Survival Rate of One-Piece Dental Implants Placed with a Flapless or Flap Protocol—A Randomized, Controlled Study: 12-Month Results

Stuart J. Froum, DDS1/Sang Choon Cho, DDS2/Nicholas Elian, DDS3
George Romanos, DDS, Dr Med Dent, PhD4/Ziad Jalbout, DDS5
Mazen Natour, DMD, MScD6/Robert Norman, PhD7
Dinah Neri, MD, CCRC8/Dennis P. Tarnow, DDS9

Dental implant–supported restorations have been used to replace single and multiple missing teeth with documented high survival rates.1–4 Traditionally, implants were placed in a two-step surgical procedure.5 In an attempt to avoid two surgical procedures, a one-piece implant and abutment was introduced.6 By using an implant for which the bone-anchorage unit and contiguous transmucosal component are manufactured as one piece, abutment connection/disconnection is avoided. This has the advantage of avoiding a gap or micromovement at the implant-abutment junction for a beneficial effect on the peri-implant soft and hard tissues.7–10

In a clinical and histologic study of 51 one-piece implants placed in 38 patients, the survival rate for the implants after 1 year of function was 100%.11 In another study, a similar implant body design with an anodically oxidized (AO) surface was used with immediate provisionalization, resulting in a survival rate of 97.3% for up to 2 years of loading.

The introduction of flapless implant surgery provided an additional

1Clinical Professor, Department of Periodontology and Implant Dentistry, New York University, New York.
2Assistant Clinical Professor and Associate Director of Clinical Research, Ashman Department of Periodontology and Implant Dentistry, New York University College of Dentistry, New York.
3Assistant Professor, Head of Division, Director of Fellowship Program, and Director of Experimental Research, Department of Periodontology and Implant Dentistry, New York University, New York.
4Professor of Clinical Dentistry, Division of Periodontology, Eastman Institute for Oral Health, University of Rochester, New York.
5Assistant Clinical Professor, Department of Periodontology and Implant Dentistry, New York University College of Dentistry, New York.
6Assistant Professor, Department of Periodontology and Implant Dentistry, New York University, New York.
7Associate Research Professor, Department of Epidemiology and Health Promotion, and Director of Biostatistics, Bluestone Center for Clinical Research, New York University Colleges of Dentistry and Nursing, New York.
8Clinical Research Coordinator, New York University Bluestone Center for Clinical Research, New York University College of Dentistry, New York.
9Professor and Director of Implant Education, Columbia University College of Dental Medicine, New York.

Correspondence to: Dr Stuart J. Froum, 17 W 54th Street, Suite 1 C/D, New York, NY 10019; fax: 212-246-7599; email: dr.froum@verizon.net.
means to minimize the trauma of the two-stage implant placement protocol.12-14 The success of implant placement using the flapless procedure was documented in a 10-year clinical retrospective study of 770 implants placed in 359 patients in partially and completely edentulous arches. The success rate at the start of the study was 74.1% in 1990, but increased to 100% in 2000.15

In a retrospective 3-year clinical study, 97 Brånemark implants were inserted in 46 patients using flapless surgery, resulting in a cumulative survival rate of 91% after 3 years.16

The purpose of this study was to compare the survival of one-piece AO surface implants (NobelDirect, Nobel Biocare) when placed with either flapless or flap surgery. Bone loss, as measured on standardized radiographs, and changes in clinical probing depths were also compared between the two groups over a 1-year period, post–definitive restoration insertion, to determine if there were any differences in using the two protocols.

Method and materials

Sixty subjects with 60 edentulous sites satisfying the inclusion criteria and requiring one or more single-tooth implants were selected and consecutively enrolled from patients presenting for implant placement at New York University Ashman Department of Periodontology and Implant Dentistry, New York, New York. Each patient underwent a thorough medical and dental history and clinical examination to determine if they satisfied the inclusion and exclusion criteria prior to their being enrolled as a subject in the study. Each subject expressing an interest in participating in the research study was prescreened using pre-existing radiographs (panoramic, intraoral, and computed axial tomographic scans [ICAT, Imaging Services]). In cases where any of these were not available or current (within 1 year), radiographs were taken and evaluated. Using computer software (SimPlant, Materialize Dental NV), each potential implant site was measured and was required to have sufficient bone width and height to accommodate a minimum 4.3-mm-diameter and 10-mm-long implant. Healthy subjects with at least one single edentulous site that was planned for an implant restoration who met these criteria were enrolled consecutively.

Prior to surgery, the 60 sites were divided into two groups based on protocol (group I, flapless; group II, flap [control]) via a computer-generated randomized schedule, determined prior to the study. All patients received a single dose of antibiotics (amoxicillin 2,000 mg or clindamycin 600 mg) 1 hour prior to surgery and continued on the same antibiotic (amoxicillin 500 mg three times per day, Teva Pharmaceuticals; clindamycin 150 mg four times per day, Ranbaxy Pharmaceuticals) for 1 week postsurgery.

Standardized periapical radiographs were taken using a Rinn holder (Dentsply) at implant insertion, following placement of the definitive restoration, and 6 and 12 months after crown placement. Probing was performed at four sites (mesiobuccal, buccal, distobuccal, and midpalatal) using a Williams probe (Hu-Friedy) to evaluate soft tissue attachment at the 6- and 12-month postloading visits. A uniform reference point (crown margin) was used for all probing sites. Individual calibration of the examiners was done prior to performing the above procedures. The examiners performing these procedures were different from those performing the surgery and did not know which implants were placed with the flap or flapless protocols.

Presurgical planning for both the test (flapless) and control (flap) groups followed guidelines described in the implant manufacturer’s procedure manual (Nobel Biocare Procedure Manual 31587 lot GB 0402, Nobel Biocare).

All surgeries were performed by postgraduate students from the Ashman Department of Periodontology and Implant Dentistry at New York University Dental Center under the guidance of one of four faculty members of the department. All surgeries were performed under local anesthesia (lidocaine 2% [Henry Schein] or carbocaine 3% [Novocol Pharmaceutical]) utilizing a surgical guide fabricated on study casts from an ideal wax-up. The surgical procedures are summarized as follows.

In all cases, the implant was placed in such a position so as to have the abutment (machined head)
and 1.5 to 2.0 mm of the rough surface extend coronal to the alveolar crest (Figs 1a to 1c and 2a). Immediately following implant placement, a standardized periapical radiograph was taken. Patients were instructed not to clean the implant or wear any removable appliance that would touch the implant. Patients returned 7 to 14 days after surgery to examine the surgical area and remove, where necessary, the sutures in the flap group. After a healing period of 8 to 12 weeks, subjects returned for implant temporization. A fixture/abutment-level impression was taken. Following the impression, a provisional single-crown restoration was fabricated using acrylic methyl methacrylate self-cure composite resin and inserted (non-occlusal loading).

The definitive restoration was prepared (porcelain-fused-to-metal crown with a semiprecious alloy) and cemented approximately 2 to 6 weeks after the final impression. Following cementation of the restoration, a standardized radiograph was taken. Pocket depths were measured using a Williams periodontal probe at the four sites described previously.
Subjects returned 6 to 7 months postloading and 12 to 13 months following insertion of the definitive restoration (Fig 2b). At both visits and in both groups, radiographs and soft tissue probing were performed. Two calibrated examiners taking the radiographs and performing the probing were not associated with performing the surgery or restoring the implant and had no knowledge of which protocol (flap or flapless) was used to place the implant.

Periapical radiographs taken at four time points were analyzed: time of implant placement, final restoration, 6-month follow-up, and 12-month follow-up. An independent examiner unaware of the treatment protocol used performed the radiographic evaluation.

For radiographic assessment, a two-stage process was completed with each patient film series (four films): (1) digitization of the films, drawing of the measurement reference lines, and adjustment of the images for optimum contrast and density, and (2) calibration of the magnification/distortion in each image to match true millimeter values and measurement of the mesial and distal bone levels in respect to the implant reference line. Missing and unreadable radiographs were taken into account in the statistical analysis as reduced sample sizes.

Each digitized radiographic image was corrected for the magnification in the image to match the true dimensions in the alveolar bone. This was done by using the known implant thread distances as a reference (NobelDirect: regular-platform thread, 0.71 mm, wide-platform thread, 0.76 mm).

Survival criteria

Implant survival criteria used in this investigation followed that published by Albrektsson and Zarb, which stipulated that implants had to be functional and stable (the stability of individual implants was tested using a torque wrench), without peri-implant radiolucency on radiographs, no suppuration or pain at the implant site, no signs of peri-implantitis, and no neuropathies or persistent paresthesia.

Statistical analysis

Characteristics of the implant (length and diameter) were summarized, and differences between treatment groups were analyzed using the Pearson chi-square test after assessment of test assumptions. The frequency of implant site
by tooth number was tabulated. Differences between groups in bone loss measures at 6 and 12 months were assessed by analysis of covariance using the final restoration measure as the covariate. The same method was used to assess probing depths. Implant survival was described in an abbreviated life table. For all tests, statistical significance was assessed at a $P$ value of .05.

**Results**

Sixty implants were enrolled in the study. Fifty-two implants completed the study at the end of 1 year post-crown insertion. Eight implants were withdrawn (1 prior to definitive restoration, 1 prior to the 6-month follow-up, 4 following the 6-month follow-up, and 2 withdrawn due to patient pregnancy. A total of 5 patients who were not pregnant (1 flap, 4 flapless) were lost to follow-up. There were no implant failures. Therefore, at 1 year post-insertion of the definitive restoration, the cumulative survival rate was 100%. Figure 3 describes the enrollment, final number of patients in the study, and time of withdrawal. There were a total of 35 females (18 in the flapless group, 17 in the flap group) and 25 males (12 in the flapless group, 13 in the
flap group). These slight differences were not statistically significant (chi-square = 0.07; \( P = .79 \)).

Twenty-two subjects in the flapless group received a 4.3-mm-diameter implant and 8 received a 5-mm-diameter implant. In the flap group, 25 subjects received a 4.3-mm-diameter implant and 5 received a 5-mm-diameter implant. There were no significant differences in the distribution of lengths (\( P = .35 \)) or diameters (\( P = .53 \) for 4.3 mm, \( P = .24 \) for 5 mm). The implant site distribution for the 60 flapless and flap sites showed the mandibular left first molar to be the most frequent for both the flapless (\( n = 8 \)) and flap (\( n = 9 \)) procedures.

Implant survival in the 52 patients that completed the study was 100%. No implant was lost in either the flapless or flap group (Table 1).

### Table 1 Implant survival in both procedures

<table>
<thead>
<tr>
<th></th>
<th>Placed/followed (n)</th>
<th>Failed (n)</th>
<th>Withdrawn (n)</th>
<th>Cumulative survival rate (%)</th>
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</thead>
<tbody>
<tr>
<td>Prior to implant insertion to 3 mo</td>
<td>59</td>
<td>0</td>
<td>1</td>
<td>100</td>
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<tr>
<td>3 to 6 mo</td>
<td>58</td>
<td>0</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>6 to 12 mo</td>
<td>52</td>
<td>0</td>
<td>6</td>
<td>100</td>
</tr>
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</table>

**Bone loss/gain**

At the time of placement of the definitive restoration, there was a statistically significant difference between the mean mesial bone gain of 0.03 ± 0.96 mm in the flapless group and 0.92 ± 1.01 mm in the surgical flap group (\( t = 3.43, \ P < .001 \)). For the distal bone measurement, the same pattern was found (flapless, 0.04 ± 1.05 mm; flap, 0.46 ± 1.04 mm). However, these differences in the flap versus flapless groups were not statistically significant (\( t = 1.50, \ P = .39 \)). This finding was similar to that present at the time of implant placement. For the mesial bone measurement, there was a statistically significant difference between the flapless group (0.94 ± 1.07 mm) and the flap group (1.73 ± 0.94 mm; \( t = 2.97, \ P = .004 \)). The distal bone measure showed a trend toward a difference, but did not reach statistical significance between the flapless (0.77 ± 0.98 mm) and flap groups (1.30 ± 1.06 mm; \( t = 1.93, \ P = .059 \)). Because of these differences, it was decided not to average the measurements, but rather to analyze them separately. There were no significant changes in the bone measures between definitive restoration and 12 months in either the flap or flapless group for the mesial (flapless, –0.18 mm, \( P = .188 \); flap, 0.008 mm, \( P > .999 \))
Table 2  Mean bone levels (mm)

<table>
<thead>
<tr>
<th></th>
<th>Flapless</th>
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<th>Flap</th>
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<tr>
<td></td>
<td>Mesial (mean ± SD)</td>
<td>Distal (mean ± SD)</td>
<td>Mesial (mean ± SD)</td>
<td>Distal (mean ± SD)</td>
</tr>
<tr>
<td>Implant placement</td>
<td>0.94 ± 1.07</td>
<td>0.77 ± 0.98</td>
<td>1.73 ± 0.94</td>
<td>1.30 ± 1.06</td>
</tr>
<tr>
<td>Definitive restoration</td>
<td>0.03 ± 0.96</td>
<td>0.04 ± 1.05</td>
<td>0.92 ± 1.00</td>
<td>0.46 ± 1.04</td>
</tr>
<tr>
<td>6 mo</td>
<td>0.17 ± 0.99</td>
<td>0.08 ± 1.05</td>
<td>0.90 ± 0.96</td>
<td>0.62 ± 1.03</td>
</tr>
<tr>
<td>12 mo</td>
<td>0.27 ± 1.00</td>
<td>0.24 ± 1.03</td>
<td>0.87 ± 0.99</td>
<td>0.60 ± 1.06</td>
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</table>

SD = standard deviation.

Fig 4  Implant bone levels following flap implant placement. (a) Implant insertion; (b) definitive restoration delivery; (c) 6 months postinsertion; and (d) 12 months postinsertion.

Fig 5  Implant bone levels following flapless implant placement. (a) Implant insertion; (b) definitive restoration delivery; (c) 6 months postinsertion; and (d) 12 months postinsertion.

and distal (flapless, -0.18 mm, \( P = .134 \); flap, -0.15 mm, \( P = .8 \)) measurements, respectively. The mean bone levels at implant placement, definitive restoration, and the 6- and 12-month follow-up visits are shown in Table 2. When adjusted for differences existing at definitive restoration using analysis of covariance, there were no statistically significant differences in bone levels between the flap or flapless group for either the 6-month mesial (\( P = .79 \)), 6-month distal (\( P = .33 \)), 12-month mesial (\( P = .59 \)), or 12-month distal (\( P = .96 \)) measurements (Figs 4 and 5). The calculated precision of the radiographic measurement method used in the study was 0.21 mm.
Pocket depth

No statistically significant differences were found between groups at baseline for any of the four probing depth measurements; therefore, mean probing depths were analyzed using analysis of covariance (Table 3). After adjusting for differences present at definitive restoration, there were no significant differences in either pocket depths at 6 (P = .48) or 12 months (P = .82) between the two groups.

Discussion

The results of the present investigation on one-piece AO surface implants show similar high cumulative survival rates (CSRs) as previously published studies with 1- and 2-year follow-ups.18,19 Finne et al18 reported a CSR of 97.9% using an immediate provisional restoration on AO surface one-piece implants 1 year following loading. In a 2-year follow-up report, the same group of authors reported a 98.8% CSR for implants placed and immediately provisionalized either not in occlusion or in light contact.19 In both studies, flap and flapless placement was performed. However, neither study made reference to any differences between the two placement protocols.

In a retrospective study of 92 AO surface implants in 58 patients in a private practice after a mean follow-up period of 17 months (range, 12 to 24 months postplacement), there were no reported failures.20 In another multicenter retrospective study,21 data on 1,009 AO surface implants placed in 554 patients revealed a clinical survival rate of 98.2% in patients followed from 6 months to 6 years. Similar high survival rates were reported by Hahn22 with the one-piece AO surface implant placed in immediate function. The current study, while reporting no loss of any implant, also specifically looked at differences in survival rates between flap and flapless insertion protocols and found no failures in either group. Moreover, the study also looked at changes in marginal bone levels around these implants placed with the two different protocols. The study examined radiographic bone levels at the time of insertion of the definitive restoration and compared

<table>
<thead>
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<th>Table 3</th>
<th>Mean probing depths (mm)</th>
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<tr>
<td></td>
<td>Flapless (mean ± SD)</td>
</tr>
<tr>
<td>Definitive restoration</td>
<td>2.26 ± 0.72</td>
</tr>
<tr>
<td>6 mo</td>
<td>2.27 ± 0.80</td>
</tr>
<tr>
<td>12 mo</td>
<td>2.20 ± 0.75</td>
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</table>

SD = standard deviation.
them to those present at the 6- and 12-month follow-up. No significant changes were found in mesial or distal bone levels in either the flap or flapless group at either time period. In a previous study, bone levels were 0.33 mm superior to the reference point at implant placement, –0.77 mm at 6 months, and –0.98 mm at 12 months. A second paper reported a mean 0.08-mm bone level change between 1 and 2 years. Based on the results of bone and soft tissue level measurements, a number of authors concluded that the one-piece AO surface implant demonstrated the ability to preserve both hard and soft tissue.

However, these conclusions are in contrast to those reported in a short-term retrospective clinical study conducted at four different centers looking at survival and marginal bone conditions around one-piece AO surface implants. The implants were either immediate/early loaded (within 2 weeks) with a provisional restoration (95 implants) or healed unloaded for 6 weeks to 6 months (22 implants). Marginal bone loss was evaluated after a mean of 10.2 months (range, 1 to 18 months) postloading. The authors reported a total failure rate of 6.3% for the immediate/early loading group and 0% for the group with unloaded healing. A higher failure rate was reported for flapless (7.9%) than flap surgery (0%). They also reported a marginal bone loss of –2.4 mm for all implants, with more bone loss in the immediate/early loading group (–2.6 mm) than the two-stage group (–1.6 mm).

An earlier 1-year prospective clinical and radiographic study by the same team reported a 5.2% failure rate with one-piece implants compared to a 1.3% failure rate with two-piece implants. They also reported that after 1 year, the mean marginal bone loss was 2.1 mm for the one-piece and 0.8 mm for the two-piece implants. The conflicting data published in the previously cited papers should be considered in light of the methods and findings of the present study. Unlike the immediate/early loading protocol used in the studies citing poor clinical outcomes, none of the implants in the current investigation were provisionalized or immediately (occlusally) loaded.

Moreover, the position of the implant body, particularly the rough surface relative to the bone, has been shown to affect bone remodeling. The current study placed all implants with 1.5 to 2.0 mm of the rough surface coronal to the marginal bone. When using a flapless protocol, a punch of 4 to 5 mm was used, and the punch hole was widened with a scalpel to allow visual access for the level of implant placement relative to the marginal bone. The additional parameter of soft tissue probing depth confirmed the radiographic measurements in evaluating the stability of hard and soft tissue at follow-up visits 6 and 12 months after insertion of the definitive restoration. The lack of any serious adverse events and the five mild adverse events related to the device, all of which resolved, are similar to the findings in a previous study.
Conclusions

The results of this study showed a 100% implant survival rate 1 year post–implant restoration with AO surface one-piece implants. There was no difference in survival rates of these implants whether a flapless or flap insertion protocol was performed. Moreover, there were no significant changes in bone levels on the mesial or distal aspects of the implants from time of definitive restoration to the 12-month follow-up in both the flap and flapless groups. The same was true with probing depths at 6 and 12 months. There was no statistically significant difference in either change in pocket depth or mean pocket depth over time between the two groups. Thus, in this randomized controlled clinical study, it appears that the one-piece AO surface implants, 1 year post–restoration insertion, show high survival rates and stable marginal bone and probing depth levels regardless of whether a flapless or flap protocol was used for implant insertion. These findings are consistent with previously published studies using one-piece implants with identical AO surfaces. Longer follow-up times with more subjects are needed to determine if long-term outcomes follow the patterns seen in the present study.

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References


