Immediate Loading of Brånemark Implants: a 24-Month Follow-Up of a Comparative Prospective Pilot Study between Mandibular Overdentures Supported by Conical® Transmucosal and Standard MK II Implants

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ABSTRACT

Background: The purpose of this prospective study is to compare the long-term outcome of immediately loaded implant-retained mandibular overdentures supported by four screw-type one-piece transmucosal implants with that of four screw-type two-piece implants inserted in the interforaminal area of the mandible and rigidly connected by a U-shaped curved

Materials and Methods: A prospective pilot study was conducted with 10 patients receiving an implant-supported overdenture in the mandible. The patients were randomly assigned to two groups. In the control group (five patients), four standard Brånemark® implants (MK II®; Nobel Biocare AB, Gothenburg, Sweden), 3.75 mm large and at least 10 mm long, were sited anterior to the mental foramina, and four standard abutments (Nobel Biocare AB) for bar construction were immediately screwed to the implants. In the test group (five patients), four conical transmucosal implants (Nobel Biocare AB), 3.75 mm large and at least 9 mm long in the threaded part, were sited anterior to the mental foramina. Immediately after implant placement, a U-shaped gold or titanium bar was fabricated and implants were immediately loaded (within 24 h) in both groups with an implant-retained overdenture. The patients were followed up for a minimum of 24 months. Implants were evaluated at the time of immediate loading and at 12 and 24 months after prosthetic loading, with the following parameters: modified plaque index (MPI), modified bleeding index (MBI), and probing depth (PD). Periimplant bone resorption was evaluated on panoramic radiographs taken 12 and 24 months after the beginning of prosthetic loading.

Results: No significant differences were found between the two groups with regard to MPI, MBI, PD, and periimplant bone resorption at 12 and 24 months. The cumulative success rate of implants according to the criteria proposed by Albrektsson and colleagues was 100% in both groups after 2 years of functional loading.

Conclusions: Results from this study demonstrated that the success rate for immediately loaded mandibular implants is similar to that obtained in cases of delayed loading and that there are no significant differences between results with two-piece implants and one-piece transmucosal implants.

KEY WORDS: dental implants, immediate implant loading, implant-supported overdentures

Dental rehabilitation with traditional removable prostheses in cases of atrophic edentulous mandibles may create functional and psychological problems for the patients because of the frequent instability of the prosthesis.

When a fixed prosthesis anchored to osseointegrated implants is not indicated due to anatomic, functional, or economic reasons, implant-retained overdentures may be a satisfying solution with reliable long-term results.[1–5] Overdentures are usually anchored to two to four implants inserted in the interforaminal area. As in the case of implant-supported fixed prostheses, a waiting period of between 3 and 6 months is usually indi-

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cated to obtain osseointegration, both in submerged and nonsubmerged implants.[6–9] This may result in discomfort to the patient who must endure the consequent delay of final rehabilitation.

As demonstrated by Ledermann[10,11] and Graber and Besimo,[12] a rigid connection of three or four interforaminal implants with a U-shaped curved Dolder bar can prevent macromovements or nonaxial load on implants in cases of immediate loading with an overdenture. In this situation osseointegration can take place normally with success rates comparable to those obtained with delayed loading, as demonstrated by a number of studies.[10–17] These results were obtained both with two-piece implants (the abutment is screwed on the implant) or one-piece implants (implant and abutment are formed as one piece),[14–17] but, to the authors' knowledge, no comparative prospective studies between these two types of implants have yet been performed.

Recently Nobel Biocare AB (Gothenburg, Sweden) presented a new type of one-piece transmucosal implant (Conical™), which appears to be suitable for immediate loading of implants connected by a bar and supporting an overdenture.

The aim of this prospective study is to compare the long-term outcome of immediately loaded implant-retained mandibular overdentures supported by four screw-type one-piece transmucosal implants (Conical) or by four screw-type two-piece implants (MK II, Nobel Biocare AB) inserted in the interforaminal area of the mandible and rigidly connected by a U-shaped curved bar.

MATERIALS AND METHODS

Ten patients, five males and five females ages 52 to 81 years (mean 60.9 yr), were selected and treated between March and July 1998. Each had presented with complete edentulism of the mandible since at least 3 months prior, and were identified as having functional difficulties with a complete denture.

Five patients presented with total edentulism of the upper arch (of which four were treated with traditional dentures and one with a removable implant-supported prosthesis); three patients presented with partial edentulism of the upper arch treated with removable prostheses; and two patients presented with a fixed rehabilitation of the upper arch. Anagraphic data and clinical features are reported in Table 1.

At the initial patient visit, evaluation and collection of baseline data were performed and recorded on case report forms. The visit included the following:

- Screening for the study, in terms of inclusion and exclusion criteria
- Completion of a medical and dental health questionnaire
- Explanation to the patient of the purpose of the study and planned treatment, including potential

TABLE 1 Anagraphic Data of Patients and Clinical Features

Patient	Sex	Age (yr)	Date of Implant Placement	Number of Implants	Implant Length (mm)*	Type of Implants	Failing Implants
Test Group							
1	M	55	March. 1998	2	13	MK II	0
				2	18	MK II	0
2	M	63	April 1998	4	18	MK II	0
3	M	57	April 1998	4	15	MK II	0
4	F	63	May 1998	4	11.5	MK II	0
5	F	66	May 1998	4	13	MK II	0
Control Group							
1	F	54	March 1998	4	15 (11)	Conical	0
2	F	81	May 1998	4	13 (9)	Conical	0
3	M	52	June 1998	4	18 (14)	Conical	0
4	F	60	June 1998	4	15 (11)	Conical	0
5	M	58	July 1998	4	18 (14)	Conical	0

F = female; M = male.

*Number in parentheses is the length of the threaded part (mm).

benefits and alternative treatment procedures
- Explanation to the patient of the risks and possible complications of treatment
- Radiographic evaluation with panoramic radiograph and lateral cephalometric radiography
- Taking of intraoral photographs
- Description of the opposing dentition, including any abnormal occlusion that the implant-supported prosthesis may encounter
- Performance of routine laboratory examinations: hematocrit, hemoglobin, white blood count, prothrombin time, partial thromboplastin time, platelet count, electrocardiography

Only healthy patients were included in this study. Jaw bone quantity, morphology, and skeletal relationship were evaluated prior to surgery with lateral cephalometric radiography and panoramic films (Figure 1). Inclusion criteria were as follows: adequate oral hygiene, absence of residual dentitions in the lower arch, absence of local inflammation, absence of oral mucosal disease, no history of local radiation therapy, residual bone height in the interforaminal area adequate to harbor four screw-type titanium implants, 3.75 mm in diameter and at least 9 mm long.

Exclusion criteria were the following: insufficient bone volume to harbor four implants, 3.75 mm in diameter and at least 9 mm long, in the interforaminal area of the mandible; severe intermaxillary skeletal discrepancy; strong gagging reflex; severe clenching or bruxism; previous reception of implants in the interforaminal area; drug or alcohol abuse; moderate or heavy smoking habit (more than 10 cigarettes/d); having undergone radiotherapy in the head and neck area or treatment with antiblastic chemotherapeutics; chronic renal disease; chronic liver disease; uncontrolled diabetes; hemophilia or other bleeding disorders or treatment with coumarin; metabolic bone disorders; immunocompromised conditions including human immunodeficiency virus; current steroid treatment; current pregnancy; general contraindications for surgical procedures; physical or psychiatric handicaps that could interfere with good oral hygiene; and presence of mucosal disease such as lichen planus.

The study was conducted on two groups: a control group and a test group, each consisting of five patients. In the test group, the patients received four Conical one-piece transmucosal implants. In the control group, the patients received four MK II implants. In both groups implants were loaded immediately after placement.

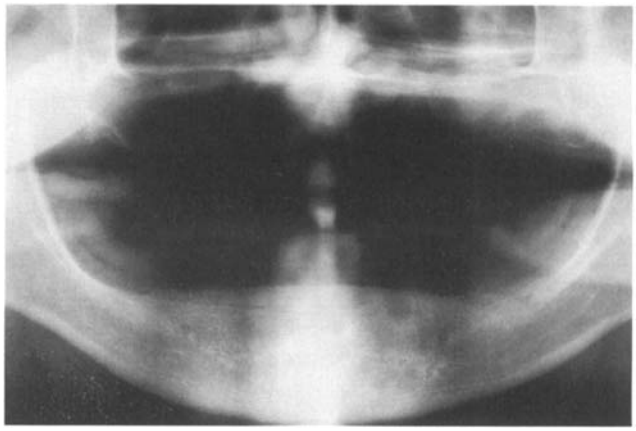

Figure 1 Preoperative panoramic radiograph.

Treatment Planning, Surgical Protocol, and Prosthetic Treatment

Surgical protocol was the same for both groups. Prerequisites for aseptic conditions included autoclavable contra-angled handpieces for reduced drilling speed with provision for cooling with sterile saline and sterile surgical procedures, instruments, and supplies. Before surgery each patient was given a mouthwash containing chlorhexidine digluconate 0.12% for 1 minute for local antisepsis. In both groups patients received oral antibiotics, from 2 hours before surgery until the third postoperative day, and nonsteroidal analgesics. Implant insertion was performed under local anesthesia; patients were premedicated with diazepam (0.2 mg/kg) assumed orally 30 minutes before surgery.

The surgical procedure was begun with an intraoral crestal incision, extending from the molar area of one side to the molar area of the opposite side, to identify both mental foramina, with mesial releasing incisions on the buccal side. Subperiosteal dissection of the mucoperiosteum was obtained both buccally and lingually to identify and visually control both sides of the symphysis. When indicated, a remodeling of the alveolar crest to obtain a larger and flat bony base was performed with a bur assembled on a straight low-speed handpiece, under irrigation with sterile saline. Implant sites were prepared according to the standard procedures of the Brånemark system. The quality of the bone was reported and judged clinically according to Lekholm and Zarb's classification[18] and with Osseo-Care™ drilling equipment for oral surgery and pros-

thetics in both groups during implant site preparation and screw insertion.

Control Group

Four traditional Brånemark implants (MK II), 3.75 mm in diameter and at least 10 mm long , were sited anterior to the mental foramina. Four standard abutments (Nobel Biocare AB) for bar construction were immediately screwed to the implants, and the mucoperiosteal flaps were accurately sutured around the abutments. Using transfer copings inserted on the abutments, an impression (Impregum F®, ESPE Dental AG, Seefeld, Germany) was taken using a previously prepared denture as an impression tray. The impression was sent immediately to the dental laboratory. On the master model obtained, which incorporated implant analogs, prefabricated Brånemark gold copings were screwed to the standard abutments, and a U-shaped Dolder bar was constructed with the gold copings soldered to bar segments.

Within 24 hours after surgery, the bar was screwed to the abutments; the accuracy of fit of the bar was checked in the mouth. If passive fit was achieved, the bar was definitely screwed to the abutments, and the patient bore the overdenture immediately. The retention system was formed by clips incorporated in the denture base.

Test Group

Four Conical transmucosal implants, 3.75 mm in diameter and at least 9 mm long in the threaded part, were sited anterior to the mental foramina. The rest of the procedure was similar to that described for the control group (Figures 2 to 4). The only difference was the direct insertion of transfer copings on the implants.

Follow-Up

Follow-up visits were scheduled for 2 weeks and then 1, 3, 6, 12, and 24 months postoperatively. Postoperative care included rinsing with 0.12% chlorhexidine gluconate mouthwash three times per day for approximately 1 minute and eating only soft foods for 2 weeks.

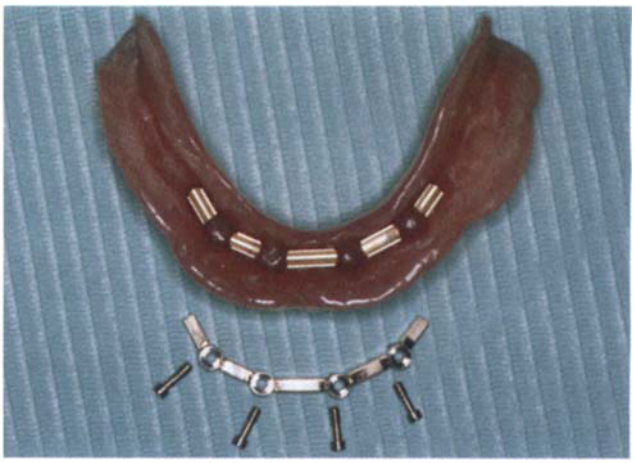

Figure 3 Test group. The bar with the implant-retained overdenture just before placement.

At the follow-up visit 1 to 2 weeks postoperatively, the sutures were removed. Patients were reinstructed in oral hygiene, which included brushing with a soft-bristled toothbrush and a topical application of chlorhexidine. At 1, 3, and 6 months postoperatively, any signs of local inflammation were detected.

Every year after final prosthetic rehabilitation, the overdentures and the bars were removed and each implant was tested individually. The following clinical parameters were recorded: gingival health (Figure 5), radiographic assessment of marginal bone loss (Figure 6), implant mobility, and success criteria.

- Gingival health was quantified by using the modified plaque index (MPI), the modified bleeding index (MBI), and probing depth (PD). MPI and

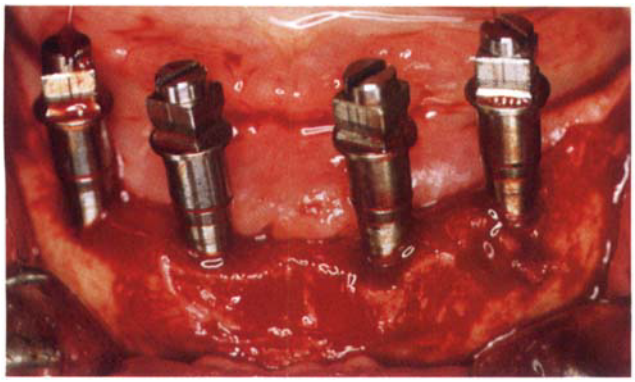

Figure 2 Test group. Intraoral situation immediately after implant placement.

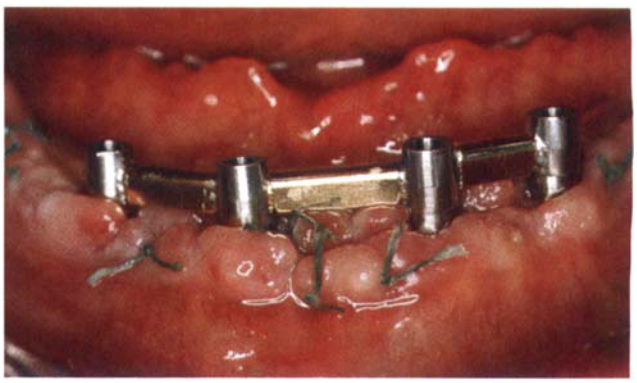

Figure 4 Test group. Intraoral situation 24 hours after implant placement.

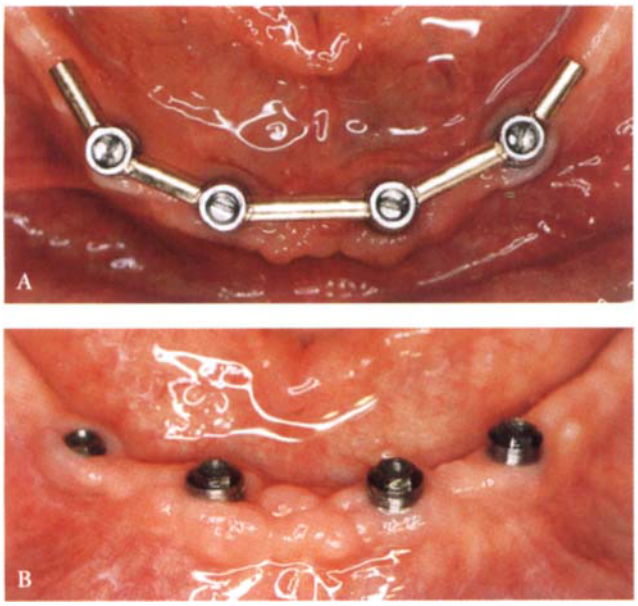

Figure 5 *A* and *B*, Test group. Clinical appearance 24 months after prosthetic loading.

MBI scores were recorded at four sites (mesial, distal, buccal, and oral) for every implant, according to the modifications described for implants by Mombelli and colleagues.[19] Probing depth was recorded on four sites per implant with a calibrated plastic probe.

- To detect any vertical bone loss around implants, panoramic film and periapical radiographs (whenever possible) were taken immediately after implant insertion and at 1 and 2 years postoperatively. To ensure parallelism and standardization of periapical radiographs, the use of a paralleling technique was performed. The bone loss was measured in millimeters.

  Crestal bone level was recorded where the marginal bone anchored directly to the implant. Measurement was done mesial and distal to each implant by means of a transparent millimeter ruler, measuring the distance between the apex of the implant and the first visible contact with the implant surface. The measurements were made to the nearest half millimeter. Because it was not always possible to take periapical radiographs due to the reduced height of the floor of the mouth, measurements were made on panoramic radiographs, which permitted an evaluation of the distance between the apex of the implant and the first implant-to-bone contact. To correct dimensional distortion, the apparent dimensions of the implant were measured on the radiographs and were compared to the actual size of implants.
- Implant mobility was tested using the handles of two dental mirrors.
- Success criteria were as follows:
  1. That an individual unattached implant was immobile when tested clinically
  2. That radiographs did not demonstrate any evidence of periimplant radiolucency
  3. That vertical bone loss was less than 0.2 mm annually following the implant's first year of service
  4. That individual implant performance was characterized by abscence of signs and symptoms such as pain, infection, neuropathies, paresthesia, and violation of the mandibular canal
  5. That, in the context of the above, a 95% success rate at the end of a 5-year observation period could be expected[20,21]

Statistical Analysis

Descriptive analysis of raw data was performed with commercial statistical software (StatView 5.0®, SAS Institute Inc., Cary, NC, USA). With the same software package, the pertinent comparisons between the relevant variables in the two groups were calculated. The Mann-Whitney *U* test was used to compare MPI, MBI, PD, and periimplant bone resorption between the two groups: a *p*-value of .05 was considered statistically relevant.

RESULTS

In the test group, 20 one-piece transmucosal implants were placed, compared with 20 two-piece implants in the control group. At the time of this writing, no

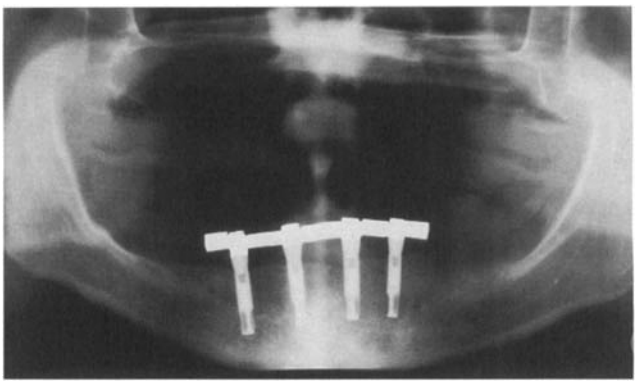

Figure 6 Test group. Panoramic radiograph 24 months after definitive prosthetic rehabilitation.

TABLE 2 MPI Values in Control and Test Groups at 12 and 24 Months after Prosthetic Loading

	MPI Values in Control Group				MPI Values in Test Group			
Measurement	M	O	D	B	M	O	D	B
At 12 Months								
Mean	0.7	0.5	0.5	0.4	0.5	0.6	0.7	0.7
SD	0.7	0.5	0.6	0.5	0.9	0.9	0.9	0.9
Median	0	0	0.5	0	0	0	0	0
IQR	1	1	1	1	1	1	1	1
At 24 Months								
Mean	0.7	0.8	0.6	0.6	0.4	0.9	1	1
SD	0.7	0.8	0.8	0.5	0.6	1.1	1.1	1.1
Median	0.5	1	0	1	0	1	1	1
IQR	1	1	1	1	1	1	2	2

B = buccal; D = distal; IQR = interquartile range; M = mesial; MPI = modified plaque index; O = oral.

implants have been lost, and no clinical complications have been reported.

As far as MPI, MBI, PD, and bone resorption values were concerned, no statistically significant differences were found between the two groups at 12 and 24 months after prosthetic loading (Tables 2 to 5). Of particular note, the values of periimplant bone resorption after prosthetic loading in both groups were within the limits proposed by Albrektsson and colleagues.[20]

The cumulative success rate of implants according to the criteria proposed by Albrektsson and colleagues[20] was 100% in both groups after 2 years of functional loading (Table 6).

DISCUSSION

The method described in this study, which uses four implants rigidly connected by a curved U-shaped bar, seems to provide good stabilization of the implants, despite the immediate loading. Thus implants seem not to be exposed to movements that might compromise osseointegration, as demonstrated by a number of authors.[10–12,14–17]

In the orthopedic literature, some studies[22,23] demonstrated the role of macromovements in tissue differentiation around endosseous implants placed in the metaphysis of bones. Macromovements induced fibrous tissue interposition between the implant surface and the bone. Similar results were found with regard to dental implants.[24,25]

Cameron and colleagues[26] introduced the hypothesis that micromovements at the bone-implant interface are tolerated below a certain threshold. Other authors

TABLE 3 MBI Values in Control and Test Groups at 12 and 24 Months after Prosthetic Loading

	MBI Values in Control Group				MBI Values in Test Group			
Measurement	M	O	D	B	M	O	D	B
At 12 Months								
Mean	0.2	0.3	0.5	0.1	0.4	0.3	0.4	0.4
SD	0.4	0.5	0.5	0.2	0.7	0.4	0.6	0.6
Median	0	0	0.5	0	0	0	0	0
IQR	0	1	1	1	1	0.25	1	1
At 24 Months								
Mean	0.3	0.6	0.6	0.4	0.3	0.3	0.6	0.5
SD	0.6	0.7	0.8	0.5	0.4	0.6	0.7	0.7
Median	0	0	0	0	0	0	0	0
IQR	0	1	1	1	0.25	0	1	1

B = buccal; D = distal; IQR = interquartile range; M = mesial; MBI = modified bleeding index; O = oral.

TABLE 4 PD Values in Control and Test Groups at 12 and 24 Months after Prosthetic Loading

	PD Values in Control Group				PD Values in Test Group			
Measurement	M	O	D	B	M	O	D	B
At 12 Months								
Mean	3.2	3	3.4	3	2.9	2.7	3.2	2.3
SD	0.7	0.5	0.7	0.8	0.7	0.6	0.6	0.5
Median	3	3	3	3	3	3	3	2
IQR	0.25	0	1	2	0.5	1	0	1
At 24 Months								
Mean	3.3	3.1	3.4	3.2	2.8	2.6	2.9	2.5
SD	0.6	0.7	0.7	0.8	0.7	0.8	0.7	0.5
Median	3	3	3	3	3	3	3	3
IQR	0.25	0	1	1.25	1	1	0.5	1

B = buccal; D = distal; IQR = interquartile range; M = mesial; PD = probing depth; O = oral.

confirmed this hypothesis.[27] These studies seemed to demonstrate that micromovements up to 150 μ should be considered excessive and therefore deleterious for osseointegration. On the contrary, movements less than 150 μ seem to be tolerated.[26,27]

Success rates of the current study (100%) are comparable to those reported in the literature for implant-retained overdentures with delayed loading.[4,28,29] As far as implant-supported overdentures with delayed loading are concerned, no correlation has been found in the literature between success rate and the type of connecting system.[30,31]

Conversely, the number of implants placed, their distribution, and the type of rigid connection appears to be critical in cases of immediate loading. The choice of four implants and a U-shaped bar that rigidly connects them is based on the idea that this number of implants may offer sufficient stability and significantly reduce movements that may compromise osseointegration.[10–12,14,17]

The use of a U-shaped bar seems to reduce rotational movements and to transfer loads to the implants mostly in a vertical direction. This may provide the basis for immediate loading of endosseous implants without compromising osseointegration. As far as the distal extension of the prosthesis is concerned, the occlusion was never extended beyond the first molars, whereas the denture basis was constructed following the same principles of normal dentures.

In the present study, no correlation was found between implant dimensions and success rate, although the sample analyzed was too small to provide statistically significant results. Nevertheless, the length and diameter of immediately loaded implants, as well as bone quality and quantity, may be important factors for the application of this technique. Although the clinical evaluation of bone quality can be quite subjective, immediate loading of implants has been applied only in

TABLE 5 Bone Resorption Values in Control and Test Groups at 12 and 24 Months after Prosthetic Loading

	Values in Control Group		Values in Test Group	
Measurement	M	D	M	D
At 12 Months				
Mean	0.7	0.8	0.5	0.6
SD	0.3	0.3	0.3	0.4
Median	0.5	0.5	0.5	0.5
IQR	0.5	0.5	0.625	0.5
At 24 Months				
Mean	0.8	0.9	0.8	0.8
SD	0.3	0.3	0.5	0.4
Median	1	1	0.5	0.5
IQR	0.5	0.3	0.5	0.5

D = distal; IQR = interquartile range; M = mesial.

TABLE 6 Life Table Analysis Showing Cumulative Survival Rates of Implants

Time	No. of Implants	Failed Implants	Implants Withdrawn	CSR (%)
Loading–1 yr	40	0	0	100
1–2 yr	40	0	0	100

CSR = cumulative survival rate.

our patients with classes 1 to 3 bone quality according to Lekholm and Zarb's classification.[18]

Periimplant soft tissues parameters (MPI, MBI, and PD) did not present significant differences between the test and control groups after 2 years of functional loading and are also consistent with those reported in the literature.[30–36] Marginal bone loss values around implants did not present statistically significant differences between the two groups and are consistent with those reported by other authors in instances of delayed loading.[13,29,34–40]

Therefore, in cases of immediate loading, the presence of a microgap between the implant and the abutment in two-component implants (as compared with monocomponent transmucosal implants) seems not to be a critical factor as far as periimplant soft tissue health and bone resorption are concerned. However, this issue is still controversial. Ericsson and colleagues,[41] in a clinical study on Nobel Biocare implants, compared the traditional two-step surgical procedure and a one-step procedure, in which abutments were immediately screwed to the implants in a transmucosal fashion, and found no differences in success rates of implants. The histologic characteristics of the periimplant tissues (epithelium, connective tissue, and marginal bone in contact with connective tissue) in cases of one-piece implants without microgap[42,43] or of two-piece implants with microgap[44,45] have been analyzed by several authors. These studies showed that the histologic structure around implants in both groups (with and without microgap) was similar to that of marginal periodontal tissues. All of these studies demonstrated that there is a biologic requirement of 3 to 4 mm of supracrestal soft tissues, composed of approximately 2 mm of ephithelium and 1 to 1.5 mm of connective tissue.

Conversely, other studies using both monocomponent and bicomponent implants demonstrated differences at the implant-to-soft-tissue interface and at the implant-to-bone interface. Abrahamson and colleagues[46] studied the influence of the manipulation of a transmucosal abutment with two-piece implants in an experimental model with a beagle dog. After implant placement a 6-month period of plaque control was initiated. Once a month during this period, the abutment in the test side in each dog was disconnected and reconnected to the implant. The control abutment remained undisturbed for 6 months. The results showed that disconnection and subsequent reconnection of the abutment component of the implant compromised the mucosal barrier and resulted in a more apical zone of connective tissue integration. The authors suggested that bone resorption could be the result of tissue reactions initiated to establish a proper biologic width of the mucosal-implant barrier. Weber and colleagues[47] examined the healed periimplant tissues adjacent to two-piece and one-piece implants in beagle dogs. The results indicated that the apical extension of the periimplant epithelium was significantly greater and the attachment level significantly lower adjacent to two-piece implants with second-stage transmucosal abutments than to one-piece implants. This suggests that implant design influences marginal periimplant tissue integration.

Owing to these controversial results, more research is needed to elucidate the effect of intrinsic (implant design) as well as extrinsic (surgical techiques, bacterial plaque, occlusal loading, and time of loading) factors in the maintenance of healthy periimplant tissues.

CONCLUSION

Preliminary results of this prospective comparative study confirmed that endosseous implants supporting mandibular overdentures can be safely loaded immediately after placement, as previously reported by other retrospective studies,[10–17] both in cases of one-piece and two-piece implants. As far as MPI, MBI, PD, and periimplant bone resorption values are concerned, no statistically significant differences were found between the two groups at 12 and 24 months after prosthetic loading.

The immediate loading can substantially reduce the time of prosthetic rehabilitation, without jeopardizing long-term results and with relevant satisfaction for patients. Success criteria proposed by Albrektsson and colleagues[20] were fulfilled in both groups at 24 months' follow-up.

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