A Comparative Clinical Investigation of 2 Early Loaded ITI Dental Implants Supporting an Overdenture in the Mandible

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The purpose of this prospective clinical study was to evaluate the efficacy of early loading of implants and to provide evidence to support simplified treatment of mandibular edentulism by using an implant designed for 1-stage surgery, combined with ball abutments to circumvent the need for a fixed prosthodontic superstructure. Historically, the recommended time between the placement and functional loading of dental implants has been 3 months in the mandible. This recommendation is the result of a systematically chosen healing time during development of implant treatment. In recent years, histologic and experimental studies have shown that specially designed implants can result in increased bone-to-implant contact at earlier healing times. Accordingly, these implants can be placed into function faster than previously recommended. In this study, 21 patients aged between 61 and 85 years with edentulous mandibles were included. All received 2 titanium plasma-sprayed, solid-screw dental implants in the interforaminal region. Ten patients had the implants loaded with an overdenture connected with ball abutments after 3 months (control group). The other 11 patients (test group) had prostheses connected to the ball abutments after a maximum of 3 weeks. Marginal bone resorption, Periotest values, and patient satisfaction were evaluated. The cumulative post-loading implant survival rate was 100% for both groups after 24 months. Marginal bone resorption after 1 year around all implants ranged from 0 to 2 mm (no significant differences between groups; $P < .05$). Periotest values for all implants 1 year after loading were below zero (range −1 to −6). The results of this clinical trial suggest that successful early loading of 2 implants is possible provided there is uncomplicated implant placement. (Int J Oral Maxillofac Implants 2001;16:246–251)

Key words: *early loading, edentulous mandible, endosseous dental implantation, overdenture prosthesis*

Edentulous patients with a severely resorbed mandible represent a significant health care problem in the growing elderly population. Despite adequate denture fabrication, it is not possible in many instances to achieve conventional optimal denture retention and stability. This may be caused by poor jaw and ridge relationship, psychologic conditions, reduced neuromuscular coordination, inadequate quality and quantity of available bone and alveolar mucosa, or inadequate vestibular depth.[1] Different treatment options are available for achieving increased retention. These include preprosthetic surgery to augment the alveolar ridge or increase the vestibular depth.

Placement of dental implants to provide anchorage for implant-supported overdentures or fixed prostheses has increasingly dominated treatment strategies for the last 2 decades.[2–5] The use of submerged dental implants to support fixed or removable prostheses for the treatment of edentulous mandibles is well documented.[3–6] However, especially during the last decade, it was demonstrated that osseointegration can also be achieved through the use of a non-submerged technique.[7–10] Historically, the recommended time between placement and functional loading of dental

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implants has been 3 months in the mandible. This recommendation is a result of systematically chosen healing times during the development of implant treatment.[11] Recent histologic and experimental studies have proven that the use of specially designed implants may result in increased and earlier bone-to-implant contact. This led to the conclusion that implants can be brought into function earlier than previously recommended.[12–14] The predictability of the original Brånemark treatment protocol has led to development aimed at simplifying the technique and reducing healing time. Ericsson and coworkers found that there was no significant difference in marginal bone resorption, irrespective of whether implants were placed according to a 1-stage or a traditional 2-stage procedure.[7,9]

During the last 10 years, the results of several studies on immediate loading of implants have been published. Schnitman and colleagues concluded in 1990 that overall long-term implant therapy was not adversely affected by this technique.[15] However, in 1997 they reported the 10-year follow-up of the same patient group, in which 4 of 28 immediately loaded implants were lost; in the standard treatment group (n = 35 submerged implants), the survival rate was 100%.[13] The implants used in this study were not designed for single-stage surgery. In a 1994 study by Henry and Rosenberg it was concluded that immediate loading of adequately placed non-submerged implants by reinsertion of a modified denture did not appear to jeopardize the process of osseointegration in the anterior mandible.[10] In 1999 Randow and others[12] reported on treatment of complete mandibular edentulism using Brånemark System implants in a 1-stage technique with loading within 20 days for a test group consisting of 16 patients. In a control group of 10 patients, a 2-stage procedure with loading after 4 months was applied. After 18 months of follow-up, no implants were lost in either patient group. Moreover, the marginal bone loss was higher in the control group.[12] Thus, immediately loaded 1-step implants have demonstrated promising results, particularly when applied in the anterior mandible. However, the reported procedures and results demonstrate variations in implant survival clinical procedure and time of actual loading, indicating that there is a lack of consensus regarding an optimal approach for immediate loading of different types of implants. If future investigations conclude that the concept of immediate loading is as safe as the initial concept for implant treatment as proposed by Brånemark, treatment of the edentulous patient can be provided at a lower cost and in a dramatically reduced treatment period.

The purpose of this prospective clinical study was to evaluate the efficacy of early loading of ITI implants (Straumann, Waldenburg, Switzerland) and to provide evidence to support simplified treatment of mandibular edentulism by using an implant designed for 1-stage surgery combined with ball abutments to circumvent the need for a fixed prosthodontic superstructure.

MATERIALS AND METHODS

Between 1997 and 1999, a total of 21 patients were consecutively enrolled in this prospective clinical study if they met stated inclusion criteria. Their ages ranged from 61 to 85 years (mean 75.7 years). The group consisted of 14 females and 7 males. All were referred for treatment of specific problems with mandibular prostheses. Preoperative clinical and radiographic examinations were carried out. Medical and psychosocial status were evaluated. None of these patients suffered from systemic disease that might increase pre- or postoperative morbidity. Thorough information about the treatment procedure and its risks and benefits was given to the patients. The preoperative examination included a panoramic radiograph, which was combined with clinical examination for the assessment of bone volume and shape in the interforaminal region. Inclusion criteria for this trial were as follows. Participants had to be more than 60 years of age and have an edentulous mandible. Patients with serious mental illness or a history of drug or alcohol abuse and patients operated on for heart disease within the last 6 months were excluded. Intraorally, attached keratinized mucosa had to be present on the alveolar crest at the implant sites. If primary implant stability could not be obtained because of poor bone quality, the patient was excluded from the study. The criteria for implant success were based upon the proposal of Albrektsson and colleagues.[16]

The patients were divided into 2 treatment groups. In the first group, which consisted of the first 10 examined individuals who fulfilled the inclusion criteria, 2 titanium plasma-sprayed solid-screw ITI dental implants were placed into the interforaminal region. Healing abutments were connected and replaced by ball abutments after 3 months. At this point, a new denture prosthesis was fabricated and connected to the ball abutments. Two weeks postoperatively, prostheses were adjusted with a soft liner to the healing abutments. This group of 10 patients served as the control. The test group consisted of 11 consecutive individuals examined who fulfilled the inclusion criteria for this

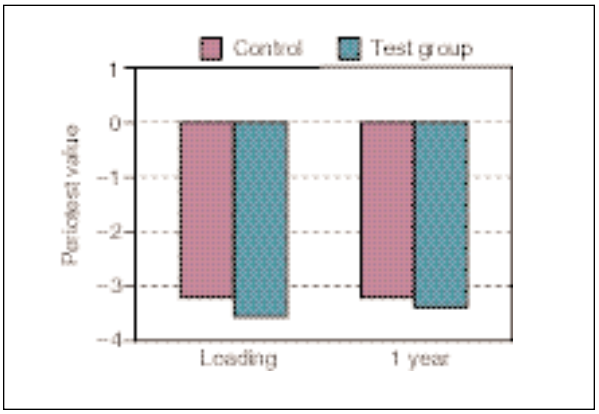

Fig 1 Periotest values for test and control groups at loading and after 1 year.

trial. These patients also had 2 ITI dental implants placed. However, when wound healing around the implants was satisfactory—that is, a maximum of 3 weeks, but not less than 2 weeks—ball abutments were connected and definitive overdentures adjusted. Consequently, within 3 weeks this test group had early loading implant treatment.

The implants were placed through mucoperiosteal flaps of limited dimension. An incision was made on the alveolar ridge crest in the interforaminal region, with a short releasing incision in the midline. The implants were placed according to the manufacturer's instruction. Implants with a diameter of 3.3 mm or 4.1 mm were used, depending on the width of available bone. The length of the implants varied from 10 to 16 mm. All implants were provided with healing abutments, adjusted to the height of the surrounding mucosa. According to the protocol, clindamycin 600 mg (Dalacin, Pharmacia & Upjohn, Wilmington, DE) was given 1 hour preoperatively, followed by 300 mg in the evening after surgery and 300 mg the first day after surgery. During healing of the peri-implant mucosa, patients used a mouthrinse with chlorhexidine twice daily.

At the time of overdenture connection, a panoramic radiograph was taken in both groups and implant stability was assessed by Periotest (Siemens, Erlangen, Germany). After 3, 6, and 12 months, and annually thereafter, the patients were recalled for clinical examination. Panoramic radiographs for assessment of marginal bone resorption and Periotest recordings were obtained at the annual appointments only. No corrections were made for the error in the use of panoramic radiographs. Marginal resorption was assessed mesially and distally. The highest score was routinely used. Bleeding on probing was evaluated at the implant sites as bleeding or no bleeding.

Patient satisfaction with the treatment was registered by asking simple oral questions, and responses were classified into 3 categories: very content, moderately content, and not satisfied. All surgical procedures and follow-up recordings were done by the same surgeon. Prosthetic treatment was performed by different colleagues in the Department of Prosthodontics.

For statistical analysis of the results, Student's *t* test was used.

RESULTS

No implants were lost during follow-up; however, 2 patients died during the study period, 1 in the control group after 1 year of follow-up and 1 shortly after loading. One patient in the test group was hospitalized shortly after implant placement and for 4 weeks she was lost to follow-up. Her implants were permanently loaded 6 weeks after surgery. In spite of this delayed loading, it was decided not to exclude her from the experimental group. After 1 year, marginal bone resorption around all implants in both groups ranged from 0 to 2 mm. Two patients in the test group had 1 implant with 1 and 2 mm marginal resorption, respectively. In the control group, 2 patients each had 1 implant with 1 mm resorption. Marginal bone resorption around all the other implants in this trial was equal to zero. For those patients who have been followed for 2 years (15 individuals), the resorption has increased at 1 implant site (from 0 mm to 1 mm). When the test and the control groups were compared, significant differences were not found ($P < .05$). One year after loading, Periotest values for all implants ranged from –1 to –6. The mean value at loading for test group implants was –3.5; after 1 year it was –3.3. In the control group, the corresponding numbers were –3.1 and –3.1 (Fig 1). The differences between the test and control groups were not significant ($P < .05$).

One patient in the experimental group had a positive Periotest value for 1 implant at the time of loading (+2). One year later, it had decreased to –5. In 6 patients, bleeding on probing was found around 1 or both implants. However, no correlation was found between marginal bone loss and bleeding on probing. Inflammation was seen in patients with a restricted rim of firm mucosa at the implant sites and where the ball abutment did not fit the height of the mucosa (too short). Unfortunately, the ball abutments were available in only 1 standard size (Fig 2). Three patients had a daily smoking habit. One of them presented with peri-implant inflammation but no marginal bone resorption. All patients in both

groups were more comfortable after treatment than before treatment. One patient suffered from erosive lichen planus and was not able to wear denture prostheses before the treatment. After the implant-retained overdenture was placed, the patient's situation improved considerably. Six patients complained about food impaction beneath the prostheses. However, these patients reported that function was still considerably better than before treatment. One patient wanted treatment with a fixed prosthesis and actually had this done in a private clinic 1.5 years after loading with the overdenture. Overall patient satisfaction after 1 year was as follows: 13 patients were very content, 6 patients were moderately content, and 1 patient was not satisfied.

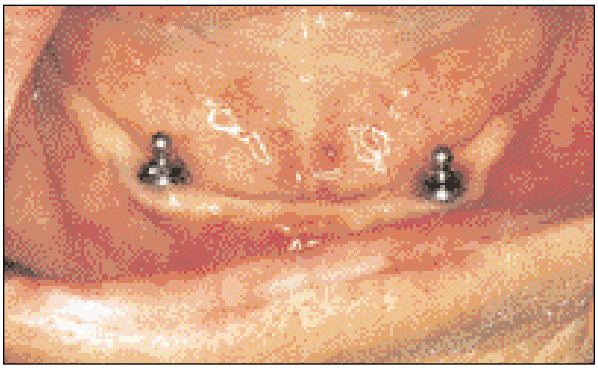

Fig 2 Ideal peri-implant conditions.

DISCUSSION

The aim of the present study was to determine the outcome of early loading of 2 ITI dental implants with an overdenture in the mandible. Edentulism is a problem predominantly in elderly people, among whom limited physical and economic resources may prevent consideration of extensive treatment. If optimal implant treatment can be provided in a short period of time with single-stage surgery and immediate loading of the implants, it would certainly be a benefit for these patients. In this trial, 11 patients were treated according to an early loading concept and compared to a control group of 10 patients, in whom standard treatment modalities were applied. The implant survival rate in both groups (100%) and the high satisfaction rate among the patients indicate that this is a promising treatment concept, although the sample size is quite small.

The outcomes of several other clinical reports have demonstrated that patient satisfaction was improved more by this treatment method than for conventional complete mandibular denture treatment in terms of function, retention, speech, and comfort.[17,18] The non-submerged approach simplifies the protocol, and several investigators have demonstrated results that were comparable to those obtained using a 2-stage surgical procedure.[8,12,19–22] The result of the next advancement in treatment protocols, the immediate loading concept, has been demonstrated in clinical studies by Randow and coworkers.[12] They concluded that this treatment approach should be strictly limited to the interforaminal area of the edentulous mandible. Brånemark and colleagues loaded implants with fixed prostheses on the day of surgery, with success rates of 98% after 1 year of patient follow-up.[14] In the present study, patients in the control group had their prostheses adjusted and relined during the osseointegration period. This apparently does not jeopardize implant osseointegration, even though such loading may deliver uncontrolled forces to the implants. This has been confirmed by the experience of at least one other group of investigators.[22]

Radiographic examination for assessment of marginal bone resorption in this study was performed with panoramic radiographs. This method may be questioned; however, standard periodic identical intraoral radiographs can be difficult to obtain in patients with edentulous and severely resorbed mandibles. Sewerin and colleagues stated that the use of strict orthogonal projection angles does not necessarily improve diagnostic accuracy.[23] Furthermore, measurement of marginal bone resorption using panoramic radiographs was used in 2 earlier studies by Røynesdal and associates[24,25] and in a clinical trial by Wismeijer and colleagues.[26] Smoking has been suggested by some investigators to contribute to implant failure.[27] In spite of the fact that 3 of the patients in this trial (14.3%) were daily smokers, it did not influence the survival rate of the implants or the rate of marginal bone resorption (0 mm in all smokers). Periotest values in this trial were all within the osseointegration range for dental implants (–7 to +9). From a clinical point of view, if an implant has a score, for instance, between –3 and +3, it is considered to be osseointegrated according to the manufacturer's directions for use. These values are influenced by the quality of the surrounding bone, the height of the connected abutment, and by angulation of the handpiece.[28–30] While this device is an objective and easily applied method for assessment of implant stability, it must be regarded as supplemental to radiographic and clinical tests (percussion mobility testing) when

evaluating the status of an individual implant.[31,32] The negative mean values assessed indicate sufficient bone anchorage of the implants.

The ITI dental implant is designed for 1-stage surgery, with a long neck that is intended to minimize problems with inflammation and bone resorption caused by contamination of the implant-abutment microgap by microorganisms from the oral environment.[33] This design may explain why only minor amounts of marginal bone resorption were seen in this trial compared to studies where 2-stage implants were used in 1-stage surgical treatment.[25] It is well known that exposure of marginal bone will result in some bone loss.[34] The second-stage surgery (abutment connection) could be another explanation for the bone loss observed in earlier studies.

There are several advantages to 1-stage surgery, when it is indicated, and even more to early loading. The number of patient surgeries is reduced. The total healing time and total treatment time are reduced. The use of ball abutments is more economical than custom-made superstructures, and it has been shown experimentally to be the most retentive system available for implant abutments.[35] However, 1-stage surgery also has some disadvantages, such as unpredictable loading forces and the inability to include augmentation techniques.

CONCLUSION

The present clinical investigation indicated that 2 solid-screw dental implants can be anchored in the interforaminal mandibular area and successfully support an overdenture placed soon after implant placement. On the assumption that primary stability of the implant is achieved and the inclusion criteria in this study are strictly followed, the early loading concept may be a promising treatment protocol for the future. In this study, survival of implants loaded 3 weeks after implant placement was similar to the survival rate of implants loaded in a more conventional time frame. However, the maximum evaluation period of 24 months after loading in this trial is short. Further evaluation for at least 5 years is necessary before a more definitive conclusion in this matter can be reached.

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