A New Device in Immediately Loaded Implant Treatment in the Edentulous Mandible

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Purpose: *This article reports preliminary clinical results of the Speed Master system, a method for immediate loading of implants for the treatment of mandibular edentulism.* ***Materials and Methods:*** *Fifteen patients with edentulous mandibles were consecutively included in the study. Each received 4 implants between the mental foramina placed using the system's surgical guides. Permanent fixed prostheses fabricated over premanufactured titanium bars were attached to the implants on the day of implant placement. The patients were followed for 15 to 27 months (mean, 19 months). Peri-implant tissues were periodically evaluated. Marginal bone loss was monitored with periapical radiographs using a computerized technique. Satisfaction was assessed by means of a questionnaire.* ***Results:*** *The overall implant and prosthetic survival rates were 100%. At the time of the final follow-up visit, mean marginal bone loss was 1.11 mm, and bleeding on probing was not observed. Only 6.7% of the patients reported any discomfort during treatment, and all patients would recommend the procedure to others.* ***Discussion:*** *The immediate loading of implants placed in the edentulous mandible with the Speed Master surgical and prosthetic protocol reduces treatment time and number of surgical procedures in comparison to classic delayed loading protocols.* ***Conclusion:*** *The rehabilitation of the mandible with an immediately delivered occlusally loaded hybrid prosthesis supported by 4 implants does not appear to jeopardize the success of the osseointegration and represents a viable treatment option.* Int J Oral Maxillofac Implants 2006;21:615–622

Key words: *edentulous, immediately loaded fixed prostheses, immediately loaded implants, mandibular implants, single-stage implant placement*

Long-term studies have demonstrated that dental implants can be successfully used for the rehabilitation of edentulous jaws.[1–3] The 2-stage surgical protocol[2] for implant placement was designed to protect the implants from possible bacterial contamination and to avoid early loading during the initial osseointegration period. Keeping the implants submerged for 3 to 6 months was considered a basic requirement for osseointegration.[1,2] Consequently, patients were obliged either to wear a removable temporary prosthesis or to be without dentition for an extended period of time.[4]

The predictability of the original treatment protocol has led to developments aimed at simplifying the technique and reducing the healing time.[5,6] Numerous authors have reported favorable clinical outcomes using single-stage implants.[7–14] With single-stage implants, transmucosal abutments are attached at the time of implant placement rather than after a 3- to 6-month healing period. However, a healing period is required before the implants can be placed into use.

The resistance of some patients to the idea of wearing a removable prosthesis and the search for simplified treatment protocols with reduced healing times gave rise to a single-stage procedure that includes submitting implants to loading immediately after placement. Schnitman and colleagues[15] estab-

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lished a protocol for immediate loading of implants in the rehabilitation of patients with totally edentulous mandibles using fixed prostheses. Brånemark and associates[5] presented an immediately loaded implant system for the same indication, but using only 3 implants. This protocol, called "Brånemark Novum," involves prefabricated components and surgical guides and allows the attachment of the permanent fixed prosthesis on the day of implant placement.

Good results have been achieved with 1-stage surgery and immediate loading techniques, particularly with implants placed in the anterior mandible. Controlled immediate loading of nonsubmerged implants does not appear to jeopardize the process of osseointegration.[6]

Several protocols[5,6,15] for the immediate loading of implants in the edentulous mandible have been proposed that allow the patient to wear a fixed prosthesis during the osseointegration period without compromising long-term success. The reported procedures and results are consistent with the goals of a simplified treatment protocol and reduced healing time.

"Speed Master" is a system designed for immediately loaded implant treatment. It enables the placement of 4 implants in the edentulous mandible using surgical guides. A permanent fixed prosthesis fabricated over a premanufactured titanium bar is attached to the implants on the day of implant placement. The objective of this investigation was to report on this new system and the preliminary clinical results that have been achieved with it in the edentulous mandible.

MATERIALS AND METHODS

The investigation was conducted at São Paulo State University, São José dos Campos School of Dentistry. Between August 2003 and October 2005, 15 patients with good medical health referred for restoration of their edentulous mandibles with endosseous implants were consecutively included in the study. Patients were required to fulfill the inclusion criteria proposed by Testori and colleagues[16] for immediate occlusal loading: *(1)* completely edentulous in the mandible; *(2)* rehabilitation with oral implants desired; *(3)* physically able to tolerate conventional surgical and restorative procedures; *(4)* informed consent signed; and *(5)* good primary stability, with the implants seated with a torque ≥ 32 Ncm. The exclusion criteria were: *(1)* active infection in the sites intended for implant placement; *(2)* systemic diseases (regardless of control) that could compromise osseointegration; *(3)* treatment with radiation therapy used for malignant tumors in the craniofacial region within the past 12 months; *(4)* refusal to cease use of cigarettes 2 weeks before and 2 weeks after the surgery; *(5)* pregnancy; and *(6)* severe bruxism.

The patients were evaluated preoperatively with respect to jaw size, bone volume, jaw relations, maxillomandibular distance, and occlusal relation. Preoperative analysis of the anatomic conditions was performed with panoramic radiography and computed tomography. Impressions were made of the maxilla and mandible, and laboratory casts were fabricated. Shade and mold of prosthetic teeth were selected, and a wax trial denture was fabricated for the mandible. The diagnostic waxup was used to clinically assess occlusion. The approval of the patients was requested, especially regarding esthetic aspects. Prior to surgery, the correct vertical dimension was registered by measuring the distance between 2 reference points marked on the patient's face with a skin marker pen, 1 on the chin and the other on the nose base.

All patients started penicillin the day before the surgery (2 g amoxicillin/day) and were premedicated 1 hour before surgery with 4 mg dexamethasone and 10 mg diazepam. Local anesthesia (2% mepivacaine/adrenaline 1:100,000) was also administered.

Surgery began with a crestal incision from the position of the right first molar to that of the left first molar. The mandible was exposed, and the mental foramina were identified. The crestal bone in the anterior region was reduced under profuse irrigation with sterile saline solution to create a 4- to 5-mm wide bone platform to accommodate the surgical guide template. Direction indicators helped to determine the final position of the template before fixation with 3 temporary screws (Fig 1). This template had 4 orifices of gradually increasing dimensions for the insertion and removal of prefabricated drill guides during implant site preparation. The drill guides were identified by their different colors (silver for the start drill and the 2.0-mm twist drill, yellow for the 3.0-mm twist drill, blue for the 3.15-mm twist drill, and purple for the 3.35-mm twist drill). Each drill was used successively, beginning with the start drill, to prepare sites for the 4 implants. The drill guide system (the template) ensured that drilling was performed always in the same position and at the same angulation. In addition to the conventional drill irrigation, frontal perforations in the template allowed profuse irrigation with sterile saline solution to compensate for the increased risk of heat generation (Fig 2). During the implant placement procedure, the insertion torque was registered by the surgical unit. Implants seated with a torque < 32 Ncm were not included in the study and were submitted to a classic delayed loading protocol. When all 4 implants (Connect AR; Conexão, São Paulo, Brazil) were in place, the temporary fixation screws and the template were removed.

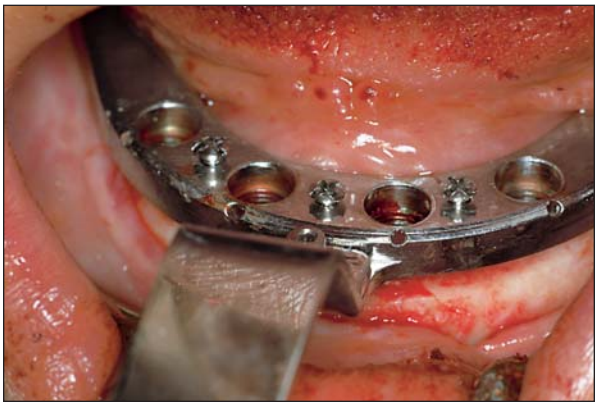

Fig 1 After reduction of the alveolar crest, the surgical guide template was affixed with 3 temporary screws.

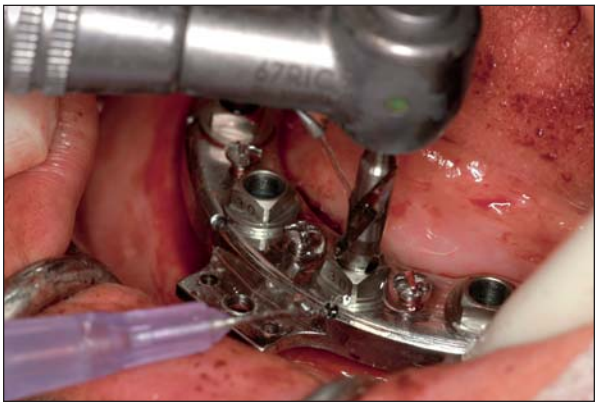

Fig 2 Drilling was conducted in the same direction with the help of the drill guides, which were identified by different colors (purple = 3.35-mm twist drill). Frontal perforations in the template allowed profuse irrigation.

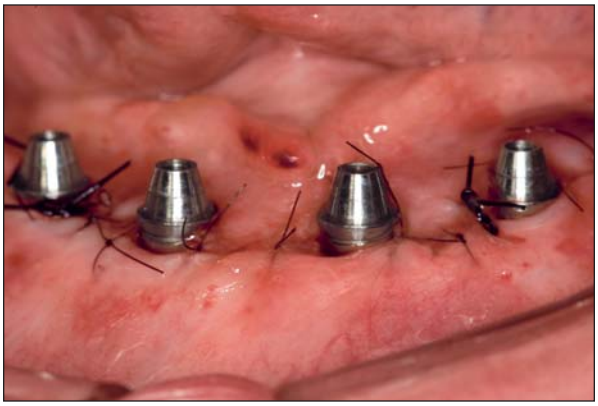

Fig 3 Abutments were connected to the implants, and soft tissues were sutured back in position.

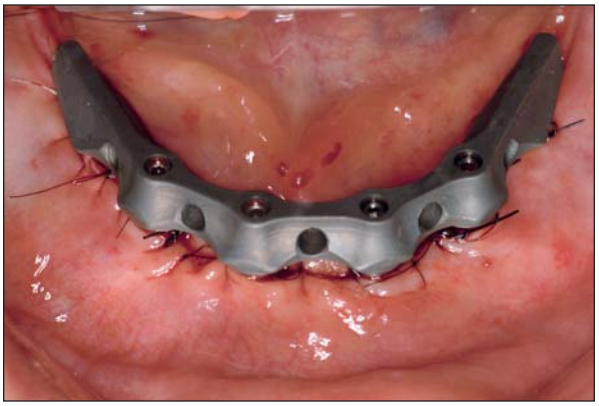

Fig 4 Prefabricated titanium bar in position to establish correct jaw relations.

Abutments were connected to the implants (022001; Conexão) by fastening screws with a torque wrench (400000; Conexão) using 20 Ncm torque. The soft tissues were readapted around the abutments and sutured into position (Fig 3). Four retaining screws were used to connect a prefabricated titanium bar to the abutments (Fig 4). Acrylic resin (GC pattern resin; GC Dental Industrial, Tokyo, Japan) was used for indexing the maxillary teeth to the titanium bar in the mandible. The distance between facial reference marks registered prior to surgery was used to establish the correct vertical dimension.

The titanium screws were removed, and impression screws were used to attach the prefabricated titanium bar to the abutments. A vinyl polysiloxane silicone impression (Aquasil; Dentsply, Petrópolis, Brazil) was made using a custom open resin tray. The impression screws were loosened, and the bar was gently removed inside the impression. Abutment analogs (101001; Conexão) were connected to the bar, and the impression was poured in stone (Durone; Dentsply, Petrópolis, Brazil) to make the working cast.

The maxillary cast was mounted in a semiadjustable articulator. The mandibular cast was mounted based on the acrylic resin index. A tooth arrangement was then placed on the titanium bar. Light-cured composite resin (Versyo; Heraeus Kulzer, Hanau, Germany) was used as the denture base material to reduce laboratory time. After curing, the polymerized prosthesis was finished and polished prior to delivery. The fixed partial denture was connected to the abutments by fastening the 4 titanium retaining screws with the torque wrench using 20 Ncm torque (Fig 5). Screw holes were closed with the same light-cured composite resin used for the denture base. The necessary occlusal adjustments were made, and the marginal adaptation of the bars to the abutments was confirmed with periapical radiographs.

Antibiotics were prescribed for 7 days postoperatively (2 g amoxicillin/d); dipyrone was also prescribed postoperatively, if necessary. Patients were

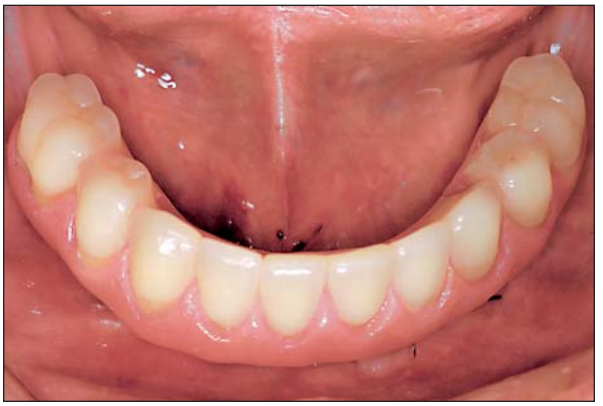

Fig 5 The finished fixed partial denture in position a few hours after the implant placement.

Table 1 Characteristics of the 40 Immediately Loaded Implants

Diameter × length (mm)	No. of implants placed
3.75 × 13	21
3.75 × 15	4
4.00 × 13	21
4.00 × 15	14
Total	60

Table 2 Patient Data and Length of Follow-up

Patient	Age (y)	Sex	Length of follow-up (mo)
ED	42	F	15
JR	74	M	27
OP	54	M	16
FH	59	F	20
MR	61	F	18
JL	64	M	19
AR	66	M	16
BI	54	F	21
RT	54	M	19
JU	47	M	19
VB	62	M	19
LS	48	F	17
GC	65	F	21
NR	63	M	19
EG	57	M	19
Mean	58		19

instructed to use cold applications (ice packs) on the face during the first 24 hours and to gently rinse the mouth after each meal using a chlorhexidine digluconate rinse (0.12%). During the first month, the patients were recommended to consume easily chewable food.

All patients included were part of a regular recall program. During the first year, they were evaluated at intervals of 3 months; subsequently, they were evaluated at 6-month intervals. The success criteria proposed by Albrektsson and Zarb[17] were applied in evaluating each implant. Bleeding on probing was measured in the 3-, 6-, 12-, and 18-month follow-up evaluations at 6 points around each implant without removing the prosthesis and was scored as either 0 (no bleeding) or 1 (bleeding occurred).[18] Peri-implant tissue condition was evaluated at each follow-up visit. Peri-implant marginal bone loss was monitored based on the periapical radiographs using a computerized measuring technique. Intraoral periapical radiographs, obtained using customized positioners at baseline (ie, on the day of implant placement) and at 6, 12, and 18 months, were scanned (HP Scanjet 3570 C; Hewlett Packard, Palo Alto, CA) at a resolution of 600 dpi and analyzed with image analysis software (Scion Image; Scion, Frederick, MD) that was able to compensate for radiographic distortion on the basis of the known diameter and length of the implants. The software calculated peri-implant marginal bone loss at the mesial and distal aspects of the implants.

For the satisfaction evaluation, the patients completed questionnaires at the 1-month follow-up visit. The questions were based on the questionnaire proposed by Brånemark and associates.[5]

RESULTS

Nine men and 6 women were enrolled in the study. The average age at the time of implant surgery was 58 years (range, 42 to 74 years).

A total of 60 implants were placed. The lengths and diameters of all the implants are summarized in Table 1. All implants were placed in the interforaminal area and seated with a torque ≥ 32 Ncm. Patients were rehabilitated with hybrid prostheses supported by 4 immediately loaded implants provided on the day of implant placement.

The patients were followed for 15 to 27 months (mean, 19 months; Table 2). There was 100% compliance with the study protocol, with no patients lost to follow-up. The cumulative survival rate was 100% at 18 months (for 10 implants). All immediately loaded implants in this study were clinically stable and met the success criteria (Figs 6 and 7). At the time of the final follow-up visit, no prosthesis had failed; thus, the prosthetic survival rate was also 100%. There were no signs of malocclusion or bruxism nor any reports of subjective masticatory malfunction for any of the patients. Mean marginal bone loss was 0.72 mm (SD = 0.28; n = 15) at 6 months,

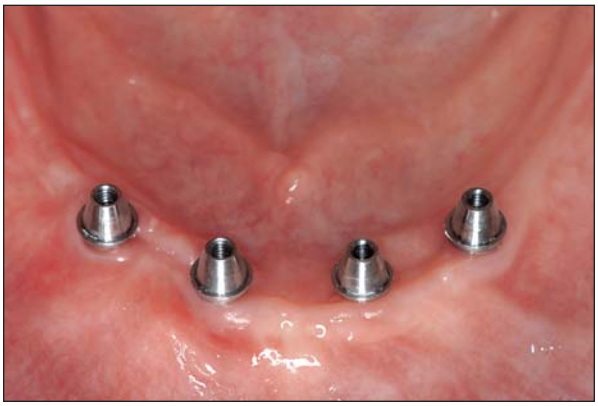

Fig 6 Clinical aspect at 12 months.

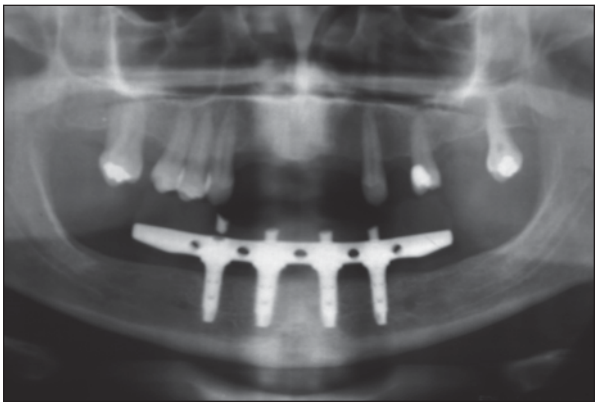

Fig 7 Panoramic radiograph at 12 months.

Table 3 Distribution of Patient Answers to Questionnaire

Question/response	n	%	Mean
1. Did you experience anything uncomfortable or unpleasant during the treatment?			
No	14	93.3	
Yes, please describe	1	6.7	
No answer	0	0	
2. On a scale from 1 to 10, where 10 equals extremely satisfied and 1 equals extremely disappointed, how satisfied are you with the treatment?	15		9.2
3. What would you say to another patient who was considering the treatment?			
I would strongly recommend it	12	80	
I would recommend it	3	20	
I would not recommend it	0	0	

0.22 mm (SD = 0.013; n = 15) at 12 months, and 0.17 mm at 18 months (SD = 0.023; n = 10). The accumulated mean marginal bone loss was 1.11 mm.

Soft tissues were completely healed after 4 weeks. At the 3-month examination, 52 implants (86.6%) did not demonstrate any sign of inflammatory tissue, while in the remaining 8 implants (13.3%) bleeding on probing was observed. In the 6- and 12-month follow-up evaluations, 56 implants (93.3%) did not demonstrate any sign of peri-implant inflammation, while in the remaining 4 implants (6.6%) bleeding on probing was observed. In the 18-month follow-up evaluation, bleeding on probing was not observed, and all implants presented healthy tissues (n = 40).

All 15 of the questionnaires issued to the patients were returned. Subjective answers demonstrated a high degree of satisfaction with the treatment outcome (Table 3). The patient questionnaire demonstrated that 93% of the patients experienced no discomfort during treatment. One subjective complaint was reported during the follow-up period: a single episode of anterior mandible paresthesia in the anterior mandible that disappeared during the first month. All patients would recommend the procedure to others.

DISCUSSION

There is a movement within implant dentistry to reduce treatment time and simplify procedures in order to increase patient tolerance and reduce the probability of complications.[16] The advantages of the treatment of mandibular edentulism with implant-supported prostheses with early occlusal function (immediate load) have been reported in the literature.[4,5,15,19,20] Careful attention should be given to the diagnostic phase, in which the feasibility of a desired final outcome is evaluated. Regardless of the technique used, the clinical, surgical, prosthetic, occlusal, and esthetic aspects, as well as the patient's expectations, must be assessed before proceeding.[6]

Biomechanical analysis of conventional implant-supported rehabilitation (2 stages) reveals that stress introduced into the implant system as a result of prosthesis misfit may be present many years after placement because of the ankylotic character of the osseointegration.[21,22] For that reason, misfit may lead to problems such as screw loosening, fracture of prosthetic components or implants, and peri-implant bone loss.[23] Thus, a precise fit between the implant

abutment and superstructure and subsequent absence of bone stress are important factors for the long-term success of implant-supported restorations. However, according to Skalak[22] and Gallucci and coworkers,[6] the static stresses caused by prosthetic misfit dissipate during the first weeks of osseointegration in the immediate load procedure, which is not possible when implants are completely osseointegrated prior to loading. The lamellar bone, present when implants are placed, initially maintains the stresses. As this bone is resorbed, the newly formed bone will probably not maintain the initial stresses. Therefore, the residual stresses caused by prosthetic misfit may be relieved by the sequence of remodeling processes that lead to osseointegration. Additionally, investigations of immediately loaded implants[6,22,24] have demonstrated that osseointegration can indeed be reached with a percentage of bone-to-implant contact that is similar to, or even higher than, that found with unloaded implants, which would account for the greater implant stability.

According to Pilliar and associates[25] and Brunski[26] there is a critical threshold of micromotion above which fibrous encapsulation prevails over osseointegration. When the amount of micromotion at the bone-implant interface is kept beneath this threshold during the healing phase, immediate occlusal loading procedures can be successful. Only excessive micromotion is directly implicated in the formation of fibrous encapsulation. This critical level, however, is not zero, as is generally interpreted. In a literature review of the effect of micromotion on the bone-implant interface, Szmukler-Moncler and associates[27] stated that the threshold for intolerable micromotion is between 50 and 150 μm.

The system investigated in the present study uses a rigid metallic structure to splint the implants, as recommended by other investigators.[4,5,16,20,24,28] The metal reinforcement reduces micromovement, provides resistance to forces in all directions, and allows osseointegration to occur safely. However, Gallucci and colleagues[6] found that a metal-free immediate provisional fixed cross-arch restoration with a continuous palatal connector did not adversely affect osseointegration of immediately loaded splinted implants.

The implants placed must be numerous enough to be distributed in different segments along the arch. The more segments used, the better the stabilization achieved. Four implants distributed along the arch, as proposed by the Speed Master technique, can compose a polygonal sustaining base with favorable distribution of occlusal forces, thus maintaining the level of micromotion beneath the critical threshold.[24–27]

Brånemark and coworkers[5] described a technique for preparation of a definitive hybrid mandibular prosthesis in 1 day. They recommended the use of three 5-mm-diameter implants inserted with a special hardware in the anterior mandible and demonstrated that 3 implants were sufficient to support the hybrid prosthesis. In the present study, the use of standard implants with a diameter of 3.75 or 4 mm was preferred because these widths offer more prosthetic and surgical flexibility. The technique used in this study avoids excessive obligatory osteoplasty. In addition, the use of more than 3 implants allows the continued use of the prosthesis in the event of a single implant failure. After removal of the failed implant and site healing, a new implant can be placed in the same position using the prefabricated surgical guide template, and the same fixed partial denture can be immediately attached.

Initial stability of the implants immediately after placement has been widely considered a basic requirement for successful immediate loading.[20,29–32] Good primary stability was considered an inclusion criterion in the present study. During the implant placement procedure, insertion torque was registered by the surgical unit. Only implants seated with a torque ≥ 32 Ncm were included in the study.

The utilization of the device described in the present paper resulted in high implant and prosthetic survival rates (100%). The implant failure rates reported by Brånemark and coworkers[5] with the Novum protocol (2%) might be explained by the fact that the failures in that investigation were not considered a consequence of the same-day prosthetic loading concept but rather of excessive heat generation from wide-diameter drills used in dense bone during the drilling sequence. In the Speed Master system, conventional drill irrigation is combined with the irrigation through frontal perforations in the template, allowing profuse irrigation with sterile saline solution, which compensates for the increased risk of heat generation. Also, standard-diameter implants were used in the present study (3.75 to 4 mm), reducing the number and diameter of the drills used during the drilling sequence.

Because implant macro- and microscopic features play a crucial role during the healing phase,[19,25,27,32] it is important, when documenting immediate loading cases, to clearly identify the type of implant being used. In this study, all patients received dual acid-etched cylindric screw-shaped internal hex implants (Connect AR; Conexão).

Tarnow and associates[20] concluded that the failure of immediately loaded implants in 2 of 10 patients was likely the result of the removal of provisional restorations to evaluate the implant stability. For this reason,

during the healing phase in the pres-ent study, the authors did not routinely remove the restorations. In most cases, soft tissues were readapted around the abutments and sutured back in position with resorbable suture. In 1 case, nylon was used, and suture removal was extremely difficult and uncomfortable for the patient because of the presence of the prosthesis.

In this study, the observed marginal bone change around the immediately loaded implants (1.11 mm) was similar to that reported for implants that were not immediately loaded. Testori and coworkers[24] and Brånemark and associates[5] achieved similar results.

At the time of the 18-month follow-up evaluation, bleeding on probing was not observed (40 implants). The small number of patients, relatively short functional period, and strict and frequent clinical evaluation, including rigorous periodontal monitoring, may explain the absence of peri-implant inflammatory tissue. The strict follow-up schedule may have helped motivate patients to comply with oral hygiene instructions at home.

A high degree of satisfaction with the new procedure was seen among the patients. The majority of the patients (93%) considered the treatment to be unrelated to discomfort and would recommend the treatment to other patients.

The ultimate goal of an immediate loading protocol is to reduce the number of surgical procedures and shorten the time frame between surgery and prosthetic delivery without sacrificing implant success rates. These new protocols will ultimately lessen patients' reservations about the procedure and result in increased acceptance of implant therapy.

CONCLUSIONS

Within its limitations (the small population of patients and short length of follow-up), this investigation demonstrated that the Speed Master surgical and prosthetic protocol allowed successful prosthetic rehabilitation of the edentulous mandible with the permanent fixed prostheses on the day of implant placement. The preliminary results suggest that the rehabilitation of the mandible by an immediate occlusally loaded hybrid prosthesis supported by 4 implants does not appear to jeopardize successful osseointegration and represents a viable alternative treatment to classic delayed loading protocols.

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