Early Loading of Unsplinted Implants Supporting Mandibular Overdentures Using a One-Stage Operative Procedure with Two Different Implant Systems: A 2-Year Report

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ABSTRACT

Background: Step-wise reduction in loading protocols is necessary to evaluate early loading of implants with mandibular overdentures.

Purpose: To compare the success rates of two different dental implant systems following conventional or early loading protocols in patients being rehabilitated with mandibular overdentures.

Materials and Methods: Forty-eight edentulous participants were randomly allocated to two different implant systems: one with a machined titanium implant surface (Sterioss, Nobel Biocare, Yorba Linda, California, USA) and the other with a roughened titanium surface (Southern Implants, Irene, South Africa). For each system, the participants were further divided into control groups, in whom mandibular implant overdentures and their respective matrices were inserted following a standard 12-week healing period, and test groups, in whom a 6-week healing period was followed prior to identical loading. Two unsplinted implants to support implant overdentures were placed in the anterior mandible of all participants, using a standardized one-stage surgical procedure. Mobility tests and marginal bone levels, as well as peri-implant parameters, were evaluated at each baseline and 52 and 104 weeks after surgery.

Results: There was no statistically significant difference in the success rates of the two systems in either control or test groups. At the 2-year evaluation, a success rate was found of 87.5% and 70.8.% for the control and test Sterioss groups, respectively, and 83.3% and 100% for the control and test Southern Implants groups were observed. For the Sterioss groups, eight implants were lost at an early stage: seven in the test group and one in the control group. For the Southern Implants control and test groups, no failures were seen at any time interval. There were no significant differences in marginal bone loss, Periotest values, and peri-implant parameters between implant systems or between any of the control or test groups.

Conclusions: Early loading, with step-wise reductions in loading protocols, of unsplinted machined Sterioss and roughened Southern Implants fixtures with mandibular overdentures is possible for up to 2 years.

KEY WORDS: early loading, implant surfaces, mandibular implant overdentures, nonsubmerged, one-stage implants

Predictable treatment of elderly edentulous patients with mandibular implant overdentures has been documented in numerous clinical studies.[1–19] Currently, the increasing acceptance of a one-stage implant procedure, either by continued use of the original nonsubmerged approach[3–5,8–11,20] or by the modified two-stage submerged procedure using a one-stage operative technique,[21–27] has enhanced the quality of the overdenture treatment paradigm for elderly edentulous patients. The acknowledged advantages of the one-stage operative technique, which include a reduction in the number of surgical procedures, the healing periods, and total treatment costs, have allowed the use of a number of different early loading protocols for this treatment modality.[9,28–30]

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Early loading protocols should be evaluated by the progressive reduction of healing times they provide in different treatment groups. It is logical that recent recommendations should be followed for safe functional loading of unsplinted implants supporting overdentures, using a step-wise sequential reduction of the healing times from the traditional 3 months, prior to loading.[31] Early or immediate loading protocols for splinted implants supporting mandibular overdentures previously have been proposed in the literature, particularly the work of earlier researchers developing the principles of the titanium plasma-sprayed (TPS) screw-shaped implant system.[32–36] Recent studies have evaluated different loading protocols with other implant systems using a splinted treatment approach.[21,23–25,37–39] There have been fewer reports that have evaluated early or immediate loading of unsplinted implants supporting mandibular overdentures in small patient groups without controlled reduction in healing periods.[29,30] In view of the fact that most if not all of the studies have evaluated immediate or early loading protocols on ITI® Dental Implant System (Straumann AG, Waldenburg, Switzerland) or Brånemark (Nobel Biocare AB, Gothenburg, Sweden) implants, there is a need for controlled prospective studies evaluating early loading protocols with other implant systems to support an evidence-based rationale for their use in the clinical setting.

The goal of this prospective clinical study was to evaluate the clinical success of early loading of Sterioss (Nobel Biocare, Yorba Linda, California, USA) and Southern Implants (Irene, South Africa) implants with mandibular overdentures using a one-stage surgical procedure.

MATERIALS AND METHODS

Patient Sample

Forty-eight edentulous participants were randomly selected from those requesting the placement of osseointegrated implants in the Clinical Overdenture Research Project (CORP) at the University of Otago, School of Dentistry. Inclusion criteria were that the participant should be edentulous, aged between 55 and 80 years, and have 13 to 15 mm of residual anterior mandibular bone. Excluded from the study were patients with type IV bone detected at the time of surgery,[40] previously bone-grafted or irradiated jaws, any history of bruxism, any history of current or previous smoking, or any systemic disease likely to compromise implant surgery. Ethical approval was obtained from the Otago Ethics Committee, and all participants gave informed consent.

Participants were randomly allocated to either the Sterioss system or the Southern Implants system on a one-by-one basis. For each system, participants were further allocated with maximum concealment into two subgroups: the control group (12 participants), in whom mandibular implant overdentures and their respective matrices were inserted following the standard 12-week healing period, or the test group (12 participants), in whom a 6-week healing period was followed by loading in a similar manner (Figure 1).

Preoperative panoramic (Scanora®, Orion Corporation, Helsinki, Finland) and conventional lateral cephalometric radiographs were used for surgical evaluation of the selected sites and determination of implant length required for bicortical anchorage. Prior to implant surgery, standardized prosthodontic procedures were used to fabricate new conventional complete maxillary and mandibular dentures for each participant.[41,42]

Surgical Procedures

Antimicrobial prophylaxis (2-g amoxicillin or clindamycin 600 mg) was given orally to each participant 1 hour before each operation, and patients were instructed to rinse their mouth with chlorhexidine digluconate solution (0.2%) for 1 minute, 10 minutes prior to commencement of the operation. Bilateral mandibular block and local infiltration to the buccal sulcus and proposed implant sites was done with lignocaine 2% (with 1:100,000 epinephrine). A mid-crestal incision over keratinized mucosa was used to gain access for the surgical placement of two Sterioss HL Series (3.8 mm) screw-shaped, externally hexed, machined or turned commercially pure titanium (c.p. Ti) implants in 24 participants, and in the other 24 participants, two Southern Implants self-tapping (3.75 mm) screw-shaped, externally hexed, surface-enhanced (roughened) Ti implants, using standard equipment. Three different surgeons placed the implants using a one-stage surgical procedure; all implants were placed vertically parallel, 22 mm apart (11 mm either side of midline) in the anterior mandible, using a modification of a previously described surgical jig.[43] Bicortical anchorage and primary stability of all implants (up to a torque of 40 Ncm) was obtained (Figure 2).

All participants had healing abutments (heights 7 mm for Sterioss, 6 mm for Southern Implants) con-

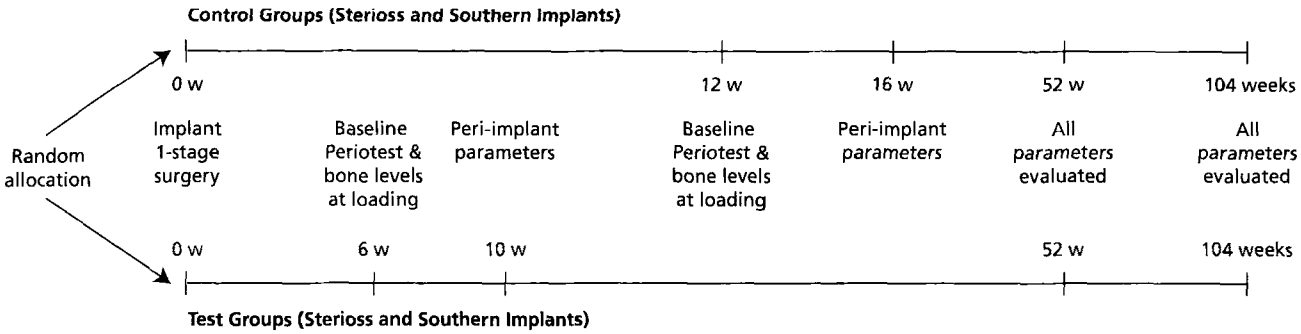

Figure 1. Outline of the study design.

nected to the implants at the time of surgery, using a previously reported one-stage procedure.[27] The mucoperiosteal flaps were carefully adapted around the healing abutments, using interrupted and horizontal mattress sutures (4–O Vicryl, Ethicon, Johnson & Johnson, Brussels, Belgium). The postsurgical antimicrobial protocol comprised a chlorhexidine digluconate 0.2% mouthrinse for 2 weeks, together with direct application of a gel form of the product to the peri-implant area. The previously constructed conventional mandibular denture was not worn for the first 2 weeks. After this period, generous relief was provided on the undersurface of the mandibular overdenture, with spacing around the healing abutments to avoid any torquing forces or initial loading. With this modification of an accepted protocol,[44] a tissue conditioner (Visco-gel, Dentsplay De Trey, Konstanz, Germany) still was applied to the dentures on the fitting surface. The participants also received standardized oral hygiene instructions, with brushing of the healing abutments to be carried out by the participants using end-tufted toothbrushes and the Colgate Total® professional toothbrush (Colgate Oral Care Co., Sydney,

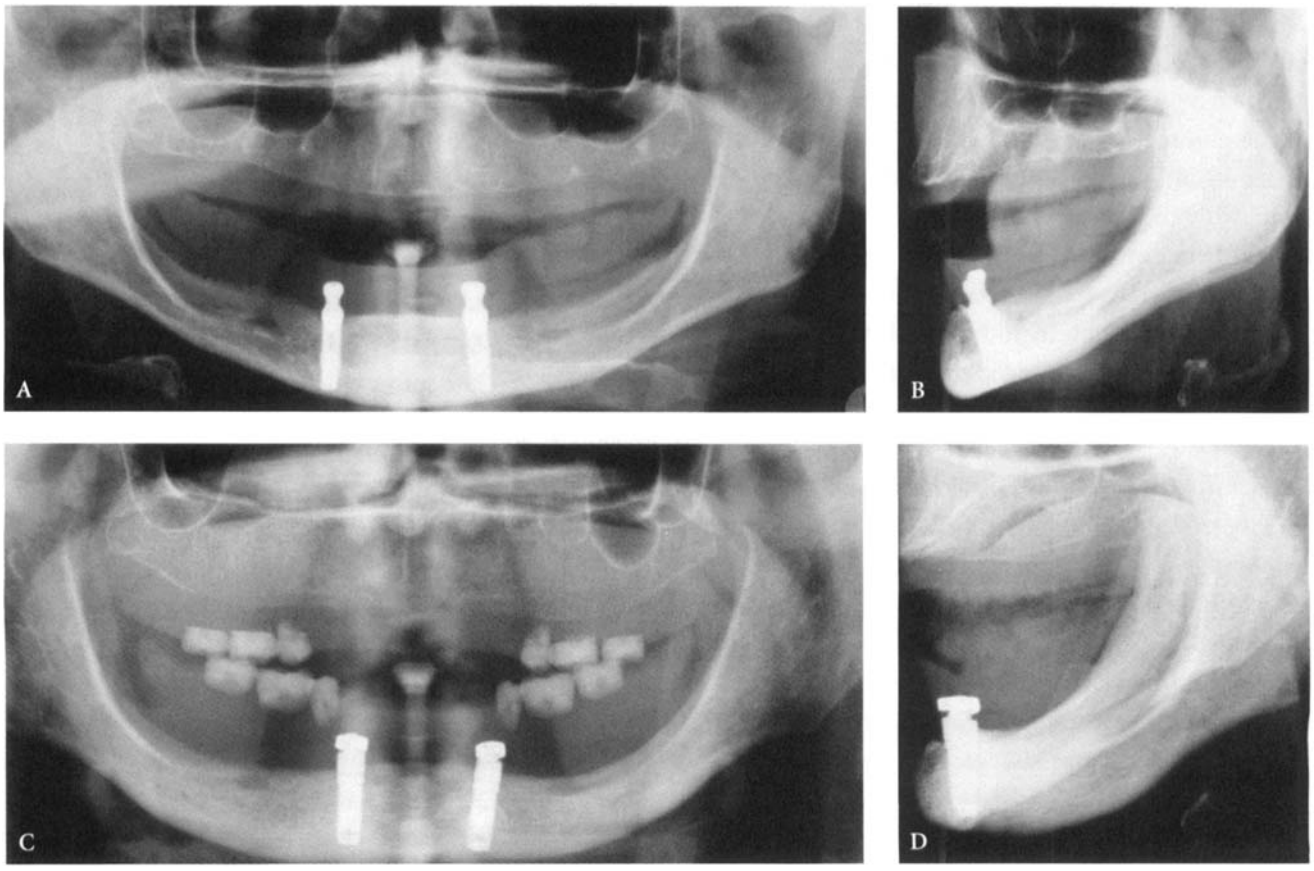

Figure 2. Panoramic and lateral cephalometric views showing bicortical anchorage: *A* and *B*, Southern Implants; *C* and *D*, Sterioss implants.

Australia). These hygiene instructions were also reinforced after permanent abutment connection and subsequent appointments.

Prosthodontic Procedures

Following removal of the healing abutments after 6 weeks (test groups) or 12 weeks (control groups), the respective ball abutments (patrices) were placed on implants and secured with the appropiate torque wrench and force (35 Ncm for Sterioss, 32 Ncm for Southern Implants). A closed-mouth reline impression was then taken (Impregum F, ESPE, Norristown, Pennsylvania) for the inclusion of respective matrices on the fitting surface of the mandibular dentures for full functional loading of the implants at either 6 or 12 weeks (depending on group). The periphery of each processed implant overdenture was relieved in the region of the ball abutments to facilitate air circulation and reduce the possibility of periabutment or peri-implant mucosal enlargement.[45]

Data Collection

Implant mobility measurements (Periotest®, Siemens AG, Germany) and standardized radiographs were taken at 6 weeks for the test groups and at 12 weeks for the control groups. Standardized intraoral radiographs of the coronal parts of individual fixtures were taken, using a modification of a previously described technique,[46] with the respective matrix (retainer) of each system being included in separate Rinn holders. Marginal bone loss was remeasured on the mesial and distal side of each implant, including 2-year radiographs, as per a related published article.[27] Both examiners were again calibrated to minimize inter- and intraobserver errors.[47] Soft-tissue peri-implant measurements recorded at four sites per implant (midmesial, mid-distal, midbuccal, and midlingual) included abutment height above mucosa, peri-implant probing depth, modified Plaque Index, modified sulcus Bleeding Index,[48] and the width of keratinized mucosa (mm). These were recorded at 4 weeks after ball abutment and a matrix placement (10 wk for test groups, 16 wk for control groups) and at 52 and 104 weeks for both groups. The rationale for waiting 4 weeks was to allow adequate mucosal healing after patrix insertion. Participants were followed up for a period of 104 weeks to evaluate their success using accepted criteria.[49,50]

Data Analysis

Marginal bone levels were computed mesially and distally for each implant from the reference point, enabling subsequent calculation of the marginal bone loss between the implant systems and the control and test groups at baseline and both the annual recalls. Mean values were computed for peri-implant parameters for each examination and compared using the Wilcoxon test for two related samples. The level of significance was set at $p < .05$.

RESULTS

Clinical Findings

Descriptive information on the lengths and types of the implants is presented in Table 1. Overall, the implants of both the Sterioss and Southern Implants control groups were longer than the respective test groups. Data on bone quantity and density are presented in Table 2. The two groups did not differ in their distribution across the bone quantity or bone density categories for either system or group ($p > .05$).

Success Rates

In the Sterioss test group, six participants had seven early implant failures, whereas only one participant had an early failure in the control group. All these failures were seen in implants 12 mm long; this finding was statistically significant ($p < .05$). No implant failures were observed in either of the Southern Implants groups. During the follow-up evaluations, lower success rate levels were seen for both the control and test Sterioss groups compared with their Southern Implants counterparts (Table 3). The Sterioss test group (early loading) showed the lowest success rate (70.8%) at the 2-year evaluation. The success rates were lower at the 2-year evaluation for both the Sterioss and Southern Implants control groups; however, this was attributable to one participant in the Sterioss group requesting to be excluded from the study and another two participants being lost from the Southern Implants group owing to their emigration. Although the Southern Implants control group showed a 2-year success rate of 83.3%, it needs to be emphasized that this was only due to the loss of the two aforementioned participants, who, after only telephonic contact with colleagues, were relegated to the survival category using the criteria.[49,50] The failed Sterioss implants had all been placed by the same surgeon. There were no later implant failures. All of the

TABLE 1. Number of Implants Placed by Length and Type

	Length of Implants (mm)						
	10	12	13	14	15	16	18
Sterioss							
Control (n = 24)	—	10	—	10	—	4	—
Test (n = 24)	—	24	—	—	—	—	—
Southern Implants							
Control (n = 24)	2	—	—	—	14	—	8
Test (n = 24)	6	—	8	—	8	—	2

remaining participants were successfully wearing the mandibular implant overdentures at the end of the second year (representing a cumulative prosthesis success rate of 100%).

The marginal bone loss around the implants at baseline and at 52 and 104 weeks is shown in Table 4. At 104 weeks, one set of radiographs for one participant was unreadable, meaning that marginal bone level measurements for that individual (in the Southern Implants test group) were not available. Mean differences between the observation periods were less than 1 mm during the first year and less than 0.2 mm in the second year, thus fulfilling the criteria for success.[50] When examining the marginal bone loss of both Sterioss and Southern Implants groups together (combined) only small bone level changes were seen between year 1 and 2, following the expected bone loss during year 1. Further statistical analysis into separate groups by both control and test categories and implant system showed minor differences of no statistical significance ($p > .05$). There were increasingly negative mean Periotest values over the 104-week period in all the groups, indicating stability of all implants (Table 5).

Peri-implant Parameters

Analysis of all sites revealed only small, not statistically significant differences between baseline and the 52- and 104-week follow-up measurements for all peri-implant parameters (see Table 5). Abutment height levels above the mucosa tended to increase with time (Figure 3). Narrow zones of keratinized mucosa (< 2 mm) were seen on average in 33% of the participants throughout the study. Small reductions were seen in plaque scores for all groups at the 52-week recall. However, this reduction was not maintained at the final evaluation where similar baseline mean plaque scores were observed. Contrary to the fluctuations seen in the mean plaque scores, the perimucosal inflammation levels maintained similar low levels throughout the observation period.

DISCUSSION

Initial mandibular overdenture treatment practice required a 12-week healing period for satisfactory osseointegration of implants prior to loading. It is corollary that following the successful application of a one-stage procedure with the same implant systems,[27] early loading should be evaluated. This study provides support for earlier loading of both unsplinted Southern Implants and Sterioss implants, with mandibular overdentures with the successful sequential reduction of healing period from 12 weeks to 6 weeks. This is in contrast to other studies on unsplinted Brånemark or ITI implants, which have evaluated the early loading protocol by proceeding directly to early loading at 2 to 3 weeks, without sequential reduction in healing times,

TABLE 2. Bone Quantity and Density, by Implant Type*

	Number of Patients			
	Sterioss		Southern Implants	
Parameter	Control	Test	Control	Test
Bone quantity				
A	2	—	—	—
B	—	2	6	—
C	2	8	4	9
D	8	2	1	1
E	—	—	1	2
Bone density				
1	—	—	1	—
2	8	5	4	6
3	4	7	7	6
4	—	—	—	—

*According to Lekholm and Zarb, 1985.

TABLE 3. Implant Success and Survival According to Criteria Specified by Albrektsson and Zarb, 1998

Evaluation Period	Success n (%)	Survival n (%)	Unaccounted for n (%)	Failure n (%)
Year 1				
Sterioss				
Control	23 (95.8)	—	—	1 (4.2)
Test	17 (70.8)	—	—	7 (29.2)
Southern Implants				
Control	24 (100)	—	—	—
Test	24 (100)	—	—	—
Year 2				
Sterioss				
Control	21 (87.5)	—	2 (8.3)	1 (4.2)
Test	17 (70.8)	—	—	7 (29.2)
Southern Implants				
Control	20 (83.3)	4 (16.7)	—	—
Test	24 (100)	—	—	—

and with smaller numbers of participants.[29,30] Similarly, although the use of splinted designs with immediate loading has produced high success rates (96.0–97.5%),[37–39] it is a more surgically demanding and costly treatment alternative that may not have the widest application in elderly population groups.

Different success rate levels were observed with the Sterioss and Southern Implants systems. The highest success rates by the 104-week evaluation were seen for the Southern Implants test group (100%) followed by the Sterioss control group (87.5%) and the Southern Implants control group (83.3%). The lowest was observed with the Sterioss test group (70.8%). By contrast, a study of 20 conical machined Brånemark implants showed a 1-year success rate of 100% in 10 individuals rehabilitated with mandibular implant overdentures opposing conventional maxillary dentures.[29] Similarly, Røynesdal and colleagues demonstrated a 2-year success rate of 100% in 21 participants, 11 of whom were treated according to an early loading protocol (functional loading 2–3 wk after surgery) using roughened TPS ITI implants.[30] Although no statistically significant differences were seen in the present study in the success rates between the two implant systems investigated and their different loading protocols, it is clinically relevant that all the early implant failures were seen in the Sterioss groups, in whom seven of the eight lost implants (87% of those failures) were lost in the early loading group. Implant length and operator variability may also be key factors, since all failures were clustered in the 12-mm length category and all had been placed by the same surgical operator. However, it is also of interest that none of the 10-mm implants in the Southern Implants groups were lost, even if they were loaded at 6 weeks. There is agreed consensus that it is difficult to identify a single

TABLE 4. Marginal Bone Loss around All Implants Combined and by Implant Type and Group

	Year 1 (mm ± SD)*	Year 2 (mm ± SD)*
Combined		
Sterioss and Southern Implants		
Mesial sites	0.16 ± 0.32	−0.01 ± 0.16†
Distal sites	0.10 ± 0.30	−0.06 ± 0.16†
By group		
Sterioss		
Control	0.10 ± 0.33	0.00 ± 0.08
Test	0.12 ± 0.15	0.00 ± 0.19
Southern Implants		
Control	0.16 ± 0.24	0.00 ± 0.08
Test	0.12 ± 0.23	−0.06 ± 0.12†
By implant type		
Sterioss		
Mesial sites	0.01 ± 0.36	0.00 ± 0.17
Distal sites	0.07 ± 0.32	−0.05 ± 0.13†
Southern Implants		
Mesial sites	0.18 ± 0.28	−0.02 ± 0.17†
Distal sites	0.10 ± 0.29	−0.07 ± 0.18†

*For Sterioss, measured from the reference point 1 mm below abutment–fixture junction; for Southern Implants, measured from the reference point at abutment–fixture junction.
†Negative value indicates gain in bone level.

TABLE 5. Periotest Values and Peri-implant Parameters (Combined Systems)

	Baseline (Mean ± SD)		1 Year (Mean ± SD)		2 Years (Mean ± SD)	
	Control	Test	Control	Test	Control	Test
Periotest values	−2.43 ± 1.23	−2.21 ± 1.43	−3.84 ± 0.96	−4.12 ± 0.89	−4.52 ± 0.79	−4.74 ± 0.89
Abutment height above mucosa (mm)	2.19 ± 1.47	2.88 ± 1.22	2.36 ± 1.27	2.86 ± 1.00	2.47 ± 1.28	3.05 ± 1.04
Peri-implant probing (mm)	2.14 ± 0.77	1.85 ± 0.54	1.98 ± 0.63	1.70 ± 0.33	1.68 ± 0.68	1.91 ± 0.44
Relative attachment level (mm)	4.34 ± 1.83	4.73 ± 1.28	4.35 ± 1.40	4.78 ± 1.19	4.16 ± 1.49	4.76 ± 1.12
Width of keratinized mucosa (mm)	2.00 ± 0.67	2.11 ± 0.85	2.06 ± 0.64	2.15 ± 0.74	1.88 ± 0.70	2.04 ± 0.84
Modified Plaque Index	1.02 ± 0.74	1.28 ± 0.77	0.73 ± 0.76	0.64 ± 0.52	1.13 ± 0.73	1.17 ± 0.79
Modified Bleeding Index	0.30 ± 0.36	0.35 ± 0.29	0.30 ± 0.38	0.38 ± 0.37	0.42 ± 0.39	0.59 ± 0.36

factor behind early failures, and it is therefore relevant to consider that osseointegration is a result of biologic and biomechanical processes and functions.[27,51–54]

The fact that the implant systems used in the present study had different surfaces needs to be discussed. The machined and turned c.p. Ti surface of the Sterioss implant differed from the roughened surface of the Southern Implants fixtures. Whether such differences influence the success rate outcome is debatable, but it may not be relevant in terms of implant success with the quality of bone usually present in the anterior mandible (so-called zone 1). Nonetheless, several studies have shown that rough surface configurations do show a higher percentage of bone–implant contact, faster bone integration, and higher removal torque values,[55,56] factors that may be important when an early loading protocol is being considered. In the present study, the success rates were clearly lower for both the Sterioss groups and the Southern Implants control group, with the exception of the Southern Implants test group; however, it is important to emphasize that the success levels after the first year were affected by unforeseen events, such as patient compliance, rather than by implant failure. There was no significant difference in the change of marginal bone levels in this study, with either roughened or machined and turned surface implants. It is noteworthy that even with the one-stage early loading groups there were only minimal bone level changes during the observation period. Results compare favorably with other studies using conventional and early loading protocols.[13,16,27]

Reservations about the effect of early loading on osseointegration have been expressed by other workers.[31,57] Histologic evaluations of different loading protocols have yielded different findings, depending on the type of implant being used. Sagara and colleagues showed that early occlusal loading led to incomplete bone apposition on implants with machined and turned surfaces.[57] On the other hand, more recently, a case report by Testori and co-workers showed successful osseointegration on two Osseotite© (Implant Innovations, Inc., Palm Beach Gardens, Florida, USA) roughened-surface implants that had been immediately loaded after surgery and retrieved after 4 months of functional loading.[58] Their results were related to implants that were splinted and used as abutments of a fixed rehabilitation. This suggests, albeit in case reports only, that immediate loading per se does not impede osseointegration. Although the findings of those two studies may not directly apply to the treatment approach used in the present study because of the number of points of methodologic difference (type and duration of the load, forces applied, animal model evaluated, and implant surface characteristics), clinical findings in this study suggest a stable osseointegrative situation supporting this early loading treatment modality for both implant systems.

The results of the mobility tests with Periotest values in this study were all within the expected range for osseointegrated dental implants and compare favorably with reported values published by other studies on early or immediate loading.[22,29,30,39] Mean negative readings had increased by the end of the 2-year evaluation, suggesting favorable osseointegration.

The authors found the collection and analysis of data on clinical peri-implant parameters valuable and important for the monitoring, maintenance, and follow-up of the peri-implant tissues of patients rehabilitated with mandibular implant overdentures, particularly in view of the unique environment underneath the overdentures and also in view of the fact that late failures (following successful prosthodontic rehabilitation) have been reported in the literature.[9,59,60] Likewise, the rela-

tion between peri-implant pathogenic microorganisms and inflammation of the marginal tissues has been confirmed and reported by several researchers.[48,53,60] A recent review of the pertinent literature regarding mandibular implant overdentures has shown that biologic complications, such as mucosal enlargement, can be seen in between 4% and 44% of patients without strict oral hygiene control.[45] In the present study, healthy peri-implant mucosal conditions were maintained throughout the observation period with only small changes in the parameters measured. Plaque scores showed a tendency to reduce by the end of the first year, but this reduction had not been maintained by the end of the second year. This observation might be explained by the repeatedly or more frequently reinforced oral hygiene instructions, which had been given initially to all the participants during the first year. Change in abutment height through mucosal recession around the abutments was observed prospectively. The well-motivated participants and the recall program followed during the study demonstrate the significance of suppressing levels of peri-mucosal inflammation in securing peri-implant health on a long-term basis for an aging edentulous population rehabilitated with overdentures.

CONCLUSIONS

1. Early loading with step-wise reduction in loading protocols of unsplinted, machined Sterioss and roughened Southern Implants fixtures with mandibular overdentures is possible for 2 years.
2. Findings support the use of this treatment modality for the edentulous mandible in the interforaminal area when primary stability has been ensured or strict surgical and prosthodontic procedures have been followed.
3. Additional prospective studies would further validate this mandibular treatment concept.

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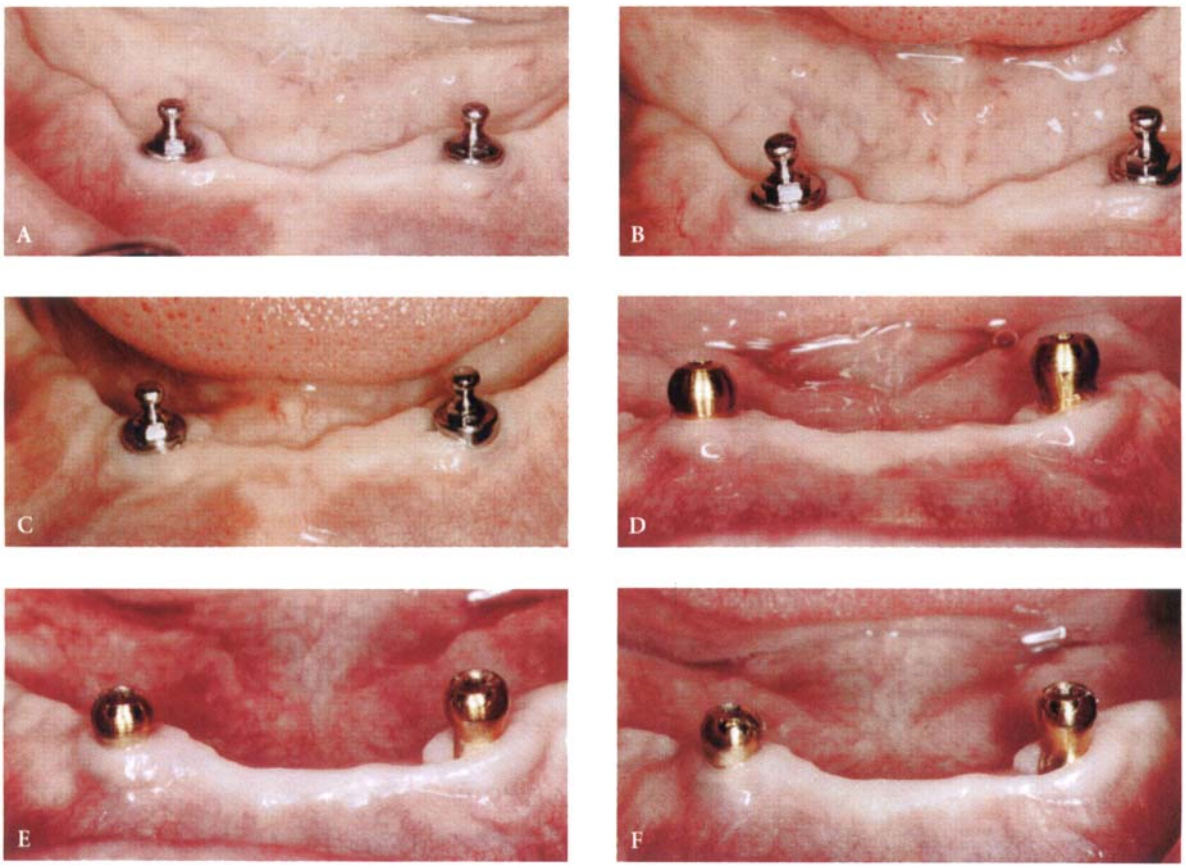

Figure 3. Example of changes of peri-implant soft tissues throughout the observaton period. Sterioss implants: *A*, at baseline; *B*, at 1 year; *C*, at 2 years; Southern Implants fixtures; *D*, at baseline; *E*, at 1 year; *F*, at 2 years.

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