributing the occlusal load.[30]

Key factors that have been linked to high success rates for immediately loaded implants include adequate primary implant stability, control of occlusal factors, and soft tissue management in the esthetic zone. Many authors have shown a correlation between high insertion torque values, implant primary stability, and survival rates both in single-tooth replacement and in partial or full-arch rehabilitations. Ottoni et al showed that the survival rates of immediately loaded single implants were linked to an insertion torque greater than 32 Ncm.[31] In this study, only one of the 10 implants placed with an insertion torque of 20 Ncm survived. The achievement of high insertion torque (more than 32 Ncm) is related to high primary stability, reducing micro- and macromovements that can induce fibrous tissue formation.[31] Cannizzaro et al compared success rates of implants inserted in a flapless procedure with medium (25 Ncm to 35 Ncm) or high (> 80 Ncm) insertion torque. Patients were followed for 6 months, and none of the implants inserted with high torque failed, unlike seven implants that were inserted with medium torque.[32] Trisi et al measured peak insertion torque in fresh, humid bovine bone samples with different densities to evaluate the relationship between micromotion and primary stability.[33] The study validated the hypothesis that implant micromotion would decrease with increasing peak insertion torque. This result supports the use of high insertion torque (more than 45 Ncm) to minimize the risk of implant failure in case of immediate implant loading.[34] Insertion torque represents the main success factor, along with the use of 5-mm-diameter implants in immediate extraction sites. Insertion torque values should be at least 50 Ncm for single implants and equal to or preferably more than 50 Ncm for each implant supporting a partial prosthesis. Avoiding cantilevers on the provisional and definitive restorations also can increase the survival rates.

Good primary stability is linked not only to high insertion torque and host bone density but also to implant geometry and surface texture.[33] The implant design tested in this study incorporates a number of features intended to enhance primary implant stability and sustain esthetic results over time. For one thing, the use of depth- and diameter-specific drills to create osteotomies that conform to the minor diameter of the implants being placed ensures that the entire implant surface contacts the full length of the osteotomy. This increases initial bone-to-implant contact, which in turn enhances primary stability. When a bony gap is present due to placement in a fresh extraction site, as occurred in the case presented here, filling the gap with bone graft material offers several benefits, including space maintenance and provision of a scaffold for new bone, as well as support for the soft tissue contours.[34]

Other elements of the T3 implant design also work to establish and sustain esthetic outcomes. The threads are designed to secure long-term engagement, the Certain internal connection system enables precise abutment mating, and the Gold-Tite Abutment Screw technology maximizes clamping forces while reducing the potential for micromotion. The surface targets different needs in two distinct regions of the implant, with a dual acid-etched Osseotite surface in the coronal region and a rougher, tri-level surface from the base of the collar to the apical tip. Finally, platform switching has been integrated into the design. This has been shown to reduce or eliminate bone resorption at the top of the implant, increasing support to facial gingival marginal tissue and papillae.

Conclusions

The results demonstrate that this novel implant can be predictably used for immediate loading, achieving a survival rate comparable to that of standard procedures. Larger patient numbers and longer follow-up periods are needed to further validate these results.

Acknowledgments

The authors reported no conflicts of interest related to this study.

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