Radiographic and Clinical Evaluation of Single-Tooth Biolok Implants: A 5-year Study

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Purpose: *The purpose of this prospective clinical and radiographic study was to evaluate Biolok implants used for single-tooth replacement during 5 years of function.* ***Materials and Methods:*** *Thirty-nine patients received Biolok implants for single-tooth replacement. Clinical and radiographic recordings were made at baseline (placement of restoration) and at 1, 3, and 5 years. Plaque Index (PI), Gingival Index (GI), and clinical attachment level were the clinical parameters recorded. Clinical attachment level was measured using a customized probing template and a standard pressure electronic probe. Bone level changes were measured from standardized radiographs. Clinical attachment level and bone level were recorded to the nearest 0.1 mm. Correlations between clinical attachment level, bone level, PI, and GI were evaluated.* ***Results:*** *The cumulative survival rate was 97.4% (38 of 39 implants). The mean clinical attachment level change over 5 years was a loss of 0.17 ± 0.23 mm. Significant correlations between clinical attachment level change and PI were found at 3 and 5 years (P < .015). Significant correlations between clinical attachment level change and GI were not found (P > .05). Mean bone loss was 0.83 ± 0.03 mm from baseline to 1 year, 0.26 ± 0.03 mm from 1 year to 3 years, and 0.14 ± 0.04 mm from 3 to 5 years. Significant correlations between bone level changes and PI or GI were not found (P > .05).* ***Discussion:*** *Over a 5-year evaluation period, the bone levels and clinical attachment levels were stable. These results were consistent with other studies of single-tooth implants.* ***Conclusions:*** *After 5 years of function, the results suggest that Biolok implants can be successfully used for single-tooth replacement.* INT J ORAL MAXILLOFAC IMPLANTS 2004;19:849–854

Key words: *alveolar bone loss, attachment levels, dental implants*

Osseointegrated implants have become a viable treatment option for completely and partially edentulous patients. Since Brånemark and associates began publishing their historic studies,[1] research has shown that good success and prognoses can be expected when implants are used within the defined treatment parameters. Subsequent studies have demonstrated the long-term success (ie, success 15 to 20 years after placement) of implants used to treat edentulous and partially edentulous patients with removable and fixed complete and partial dentures.[2–4] Clinical parameters determining the short- and long-term success of dental implants and the early loss of peri-implant bone remain the subject of intense study.[5–10] The interest in these areas stems from the need to minimize the occurrence of significant complications associated with implant failure.

Implants used for single-tooth replacement represent a more recent evolution of implant dentistry. Several studies have shown excellent results over a 1- to 3-year period[11–15]; more recent single-tooth replacement studies extending to 5 years or beyond report similar results.[16–20] Biolok implants (Biolok,

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Table 1 Patient Selection Criteria

Inclusion criteria
• 18 years of age or older
• Willingness to participate for the duration of the study
• Willingness to provide informed consent
• Edentulous in 1 or more: anterior mandible, posterior mandible, or maxilla
• Absence of soft tissue pathology
• Absence of oral dental pathology
• Good general health
• Sufficient available bone to fully accommodate the implant without impinging on vital structures
Exclusion criteria
• Uncontrollable metabolic disease
• Compromised immune system
• 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 at 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 The 3 types of Biolok implants used were *(left to right)* titanium cylinder, titanium screw, and HA-coated cylinder.

Deerfield, FL) have shown excellent clinical results after 5 years in function[21] but have yet to be evaluated for single-tooth replacement.

This article reports on the results of a 5-year prospective radiographic and clinical study of 39 Biolok implants used for single-tooth replacement.

MATERIALS AND METHODS

Thirty-nine patients of the Ohio State University Implant Clinic were randomly assigned to receive implants for single-tooth replacement. All participants signed an informed consent form prior to enrollment in the study. The study protocol and informed consent were previously approved by the Ohio State University Institutional Review Board. Inclusion and exclusion criteria[22] are shown in Table 1. The age, gender, and race of each patient were noted. In addition, patient health, implant location, and periodontal assessment of the surgical and surrounding areas were noted. The surgical data included the date of implant placement and date of implant uncovering.

Three types of Biolok implants, titanium cylinder-type, titanium screw-type, and hydroxyapatite (HA)–coated cylinder-type (Fig 1), were placed in different areas of both the maxilla and mandible to replace single teeth. The implants used featured a 1-mm polished collar and an external hex. Of the 39 implants placed, 22 replaced molars (20 mandibular, 2 maxillary), 15 replaced premolars (8 mandibular, 7 maxillary), and 2 replaced maxillary central incisors; 13 were HA-coated cylinders, 14 were titanium cylinders, and 12 were titanium screw-type implants. The implant diameters used were 3.3 mm, 3.75 mm, and 4.0 mm, while the implant lengths were 10 mm, 13 mm, and 15 mm (Fig 2). A strict surgical protocol was used to minimize heat-induced trauma to the surgical site. All implants were placed in a 2-stage procedure. A baseline radiograph was taken after implant placement. After a healing period of approximately 6 months in the maxilla and 4 months in the mandible, the implants were loaded. One to 2 adjacent natural teeth, visible in the same radiographic view as the implant, were randomly selected in each patient to serve as control sites. Examples of patient radiographs used in this study are shown in Fig 3.

Clinical Parameters

A thorough clinical examination was performed at baseline (placement of restoration) and at 1 year, 3 years, and 5 years postloading. Each implant was evaluated using Plaque Index (PI)[23] and Gingival Index (GI).[24] Clinical attachment levels were measured to the nearest 0.1 mm using a standard-pressure electronic probe (Florida Probe, Gainesville, FL). Measurements were made from a fixed reference point at the top of an occlusal probing template. The template was made of acrylic resin and provided reference points for the placement of the probe along the long axis of the implants.

Radiographic Analysis

Bone loss was measured from standardized radiographs by a single examiner (RT). All radiographs

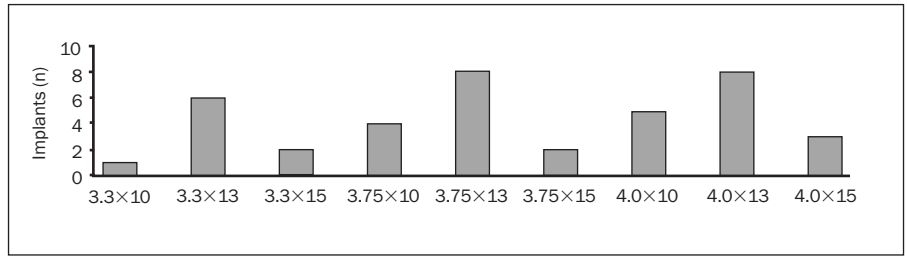

Fig 2 Number of implants placed by size.

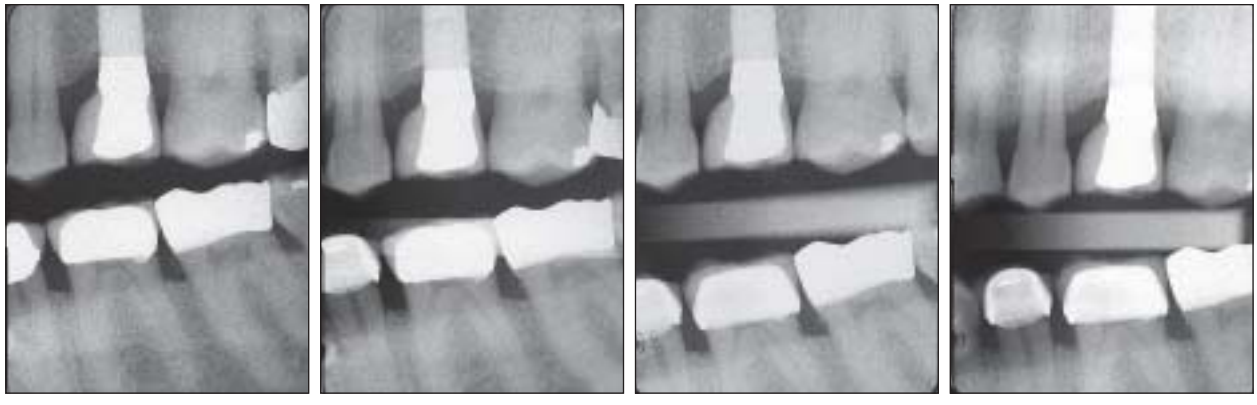

Fig 3 Radiographs from a representative case at *(left to right)* baseline, 1 year, 3 year, and 5 years.

were taken according to protocol at the baseline visit and at the 1-year, 3-year, and 5-year recall visits.[25] The standardized radiographs were scanned and analyzed using the Meazure 1.0 program (C Thing Software, Sunnyvale, CA). This program was used to calibrate each image so that measurements could be made. A known measurement of each implant was used as the standard for calibration. Comparative measurements of the mesial and distal crestal bone levels adjacent to the implants were made to the nearest 0.1 mm. Both implants and control teeth were measured. The change in the coronal extent of alveolar bone immediately surrounding the implant was calculated for the period between each visit.

Reliability

Intra-examiner reliability of crestal bone measurements was determined by repeating measurements on 10 control teeth and 10 implants. The intraclass correlation coefficients were calculated to be 0.60 (95% CI, 0.911 to 0.180) for teeth and 0.930 (95% CI, 0.982 to 0.758).

Statistical Analysis

Crestal bone heights and attachment levels were compared for the proximal aspects of all implants. This comparison was done using a repeated-measures factorial analysis of variance with implant type and time as the independent variables. Post hoc testing was done using the Tukey-Kramer procedure. With a nondirectional alpha risk of .05, the power to detect a difference of ± 0.025 mm of crestal bone height and ± 0.15 mm of clinical attachment loss was ≥ 0.96. Spearman correlation coefficients were used to assess the relationship of the clinical parameters (PI, GI) to attachment level changes and bone loss.

RESULTS

An overall survival rate of 97.4% was obtained for all sites. For the comparisons, the failed implant was excluded since the failure occurred between baseline and year 1. No significant differences were found between the 3 implant types (HA-coated cylinder, titanium cylinder, and titanium screw) for any of the clinical parameters studied ($F = 0.7$, $P = .504$, $df = 2$) (Figs 4 and 5). Therefore, all implants were grouped together for further analyses.

Attachment Levels

The mean clinical attachment level change over 5 years was a loss of 0.17 ± 0.23 mm (Table 2). The mean clinical attachment level changes were

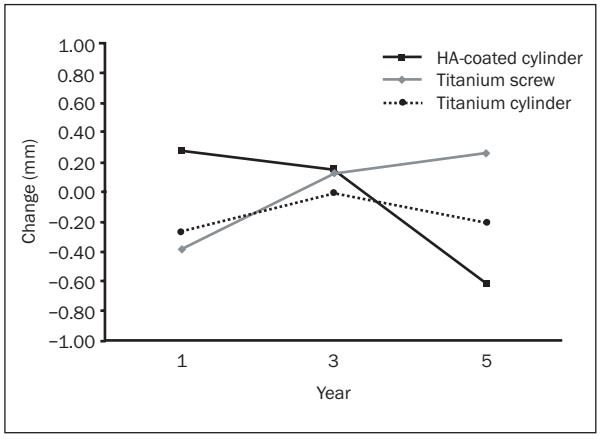

Fig 4 Mean attachment level change from baseline.

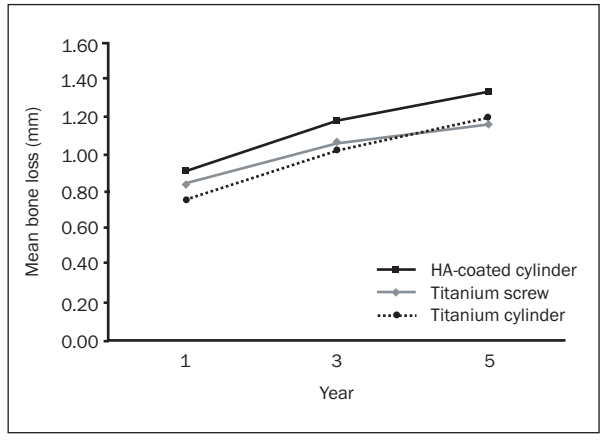

Fig 5 Mean bone loss from baseline.

Table 2 Clinical Attachment Level and Bone Level Changes from Baseline (in mm)

Variable	Year 1	Year 3	Year 5
Clinical attachment level	–0.12 ± 0.21	0.09 ± 0.22	–0.17 ± 0.23
Bone level	–0.83 ± 0.03	–1.09 ± 0.03	–1.23 ± 0.04

Values are the mean ± SD from 38 implants.

Table 3 Correlation Between Clinical Attachment Level, Radiographic Bone Level, and GI or PI

Parameter/year	Rho	*P*
Clinical attachment level vs GI		
1	–0.027	.869
3	0.203	.227
5	0.150	.406
Clinical attachment level vs PI		
1	0.028	.865
3	0.415	.011*
5	0.491	.004*
Bone level vs GI		
1	0.042	.683
3	0.122	.245
5	0.051	.652
Bone level vs PI		
1	–0.133	.193
3	–0.044	.679
5	–0.038	.738

*Value was considered significant ($P < .05$).

–0.12 ± 0.21 mm from baseline to 1 year, +0.21 ± 0.23 mm from 1 year to 3 years, and –0.26 ± 0.24 mm from 3 to 5 years.

Bone Levels

The mean bone level change over 5 years was a loss of 1.23 ± 0.04 mm (Table 3). The mean bone loss was 0.83 ± 0.03 mm from baseline to 1 year, 0.26 ± 0.03 mm from 1 year to 3 years, and 0.14 ± 0.04 mm from 3 to 5 years.

Correlations Between Clinical and Radiographic Parameters

At baseline, the mean GI was 0.23, and the mean PI was 0.04. These values increased to 0.33 and 0.5 for GI and PI, respectively, at 5 years. When the average absolute bone loss was compared to the average GI and average PI during recall visits, no statistically significant associations were found at any of the measurement sites around the implant.

When the average absolute change in attachment level was compared to the average PI score, a significant change in attachment level effect was found for site ($F = 6.17$, df = 3/102, $P < .001$) but not for year ($F = 0.46$, df = 2/60, $P = .631$) or year by site interaction ($F = 0.84$, df = 6/180, $P = .537$). Three of the probing sites showed statistically significant changes at 5 years (distolingual = 0.37 mm, mesiobuccal = –0.38 mm, and mesiolingual = –0.41 mm). Statistically significant correlations were found between attachment level changes and PI at 3 years and 5 years (Table 3). No correlation was found between attachment level changes and GI.

DISCUSSION

The implant survival rate, bone levels, and attachment levels assessed in this study were found to be clinically acceptable at all follow-up examinations (ie, 1, 3, and 5 years postloading). The implant survival rate and bone levels found were similar to those found in previous studies of either single-tooth implants[12,17,26] or implants supporting fixed partial dentures.[27,28] There was no correlation

between the bone loss surrounding the implants and the bone loss surrounding the control teeth during the first year (data not shown). This concurs with a study by Hultin and associates, who found no correlation between bone loss around implants and bone loss around natural teeth over a 5-year period.[29]

The greater bone loss observed during the first year of function is also consistent with previous studies of single-tooth implants.[12,17] This exaggerated bone loss during the first year, which levels off in subsequent years, is considered to be the result, in part, of the formation of biologic width around the implants.[10,30] Besides formation of biologic width, other factors, such as the microgap at the implant-abutment interface,[28,31] have been implicated in the crestal bone loss surrounding implants.[10] Randomized, well-controlled clinical trials are needed to clarify the causes of early peri-implant bone loss.[10]

Although the attachment levels fluctuated over the 5-year time period, the changes were not considered clinically significant, and it can be said that the attachment levels surrounding the implants were stable over the time period studied. Several investigators have had similar results.[9,32,33]

The differences in bone levels and attachment levels among the implant types were not significant. Again, this finding is consistent with those of other studies. Manz found bone loss around non–HA-coated implants to be greater initially; however, it then stabilized and did not differ significantly from bone loss around HA-coated implants after a 2-year period.[30] Morris and associates also found no clinically significant difference between the periodontal-type measurements for HA-coated and non–HA-coated implants followed for a period of 3 years. He stated that the concerns about HA-coated implants being associated with adverse periodontal responses appeared to be unfounded for a period of clinical performance up to 36 months.[34]

The present study did not find PI or GI to be correlated with peri-implant bone loss. The literature offers mixed results in this regard. Although some studies have shown positive correlation between clinical parameters of inflammation and peri-implant bone loss,[5,7] others have not.[6,9] A likely explanation for the results of the present study is the fact that PI and GI values exhibited limited variability. A moderate, positive correlation was found between attachment level change around the implants and PI (highest rho = 0.49) but not between attachment level change and GI. As with the lack of correlation between bone loss and GI or PI, the limited variability in PI and GI values may account for these results. Despite the fact that proper plaque control, elimination of peri-implant mucosal inflammation, and control of gingival and periodontal disease of natural teeth are considered essential for the long-term maintenance of dental implants,[35,36] a systematic review of the literature revealed a lack of reliable evidence for the most effective regimens for long-term maintenance.[36]

Measurement error associated with the radiographs may have had an effect on the bone loss results. The radiographic method was standardized; however, there are inherent limitations in comparing radiographs taken at different points in time. In addition, detecting the exact height of bone adjacent to the implant may be difficult at times. When changes between follow-up examinations are minimal, even a small measurement error could mask any true changes.

Dental implants used for single-tooth replacement are a predictable treatment modality. However, better methods are needed to detect early soft tissue and bony changes complimentary to the clinical and radiographic parameters currently used and to assess possible risks related to implant success. Animal studies may offer insights into possible markers and mechanisms of peri-implant tissue breakdown and promising treatment approaches to regenerate peri-implant bone defects.[37–39] Nevertheless, randomized clinical trials and controlled investigations on early signs of tissue destruction, treatment of peri-implant breakdown, and regeneration of tissues are needed to complement and advance existing knowledge.[10,35,36]

CONCLUSIONS

Over a 5-year evaluation period, bone levels and clinical attachment levels were stable for single-tooth Biolok implants in function in this patient population. Small, statistically significant differences at the individual site level were not considered clinically significant. PI and GI were not correlated with implant bone loss. A moderate correlation was found between PI and attachment level change but not between GI and attachment level change. These results suggest that Biolok implants can be used successfully for single-tooth replacement.

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