Two-center clinical trial of implant-retained mandibular overdentures versus complete dentures – chewing ability


Abstract - This study is a two-center clinical trial with the aim to assess the treatment effects of implant-retained mandibular overdentures versus conventional complete dentures. Treatment had been assigned according to a balanced allocation method. The following criteria were used to enhance the comparability of the treatment groups: age, gender, the edentulous period of the mandible, the number of previously made mandibular dentures, the number of years having worn the present mandibular denture and the symphyseal bone height. 151 patients with severely resorbed mandibles participated in the study, they were treated at two centers. Ninety-one patients received an implant-retained mandibular overdenture (IRO) and 60 patients a conventional complete denture (CD). Since some patients refused the allocated treatment the “Intention To Treat” principle was applied. This implies that patients are evaluated in the originally allocated treatment group regardless of the actual treatment they received. Patient’s experiences were evaluated before treatment and 1 yr after insertion of the new dentures. Results before treatment showed that both treatment groups were comparable: they were dissatisfied with their mandibular denture and they could hardly chew tough or hard foods. One year after insertion of the new dentures the IRO-group was satisfied with their mandibular denture, whereas only one third of the CD-group was satisfied. With respect to the chewing ability the IRO-group scored significantly better than the CD-group (P≤0.0001).

The continuous resorption of the alveolar ridge after extraction of all teeth can eventually result in a jaw anatomy which offers inadequate support for dentures (1). Especially when the mandibular alveolar ridge has become severely reduced patients often complain about instability, pain and inability to chew tough or hard foods. To improve denture retention and stability preprosthetic surgical techniques such as ridge augmentation, vestibuloplasty and lowering of the floor of the mouth were used up to 5 yr ago with varying rates of success. Currently osseointegrated implants seem to become a more reliable form of treatment for these patients.

A high rate of success has been documented in long-term studies for osseointegrated implants supporting fixed prostheses in edentulous jaws (2, 3). Little attention, however, is paid to implant-retained overdentures. Reports have been published only in recent years. Short-term results (4-6) as well as results of 5-yr longitudinal studies (7, 8) seem to be comparable to those of implants supporting fixed prostheses.

Few studies have reported on patients with severely resorbed mandibles (Class VI, 9). Tripplett et al. (10) selected 28 subjects with a mandibular bone height of 10 mm or less who had been wearing an implant-retained prosthesis for at least 1 yr. Nineteen patients had a fixed prosthesis and nine an overdenture on Brånemark implants. The overall survival-rate (of individual implants) was 94% 1 yr after treatment. Donatsky (11)
studied 26 patients with severe alveolar bone loss who were eligible for vestibuloplasty and lowering of the floor of the mouth with skin graft. They were treated with Bränemark implants and ball-attachments to stabilize an overdenture. A success-rate of 97% 1 yr after treatment was reported. Both studies, however, are retrospective and mainly focused on clinical aspects.

Although considerable advancements have been made with osseointegrated implants during the last decades randomized controlled clinical trials have been lacking. In spite of recommendations to perform phase-III randomized clinical trials (12-15), most studies are not comparative since only one implant-system was used without a control-treatment. KAPUR (13) published about treatment with implants in a randomized clinical trial. In partially edentulous patients he compared the effectiveness of fixed partial prostheses retained by a blade-vent implant with removable partial prostheses dentures (Kennedy Class I). Only DE GRANDMONT et al. and FEINE et al. (18) reported about treatment with implants in a clinical trial with edentulous patients. They compared different types of implant-retained prostheses: fixed and removable prostheses. No studies of edentulous patients with severely resorbed mandibles have been published in which different implant systems were compared. For that reason a two-center randomized clinical trial was started. The aim of the study was to compare the treatment effects of implant-retained mandibular overdentures, using different implant-systems, with new conventional complete dentures. Clinical as well as patient-related aspects were evaluated. In this paper the design of the study is presented. Special attention is paid to patient selection, randomization and treatment refusal. The results will focus on the subjective chewing ability.

Material and methods

Patient selection – The subjects selected for this study were edentulous patients with severely resorbed mandibles and persistent problems wearing conventional complete dentures. They were referred by general practitioners to a University clinic. Two clinics participated in this study, e.g. the Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics (University Hospital Groningen) and the Department of Oral Function and Prosthetic Dentistry and the Department of Oral and Maxillofacial Surgery (University of Nijmegen). The subjects were screened for their eligibility by a prosthodontist and an oral surgeon. To select patients with severely resorbed mandibles the mandibular symphyseal bone height was measured on a standardized lateral cephalogram. Patients with a bone height of 15 mm or less were eligible. The criteria for inclusion in the clinical trial are summarized in Table 1.

Study design and sample size – The design of the study differed in one aspect between the two centers: the ethical committee at the University of Nijmegen gave approval for a randomized clinical trial, i.e. eligible patients were asked to give their written consent for participation in the trial before allocation of treatment took place; at the University of Groningen the ethical committee required pre-randomization (randomized consent trial; 19, 20), i.e. treatment was allocated before patients gave their written consent. Since some patients refused treatment after allocation, the “Intention To Treat” principle was applied (20, 21). This implies that patients are evaluated in the originally allocated treatment group regardless of the actual treatment they received.

The sample size was aimed at 150 subjects: 90 subjects were to receive an Implant-Retained mandibular Overdenture (IRO) and 60 subjects a Conventional mandibular Denture (CD). Three different implant systems were applied: (a) the Bränemark-system (Nobelpharma, AB, Göteborg, Sweden), a titanium screw-type cylinder; (b) the IMZ-system (Friedrichsfeld, Mannheim, Germany), a titanium cylinder with titanium-plasma-spray coating; and (c) the transmandibular implant-system according to Bosker (Krijnen, Medical BV, Beesd, the Netherlands), consisting of a baseplate, four posts and five cortical screws made of a gold-alloy. A conventional mandibular denture served as control treatment. All patients received a new maxillary denture. To be able to study the surplus value of implant-retained overdentures compared to conventional complete dentures all groups with implant-retained overdentures were taken together.

Treatment assignment – Treatment was allocated using a balancing procedure (22), aiming at an equal distribution of patients over the treatment groups regarding variables that may interfere with the outcome of the study (balancing criteria). In this trial the criteria were age, gender, the edentulous period of the mandible, the number of previously made mandibular dentures, the number of years having worn the present mandibular denture and the symphyseal bone height of the mandible. A computer-program was used for the allocation of patients to the treatment groups.

Surgical and prosthodontic procedures – In case of perucmosal implants according to the Bränemark- (23) and IMZ-system (24) two fixtures were interforaminally inserted under local anesthesia. Patients were not allowed to wear the mandibular denture during the first 2 weeks after surgery. After initial wound healing the denture was adjusted with a soft-liner and a soft diet was prescribed. After a healing period of 3 months the second stage surgery was performed (i.e. abutment connection). The mandibular overdentures were supported by a single bar-clip attachment.

The transmandibular implant according to BOSKER (25) was inserted under general anesthesia. The day after surgery the superstructure was placed, consisting of a triple-bar construction with cantilever extensions. During a period of three months patients were not allowed to eat solid food or to wear the mandibular denture. After this period the manufacturing of the new maxillary denture and the mandibular overdenture was started.

In all treatment groups the dentures were manufactured with an optimal fit and according to the balanced occlusion principle.

Table 1. Inclusion-criteria

1. No history of preprosthetic surgery (e.g. vestibuloplasty)
2. A mandibular symphyseal bone height of less than 15 mm, but more than 8 mm as measured on a standardized lateral cephalogram.
3. No implants inserted before, either in the mandible or in the maxilla.
4. The absence of medical risks interfering with the treatment or with (expected) implant success.
**Patient's experiences** — Before treatment and 1 yr after insertion of the new dentures patients were asked whether they were satisfied with their dentures in general, their mandibular and maxillary denture separately, and their chewing ability in general. They were also asked to rate their opinion about their chewing ability of eight different types of food. The items were measured on a 3-point ordinal scale. Factor and reliability analyses were carried out on the questions about types of food. On the initial scores three factors appeared: “soft food” (e.g. vegetables), “tough food” (e.g. steak) and “hard food” (apple, carrot). The reliability coefficients Cronbach's α appeared to be quite satisfactory for all factors, 0.74, 0.80 and 0.81, respectively. Final scores were calculated as the mean of the item score, ranging from 0 (good) up to 2 (bad). One year after treatment the scale structure was checked. Changes in the originally constructed scales were not necessary. Only the scale “soft food” is left out in further analysis because it did not vary after treatment: all patients were able to eat soft food.

**Statistical analysis** — Differences in treatment were analyzed using a 2-way ANOVA, according to treatment and center to correct for possible confounding. The data obtained at the 1-yr evaluation were used to analyze the differences between the IRO and CD groups rather than comparing the data before with the data after treatment (“difference scores”).

The “difference scores” were not analyzed for several reasons. Firstly, the measurement-error is encountered twice in the “difference scores”, while in the data of the 1-yr evaluation the measurement-error is encountered only once. Secondly, the initial situation of the patients with respect to the quality of the complete dentures may have shown considerable differences. Thirdly, “difference scores” may be subjected to a “Regression to the Mean” effect (26) since the participants may be regarded as an extreme group of patients, given their request for treatment (self selection).

**Results**

Sample sample — During the enrollment period from December 1989 till September 1991 treatment was allocated to 157 patients. Table 2 shows that 148 patients were treated according to allocation and 9 patients refused the allocated treatment. For the patients who refused the allocated treatment, the “Intention To Treat” principle was applied, as mentioned before.

At the baseline the IRO group consisted of 93 patients: 88 of them received an implant-retained mandibular overdenture and a maxillary denture. The five patients who refused the allocated treatment did not want surgery and did not ask for any other treatment. One year after insertion of the new dentures, two patients were lost to follow-up: they refused evaluation.

The CD group consisted of 64 patients at the baseline. Sixty of them received a set of conventional complete denture and four refused the allocated treatment. One patient wanted implants, one thought the treatment was too expensive and the other two did not expect any real improvement of new dentures. The patient who wanted implants received this treatment, but was excluded from the study. The other three patients did not ask for further treatment. At the 1-yr evaluation four patients were lost to follow-up: one died and three refused evaluation.

Since six patients did not participate in the 1-yr evaluation, 151 patients remained. This group consisted of 116 females and 35 males, their age varied from 35 to 84 yr, with an average of 56 yr (sd 9 yr). The characteristics of the patients and balancing criteria are presented in Table 3. The comparability of all groups before treatment was tested by analysis of variance (2-way ANOVA) for the following variables: age, gender, edentulous period of the mandible and the maxilla, the number of mandibular and maxillary dentures, the age of the present mandibular and maxillary denture and the mandibular bone height. No significant differences were found except for the edentulous period in the mandible and the maxilla: the CD group was edentulous for a significantly longer period than the IRO group.

**Table 2. Patients treated or not treated according to allocation**

<table>
<thead>
<tr>
<th>Treatment according to allocation</th>
<th>Treatment not according to allocation</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>baseline</td>
<td>1 yr</td>
<td>baseline</td>
</tr>
<tr>
<td>IRO</td>
<td>88</td>
<td>86</td>
</tr>
<tr>
<td>CD</td>
<td>60</td>
<td>56</td>
</tr>
<tr>
<td>Total</td>
<td>148</td>
<td>142</td>
</tr>
</tbody>
</table>

* Subjected to “Intention To Treat” analysis.

**Table 3. Patient characteristics and balancing criteria (mean (sd) or percentages (%)).**

<table>
<thead>
<tr>
<th></th>
<th>IRO (n=91)</th>
<th>CD (n=60)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in yr (sd)</td>
<td>54 (9)</td>
<td>58 (10)</td>
<td>56 (9)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (%)</td>
<td>21%</td>
<td>25%</td>
<td>23%</td>
</tr>
<tr>
<td>Female (%)</td>
<td>79%</td>
<td>75%</td>
<td>77%</td>
</tr>
<tr>
<td>Center</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Groningen (%)</td>
<td>32%</td>
<td>52%</td>
<td>40%</td>
</tr>
<tr>
<td>Nijmegen (%)</td>
<td>68%</td>
<td>48%</td>
<td>60%</td>
</tr>
<tr>
<td>Edentulous period mandible in years (sd)</td>
<td>22 (8)</td>
<td>25 (9)</td>
<td>23 (9)</td>
</tr>
<tr>
<td>Edentulous period maxilla in years (sd)</td>
<td>24 (8)</td>
<td>28 (9)</td>
<td>26 (9)</td>
</tr>
<tr>
<td>Number of mandibular dentures (sd)</td>
<td>3 (1.5)</td>
<td>3 (1)</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Number of maxillary dentures (sd)</td>
<td>3 (1.5)</td>
<td>3 (1)</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Age present mandibular denture (sd)</td>
<td>6 (5)</td>
<td>7 (5)</td>
<td>7 (5)</td>
</tr>
<tr>
<td>Age present maxillary denture (sd)</td>
<td>7 (5)</td>
<td>7 (5)</td>
<td>7 (5)</td>
</tr>
<tr>
<td>Mandibular bone height in mm (sd)</td>
<td>13.6 (1.5)</td>
<td>13.4 (2.0)</td>
<td>13.5 (1.7)</td>
</tr>
</tbody>
</table>

1 Balancing criteria.
Fig. 1. Distribution in percentages of answers to the questions about denture satisfaction before treatment.

1 = satisfied, 2 = neutral, 3 = dissatisfied

general: Are you satisfied with your dentures in general?
upper: Are you satisfied with your upper denture?
lower: Are you satisfied with your lower denture?
eating: How satisfied are you about eating with your dentures?

Fig. 2. Distribution in percentages of answers to the questions about denture satisfaction 1 yr after treatment.

1 = satisfied, 2 = neutral, 3 = dissatisfied

general: Are you satisfied with your dentures in general?
upper: Are you satisfied with your upper denture?
lower: Are you satisfied with your lower denture?
eating: How satisfied are you about eating with your dentures?

Discussion

In a clinical trial the experience of a group of patients on the new treatment is always evaluated by comparing it to a control group. In this trial of implant-retained overdentures in patients with severely resorbed mandibles the standard treatment was chosen to be conventional complete dentures. An option might have been ridge augmentation combined with vestibuloplasty and lowering of the floor of the mouth, followed by a set of new complete dentures. But this treatment option has several disadvantages. The gain in height of the alveolar ridge will diminish in the years after surgery and mental nerve disturbances will occur. STOEINGA (27) reported 48% loss within 5 yr after surgery, FREIHOFER & HOPPENREIJS (28) 50%; moreover, 29% of the mental nerves showed disturbance in function 1 yr after augmentation (28). Taking into account these disadvantages, ridge augmentation was not considered to be a realistic control-treatment.

The study was started in the fall of 1989. It took until September 1991 to select 157 patients who were eligible and willing to enter this clinical trial. The long intake period can be partly explained by the inclusion-criteria (Table 1): only patients with severely resorbed mandibles were allowed to enter the study. Furthermore the balancing procedure was an uncertain factor for the patients. There was a chance on implant treatment under general or local anesthe-
sia and treatment with just a new set of dentures. Therefore several patients refused consent.

At entry into the trial the objectives and the consequences of participating in the trial were carefully explained to all patients to reduce treatment refusal. Nevertheless, nine of the 157 selected patients refused treatment after allocation had taken place. To prevent selection bias the "Intention To Treat" principle was applied (20, 21). This means that all patients are evaluated in the originally allocated treatment group regardless of the actual treatment they received. In consequence the contrast between the two treatment groups has probably diminished because patients who had refused implant treatment and had not received any treatment at all were evaluated in the IRO group and, conversely, patients who had refused complete dentures and received implant treatment were evaluated in the CD group. An alternative way to handle this problem was to evaluate only those patients who had received the allocated treatment. This would introduce selection bias with respect to motivation when comparing the IRO with the CD group. The contemporary opinion in clinical epidemiology is to avoid selection bias and to choose the "Intention to Treat" principle (29).

The randomization method used for assignment of treatment to patients resulted in two groups with comparable general characteristics at entry; only the mean edentulous period for both the maxilla and the mandible differed significantly between the two treatment groups. Patients' denture satisfaction before treatment was also comparable, as expected (Fig. 1). The same can be concluded for the chewing ability scales before treatment: there were no significant differences between the IRO and CD group.

One year after insertion of the new dentures the majority of the patients of the IRO group were satisfied with their dentures and their chewing ability (Figs. 2-4).

Of the CD group only one third was satisfied with the mandibular denture. This was less than expected and not consistent with reports of Van Waas et al. (30) and Kalk et al. (31). In their study they compared three groups of patients: one group treated with vestibuloplasty and lowering of the floor of the mouth, one group with severely resorbed mandibles and one group with normal ridges. All groups had the same high degree of denture satisfaction.

The answers of the CD group to the question about denture satisfaction in general did not correspond with those about the mandibular denture: about two-thirds were satisfied with their dentures in general, while one-third was satisfied with the mandibular denture. This could be explained by the high rate of satisfaction with the maxillary denture.

One year after insertion of the new dentures the IRO group scored significantly better than the CD group on the chewing ability scales. These results are in accordance with those of Lindquist & Carlsson (32) for fixed prostheses. They found that the chewing ability improved significantly after insertion of mandibular fixed prostheses. The results of Haraldson et al. (33) seem to be in contrast with the results of this study. They reported no significant improvement in chewing ability after treatment with an implant-retained mandibular overdenture. However, both these studies have several limitations: the numbers of patients in these studies were small (27 versus 9), the selection of patients for treatment may have differed, treatment was not randomly assigned to the patients and no control group was included. The study of Grandmont et al. (17) does not have these design flaws. In a cross-over clinical trial patients assigned significantly higher scores to mandibular fixed prostheses as well as implant-retained mandibular overdentures with respect to chewing ability. The results of our study are in accordance with the results of Grandmont et al. (17).

The mean scores of the chewing ability scales in Figs. 3 and 4 show that the CD-group still had problems with chewing tough and hard food. These results correspond with those of Gunne & Wall (34). They reported that new conventional complete dentures improved the subjective chewing ability, but that chewing tough or hard foodstuffs was difficult.
Comparing the results before and after treatment for the CD group the mean scores for the chewing ability scales have improved slightly. Patients were also more positive about their complete dentures in general and mandibular and maxillary denture separately after treatment. Conclusions, however, should be drawn with caution as a non-treated group was not included in this study and the improvement of the CD group may also be due to a "regression to the mean" effect (26). This could indicate some improvement for statistical reasons, without any real treatment benefit.

Due to the two-center design of the study with a randomized treatment assignment this clinical trial provides a high external validity. The results are valid for groups of denture wearers with persistent problems caused by severe resorption of the mandible, who are referred to a University Clinic. After the first year, results are positive for the implant group and negative for the complete denture group. However, the long-term results remain to be evaluated in the future to assess the real benefits of this promising implant overdenture therapy.

Acknowledgement - This study is part of the Academic Dutch Implant Overdenture Study (ADIOS) supported by the National Health Insurance Council (Grant OG: 89-76).

References


