Long-Term Follow-up of Hydroxyapatite-Coated Dental Implants—A Clinical Trial

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Purpose: *The purpose of this study was to report the long-term (8- to 10-year) results of hydroxyapatite (HA) -coated dental implants and compare them to the 5-year results as well as to long-term results of both HA and titanium dental implants reported in the literature.* ***Materials and Methods:*** *Patients were recruited, screened, and accepted or rejected sequentially based on specific inclusion/exclusion criteria. Implant placement was performed according to the manufacturer's instructions, followed by prosthetic reconstruction. Routine follow-up examinations were performed for a 5-year period. At 10 years all patients were contacted by mail and invited to participate in a longer-term follow-up of dental implants. All participants provided informed consent and underwent a complete history, including clinical and radiographic examination. The data obtained were statistically analyzed using life tables.* ***Results:*** *A total of 302 implants were placed in 90 patients whose average age was 54.3 years (SD 13.2 years). Of these, 114 implants in 40 patients were examined at 10 years, 88 in the mandible and 26 in the maxilla. The cumulative survival rate was 85.40% in the mandible and 70.59% in the maxilla. The total survival rate was 81.97%.* ***Conclusions:*** *The 10-year success rate of HA-coated dental implants was 82%. The success rate is higher in the mandible as compared to the maxilla. The 10-year results are inferior to the 5-year results.* (Clinical Trial) Int J Oral Maxillofac Implants 2007;22: 963–968

Key words: *coated implants, dental implants, hydroxyapatite*

In 1991, the University of Manitoba undertook a prospective, nonrandomized, sequentially enrolled, longitudinal, clinical trial using hydroxyapatite (HA) -coated dental implants (Omniloc). Patients were treated and data were collected for 5 years. However, the results of this study were not reported. Follow-up was not conducted after 5 years. Longer-term prospective follow-up data on HA-coated dental implants are sparse in the dental literature. The purpose of this study was to report the long-term (8- to 10-year) results of HA-coated dental implants and compare them to the 5-year results as well as the long-term results of both HA and titanium dental implants reported in the literature.

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MATERIALS AND METHODS

Prospective 5-year Evaluation

In January 1991, with approval from the Committee on Research Involving Human Subjects of the University of Manitoba, patients were screened and selected according to strict inclusion and exclusion criteria (Figs 1a and 1b). After giving their informed consent, all participants underwent a detailed oral examination and prosthetic assessment.

Implant placement was performed according to the manufacturer's instructions (Omniloc; Calcitek, Carlsbad, CA). The implants, together with their cover screws, remained covered by mucoperiosteum and

1. Patient is edentulous in the anterior or posterior maxilla or mandible.
2. Patient is at least 18 years old.
3. Patient is willing and able to give informed consent.
4. Patient is willing to participate for the duration of the study.

Fig 1a Inclusion criteria.

1. Patient has a history of alcoholism or drug abuse.
2. Patient smokes or chews tobacco.
3. Patient has an uncontrolled metabolic disease.
4. Patient is immunocompromised.
5. Patient has uncompensated systemic disease.
6. Patient is mentally ill.
7. Patient has undergone radiation treatment to the surgical site.
8. Patient has debilitating temporomandibular joint pathosis.
9. Patient has untreated dental disease.
10. Patient is pregnant.
11. Patient is a prisoner.

Fig 1b Exclusion criteria.

1. Individual implant is immobile when tested clinically.
2. Undistorted radiograph does not demonstrate any evidence of peri-implant radiolucency.
3. Mean vertical bone loss is less than 30% (from baseline).
4. Individual implant performance is characterized by an absence of persistent pain, discomfort, or infection.
5. Implant design does not preclude placement of a crown or prosthesis with an appearance considered satisfactory by the patient and clinician.

Fig 2 Success criteria.

Table 1 Prosthesis Designs for the Study Sample

Type of restoration	No. of prostheses
Fixed detachable	21
Implant-supported	
FPD	37
Overdenture	4
Implant-tissue supported	
Overdenture	21
Partial	1
RPD	1
FPD	5
Single tooth	
Cemented	4
Screw-retained	25
Tooth/tissue-supported RPD	2

FPD = fixed partial denture; RPD = removable partial denture.

unloaded for a minimum of 12 weeks in the mandible and 20 weeks in the maxilla. The cover screws were then exposed, and temporary gingival cuffs or abutments for removable prostheses were selected so that the cuffs extended 2 to 3 mm above the soft tissue. Radiographs were obtained to verify complete seating of abutments and to confirm osseointegration.

The prosthetic phase was performed 2 weeks following stage-2 surgery. Screw-retained prostheses were used when possible to facilitate prosthesis removal for evaluation. The restorative treatment of an arch may have encompassed a single-tooth restoration, a multiple implant–supported fixed partial denture, an implant/tooth–supported fixed partial denture, a fixed detachable restoration, an implant-supported overdenture, or an implant/tissue–supported overdenture.

Oral hygiene compliance and clinical evaluation of the soft tissue and prostheses, as well as probing depth (Florida periodontal probe) and attachment measurements, were performed at 6-month intervals for the first 5-year period. Standardized periapical radiographs were obtained annually.

Long-term Recall

All patients in the previous Calcitek Implant System clinical trial were contacted by mail and invited to participate in a longer-term follow-up of their HA-coated dental implants.

All participants were asked to provide opinions regarding the current status of their implants, which included any discomfort, their satisfaction with the implants, and the functional ability of the implants.

Clinical examination, including inspection, palpation, percussion, and probing of the implants, was performed. The clinical performance of implants was evaluated on the basis of the Gingival Bleeding Index,[1] gingival crevice depth,[2,3] and the Mobility Index for implants.[4] Periapical radiographs were used to assess the bone level.

An implant was considered successful if it was immobile when tested clinically, if no evidence of peri-implant radiolucency was observed, if the mean vertical bone loss was less than 30%, and if there was no persistent pain, discomfort, or infection (Fig 2).

Statistical Methods

Data analysis on the individual indices of gingival bleeding, attachment level, occlusion, bone loss, implant mobility, and prosthodontic stability were included in the overall analysis. Failure and complication rates were also statistically interpreted and reported using life table analysis techniques. Statistical analysis software (SAS software; SAS Institute, Cary, NC) was used.

Table 2 Life Table Analysis Using Study Success Criteria

Years postrestoration	No. at beginning of interval	Failed during interval	Withdrawn during interval	Proportion of failed implants	Proportion of surviving implants	Cumulative survival to end of interval
0–1	294	6	0	0.0204	0.9796	0.9796
1–2	288	6	6	0.0211	0.9789	0.9590
2–3	276	4	0	0.0145	0.9855	0.9451
3–4	272	2	9	0.0075	0.9925	0.9380
4–5	261	7	106	0.0337	0.9663	0.9064
5–6	148	11	23	0.0880	0.9120	0.8776
6–10	114	17	0	0.1490	0.8510	0.8197

RESULTS

Prospective 5-year Evaluation

A total of 302 implants were placed in 90 patients whose average age was 54.3 years (SD 13.2 years). More than half (51.1%) of the subjects were female. Of the 302 implants placed surgically, 76 were in the maxilla and 226 were in the mandible. Twenty-nine (9.6%) were placed in the posterior maxilla, 47 (15.6%) in the anterior maxilla, 90 (29.8%) in the posterior mandible, and 136 (45%) in the anterior mandible.

Two hundred ninety-four of the 302 implants were restored, 68 (23.1%) in the maxilla and 226 (76.9%) in the mandible. Twenty-nine (9.9%) were restored in the posterior maxilla, 39 (13.3%) in the anterior maxilla, 90 (30.6%) in the posterior mandible, and 136 (46.3%) in the anterior mandible. Different restorative designs were used (Table 1).

Oral hygiene compliance and clinical evaluation of the soft tissue and prostheses as well as probing depth and attachment measurements were performed at 6-month intervals for the first 5-year period. Radiographic data were obtained annually.

Success rate was calculated for 6 intervals postrestoration. The cumulative survival rate over the 5- to 6-year interval was 90.26% in the mandible and 78.47% in the maxilla (Table 2).

Success rates were calculated according to the location of the implant. The anterior mandible had a success rate of 93.4%, while the success rate of the posterior mandible was 85.6%. The anterior maxilla had the lowest success rate (76.9%); the success rate for the posterior maxilla was 82.2%. Based on the Wilcoxon test for equality, which was used to compare the mandibular and maxillary survival estimates over time, there was a statistically significant difference between the 2 survival curves ($P < .001$).

Eight clinical failures occurred prior to restoration. Implant removal was necessary due to excessive vertical bone loss from infection, excessive occlusion, and/or poor oral hygiene.

Using broadened clinical success criteria (with implants that were immobile and in function considered successful), the overall survival rate was 98% for all implants. Analysis by location resulted in a survival rate of 100% in the mandible and 91% in the maxilla.

Table 3 Symptoms as Described by Patients

	No. of patients	Percentage (%)
Pain		
No pain	33	84.62
Mild pain	5	12.82
Moderate pain	1	2.56
Severe pain	0	
Function		
Normal chewing	37	94.87
Discomfort with chewing	0	0.0
Unable to chew	2	5.13
Bleeding		
No bleeding	36	92.31
Bleeding with brushing	1	2.56
Spontaneous bleeding	2	5.13

Long-term Recall

Of the 90 patients included in the initial study, 40 agreed to participate in a recall appointment. The remaining patients were uninterested (15 patients), deceased (3 patients), or lost to contact (32 patients). A total of 114 dental implants had been placed in the 40 patients—88 in the mandible and 26 in the maxilla. Of the 40 patients, 25 (62.5%) had removable prostheses, 14 (35%) had fixed prostheses, and 1 patient had no prosthesis.

A visual analog scale was used to assess pain[5] on a scale from 1 to 10; if pain was reported, it was classified as either mild, moderate, or severe. Thirty-three patients (84.62%) reported no pain; 5 patients (12.82%) reported mild pain; and 1 patient (2.56%) reported moderate pain. Normal chewing was reported by 37 (94.87%) patients. None of the patients reported discomfort during chewing, while 2 patients (5.13%) reported inability to chew due to other reasons (loss of prosthesis, missing opposing dentition). One patient complained of bleeding with brushing, and 2 complained of spontaneous bleeding (Table 3).

Table 4 Clinical Assessment of Patients at 10 Years

	Mesial		Buccal		Distal		Lingual	
	n	%	n	%	n	%	n	%
Bleeding Index								
0	79	69.30	75	65.79	75	65.79	69	60.53
1	24	21.05	30	26.32	29	25.44	36	31.58
2	11	9.65	9	7.89	8	7.02	9	7.89
3	0	0	0		2	1.75	0	0
Pocket depth								
1 mm	1	0.88	1	0.88	2	1.75	0	0
2 mm	15	13.16	17	14.91	8	7.02	31	27.19
3 mm	53	46.49	60	52.63	75	65.79	45	39.47
4 mm	28	24.56	22	19.30	29	25.44	25	21.93
> 4 mm	17	14.81	14	12.28	0	0	13	11.40

Table 5 Mean Bone Loss on Radiographs at 10 Years

	Horizontal bone loss	Vertical bone loss
0 to 2 mm	109	99
2 to 4 mm	3	9
> 4 mm	2	6

Gingival bleeding, gingival depth, and mobility were clinically evaluated. Seventy-nine implants were given a Bleeding Index score of 0 for at least 1 surface, 36 were given a score of 1 for at least 1 surface, 11 a score of 2 for at least 1 surface, and 2 a score of 3 for at least 1 surface. Using the periodontal probe, measurements of the crevice depth were recorded for 4 surfaces per implant. Seventeen implants (14.81%) had a pocket depth greater than 4 mm for at least 1 surface. Of the 114 implants, 1 implant had grade 2 mobility, while 2 implants were given grade 3 mobility (Table 4).

An intraoral positioner was used to maintain a periapical film parallel to the long axis of the implant. A periapical radiograph was obtained for each implant. All periapical radiographs were evaluated for radiolucency and horizontal and vertical bone loss and compared to baseline radiographs. The distance between the top of the cervical collar of the implant to the first bone contact was measured by 2 observers, and the average of the 2 measurements was calculated. This was preformed for the baseline, 5-year, and 10-year radiographs. One hundred and nine implants had horizontal bone loss of less than 2 mm, three implants of 2 to 4 mm, and 2 implants had more than 4 mm. Vertical bone loss was less than 2 mm in 99 implants, 2 to 4 mm in 9 implants, and more than 4 mm in 6 implants. Two implants were observed with peri-implant radiolucency (Table 5).

In the life table analysis, a total of 114 implants were included in the 10-year interval in which 88 were in the mandible and 26 were in the maxilla. The success rate was calculated according to the study success criteria. The total survival rate was 81.97% (Table 2), with a survival rate of 85.40% in the mandible and 70.59% in the maxilla.

When broadened clinical criteria were used to evaluate success (implants considered successful if they were immobile and in function), the survival rate increased to 96.94%, with survival rates of 99.56% in the mandible and 88.24% in the maxilla. Three implants were categorized as failures, 2 in the maxilla and one in the mandible. Implant success according to the location shows a 100% success rate in the anterior mandible as being the highest success rate, while the posterior maxilla had the lowest success rate (82.2%).

DISCUSSION

HA-coated dental implants have been used clinically since 1984. However, their clinical predictability and indications for use remain controversial. Numerous reports have been published that question the long-term stability and prognosis of HA-coated dental implants.[6,7] These reports suggest that HA coating is unstable, has an increased susceptibility to bacterial infection, may be predisposed to rapid osseous breakdown or saucerization at the implant site, and does not demonstrate significant advantages over titanium implants.[1] However, the majority of the data used to support these arguments are anecdotal in nature and were derived from isolated case reports.[8]

One of the strongest arguments against the routine use of HA-coated implants is the general lack of long-term documentation on their survival.[8] Kent et al[9] and Babbush and Shimura[10] reported 5-year suc-

cess rates of 95% for HA coated cylinders. Lozada et al[11] experienced an 8-year success rate of 95% in a retrospective study for HA-coated threaded implants. Buchs et al reported a 5-year post restoration life table success rate of 96% for HA-coated threaded implants.[9–12] Hahn and Vassos reported a 6-year success rate of 96.4% in their prospective study of HA cylindric implants.[13]

In a randomized controlled multicenter study, Jeffcoat et al[14] compared HA-coated threaded, HA-coated cylindric, and titanium threaded dental implants in 120 edentulous patients over a 5-year period. The HA-coated cylindric implants were associated with a cumulative survival rate of 99.0%, while the HA-coated threaded and the titanium dental implants were associated with cumulative survival rates of 97.7% and 95.2%, respectively ($P < .06$).

In a prospective study of 429 HA-coated cylindric Omniloc implants, McGlumphy et al[15] reported a cumulative survival rate of 96% at 5 years and 95% at 7 years. The life table analyses in that study showed that only 27.3% of the implants were included in the 7-year interval; a high number of implants were withdrawn during that interval. Haas et al[16] reported a total survival rate of 89.9% at 100 months. Only 51 implants in 23 patients were followed for the 9-year period. In this study, 38.7% of the implants were followed for a period of 10 years. The high number of withdrawals in the 6- to 10-year interval was partly due to fees encountered by the patients beyond the 5-year interval of the study.

In a meta-analytic review article of HA-coated implants, Lee et al[17] did not find any differences in survival between HA-coated dental implants and uncoated titanium dental implants. They also reported that the yearly interval survival rate did not drop below 90% in any of the studies that they reviewed.

Wheeler[18] observed poor long-term performance with HA-coated cylindric implants in his retrospective study. He suggested that HA-coated implants, after early success, began to fail several years postrestoration and that late failures were typically associated with peri-implantitis.[18] In 1999, Watson et al[19] reported a cumulative success rate of 58% in his 4-year prospective study of 33 single-tooth HA-coated implants.

In the present study, 114 of 294 restored dental implants (38.78%) were followed for 10 years. At 10 years, 17 implants, 11 in the mandible and 6 in the maxilla, were classified as failures based on preestablished criteria. These criteria were identical to those reported previously by Smith and Zarb[20] and Spiekermann et al.[21] The survival rate increased dramatically when the radiographic evaluation was excluded from the success criteria for the 10-year data. The cumulative survival rate increased to 96.94%—99.56% in the mandible and 88.24% in the maxilla.

After 5 years, Jemt and Lekholm[22] reported a success rate of 97.2% for titanium implants in the posterior maxilla and mandible. However, Adell et al[23] reported a cumulative survival rate of 93% at 5 years, 88% at 10 years, and 82% at 15 years. Another long-term prospective study by Ekelund et al[24] of Brånemark implants in edentulous mandible showed a 20-year cumulative survival rate of 98.9%.

CONCLUSIONS

1. The long-term (10-year) success rate of cylindric HA-coated dental implants was 82%.
2. The long-term success rate was better in the mandible than in the maxilla (85.4% vs 70.6%).
3. The success rate of HA-coated dental implants decreased from 88% at the 5- to 6-year interval to 82% after 10 years.
4. The long-term (10-year) success rate of cylindric HA-coated dental implants (82%) is inferior to those reported for threaded titanium implants (approximately 88%).

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