Prospective Study of 429 Hydroxyapatite-coated Cylindric Omniloc Implants Placed in 121 Patients

Edwin A. McGlumphy, DDS, MS[1]/Larry J. Peterson, DDS, MS[2]/Peter E. Larsen, DDS[3]/Marjorie K. Jeffcoat, DMD[4]

Purpose: *Controversy over the long-term clinical effectiveness of hydroxyapatite (HA) -coated dental implants still persists, despite numerous clinical studies documenting high survival rates. The Ohio State University College of Dentistry undertook a 5-year prospective study of 429 HA-coated cylindric implants placed into 121 patients to determine the long-term clinical performance of the implants.* ***Materials and Methods:*** *All study subjects were patients screened and evaluated in the university's dental clinic by one of the principal investigators and one member of the surgical team. A total of 429 HA-coated implants were placed in 121 patients. The Ohio State University Human Subjects Committee approved and reviewed this study.* ***Results:*** *At the time of this report, 375 implants had completed 5 years of clinical follow-up. Beyond the 5-year limit of the study, 282 implants had completed 6 years and 114 implants had completed 7 years of clinical monitoring. The cumulative survival rate was 96% at 5 years and 95% at 7 years of follow-up. Mean combined mesial/distal bone loss was 1.2 mm in the mandible and 1.4 mm in the maxilla after 5 years of functional loading. Implant failures were most commonly associated with short implants or angled abutments.* ***Discussion:*** *Prospective clinical data are extremely valuable for clinicians evaluating the reliability of dental implant systems. In the present study, the implants achieved 100% osseointegration with minimal marginal bone loss, and 96% of the implants remained in function at 5 years.* ***Conclusion:*** *The HA-coated cylindric implants in this study provided a predictable means of oral rehabilitation.* (Int J Oral Maxillofac Implants 2003;18: 82–92)

Key words: *dental implants, hydroxyapatite, prospective study, survival rate*

Clinical decision-making is a challenge faced by every healthcare practitioner. In selecting a dental implant system from the many options currently marketed, it is imperative to evaluate all available evidence of the system's success. Since the early 1980s, when contemporary implant dentistry was first introduced in the United States, the proliferation of implant designs, materials, surface coatings, and surgical and restorative techniques has been bolstered by numerous reports of high clinical success rates with most systems.[1–9] Unfortunately, there have been very few large-scale, prospective studies that have followed rigorous clinical protocols and monitored all patients periodically for a prolonged period of time.[10,11] Much of the research available to assist clinicians in the evaluation and selection of a dental implant system must often be based on retrospective or small case studies that do not provide adequate hard data to fully support the decision-making process.

This article reports on the results of a long-term, prospective clinical study of 429 hydroxyapatite

[1]Associate Professor, Restorative and Prosthetic Dentistry, College of Dentistry, The Ohio State University, Columbus, Ohio.
[2]Clinical Professor, Oral and Maxillofacial Surgery, College of Dentistry, The Ohio State University, Columbus, Ohio.
[3]Professor, Oral and Maxillofacial Surgery, College of Dentistry, The Ohio State University, Columbus, Ohio.
[4]Rosen Professor and Chair, Department of Periodontology, University of Alabama School of Dentistry, South Birmingham, Alabama.

Reprint requests: Dr Ed McGlumphy, Ohio State University College of Dentistry, PO Box 182357, 305 W. 12th Ave, Columbus, Ohio 43218-2357. E-mail: mcglumphy.1@osu.edu

(HA) -coated cylindric implants (Omniloc, Centerpulse Dental, Carlsbad, CA) placed in 121 patients.

MATERIALS AND METHODS

The study was reviewed and approved by the Human Subjects Committee and conducted as a joint project by the departments of Oral and Maxillofacial Surgery (OMS) and Prosthetic Dentistry in the Dental Clinic of the Ohio State University (OSU) College of Dentistry.

Patient Selection and Treatment Planning

All study candidates were patients screened according to strict inclusion and exclusion criteria (Fig 1) and evaluated in the university's dental clinic by one of the principal investigators and one member of the surgical team. Detailed oral examinations were conducted and documented. Radiographic examinations included at least 1 of the following: panoramic, lateral cephalometric, and/or occlusal radiographs. A treatment-planning team consisting of 1 surgical dentist and 1 restorative dentist was assigned to each study patient to formulate a comprehensive treatment plan. Diagnostic casts and articulator mountings were fabricated and utilized. Existing prostheses were evaluated and assessed for esthetics, vertical dimension of occlusion, centric occlusion, stability, and retention. Any pre-existing dental pathologies were treated or eliminated. The scope of the study, its intended benefits and risks, and treatment alternatives were thoroughly discussed with the patients. Each candidate signed an extensive patient consent form before formal admission into the study. Prior to implant placement, a surgical template was fabricated from a diagnostic waxup and provided to the surgeon.

Inclusion criteria
- 18 years of age or older
- Willing to participate for the duration of the study
- Willing to provide informed consent
- Edentulous in 1 or more of the following areas: anterior mandible, posterior mandible, maxilla
- Absence of soft tissue, oral, or dental pathologies
- Good general health
- Sufficient available bone to fully accomodate the implant without impinging on vital structures

Exclusion criteria
- Uncontrollable metabolic disease
- Immunocompromised
- Uncompensated systemic disease
- Mental illness
- Prior radiation treatment of the surgical site
- History of alcoholism or drug abuse
- Excessive smoking
- Previous implant placement or graft to the surgical site
- Debilitating temporomandibular joint pathosis
- Untreated dental disease
- Pregnancy
- Prisoner status
- Less than 5 mm of bone width based on oral examination
- Less than 10 mm of bone height based on radiographic examination

Fig 1 Patient selection criteria.

Surgical Phase

The patients were prepared for aseptic surgery. Intravenous sedation was administered, which most commonly consisted of a combination of meperidine hydrochloride (Demerol, Sanofi-Synthelabo, New York, NY) and diazepam (Valium, Hoffmann-La Roche, Nutley, NJ). All patients received a single dose of penicillin or clindamycin. Anesthesia was achieved with 2% lidocaine and 1:100,000 epinephrine by local infiltration in the maxilla and inferior alveolar block in the mandible.

Surgical placement of the implants was conducted by one of the investigators or by one of the OMS residents under the direct supervision of an investigator. The osteotomies were prepared according to the manufacturer's protocol with internally irrigated burs in a slow-speed (600 to 800 rpm) handpiece with high torque. At least 2 mm of space was maintained above the inferior alveolar canal or below the maxillary sinus after preparation of the osteotomy. In addition, 2 mm of space was maintained between implants and adjacent natural teeth, and a minimum of 1 mm of residual bone was maintained on the lingual and buccal plates of the receptor sites. No graft material was used to augment bone for any study implants.

The surgical goal was to place the implants flush with the adjacent bone so that the preattached cover screws extended slightly less than 1 mm above the crest of the ridge. Once the implant was placed, the actual distance from the top of the cover screw to the buccal crestal bone was recorded for each patient. An intraoral photograph was taken of each implant, and then primary closure of the mucosa was achieved with 3-0 black nylon sutures (Supramid, S. Jackson, Alexandria, VA).

Immediately following surgery, the surgeons recorded the following pertinent data on standardized forms about the surgical procedure: flap design, incision location, bone recontouring prior to placement (yes/no), vertical relationship of implant to crestal bone (below/above/even), perioperative medication, and surgical site complications. Postoperative patient follow-up was conducted at 1 week, 3

weeks, and 6 weeks. Any surgery-related complications, such as infection and pain, were noted as adverse events and treated. The implants were provided an undisturbed, submerged healing period of at least 3 months in the mandible and 6 months in the maxilla. Postoperative radiographs were taken on the day of implant placement (stage 1 surgery).

At stage 2 surgery, a mucoperiosteal flap was reflected, and an intraoral photograph was taken of the implants before proceeding. The cover screws were then removed, and gingival cuffs that extended at least 2 mm above the soft tissue were placed. The soft tissue was recontoured as necessary, sutured around the gingival cuffs, and given approximately 2 weeks to fully heal before the patient was referred for restoration.

Restorative Phase

The implants were restored by both OSU prosthodontic faculty and residents according to 3 basic guidelines: *(1)* screw-retained prostheses were to be fabricated to facilitate future removal for implant evaluation, *(2)* adjacent implants were to be splinted, and *(3)* the splinting of implants to natural teeth was avoided whenever possible. Typically, fixed restorations in partially edentulous patients were completed in 2 to 4 appointments over 5 weeks, and edentulous patients were restored in 6 to 7 appointments over 8 weeks. Abutment and prosthesis fixation screws were finger-tightened without a torque wrench.

Fixed implant restorations in partially edentulous patients were fabricated with gold-palladium alloy and standard dental porcelains, except for all-alloy restorations, which were Type III gold. Anterior guidance, with posterior disclusion, was the desired occlusal scheme. In completely edentulous patients, gold-palladium bars and frameworks were cast. Denture resin (Lucitone 199, Dentsply, York, PA) and standard denture teeth were used in the fabrication of the edentulous restorations. When the implant restoration opposed a complete denture, bilateral balanced occlusion was achieved. If natural teeth or additional implant restorations formed the opposing dentition, anterior guidance was again the desired occlusion.

All definitive restorations were checked for adequate occlusal adjustment and framework fit by the principal investigator. Framework fit was evaluated by the "Sheffield fitting test,"[12] whereby the distal end of the framework was attached to its corresponding abutment by 1 screw. If a gap was present between the framework and its other abutments and could be closed with a second screw, the framework was sectioned and soldered to provide a passive fit. Complete seating of all frameworks and abutments was verified radiographically.

Examination Phase

Within 2 weeks after delivery of the definitive restoration, baseline data were collected. A modest financial reward was given to the patient as an incentive to return for follow-up.

Periodontal Indices. Attachment level, gingival bleeding, and Plaque Index were recorded 2 weeks after loading (baseline) and at each clinical follow-up appointment. A standard 20-g pressure probe (Florida Probe, Gainesville, FL) was used to record probing depths and attachment levels. This instrument was calibrated to ± 0.1 mm before each patient evaluation. A standardized probing template was constructed for each patient, which assured consistent probing locations on the mesial, distal, buccal, and lingual of each implant. The probing template also acted as a fixed reference point to allow accurate assessment of changes in attachment levels.

Mobility. Each implant was assessed for mobility by manual inspection and with the Periotest instrument (Siemens AG, Munich, Germany). The probe tip of the Periotest was always positioned as close to the free gingival margin as possible (approximately 2 mm coronal to it) on the midline of the buccal surface of the abutment. If the restoration did not have a supragingival abutment, a supragingival healing abutment was placed before each measurement.

Radiographic Examination. Standardized vertical bitewing radiographs, utilizing a jig with the patient positioned in a cephalometric head holder, were obtained for each implant according to a previously published protocol.[13] Duplicate films were utilized so that one copy could be mailed to a third-party evaluation service for digitizing, angle correction, and comparison. All evaluation parameter measurements were repeated at semi-annual recall examination and prophylaxis appointments. Patients were given 2 weeks on either side of their appointment date to actually complete the appointment.

Statistical Analyses. For statistical comparisons between groups (eg, success/failure by mandible/maxilla), the chi-square statistic was used to calculate the *P* values. For those with fewer than 5 data points, the Fisher-exact test was used. The data points of the analyses included gingival bleeding, Plaque Index, attachment level, occlusion, bone loss, implant mobility, and prosthodontic stability. Failure and complication rates were also analyzed statistically and reported using life table analysis techniques. Statistical analysis software (SAS Software, SAS Institute, Cary, NC) was used.

Table 1 No. of Adverse Events at Implant Sites and Prostheses at 5 Years

	Maxilla		Mandible	
Complication	Anterior	Posterior	Anterior	Posterior
Loose screws[1]	15	25	19	54
Broken scews	0	0	1	2
Loose abutments	1	1	1	7
Broken abutments[1]	1	3	57	42
Implant mobility	6	4	0	3
Implant removed[2]	6	3	0	7
Abrasion to the prosthesis[3]	0	1	0	1
Infection[1,4]	12	7	0	10
Bone loss[1,5]	14	3	0	12
Persistent localized pain[1,6]	2	1	0	5

[1]Includes multiple occurrences of the event per implant site; [2]Mandbile: 6 implants removed from 2 patients, maxilla: 10 implants removed from 3 patients; [3]Limited to 2 patients; [4]Limited to 5 patients; [5]Limited to 6 patients; [6]Limited to 3 patients.

Table 2 Distribution of Prosthesis Types by Location

	Mandible		Maxilla		
Design	Anterior	Posterior	Anterior	Posterior	Total
Screw-retained denture (hybrid)	29	0	1	5	35
Fixed partial denture (FPD)	1	48	6	9	64
Overdenture	1	0	0	1	2
Implant/tissue–supported overdenture	1	0	0	0	1
Implant-tooth FPD	0	1	1	0	2
Single tooth, cemented	4	3	7	3	17
Single tooth, screw-retained	0	19	11	8	38
Total	36	71	26	26	159

Definitions and Success Criteria

In the present study, "implant success" was used to describe the cumulative performance of an implant according to a given parameter (eg, percent success by implant diameter), and "implant survival" was used to describe the performance of a dental implant over a set of specific time intervals (eg, survival at baseline and 5 years). In addition, the criteria for clinical implant success in this study required that the implant was load-bearing and fully functioning and that it adequately met the prosthodontic needs of the patient. Furthermore, there could be no significant damage to adjacent structures or implant mobility when clinically tested; nor could there be peri-implant radiolucency, persistent or recurrent pain, infection, or detrimental crestal bone loss.

RESULTS

A total of 121 healthy partially and completely edentulous study patients (63 men and 58 women) ranging in age from 18 to 79 years (mean 49 years) were enrolled. The study protocol mandated 1 follow-up visit every 6 months for the 5-year duration of the study. Of the 121 study patients, 78 (64.5%) completed the 5-year study. Beyond the scope of the study, some participating clinicians continued to gather data from patients during routine hygiene and maintenance visits for an additional 2 years: 32 patients (26.4%) completed a sixth year and 3 patients (2.5%) completed a seventh year of supplemental follow-up appointments. Surgical and prosthetic complications were rare (Table 1). The distribution of prosthetic restorations is presented in Table 2.

Table 3a Life Table of Post-Restoration Implant Survival at 5 Years

Location/years post-restoration	No. of implants: Start of interval	Failed	Withdrawn	Survival rate (%)	Cumulative survival rate (%)
All implants					
0–1	417	0	1	100	100
1–2	416	0	5	100	100
2–3	411	7	10	98	98
3–4	394	9	10	98	96
4–5	375	0	93	100	96
Mandible					
0–1	309	0	1	100	100
1–2	308	0	5	100	100
2–3	303	3	6	99	99
3–4	294	3	10	99	98
4–5	281	0	58	100	98
Maxilla					
0–1	108	0	0	100	100
1–2	108	0	0	100	100
2–3	108	4	4	96	96
3–4	100	6	0	94	90
4–5	94	0	35	100	90

Table 3b Post-Study Continuing Patients: Life Table of Post-Restoration Implant Survival at 6 to 7 Years

Location/years post-restoration	No. of implants: Start of interval	Failed	Withdrawn	Survival rate (%)	Cumulative survival rate (%)
All implants					
5–6	282	2	166	99	95
6–7	114	0	105	100	95
Mandible					
5–6	223	2	129	99	97
6–7	92	0	85	100	97
Maxilla					
5–6	59	0	37	100	90
6–7	22	0	20	100	90

Follow-up time exceeded the 5-year duration of the study.

Implant Survival

A total of 429 implants were placed in this study, 319 (74%) in the mandible and 110 (26%) in the maxilla. Implant placement was divided fairly equally between the anterior and posterior regions of the mandible (anterior = 156, posterior = 163) and maxilla (anterior = 55, posterior = 55). One patient with 12 implants became chronically ill and did not return for phase 2 surgery, which left 417 implants (97.2%) that began the post-restoration monitoring period. Of these, none had failed to integrate at the time of stage 2 surgery.

Cumulative survival rates were calculated for all implants actively participating in the study. During the 5-year observation period of the study, 16 implants failed in 5 patients: 7 in 1 patient, 4 in 1 patient, 2 in each of 2 patients, and 1 in 1 patient (Tables 1 and 3a). A total of 119 implants failed or were withdrawn from the study, which left 282 implants (67.6%) in place at the close of the study (Table 3a). Patients lost to follow-up for various non–implant-related reasons were listed as "withdrawn" (Table 4). All implant failures and patient withdrawals were listed in the statistical database

Table 4 Reasons for Patient Withdrawal at 5 Years

Reason	No. of withdrawals
Completed study in year 4–5	61
Moved	8
Insufficient bone	4
Unrelated medical problem	4
Death	4
Lost contact	4
Selection criteria not met	3
All implants failed	3
Refused to continue treatment	1
Financial difficulty	1

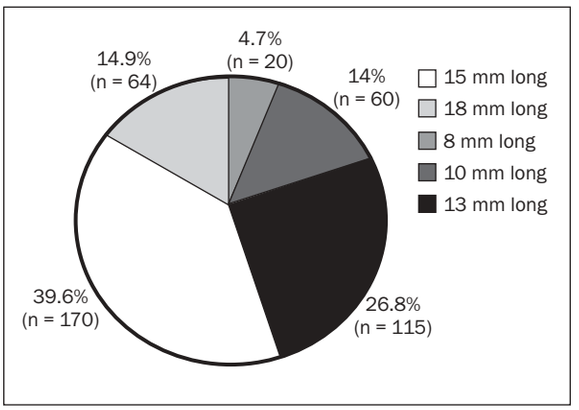

Fig 2 Distribution of Implants by length.

Table 5 Success by Implant Length at 5 Years

	Overall				Maxilla				Mandible			
	Implants		Success[1,4]		Implants		Success[2,4]		Implants		Success[3,4]	
Length	No. placed	No. failed	No.	%	No. placed	No. failed	No.	%	No. placed	No. failed	No.	%
8 mm	20	4	16	80.0	2	2	0	0	18	2	16	88.9
10 mm	60	7	53	88.3	14	2	12	85.7	46	5	41	89.1
13 mm	112	2	110	98.2	25	2	23	92.0	87	0	87	100.0
15 mm	161	5	156	96.9	52	4	48	92.3	109	1	108	99.1
18 mm	64	0	64	100.0	15	0	15	100.0	49	0	49	100.0
Total	417	18	399	95.7	108	10	98	90.7	309	8	301	97.4

[1]Chi-square = 24.95, $P < .001$; [2]chi-square = 21.75, $P < .001$; [3]chi-square = 22.51, $P < .001$; [4]There was a significant difference in success rates by implant length. Implant length significantly affected success.

(Tables 1 and 3a). In all cases, failed implants were removed and the patients were subsequently treated after bone healing but not re-entered into the study.

At the 5-year conclusion of the study, the cumulative implant survival rates were 96% for all implants placed, 98% for all mandibular implants, and 90% for all maxillary implants (Table 3a). For the patients who continued beyond 5 years, the cumulative survival rates in the 6- to 7-year period were 95% (n = 114) for all implants placed, 97% (n = 92) for all mandibular implants, and 90% (n = 22) for all maxillary implants placed (Table 3b).

Table 6 Success by Implant Diameter at 5 Years

Implant diameter	Implants		Success*	
	No. placed	No. failed	No.	%
3.25 mm	69	4	65	94.2
4.0 mm	360	12	348	96.6
Total	429	16	413	96.3

*Chi-square = 0.525, $P \geq .05$; no significant difference between success rates by implant diamter. Implant diameter did not affect implant success.

Implant Success

Implant Success by Length. Implant length ranged from 8 to 18 mm (Fig 2). To evaluate the influence of implant length on implant success, chi-square tests were performed to evaluate differences in clinical success based on implant length. The analyses indicated a significant difference in success rates by implant length for the entire population (chi-square = 24.95, $P < .001$), as well as the maxillary (chi-square = 21.75, $P < .001$) and mandibular (chi-square = 22.51, $P < .001$) populations separately; therefore, implant length did significantly affect implant success (Table 5).

Implant Success by Diameter. Implant diameters were 3.25 mm and 4.0 mm. The standard-diameter (4.0-mm) implant was used 360 times (84%) and the narrow-diameter (3.25-mm) implant was used 69 times (16%). To evaluate whether implant diameter affected the success of the implant, a chi-square test was performed. The chi-square analysis for the

Table 7 Mean Combined Mesial/Distal Bone Loss by Jaw Location at 5 Years

Location/ time	No. of implants	Mean (mm)	SD (mm)	Range (mm)
Mandible				
Baseline*	297	0.2	0.6	0–3.6
5 years	254	1.2	1.0	0–7.8
Anterior				
Baseline*	141	0.3	0.7	0–3.6
5 years	133	1.3	1.1	0–7.8
Posterior				
Baseline*	156	0.2	0.4	0–2.2
5 years	121	1.0	0.8	0–4.4
Maxilla				
Baseline*	95	0.2	0.4	0–2.3
5 years	84	1.4	1.3	0–7.5
Anterior				
Baseline*	44	0.1	0.4	0–2.3
5 years	40	1.8	1.5	0.2–7.5
Posterior				
Baseline*	51	0.2	0.4	0–1.6
5 years	44	1.1	0.9	0–4.1

*Measured within 2 weeks after prosthetic loading.

Table 8 Mean Combined Mesial/Distal Bone Loss by Abutment Type at 5 Years

Abutment type/time	No. of implants	Mean (mm)	SD (mm)	Range (mm)
Angled				
Baseline*	18	0.4	0.7	0–2.2
5 years	15	1.1	1.1	0–4.3
Straight				
Baseline*	374	0.2	0.5	0–3.6
5 years	323	1.3	1.1	0–7.8

*Measured within 2 weeks after prosthetic loading.

Table 9 Mean Periotest Values by Implant Success/Failure at 5 Years

Implant status/time	No. of implants	Mean (mm)	SD (mm)	Range (mm)
Successful				
Baseline*	399	–4.386	2.522	–8.0 to 7.0
5 years	368	–3.959	2.373	–7.0 to 6.0
Failed				
Baseline*	18	–1.222	4.305	–8.0 to 8.0
5 years	2	–1.000	7.071	–6.0 to 4.0

*Measured within 2 weeks after prosthetic loading.
Maxillary and mandibular implants were combined.

whole population (chi-square = 0.525, $P > 0.05$) indicated no significant difference in success rates by implant diameter; therefore, implant diameter did not significantly affect implant success (Table 6).

Marginal Bone Changes

Mean Combined Mesial/Distal Bone Loss by Jaw Location. Baseline bone loss was 0.2 mm in both jaws. At 5 years, the mean combined bone loss was 1.2 mm in the mandible (n = 254; range = 0 to 7.8 mm) and 1.4 mm in the maxilla (n = 84; range = 0 to 7.5 mm) (Table 7).

Success Rates by Abutment Type

Implants that were restored with angled abutments had a higher failure rate (20.8%) compared to implants restored with straight abutments (3.3%), but there was no statistically significant difference in marginal bone loss between restorations using the 2 types of abutments (Table 8).

Mobility

Manual Testing. All of the implants placed in this study were deemed to be clinically osseointegrated at the second-stage surgical uncovering. A total of 12 implants exhibited mobility after loading (Table 1) and were listed as failures (Table 3a). The implants were removed and the patients were treated after bone healing but not re-entered into the study.

Periotest Results. Periotest values for combined maxillary and mandibular implants ranged from –7.0 to 6.0 (mean = –3.959) for successful implants and –6.0 to 4.0 (mean = –1.0) for failed implants at 5 years (Table 9).

Periodontal Indices

Combined mesial/distal/buccal/lingual measurements were calculated for each index at 5 years (Table 10). Attachment Level Index ranged from 4.35 to 14.40 (mean = 6.784) for successful implants and from 5.20 to 10.10 (mean = 7.65) for failed implants. Gingival Bleeding Index ranged from 0 to 2.0 (mean = 0.288) for successful implants and from 0.25 to 2.0 (mean = 1.125) for failed implants. Plaque Index ranged from 0 to 2.0 (mean = 0.240) for successful implants and from 0 to 0.25 (mean = 0.125) for failed implants.

DISCUSSION

The current study presents up to 7 years of prospective data on the functional loading of HA-coated cylindric implants placed in the maxillae and mandibles of partially and completely edentulous patients and restored with a variety of prostheses. The prospective nature of the study generated important new data on implant survival and crestal bone changes. In reviewing the body of published literature on HA-coated cylinders, it is often very difficult to compare one implant study with another, since there are no generally accepted criteria for determining implant success.[14] In fact, many clinical studies simply report success as "implant survival" without stating any criteria used for evaluation.

At the very minimum, it may often be assumed that most studies equate implant survival with the ability of an implant to adequately serve in the prosthodontic capacity for which it was placed without engendering irresolvable clinical pathologies. This underlying assumption is reflected in other studies of HA-coated cylindric implants. In a meta-analysis of 12 studies of HA-coated cylindric implants, Lee and coworkers[15] reported that cumulative survival rates ranged from 79.2% to 98.5% (mean = 91.9%, mode = 93.9%) after 5 to 8 years of clinical follow-up. This same concept is also incorporated in the stated success criteria of the present study. The cumulative survival rate of 95% beyond the 5-year period (Table 3b) for all implants in the present study was basically equivalent to the mean survival rate of 91.9% for all 12 studies analyzed by Lee and coworkers.[15] While some researchers[16] have reported higher late-term failures with HA-coated implants, the present study found that implant failures diminished to none in the fifth and final year of the study. Two (0.007%) additional failures occurred in the supplemental sixth-year continuing patient group. These results thus concur with the finding of Lee and coworkers[15] that the HA coating did not compromise the long-term survival of dental implants. Shorter implants (ie, 8 and 10 mm in length) exhibited slightly higher failure rates than longer implants (ie, 13, 15, and 18 mm in length), especially in the maxilla (Table 5).

In studies cited by Lee and coworkers,[15] progressive bone loss around HA-coated cylindric implants was cited as an adverse event. During the developmental period of modern implant dentistry, marginal bone loss was deemed an important criterion of implant success, because few treatments were available to address the problem. Researchers of that era reported that marginal bone loss ranged from 1 to 1.5 mm during the first year after prosthesis connection and then dropped to 0.05 to 0.1 mm per annum thereafter.[11,17] However, those data were based on measurements of bone loss made from the bottom of the 2-mm-deep countersink inside the implant's receptor site, rather than from the crest of the ridge.[18] When the 2 mm of bone from the crest of the ridge to the bottom of the countersink were included, those figures actually represented a range of 3 to 3.5 mm of crestal bone loss sustained during the first year of implant loading. Later researchers called for less than 1.0 mm of bone loss during the first year after loading, followed by less than 0.2 mm annually thereafter, as part of a proposed set of success criteria for uncoated titanium screw-type implants.[19] In the present study, marginal bone changes of 1.2 mm in the mandible and 1.4 mm in the maxilla at 5 years (Table 7) met this criterion.

More than 2 decades of research have documented HA coating on dental implants to be highly effective in achieving and maintaining good bony fixation.[20–30] In a study by Clark,[31] HA-coated implants exhibited bone apposition ranging from 50% to 95% of the implant surface, in comparison to 50% apposition with commercially pure titanium and titanium-aluminum-vanadium surfaces. Other

Table 10 Periodontal Index Values by Implant Success/Failure at 5 Years

Index	No. of implants	Mean (mm)	SD (mm)	Range (mm)
Attachment level				
Successful implants				
Baseline*	398	7.189	1.547	2.75–13.80
5 years	369	6.784	1.572	4.35–14.30
Failed implants				
Baseline*	18	6.936	1.176	4.90–9.25
5 years	2	7.650	3.465	5.20–10.10
Gingival bleeding				
Successful implants				
Baseline*	399	0.085	0.298	0–2.00
5 years	369	0.288	0.497	0–2.00
Failed implants				
Baseline*	18	0.056	0.236	0–1.00
5 years	2	1.125	1.237	0.25–2.00
Plaque				
Successful implants				
Baseline*	399	0.108	0.305	0–2.00
5 years	369	0.240	0.409	0–2.00
Failed implants				
Baseline*	18	0.083	0.121	0–0.25
5 years	2	0.125	0.177	0–0.25

Mean combined mesial/distal/buccal/lingual measurements.
*Measured within 2 weeks after prosthetic loading.

comparative studies of HA-coated versus uncoated implants also reported that HA coating achieved significantly more bone apposition,[32–34] faster healing time,[3,35] and stronger integration with the bone.[34]

The implant used in the present study was an HA-coated cylinder with a 0.6-mm-deep internal octagon connection. As research in biomaterials, implant surface science, and implant prosthodontics has progressed, this implant design has continued to evolve. In the 1990s, some researchers reported that implants with high crystallinity exhibited greater resistance to dissolution, while implants with low crystallinity experienced greater degradation and less bone apposition in comparison studies.[36,37] Kay[38] stated that the percentage of the crystalline phase should be maximized and contain no less than 90% crystalline HA. Although these improvements have been made,[39,40] the importance of the HA-coated cylinders in the present study achieving 100% initial integration and 96% success with a mean marginal bone loss of only 1.3 mm at 5 years of functional loading should not be diminished.

The higher incidence of screw loosening and abutment fracture in the mandible compared to the maxilla may be attributed to several factors. Binon[41] reported that the geometry of the implant-abutment interface is one of the primary determinates of joint integrity and antirotational stability. In partially edentulous cases, especially single-tooth restorations, the implant-abutment interface and abutment screw are subjected to greater lateral bending loads, tipping, and elongation than bilaterally splinted implants in edentulous cases,[41–43] which can cause joint opening and screw loosening.[41,42,44–47] Implant-abutment interfaces that provide a narrow prosthetic platform with limited interfacial contact by the mating geometry have been reported to be particularly vulnerable to the negative effects of occlusal tipping forces.[41,48,49]

In the present study, the integrity of the implant-abutment connection may have been compromised by these same dynamics, because of the shallow (0.6-mm) depth of the mating interface. In addition, the establishment of torque limits for tightening prosthesis/abutment retention screws proposed by various researchers[50–53] had not yet been incorporated into the system at the time of this study, and all screws were finger-tightened. These limitations were multiplied in the mandible, where approximately twice as many prostheses were placed (n = 107) compared to the maxilla (n = 52) (Table 2). Furthermore, nearly twice the number of mandibular restorations were placed in the high-stress posterior jaw (n = 71) compared to the anterior region (n = 36), and all of the mandibular posterior prostheses were placed in partially edentulous patients (Table 2). Since this study was conducted, torque limits for abutment and fixation screw attachment have been implemented, and the implant-abutment connection was redesigned to provide a deeper octagonal interface with narrower manufacturing tolerances.[54,55]

CONCLUSIONS

1. The HA-coated cylindric implants tested in this study achieved 100% osseointegration at the second-stage uncovering.
2. At 5 years post-restoration, 95% of these implants remained in function.
3. Implant failures were most commonly associated with short implants or angled abutments.
4. The implants in this study provided a predictable means of oral rehabilitation in this study population.

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