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Implant-retained mandibular overdentures; clinical and psychosocial aspects.

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Summary

Loss of teeth results in a gradual resorption of the bone of the alveolar ridge. The general pattern of this resorption has been described by Tallgren (1972) and Cawood (1988). In severe cases, resorption of the mandibular body and basal maxillary bone may also occur. As a consequence, the denture bearing area progressively reduces, eventually causing loss of retention and stability of the prostheses. With time, pain and increasing difficulty with oral functioning may occur to an extent that interferes with proper nutritional intake and the patients' ability to communicate with ease and confidence.

The degree of resorption of alveolar bone in the mandible is four times as high as that in the maxilla. In addition, right from the beginning the bearing area of a lower denture already is far less than that of an upper denture. As a result, retention problems, and difficulty with functioning particularly relates to the lower denture, and may be experienced as a heavy burden by many patients.

Conventional treatment methods such as manufacturing a new set of prostheses with or without preceding preprosthetic surgery have been available. Today denture retention and stability can also be considerably improved by an implant-retained mandibular overdenture. Until now, no properly designed controlled prospective investigations with edentulous patients have been carried out to demonstrate the frequently suggested surplus-value of implant-retained overdentures.

The aim of this thesis was to compare the treatment outcome of implant-retained mandibular overdentures, using three different supporting implant systems, with two conventional treatment procedures, i.e. construction of a new set of dentures of high quality with or without preceding preprosthetic surgery. The comparison addresses patient related aspects as well as clinical aspects.

This investigation has been performed as a two-center clinical trial. The two centres involved are the Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics, University Hospital Groningen and the Department of Oral Function and Prosthetic Dentistry, University of Nijmegen, The Netherlands.

The sample size was aimed at 240 subjects subdivided as follows:

- **Implant Retained Overdenture (IRO)** group: 120 subjects for treatment with an overdenture retained by dental implants in the lower jaw and a new denture in the upper jaw
- **PreProsthetic Surgery (PPS)** group: 30 subjects for surgical treatment

consisting of an interforaminal vestibuloplasty and deepening of the floor of the mouth before inserting new complete dentures

- Complete Dentures (CD) group: 90 subjects for treatment consisting of manufacturing new complete dentures alone, serving as a non-surgical control group.

Three different implant systems were applied: The Brånemark-system, a titanium screw-type cylinder (**Brå**); the IMZ-system, a titanium cylinder (**IMZ**); and a transmandibular implant-system, consisting of a submental baseplate, four posts and five cortical screws (**TMI**). The preprosthetic surgery was carried out according to the buccal onlay procedure. All patients received also a new maxillary denture.

This two-center clinical trial can be divided in three different parts (Table 1):

Groningen I patients with a mandibular symphyseal bone height (on a lateral cephalogram) between 8 and 15 mm,

Groningen II patients with a mandibular symphyseal bone height between 16 and 25 mm,

Nijmegen I patients with a mandibular symphyseal bone height between 8 and 15 mm.

The two parts concerning the jawbone height between 8 and 15 mm of Groningen and Nijmegen is the two-center study.

Table 1 Intended number of patients

Groningen I (8-15mm)	n=60
Per mucosal implants + overdenture*	30
Conventional denture	30
Groningen II (16-25mm)	n=90
Per mucosal implants + overdenture*	30
Preprosthetic surgery + conventional denture	30
Conventional denture	30
Nijmegen I (8-15mm)	n=90
IMZ implants + overdenture	30
TMI-system + overdenture	30
Conventional denture	30

* IMZ- or Brå-implants

TWO-CENTER CLINICAL TRIAL

In **chapter 2**, a comparison is made of the subjective evaluation of the chewing ability of implant-retained mandibular overdentures, using different implant-systems, with new conventional complete dentures.

The subjects selected were edentulous during many years and showed severe resorption in the mandible, with persistent problems wearing 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, and the number of years having worn the present mandibular denture. The symphyseal bone height was measured on a cephalometric radiograph. A total of 151 patients participated in the study. They were treated at two centers; 91 patients received an implant-retained mandibular overdenture (IRO) and 60 patients a new conventional complete denture of high quality (CD). If patients refused the allocated treatment the 'Intention To Treat' principle was applied.

In case of permucosal implants according to the Brånemark- and IMZ-system two fixtures were interforaminally inserted under local anaesthesia. After a healing period of three months the second stage surgery was performed (i.e. abutment connection). The mandibular overdentures were supported by a single bar-clip attachment. In the transmandibular implant group the superstructure was placed the day after surgery, consisting of a triple-bar construction with cantilever extensions. In all treatment groups the dentures were manufactured with an optimal fit and according to the balanced occlusion principle.

Patient's chewing experiences were evaluated before treatment and one year after insertion of the new dentures. Results before treatment showed that both treatment groups were comparable: they were dissatisfied with their lower denture and could hardly chew tough or hard foods. One year after insertion of the new dentures in the IRO-group all participants were satisfied with their lower 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 ($p \leq 0.0001$).

The results of this two-center study imply a considerable improvement of the group treated with implants. The design of this study provides a high

external validity of the results. Of course the long term results remain to be evaluated to assess the real benefits of this promising implant-overdenture treatment.

In **chapter 3**, the treatment outcome of full denture treatment with or without implant-support was assessed in a two-center clinical trial (Groningen and Nijmegen). The outcome assessment focused on the patient's general subjective evaluation. Thirty-four men and 117 women (mean age 56 ± 9 , range 35 to 84 years) participated in the study. The mean height of the mandible was 13 ± 2 mm (min 8 mm, max 15 mm), measured on a lateral cephalometric radiograph. The patients were randomly assigned to either a group treated with implant-retained mandibular overdentures and a new maxillary denture (Implant-Retained Overdenture group, IRO), or to a non-surgical control group treated with a new set of complete dentures (Conventional Dentures group, CD). Assignment was executed by means of a balancing allocation method to ensure comparability of the groups regarding age, gender, edentulous period in the lower jaw, 'age' of the lower denture, and mandibular jaw bone height.

In case of permucosal implants according to Brånemark implant system or IMZ implants two fixtures were inserted. After healing of the second phase, a new maxillary denture and a mandibular overdenture on a round shaped Ackerman bar were manufactured. In the transmandibular implant group (TMI) a triple-bar construction with cantilever extensions was used. One day post-operatively this suprastructure was placed. After a healing period of three months, a new maxillary denture and the mandibular overdenture were made. The non-surgical control group was treated by manufacturing a new set of dentures of high quality, with an optimal fit and balanced occlusion and articulation.

Assessments were performed prior to treatment, and one year following insertion of the new set of dentures. For subjects who refused the allocated treatment, the 'Intention To Treat' principle was applied. The main outcome measures were assessed using questionnaires focusing on 'denture satisfaction', denture-related complaints and 'a general satisfaction rate'. Based on the baseline data, principal component factor analysis with varimax rotation of the 'denture complaints' questionnaire revealed six interpretable scales: (A) 'Complaints

lower denture';(B) 'Complaints upper denture'; (C) 'Functional complaints in general'; (D) 'Physiognomy'; (E) 'Neutral space'; (F) 'Aesthetics'.

The results at the one year evaluation showed for four of the six factors significantly better scores for the IRO-group than for the CD-group (scale F is left out of further analysis because it did not vary after treatment). The same significant better score was found for the 'general satisfaction rate' for the IRO-group.

After one year all patients with a severely resorbed mandible, treated with an implant-retained overdenture in the lower jaw and a new denture in the upper jaw appeared to be satisfied, especially with regard to their lower denture. This favourable outcome was also reflected by the overall satisfaction rate: the majority (85%) had a score of 8 (rate 1-10) or even higher. The results found in the CD-group, treated with a new set of conventional dentures of high quality, were less favourable than those in the IRO-group. Regarding the main problem area in the CD-group, i.e. the lower denture, one third of the total number of patients was satisfied, but also one third was dissatisfied.

For patients with a severely resorbed mandible overdentures retained by dental implants appear to provide a more satisfactory solution to their denture-related problems than making new dentures alone. The two-center design of this study provides a high external validity of the results. The long term results, however remain to be evaluated to assess the real benefits of this promising implant-overdenture treatment.

In **chapter 4**, the treatment effects of mandibular overdentures on three different implant-systems in edentulous patients were compared, in a controlled clinical trial, one year after insertion of the new dentures. The three implant-systems used were the Brånemark-system (Brå) and the IMZ-system (IMZ) and a transmandibular system (TMI).

At the two departments (Groningen and Nijmegen) treatment was randomly assigned to 20 men and 73 women with a mandibular bone height of 8 to 15 mm as measured on a lateral cephalogram. All patients received a new maxillary denture and a mandibular overdenture. The variables used for treatment outcome assessment mainly were focused on the clinical aspects of the three implant-systems (Brå, IMZ or TMI). The measurement methods used for

the clinical treatment outcome evaluation included the following peri-implant parameters: Plaque Index (PI); Bleeding Index (BI); Gingiva Index (GI); Probing depth (PD); Keratinized mucosa (KM); and Lip or chin dysesthesia. Orthopantomographic radiographs (OPT) were used for the radiographic evaluation. According to the Delphi-method a Clinical Implant Performance scale (CIP-scale) was constructed based on all conceivable complications of the different implant systems.

The results of the peri-implant parameters and the radiographic score showed no significant differences for the three implant systems. The results for the CIP-scale were very promising, however, somewhat less favourable for the TMI-group than for the permucosal implants (IMZ and Brå), the slight differences were not significant for the three systems used.

The results indicate that either two IMZ-, or two Brå-implants or a TMI-system connected with a bar in the lower jaw supply a proper base for the support of an overdenture; the condition of the peri-implant tissues was good.

CLINICAL TRIAL GRONINGEN

In **chapter 5**, aftercare treatment during the first year was evaluated and compared for the patients treated in a prospective randomized controlled clinical trial at the Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics, University Hospital Groningen. A total of 150 patients were treated with an implant-retained mandibular overdenture on either two IMZ- or two Brånemark-implants (IRO-group), or with conventional dentures of high quality (CD-group) with or without pre-prosthetic surgery PPS-group). The subjects were edentulous in upper and lower jaw for at least one year. Patients with a total mandibular bone height of 8-25 mm as measured at the symphysis on a lateral cephalogram, i.e. Cawood class IV, V, VI and VII were included in the study.

The non-surgical control group (CD) was treated by manufacturing a new set of dentures of high quality with an optimal fit and balanced articulation. A vestibuloplasty was carried out in the PPS-group under general anaesthesia, according to the buccal onlay procedure. After a healing period of four weeks, new complete dentures were made. A vestibuloplasty was not performed in the 8-15 mm patient group as in this group the obtainable increase of the denture bearing area by this method is insignificant. In the IRO-group two permucosal implants according to the IMZ-system or the Brånemark-system were interforaminally inserted in the mandible under local anaesthesia. After the healing of the second stage surgery, i.e. abutment connection, the manufacturing of the new maxillary denture and mandibular overdenture was started. This overdenture was fixed by a single bar-clip attachment.

During the first year following placement of the conventional dentures or implant-retained prosthesis the type of needed aftercare were registered. In all groups, the nature of aftercare consisted of surgical, prosthodontic, and oral hygiene components. In addition, the time needed for these procedures by the dentist, surgeon and dental hygienist was assessed. No significant differences in the mean number of visits and the time needed by the dentist was observed between the conventionally treated groups and the groups treated with implants. The patients with a low mandibular height treated with a conventional denture needed less aftercare than the conventionally treated patients with a high mandibular height, although this difference is not significant. The explanation of

this contradiction probably is that the high mandibular height is often accompanied by a very narrow sharp ridge.

Concerning the Brånemark and IMZ implant systems, no differences in amount of aftercare applied by the dental hygienist were observed. In this study gingival hyperplasia needed surgical correction in two IMZ-patients only. During the first year of aftercare, the average time needed by the dentist was 30 minutes and by the dental hygienist was 2 hours.

We could not demonstrate any differences with regard to the amount of prosthodontic aftercare needed for conventional dentures and for patients treated with implants, and also not between the two implant systems studied. Patients treated with an implant-retained prosthesis needed relatively much support by the dental hygienist for maintaining a proper level of oral hygiene. It is important to know the long-term efficacy of this treatment, since oral hygiene maintenance requirements form an essential aspect in the indication and planning of implants.

In **chapter 6**, denture satisfaction and chewing ability of edentulous patients with denture related problems was compared. The patients were treated at the Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics, University Hospital Groningen, The Netherlands, in a controlled clinical trial with dental implants or with preprosthetic surgery or with full dentures alone (as a control).

Thirty-eight men and 52 women participated in the study. The mean height of the anterior mandible was 21 mm (range 16-25 mm), measured on a lateral cephalometric radiograph. The subjects were randomly assigned to three groups:

- IRO** Implant-Retained Overdenture group, treated with implant-retained mandibular overdentures and a new maxillary denture
- PPS** PreProsthetic Surgery group, treated surgically by a interforaminal vestibuloplasty and deepening of the floor of the mouth before inserting new complete dentures
- CD** Conventional Dentures group, treated with a new set of complete dentures.

Assignment was executed by means of a balancing allocation method to ensure comparability of the groups regarding age, gender, edentulous period in the

lower jaw, 'age' of the lower denture, and mandibular jaw bone height as measured on a lateral cephalogram.

In the IRO-group, permucosal implants according to Brånemark or IMZ were randomly applied. Two fixtures were inserted in or between the canine regions under local anaesthesia. After healing from the second stage surgery (i.e. abutment connection) the prosthodontic treatment was performed. All patients received a new maxillary denture and a mandibular overdenture on a round shaped Ackerman bar with a clip attachment in the overdenture. The PPS- and CD-group were treated by manufacturing a new set of dentures with an optimal fit and balanced articulation.

The main outcome measures were denture satisfaction and chewing ability. For this purpose questionnaires were used focusing on denture-related complaints and the ability to chew different types of food. Also an overall denture satisfaction rate was scored.

Based on the baseline data from the 'denture complaints' and 'chewing ability' questionnaires, nine interpretable factors could be extracted: (A) 'Complaints lower denture'; (B) 'Complaints upper denture'; (C) 'Functional complaints in general'; (D) 'Physiognomy'; (E) 'Neutral space'; (F) 'Aesthetics'; (G) 'Soft' food; (H) 'Tough' food; (I) 'Hard' food.

The results of the one-year evaluation showed significantly better scores for both the IRO and PPS group for the scales 'functional complaints lower denture' and 'neutral space' than for the CD-group. The scale 'functional complaints lower denture' showed even significantly better scores for the IRO-group as compared to the PPS-group. The scale 'functional complaints in general' showed significantly better scores for the PPS-group than for the CD-group. Two scales of the chewing ability questionnaire, i.e. 'hard food' and 'tough food', showed significantly better scores for both the IRO- and the PPS-group as compared to the CD-group. A similar improvement is also reflected by the 'overall denture satisfaction rate': the IRO-group and the PPS-group scored significantly higher than the CD-group. The factors 'Aesthetics' and 'Soft' food (F and G) did not vary following treatment and were excluded from the outcome analysis.

We conclude that after one year, denture satisfaction and chewing ability were most favourable in the group treated with implant retained mandibular overdentures (IRO). The results of the group treated with complete dentures

(CD) were less promising. Although the preprosthetic surgery group (PPS) also yielded good results, the best short term results were obtained in the group treated with implant retained mandibular overdentures (IRO). The long term results remain to be evaluated to assess the ultimate benefits of this promising implant-overdenture therapy.

In **chapter 7**, the treatment effects of mandibular overdentures on two different implant-systems in edentulous patients were compared in a controlled clinical trial one year after insertion of the new dentures. The two implant-systems used were the Brånemark-system (Brå) and the IMZ-system (IMZ).

At the Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics, University Hospital Groningen, treatment was randomly assigned to 19 men and 41 women with a mandibular bone height of 8 to 25 mm as measured at the symphysis on a lateral cephalogram. Two different implant-systems (Brå and IMZ) were randomly applied. Two fixtures were inserted under local anaesthesia. After a healing period of three months, the second stage surgery (i.e. abutment connection) was performed, the subsequent prosthodontic treatment was performed according to a standard procedure. All patients received a new maxillary denture and a mandibular overdenture. The implants were connected by a round shaped Ackerman bar with a clip attachment in the mandibular overdenture.

The variables used for treatment outcome assessment mainly were focused on the clinical aspects of the two implant-systems (Brå or IMZ). The measurement methods used for the clinical treatment outcome evaluation included the following peri-implant parameters: Plaque Index (PI); Bleeding Index (BI); Gingiva Index (GI); Probing depth (PD); Keratinized gingiva (KG); Lip or chin dysesthesia. Orthopantomographic radiographs (OPT) were used for radiographic evaluation. According to the Delphi-method a Clinical Implant Performance scale (CIP-scale) was constructed based on all conceivable complications of the different implant systems.

The results of one of the peri-implant parameters and the radiographical score showed significant differences considering the (pseudo) pocket probing depth (Brå better than IMZ, $p < 0.001$) and the röntgen-score (IMZ better than Brå, $p < 0.003$). The results for the CIP-scale were very promising, the results of

the Brå-group were less favourable than for the IMZ-group, however differences were not significant.

The results indicate that either two IMZ-implants, or two Brånemark implants connected with a bar in the lower jaw supply a proper base for the support of an overdenture; the condition of the peri-implant tissues was good. This study is an attempt to compare the clinical performance of two different implant systems in a clinical trial. To assess the possible clinical differences between different implant systems middle- and long term evaluation is necessary.

In **chapter 8**, the impact of the dental implants on the quality of life will be described in comparison with two conventional treatments. The patients were treated at the Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics, University Hospital Groningen, The Netherlands, in a controlled clinical trial with dental implants or with preprosthetic surgery or with full dentures alone (as a control).

The subjects were randomly assigned to three groups:

IRO Implant-Retained Overdenture group, treated with implant-retained mandibular overdentures and a new maxillary denture

PPS PreProsthetic Surgery group, treated surgically by a interforaminal vestibuloplasty and deepening of the floor of the mouth before inserting new complete dentures

CD Conventional Dentures group, treated with a new set of complete dentures.

In the IRO-group, permucosal implants according to Brånemark or IMZ were randomly applied. The PPS- and CD-group were treated by manufacturing a new set of dentures with an optimal fit and balanced articulation.

The psycho-social impact has been operationalized with the next scales: Groningen Activity Restriction Scale - Dentistry (GARS-D); Psychological Well-being scale for Denture Patients and Hopkins Symptom Check List (HSCL). The general quality of life was assessed with the Linear Analogue Self Assessment method (LASA, 1 item version, Andrews, 1976); 'Expectations about the treatment / 'Outcome of the expectations'.

Before treatment the IRO-group, the PPS-group and the CD-group did not differ significantly as to the impact the dental condition had on their social

activities. The average scores in all the three groups on almost all specific quality of life aspects had improved significantly 12 months after treatment. This means that on average all patients experienced less restrictions in their social activities and had less psychological problems because of their full dentures. No impact on the general quality of life was established. It is concluded that all three dental treatments, if carried out under comparable circumstances, have the same positive effect on dental health related quality of life.