Three-Year Evaluation of Single-Tooth Implants Restored 3 Weeks After 1-Stage Surgery

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Purpose: *The possibility of expediting dental implant therapy by early or immediate loading protocols requires long-term clinical investigation. The aim of this prospective cohort trial was to determine the 3-year implant success rate and prosthesis complications associated with functional loading 3 weeks after 1-stage placement of Astra Tech single-tooth implants replacing maxillary anterior teeth. A secondary objective was to determine peri-implant tissue responses at these implants.* ***Materials and Methods:*** *The peri-implant bone and mucosal conditions of 43 implants in 39 subjects were radiographically and clinically measured 3 years after implant placement.* ***Results:*** *Of the 48 patients originally treated, 39 patients and 43 implants were examined at the 3-year time point. Three of 54 implants failed within the first year. No additional failures were recorded since the 12-month reporting period. Peri-implant bone levels were stable for the 3-year period following implant placement. The change in marginal bone levels after 3 years was 0.42 ± 0.59 mm. Papilla growth was measured at 1 and 3 years (0.61 ± 0.95 mm and 0.74 ± 0.79 mm, respectively). The buccal peri-implant tissue dimensions at the gingival zenith also increased at 1 and 3 years (0.34 ± 0.94 mm and 0.51 ± 1.42 mm, respectively). No abutment screw loosening or fracture occurred.* ***Discussion and Conclusions:*** *Early loading of endosseous dental implants placed in healed ridges offers select benefits to clinicians and their patients.* (Clinical Trial) Int J Oral Maxillofac Implants 2007;22:791–800

Key words: *early loading, immediate loading, implant success, peri-implant esthetics, prospective clinical trials, single-tooth implants*

The use of expedited approaches to dental implant therapy (early or immediate loading) is of growing interest among clinicians and patients. The basis for endosseous dental implant success is osseointegration, and the basis for implant prosthesis success remains prosthesis stability.[1] The possibility that osseointegration may be attained by implant placement and early loading or provisionalization is of clinical interest. Initial reports suggest that early and/or immediate loading of endosseous dental implants may result in osseointegration.[2–7] For example, the results at the 12-month time point for the placement of a crown in function at 3 weeks following 1-stage placement of an Astra Tech ST implant in healed alveolar ridges showed a 96.2% implant success rate; no complications were reported for the single crown prostheses or abutments.[8] This early report compared favorably with the 97% implant success rate after 5 years and 17% complication rate after 2 years calculated by meta-analysis for anterior single-tooth implants.[9] To date, however, longer-term evaluations of early or immediately loaded single-tooth implants have not been available to guide clinical decision making. The aim of this project was to examine the possibility of early loading by provisional crown placement on abutments connected to implants placed in healed maxillary anterior alveolar ridges. This 3-year report details the implant success rate and prosthesis complications experienced by patients previously examined 12 months after early

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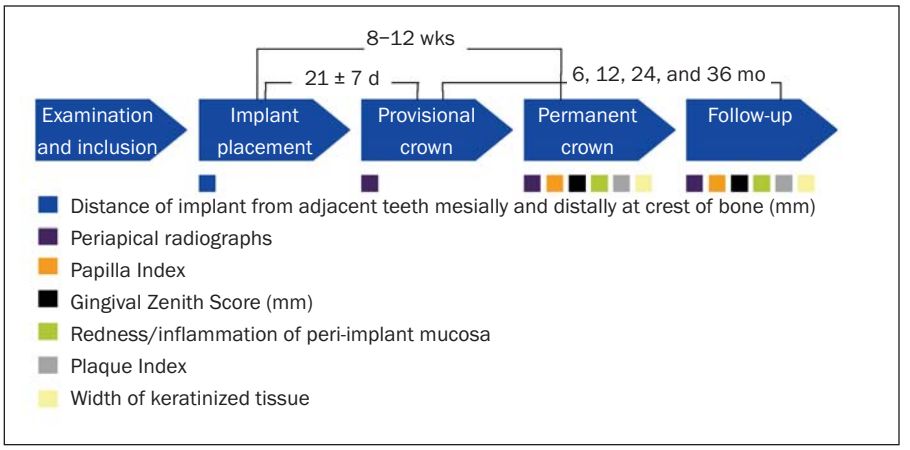


Fig 1 Flowchart of clinical protocol and procedures.

provisional loading of single anterior maxillary implants.

MATERIALS AND METHODS

This open, 3-year prospective cohort trial was performed at 2 centers: the Department of Prosthodontics at the University of North Carolina School of Dentistry and the Departments of Oral and Maxillofacial Surgery and Prosthodontics, Kalmar County Hospital, Sweden. Patient recruitment and treatment at the 2 centers was conducted in accordance with the Declaration of Helsinki under the supervision of the centers' Committees for Investigations Involving Human Subjects.

Treatment and Evaluation

The treatment protocol for this patient cohort has been published.[8] Eligible patients providing informed consent were enrolled. Patient characteristics and diagnostic information, including tomograms of edentulous anterior alveolar ridges, were recorded. Subsequent implant placement by standard procedures was performed in a 1-stage procedure using light finger pressure to place a healing abutment extending through the peri-implant mucosa. After 3 weeks, the definitive restorative abutment, which provided a restorative margin approximately 1 mm below the mucosal margin, was placed with finger pressure, and a provisional crown (ProTemp Garant; ESPE America, Norristown, PA) was cemented with Temp-Bond (Kerr USA, Romulus, MI). The abutments (Abutment ST; AstraTech, Mölndal, Sweden) were not modified by preparation. Any implant demonstrating mobility at abutment connection was considered a failure and was recorded and included in the failure analysis. Placement of the provisional crown represented the baseline time point for the study. All provisional crowns were placed with demonstrable contacts (holding shim stock) in maximum intercuspal position with limited or no eccentric contacts. Periapical radiographs were obtained at this time point. At 8 weeks after implant placement, the abutment screw was tightened with forceful finger pressure without a torque controller, and a definitive impression of the abutment and adjacent tissues was made. Any implant demonstrating mobility at this point was considered a failure and included in the failure analysis. Eight to 12 weeks after implant placement, the permanent crown was cemented with glass ionomer cement (Ketac Cem; Premier, Norristown, PA). Oral hygiene instructions were provided, and a periapical radiograph was obtained. Follow-up examinations, including clinical measurements, assessments, and periapical radiographs, were performed at 6 months and 1 and 3 years (Fig 1). At all recall visits, the presence or absence of plaque and inflammation and the distances from the incisal edges to the mesial and distal papillae were measured using a periodontal probe, and the mean distance from the papilla to the incisal edge was recorded as a papilla index. In a similar manner, the distance from the buccal gingival zenith to the incisal edge was recorded as a gingival zenith score. The width of the buccal keratinized mucosa was recorded to the nearest millimeter. A single independent investigator recorded peri-implant radiolucency (present or absent) and marginal bone level (the distance between implant reference point and marginal bone level mesially and distally in millimeters). Adverse events and complications, including mechanical or biological failure of crown, abutment, or the implant, were recorded. In the previously published 1-year report[8] 1 patient was excluded due to deviation in loading time. Following final source data verification the protocol definition of loading time for this 3-year report was extended to 21 ± 7 days. This resulted in the inclusion of the previously excluded patient.

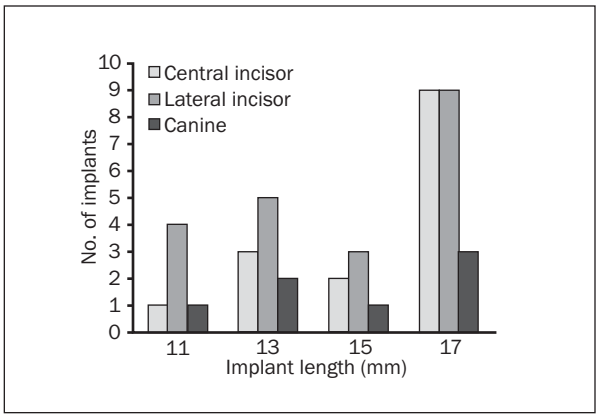


Fig 2 Implant length versus replaced tooth location (all 4.5-mm Astra Tech ST implants).

Table 1 Cumulative Implant Survival Rate (%)

Observation period	No. of implants	Failures	Withdrawals	Cumulative survival rate (%)
Insertion to loading	54	0	0	100
Loading to definitive crown placement	54	3	0	94.4
Definitive crown placement to 6 mo	51	0	0	94.4
6 mo to 1 y	51	0	1	94.4
1 to 3 y	50	0	7	94.4

Statistical Analysis

The measured changes in marginal bone levels from provisional crown to the other time points were calculated for each patient, surface, and implant. For patients with multiple implants, the calculated mean values of the changes were used for descriptive statistics, including 95% confidence intervals. The confidence intervals were calculated assuming that the changes in marginal bone levels were normally distributed. The *P* value was calculated by means of the Wilcoxon signed rank test. The hypothesis tested was that there would be no change over time. For the relation between papilla restoration and the distance of the implant to the adjacent tooth, the hypothesis that the change from baseline was equal among the 3 groups was tested by means of the Kruskal-Wallis test.

RESULTS

Patient Characteristics and Recall

Of the 54 implants placed in the 48 patients initially treated, 3 implants in 3 individuals were lost because of implant failure (instability), and 43 implants in 39 patients were successfully followed and fully evaluated at the 3-year time point. Patients were lost because of geographic relocation between implant placement and the 12-month recall (1 implant in 1 patient), between the 12- and 24-month recalls (4 implants in 4 patients), and between the 24- and 36-month recalls (3 implants in 2 patients). For 42 of 48 patients, implants were loaded as per protocol (21 ± 7 days). For 6 patients, loading occurred at 29 to 37 days. For the 48 enrolled patients, the average time to loading was 24 ± 4.9 days). The present analysis includes all patients treated.

Implant Characteristics

At the 3-year time point, 39 patients (18 male and 21 female) were evaluated. Of the 43 implants, 15 were in central incisor locations, 21 were in lateral incisor locations, and 7 were in canine locations. The implant location, dimension, and distribution are summarized in Fig 2.

Implant Survival, Complications, and Adverse Events

During the first 12-month evaluation period, 3 of 54 implants failed. One of the failures was observed in an implant loaded 2 weeks following placement; the failure occurred 3 weeks after implant loading. Another failure was observed 5 weeks after implant loading, which was carried out 4 weeks following placement. The third failure was observed 8.5 weeks after implant loading, which occurred 3 weeks following placement. No additional implant failures were recorded after placement of the definitive crown. Implant survival at 1 and 3 years is summarized in Table 1.

Complications included minor incisal porcelain fracture of 3 crowns, loosening of 2 crowns placed with temporary cement, 1 episode of tenderness of the buccal mucosa, and 1 peri-implant mucosa defect. No abutment loosening was reported. Of the 8 adverse events recorded, 3 were considered by the investigator to be dental or implant related.

Peri-implant Mucosal Responses

Plaque accumulation and peri-implant mucosal inflammation at implant abutments and crowns remained low over the 3-year evaluation period. Inflammation was scored as peri-implant mucosal redness and decreased from the 12-week time point

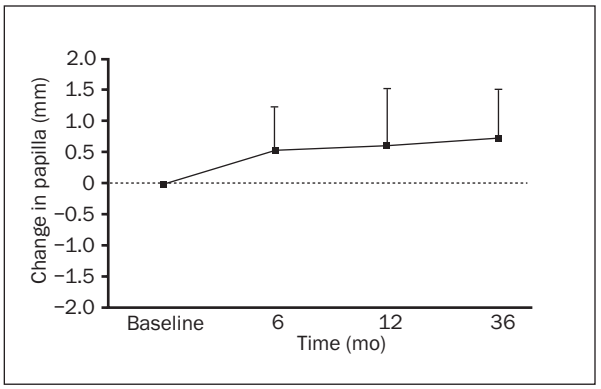


Fig 3a The measured change in the location of the papilla from the incisal reference point versus time. The values plotted represent cumulative change from the time of permanent crown placement to 36 months. Positive score denotes tissue growth toward incisal edge.

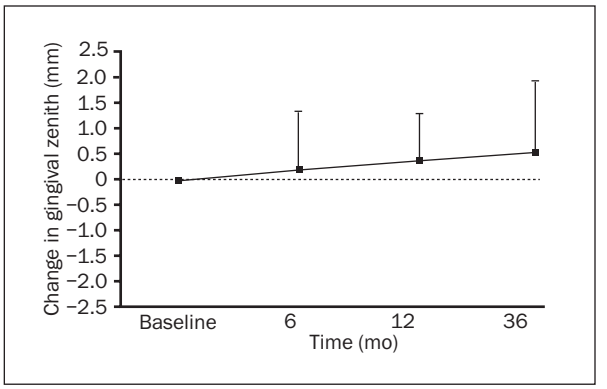


Fig 3b The measured change in the location of the gingival zenith from the incisal reference point versus time. The values plotted represent cumulative change from the time of permanent crown placement to 36 months. Positive score denotes tissue growth toward incisal edge.

to the 12-month evaluation. At 3 years, peri-implant mucosal redness remained at approximately 4% of all sites evaluated.

Measured changes in peri-implant mucosal architecture recorded as papilla index and buccal mucosa dimensions revealed early and continued positive changes in peri-implant tissues. The positive change in papilla index from delivery of the definitive crown was 0.53 mm at 6 months, 0.61 mm at 1 year, and 0.74 mm at 3 years (Fig 3a). The distance from the incisal edge to the gingival zenith was reduced, further indicating tissue growth (Fig 3b). The buccal peri-implant tissue dimensions at the gingival zenith increased at 1 and 3 years (0.34 ± 0.94 mm and 0.51 ± 1.42 mm, respectively). Parallel increases in the width of keratinized tissue were recorded. This result was not affected by implant-tooth proximity; there was no statistical relationship between papilla restoration and the distance of the implant to the adjacent tooth ($P > .05$).

Radiographic Changes in Cortical Bone Relationships

The location of mesial and distal cortical bone at the implant reference point was measured at baseline (provisional crown), placement of the definitive crown, 6 months, 1 year, 2 years, and 3 years following provisional crown placement. Initial changes in marginal bone level occurred between baseline (abutment placement at 3 weeks) and placement of the definitive crown (0.47 ± 0.44 mm; $P < .001$). Further changes at 1 year (0.72 ± 0.78 mm) and at 3 years (0.42 ± 0.59 mm) were not significantly different from definitive crown placement (Fig 4). The distribution of the measured change in marginal bone levels among the implants evaluated after 3 years is shown in Fig 4b.

DISCUSSION

The goal of this prospective clinical cohort trial was to evaluate the implant success, peri-implant mucosa, and bone changes following the 1-stage placement and early functional loading of single-tooth implants placed in edentulous alveolar ridges of the anterior maxilla. The main findings after 3 years were that early functional loading of TiO_2-grit blasted, microthread implants for single anterior maxillary tooth replacement is associated with implant success (94.4%), rapid formation of peri-implant mucosal architecture without buccal mucosal recession, and minimal and limited crestal bone loss with no abutment-related complications (Fig 5).

For a clearer comparison with other investigations, a review of the loading conditions may be helpful. In this study, early loading was performed 21 ± 7 days after surgery for 42 of the 48 patients (range, 14 to 37 days; mean, 24 days for all patients). All provisional crowns were placed with demonstrable contacts (holding shim stock) in maximum intercuspal position, having limited or eliminated eccentric contacts. This early loading approach did not involve immediate placement and thus is distinct from immediate functional loading (loading at the time of implant placement) and immediate provisionalization, which implies no occlusal function for the provisional crown during healing.

This study did not directly compare the clinical outcomes of early loading with conventional implant procedures. However, a primary concern facing clinicians when selecting a loading protocol may be implant survival. For the evaluated implants, a 94.4% success rate was recorded. For the particular implant system used, single-tooth replacement by a 2-stage surgical approach achieves 95% to 100% success.[9–12]

Fig 4 *Changes in marginal bone levels from placement to 3-year recall.*

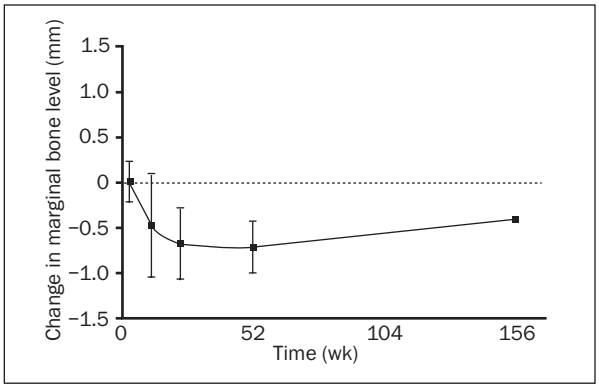


Fig 4a Plot of average marginal bone level (± SD) versus time. Implant placement = 0 weeks; baseline = 3 weeks.

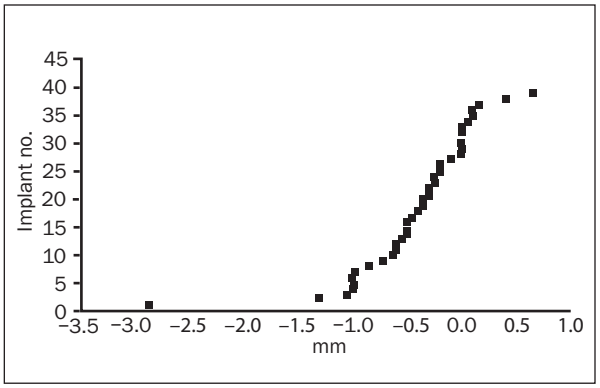


Fig 4b Distribution in the total change in marginal bone levels measured at completion of the study (n = 41 implants).

Fig 4c *(left)* Typical bone response at implant 3 weeks following implant placement (maxillary right canine).

Fig 4d *(right)* Typical bone response at implant 12 weeks following implant placement (maxillary right canine).

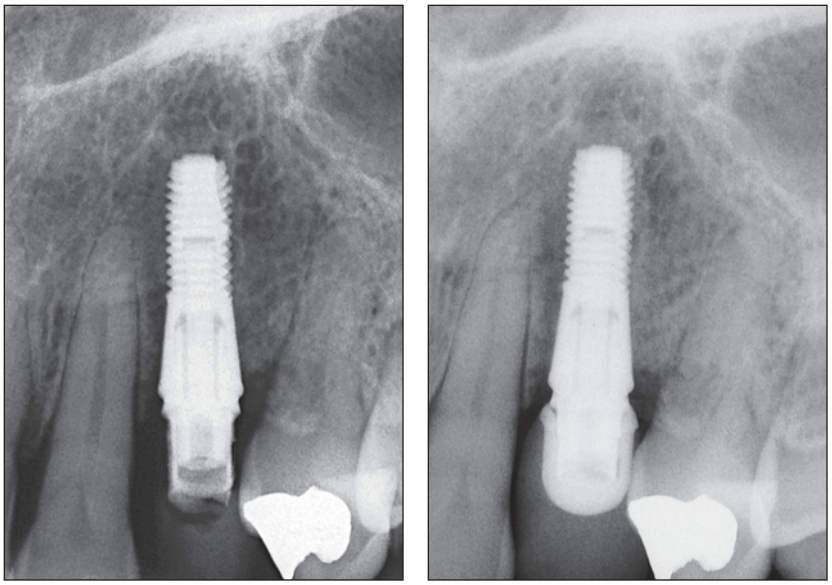


Fig 4e *(left)* Typical bone response at implant 1 year following implant placement (maxillary right canine).

Fig 4f *(right)* Typical bone response at implant 3 years following implant placement (maxillary right canine).

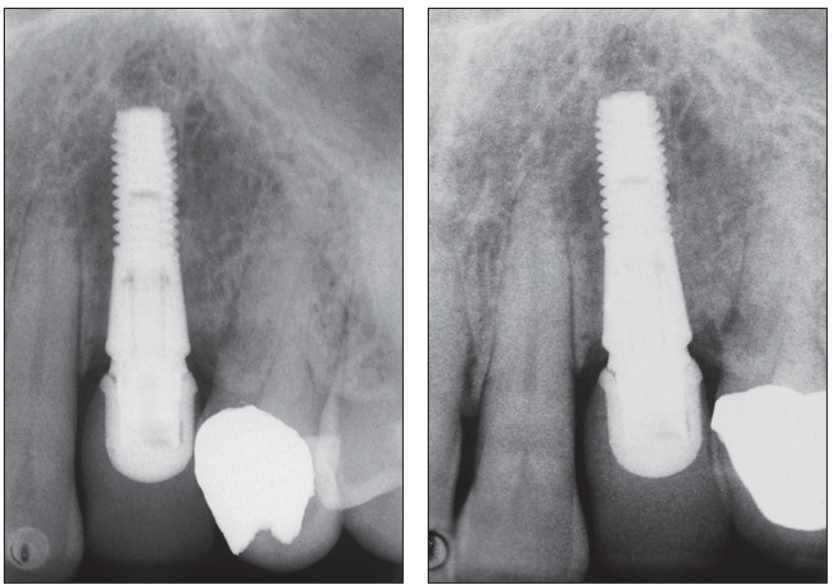


Fig 5 *Clinical and radiographic representation of peri-implant mucosal architecture and related peri-implant bone levels following early implant loading in healed alveolar ridge.*

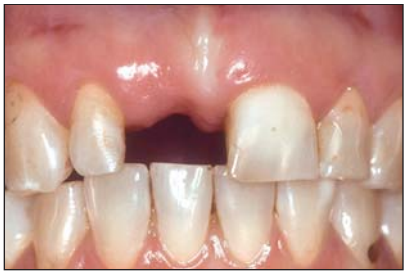


Fig 5a Preoperative condition of patient with missing maxillary right central incisor.

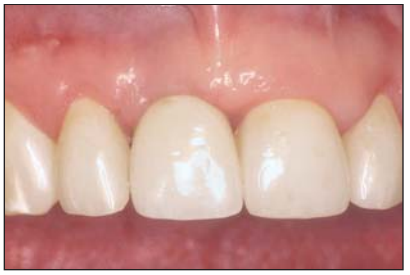


Fig 5b Clinical condition of maxillary right central incisor crown 1 year following implant placement.

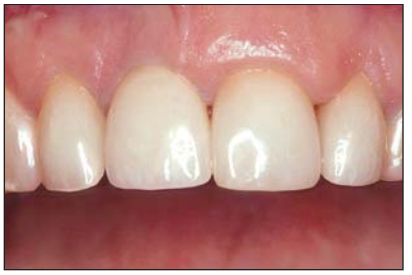


Fig 5c Clinical condition of maxillary right central incisor crown 3 years following implant placement.

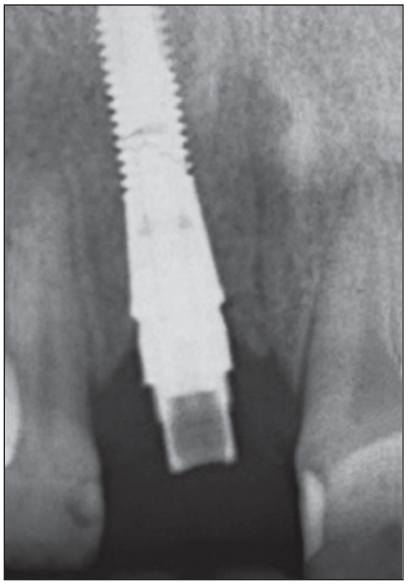


Fig 5d Radiographic evaluation of the implant-bone relationship at the time of implant placement.

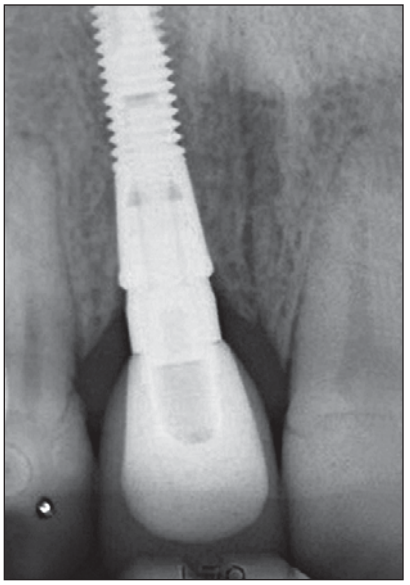


Fig 5e Radiographic evaluation of the implant-bone relationship 1 year following implant placement.

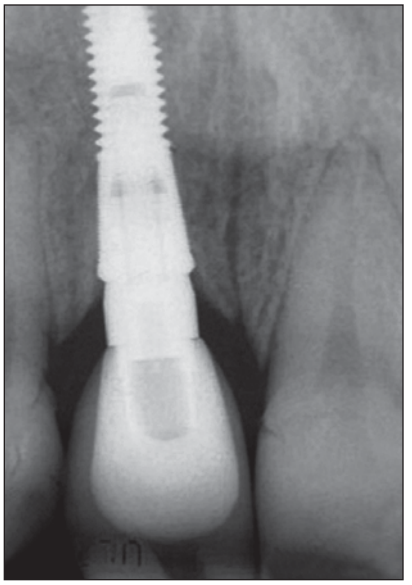


Fig 5f Radiographic evaluation of the implant-bone relationship 3 years following implant placement.

A 97% survival rate has been calculated by meta-analysis of 570 single-tooth implants.[13] Therefore, present success rates are similar to the clinical results reported for conventional 2-stage surgery or loading with this or other dental implant systems.[14,15] A review of early and immediate loading of implants in healed ridges indicated that relatively high implant survival levels are possible.[16] However, there are few long-term, prospective comparative studies. One recent cohort investigation including both immediate and conventional loading protocols suggested that there may be increased risk of implant loss associated with immediate loading protocols.[17]

A second concern for early or immediate loading is the predictability of peri-implant mucosal healing, which affects esthetic outcomes. For the procedures and components used here, this concern is answered by the rapid positive peri-implant mucosal adaptation to the implant abutment and crowns demonstrated. The rapid and reproducible reformation of peri-implant mucosa within the gingival embrasures is attributed to minimal marginal bone adaptation, the early delivery of well-formed provisional restorations, and the absence of abutment screw loosening during the provisionalization period.

The gain in buccal tissue dimension at 3 to 6 months evidenced through the gingival zenith scores (approximately 0.5 mm) contrasts with the reported loss of tissue using conventional procedures and different components (Table 2). In previous studies of single-tooth implant restoration, buccal peri-implant mucosal recession has been reported; Small and Tarnow recommended a 3-month waiting period between abutment placement

and definitive crown placement because approximately 1 mm of peri-implant tissue recession is generally expected during this period.[18] Also, after 1 year, approximately 1.0 mm peri-implant tissue recession was measured at Straumann implants placed by a 1-stage procedure.[19] With immediate placement and loading of Steri-Oss Replace implants, Kan et al[20] reported 0.55 mm peri-implant mucosal recession. More recently, Friberg et al[21] and Cardaropoli et al[22] also indicated that buccal peri-implant mucosa resorption may be expected. The peri-implant tissue changes measured during this 3-year investigation suggest that buccal tissue recession previously reported following implant placement and restoration was limited and, on average, prevented. Confirmation of this novel observation is needed.

The resultant buccal mucosal architecture at a dental implant crown is 1 of several factors included in 2 objective implant esthetics scoring systems.[23,24] While no direct and statistically valid comparison has been made among tooth replacements using diverse procedures, components, or dental implant systems, the peri-implant mucosal responses reported here represent clinically beneficial maintenance/gain of soft tissue surrounding single-tooth implant restorations. This result documents a critical factor affecting clinical success and patient satisfaction when anterior single crowns are concerned.

This study utilized a modular implant system (separate transmucosal abutment and endosseous implant) for 1-stage surgery. The implant survival data, the low level or absence of peri-implant inflammation, and the positive tissue architectural changes compare favorably with the results recorded for single tooth replacement with immediate loading of unitary design or 1-piece implants.[7] One potential advantage of a separate transmucosal abutment and endosseous implant is that the ability to change abutment dimension or material may be used to accommodate unanticipated changes or complications with peri-implant mucosal healing. The stability of the interface (evidenced by the reported absence of loosening or other complications during the provisionalization or follow-up periods) may contribute to the peri-implant tissue responses.

Early provisional restoration placement on implants to promote peri-implant mucosal healing has been recently advocated.[25,26] A 3-year examination suggested that the soft tissue advantages of early provisionalization were not sustained.[27] The present contrary observation of early and maintained peri-implant soft tissue architecture may reflect differences in component-tissue interactions and support this approach to esthetic tooth replacement. The reproducible nature of soft tissue responses, including papilla formation and increased buccal keratinized tissue, is a possible advantage of an early provisionalization or functional loading procedure that should be weighed against the apparently limited additional risk (Fig 6).

Table 2 Peri-implant Mucosa Change in the Literature

Implant/abutment	Peri-implant mucosa change	Reference
Parallel screw Dual acid etched External hex	−1.0 mm	Small and Tarnow[18]
Solid screw Blasted and etched Unitary design	−0.6 mm (6 mo) −1.6 mm (24 mo)	Oates et al[19]
Tapered screw HA-coated Internal connection	−0.53 ± 0.39 mm (papilla, 1 y) −0.55 ± 0.53 mm (gingival, 1 y)	Kan et al[20]
Tapered screw TiO_2-grit blast Conus, internal interference fit	+0.74 ± 0.79 mm (papilla, 3 y) +0.51 ± 1.42 mm (gingival, 3 y)	This report

These positive architectural changes were associated with a relative lack of inflammation present in the peri-implant tissues after the initial healing period of 3 weeks. Little plaque accumulation was noted. The absence of redness and inflammation may further reflect the absence of abutment loosening or micromotion.[28] Binon indicated that interference-fit abutments such as conical implant-abutment interfaces lack significant micromotion.[29] Peri-implant inflammation was generally absent at 3 years in this study. While this lack of inflammation and limited bone resorption is encouraging, no data was contributed from the implants lost to follow-up. Longer-term evaluation may provide further insight into the potential risk of the TiO-blast surface to peri-implant inflammation. However, it is encouraging that 5-year prospective studies of TiO_2-grit blast single-tooth implants placed by a 2-stage procedure reveal similar peri-implant mucosal and marginal bone status.[30] Another report of periodontal patient responses to the TiO-blast surface indicated a relatively low risk of peri-implant mucosal inflammation at the moderately rough TiO_2-grit blasted implants after 5 and 10 years.[31,32] The absence of plaque accumulation and the lack of inflammation at dental implant prostheses should be encouraged and reinforced by frequent evaluation, including periodontal probing of peri-implant tissues.

Fig 6 *Tissue architecture and crestal bone responses at early loaded microthread, TiO_2-grit blasted implant.*

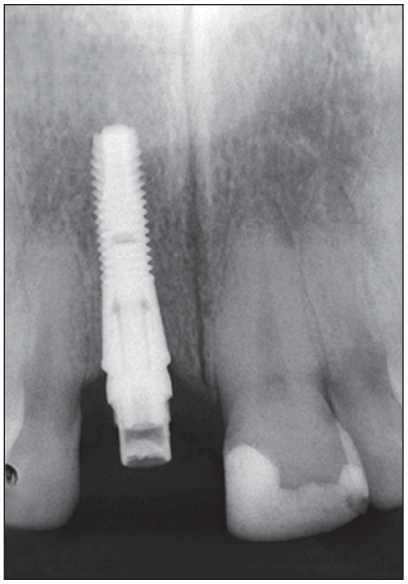


Fig 6a Radiographic evaluation of implant at 3 weeks following placement revealed modest depth of placement and selection of a 1.0-mm abutment for provisional restoration. Clinical implant depth of placement was coincident with the buccal crest of bone.

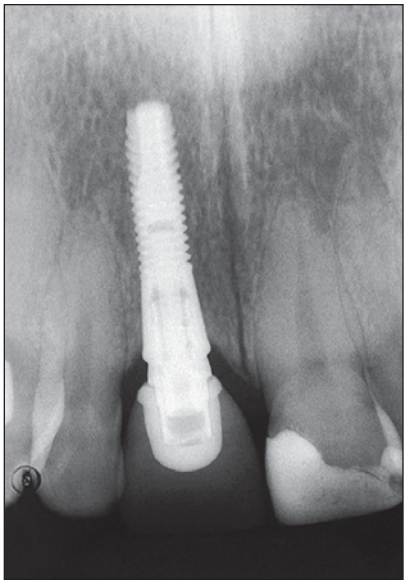


Fig 6b Radiographic evaluation of an implant-supported crown at 1 year following placement.

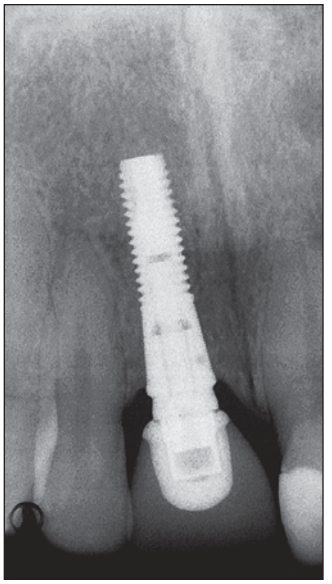
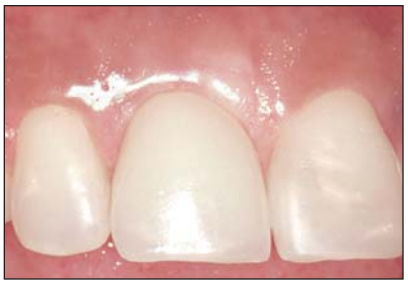


Fig 6c Radiographic evaluation of an implant-supported crown at 3 years following implant placement. Crestal bone adaptation appeared to follow the clinical crown-abutment contour, and bone contact at the implant approximated the implant-abutment interface.



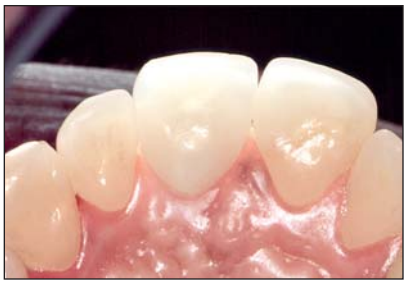


Fig 6d *(left)* Facial clinical photograph 1 year following implant placement. Clinical crown margin was 1 mm beyond the gingival zenith.

Fig 6e *(right)* Lingual clinical photograph 1 year following implant placement. Tissue contours were equally well adapted to natural teeth and implant-supported crown.

The third concern related to early loading was the possible effect of the clinical protocol on crestal bone preservation. Previous investigations have revealed a small and limited change in marginal bone levels for the implant system used in this investigation.[9–12] The current radiographic assessment of the crestal bone changes indicated a statistically significant change after implant placement that was similar in magnitude to the changes in marginal bone levels previously reported for the same components used in different procedures.[9–12,30] Early functional loading does not jeopardize this positive bone response, but neither may it be responsible for this result. It has been suggested that the use of a conus implant-abutment interface, a microthread design, and a moderately rough implant surface in crestal bone precludes crestal bone loss.[33–36] This complex of implant features may contribute to the clinical management of relevant biological processes in adjacent tissues. The aforementioned lack of micromotion at implant-abutment interfaces further coincides with the absence of crestal bone loss.[28] Direct comparison of crestal bone responses with this combination of implant design features and others should be undertaken.

The fourth concern focused on implant complications, particularly abutment and prosthetic complications. The absence of abutment and abutment screw complications reported is an important finding, because components were not assembled with torque controlling devices or gold screws. The geometric locking of a conical implant-abutment interface may reduce bending moments and prevent the loosening or overloading of the abutment screw.[29]

The lack of such component complications has been previously reported for other uses of this and other conus interfaces[12] and contrasts with the higher complication rate for screw loosening of single anterior implants.[37] This may be of special importance to immediate or early loading procedures where implant-abutment connections may not be torqued beyond 20 to 25 Ncm and where loosening of the implant-abutment connection could lead to microbial invasion with inflammation or malocclusion and mechanical failure of the yet-to-be integrated implant.

There are clear advantages and disadvantages to early or immediate loading procedures that affect the patient and clinician. The pragmatic advantages are obvious. However, the risks and benefits of early and immediate loading procedures require definition. This study highlights both potential risks and benefits. Well-formed and fully healed alveolar ridges were the focus of this investigation. The additional risk of implant failure appeared small. While early loading in healed anterior maxillary ridges appears to result in osseointegration success, comparative studies have not been performed. Extending an interpretation of these results to other locations is not supported by these data. Regarding benefits, the reproducible nature of the peri-implant mucosal responses suggests that there may be esthetic benefits beyond the immediacy of restoration. These benefits can be included in any calculation of risk-benefit ratios for individual patients.

CONCLUSION

In this 3-year, prospective clinical cohort trial, the outcomes of early functional loading of single-tooth anterior maxillary dental implants indicate successful osseointegration and prosthesis stability. Early functional loading and the requisite management of peri-implant tissues has benefits in terms of peri-implant mucosal architecture. Increased buccal mucosa and papilla reformation occurred early and consistently following implant placement. After 3 years, the marginal bone and peri-implant soft tissue architectural determinants of esthetics demonstrated stability. Continued effort to define peri-implant tissue responses to different surgical procedures is needed to assure reproducible clinical control of implant restorations in diverse clinical situations.

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