A Comparison of Hydroxyapatite (HA) -coated Threaded, HA-coated Cylindric, and Titanium Threaded Endosseous Dental Implants

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Purpose: *The purpose of this study was to compare the success of hydroxyapatite (HA) -coated and machined titanium (Ti) implants in a 5-year randomized, controlled clinical trial conducted at 2 centers.* ***Materials and Methods:*** *Each of 120 edentulous patients received HA-coated threaded, HA-coated cylindric, and machined Ti threaded implants in a randomized design using 5 or 6 implants. Digital radiographs allowed for yearly measurements of bone loss. Calibrated clinicians also measured mobility, Gingival Index, Plaque Index, probing depth, and recession. A Kaplan-Meier analysis was used to compare the proportion of ailing implants (defined as less than 2 mm of alveolar bone loss over 5 years) for each type of implant design. The criteria employed to assess implant outcome included the need for successful implants to lose less than 2 mm of bone support over the 5 years following placement of the prosthesis.* ***Results:*** *This analysis revealed that 95.2% of machined Ti threaded implants and 97.92% of HA-coated threaded implants were successful, while 99.0% of HA-coated cylindric implants experienced less than 2 mm of bone loss ($P < .06$).* ***Discussion:*** *All types of implants placed in this study had success rates above 95%.* ***Conclusion:*** *Over 5 years, the success rate tended to favor HA-coated implants.* (INT J ORAL MAXILLOFAC IMPLANTS 2003;18:406–410)

Key words: *endosseous dental implants, human clinical trials, hydroxyapatites*

Endosseous dental implants have been used in dentistry for many years in an attempt to improve appearance and provide the functional ability of natural dentition. Materials and designs have evolved in an attempt to arrive at the optimal combination of material and design that would ensure implant permanence.

Hydroxyapatite (HA) -coated endosseous dental implants were introduced to dentistry several decades ago. The purpose of the HA was to provide a bioactive coating to facilitate osseointegration. Many early HA implants presented with technical problems, including chipping of the HA and contamination of the implant during placement or upon exposure of the coating, which resulted in the loss of alveolar bone and attachment. Current manufacturing and clinical care are designed to limit these problems. Case reports and uncontrolled studies have led clinicians to ask whether the HA failure rate is higher than that of the titanium (Ti) threaded implant.[1–4] The overall objective of this study was to compare the efficacy of the HA-coated threaded endosseous dental implant and HA-coated cylindric endosseous dental implant with that of the machined Ti threaded endosseous dental implant as a control; all were placed in a 2-stage procedure.

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MATERIALS AND METHODS

Study Design

The study was a single-blinded, multicenter, randomized, controlled study with an identified control (machined-surface Ti threaded endosseous implants, Nobel Biocare USA, Yorba Linda, CA). The study

was carried out at 2 university sites (the University of Alabama at Birmingham and Ohio State University) and consisted of a randomized, partially masked, Latin square design.

Sixty patients were included at each site. The appropriate institutional review boards approved the study, and informed consent was obtained in writing from each subject. The study design blinded all investigators except for the dentist placing the implants, who had to know the type of implant being placed.

Patients

Patients enrolled in the study were completely edentulous and indicated for an implant-supported fixed-removable prosthesis with permucosal element abutments in the mandible. Patients presented with the following inclusion and exclusion criteria.

Inclusion Criteria. Patients were required to meet the following criteria: *(1)* 18 to 70 years of age, *(2)* motivated to have implant therapy, *(3)* edentulous in the mandible and able to accommodate 5 or 6 implants between the mental foramina, *(4)* ASA Grade I or II, *(5)* mandible height of 10 mm or more on diagnostic radiograph, *(6)* adequate ridge width to permit placement of planned implants, and *(7)* willing to complete the 66-month study.

Exclusion Criteria. Patients were excluded from the study if any of the following applied: *(1)* subject less than 18 or greater than 70 years of age, *(2)* subject pregnant or nursing, *(3)* subject used tobacco within 3 months prior to the study surgery date, *(4)* presence of untreated periodontitis, *(5)* current radiation therapy or history of head/neck radiation therapy, *(6)* presence of insulin-dependent diabetes, *(7)* ASA Grade III or IV, *(8)* immunosuppressive disorders or therapy present or required, *(9)* could not or would not meet the study requirements, *(10)* prior endosseous implant surgeries in the mandible, *(11)* current alcohol or substance abuse, *(12)* presence of prosthetic heart valve, or *(13)* excessive parafunctional habits.

Randomization Schedule

Randomization schedules were used to determine which implants each patient enrolled in the study would receive. These schedules were designed to provide a balanced distribution of control and test implants.

The position in which each implant was to be placed was also specified by the randomization schedule. Each patient thus received a mix of HA-coated cylindric implants, HA-coated threaded implants, and machined Ti threaded implants. Furthermore, the position of these implants in the arch was randomized. Thus, the distribution of the implants within the arch varied from patient to patient to ensure that a balance of implants would be placed in the most distal positions in the arch to support the prosthesis. Figure 1 shows an example of the randomization code for a patient receiving 6 implants between the mental foramina.

Sample Randomization Schedule for Patients with Six Implants

Codes for implant position

Region	Range of tooth positions
1	19–22
2	20–23
3	23–26
4	23–26
5	26–29
6	27–30

Codes for implant designs

Code	Implant design
a	Machined titanium threaded (no coating)
b	Titanium threaded (HA-coated)
c	Titanium cylindric (HA-coated)

Implant selection for each patient by region

	Region					
Patient no.	1	2	3	4	5	6
1	a	b	c	c	b	a
2	b	c	a	a	c	b
3	c	a	b	b	a	c

Fig 1 Sample randomization schedule. As each subject was enrolled in the study, the number of implants that the patient required was determined. Separate tables were available for patients receiving 5 or 6 implants. A representative portion of the specific randomization schedules for patients who received 6 implants is presented.

Operative Procedures

Implants were placed in 2 surgical stages. For both stage 1 and stage 2 surgery, operative medications necessary for patient care were used, including antibiotics when indicated for prophylaxis for subacute bacterial endocarditis. Postsurgical analgesics were prescribed and/or dispensed as necessary. All patients were given 1 bottle of a chlorhexidine mouthwash and instructed to use this daily for 1 week following surgery. Sutures were removed approximately 2 weeks after surgery. Exposure of the implant (ie, second-stage surgery) occurred no sooner than 3 months after placement.

Prosthetic Attachment and Follow-up Assessments

All patients received temporary removable dentures for use during the healing period for the stage 1 surgical procedure.

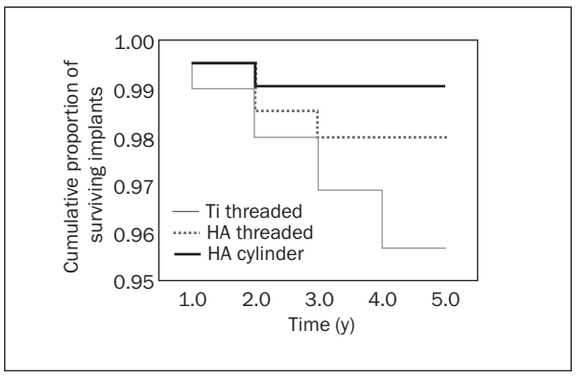

Fig 2 Cumulative implant survival for the 5 years following prosthetic placement. Note that the definition of success included loss of bone less than or equal to 2 mm over the entire study period after placement.

Implant-retained bars and screw-retained fixed-removable mandibular prostheses were fabricated and placed in each subject. Fabrication of the prosthetic attachment occurred when stage 2 surgery wounds had healed (on average 2 weeks after stage 2 surgery). From the date of prosthetic attachment, patients were evaluated for a total of 60 months. The patients received a prophylactic exam and were committed to a specific follow-up schedule. The prophylactic exam included hygienic evaluation and implant prophylaxis. Measurements of mobility,[5] probing depth, Gingival Index (GI),[6] Plaque Index (PI),[6] and recession were taken yearly by calibrated investigators. Periapical radiographs and vertical bitewing radiographs were standardized using a head holder as previously described.[7,8] Radiographs were taken on an annual basis to measure bone loss.

Measurements of pocket depth were taken using a Florida Probe (set at 20 g) and were measured to the nearest millimeter from the base of the pocket to the gingival margin at the following positions: buccal, mesial, lingual, and distal. Gingival recession was defined as the distance from the superior end of the abutment to the gingival margin, recorded in half-millimeter increments.

All examiners were carefully calibrated to ensure standardization across centers. For clinical measurements, such as PI, probing depth, GI, and recession, a separate standardization study was performed. A "gold standard" clinician first examined a patient, and repeat examinations were performed by the other examiners. To participate, an investigator had to be able to perform a repeat examination with readings within 0.5 mm of the gold standard clinician. As well, to test the reliability of the radiographic data, 10% of the radiographs were coded and reanalyzed. The distance between the top of the implant and the alveolar crest was measured. The mean difference in the original and repeat reading of the distance between the top of the implant and the alveolar crest was less than 0.2 mm.

Success/Failure Criteria

Success was declared when an implant that supported a prosthesis enabled restoration of masticatory function and was absent of any conditions of failure as follows. The implant had to exhibit less than 2 mm of bone loss during the 5-year postloading period from the baseline measurement determined at the time the implant was placed.

An implant was considered a failure if 1 or more of the following conditions were identified: mobility (following removal of the prosthesis); chronic, unresolved pain; implant loss; or radiolucency around the implant.

Analysis of Data

Kaplan-Meier survival analysis and life table methods (with a generalization of Gehan's general Wilcoxon test) were used to analyze time to failure of the implants to determine differences in survival times between the HA-coated test implants and machined Ti implants as well as between the 2 types of HA-coated implants.

RESULTS

Success rates did not vary significantly by implant type at the time of second-stage surgery. Failure at this stage included findings of mobility, pain, or radiolucency. A total of 615 implants were studied. At Ohio State University, 1 machined Ti threaded implant and 1 HA-coated cylinder in 1 patient did not meet the success criteria at the time of second-stage surgery. Four machined Ti threaded implants did not meet the criteria for success at the time of prosthesis placement. At the University of Alabama at Birmingham, 1 machined Ti threaded implant did not meet the success criteria. No HA threaded or cylindric implants were judged as failures. As previously described, patients were followed for a 5-year period after placement of the restoration. No implant failed during this interval, according to the initial success criteria.

For the 5-year follow-up period, a successful implant was considered to be one that did not lose more than 2 mm of bone after placement, as determined by the most severely involved implant of each coating within a given patient. This analysis permitted the sample size to be equal to the number of patients. Kaplan-Meier analysis was used to evaluate the success rate according to this criterion. The results are shown in Fig 2. HA-coated cylinders had

Table 1 Clinical Measurements at Baseline (Mean ± SD)

	Machined Ti threaded	HA threaded	HA cylinder
Plaque Index	0.65 ± 0.05	0.64 ± 0.05	0.68 ± 0.05
Gingival Index	0.56 ± 0.05	0.52 ± 0.05	0.61 ± 0.05
Probing pocket depth	2.15 ± 0.09	2.15 ± 0.08	2.18 ± 0.09
Gingival recession	1.91 ± 0.10	1.79 ± 0.09	1.84 ± 0.09

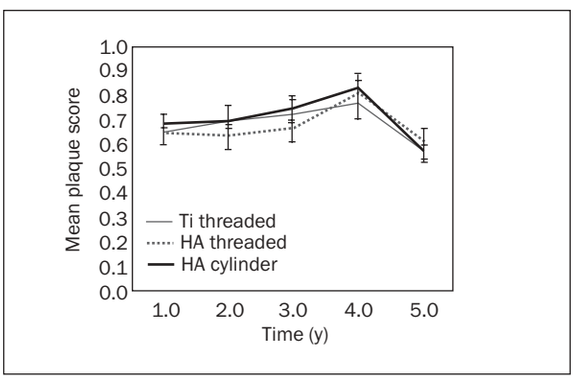

Fig 3 Mean PI scores. There were no significant differences by implant type.

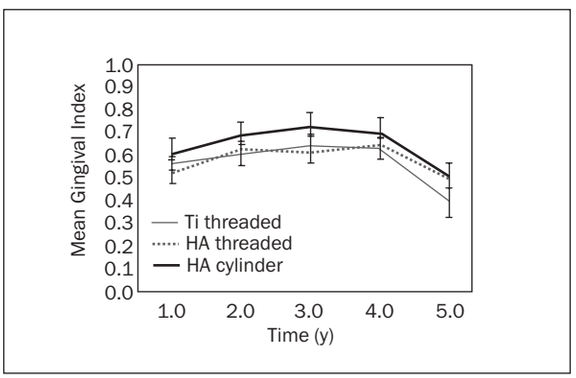

Fig 4 Mean GI scores, as calculated using the worst score per implant type. There were no significant differences by implant type.

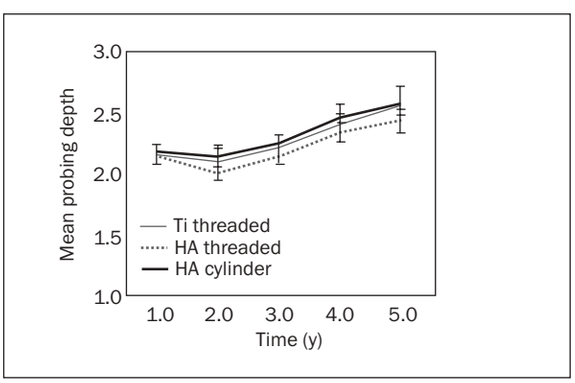

Fig 5 Mean probing depth. There were no significant differences by implant type.

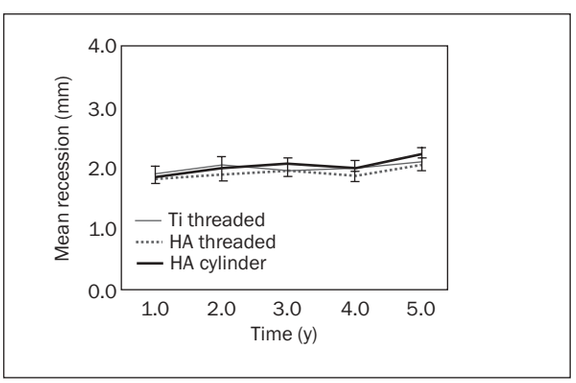

Fig 6 Mean recession measured relative to the superior end of the abutment. There were no significant differences by implant type.

the highest success rate 5 years after restoration (99.0%, $P < .06$), followed by HA-coated threaded implants (97.9%) and Ti threaded implants (95.2%).

PI, GI, probing depths, and recession were tested separately using a multifactorial analysis of variance. The factors of interest were implant type, time, and the interaction between implant type and time. Post hoc tests permitted testing of individual differences between groups at different time points.

Table 1 shows the clinical measurements obtained at baseline. There were no significant differences in PI, GI, probing pocket depth, or gingival recession between implant types at baseline.

The mean PI score over time according to implant type is shown in Fig 3. While the mean plaque score had improved significantly by year 5 ($P < .001$), there was no significant difference by implant type.

The worst GI score for each implant was used to determine a patient mean. The mean GI is shown in Fig 4. The GI was relatively low in each group and decreased to less than 0.55 in year 5. There was no significant difference by implant type.

The mean probing depth over time by implant type is shown in Fig 5. Mean probing depths remained low throughout the study (< 2.6 mm).

Mean gingival recession over time by implant type is shown in Fig 6. There was no significant difference by implant type. Note that recession was measured from the superior end of the abutment to the gingival margin.

DISCUSSION

This article describes the results of a randomized, controlled clinical trial designed to determine and compare the success rates of 3 types of implants. The study design permitted comparison of HA-coated and machined Ti implants utilized in each subject. To facilitate comparison, all patients also received the same bar-retained, fixed-removable prosthesis.

Clearly, this type of randomized clinical trial best describes the population under study. In this case, the subjects were compliant with respect to recall and hygiene, as evident by plaque scores below 0.6 at 5 years. The population was in good general health overall and denied smoking within 3 months of implant placement.

Several prior reports have addressed the issue of HA coatings and implant survival.[2,9,10] In a meta-analysis of 11 reports meeting the authors' criteria of inclusion, Lee and coworkers[9] concluded that HA-coated implants do not pose a substantial risk. In a 3-year study using soft tissue measurements, Morris and associates[10] concluded that concerns about an association between HA-coated implants and adverse clinical performance were unfounded. The results for HA-coated implants in this study compare well with those for machined Ti threaded implants.[11–13]

The definition of success in this trial went beyond that of implant failure. Many criteria have been proposed and used in the literature.[14,15] In this study, 5-year cumulative alveolar bone loss less than or equal to 2 mm was used as part of the long-term success criteria.

In spite of the use of these criteria, the high success rate achieved compares favorably with the results of other studies, with the success rates exceeding 95% in the 5 years after loading. This type of study speaks to the need for controlled trials to address key issues in implant dentistry. Through such trials, the profession will be able to minimize bias in evaluating clinical hypotheses.

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REFERENCES

1. Albrektsson T. Hydroxyapatite-coated implants: A case against their use. J Oral Maxillofac Surg 1998;56:1312–1326.
2. Cochran D. Implant therapy I. Ann Periodontol 1996;1: 707–791.
3. Block MS, Kent JN. Cylindrical HA-coated implants—8-year observations. Compendium 1993;(suppl 15):S526–S532.
4. Cochran DL. A comparison of endosseous dental implant surfaces. J Periodontol 1999;70:1523–1539.
5. Miller SC. Textbook of Periodontia, ed 3. Philadelphia: Blakestone, 1950.
6. Loe H. The Gingival Index, the Plaque Index and the Retention Index Systems, Part II. J Periodontol 1967;38: 610–616.
7. Jeffcoat MK, Reddy MS, Webber RL, Williams RC, Ruttimann UK. Extraoral control of geometry for digital subtraction radiography. J Periodont Res 1987;22:396–402.
8. Jeffcoat MK, Reddy MS. Digital subtraction radiography for longitudinal assessment of peri-implant bone change: Method and validation. Adv Dent Res 1993;7:196–201.
9. Lee JJ, Rouhfar L, Beirne OR. Survival of hydroxyapatite-coated implants: A meta-analytic review. J Oral Maxillofac Surg 2000;58:1372–1379, discussion 1379–1380.
10. Morris HF, Ochi S, Spray JR, Olson JW. Periodontal-type measurements associated with hydroxyapatite-coated and non-HA-coated implants: Uncovering to 36 months. Ann Periodontol 2000;5:556–567.
11. Brånemark P-I, Svensson B, van Steenberghe D. Ten-year survival rates of fixed prostheses on four or six implants ad modum Brånemark in full edentulism. Clin Oral Implants Res 1995;6:227–231.
12. Albrektsson T, Dahl E, Enbom L, et al. Osseointegrated oral implants: A Swedish multicenter study of 8139 consecutively inserted Nobelpharma implants. J Periodontol 1988;59: 287–296.
13. Adell R, Eriksson B, Lekholm U, Brånemark P-I, Jemt T. A long-term follow-up study of osseointegrated implants in the treatment of totally edentulous jaws. Int J Oral Maxillofac Surg 1990;5:347–359.
14. Smith D, Zarb G. Criteria for success of osseointegrated endosseous implants. J Prosthet Dent 1989;62:567–572.
15. Albreksson T, Zarb G, Worthington P, Eriksson AR. The long-term efficacy of currently used dental implants: A review and proposed criteria of success. Int J Oral Maxillofac Implants 1986;1:11–25.