
Use of the Endopore Dental Implant to Restore Single Teeth in the Maxilla: Protocol and Early Results

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This report outlines the experimental, surgical, and prosthodontic protocols for a prospective clinical trial using the Endopore dental implant to replace single maxillary teeth. Twenty patients (10 male, 10 female) ranging in age from 30 to 60 years each received one implant (mean length 10.1 mm), which, after an initial healing period of 4 months, was restored with a single crown. Records collected included radiographs, Periotest mobility measurements, supragingival Plaque Index, and an assessment of peri-implant soft tissue health using pocket probing depths, sulcular bleeding following probing, and probing attachment levels. Radiographs were exposed at predetermined intervals following crown placement (1 and 6 months, and then yearly) in a standardized procedure using a specialized filmholder that attaches to each implant after removal of the crown. At the time of this preliminary report, all of the 20 implants placed had been uncovered and were in function; 16 of the implants had been in function for 6 months or more, 14 had passed 1 year of function, and 3 had passed the 2-year function point. There have been no failures to date.

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The use of root-form dental implants to restore missing single teeth has become an increasingly popular treatment, especially where it is unnecessary or inappropriate to involve the contiguous teeth as

abutments for a traditional fixed prosthesis. While long-term clinical trial data on the performance of implants in this application are not yet available, early results, at least for threaded implant designs, appear to be promising. One of the first investigators to pursue this treatment alternative with the Brånemark implant was Jemt,¹ but many changes in surgical and prosthetic technique have evolved to optimize the esthetic outcome since this early report was published. Jemt et al² reported 3-year results of a study in which 21 single Brånemark implants were placed in the maxillae of 15 patients. While all of the implants became integrated, two implants in one patient were lost in the third year of function, resulting in a 3-year survival rate of approximately 90%. Jemt and coauthors³ have also reported the first-year results of an international prospective multicenter trial of Brånemark implants used as single tooth replacements. Ninety-two patients received 107 implants, 88 of which were in the maxilla, and 74 of these being at least 13 mm in length. One maxillary implant failed to integrate, while two others failed

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during the first year of function, for a 1-year survival rate of almost 97%. A 3-year follow-up of these patients showed no additional implant losses, although six of the patients included in the 1-year report had been lost to the study by this time.⁴

Schmitt and Zarb⁵ reported separately the results of their contribution to the Jemt multicenter trial of single-tooth Brånemark implants. In their study, 40 implants, 28 of which were in the maxilla, were placed in 32 patients, and all of these appear to have become successfully integrated. The mean implant length was not reported, but all implants used were at least 10 mm in length, and at the time of the report the functional period ranged from 1.4 to 6.6 years. Likewise, Andersson and coworkers⁶ reported the 2- to 3-year results of a prospective study in which 62 Brånemark implants were placed in the maxillae of 57 patients. The majority of implants placed were 15 mm or more in length. One of the 62 maxillary implants failed to integrate, giving a survival rate of 98% at the time of the report; however, three patients had been lost to follow-up, and this fact is not reflected as accurately as it would be if the authors had presented the survival data in a life table analysis. One interesting observation was that the presence of a single-tooth implant appeared to promote crestal bone loss at the implant-facing surfaces of adjacent teeth. This loss was correlated to the horizontal distance between implant and tooth, was most extensive when this distance was greater than 2 mm, and was most prominent for maxillary lateral incisors.

Beginning in 1983, in a series of ongoing animal and human clinical trial investigations, a novel root-form endosseous dental implant device has been developed and tested that would appear to have a number of advantages over most currently available implant systems.⁷⁻¹¹ This implant has been labelled the "Endopore" because it is placed endosseously (endo) and uses a porous surface geometry (pore) to achieve osseointegration by bone ingrowth into a multilayered surface coat of sintered spheroidal particles of titanium alloy. The advantages of the design include shorter implant lengths (currently available in lengths of 7, 9, and 12 mm with a diameter of 4.1 mm; in a 9 mm length with a diameter of 3.5 mm; and in 5 and 7 mm lengths with a diameter of 5 mm), which are made possible by the substantial increase in surface area provided for contact with bone (ie, at least 3 times that of a threaded machined implant of the same length). Additional advantages include minimal instrumentation and uncomplicated four-step surgical placement protocol; tapered implant shape minimizing the risk of damage to adjacent tooth roots during placement, even in narrow edentulous sites (this feature also reduces the risk of creating a corti-

cal fenestration where concavities exist in the ridge form); shorter initial healing times; and excellent resistance to torsional forces resulting from the three-dimensional nature of the bone-implant interface formed within the porous surface coat.

The first human clinical trial, begun in 1989, involved the placement of three implants in the anterior mandible of each of 52 completely edentulous patients for whom conventional removable prostheses were no longer viable.⁸ After an initial healing interval of 10 weeks, these implants were used as freestanding units to support an overdenture. The 3- to 4-year results^{9,12} showed almost 95% success on a per-implant basis, with mean annual bone loss figures well below those presently accepted as compatible with long-term implant survival.^{13,14} These results remained relatively unchanged at 5 years.¹⁰

A series of human clinical trials designed to test the Endopore dental implant in partially edentulous patients has been undertaken at the University of Toronto. One of these trials includes a group of patients each requiring a single tooth implant in the maxilla. It is the purpose of this report to describe the experimental protocol and early results for this group of patients.

Materials and Methods

Patient Selection. This investigation involved 20 patients ranging in age from 30 to 60 years (mean 43.5), who each wished to have one maxillary tooth replaced with a single implant-supported restoration. There were 10 women and 10 men in the group, and the implants were needed to replace 6 incisors, 1 canine, 12 premolars, and 1 molar.

Records collected included a medical history, periodontal assessment, diagnostic casts, and both periapical and panoramic radiographs. For protocol reasons, patients requiring bony ridge augmentation procedures to increase ridge width were not included in this group. A minimum ridge width of 5 mm was required for the patients to participate in the trial. Any patient requiring treatment procedures to manage periodontal disease was referred for the necessary care before the commencement of the implant procedures. Only nonsmokers were accepted for the investigation because of the known association between cigarette smoking and both impaired intraoral wound healing¹⁵ and an increased risk of dental implant failure.¹⁶ All patients were medically fit.

Preoperative Preparations. Following completion of an institutional consent-to-treat form and all necessary periodontal and other dental treatment, the implant surgery was carried out as a two-stage protocol. For 7 days prior to first-stage surgery, each

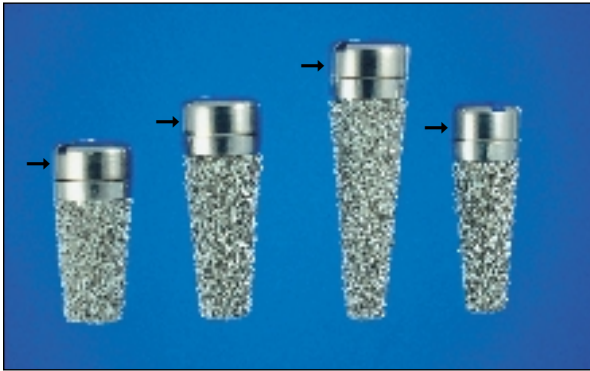


Fig 1a The implants available for use in this study, shown with the healing caps (*arrows*) in place. Lengths were 7, 9, and 12 mm, each with a maximum (coronal) diameter of 4.1 mm, and a 9-mm “mini” with a maximum diameter of 3.5 mm. Each of these models had a 1-mm coronal machined segment, while the rest of its length was porous-coated.



Fig 1b The specialized instruments required included a single pilot bur (*right*), a separate implant bur for the selected implant model (*center*), and a trial-fit gauge (*left*), again specific for the implant length chosen. The latter instrument was used to check the size, depth, and orientation of the prepared site just prior to implant placement.

patient was asked to rinse with 0.12% chlorhexidine gluconate for 30 seconds twice daily. As well, beginning 24 hours preoperatively, patients were instructed to take 800 mg of ibuprofen every 8 hours and to continue this regimen through the first postoperative day to help minimize swelling and discomfort postoperatively. A surgical template generally was not used.

Armamentarium. The implants used in this study are presented in Fig 1a. They were available in lengths of 7, 9, and 12 mm with a maximum (coronal) diameter of 4.1 mm, and in a length of 9 mm and a diameter of 3.5 mm (“mini” implant). The implant was provided by the manufacturer (Innova, Toronto, Ontario, Canada) with the healing cap already in place and with a detachable plastic handle for ease of handling at the time of implantation. Specialized instrumentation (Fig 1b) was minimal and included a pilot bur, a separate implant bur for each of the four implant models (one exception is that the same implant bur was used for both the 12-mm regular and the 9-mm “mini” implants, and appropriate markings appear on this bur), a trial fit gauge (again, a separate one for each implant model), and a Teflon-tipped punch for use with a surgical mallet to drive the implant to its final, fully seated position as described and illustrated previously.⁹

Surgical Protocol. All implants were placed using strict operating room technique, but in a dental operatory setting. A paracrestal incision was made on the palatal aspect of the edentulous site, and the necessary vertical incisions extended buccally so as to preserve the interproximal papillae if at all possible (Fig 2a). A full-thickness flap was then elevated buccally sufficiently to visualize the alveolar ridge anatomy. Next, the intended implant site was marked with a No. 6 round bur by scoring the upper cortex. Following this, site preparation was begun with the pilot bur at a drill speed of 1000 rpm and with both internal and external saline irrigation to establish appropriate depth for the implant being used. There was only one pilot bur in the instrument kit, and it was marked at depths of 7, 9, and 12 mm (Fig 1b). Having established site depth with the pilot bur, the final configuration of the implant socket was completed using the appropriate implant bur at a speed of 700 rpm. Care was taken with this step since it is important not to overdrill the site, so as to subsequently avoid overseating the tapered, self-seating implant root component (ie, positioning it too far subcrestally). The rationale for this approach is that it is desirable to have as much as possible of the upper cortex in contact with the porous segment to use this



Fig 2a The intended implant site following flap elevation; the proximal surfaces of the contiguous teeth had been modified by the patient's dentist for purposes unrelated to the implant procedure.

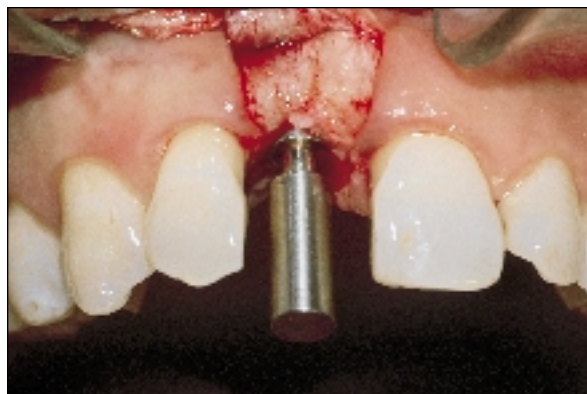
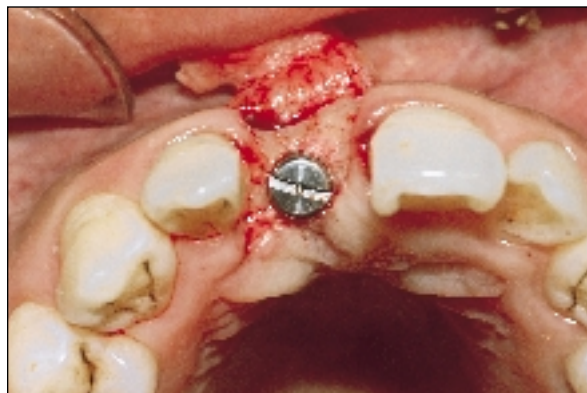


Fig 2b The trial-fit gauge in place following site preparation.



Figs 2c and 2d The seated implant, with only the healing cap above the alveolar crest.

bone to support the implant. The final depth and orientation of the prepared site were then checked by inserting the appropriate trial-fit gauge. If the site has been properly prepared, the top of the conical end of this tool should be more or less flush with the alveolar crest (Fig 2b).

Once site preparation was completed, and following vigorous saline irrigation, the implant was placed and driven to its final fully seated position with several firm taps using the Teflon-tipped punch and mallet. The properly placed implant was fully submerged in bone with little more than the healing cap above the bony crest (Figs 2c and 2d).

Reentry Surgery. Reentry surgery was scheduled 4 months following implantation. A small incision was made over each implant and the soft tissue reflected sufficiently to permit removal of the healing cap and visualization of the top of the implant-root component. An expanded temporary healing abutment (in lengths of 4.0 mm and 6.5 mm and a maximum diam-

eter of 5.4 mm for the 4.1-mm-diameter implant root, and a maximum diameter of 4.7 mm for the 9-mm "mini" implant) (Fig 3a) was attached to the implant after the healing cap was removed, and the gingival tissue was sutured tightly around it (Fig 3b). The patient was instructed in appropriate hygiene technique and asked to apply topical chlorhexidine around the implant periphery with a single-tufted brush or cotton swab at least three times daily. The sutures were removed after 7 to 10 days, and the soft tissues were allowed to heal for at least 1 month before prosthodontic procedures were begun. This waiting period also offered the advantage of providing some "progressive loading," during which time it is expected that more bone will invade the porous-surface coat of the implant root.

Prosthodontic Protocol. The prosthodontic abutments used in this investigation are shown in Fig 4a. These included two types of machined titanium alloy abutments and a plastic UCLA abutment



Figs 3a and 3b An expanded diameter temporary healing abutment (*left*) has been placed at the reentry stage (*below*).



Fig 4a The prosthetic abutments and the retaining screw (*far right*) available for use in this trial. The UCLA plastic castable abutment (*far left*) was used exclusively for the final restorations.



Fig 4b The permanent crown seated (maxillary right central incisor). Chlorhexidine staining, which will be removed, is still visible on many of the teeth.

(Attachments International, San Mateo, CA), all of which had a hexed base for prevention of rotation and screw loosening. As will be outlined below, the UCLA abutment was used exclusively to produce all of the permanent restorations in this group of patients. When a provisional crown was required, it was fabricated from polymethylmethacrylate (PMMA-Jet, Ash Temple, Toronto, Canada) using one of the metal abutments with a machined collar region of sufficient height to ensure that the PMMA margins of the temporary crown were supragingival and therefore not likely to elicit a peri-implant mucosal inflammatory response. Minimal contact in centric occlusion was provided for provisional restorations by instructing patients to close in maximum intercuspation with heavy muscle force so as to load the periodontal ligament of adjacent

teeth while adjusting centric occlusion on implant-supported crowns. Anterior provisional restorations were adjusted to provide light contact in lateral excursions and posterior provisional restorations were adjusted to cuspid guidance. The occlusion of these provisional restorations was adjusted so as to provide minimal contact in centric and lateral excursions.

For fabrication of the final crown (Fig 4b), in each case a transfer coping (Innova, No. 06-TCA) was attached to the implant, and a silicone impression was obtained using a custom acrylic resin tray. A master cast containing an implant analogue was produced in gypsum with a removable silicone gingival cuff to facilitate laboratory procedures. Both the working and opposing casts were mounted in centric occlusion on a semi-adjustable articulator using an arbitrary hinge-axis transfer bow.

In all cases, a hexed plastic burn-out UCLA abutment was customized to support wax pattern fabrication. All final implant-supported restorations were porcelain-bonded to metal crowns fabricated from gold alloy (Special White, Degussa, Long Island City, NY). A lapping tool (Innova, No. 07-0155) was used in the laboratory to refine the cast hexagonal restoration-implant interface. All restorations were evaluated clinically and radiographically at the preglaze (biscuit bake) stage for fit and contour. The crown design permitted access palatally or occlusally as appropriate to a titanium alloy retaining screw used to secure the crown to the implant root. Occlusion was evaluated and refined to meet the same criteria applied to provisional restorations to avoid accidental selective overloading of implant-supported crowns.

At placement, maximum tightening of the retaining screw was achieved using a manual wrench, and the palatal crown access hole was sealed using a cotton pellet soaked in 0.12 chlorhexidine solution followed with Cavit (Premier Dental, Toronto, Canada). After the first month of function, the crown was removed to permit collection of baseline clinical and radiographic records (see below); the crown was then replaced using a composite resin (Adaptic, Dentsply, Toronto, Canada) to seal the access hole until the next scheduled examination.

Follow-Up Radiographic and Clinical Examination. Radiographic examinations were scheduled for each implant in this group at baseline (ie, 1 month after prosthesis placement), at 6 months following placement, and annually thereafter. For the exposure of each of these radiographic films, a custom-made stainless-steel filmholder, modified after a prototype used in earlier work,^{8,9} was connected to each implant after removal of the crown. This modified filmholder permitted an infinite number of vertical film positions to accommodate various anatomic restrictions presented by the hard palate. The x-ray tube was connected directly to the filmholder using a Rinn extension arm and locating ring, which in turn was attached to the directing cone to standardize sequential films and therefore minimize interpretation error in measuring bone height.¹⁷ The films were all exposed using the same calibrated x-ray machine and developed manually in batches, always using fresh chemicals. At the same visits, periodontal probing measurements of the peri-implant soft tissues and Periotest (Siemens Medical Systems, Charlotte, NC) measurements of implant subclinical "mobility" were performed as previously described.¹² A modified assessment technique for determining supragingival plaque accumulation on the implant crowns was used as follows: each crown was removed and immediately immersed in a plaque-disclosing solution (Trace 28, Lorvic, St. Louis, MO)

diluted 1:10 with sterile water for 3 minutes. After rinsing with water, the presence of stained plaque was assessed using the criteria of Silness and L  e.¹⁸

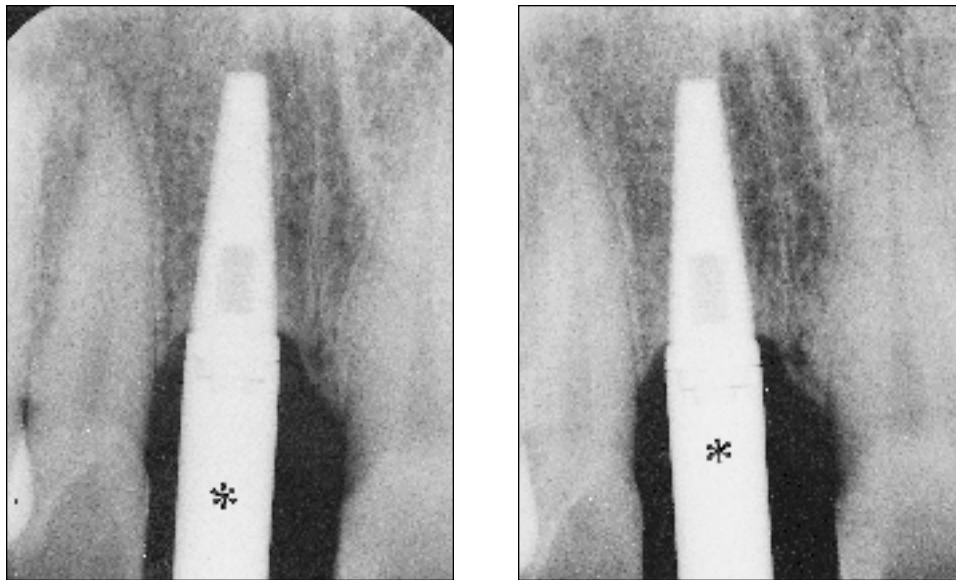
Results

There were seven 12-mm, eight 9-mm, and five 9-mm "mini" implants placed in this group of patients. While the majority of these implants remained fully submerged throughout the 4-month initial healing period, seven of the implant healing caps became partially or completely exposed sometime before reentry. When this happened, the patient was asked to cleanse the site three times daily using a cotton swab and 0.12% chlorhexidine solution. Otherwise, there were no postoperative complications to report. The majority of patients reported minimal postoperative discomfort and/or swelling. Loosening of the prosthesis retaining screws, as has been reported by others to be a problem with some implant manufacturers' components (eg, Sherwood and Sullivan,¹⁹ Eklfeldt et al²⁰), to date has not been observed in this patient group.

All of the implants in this group have been uncovered, and none has failed to integrate. Baseline and 6-month radiographs were obtained for 17 patients, 1-year films for 14 of these patients, and 2-year radiographs for 5 of the patients at the time this report was prepared. The pattern of crestal bone remodeling observed in the standardized radiographs (Figs 5a and 5b) was as expected from earlier animal work^{7,21,22} and from human data collected from a group of completely edentulous patients treated with overdentures.^{9,10} Bone remodeling occurred until the alveolar crest approached the junction of the porous and machined collar segments of the implant-root component. Significant periodontal bone loss in relation to the implant-facing surfaces of the adjacent teeth has not as yet been seen.

A frequency distribution of the individual bone loss values measured on the mesial and distal surfaces of implants that have passed 6 months, 1 year, and 2 years of function is shown in Fig 6. The most common finding at 6 months and 1 year was no detectable bone loss, but the values ranged from a loss of 1.2 mm (at one surface after 1 year) to a gain of 0.7 mm (at one surface after 1 year).

A frequency distribution of the Periotest measurements taken at baseline, 1 year, and 2 years is displayed in Fig 7. The majority of these measurements were zero or less, and there was a trend of lower values as time in function increased. A more thorough analysis of these data and of the remaining parameters being measured in the study will be reported when all of the implants in the group have passed 2 years of function.



Figs 5a and 5b Radiographs of the implant shown in Figs 2 and 4 (left) at baseline (ie, at 1 month; see Fig 4b), and (right) at 6 months after crown placement. In each instance, the crown has been removed and the radiographic filmholder connected directly to the implant root with a spacer (*).

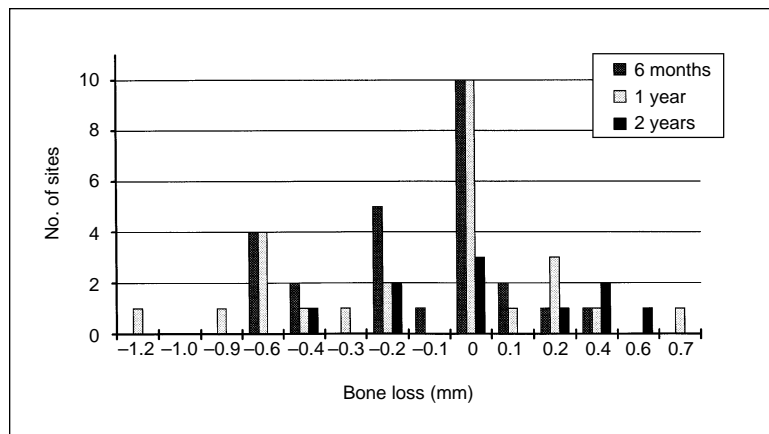


Fig 6 A frequency distribution of radiographic changes in crestal bone height adjacent to mesial and distal surfaces of the implants under study after 6 months, 1 year, and 2 years of function.

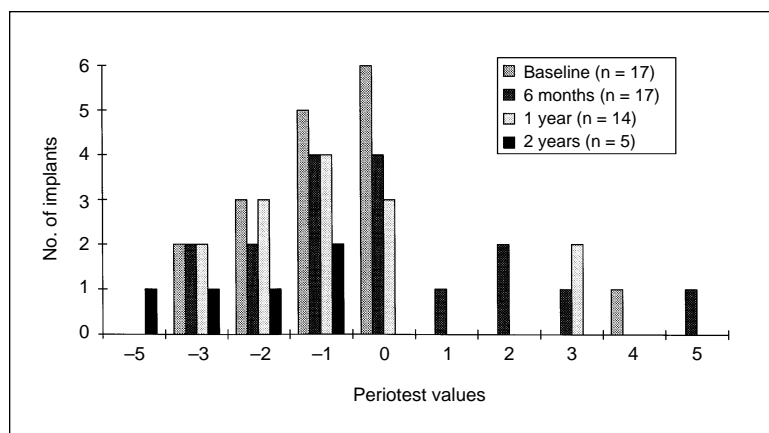


Fig 7 A frequency distribution of Periost values (subclinical mobility measurements) for the implants under study after 6 months, 1 year, and 2 years of function.

Discussion

It is generally held that the maxilla presents the greater challenge in achieving osseointegration of an endosseous root-form dental implant, principally because maxillary bone is almost always much more cancellous in character than mandibular bone. Thus, greater failure rates are expected in both partially and completely edentulous maxillae, at least for machined threaded implants.²³⁻²⁸ For this reason, attention was given to maxillary sites in the present application of the Endopore implant in the restoration of single teeth. It was felt that the implant, with its substantially larger surface area, osteoconductive surface geometry, and secure fixation by bone ingrowth,^{7,29,30} might perform better in the maxilla than some other currently available implant systems. While the study is still in its early days, with only 14 of the 20 single-tooth implants placed currently beyond 1 year of function, the preliminary data are promising, as 100% of the implants became osseointegrated in the 4-month initial healing period allowed, and the pattern of crestal bone remodeling to date is as expected from earlier work.

Current consensus also dictates that long implants must be used in the maxilla to avoid an increased risk of failure. For example, van Steenberghe et al²⁵ reported a greater rate of failure in the maxillae of partially edentulous patients when Brånemark implants of less than 13-mm length were used. This conclusion was borne out by the 1-year results of the multicenter trial of the Brånemark implant used to replace single missing maxillary teeth, as reported by Jemt et al.³ Of the 88 implants placed, 3 failed, and these were 7, 10, and 13 mm in length, respectively. Interestingly, taking each category of implant length separately, the failure rates were 50% for 7-mm implants (1 of 2), 8% for 10-mm implants (1 of 12), 3% for 13-mm implants (1 of 34), and 0% for the remaining implants, up to 20 mm in length. Results of the present study are therefore of even greater interest since the mean implant length used was only 10.1 mm, including 13 of the 20 implants under study being only 9 mm in length.

All of the implants in this group were restored using the UCLA abutment concept to fabricate cast one-piece, screw-retained prostheses as described originally by Lewis and coworkers³¹ and others.³²⁻³⁴ The main reason for taking this approach was to permit easy removal of the single crowns at regular intervals and the attachment of a radiographic filmholder designed to allow collection of standardized sequential radiographs. However, the other advantages of this prosthetic protocol include optimal esthetics, good soft tissue health, ability to improve less-than-ideal implant angulation, and suitability for

situations with limited interocclusal space or less-than-optimal interproximal distance between an implant and its contiguous teeth.

One potential disadvantage of a dental implant with a porous surface topography like that of the Endopore is a perceived increased risk of implant failure resulting from contamination with dental plaque, as has been reported to occur with hydroxyapatite-coated cylindrical press-fit implants³⁵⁻³⁷ when the porous hydroxyapatite surface has become exposed to the oral environment. This situation is unlikely with the Endopore if the implant has been placed according to the prescribed protocol, and has not been seen in the patients reported here. If the implant root component is initially placed so that the porous-coated segment is completely submerged in bone, and sufficient time has elapsed for the necessary bone ingrowth to occur, once implant function begins, bone remodeling is generally limited to the machined coronal segment of the implant-root component, as shown in earlier animal and human investigations^{7,9-11,21} and reaffirmed here. Regions of high stress do not develop in the crestal bone adjacent to the tapered, porous-coated Endopore implant root,³⁸ as they do with machined threaded and other cylindrical root-form dental implant designs.^{39,40} Therefore, provided that the principles of occlusion necessary to ensure optimal function of any dental implant are observed,^{41,42} progressive crestal bone resorption with resultant exposure of the porous coat to the oral environment has not been seen with the Endopore. Naturally, patient selection and soft tissue management are also important, as with the successful application of any dental implant system. Thus, nonsmokers are preferred since smoking is a known risk factor for implants,¹⁶ probably because of an increased tendency to bone loss as occurs as well around teeth in smokers.^{43,44} Likewise, patients with good daily home maintenance are preferred since poor plaque control and the resultant chronic peri-implant soft tissue inflammation can lead to increased crestal bone loss around dental implants.⁴⁵ In addition, it is appropriate to ensure that soft tissue pocketing around the implant at the time of prosthesis placement is limited to the usual range associated with periodontal health, ie, not exceeding 3 mm in depth. If this is found not to be the case, it is appropriate at second-stage surgery, or even after soft tissue maturation has occurred, to do minor gingival surgery to reduce unwanted "pocket" depth before prosthesis placement. The concept of minimizing soft tissue pocket depth around implants can only be considered good case management, since long-term success with dental implants is associated with shallow and decreasing pocket probing depth.⁴⁶

Other than the considerable technical challenge of achieving an esthetically pleasing result, the risk in using dental implants to replace single missing teeth is the possible damage to adjacent tooth roots during preparation of the implant socket, and increased periodontal bone loss in relation to such teeth once the implant has been connected to an abutment and is placed in function. In regard to the latter, Andersson et al⁶ reported that there was increased crestal bone loss in relation to the implant-facing surface, as opposed to the tooth-facing surface, of teeth adjacent to single-tooth Brånemark implants. The most extensive bone loss was observed at maxillary lateral incisors facing an implant, or at other teeth when the distance between the implant and the implant-facing tooth surface was less than 2 mm. Similar results were reported by Esposito and colleagues.⁴⁷ An explanation for the observed periodontal bone loss was not provided, but it may relate somehow to the same high stresses that lead to peri-implant crestal bone loss in the immediate vicinity of cylindrical dental implants, as discussed above, especially where the thickness of the septal bone between implant and tooth is minimal. Similar bone loss at the implant-facing surfaces of teeth has not been seen in the current study.

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