Short Communication

A Randomized Controlled Clinical Trial of Conventional and Immediately Loaded Tapered Implants with Screw-Retained Crowns

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Purpose: Surgical, prosthodontic, and esthetic outcomes of conventional and immediately loaded, single, tapered, roughened-surface Southern implants in the anterior maxilla that were restored with screw-retained crowns were compared over 1 year. ***Materials and Methods:*** Standardized surgical and prosthodontic procedures were followed and accepted criteria were used for assessment. ***Results:*** There were no significant differences within or between the control and test groups for age, gender, bone quality or quantity, implant stability measurements at surgery, or implant length. ***Conclusion:*** After 1 year, the implants that had been immediately loaded with single provisional crowns at surgery and definitive crowns 8 weeks later were as successful as conventionally loaded 2-stage implants.
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Extended treatment times, 2 surgical interventions, and the need for interim prostheses during healing are disadvantages of conventional implant treatment. There is no universal agreement on acceptable loading protocols for single implant crowns. The aim of this randomized controlled clinical trial was to compare the surgical and prosthodontic outcomes of conventional loading with immediate loading, using roughened-surface, tapered implants in the anterior maxilla (between premolars) restored with screw-retained single crowns. The hypotheses were:

1. There would be no difference in implant success rates between the 2 treatment protocols using accepted criteria.[1]
2. There would be no difference in the prosthodontic maintenance requirements of the screw-retained implant crowns between the 2 treatment protocols using accepted criteria.[2]
3. There would be no difference in the implant crown mucosal response, including the interdental papillae,[3,4] between the 2 treatment protocols using established peri-implant parameters.[4]

Materials and Methods

All necessary ethical approvals and consents were obtained. Participants (mean age, 43.25 years; range, 23 to 71 years) satisfying defined inclusion/exclusion criteria were randomly allocated using sealed envelopes to the conventional loading (n = 14) or immediate loading group (n = 14). This was done after prosthodontic consultation but prior to surgical consultation. Each proposed implant site had to have mesial and distal adjacent teeth. Tapered, roughened-surface implants (Southern Implants) were placed using a standardized surgical technique. Implant-level impressions were made at surgery for all participants. For the conventional loading group, screw-retained provisional crowns[4] were placed at second-stage surgery, after a

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Table 1 Mean Radiographic Changes (mm and SD) in Bone Levels

Site	Conventional loading	Immediate loading
Mesial	0.56 (1.90)	0.69 (1.36)
Distal	0.99 (1.18)	0.58 (0.95)

Table 2 Four-Field Table of Implant Outcomes

Implant outcome	Conventional loading group (n = 14)	Immediate loading group (n = 14)
Success	6	8
Survival	6	5
Unknown	2	0
Failed	0	1

26-week healing period, and for the immediate loading group, provisional crowns were placed within 4 hours of implant placement. Provisional crowns were cleared from occlusion using 200-µm articulating paper. Definitive screw-retained metal-ceramic crowns were placed into occlusion for all participants 8 weeks after provisionalization.

Standardized radiographs and implant stability tests were performed at surgery, definitive crown placement, and 1 year (mean, 54 weeks; range, 45 to 62 weeks). Radiographs were digitally photographed and electronically measured to detect changes in bone height (NIH Image). A peripheral stain reference line was incorporated into all definitive crowns at the gingival margin to facilitate accurate peri-implant mucosal measurements. Peri-implant mucosal response[4] and Papilla Index[3] for esthetic assessment were recorded 4 weeks after definitive crown placement and at 1 year using manual (Williams probe) and electronic (Florida Probe) measurements. Surgical and prosthodontic outcomes were assessed.[2]

The groups were compared using paired and independent samples *t* tests. Nonparametric tests (eg, Mann-Whitney U test) were used where appropriate. Mean plaque indices for each site and combined mean plaque indices at implant, patient, and group levels were compared using analysis of variance. Categorical measures were compared using the Chi-square test. Significance was set at $P < .05$.

Results

There were no significant differences within or between the conventional and immediate loading groups for age, gender, bone quality or quantity, or implant length. Bone quantity B according to the Lekholm and Zarb classification[5] was recorded for 79% of sites and quality 3 was recorded for 89% of sites. In the conventional loading group, 2 patients failed to attend the 1-year recall. The immediate loading group had 1 failed implant and another participant who emigrated allocated to survival based on e-mail correspondence. Thirty-five percent of the conventional loading group and 50% of the immediate loading group had bone volume deficiencies treated with autogenous bone without membrane stabilization. Implant stability tests showed no significant differences or changes within or between groups over 1 year. There was no statistically significant difference within or between groups for mean marginal bone change over 1 year (Table 1). Radiographic bone loss at 1 site greater than 1.5 mm over 1 year was recorded for 6 implants in the conventional loading group and 4 implants in the immediate loading group, affecting the success outcome[1] (Table 2). No prosthodontic maintenance was required for the screw-retained definitive crowns. There were no statistically significant differences in the mucosal response or Papilla Index within or between the 2 groups at 1 year. The short follow-up period and the possibility that the small sample size may have caused a type 2 statistical error have to be taken into consideration.

Conclusion

Tapered, roughened-surface Southern implants immediately loaded with single provisional crowns at surgery and definitive crowns 8 weeks later were as successful as conventionally loaded 2-stage implants over a period of 1 year.

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Literature Abstract

Mandibular overdentures supported by 2 or 4 endosseous implants

The aim of this 5-year prospective comparative study was to evaluate treatment outcome (survival rate, condition of hard and soft peri-implant tissues, patient satisfaction, prosthetic and surgical aftercare) of mandibular overdentures supported by 2 or 4 implants. Sixty edentulous patients (39 women, 21 men; mean age 54.9 years; median 52 years; range 38 to 81 years) with a mandibular height between 12 and 18 mm (Cawood Classification V-VI) participated and were randomly assigned to 2 groups. Thirty patients were treated with an overdentures supported by 2 IMZ implants (group A) and 30 patients were treated with an overdentures supported by 4 IMZ implants (group B). Standardized clinical (presence of plaque, calculus and bleeding) and radiographic (mesial and distal bone level using reproducible radiograph with beam direction device) parameters were evaluated 6 weeks after completion of the prosthetic treatment and after 1, 2, 3, 4, and 5 years of functional loading. Prosthetic and surgical aftercare was scored during the evaluation period. The patient satisfaction questionnaires consisted of 54 items divided in 6 scales: A) 9 items concerning functional problems of the mandibular dentures; B) 9 items concerning functional problems of the maxillary dentures; C) 18 items concerning functional problems/complaints in general; D) 3 items concerning facial esthetics; E) 3 items concerning accidental lip, cheek, and tongue biting; F) 12 items concerning esthetics of the dentures. One implant was lost (group A) during the healing period giving a success rate of 99%. There were no significant differences with regard to any of the studied clinical or radiographic parameters of the peri-implant tissues between the groups. None of the patients reported sensory disturbances in the lip or chin region. No differences in satisfaction were observed between the groups. With regard to aftercare, there was a tendency of a greater need of prosthetic interventions in group A, while correction of soft-tissue problems was restricted to patients of group B. There is no difference in clinical and radiographical state of patients treated with an overdenture on 2 or 4 implants during a 5-year evaluation period. Patients of both groups were as satisfied with their overdentures.

Visser A, Raghoebar GM, Meijer HJA, Batenburg RHK, Vissink A. *Clin Oral Implants Res* 2005;16:19–25. **References:** 29. **Reprints:** Dr A Visser, Dept of Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics, University Hospital Groningen, PO Box 30.001, NL-9700 RB Groningen, The Netherlands. Fax: +31-(0)50-3611136. E-mail: a.visser@kchir.azg.nl—*Tee-Khin Neo, Singapore*