The Longitudinal Clinical Efficacy of Osseointegrated Dental Implants: A 3-Year Report


The impressive Swedish reports suggesting predictable and frequent longitudinal success with osseointegration in edentulous patients demanded a replication study to underscore the merit of universal application. This is a report from the Toronto prospective study where traditional clinical criteria were used to assess the long-term efficacy of the Brånemark technique. While the duration of the study is relatively short (maximum 3 years) it appears to support the Swedish researchers' results. Furthermore, alternate prosthetic methodologies are described, and the argument is advanced that the surrogate gingival and periodontal indices used may not be suitable for assessing the clinical evidence of osseointegration.

Progressive and irreversible residual ridge reduction appears to be an inevitable sequel to the long-term use of complete dentures.¹

Preprosthetic surgical methods such as alveolar ridge augmentation and vestibuloplasty procedures can increase the denture-bearing area. The obtained results are unpredictable, however and often fall short of the prosthodontist's, the surgeon's, and the patient's expectations.²

The concept of dental implants has long been an exciting one for the prosthodontist. Regrettably, most dental implants used in humans have been prescribed after only rudimentary scientific investigation of their long-term efficacy. Their clinical evaluation has been largely retrospective, with conflicting views as to which criteria constitute a "successful" implant.³

The only longitudinally documented study that meets recently proposed criteria for success⁴ is the work of the University of Gothenburg research team led by Brånemark.⁵ He introduced the term "osseointegration" to denote a predictably favorable host bone response to the implantation of unalloyed titanium tooth root analogues, or implants.

A previous preliminary report on the implants suggested optimism for the technique.⁶ The purpose of this article is to present the 3-year longitudinal results of an independent team's clinical use of osseointegrated implants.

Materials and methods
Twenty-six patients (5 men and 21 women) were involved in the present study. This group represents approximately just over half of our total patient sample which has now been monitored for up to 8 years. The patients had implant-supported bridges in function for 1 to 3 years. All patients had been edentulous for at least 5 years. Ages ranged from 20 to 69 years of age, with a mean age of 52 years. Most patients had experienced considerable difficulties with their mandibular dentures and presented with advanced residual ridge reduction accompanied by one or more of the following: poor oral motor coordination, low tissue tolerance, long-standing parafunctional habits, and hyperactive gag reflex.

After routine medical, dental, and radiographic assessment, all patients were evaluated by a prosthodontist and an oral surgeon (Drs. G.A. Zarb and J. M. Symington) to determine (1) whether the "osseointegration" procedure was the optimal form of treatment for the patient, and (2) whether the procedure was feasible for the patient. Each patient was counseled on the nature of the treatment. Exclusion criteria included a history of drug abuse and unrealistic expectations regarding cosmetic improvement of previous prosthetic results.

Surgery was carried out using the two-stage technique; described by Brånemark. Gentle surgical methods were used to place four to six threaded unalloyed titanium cylinders, in the body of the mandible, between mental foramina. The reflected mucoperiosteal flap was readapted to completely cover the implants, and the area allowed to heal undisturbed for 4 to 6 months (Fig. 1). During this healing period approximately half of the patient sample wore their dentures, while the other half did not. The denture wearers had the fitting surface of their dentures generously relieved. Also, a tissue conditioner was used. The tissue conditioners were changed regularly to ensure their ongoing resiliency. At the end of the healing period, a second surgical procedure was performed to connect the titanium implant with an abutment component that extended through the mucoperiostium. A periodontal surgical dressing was placed around the abutments and kept in position for approximately 2 weeks. After 2 weeks, the dressing was removed, the patient was instructed in oral hygiene procedures, and prosthodontic treatment was started.

The prosthodontic techniques used in this study differed from those reported by Brånemark et al. in two ways: (1) a different laboratory protocol was used (Figs. 2 to 4), and (2) a silver palladium, type III alloy (Albacast, J.F. Jelenko Co.) was cast directly to the gold alloy cylinders that were screwed onto the titanium abutments. A fixed prosthesis, that could be electively unscrewed from its abutments was fabricated. This technique has been shown to produce a strong, uniform, junction between coping and framework. Some early problems with fracture in the cantilevered portion of the bridge necessitated a change in our original choice of alloy, and a type IV alloy (PalliaM, DeGussa Co.) was substituted. This alloy was chosen because of its desirable elastic modulus, hardness, tensile strength, and yield strength values.
Stock acrylic resin teeth were used, and were processed to the alloy framework with a commercial acrylic resin (Myers on Duraflow, Myerson Co.). With the exception of two patients, all patients had a complete denture opposing the implant-supported bridge. A balanced occlusion with a neutral incisal guidance was designed for each patient.

Within 1 to 3 months after bridge insertion, the first stage of long-term evaluation of both prosthesis and gingival response around the implant was carried out. Evaluations were repeated yearly. With the bridge removed, the following indexes were applied.

1. **Attached gingiva index.** Each surface of the implant was assessed to determine the extent of keratinized mucosa present around the implant. The amount of keratinized mucosa was quantified as described in Table 1.

2. **Plaque index.** The Loe\textsuperscript{7} index was used to assess the amount of plaque retained on each surface of the implant. Plaque retention was quantified as outlined in Table 2.

3. **Pocket depth.** Pocket depth was evaluated with the aid of a Michigan "O" probe. Each surface of the implant was measured using light probing force (20 g). Probing force levels were evaluated by repeated double-blind measures on a balance. Pocket depths were recorded to the nearest 0.5 mm.

4. **Gingival inflammation.** Gingival inflammation was evaluated using the Loe index\textsuperscript{9} (Table 3). Gingival inflammation was assessed approximately 10 seconds after the probing measurement was carried out. Scores were recorded for each surface as done for the previous indexes.

5. **Mobility.** Implant mobility was assessed by placing the implant abutment between the metal handles of two mirrors and exerting a heavy rocking force to the abutment. If no clinically detectable mobility was detected, the implant was assigned a score of 1.

Periapical radiographs of each implant were taken at the time of abutment connection, and then at yearly intervals. Radiographs were taken using a Ritter long cone 70 kV x-ray unit set at 10 mA with an exposure time of 0.5 seconds. A specially modified film holder was used to hold size O Kodak Ultraspeed x-ray film. The holder was positioned so that the plane of the film was parallel to the long axis of the implant. In severely resorbed mandibles with a shallow lingual vestibule, it was not always possible to radiograph the entire length of the implant in a strictly parallel manner. In these situations, only the upper portion of the implant was radiographed. The degree of parallelism achieved was assessed by examination of the radiograph under an Olympus binocular microscope at 20×. If the x-ray beam was off by 20 degrees or more, the implant threads could not be clearly visualized and such radiographs were not used in bone height measurements.\textsuperscript{10} Bone height
measurements were assessed as outlined on Fig. 5. All radiographs were assessed for the presence of peri-implant radiolucency (Figs. 6 and 7).

Since the distance between implant threads is known, the integral millimeter scale in the microscope was used to check each radiograph for enlargement distortion. Once calibrated, the millimeter scale was used to measure marginal bone height on the mesial and distal surfaces of the implant. Data were entered into a relational data base using the UNIX operating system. Statistical analysis was carried out using the Statistical Analysis System (SAS). For each index, a three-factor analysis of variance (ANOVA) with repeated measures on two factors was applied. The three factors were implant number (or site), implant surface, and year. The two repeated measures were the implant surface and the year.

**Results**

Implant data are summarized in Tables 4a and 4b for the 26 patients evaluated in this portion of the study. Two patients had additional implants placed at a second surgical visit. Otherwise, all other patients had only one implant placement operation. Eighteen of the original 151 implants placed were not "osseointegrated." They exhibited mobility and/or peri-implant radiolucency at the time of abutment connection or stage II surgery and were removed.

Another, and probably an even more important measure of success is the number of prostheses that remained in continuous function. Ninety-six percent of the patients (n = 25) in this study experienced continuous fixed bridge function (Table 4b). One patient lost two implants so that the three remaining implants were located all on the one side. An overdenture retained by a cast bar attached to the three implants was constructed for this patient. She declined an offer for further surgery to place additional implants in order to enable her to wear a fixed prosthesis because of her complete satisfaction with her osseointegrated overdenture support.

Seven implants were not used as abutments although they were osseointegrated at the time of the prosthesis fabrication; that is, they did not exhibit mobility or peri-implant radiolucency. Abutments were not connected to these implants (termed sleepers) because they were located in prosthetically inconvenient positions. These implants were sealed, and covered with a mucosal flap. An inconvenient position referred to one which was either too close to an adjacent implant for proper oral hygiene maintenance, or was too far buccally or lingually inclined. We are not including the sleepers in our success calculations. Consequently, results show that 126 of the utilized 144 implants were successful. This works out to be a success rate of 87.5% for the individual implants.

Twelve of the original 26 alloy frameworks constructed developed fractures in the cantilevered portion of the prosthesis within the first few months of function. As a result of laboratory tests using diverse designs new frameworks were designed with an increased cross-sectional area of metal at the junction with the cantilevered
regions. Furthermore the silver-palladium alloy was changed to one with a higher yield and tensile strength (Palliag M). No subsequent framework fractures with any of the treated patients have been encountered.

Two gold alloy screws (used to fasten the bridge to the abutment) fractured during the clinical observation period. When these screws were replaced, a "springiness" in the fit of the framework was detected. We felt that these screws fatigued as a result of a framework that was not completely passive and remade the prosthesis.

The recorded observation period for the index scores for the patients spans a two-year period in this report. The reported readings were made at the end of both the second and third years of observation (Figs. 8 to 11). Subsequent measurement, made by two observers at the end of the first year had been recorded by only one of the observers (G.A.Z.), and were therefore regarded as not fully standardized. Nonetheless, the first recorded average pocket depths were in the 4 to 5 mm region, which is not significantly different from the average values reflected in Table 5. We suspect that one of the effects of a standardized index recording, e.g., pocket depth measurement, was a gentler and more even probing effort. Four of our readings were inadequate and were therefore discarded.

The gingival index scores are summarized in Table 5. Figure 8 graphically depicts changes in index score over a two-year period. Significant ANOVA differences were not present for any of the combinations assessed. It is interesting to note that at least 50% of all the titanium implant surfaces of the implants have unkeratinized mucosa present, and approximately 80% of the surfaces of the implants have unkeratinized mucosa present on the vestibular surfaces.

Figure 9 depicts plaque scores over a two-year observation period. Significant ANOVA differences (P < 0.05) were noted for plaque index scores by site, by patient, and by year. These results reflect the individual variation in oral hygiene effectiveness from patient to patient, and from time to time.

Gingival index scores over the observation period are seen in Fig. 10. Significant differences were noted for site (P < 0.05), patient ID (P < .008), year (P < 0.005), the site by year (P < 0.02), and patient ID by year (P < 0.001).

Figure 11 presents a histogram of pocket depths over the observation period. The mean pocket depth for year 1 to 2 was 3.6 mm and 3.9 mm for year 2 to 3. The range in pocket depth varied from 0 to 10 mm. ANOVA results show significant differences for implant site (P < 0.0001), patient ID (P < 0.0001), and year (P < 0.02).

Radiographic bone loss data for mesial and distal implant surfaces over the observation period are recorded in Table 6. Bone loss in the first year after implant placement averaged 1.6 mm. Bone loss in subsequent years averaged 0.13 mm.
Paired $t$-tests were used to assess (1) whether significant differences in bone loss occurred between year 2 and year 3 of the observation period and (2) whether significant differences in bone loss occurred between mesial and distal surfaces. No significant differences ($P < 0.05$) were noted.

**Discussion**

Our limited observation period underscores the interim nature of this report. Although several implant reports of the anecdotal variety claim good short-term results,\textsuperscript{11-13} it is clear that longitudinal scientific scrutiny should be the yardstick used.\textsuperscript{4} Since our reported results are similar to Brånemark's early ones,\textsuperscript{5} and to Adell's study,\textsuperscript{14} which parallels ours, it is tempting for us to predict that our patients will enjoy longitudinal success similar to that reported by our Swedish colleagues.

The observed success rate of 87.5% for individual implants is eminently acceptable,\textsuperscript{4} particularly when seen in the context of two very compelling considerations. First, in spite of the impressive scientific documentation underscoring the efficacy of the Brånemark method,\textsuperscript{14} a specific formula that reconciles size or extent of prostheses with osseointegrated surface area is not available. The clinical tendency is, therefore, to play safe and prescribe more implants than necessary, even if local bone conditions may not be ideal ones. Therefore, the actual number of osseointegrated fixtures should probably be considered more in terms of the number needed to ensure fixed bridge long-term support (96% in this case) rather than an absolute percentile success score of the individual fixtures (87.5% in this study). Ongoing research is bound to define more accurately the relationship between anticipated stress loading of prescribed prostheses, and the requisite area of osseointegrated support. Second, this report includes an initial patient technique learning/skill acquisition group. The recorded individual implant failures—albeit 12.5%, and inconsequential in terms of the ultimate prosthetic success—should be regarded as a reflection of our earlier fluctuating skills, rather than as an indication of some shortcoming in the osseointegration method per se.

The "osseointegration" methods used and described in this study, are identical to Brånemarks as far as the surgical application is concerned, and require scrupulous attention to detail. Surgical placement of the implant so that the host bone site for the implant is prepared gently and not overinstrumented, must be done with care. Otherwise, the early immobilization that appears to be so important\textsuperscript{15} in the development of a bone to implant interface, will not occur. Similarly, both the prosthodontist and the oral surgeon must carefully decide upon the best location for the implants. Thus, the patient is ensured that the optimal number of implants can be placed, optimal access for oral hygiene maintenance provided, and the esthetic result of the prosthesis is not compromised. A number of the problems in this initial treatment group study related to fixture location which ultimately led to less than optimal prosthetic abutment location. Hence, the decision to not use these potential
abutments and convert them to sleepers.

Fixture location can also influence the gingival response. If the fixture is placed too far labially, lip and/or muscle pull can prevent proper adaptation of gingival tissues, and lead to chronic irritation. Fixtures that are too short can also act as a local gingival irritant in the same manner as a subgingival crown margin.

Prosthodontic treatment must also be provided with considerable care and skill. In the absence of a periodontal ligament, no adjustment or movement of the implant to compensate for slight prosthetic inaccuracies is permitted. Improper or nonpassive fit can lead to implant components that are under tension. Subsequently, their fracture or microfracture of the bone surrounding the implant and loss of osseointegration can result.

The prosthesis used in this study represents a new design. As with any new design, modifications are introduced as new techniques are implemented. A change of the selected silver-palladium alloy from type III to type IV, eliminated early problems of fracture of the cantilevered portion of the bridge. The techniques used in the construction of these prostheses have been previously described. The new design has proved to be accurate, esthetic, and highly cost efficient.

In spite of the relatively crude resolution level of this technique, radiographs are important measures of implant success (Figs. 12a to 13). Implants that demonstrate clinical mobility almost invariably demonstrate a radiolucent area around the implant. These implants are considered failures and are removed. Radiographs are also used to measure yearly bone loss around the implant. While our figures compare favorably with those of Brånemark and Adell, currently improved methods to monitor the very small (0.1 mm) yearly bone losses that occur are being developed.

The methods of measuring the peri-implant response are not that definitive at this stage. In this study conventional periodontal indexes were used, but they were not always easy to extrapolate to the implant situation.

The results of the attached gingiva index support the concept that attached mucosa, perhaps even more significantly than around natural teeth, does not appear to be necessary for the maintenance of peri-implant health. In this context it is interesting to note the high percentage of implant surfaces surrounded by unkeratinized/unattached mucosa. The attached gingival index provided a reasonable assessment of the type of soft tissues perforated by the implant. The location of keratinized and unkeratinized mucosa, relative to the implant, did not change significantly from year to year.

The plaque scores from this study are comparable to those reported for natural teeth. Excessive plaque build-up can lead to gingival irritation and inflammation in the same manner as it could in the natural dentition. Hygiene maintenance is more
difficult, since the patient must clean the implants with the prosthesis in position. Consequently, careful attention to the prosthesis design is necessary so as to facilitate optimal hygiene maintenance.

The gingival index results are also comparable to those for natural teeth. However, this index is difficult to apply in a reproducible fashion in the natural dentition and it is even more difficult to apply in the implant situation. The results of this index appear to be unreliable for implant evaluation.

Pocket depth readings are generally higher for the implants assessed in this study than for the natural dentition. It should be emphasized that a large number of implants traversed unattached mucosa. Our pocket depth results are comparable to those reported by Adell.\textsuperscript{14} In this study it was difficult to determine whether or not a more severe gingival response occurs around implants with deep pockets. Yearly bone loss data demonstrate a large range, and emphasize the necessity of following implants with deep pockets to determine whether or not bone loss figures will increase with time.

Recent reports\textsuperscript{19} have shown relatively healthy microflora, even in deep pockets around osseointegrated implants. This tends to underscore the many unanswered questions related to the peri-implant pocket region. As a result of these observations, it is tempting to conclude that conventional periodontal indexes do not accurately describe the peri-implant gingival response.

Our preliminary observations suggest that conventional clinical wisdom can be readily applied to the design and maintenance of optimal prosthodontic therapy for patients who undergo this technique of osseointegration. The use of standard clinical criteria of success can be selectively borrowed, or moved laterally, to longitudinally monitor the efficacy of osseointegration. However the entire milieu of transepithelial titanium abutments is clearly quite different from the one around the natural tooth. In this regard, at least three considerations are involved; (1) plaque quality and quantity, (2) epithelial response, and (3) stress transmission via a bony interface with titanium. While all of these areas are currently under investigation, in the interim we are inclined to suggest that the only clinical criteria that will ultimately prove significant in longitudinal analysis are implant mobility and the radiographic appearance of the implants' surrounding bone.\textsuperscript{4} Although inseparable as far as a long-term relationship is concerned, both criteria can be assessed separately. The significance of the gingival response may well be of an academic nature, although it cannot be ignored.

Conclusions

The observations from this replication study suggest the following preliminary conclusions:

1. Osseointegrated dental implants can be used with predictable success at least in the short term. A documented success rate of 87.5\% for individual implants and
96% for implant-supported bridges appears to be a compelling endorsement of osseointegration. This reinforces the claim of Brånemark et al.\textsuperscript{5} and Adell.\textsuperscript{14}

2. Alternative prosthodontic techniques to those proposed by Brånemark are feasible and probably desirable. The proposed prosthodontic approach is simple, versatile, and relatively inexpensive.\textsuperscript{6,8}

3. There appears to be growing evidence that conventional soft tissue health indexes are not necessarily reliable yardsticks to monitor implant efficacy.

Acknowledgments

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Table 1. Attached gingiva index

0 = No keratinized epithelium
1 = 1 mm or less keratinized epithelium
2 = 2 mm or < 2/≤1 keratinized epithelium
3 = >2 mm keratinized epithelium

To be measured on M.V.D.L.

Table 2. Plaque index

Criteria:
0 = No plaque in the gingival area. The surface is tested by running a pointed probe across the implant surface at the entrance of the gingival crevice. If no plaque adheres to the point of the probe, the area is considered clean.
1 = A film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may only be recognized by running a probe across the tooth surface.
2 = Moderate accumulation of soft debris within the gingival pocket, on the gingival margin and/or adjacent tooth surface, which can be seen by the naked eye.
3 = Abundance of soft matter within the gingival pocket and/or on the gingival margin and adjacent tooth surface.

Scoring requires light, drying of the teeth and gingiva, mirror, and a probe.
Total score is divided by four to get index for tooth.
To be measured on M.V.D.L.

Table 3. Gingival index

Criteria:
0 = Normal gingiva.
1 = Mild inflammation—slight change in color, slight edema. No bleeding on probing.
2 = Moderate inflammation—redness, edema, and glazing. Bleeding on probing.
3 = Severe inflammation—marked redness and edema. Ulceration. Tendency to spontaneous bleeding.

Scoring requires light, drying of the teeth and gingiva, mirror, and a Michigan "O" probe.
Total score is divided by 4 to get index for tooth.
Can score only one interprox. Score and multiply by 2.
To be measured on M.V.D.L.
### Table 4a Implant data for three-year observation period

<table>
<thead>
<tr>
<th>Total no. of implants placed (not including sleepers)</th>
<th>No. lost</th>
<th>No. of sleepers (unused potential osseointegrated abutments)</th>
<th>No. osseointegrated and used (not including the osseointegrated sleepers)</th>
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<td>Upper</td>
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<tr>
<td>Lower</td>
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<td>18</td>
<td>114</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>144</strong></td>
<td><strong>18 (12.5%)</strong></td>
<td><strong>126 (87.5%)</strong></td>
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### Table 4b Types of implant supported prostheses

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<th>Fixed bridges</th>
<th>Overdenture</th>
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<tr>
<td>Women</td>
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<td>0</td>
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<tr>
<td>Lower prostheses</td>
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<tr>
<td>Men</td>
<td>4</td>
<td>1</td>
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<tr>
<td>Women</td>
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<td><strong>Total No.</strong></td>
<td><strong>25 (96%)</strong></td>
<td><strong>1 (4%)</strong></td>
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Table 5  Index Data

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<td>Mean</td>
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<td></td>
<td>V</td>
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<td>D</td>
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<td>1.3</td>
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Table 6  Radiographic Data

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</table>
Fig. 1 Treatment sequence and recall schedule.

Fig. 2 Tissue surface of cast silver-palladium framework with artificial teeth processed onto the framework.
Fig. 3 Occlusal view of completed prosthesis.

Fig. 4 Intraoral, occlusal view of the attached (via screws) osseointegrated prosthesis.
Fig. 5 Implant components and bone height measurement calculations.
Fig. 6 Radiograph used for research purposes: example of successfully integrated implant fixture.

Fig. 7 Radiograph of failing implant fixture (note the peri-implant radiolucency).
Fig. 8 Attached gingiva index, year 2 and 3.
Fig. 9 Plaque index, year 2 and 3.

Fig. 10 Gingival index, year 2 and 3.
Fig. 11 Pocket depth, year 2 and 3.
Figs. 12a and 12b Preoperative radiographs.

removal of the prosthesis. A special holder was designed to place each periapical film in a specific reproducible position at each annual radiographic monitoring session. This method ensures the sort of measurements used in Table 6.