A Prospective Human Clinical Trial of Endopore Dental Implants in Restoring the Partially Edentulous Maxilla Using Fixed Prostheses

Douglas A. Deporter, DDS[1]/Reynaldo Todescan, DDS, PhD[1]/Philip A. Watson, DDS, MScD[1]/
Michael Pharoah, DDS, MSc[1]/Robert M. Pilliar, BASc, PhD[1]/George Tomlinson, MSc, PhD[1]

This is the first report of a group of 50 partially edentulous patients who received a total of 151 Endopore dental implants in the maxilla. A mean implant length of 8.7 mm was used, and 76.8% of implants were placed in the posterior maxilla. At re-entry, all implants appeared to be osseointegrated and were used to support fixed prostheses. Approximately half of the crowns (57%) in these prostheses were splinted to one another, while the remainder (43%) were not. At the time of this report, the mean functional time was 34.6 months and the cumulative survival rate was 97.3% (4 implants had failed). Analysis of carefully standardized sequential radiographs indicated no significant changes in mean crestal bone levels between baseline and any of the examination times (after 6 months, 1 year, and 2 years in function). There were no detectable correlations between crestal bone loss and the factors implant length (7, 9, or 12 mm); implant diameter (3.5, 4.1, or 5.0 mm); implant position anteriorly or posteriorly in the maxilla; or whether or not the implant-supported crowns were splinted. (Int J Oral Maxillofac Implants 2001;16:527–536)

Key words: *implant-supported prostheses, partially edentulous maxilla, porous-surfaced dental implant*

The results of human clinical trials with threaded, machined-surface, commercially pure titanium (cpTi) dental implants, such as the original Brånemark System implant (Nobel Biocare, Göteborg, Sweden), placed in partially edentulous patients indicate reasonable 5-year success rates[1] (92% and 94%, respectively, for maxillae and mandibles). The majority of failed implants were either 7 or 10 mm in length,[1] confirming the earlier comments by Lekholm and colleagues that there was an increased risk of failure with implant lengths less than 10 mm in the mandible or less than 13 mm in the maxilla.[2] Similar findings were reported by Bahat,[3] in that most failed Brånemark System threaded implants were 7 mm in length (9.5% failures with 7 mm implants, compared to 3.8% with all other lengths), while even higher failure rates (25%) were reported by Wyatt and Zarb[4] for 7-mm-long Brånemark System implants placed in partially edentulous patients.

It has generally been agreed that the maxilla is more difficult to treat successfully with dental implants than the mandible[1,5–9] and that outcomes in the posterior maxilla are the least predictable.[3,6,10–12] These observations have been related primarily to poor bone density.[6,13–17] To overcome these difficulties, newer implant designs have employed the use of surface textures such as titanium[18] or hydroxyapatite (HA) plasma-sprayed surfaces or surfaces treated by sandblasting and/or chemical etching.[19] A placement technique using hand osteotomes rather than burs also has been promoted as preferable for placing endosseous root-form dental implants in Type III and IV maxillary bone.[20] Textured surfaces have been used on both threaded and press-fit cylindric implants, but while initial maxillary success rates

[1]University of Toronto, Faculty of Dentistry, Toronto, Ontario, Canada.

Reprint requests: Dr D. A. Deporter, University of Toronto, Faculty of Dentistry, 124 Edward Street, Toronto, Ontario, Canada M5G 1G6. Fax: (416) 979-4936. E-mail: douglas.deporter@utoronto.ca

Fig 1 Implant designs used in this investigation, all shown with healing caps in situ. *(Left to right)* 5 mm long × 5 mm diameter, 7 mm long × 5 mm diameter, 7 mm long × 4.1 mm diameter, 9 mm long × 3.5 mm diameter, 9 mm long × 4.1 mm diameter, and 12 mm long × 4.1 mm diameter. Each of these has a 1-mm-long machined coronal collar region, and the remainder of the implant has a sintered porous-surfaced finish.

were better for Ti plasma-sprayed cylinders[18] (IMZ, Friatec, Friedrichsfeld, Germany) and for HA plasma-sprayed threaded or press-fit cylindric implants[6] (Steri-Oss, Nobel Biocare; mean implant length, 12.3 mm), longer-term studies (ie, 8 to 10 years) with similar implants showed a high percentage of late failures.[9,21–24]

An alterative surface "texture" is that created by high-temperature solid-state sintering, which results in a multilayered porous surface zone (overall thickness 0.3 mm) of spherical particles of titanium-aluminum-vanadium (Ti-6Al-4V) of a defined size range and resulting porosity suitable for implant fixation by bone ingrowth.[25–31] This porous surface has been shown to be osteoconductive and to allow for bone ingrowth and mechanical interlocking at the bone interface region,[25,30,32] allowing shorter-length implants to be used routinely.[25,26,28,29,33] In this prospective trial, the performance of this implant design was tested in short lengths in the partially edentulous maxilla.

MATERIALS AND METHODS

Patient Population

The patients enrolled in this trial included 25 men and 25 women with a mean age of 53.7 years (range, 25 to 76 years) who, with 3 exceptions, each required 2 or more dental implants and an implant-supported fixed restoration in the maxilla. The 3 exceptions involved 2 patients who required the replacement of 2 teeth, but had sufficient mesiodistal arch length to receive only 1 implant. In each situation, only 1 implant was used to support a 2-unit prosthesis. More specifically, a lateral incisor implant carried a cantilevered canine crown, a second premolar implant carried a first premolar crown, and a canine implant carried a cantilevered first premolar crown.

A total of 151 implants were placed, including where possible 1 implant for each tooth requiring replacement. All patients claimed to be currently nonsmokers and were otherwise medically fit. Each was given a detailed oral and written description of the risks and benefits of the proposed treatment, and all patients then signed a consent-to-treat agreement. Pretreatment records collected included a medical history, a full-mouth series of periapical radiographs using the long-cone paralleling technique and polydirectional tomographic images of the sites intended for implant placement, diagnostic casts, and a full dental and periodontal assessment of the remaining teeth. Patients with existing periodontal disease were referred to have this condition treated prior to implant placement.[34]

Implant System

The implant used was the Endopore implant system (Innova Corporation, Toronto, Ontario, Canada), an endosseous tapered root-form design developed at the University of Toronto.[25–28,30,35] The implant designs used in this trial are shown in Fig 1 and included 7-, 9-, and 12-mm-long implants (4.1-mm diameter), a 9-mm "mini" implant (diameter 3.5 mm), and 5- and 7-mm-long "wide-body" implants (5.0-mm diameter). For each of the implant designs, the coronal 1 mm had a machined surface finish, while the remainder of the implant length had the sintered porous-surfaced structure described by Pilliar and coworkers.[36] All implants had a "universal" external hexagon connection.

Surgical Technique

The standard protocol for surgical placement in the partially edentulous maxilla using surgical burs has been described.[28] Implant sites were created with a pilot bur to establish site depth, followed by a side-cutting tapered implant bur. Each site was checked for size with a "trial-fit" gauge and the implant was placed and fully seated with a surgical mallet. This procedure was used to place 79 implants (ie, 52.3% of the total number of implants placed) in 26 of the 50 patients. However, at about this time, osteotome techniques for the placement of press-fit implants in maxillary bone developed by Summers[20,37] were published, and the porous-surfaced implant seemed ideal for use with this osteotome approach in Types III or IV maxillary bone and/or where ridge width

was too narrow to permit the use of burs. Therefore, in the remaining patients, a modified Summers technique was used where appropriate (72 implants, or 47.7%).[33]

Whether implants had been placed using surgical burs or osteotomes, re-entry surgery was scheduled at 4 months after placement, unless a simultaneous indirect sinus elevation procedure had also been done (which was the case for 26 implants in 16 patients[38]); in these patients, the affected implant sites were left to heal for 6 months. Other exceptions included those patients in whom a perforation and/or a fracture of the buccal plate had occurred during implant placement with osteotomes. This situation occurred with 39 implants in 22 patients, and in most instances the problem area was covered with a Dynagraft Matrix (GenSci Regeneration Laboratories, Irvine, CA), a sponge of human tendon collagen carrying freeze-dried, demineralized bone particles, and allowed to heal for 6 months.

Prosthetic Treatment

Following re-entry, healing abutments were left in situ for approximately 4 weeks before prosthesis fabrication was begun. It was not possible to adhere to this protocol with 2 patients, and in these situations (see "Results"), much longer intervals elapsed between re-entry and prosthesis placement. For all implants, the final impression was made at the implant level employing a closed-tray technique and transfer copings (Innova Corporation). Custom-made impression trays and polyether (Polyjel NF, Dentsply International, York, PA) or polyvinyl siloxane (Poly-Sil, SciCan/Lux and Zwingenberger Ltd, Toronto, Canada) impression materials were used. Porcelain-fused-to-metal crowns were fabricated with the aid of plastic UCLA-type abutments that were subsequently cast in gold alloy (Olympia, JF Jelenko, Armonk, NY), to which porcelain was added.

Of the 151 implants, approximately half (43%) were restored with individual (ie, non-splinted) crowns, while the remainder (57%) were splinted to other implants, in most instances as part of a fixed partial prosthesis with 1 or more pontics. For connected (splinted) units, a Duralay index (Reliance Corporation, Worth, IL) was obtained in the mouth prior to soldering. The majority of the restorations were made retrievable. In a few instances, however, because of implant positioning, the restorations needed to be cement-retained. In these situations, custom abutments were fabricated and the restorations secured with temporary cement (Temp-Bond, Kerr Corporation, Romulus, MI). Any necessary occlusal or contact point adjustments were made at the first bisquet bake stage. At the time of prosthesis placement, the retaining screws for all abutments were secured to their respective implants with a torquing wrench (Attachments International, San Mateo, CA) set at 32 Ncm.

Postimplantation Data Collection

Posttreatment records were collected at baseline (ie, 1 month after prosthesis placement), after 6 months of function, and annually thereafter. At each session, the prosthesis was removed and subclinical mobility testing done using a Periotest device (Siemens Medical, Charlotte, NC). Radiographs were collected using a specialized stainless steel film holder[26,39] connected to each implant individually. The x-ray tube was connected directly to the film holder using a Rinn extension arm and locating ring (Rinn Corporation, Elgin, IL), which in turn was attached to the directing cone to standardize image geometry of sequential films and therefore minimize interpretation error in measuring bone height in the sequential films. All films were exposed using the same calibrated x-ray machine and developed manually in batches, always using freshly prepared chemistry. The film holder also incorporated an aluminum stepwedge to provide a constant image density standard for the sequential films.

All radiographs were masked and viewed in a darkened room by one radiologist. Measurements of the position of the alveolar crest relative to the machined surface/porous surface junction on the mesial and distal surfaces of each implant were made with a reticle and 6× magnification, recognizing an intraobserver measurement error of 0.2 mm.[35]

Statistical Analyses

Univariate analyses were used to describe the study population demographically and their experience in the study. Specifically, these analyses resulted in frequency distributions describing the procedures performed, implant lengths and diameters used, implant locations by tooth position, and whether implants were splinted. Implant performance was determined using life table analysis.[40]

Radiographic data were from 151 implants in 50 patients, and therefore implants were not independent. Accordingly, regression analyses employing mixed models were used to account for both between-person and within-person variation using the mixed procedure in SAS Software (SAS Institute, Cary, NC).[41] Mesial and distal bone loss measurements were first assessed separately for changes in bone height over time, ie, between sequential radiographs. Following this, average bone loss data for each implant (ie, averaging the mesial and distal bone height values for each implant) between examination

Table 1 Implant Location by Tooth Type

Tooth location	Frequency	Percent
Incisors	28	18.6
Canines	7	4.6
Premolars	72	47.7
First molars	34	22.5
Second molars	10	6.6

Table 2 Implant Lengths Used

Implant length and diameter	Frequency	Percent
5-mm wide-body (5.0 mm)	2	1.3
7-mm regular-diameter (4.1 mm)	25	16.6
7-mm wide-body (5.0 mm)	19	12.6
9-mm regular-diameter (4.1 mm)	49	32.4
9-mm "mini" (3.5 mm diameter)	40	26.5
12-mm regular-diameter (4.1 mm)	16	10.6

Mean implant length = 8.7 mm.

Table 3 Life Table Analysis

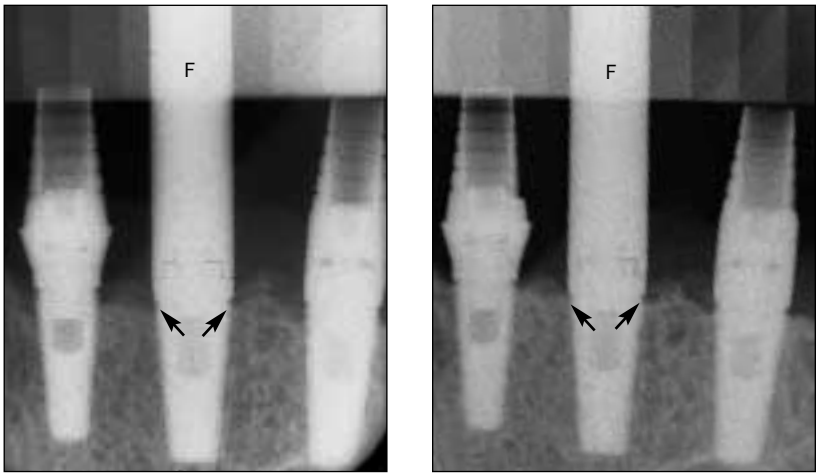
Time in function (mo)	Implants at start of interval	Implants yet to complete interval	Implant failures	Interval failure rate	Cumulative survival rate
0 to 12	151	11	4	2.7%	97.3%
13 to 24	136	37	0	0%	97.3%
25 to 36	99	16	0	0%	97.3%
37 to 48	83	61	0	0%	97.3%
49 to 60	22	19	0	0%	97.3%

intervals were computed and assessed for changes in sequential radiographs. In these models, the differences in mean bone loss across subjects were modeled as a random effect. Further models were used to assess whether bone loss was significantly affected by any of the following: time, anterior versus posterior location, implant length, implant diameter, and whether the implant was splinted. Here, subject-mean bone losses were again modeled as a random effect, and implant location, length, etc, were modeled as fixed effects. Analyses were first performed separately for mesial and distal implant surfaces and then repeated on the averaged (per-implant) data.

RESULTS

The locations by tooth type of the 151 implants placed in the maxillae of the 50 patients in the study are shown in Table 1. The majority (76.8%) of implants were placed in the posterior maxilla. Table 2 provides information on the implant designs used (see also Fig 1) and the mean implant length (8.7 mm); 27.0% of the implants were small-diameter (3.5 mm), 60.1% were regular-diameter (4.1 mm), and 12.8% were wide-diameter (5.0 mm).

All implants became integrated and all were used for the prosthetic restorations (ie, there were no "sleepers"). There was 1 implant failure after 5 months of function in a male patient who had received three 12-mm implants bilaterally to restore maxillary premolars and first molars. This implant had been placed in the maxillary right first molar site using surgical burs. There were also 3 more failures in a single quadrant of a second patient. This patient had received 4 implants in the left quadrant to replace a lateral incisor, canine, and first and second premolars. These had been placed using osteotomes and there had been some fractures of the buccal plate of bone at that time, which were covered with a Dynagraft Matrix. After re-entry the patient was unavailable to receive a definitive prosthesis until 18 months later. During this period, the patient wore a temporary acrylic resin distal-extension removable partial denture. At the time of definitive prosthesis placement, these implants appeared healthy in the radiographs taken, but within 3 months, 3 of the 4 showed signs of bone loss suggestive of impending failure (lateral incisor, 9-mm "mini"; canine, 9-mm regular-diameter implant; and first premolar, 9-mm regular-diameter implant). Shortly thereafter, these 3 implants were removed, giving a survival rate of 97.3% for the study group (Table 3), with a mean functional time of 34.6 months (range, 5.1 to 68.6 months). To date, no patients have been lost to follow-up.



Figs 2a and 2b Sample radiographs of 1 implant from 1 patient at baseline *(left)* and 2 years *(right)*. The prostheses have been removed and a stainless steel film holder (F) attached to this implant. The crestal bone had resorbed to the vicinity of the machined surface/porous surface junction *(arrows)* by the time of the baseline examination and remained stable thereafter.

Table 4 Within-Person Average Bone Loss Between Consecutive Measurements

Time interval (mo)	n*	Lower 95% limit†	Sample mean†	Upper 95% limit†	Standard error	*P* value
0 to 6	114	+0.034	–0.013	–0.060	0.023	.57
7 to 12	91	+0.024	–0.011	–0.046	0.017	.53
13 to 24	79	+0.014	–0.038	–0.090	0.025	.14

*Number of implants with radiographs available for assessment.
†Positive values indicate bone gain; negative values indicate bone loss.

Radiographic Results

At the time of this report, radiographic data had been analyzed for 131 implants at baseline, 119 implants after 6 months of function, 100 implants after 1 year of function, 88 implants after 2 years of function, and only 62 implants beyond 2 years. Sample radiographs of 1 patient out to 2 years are shown in Figs 2a and 2b. The data extending to 2 years are displayed in Table 4 and represent changes in bone level between the time intervals baseline to 6 months, 6 months to 1 year, and 1 to 2 years. Negative values indicate bone loss, while positive values represent apparent bone gain. As indicated above, in the initial analysis, data from the mesial surfaces of the implants were analyzed separately from those for the distal surfaces. Since there were no detectable differences between the means for these surfaces, the mesial and distal results were combined in preparing Table 4. They show that there were no significant changes in mean bone levels between baseline and any of the examination times, ie, that the alveolar crest remained stable at or near the machined surface/porous surface junction from the onset of implant function.

Figure 3 is a frequency distribution of the data used to prepare Table 4. It can be seen that for all 3 time intervals the greatest number of sites showed no bone loss, ie, had a value of zero, and that this number increased rather than decreased with time in function. If 0.3 mm is considered to be the inherent error in reading standardized periapical radiographs,[42] then the great majority of measurements (about 85% at 2 years) fall within this range of error (± 0.3 mm), suggesting minimal if any change from zero, ie, that the majority of sites demonstrated stable crestal bone levels. However, only 88 of the remaining 147 implants had reached 2 years or more in function at the time of this report, and therefore incontrovertible conclusions on crestal bone level changes beyond 1 year cannot be made from the present data.

As shown in Table 5, there were no detectable effects on crestal bone loss at any of the 3 time intervals with respect to whether the implant was

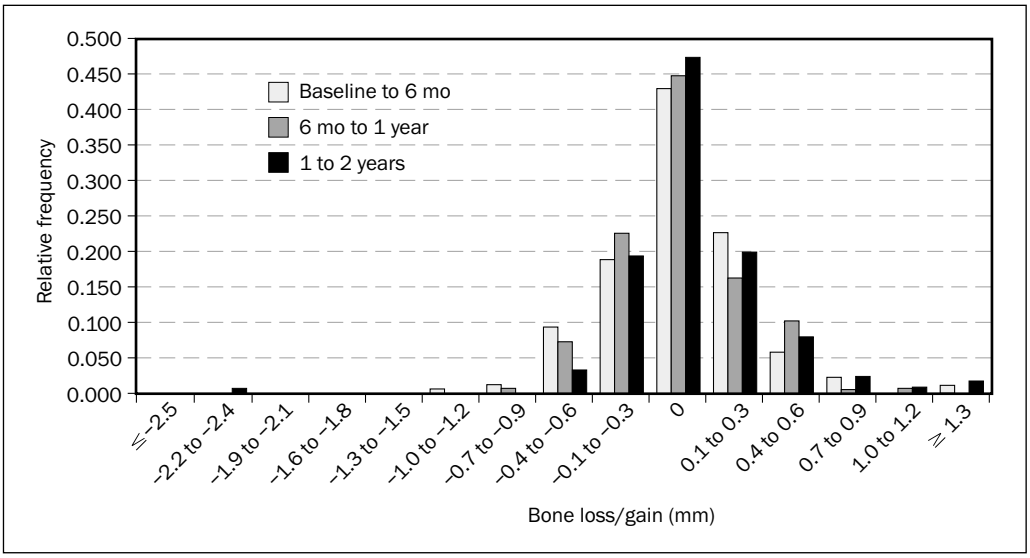


Fig 3 Frequency distribution of the changes in crestal bone levels for the time intervals baseline to 6 months, 6 months to 1 year, and 1 to 2 years. Mean values for these data are given in Table 4.

Table 5 Significance of Predictors Studied and Crestal Bone Loss

	Time interval		
Predictors	**0 to 6 months**	**7 to 12 months**	**13 to 24 months**
Anterior vs posterior location	*P* = .57	*P* = .99	*P* = .21
Implant length	*P* = .76	*P* = .55	*P* = .12
Implant diameter	*P* = .74	*P* = .05	*P* = .65
Splinted vs non-splinted	*P* = .51	*P* = .07	*P* = .82

placed in the anterior or posterior maxilla (0 to 6 months, *P* = .57; 7 to 12 months, *P* = .99; 13 to 24 months, *P* = .21). There were also no detectable effects of implant length or implant diameter on bone loss during any of the 3 time intervals. Finally, there were no detectable effects of splinting or not on crestal bone loss at any of the time intervals (0 to 6 months, *P* = .51; 7 to 12 months, *P* = .07; 13 to 24 months, *P* = .82).

DISCUSSION

This is the initial report on a prospective study involving 50 partially edentulous patients who, with 3 exceptions, each received 2 or more sintered porous-surfaced dental implants and fixed restorations in the maxilla. Unlike many earlier investigations,[2,43] there were no "sleeping" implants left covered because of prosthetically untenable implant location and/or orientation. At the time of this report, all remaining implants were in function, with a mean functional period of 34.6 months (SD 16.4 months) and with 136 implants past 1 year of function. The mean implant length used was 8.7 mm, which, with one possible exception (ten Bruggenkate and associates[44]), appears to be the shortest mean length for any endosseous root-form dental implant used to date in restoration of the partially edentulous maxilla.

The cumulative survival rate was 97.3% (4 implants were lost; one 12-mm-long, one 9-mm-long

"mini," and two 9-mm-long implants). The reasons for implant loss in these 2 patients are speculated to be as follows. The patient who lost the single 12-mm-long implant had received 2 other implants in the same quadrant, all placed with burs. The bone quality was Type III, and the site may have been better managed with osteotomes. The other 3 failures occurred in a single patient and a single quadrant. These implants had been placed in a narrow ridge using osteotomes, and fractures of the buccal cortical plate had occurred. Furthermore, this patient did not receive a definitive prosthesis until 18 months after re-entry (instead of the usual 4 months), during which time a temporary, removable, distal-extension, acrylic resin partial denture was worn over the healing abutments of the exposed implants. It is speculated that during this excessively long interval, the temporary denture may have caused trauma to the already compromised buccal plate of bone, leading to its resorption; and, indeed, at the time of implant removal no buccal plate of bone remained in these sites.

In the present investigation, available radiographic measurements of crestal bone loss collected at baseline and after 6 months and 1 and 2 years in function were presented and indicated no significant changes between baseline and any of the functional times analyzed. Earlier studies in canine[25] and human[26] mandibles had established that the pattern of crestal bone remodeling in relation to porous-surfaced implants was dictated by the original position of the bone crest in relation to the machined surface/porous surface junction. Bone loss occurred primarily around the machined collar of the implant, and this was related to a stress-shielding effect.[31,45] In both of these earlier studies[25,26] the implant design included a 2-mm machined collar, the majority of which was buried in bone at the time of implant placement. As a consequence, it took at least 1 year in the dog and up to 3 years in the human anterior mandible for the radiographic image of the crest to reach equilibrium. By contrast, in the present study, the machined collar region of the implant was only 1 mm long, and this appeared to limit the degree of predicted crestal remodeling,[35] perhaps explaining why the mean crestal bone levels were already stable by the time baseline radiographs were taken, ie, 1 month after prosthesis placement.

The radiographic data collected here were also assessed (see Table 5) for the effects of implant location, implant length, implant width, and the use of free-standing or splinted units in the prosthesis design. None of these factors had any effect on the crestal bone levels in this study population. Thus, whether an implant was located in the anterior or posterior maxilla made no difference in mean bone loss. Neither implant length (7, 9, or 12 mm) nor implant diameter (3.5, 4.1, or 5.0 mm) caused variation in the degree of crestal bone loss; and finally, and perhaps most interesting, there was no significant difference in crestal bone loss whether the implant units were splinted or not.

The consensus on the use of endosseous root-form dental implants in the maxilla is that long implants are necessary for success[46,47] to ensure sufficient surface area for bone contact.[2,6,9,11,22,23,48–50] In the present study, the mean implant length used was only 8.7 mm, and the survival rate appears to be equivalent to or better than those reported for other implant devices, since none of the 7-mm-long implants used were lost. The present results are also an improvement upon those of an earlier study of a group of completely edentulous patients who each had mandibles restored with 3 free-standing implants and an overdenture. The mean implant length used in that earlier study also was 8.7 mm, and the 5- to 6-year cumulative survival rate was 93.4%.[29]

The present results indicate that the porous-surfaced implant used performed more or less the same in the posterior maxilla as in the anterior maxilla. Only 4 implants of the 151 placed failed, and these included 2 anteriorly and 2 posteriorly located implants. Reports from investigators using other endosseous root-form dental implants have been contradictory in regard to their relative effectiveness in the anterior versus posterior maxilla. Zarb and Schmitt[51,52] reported somewhat better results posteriorly (97.6%; mean implant length not provided) with Brånemark System implants. Likewise, Jemt and Lekholm[53] found 3% failure in 101 Brånemark System implants (mean length not given, but the majority of failures were 7 mm in length) placed in posterior regions of the maxillae of 31 patients. The majority of these (3 of 4) failed to integrate. Conversely, Bahat[3] reported that more failures occurred in the posterior than in the anterior maxilla for similar machined-surface implants. The failure rate in the posterior maxilla was 4.8% (or 9.5% if only 7-mm implants were considered), and the majority of failures occurred at exposure or within 3 weeks to 4 months after loading. Similar results (about 5% failure, and generally before loading) in the posterior maxilla were reported by Nevins and Langer[10] and by Becker and Becker.[54]

Most other reports on the use of dental implants to restore the partially edentulous maxilla do not report separately the results in the anterior versus the posterior maxilla. In these reports, the failure rates with traditional threaded implants range from

about 3% within 1 year of placement[2,53] to 6% to 10.7% after 2 to 6 years in function.[1,8,11,55–57]

In the present study, all prosthetic restorations were supported by implants only and followed the principles of prosthesis design and occlusion established by others.[58,59] While it has been suggested that there would appear to be no negative impact of combining implants with natural teeth as prosthesis abutments,[60–62] except for occasional intrusion of natural-tooth abutments,[63,64] it was felt that if teeth as well as implants had been used to support prostheses in the present study, criticism may have been raised because of possible sheltering of the implants from full functional loading.[65,66] No particular ratio of implants to prosthetic units (eg, as suggested by Zarb and Schmitt[51]) was used. The rationale was simply to use as many implants as possible (ie, an implant for each missing tooth, if space permitted), as is generally done in clinical investigations of this sort.

CONCLUSION

The purpose of this report was to describe the protocol being followed and the early results found in a prospective study using a root-form, porous-surfaced dental implant to restore partially edentulous maxillae. To date, the 50 patients enrolled in the study have implants that have been in function for a mean period of 34.6 months (range, 5.1 to 68.6 months). The cumulative survival rate is 97.3% (4 implants were lost), despite a mean implant length of only 8.7 mm, and an analysis of crestal bone loss indicated no significant change from baseline to 2 years of implant function, although only 88 of the remaining 147 implants had reached 2 or more years in function at the time of preparation of this report.

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