Brånemark Novum®: A New Treatment Concept for Rehabilitation of the Edentulous Mandible. Preliminary Results from a Prospective Clinical Follow-up Study

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ABSTRACT

Background: Brånemark fixtures were originally prescribed to be placed in two surgical stages. During the past years, reports on the placement of machined titanium implants in a one-stage procedure have been published, and the results have been encouraging. Recently there has been considerable interest in early or immediate loading.

Purpose: The purpose of this article is to report the preliminary clinical results of a new method for implant treatment of the edentulous mandible. The new protocol involves prefabricated components and surgical guides, elimination of the prosthetic impression procedure and attachment of the permanent fixed bridge on the day of implant placement.

Methods: Fifty patients (26 males, 24 females) received 150 Brånemark Novum® implants and were followed from 6 months to 3 years after implant placement. Bone width and height were determined preoperatively with the use of radiographs. The jaw was reduced in height to accommodate three special 5-mm wide implants. Precise implant positioning was accomplished with special drilling templates. Drill guides were placed over the drilling templates during site preparation using a series of specially designed drills. After the mucosa had been sutured back into position, a prefabricated titanium lower bar was connected with titanium screws to the transmucosal fixture. Another titanium bar was then attached by the prosthodontist, and a bite registration was performed. The bridge was attached to the upper bar. The permanent reconstruction was provided to the patient later the same day.

Results: Three implants were lost to follow-up and three failed, resulting in an overall survival rate of 98%. One prosthesis failed, leaving a prosthetic survival rate of 98%. The average treatment time was approximately 7 hours. At the baseline examination, the marginal bone level was 0.72 mm below the reference point. The average marginal bone loss was 0.2 mm per year and 0.26 mm between the 3-month and 1-year control visits. The accumulated mean bone loss, including baseline, was −1.25 mm. A patient questionnaire demonstrated that 94% of the patients did not experience any discomfort during treatment and all patients would recommend the procedure to others.

Conclusion: The results of this study indicate that the precise surgical and prosthetic protocol allows successful prosthetic rehabilitation of mandibular edentulism and that the permanent reconstruction can be provided to the patient on the day of fixture surgery.

KEY WORDS: Brånemark System implants, edentulous, mandibular, one-stage method

Oral and maxillofacial rehabilitation based on osseointegrated oral titanium implants (fixtures) ad modum Brånemark is a highly successful treatment modality that has been clinically documented in more than 2000 scientific publications over the past 35 years. Since the first articles were published on the rehabilitation of completely edentulous patients in 1969 and
10-year results in 1977, the procedure has expanded to include treatment of all types of edentulism with predictable success rates.1–6

ONE-STAGE SURGERY

The Bränemark System originally was described as a two-stage technique prescribing the fixtures to be submerged during the initial healing period to allow for complete healing and remodeling of the bone prior to functional loading.2 The predictability of the original treatment protocol has led to developments aimed at simplifying the technique and reducing the healing time. One such approach, described by Ericsson et al in 1994,7 has been to attach the transmucosal abutment at the time of implant surgery rather than after the 3- to 6-month healing period. The authors reported that after the first year following insertion of fixed cross-arch bridges, the bone loss around the 63 anterior mandibular implants was approximately 1 mm irrespective of whether the implants were placed according to a one-stage or a traditional two-stage procedure. Two of 33 fixtures were reported to be lost in the one-stage group. The same team later reported that the marginal bone levels around the implants in both groups were stable after 12 and 60 months.8 Becker et al reported similar results in a long-term multicenter study involving one-stage surgical placement of 135 Bränemark fixtures into both maxillae and mandibles of 63 patients.9 The majority of the implants were inserted in bone quality 2 and bone quantity B as graded according to the Lekholm and Zarb index.10 Crestal bone resorption in mandibles and maxillae was reported to be statistically and clinically insignificant. Six implants were lost prior to loading and one implant was not restored, resulting in an implant survival rate of 95.6%. In 1998, Collaert and de Bruyn compared one- and two-stage surgeries in 50 completely edentulous and 35 partially edentulous mandibles.11 Of 170 fixtures placed using a one-stage approach, 2.4% were reported lost prior to prosthetic reconstruction. As controls, 17 patients received 70 fixtures placed according to a two-stage procedure, of which 7.1% were found loose at abutment connection.

IMMEDIATE LOADING

The first report on immediate loading of Bränemark System implants was published by Schnitman et al in 1990.12 In that study, five or six fixtures were placed in the anterior mandible of each patient together with two fixtures placed distolingual of the foramina. Abutments were connected immediately at implant surgery to the two distolingual implants and to one fixture in the symphyseal region. The remaining fixtures were used as controls and were allowed to heal in a traditional manner. A previously constructed mandibular denture was converted into a fixed bridge supported by the three exposed implants. Schnitman et al concluded that the “overall long-term implant therapy was not adversely affected by this technique.” In 1997, Schnitman et al published the 10-year results of the same patient population.13 At that time, 4 of the 28 immediately placed implants had been lost in four patients, whereas no fixture losses had occurred in the control group.

Another study, published by Henry and Rosenberg in 1994, involved five patients and 30 Bränemark System fixtures.14 Each patient received six implants of which four were immediately loaded and two were left submerged, in the event of failure. A provisional removable overdenture was attached to the exposed non-connected implants at the time of implant surgery. The overdenture was replaced by a fixed permanent prosthesis after 7 weeks. The cantilever was minimized the first year and then extended to full length the second year. The authors reported an initial fixture success rate of 100% and concluded that “controlled immediate loading of adequately installed nonsubmerged implants by reinsertion of a modified denture, does not appear to jeopardize the process of osseointegration in the anterior mandible.”

A preliminary study, also pertaining to immediate loading of Bränemark System fixtures, was published by Balshi and Wolffinger in 1997.15 They reported on 10 patients who received 130 implants; of these, 40 were loaded immediately and 90 were submerged. A minimum of 10 implants were placed in each jaw and four of these implants were exposed to immediate loading. Eight of the 40 immediately loaded implants were lost prior to or at second-stage surgery, compared to four of the 90 submerged fixtures.

The most recent study, published by Randow et al in February 1999,16 reported 16 patients treated for their complete mandibular edentulism with a total of 88 Bränemark System implants, using a one-stage procedure. Fixed rigid prosthetic reconstructions were placed within 20 days of implant surgery. These patients were compared to a control group consisting of 11 patients treated in the mandible with a two-stage procedure in which the implants were loaded after 4 months.
of healing. After 18 months of follow-up, no implants were lost in either patient group. The authors found a mean bone loss of 0.4 mm in the experimental group, compared to a mean loss of 0.8 mm in the group treated with the two-stage procedure. The difference between the two groups was not statistically significant.

In summary, one-stage surgery and immediate loading techniques seem to demonstrate promising results, particularly when the fixtures have been inserted in the anterior mandible. The reported procedures and results are consistent with the goal of a simplified treatment protocol and reduced healing time. Yet the existing reports demonstrate variations in fixture survival, clinical procedure, and time of actual loading. This indicates that there is a lack of knowledge or consensus regarding the optimal approach to performing immediate loading of Brånemark System implants. In addition, the frequency of implant loss has, in general, tended to be higher than when a two-stage protocol has been applied. This may be related to uncontrolled forces applied to unconnected transmucosal components, which may be eliminated if a rigid fixed construction is attached to the implants at fixture surgery. Professor Richard Skalak evaluated this hypothesis together with Per-Ingvar Brånemark in 1995, and together they developed a new approach to immediate loading of the edentulous mandible with the use of prefabricated components.

AIMS OF THIS INVESTIGATION

The aims of the current investigation were to:

1. Continuously shorten the unloaded healing period, with the ultimate objective being the development of a same-day treatment protocol.

2. Evaluate a new standardized methodology designed for:
   - rigid connection of the implants at the time of implant surgery,
   - prefabricated surgical and prosthetic components,
   - elimination of the healing period,
   - elimination of the prosthetic impression, and
   - delivery of the final prosthetic reconstruction on the day of fixture surgery.

3. Report the initial clinical results of the new treatment protocol.

MATERIALS AND METHODS

Patient Characteristics

Patients referred to Brånemark Osseointegration Center (BOC) in Göteborg, Sweden, for bone-anchored treatment of their edentulous mandibles were consecutively included in the study, unless

- the patient declined participation,
- the anatomic situation did not allow for the treatment, or
- medical conditions contraindicated implant therapy.

The inclusion period started in February 1996 and ended in June 1998 when 50 patients (26 males; 24 females) had been treated with a total of 150 fixtures according to the revised surgical and prosthetic protocols described below. The mean age of the patients was 64 years (range, 45–86 yr) (Table 1).

In general, the patients were in good medical health, although 14 of the subjects were smokers. It was also found that most of the patients (n = 31) had been edentulous in their mandible less than 1 year, 9 for 1 to 5 years, and 10 patients had been edentulous more than 5 years.

Each fixture site was graded with regard to jaw shape and bone quality according to the index of Lekholm and Zarb. It was found that the majority of the jaws belonged to quality group 2 and quantity group B (Table 2).

At the time of treatment, 34 patients were using removable dentures in their upper jaw; 11 had tooth-supported bridges or crowns or their natural dentitions, whereas 5 had implant-supported fixed reconstructions.

<p>| TABLE 1. Distribution of Patients by Age Group |
|---------------|------------------|</p>
<table>
<thead>
<tr>
<th>Age (yr) (mean = 64)</th>
<th>Number of Patients n = 50 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>45-50</td>
<td>5 (10)</td>
</tr>
<tr>
<td>51-60</td>
<td>11 (22)</td>
</tr>
<tr>
<td>61-70</td>
<td>20 (40)</td>
</tr>
<tr>
<td>71-80</td>
<td>11 (22)</td>
</tr>
<tr>
<td>81-90</td>
<td>3 (6)</td>
</tr>
</tbody>
</table>

<p>| TABLE 2. Bone Quality and Quantity Distribution by Fixture Site (n = 150)* |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| Fixure sites    | Bone Quality Grade | Bone Quantity Grade |
|-----------------|-----------------|-----------------|-----------------|-----------------|</p>
<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>123</td>
<td>26</td>
<td>0</td>
<td></td>
<td>42</td>
<td>75</td>
<td>30</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

*Lekholm and Zarb"
Preoperative Evaluation
The patients were preoperatively evaluated with respect to jaw size, bone volume, bone density, jaw relations, intermaxillary distance, occlusal relation, and conditions of the opposing dentition. A thorough evaluation of the general health status was conducted to ensure that the patient could withstand a 2-hour operation. Preoperative analysis of the anatomic conditions and possible pathology in the mandible was evaluated with panoramic, lateral, and intraoral periapical radiographs. These were supplemented with cross-sectional occlusal projections (axial views). An impression was taken of the upper jaw, and a laboratory model was fabricated. When applicable, the preexisting completely removable maxillary prosthesis was used as the laboratory model. The shades and shapes of the new teeth were selected, and it was determined if any or all of the teeth of the existing mandibular denture could be incorporated in the new bridge. Prior to surgery, the correct vertical dimension was registered and reference points were marked on the patient's face with a skin marker pen.

Following the preoperative examinations, the same-day treatment could start. It included the following five major treatment steps (Figure 1):

1. Implant placement
2. Lower bar attachment
3. Upper bar connection and bite registration
4. Prosthetic and laboratory procedures
5. Delivery of the final reconstruction.

Surgical Protocol
General anesthesia (Forene®, Abbott Laboratories, USA) with nasal intubation was used in 11 patients. For the majority of patients (n = 39) local anesthesia with 2% Xylocain® adrenalin (20 mg/mL + 12.5 μg/mL; Astra Läkemedel AB, Sweden) combined with intravenous sedation (Diprivan®, Zeneca Pharmaceuticals Ltd., United Kingdom, and Dormicum®, Hoffmann-La Roche Pharmaceuticals, Switzerland) were administered. The patients were premedicated with 1 mg flunitrazepam (Bota Läkemedel AB, Sweden) and 2 g phenoxymethyl penicillin (Kavepenin® Astra Läkemedel AB, Sweden). Based on the preoperative radiographic examination (Figure 2), surgery began with a crestal or vestibular incision made from the first molar to the contralateral first molar. After exposing the jaw bone, with particular attention to the lingual side, the nerve locations were identified, and the crestal jaw bone in the anterior region was reduced with twist reamer drills under profuse irrigation with sterile, isotonic saline solution (Figure 3). This was done to create an approximately 7-mm wide bone platform designed to accommodate prefabricated templates made of titanium (Figure 4). Four different templates were used during the drilling procedure, to follow the increasing diameter of the preparations, which were made with specially designed drills. The first template used was the guide template, which marked the position of the sites, starting with the marking of the central fixture position with a standard round bur (Figure 5). The marked position was enlarged with the 2-mm twist drill. A guide pin was
then placed through the guide template into the drilled site, and two additional fixture sites were marked. The second template determined the final position and was, therefore, called the evaluation template. It was equipped with a guide pin that was inserted in the center preparation and allowed for a complete evaluation of location, angulation, and parallelism (Figure 6). The 2-mm twist drill was used again in the two distal sites to ensure optimal direction. The evaluation template was replaced with the positioning template, which was attached with guide pins in the two distal screw holes (Figure 7). A drill guide was placed on top of the positioning template, and the central fixture site was completely prepared using special drill guides of gradually increasing dimensions. The central fixture was then inserted (Figure 8). A V-template was subsequently attached with temporary screws, whereafter the preparations for the two side fixtures were made through the prefabricated drill guides (Figure 9). Finally, the two distal fixtures were inserted and the template was removed (Figure 10).

Considering that wide diameter fixtures were used in the usually large volume of dense cortical bone characterizing the mandible, the drilling sequence was designed to compensate for the increased risk of heat generation. The preparation was successively increased with the following drill diameters: 2.0-mm twist drill, 2.5-mm, 3.0-mm, 3.5-mm, 4.0-mm, 4.2-mm, 4.3-mm, and 4.4-mm (see Figure 7). A 5-mm screw tap was then used in most cases, followed by insertion of the fixture.

When all three fixtures had been placed, the temporary fixation screws and the V-template were removed (Figure 11). The soft tissues were readapted around the implants and sutured back into position with absorb-
able sutures. A thin silicone support sheet was placed on the mucosa surrounding the implants to counteract edema and seal the incision. Thereafter, titanium screws were used to connect the prefabricated titanium bar (the lower bar) to the transmucosal portion of the implants (Figure 12).

In the present study, 150 fixtures were placed in 50 patients. The threaded part of the fixture was 13 mm long and 5 mm in diameter. The fixtures were characterized by a new geometric design involving an altered apex and a transmucosal portion varying in height between 4, 5, and 7 mm. The majority of the fixtures (n = 123) were placed in bone quality 2; 1 fixture was placed in bone quality 1, and 26 were placed in bone quality 3. Most of the fixture sites demonstrated good bone volume (see Table 2).

**Prosthetic Protocol**

The surgical procedure was immediately followed by a modified prosthetic protocol, starting with the placement of a second prefabricated titanium bar (the upper bar) on top of the lower bar installed at surgery (Figure 13). The upper bar was secured with two temporary screws for rigid fixation. The preoperatively made reference marks were used when the jaw relations were registered to establish correct vertical dimensions. Wax or silicone putty material was used for indexing the maxillary teeth to the titanium bar in the mandible (Figure 14). The upper bar and the occlusal index were then gently removed and presented to the inhouse laboratory technician for fabrication of the prosthetic reconstruction. No conventional impression was taken of the individual fixtures or the surrounding oral mucosa.
Laboratory Protocol

The upper bar was mounted on a laboratory replica of the lower bar, and the index was placed in the correct position between the upper bar and the maxillary model. When applicable, the patient's upper denture was used as the working model. The jaw models were then mounted in an articulator. If the interarch distance was limited, the upper bar was reduced to the appropriate height with the use of hard-steel drills. A tooth setup in wax was then placed on the upper bar and tried in the patient. Flasking, boiling, and deflasking procedures followed, and heat-cured acrylic (ProBase Hot®, Ivoclar, Liechtenstein) was mixed and cured according to the manufacturer's recommendations. The polymerized bridge was polished and finished for delivery.

Bridge Delivery

The new bridge was attached with four retaining screws that were tightened with an electric torque device with preset values (20–45 Ncm). Occlusion and jaw relations were checked and necessary adjustments were made. Screw access-holes were temporarily sealed with light-body silicone, and the patient was sent home with the final restoration in place (Figure 15 and 16). A follow-up visit was scheduled within 2 weeks.
Postoperative Care
Anti-biotics (Kavepenin® 2 g × 2 dpi) were prescribed for 10 days postoperatively. To minimize postoperative pain, all patients were offered analgesics (Panodil®, Sterling Winthrop Drug Inc., USA). In the majority of cases, the need for pain medication was limited to 1 or 2 days. The patients were instructed in how to carefully rinse their mouth with saline solution after each meal. During the first week, the patients were recommended to consume liquid or light food that was easily chewable.

Clinical and Radiographic Follow-up Examinations
After 1 to 2 weeks, a postoperative examination was conducted to evaluate the healing conditions. The sutures and the silicone support sheet were removed, and the patient received oral hygiene instructions. All treated patients were then placed in a follow-up program with the first recall taking place after 3 months and the second after 6 months. Thereafter, the patients were scheduled for annual examinations. At the 3-month visit, the soft-tissue adaptation was examined,
and if necessary, the posterior cantilevers of the bridge were relined. Stability of the screws connecting the bridge was checked, and the screw access holes were then sealed with a composite material after a cotton pellet had been placed to cover the screw head.

Patient satisfaction was measured through a questionnaire that was completed by the patient no earlier than 10 days postoperatively. Twenty questions were asked, and the results will be presented in a separate study.

The majority of the patients \( (n = 42) \) have attended the subsequent 1-year follow-up visit, at which time clinical and radiographic examinations were performed. The bridge stability was manually evaluated. Masticatory function, esthetics, and phonetic aspects were evaluated through discussions with the patient and visual inspection. The same examinations were performed on the 13 patients who have so far attended their 2-year follow-up visit.

To date, only three patients have attended the 3-year follow-up examination. In addition to the standard annual follow-up procedure described above, the bridges were removed and the individual implant stability was evaluated.

Radiographic evaluations were conducted after 3 and 6 months, and thereafter at each consecutive annual follow-up visit. Intraoral periapical radiographs and dental scanograms with a Scanora® multimodel unit (Soredex, Orion Corporation, Finland) were taken to verify implant integration, assess component condition, and measure potential marginal bone loss.\(^{18}\)

For this preliminary report, the bone level was determined relative to a reference point located 0.5 mm above the first thread on the mesial and distal surfaces of the fixtures (Figure 17). A mean for each implant was thereafter calculated. The average bone loss was also calculated for all implants assessed at each examination. The implants were considered to have been inserted to the reference point at surgery.

**Success Criteria**

A fixture was considered successful if the following criteria were met\(^{19}\):

- The fixture was clinically stable (i.e., no mobility or sign of mobility was found when the prosthesis was manually examined).
- There was no sign of pain, infection, or other pathologic reaction in the hard or soft peri-implant tissue.
- There was no sign of radiographic radiolucency around the fixture.
- The mean marginal bone loss did not exceed 1.5 mm in total after 3 years or 0.2 mm between scheduled examinations, as measured from the baseline radiograph reference point.

A fixture was considered surviving if

- it was still in function without complications, but the marginal bone loss was in excess of what was stated in the success rate requirements, or
- evidence to verify success was lacking.

A fixture was considered a failure if

- it was removed for any reason,
- it had fractured beyond repair and could no longer function as support for the prosthesis, or
- it did not fit any of the success or survival criteria.

A prosthetic construction was considered success-
ful if it had been in continuous and unrestricted function and was stable upon manual clinical examination.

Follow-up Time and Patients Lost to Follow-up
During the follow-up period ending in April 1999, one patient with three fixtures dropped out of the study after the 6-month follow-up visit due to sudden death in lung cancer. All remaining 49 patients have been followed since the time of implant placement. At the end of the preliminary study period, 49 patients had been followed 6 months after implant placement, 42 patients had been followed 1 year, 13 patients 2 years, and 3 patients 3 years (Table 3).

RESULTS

Clinical Results
At the time of evaluation of the preliminary study results, 47 of the 50 patients demonstrated successfully integrated implants and stable prosthetic bridges. As previously stated, one patient with three fixtures was lost to follow-up. In another two patients, three implants failed, as follows:

- One patient had two fixtures removed after 2 months because of bridge and implant mobility and was considered failed within the study at that time. The three implants had initially been loaded 2 days after implant surgery. Five months after the failures, the two failed fixtures were replaced in the same implant positions, and a new bridge was fabricated. The patient did not experience any further problems with the function of the new bridge. The new fixtures and bridge have not been included in the study and the still osseointegrated implant has been considered as withdrawn.
- One patient had three implants loaded after 7 days. A radiolucency zone was found around one implant at the 3-month follow-up examination. The fixture was removed after 9 months. The bridge was restabi-
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Figure 16. Final restoration seen from underneath.

Consequently a total of three fixtures have been lost to follow-up, and three fixtures have failed to date. Thus, the overall survival rate of the fixtures was 98% (see Table 3). The prosthetic survival rate was 98% at the latest follow-up visit.

There were no signs of malocclusion or bruxism nor any reports of subjective masticatory malfunction in any of the patients. Besides the above-mentioned implant losses, no other complications were reported during the follow-up period.

The average treatment time from implant insertion to connection of the prosthetic reconstruction was approximately 7 hours. The study aim of developing a 1-day protocol was met as the healing period decreased from 40 days down to 0, with the “7 hour/0 days group” (n = 22) being the largest (Table 4).

**Radiographic Results**

At the baseline examination after 3 months, the mean marginal bone level was located 0.72 mm (SD = 0.77; n = 149) apically to the used reference point. The mean marginal bone loss for the time interval between 3-month and 6-month examinations was 0.05 mm (SD = 0.31; n = 146), using the fixture as the measurement unit. The corresponding values for the time intervals 3 months to 1 year, 3 months to 2 years, and 3 months to 3 years were 0.13 mm (SD = 0.47; n = 128), 0.26 mm (SD = 0.74; n = 33), and 0.53 mm (SD = 1.33; n = 12), respectively. The majority of the patients showed no progressive marginal bone loss over time. When studying individual implants, an increased bone density with time could be observed in intraoral radiographs (Figure 18).
Patient Satisfaction

Of the 50 questionnaires issued to the patients, 37 were returned. The answers by two patients who chose to be anonymous were not included in the results, as it could not be verified that they belonged to the 50 first-treated patients reported on in the present study. The patient answers demonstrated a high degree of satisfaction with the treatment outcome (Table 5).

DISCUSSION

The main goal of the study was to eliminate the unloaded healing period when performing oral implant treatment, while still providing a predictable, permanent, and successful treatment result. This aim was met with the new treatment concept. The foundation of the current treatment principles originates from cooperative efforts with the late Richard Skalak, who clarified the prerequisites for success with an immediate loading concept that would provide for a favorable biologic adaptation of the bone to same-day loading of the final reconstruction.17 The studies reviewed in the introduction reported on loading either of the provisional bridges immediately, or the permanent constructions after 3 weeks.12–16 Even if the reports showed promising results, these protocols still imply some healing time prior to connection of the permanent reconstruction. Consequently, the Brånemark Novum® concept is the first oral implant protocol with which it is possible to create a successful 1-day final treatment result in the edentulous mandible.

The low implant and prosthetic failure rates (2%) reported in this study compete well with what has been previously reported on the Brånemark Classic protocol when patients have been followed the same length of time.6,20–22 In the case of the first implant failure of the present study, the fixed prosthesis was connected after 2 days, and in the case of the second failure, after 7 days. The failures were not considered a consequence of the same-day prosthetic loading concept per se, but rather of excessive heat generation from wide-diameter drills used in dense bone during the initial attempts to reduce the number of steps in the drilling sequence.

The accumulated mean bone resorption (including the baseline value of −0.72 mm) from the reference point were 0.9 mm after 1 year and 1.0 mm after 2 years. These figures may indicate more bone loss than was actually occurring, as no radiographs were taken immediately after implant placement and it has been assumed that the implants were placed in the bone down to the reference point. There are too few observations in the 3-year follow-up group to make a statistical analysis. The 1- and 2-year results compare well with data reported on the Brånemark Classic procedure,6,19,23 as the average loss did not exceed 0.2 mm per year when calculated from the 3-month examination.

A successful outcome and a high degree of satisfaction with the new procedure was seen among the patients as all of them stated that they were pleased

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### TABLE 3. Distribution of Patients and Fixture Status at Each Follow-up Examination

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Number of Patients Attending</th>
<th>Failing Fixtures (Patients)</th>
<th>Fixtures (Patients) Lost to Follow-up</th>
<th>Evaluated Successful Fixtures</th>
<th>Cumulative Success Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 mo</td>
<td>50</td>
<td>3 (2*)</td>
<td>1 (1*)</td>
<td>146</td>
<td>98</td>
</tr>
<tr>
<td>6 mo</td>
<td>49</td>
<td>0</td>
<td>0</td>
<td>146</td>
<td>98</td>
</tr>
<tr>
<td>1 yr</td>
<td>42</td>
<td>0</td>
<td>3 (1*)</td>
<td>125</td>
<td>98</td>
</tr>
<tr>
<td>2 yr</td>
<td>13</td>
<td>0</td>
<td>0</td>
<td>39</td>
<td>5</td>
</tr>
<tr>
<td>3 yr</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>9</td>
<td>5</td>
</tr>
</tbody>
</table>

*One patient was withdrawn from the study due to two failed fixtures. The remaining integrated implant was considered withdrawn from the study.

+One patient had, after losing one fixture, the bridge reestablished on the two remaining fixtures. The patient was therefore still included in the study after 18 months of follow-up.

*One patient deceased before the 1 year check-up.

Too few for statistical analysis.

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### TABLE 4. Distribution of Patients with Regard to Number of Days of Healing Prior to Prosthetic Loading

<table>
<thead>
<tr>
<th>Days of Healing</th>
<th>Number of Patients (n = 50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>22</td>
</tr>
<tr>
<td>1–2</td>
<td>6</td>
</tr>
<tr>
<td>3–10</td>
<td>6</td>
</tr>
<tr>
<td>11–20</td>
<td>7</td>
</tr>
<tr>
<td>21–30</td>
<td>6</td>
</tr>
<tr>
<td>31–40</td>
<td>3</td>
</tr>
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</table>
with the results and would recommend the treatment to other patients. The majority of the patients also considered the treatment to be unrelated to discomfort.

The results clarify that it is possible to meet the objective of eliminating the unloaded healing time through same-day loading of the permanent bridge when

<table>
<thead>
<tr>
<th>TABLE 5. Distribution of Patient Answers to Questionnaire</th>
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<tbody>
<tr>
<td>Response</td>
</tr>
<tr>
<td>1. Did you experience anything uncomfortable or unpleasant during the treatment?</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Yes, please describe</td>
</tr>
<tr>
<td>No answer</td>
</tr>
<tr>
<td>2. How long were you absent from work or your other activities due to the treatment?</td>
</tr>
<tr>
<td>Not at all after surgery</td>
</tr>
<tr>
<td>1 day</td>
</tr>
<tr>
<td>2 days</td>
</tr>
<tr>
<td>3 days to 1 week</td>
</tr>
<tr>
<td>More than 1 week</td>
</tr>
<tr>
<td>No answer</td>
</tr>
<tr>
<td>3. What is the main advantage of the same-day treatment?</td>
</tr>
<tr>
<td>Fewer treatment sessions save time</td>
</tr>
<tr>
<td>No waiting time for the final teeth</td>
</tr>
<tr>
<td>Costs less</td>
</tr>
<tr>
<td>Other advantages</td>
</tr>
<tr>
<td>No answer</td>
</tr>
<tr>
<td>4. On a scale from 1 to 10, where 10 equals extremely satisfied and 1 equals extremely disappointed, how satisfied are you with the treatment?</td>
</tr>
<tr>
<td>No answer</td>
</tr>
<tr>
<td>Average of 36 replies</td>
</tr>
<tr>
<td>Median of 36 replies</td>
</tr>
<tr>
<td>5. What would you say to another patient who was considering the treatment?</td>
</tr>
<tr>
<td>I would strongly recommend it.</td>
</tr>
<tr>
<td>I would recommend it</td>
</tr>
<tr>
<td>I would recommend it with hesitation.</td>
</tr>
<tr>
<td>I would recommend against it</td>
</tr>
<tr>
<td>No answer</td>
</tr>
</tbody>
</table>
applying the Brånemark Novum® concept described in this study. By rigidly connecting the implants from the start with a lower bar to which an upper bar supporting the teeth could be connected, it also was possible to eliminate the prosthetic impression procedure. The prefabricated components made it possible to provide the patients with a permanent reconstruction on the day of fixture placement. Therefore, the treatment concept has been incorporated into the routine treatment of mandibular edentulism at the Brånemark Osseointegration Center in Göteborg, Sweden.

CONCLUSIONS

Based on the material presented in this study, it can be concluded that the new, standardized Brånemark Novum® protocol, involving the use of

- prefabricated surgical and prosthetic components,
- transmucosal fixture components,
- a prefabricated bridge framework,
- rigid connection of the implants at the time of fixture surgery, and
- a revised prosthetic protocol that eliminates the impression,

resulted in high implant success (98%), significantly reduced treatment time (7 hours for 22 patients), and postoperatively satisfied patients. In addition, the new protocol yielded less than 1 mm of bone loss during the first year of function and predictable patient treatment within the follow-up period. Consequently, the preliminary results of the new approach indicate that it is a useful and safe technique for immediate loading of fixed reconstructions on mandibular dental implants. No comparative studies of a 1-day procedure exist. To further elucidate the potential of the new treatment protocol, it will be evaluated in multicenter clinical trials.

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