IMMEDIATE FUNCTION OF CORTICALLY ANCHORED DISK-DESIGN IMPLANTS WITHOUT BONE AUGMENTATION IN MODERATELY TO SEVERELY RESORBED COMPLETELY EDENTULOUS MAXILLAE

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The completely edentulous maxilla remains a challenge in implant dentistry. Conventional two-stage surgical techniques require two independent invasive surgeries separated by a 5-6-month healing period. In addition, an increased risk of trauma to the implant-bone interface may be caused by a removable transitional complete denture during the interim submerged period, which can compromise implant success or increase crestal bone loss around the implants during initial bone healing. The purpose of this clinical trial was to evaluate the safety and efficacy of immediately loading a fixed implant-supported prosthesis without bone augmentation in moderately to severely resorbed, completely edentulous maxillae. Over a 41-month period, 783 titanium implants (627 laterally inserted disk implants, with or without 156 axially inserted Structure implants) were placed in 72 consecutive patients with completely edentulous maxillae using an immediate loading protocol. After 6 months of function, the fixed restorations were removed and each implant status was verified using radiographs, Periotest evaluations, clinical osseointegration criteria, and torque testing at 20 N-cm. Six months postoperatively, 98% of the implants were radiologically and clinically osseointegrated. Fifty-six gold screws (7%) required retightening after 10 months, but no screw fractures occurred during this study period. The postrestorative follow-up of these patients ranged from 6 to 48 months. As of this report, all of the fixed prostheses remain functional, and no additional implants have been lost. This clinical trial demonstrates that immediate loading of nonsubmerged, laterally inserted disk-design implants may provide adequate primary anchorage and long-term osseointegration in completely edentulous maxillae. The initial multicortical anchorage afforded by the disk-design implant in this study, coupled with biomechanical splinting of the disks (sometimes with more traditional root-form design implants) using a rigid prosthesis, permits a one-stage predictable implant procedure offering rapid restoration of patients to masticatory function.
INTRODUCTION

Predictable implant management for completely edentulous maxillae with moderate to severe atrophy using conventional two-stage surgical techniques remains a challenge in implant dentistry. Jemt reported a cumulative survival rate of only 69.9% with grade 1 titanium screws (Bränemark) placed in almost 100 severely resorbed maxillae. Jaffin reported a 56% implant loss when implants were placed into maxillae with Type IV bone. Over the years, controversy has existed between advocates of immediate implant loading and proponents of delayed protocols. Early research on immediate loading with root-form implants was conducted with vitallium screws in the 1930s by Alvin and Moses Strock and was often criticized for inducing fibrosis and increased implant failure. The two-stage surgical approach of Bränemark, using a submerged healing period, became the treatment of choice for root-form implants from 1980 to 1990. Schnitman reintroduced the concept of immediate loading for completely edentulous patients in the mandible with a threaded titanium implant in 1990. Tarnow also published a pilot study and expanded the procedure for completely edentulous maxillae. These combined trials of 19 patients over a 9-year period have resulted in implant survival of over 93% (21 of 25 implants for Schnitman and 67 of 69 implants for Tarnow). Unlike the traditional root-form implants, which are primarily designed to be supported by trabecular bone, the approach described in this article uses a disk implant, which is inserted from the lateral aspect of the host bone and provides multicortical support.

MATERIALS AND METHODS

From September 1993 to February 1997, 72 patients (48 women, 24 men) were entered into this study. The mean age at implant surgery was 62 years (range 42–85 years). All patients had completely edentulous maxillae and Misch-Judy division C-h or D resorption. Mean residual bone height in the premaxilla was under 6 mm and bone height below the sinus area was less than 8 mm as determined by analysis of Dentascan CT imaging. No patient in this study reported a general health problem that would contraindicate implant surgery. After extensive interviews, all were considered psychologically fit to undergo the procedure. Informed consent was obtained after explanation of the benefits and risks of the proposed technique as well as other implant alternatives (ie, submerged two-stage surgery, one-stage nonsubmerged, bone grafting from the ilium or cranium, and/or removable conventional dentures retained by implant-supported bars). The patients selecting this protocol were also informed of the need for frequent office visits during the 4–7-day period following surgery, which was required for fabrication of the prosthesis and during which time no prosthesis was to be worn. The deleterious effects of smoking were also stressed, as was the need for proper oral hygiene and, in particular, peri-implant maintenance.

Implants

The Diskimplant and Structure implant (Victory S.A., Nice, France) were the two types of commercially pure, grade II titanium implants used in this clinical trial (Figs 1, 2). Over a 41-month period, 783 implants (82% Diskimplants and 18% Structure implants) were placed in the edentulous maxillae of 72 consecutive patients. Eight to 12 implants were inserted into each maxilla. Diskimplants are designed to engage lateral and crestal regions of cortical bone. They are impacted laterally into an osteotomy site prepared by a dedicated titanium osteotome mounted on a high-speed air turbine designed to cut at 60 psi. Single-, double-, or triple-disk models (depending on available bone dimensions) were inserted with the purpose of achieving multicortical support (Figs 3–6). In certain cases, anchorage was further increased by adding axially inserted, microthreaded screw-type Structure implants of various lengths, primarily in the region of the tuberosity. This implant has a multithread pitch of 0.40 mm, which offers increased surface area.

Immediate loading protocol

The patient was premedicated with Atarax (100 mg), a Lamalone suppository, amoxicillin (1.5 g), and diazepam (20 mg) 45 minutes before surgery. Regional and local anesthesia (Alphacaine) was administered 25 minutes before surgery. Bone volume, density, and the perimeter of the arch determined the number of implants to be placed, which ranged from 8 to 12 Diskimplants and up to 4 Structure implants. Bone height around each implant was recorded at insertion. Transgingival, cylindrical abutments for screw retention of appropriate height were connected to the implants at the end of the implantation procedure and were tightened to 20 N-cm. The flaps were sutured around these abutments for primary closure. Machined titanium impression copings were screwed onto the implant abutments and then were bound with dental floss and Duray resin (Dentsply-DeTrey, Montigny le Bretonneux, France). An impression and bite registration were made with a class A, irreversible hydrocolloid (Calgin, Satelec-Pierre Rolland, Mergnac, France), which transferred the locations of the impression copings into a stone cast, thereby permitting prosthesis fabrication to be completed using the indirect technique.

Bone quality is determined at the moment of surgery. An accurate tool for achieving tricortical anchorage, the specially designed grade 2 pure titanium osteotome (cutter) is compatible with use in small bone volumes as well as in low-density bone. The traditional morphological (ABCDE) and bone density (1, 2, 3, 4) classifications were adapted and redefined types I, II, III, and IV bone. All of the patients in this
FIGURES 1–12. FIGURE 1. Battery of single and multiple disks with their cutting instruments and Structure implant all made of commercially pure titanium. The titanium cutters are used with a high-speed turbine (60 psi). These pure titanium single-, double-, and triple-disk Diskimplants and microthreaded, self-tapping Structure implant are certified ISO 9001, EN 46001, and CE 0413 by the Swedish notified body SEMKO (Stockholm, Sweden). FIGURE 2. Double disk with a large surface basal area (diameter 15 mm) and a 9-mm crestal disk. Screw-type microthread self-tapping pure titanium Structure implant 18 mm in length and 3.75 mm in diameter. FIGURE 3. Principle of immediate multicortical support: 1 crestal, 2 lingual, 3 buccal with a monodisk implant. FIGURE 4. CT scan showing the tricortical support in the maxilla. FIGURE 5. Illustration of the lateral osteotomy protocol for double Diskimplant insertion in the maxilla: The pure titanium cutter mounted on a high-speed turbine prepares the implant site under copious water spray. FIGURE 6. Application on human of lateral osteotomy in the maxilla. Note the plastic suction close to the drilling area to avoid polymetallism in case of contact with the cutter. FIGURE 7. Rigid screw-secured fixed prosthesis (gold and acrylic) is made. FIGURE 8. Occlusal view of the immediately loaded bridge 1 month after surgery. Recheck of the occlusion. FIGURE 9. Maintenance of a ceramic-baked-to-gold full upper bridge on eight Diskimplants with interdental tips. FIGURE 10. Sixty-eight-year-old female patient: ceramic screw-secured bridge on 10 Diskimplants. Notice excellent oral hygiene. FIGURE 11. Occlusal view after occlusal screw holes obtunded. FIGURE 12. Microradiograph of a human block section showing intimate contact between bone and commercially pure titanium of an immediately loaded Diskimplant-type implant after 9 years of function. This biopsy was done prior to radiotherapy.
FIGURES 13–24. FIGURE 13. Intro-operative view of triple-disk implants, which are very useful in high, thin premaxillary ridges in the sinus area. Lateral osteotomy through the sinus wall from the buccal to the palatal plate. The sinus membrane was elevated through the opening and filled with bone particles collected on the crestal area. The triple disk was then inserted. FIGURE 14. Pick-up type impression with machined titanium impression copings connected together with Dunalay resin. FIGURE 15. Human osteoblast cell culture from the mandible on the surface of commercially pure titanium disks. Note the perpendicular arrangement of the bone cells at the surface of the disk. FIGURE 16. Atrophic maxilla and Type IV bone (maxilla and mandible) in a 56-year-old woman. FIGURE 17. Immediate loading of the maxilla (two double Diskimplants, 9 triple Diskimplants), delayed loading in the mandible (three separate bridges) using 10 Structure implants. FIGURE 18. Fixed prosthesis secured by gold alloy screws on 11 Diskimplants. Rigid Type IV gold framework with acrylic teeth. The anterior region (canine to canine) has a gold occlusal surface. FIGURE 19. Illustration of the lateral osteotomy protocol for Diskimplant insertion in the mandible: (a) the pure titanium cutter mounted on a high-speed turbine prepares the implant site under copious water spray; (b) tricortical anchorage of the Diskimplant following impaction into the bone; (c) transgingival abutment with a screw-secured prosthesis. FIGURE 20. Immediate loading of the maxilla and mandible: maxillary prosthesis of Type IV gold and acrylic resin; mandible: conventional fixed prosthesis on a gold framework. Note use of disk and root-form implants. FIGURE 21. Intraoral view of the screw-secured immediate function prosthesis 3 days after installation. Note the incomplete healing of the palate on the right side. FIGURE 22. Ten triple Diskimplants and two double Diskimplants in the maxilla (±3 mm bucco-lingual width). The screw-retained, implant-supported prosthesis was placed 5 days after implant installation. The vestibular osteotomy site was filled in with autologous bone chips collected along the buccal wall during implant surgery; the site was then protected by hydroxyapatite to prevent the penetration of connective tissue (42-year-old woman). FIGURE 23. Example of one of the first immediately loaded, maxillary fixed, Diskimplant-supported prostheses fabricated in 1985 for a woman aged 77 years. Panoramic radiograph after 13 years of function. Patient now aged 90 years (1998). Five Structure implants were installed in the mandible in 1992 using a delayed loading procedure. FIGURE 24. Internal view of the screw-secured prosthesis with a strong and rigid gold frame.
study had a class D or E maxilla; they could not reasonably have been considered candidates for a traditional screw-type, implant-supported prosthesis unless prior bone grafting was performed.

**Lateral osteotomy**

Using a 300,000-rpm high-speed turbine (≥60 psi), the Diskimplant site is drilled under spray and lateral saline irrigation. Bone quality is evaluated when the lateral T-shaped incision is made with a 5-mm-diameter tracing cutter used to start the vertical incision.

Type I bone (very high density). A horizontal osteotomy is made with a 5-mm-diameter cutter until the vertical shaft touches the buccal plate; a 700 XXL carbide bur is required for the entire vertical bone incision. The diameter 5-mm cutter is then reutilized to reshape the implant site. The procedure is completed using a final cutter, the diameter of which corresponds to that of the future implant (5–15 mm), selected as a function of bone width.

Type II bone (high density). A horizontal osteotomy is made with a 5-mm-diameter cutter until the vertical shaft touches the buccal plate; a 700 XXL carbide bur is required for the entire vertical bone incision. The diameter 5-mm cutter is then reutilized to reshape the implant site. The procedure is completed using a final cutter, the diameter of which corresponds to that of the future implant (5–15 mm), selected as a function of bone width.

Type III bone (medium density). A T-shaped osteotomy (vertical and horizontal incisions) is made at 3 bars (60 psi) with a 5-mm-diameter cutter. A final cutter with the same diameter as the future implant (5–15 mm) completes the procedure.

Type IV bone (low density). The complete T-shaped osteotomy can be performed at reduced air pressure (2.3 bars, 40 psi) by a single passage of the final cutter of a diameter corresponding to that of the future implant (5–15 mm).

**Crestal (axial) osteotomy (canine and tuberosity regions)**

Bone quality is evaluated during crestal (axial) osteotomy in the canine and the maxillo-pterigoid areas.

Type I bone. Crestal osteotomy is performed at 1,000 rpm with a Structure number 1 handpiece using a pilot drill, a final drill, a dense-bone drill, a titanium tap, and finally the self-tapping Structure implant.

Type II bone. Pilot drill, final drill, dense-bone drill, self-tapping Structure implant.

Type III bone. Pilot drill, final drill, then the directly self-tapping Structure implant.

Type IV bone. Manual osteotomy can be performed without a handpiece. A small opening is made in an apical cortical plate (sinus floor, pterygoid extension) by gently tapping the manual osteotome. The Structure implant can then simply be pushed in and locked in the apical cortical plate of the pterygoid extension or sinus floor by rotating it one and a half turns.

**Postoperative care**

During the immediate postoperative period, patients were instructed to refrain from brushing the surgical site. Mouthwashes were also prohibited for 48 hours after surgery. Oral cleaning was performed regularly by the dental team with 3% hydrogen peroxide and disposable cotton swabs. Patients were instructed to consume only soft foods during the initial soft tissue healing. Smokers were encouraged not to resume tobacco use for at least 3 months.

**Prosthetic technique**

The impressions were poured in stone using implant abutment analogs connected to the indirect impression transfers. These models were then mounted on an articulator with the appropriate bite registration. Commercial denture teeth (Vivadent, Saint Jorioz, France) were luted with acrylic to the titanium impression copings that had been used to make the impression. This device, which was secured to the abutment replicas with titanium laboratory screws, served as a try-in for the denture.

The laboratory then fabricated either a type IV gold alloy framework, cast on machined gold cylinders, which served as a superstructure for the denture teeth, or a porcelain-to-metal anatom-type casting. These were completed in 2–3 days (Fig 7).

Following this, an aesthetic try-in of the chosen prosthesis was made and the occlusion reverified. When required for cosmetic reasons, detachable or fixed artificial gingivae were incorporated in the prosthesis to support the lips and cheeks. The selection of the type of gingival facade was based primarily on hygiene considerations.

The sixth day after surgery, the sutures were removed and the definitive screw-retained prosthesis was delivered. Occlusion was rechecked and verified for equal force contacts in centric occlusion. The titanium abutment screws were retightened to 20 N-cm. The gold alloy prosthesis-retaining screws were tightened to 10 N-cm. These screws were retightened the following day (10 N-cm) to compensate for the Young’s modulus of the metallic components and the flexibility of the supporting bone (Fig 8).

Fifteen to 30 days after prosthesis delivery, the screws were evaluated for retention by applying 10 N-cm with a torque wrench, and occlusion again was verified. Hygiene and maintenance techniques were reviewed and evaluated (Figs 9, 10).

**Follow-up**

Patients were seen every month for the first 6 months, with special care paid to occlusion and hygiene (the pontics
were relieved from gingival contact and there were open embrasures for purposes of cleaning). After 6 months, the screw-secured prosthesis was removed for the first time and each implant was individually checked using a clinical implant quality scale\textsuperscript{16} and the Periotest for evaluation (Siemens, Ben- sheim, Germany). Periapical radiographs were taken using the long cone technique, and the bone level was radiologically determined. The definitive prosthesis was then replaced with its gold alloy screws tightened to 10 N-cm. Hygiene, phonetics, and occlusion were evaluated and verified to be unchanged. The screws were evaluated again for tightness with a torque wrench the following day. Thereafter, patients were seen for clinical and radiographic follow-up every 6 months. The access holes for the gold screws were filled in with composite after 1 year of function, and the prosthesis was not removed unless warranted by clinical signs of mobility, pain, or radiographic bone loss (Fig 11).

**RESULTS**

All implants in this clinical report were followed up for at least 9 months after prosthesis delivery, and 171 implants have been followed up for more than 3 years (Table 1). The 641 disk-design Diskimplants (82\%) included 349 triple-disk models, 148 double-disk models, and 144 single-disk models. The 142 axially inserted Structure implants represented 18\% of all implants installed. The most frequent implant site was the premaxillary region (54\%), followed by the region below the sinus area (31\%) and the maxillary tuberosity region (15\%). Most implants placed in the tuberosity (88\%) were Structure implants, whereas single-disk models predominated in the sinus area. Double-disk and triple-disk models were most common in the canine eminence region (Table 2).

Six months after surgery, 98\% of the implants were considered osseointegrated using the clinical criteria of Misch\textsuperscript{19} (absence of movement, pain, or pathology on radiologic images). Probing depth evaluations were not performed. At clinical examination, the peri-implant tissues appeared healthy in all patients. Probing was excluded in order to avoid mechanical breakdown of the epithelial and connective cell adhesions to the titanium implant shaft or abutment, which might have caused iatrogenic bacterial penetration, contamination of the layer of titanium oxide, and a subsequent risk of fistula formation.

Bone density at the time of surgery was generally type II or III. Type II and type III bone predominated in the premaxilla and infrasinus regions, whereas type IV bone was most frequently found in the tuberosity (70\%). Very little type I bone was encountered (3\%) and when seen was exclusively found in the premaxilla. Vertical bone loss was measured using the implant as a dimensional reference. Mean vertical bone loss around the 641 immediately loaded Diskimplants was 0.4 mm at 6 months and an additional 0.1 mm at 10 months. No additional vertical bone loss was observed at subsequent measurements. In 12\% of the cases, 0.5–2 mm of new bone above the original crestal level was measured around the implant abutments.

Mean Periotest values (PTV) after 6 months of function were −2.2 PTV for the 438 implants in the premaxilla (504 Diskimplants, 24 Structure implants), 0.8 PTV for the 201 implants in the area below the sinus (201 Diskimplants), and −1.02 PTV for the 144 implants installed in the tuberosity (118 Structure implants, 26 Diskimplants). The mean Periotest score of the cortically anchored implant/fixed prosthetic unit was −5 PTV (standard deviation [SD] = ±1) at the time of loading. This value was unchanged after 9 months of function (Table 3).

As of November 1997, the 783 implants placed in these 72 patients were still in place, and all the definitive fixed prostheses were still functional. Two fixed prostheses were refabricated after 6 months of functions for aesthetic and phonetic reasons. The initial fixed prosthesis was used in these two cases in order to transfer the position of the abutments and to preserve the occlusion. A total of 56 (7\%) gold alloy retaining screws required retightening after 10 months. No fractures of the implant abutment screws or gold retaining screws were observed during the duration of this study (Table 4).
DISCUSSION

Histologic proof of osseointegration of immediately loaded, laterally inserted, disk-type implants was first obtained in 1985 when a Juillet T3D titanium implant (precursor of the Diskimplant used in this study) was removed from a patient prior to therapeutic irradiation. Gross examination revealed a healthy sulcus and absence of crater formation around the threaded shaft of this maxillary implant, which had been in function for 9 years. Light microscopy, tetracycline labeling, and microangiography demonstrated new bone formation at the surface of this titanium implant.\(^1\) (Fig 12).

Use of a high speed turbine (300,000 rpm) to prepare the site for lateral disk insertion does not cause any elevation in temperature harmful to bone. Previous research demonstrated that the maximum temperature during drilling with the pure titanium osteotome was 32°C,\(^1\) which is far from the critical temperature of 44°C cited by Ericksson et al as the upper limit before irreversible bone tissue injury.\(^1\)

The two implant designs used in this study share a number of features that contributed to the clinical success of the procedure (Figs 13, 14). Increased contact between bone cells and their microrough titanium surfaces (10 μm) and increased adhesion of gingival cells to their mirror-polished cervical segments have been demonstrated in vitro by human cell cultures (Fig 15).\(^1\) The 0.25 mm deep microthread increases the mechanical strength of the implant body, while the similar design of the prosthetics screw reduces the risk of abutment or prosthesis-screw loosening. No implant or screw fractures occurred during this longitudinal study. In contrast, Balshi reported numerous screw fractures with the two-stage technique using the Bränemark implant for fixed restorations.\(^3\)

Finally, both implant systems utilize the same prosthetic components, which facilitates laboratory procedures.

The increased initial cortical support from the buccal to the dense palatal bone plate provided by the disk design allows the immediate connection to a screw-secured fixed prosthesis. Potential micromovements are reduced and internal tensions are rapidly dissipated within the bone. This favors bone reconstruction and remodeling around the implants, as confirmed by the Periotest scores after 9 months of function (Table 5).

Two fixed prostheses were completely refabricated (including replace-
ment of the abutments) in order to resolve aesthetic and speech problems. To avoid such incidents, transgingival abutments that are 1 mm shorter than the gingival depth as measured at implant installation should be used to anticipate tissue retraction.

This immediate loading protocol requires more implants than the conventional two-stage technique to ensure optimal stress distribution. Eight to 12 implants are usually required in low-density maxillary bone. The primary multicortical anchorage achieved with the large base of these laterally insert-

**Figures 25–30.** Figure 25. After 6 months of function, implant osseointegration is checked using the Periotest instrument. This can be rechecked annually. Figure 26. Monodisk in place in the molar region of the mandible at a depth of 1 mm (diameter of 10 mm). Figure 27. Insertion of three monodisks at a depth of 1.5 mm in a 76-year-old patient in 1984. Immediate function technique. Figure 28. Clinical view of the prosthetic reconstruction (ceramic fused to gold) in the upper and lower jaw. Figures 29 and 30. Cosmetic aspect of the maxillary reconstruction.
ed implants improves load distribution and initial stability, as demonstrated by finite element stress analysis.16,17 These implants also offer an attractive alternative, even in small bone volumes,18 to conventional root-form placement, which often requires bone grafting. The base of the disk can help to maintain small autologous bone chips (or porous hydroxyapatite granules) placed under the periosteum, which, with the resulting coagulum, encourages osseointegration (Figs 16±20; appendix).

Screw-type Structure implants were, on occasion, combined with disk models to increase support in the tuberosity and canine regions. Whether screw-type or press fit cylinder implants alone, without the multicortical support provided by disks, are acceptable in the management of atrophic edentulous maxillae using this immediate loading protocol will require further investigation. No patients in this report were treated solely with Structure implants (Table 6).

All of the fixed prostheses in this study were screw retained. Occasional problems with implant parallelism were overcome by incorporating gold cylinders directly in the castings. Assembly of components by screwing their two flat surfaces together increased stability and maintained accurate fit. Cement-retained techniques may be used with equal satisfaction in selected cases.

The major difficulty with this technique concerns training of the surgical and prosthetic teams. The impression for the prosthesis is taken immediately after surgery, which increases chair time. In addition, the dental laboratory must be able to handle their responsibilities within the allotted time. The 4-7 days required for fabrication of the screw-retained prosthesis permits its insertion prior to completion of the bone-repair process. The prosthesis must be completed before the 10th postoperative day because osteoclast activity increases exponentially from day 10 to approximately day 21. Locating the implants in place with the prosthesis as soon as possible after surgery thus has both mechanical and biological justification; it guarantees the stability of the implant-supported prosthesis and eliminates the effects of any prosthetic technical inaccuracies before mineralization and osseointegration occur. As the 8±12 Diskimplants with their relatively malleable titanium bases and shafts adapt to the rigid prosthesis, bone formation will continue. As a consequence, the fixed prostheses in this study did not require sectioning to improve the accuracy of fit (Figs 21-24).

Immediate loading of cortically anchored implants avoids soft tissue injury that might be caused by a removable appliance and promotes blood supply and healing of bone and periosteum, thereby stimulating osseointegration. Patients appreciate the rapid rehabilitation and are willing to comply with the need for multiple office visits. A single annual radiologic check-up is sufficient after the second year of function, at which time the Periotest evaluations can be continued upon superstructure removal (Fig 25).

**Conclusion**

Immediate loading of laterally inserted disk-design implants with a fixed, functional prosthesis is a safe and reliable method for management of the completely edentulous maxilla. The initial bucco-palatal cortical anchorage achieved with these implants ensures sufficient stability for osseointegration, and the lateral insertion technique makes them suitable for seating in atrophic maxillae (Figs 26-30, Table 7). Extension of the technique for the treatment of total and partial mandibular edentulism is the subject of ongoing research.19

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**Table 7**

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<th>Time</th>
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17. Scortecci G. Diskimplant system yields tricortical support to make the most of available bone. Dent Implantol Update 1991;2:72–74.

