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Mandibular overdentures supported by two or four endosseous implants
A 5-year prospective study

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Key words: edentulous mandible, endosseous dental implants, overdentures, prospective study

Abstract
Objective: The aim of this 5-year prospective comparative study was to evaluate treatment outcome (survival rate, condition of hard and soft peri-implant tissues, patient satisfaction, prosthetic and surgical aftercare) of mandibular overdentures supported by two or four implants.

Material and methods: Sixty edentulous patients with a mandibular height between 12 and 18 mm participated. Thirty patients were treated with an overdenture supported by two IMZ implants (group A) and 30 patients were treated with an overdenture supported by four IMZ implants (group B). Standardised clinical and radiographic parameters were evaluated 6 weeks after completion of the prosthetic treatment and after 1, 2, 3, 4 and 5 years of functional loading. Prosthetic and surgical aftercare was scored during the evaluation period.

Results: One implant was lost (group A) during the healing period. There were no significant differences with regard to any of the studied clinical or radiographic parameters of the peri-implant tissues between the groups. None of the patients reported sensory disturbances in the lip or chin region. No differences in satisfaction were observed between the groups. With regard to aftercare, there was a tendency of a greater need of prosthetic interventions in group A, while correction of soft-tissue problems was restricted to patients of group B.

Conclusion: There is no difference in clinical and radiographical state of patients treated with an overdenture on two or four implants during a 5-year evaluation period. Patients of both groups were as satisfied with their overdentures.

Edentulous patients often experience problems with their mandibular complete dentures. Lack of stability and retention of their mandibular denture, together with a decreased chewing ability are the main complaints of these patients [Van Waas 1990]. A modern and currently frequently used treatment possibility is to place endosseous implants in the mandible to support an overdenture [Short communication 2002]. This is an approach that already was studied by Jemt and Lindqvist in the 1980s [Jemt et al. 1985] and still is of great value in the rehabilitation of edentulous patients [Batenburg et al. 1998a]. The survival rate of implants, either placed as a one- or two-stage procedure, applied to support a mandibular overdenture has been shown to be successful in over 96% of all cases [Batenburg et al. 1998a; Buser et al. 1999; Heydenrijk et al. 2002]. The 10-year survival rates of implants to support mandibular overdentures

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tended to be slightly higher than survival rates of endosseous implants in the mandible used to support fixed full-arch bridges, fixed partial dentures or single crowns [Mericke-Stern et al. 2001; Ferrigno et al. 2002].

For general application in the edentulous mandible, a treatment concept utilising two or four implants to support a mandibular overdenture has been proposed [Batenburg et al. 1998a, 1998b]. Studies prospectively comparing various implant systems and/or number of implants are still sparsely reported in the literature. Most prospective mandibular overdenture studies with a follow-up period of at least 5 years evaluated one implant system and a fixed number of implants only, e.g. the studies of Mericke-Stern et al. [1994] and Behnke et al. [2002] with the ITI dental implant system [Straumann AG, Waldenburg, Switzerland], and Jemt et al. [1996] and Naert et al. [1998] with the Bränemark implant system [Nobel Biocare, Gothenburg, Sweden]. Although these studies conclude that both one- and two-stage implants as well as treatment concepts with either two or four implants result in a good treatment outcome regarding prosthetic rehabilitation of the patient with problems with their mandibular dentures, there is still a need for comparing the treatment outcome of two vs. four implants in a prospective study with predefined inclusion and exclusion criteria. Only randomised evaluation studies comparing two or more treatment modalities can be conclusive [Antczak-Bouckoms 1988; Barnes 1990]. Currently, few prospective studies have been published comparing the treatment concept with two or four endosseous implants to support a mandibular overdenture, all with a rather short evaluation period [Wismeijer et al. 1997, 1999; Batenburg et al. 1998b]. Therefore, the aim of this prospective comparative study was to evaluate treatment outcome (survival rate, condition of hard and soft peri-implant tissues, patient satisfaction, prosthetic and surgical aftercare) of mandibular overdentures supported by two or four implants during a 5-year evaluation period.

Material and methods

Patient selection and treatment

Sixty edentulous patients [39 women, 21 men; mean age, 54.9 years; median, 52 years; range, 38–81 years] were selected. They were all referred by their dentist or general medical practitioner to our clinic for Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics. All patients were suffering from reduced stability and insufficient retention of their mandibular denture. Inclusion criteria for the clinical trial were an edentulous period of at least 2 years and severe resorption of the mandible [mandibular height in the symphysis region between 12 and 18 mm], class V–VI according to the Cawood classification [Cawood & Howell 1988]. Patients with a history of radiotherapy in the head and neck region or a history of preprosthetic surgery or previous implant placement were excluded. The hospital medical ethical committee approved the study.

The patients were informed about the treatment options [overdenture on two or four endosseous implants] which were both appropriate in the included patients. Written informed consent was obtained from all participants. Treatment was randomly allocated by lots resulting in 30 patients [group A] to be treated with two IMZ implants [titanium plasma spread (TPS), Friedrichsfeld AG, Mannheim, Germany] and 30 patients [group B] to be treated with four IMZ implants. The baseline characteristics presented in Table 1.

Three months after implant placement, second-stage surgery (thinning of the peri-implant mucosa and placement of the abutment) was performed. Two weeks thereafter, standard prosthetic treatment was carried out: a new maxillary complete denture and a mandibular overdenture supported by an individual made round bar with no distal extensions and clip attachment. One experienced oral-maxillofacial surgeon and one experienced prosthodontist treated all patients.

Clinical analysis

The clinical analysis included a number of parameters. Loose and lost implants were scored any time after placement. For presence of plaque, the index according to Mombelli et al. [1987] was used [score 0: no detection of plaque, score 1: plaque can be detected by running a probe across the smooth marginal surface of the abutment and implant, score 2: plaque can be seen by the naked eye, score 3: abundance of plaque]. The presence of calculus [score 1] or the absence of calculus [score 0] was scored. To qualify the degree of peri-implant inflammation, the modified Löe and Silness index [Löe & Silness 1963] was used [score 0: normal peri-implant mucosa, score 1: mild inflammation, slight change in colour, slight oedema; score 2: moderate inflammation, redness, oedema and swelling; score 3: severe inflammation, marked redness and oedema, ulceration]. For bleeding, the bleeding index according to Mombelli et al. [1987] was used [score 0: no bleeding when using a periodontal probe, score 1: isolated bleeding spots visible, score 2: a confluent red line of blood along

### Table 1. Baseline characteristics of groups A and B

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group A (n = 30)</th>
<th>Group B (n = 30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age in years (SD, range)</td>
<td>54 (8.7, 38–77)</td>
<td>55.7 (12.3, 35–79)</td>
</tr>
<tr>
<td>Gender (number of males/females)</td>
<td>9/21</td>
<td>6/24</td>
</tr>
<tr>
<td>Mean edentulous period lower jaw in years (SD)</td>
<td>21 (9)</td>
<td>21.8 (10.5)</td>
</tr>
<tr>
<td>Mean mandibular bone height in mm (SD)</td>
<td>15.8 (2.3)</td>
<td>15.7 (2.7)</td>
</tr>
<tr>
<td>Mean bone quality (possible score 1–4)</td>
<td>3</td>
<td>2.7</td>
</tr>
</tbody>
</table>

SD, standard deviation.

### Table 2. Distribution of lengths of inserted IMZ implants

<table>
<thead>
<tr>
<th>Length (mm)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 IMZ</td>
<td>11</td>
</tr>
<tr>
<td>3 IMZ</td>
<td>13</td>
</tr>
<tr>
<td>4 IMZ</td>
<td>15</td>
</tr>
</tbody>
</table>

Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics. All patients were suffering from reduced stability and insufficient retention of their mandibular denture. Inclusion criteria for the clinical trial were an edentulous period of at least 2 years and severe resorption of the mandible [mandibular height in the symphysis region between 12 and 18 mm], class V–VI according to the Cawood classification [Cawood & Howell 1988]. Patients with a history of radiotherapy in the head and neck region or a history of preprosthetic surgery or previous implant placement were excluded. The hospital medical ethical committee approved the study.

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The implants were inserted under local anaesthesia in the interforaminal region according to the procedure described by Kirsch [1983]. All implants were placed as a two-stage procedure by the same oral surgeon. In group A, the implants were placed in the canine region of the mandible, about 1 cm left and right from the midline. In group B, there was an equal distance between the four implants and the most lateral implants were placed at least 5 mm medially of the mental foramen. Standard postoperative treatment was composed of analgesics and chlorhexidine 0.2% mouthrinses, but no antibiotics. The distribution of the lengths of the implants is presented in Table 2.
the mucosa margin, score 3: heavy or profuse bleeding). Probing depth was measured at four sites of each implant (mesially, labially, distally, lingually) by using a periodontal probe (Merit B, Hu Friedy, Chicago, IL, USA) after removal of the bar; the distance between the marginal border of the mucosa and the tip of the periodontal probe was scored as the probing depth.

**Radiographic analysis**
Standardised intraoral radiographs using the long cone technique of each implant were obtained using a beam direction device as described by Meijer et al. (1992) [Fig. 1a]. Analysis was done with a digital sliding gauge (Helios digit E 2056, Schneider & Kern, Niedernhall, Germany). Two-point measurements were made along the implant axis from a fixed reference point (connection between abutment and the goldcap of the bar structure, Fig. 1b) to the level of bone (Meijer et al. 1993). Measurement was performed mesially and distally of each implant. The jawbone quality was scored according to the classification of Lekholm & Zarb (1985) [Table 1].

**Patient satisfaction**
The questionnaire focused on complaints and consisted of 54 items [Vervoorn et al. 1988]. It was divided into six scales:

- [A] Nine items concerning functional problems of the lower denture,
- [B] nine items concerning functional problems of the upper denture,
- [C] 18 items concerning functional problems/complaints in general,
- [D] three items concerning facial aesthetics,
- [E] three items concerning accidental lip, cheek and tongue biting (‘neutral space’),
- [F] 12 items concerning aesthetics of the denture.

The extent of each specific complaint could be expressed on a four-point rating scale (0 = no complaints, 1 = little, 2 = moderate, 3 = severe complaints).

**Data collection**
Pretreatment satisfaction of the patients with their dentures was scored according to the method described above. The subsequent data collection [clinical analysis,
radiographic analysis, patient satisfaction) of all patients was performed as in the following: $T_0$ (baseline evaluation, 6 weeks after placement of the overdenture) and 1 ($T_1$), 2 ($T_2$), 3 ($T_3$), 4 ($T_4$) and 5 ($T_5$) years after placement of the overdenture. One independent investigator performed the measurements in all patients to prevent inter-observer differences. Prosthetic and surgical aftercare was continuously scored during the 5-year follow-up.

**Statistical analysis**

The data were analysed using t-tests for the continuous data and Mann–Whitney tests for the ordinal data. The correlation was tested using Pearson's correlation tests (SPSS for Windows, version 10.0, SPSS Incorporated, Chicago, IL, USA). In all tests, a significance level of 0.05 was chosen.

**Results**

All patients completed $T_0$ (evaluation 6 weeks after placement of the overdenture). At $T_1$ (evaluation 1 year after placement of the overdenture), one patient (group A) had died because of an accident and one patient (group B) had moved. At $T_3$ (evaluation 5 year after placement of the overdenture), two patients (group B) had died.

With regard to the variables studied, no significant differences occurred between $T_1$, $T_2$, $T_3$, $T_4$ and $T_5$. For reasons of clarity, only the results of the 1 ($T_1$) and 5 ($T_5$) years follow-up are given with exception of marginal bone loss as a function of time.

**Clinical parameters**

During the healing period prior to the abutment connection operation, one implant was lost in group A (implant length 11 mm) resulting in a survival rate of the implants 5 years after loading of 99.9% (cumulative survival for IMZ implants, either placed in a two- or four-implant concept). After a period of 6 months, a new IMZ implant was successfully placed; this patient was included in the study for follow-up evaluation. During the functional period, no implants were lost.

The mean scores of the six scales of the questionnaire focusing on the complaints of the patients are listed in Table 4. Before treatment, patients from both groups were equally dissatisfied with regard to their lower dentures. The functional complaints had significantly improved at the 1-year evaluation ($P<0.05$) and remained at this level during the 5-year follow-up. Also (facial) aesthetics and neutral space had significantly improved at both the 1- and 5-year follow-up ($P<0.05$). After treatment, patients of both groups were equally satisfied with their overdentures.

**Prosthetic and surgical aftercare**

The overall prosthetic aftercare during the 5-year follow-up is listed in Table 5. Concerning the prosthetic aftercare, there was a tendency of a greater need of prosthetic interventions in group A, while surgical correction of soft tissues seemed merely a problem restricted to patients of group B. In the first year after placement, hardly any interventions were needed.

**Radiographic parameters**

The marginal bone loss as a function of time is shown in Figs 1 and 2. The average annual bone loss over 5 years of time was 0.32 and 0.25 mm in groups A and B, respectively. No significant differences in bone loss were observed between both groups.

**Table 4. Mean score of six scales concerning the denture complaints before, and 1 and 5 years after treatment (possible range, 0–3)**

<table>
<thead>
<tr>
<th></th>
<th>Pretreatment</th>
<th>$T_1^*$</th>
<th>$T_5^*$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$T_0$</td>
<td>$T_5$</td>
<td>$T_0$</td>
</tr>
<tr>
<td></td>
<td>Group A ($n = 30$)</td>
<td>Significance</td>
<td>Group A ($n = 29$)</td>
</tr>
<tr>
<td>(A) Functional complaints about lower denture</td>
<td>2.2</td>
<td>2.2</td>
<td>Not sig.</td>
</tr>
<tr>
<td>(B) Functional complaints about upper denture</td>
<td>0.4</td>
<td>0.5</td>
<td>Not sig.</td>
</tr>
<tr>
<td>(C) Functional complaints in general</td>
<td>1</td>
<td>1</td>
<td>Not sig.</td>
</tr>
<tr>
<td>(D) Facial aesthetics</td>
<td>1.1</td>
<td>0.6</td>
<td>Not sig.</td>
</tr>
<tr>
<td>(E) ‘Neutral space’</td>
<td>0.6</td>
<td>0.6</td>
<td>Not sig.</td>
</tr>
<tr>
<td>(F) Aesthetics</td>
<td>0.4</td>
<td>0.4</td>
<td>Not sig.</td>
</tr>
</tbody>
</table>

*Functional complaints had significantly improved between $T_0$ and the other evaluation times ($P<0.05$).
Not sig., not significant.
Prosthetic corrections mainly consisted of placing new clips or fastening loose clips. Also repair of the denture base or elements occurred rather frequently, while there was almost no need for relining of dentures or readjustment of occlusion. Surgical interventions were only needed in patients of group B and consisted of gingivectomy (one patient) and palatal mucosa grafts (five patients) because of peri-implant hyperplasia of the mucosa and tissue overgrowth of the implants.

Discussion

This is the first prospective study evaluating mandibular overdentures supported by two or four endosseous implants. The 5-year survival rate of IMZ implants in this prospective study is over 99%. This percentage is comparable with other prospective studies which have reported survival rates of implants supporting an overdenture ranging from 86% to 98.8% (Mericske-Stern et al. 1994; Jemt et al. 1996; Naert et al. 1998; Meijer et al. 2000, 2001; Behneke et al. 2002). Comparison of the clinical and radiographic parameters between these studies is difficult because of the variation in clinical and radiographic parameters used.

The mean indices for plaque, calculus, gingiva and bleeding were very low at all evaluation periods for the groups. Also no differences in loss of marginal bone were observed. The scores are comparable with the studies of Meijer et al. (2000, 2001) in which the same criteria were used. The strict oral hygiene regime to which patients were subjected provided healthy peri-implant tissues.

Peri-operative antimicrobial treatment was not given either during the surgical procedures for insertion of implants and abutment connection. Given the high survival rate in this study it can be doubted whether there is still a rationale for the use of these agents in this type of surgery. To our opinion insertion of implants in the edentulous mandible is a predictable treatment modality and there seems to be no need for antimicrobial agents other than a chlorhexidine mouthrinse and proper oral hygiene.

There was only a need for gingivectomy and palatal mucosa grafts in patients of group B. In our opinion, this might be caused by the fact that the distance between the implants in group B was smaller than group A. Further research regarding this subject is needed before any conclusion can be drawn.

With regard to marginal bone level, no significant differences were noted in increase of bone defects between groups A and B during the evaluation period. This is in agreement with the study of Wismeijer et al. (1997, 1999). These authors showed a significantly higher bone loss around the central implants as compared with the lateral implants. In the present study, there was no significant difference with regard to peri-implant bone loss between any of the four implants in group B during the evaluation period.

Intraoral radiographs were used in the study of Jemt et al. (1996), who reported 0.5 mm bone loss during the entire 5-year follow-up. Naert et al. (1998) reported 0.6 mm during the first year and thereafter an average annual bone loss of less than 0.1 mm. Bone loss reported in the present study is comparable with the results of the mentioned studies. Marginal bone loss was 0.7 mm for group A and 0.4 mm for group B during the first year. This phenomenon of up to 1 mm bone loss has been described previously (Adell et al. 1981) and is related to maturation of bone after implant placement and adaptation of bone to withstand functional forces. An annual bone loss of 0.2 mm after this period has been recognised as acceptable (Albrektsson et al. 1986). In the present study, annual bone loss was seen in all groups, but did not exceed 0.2 mm. No correlation between the radiographic and peri-implant parameters was observed. Obviously, the clinical peri-implant parameters do not always predict the results of the radiographic peri-implant bone loss (Batenburg et al. 1998a, 1998b).

From this study, it is concluded that there is no difference in clinical and radiographical state of patients treated with an overdenture on two or four implants (in cases of Cawood class IV–VI resorption) during a 5-year evaluation period. Patients of both groups were as satisfied with their overdentures.

Résumé

Le but de cette étude comparative et prospective de cinq années a été d’évaluer la guérison [taux de survie, condition des tissus paroimplantaires mus aux et durs, satisfaction du patient, prothèse et chirurgie] de prothèses mandibulaires sur deux ou quatre implants. Soixante édentés avec une hauteur mandibulaire entre douze et 18 mm ont participé. Trente patients ont été traités avec une prothèse ancrée sur deux implants IMZ (groupe A) tandis que les trente autres ont été traités avec une prothèse ancrée sur quatre implants IMZ (groupe B). Les paramètres radiographiques et cliniques standards ont été évalués six semaines après la mise en place de la prothèse et ensuite une, deux, trois, quatre et cinq années après la mise en charge fonctionnelle. Le suivi chirurgical et prothétique a été évalué durant cette période. Un implant a été perdu dans le groupe A durant la période de guérison. Il n’y avait aucune différence significative en ce qui concerne aucun des paramètres radiographiques et cliniques étudiés des tissus paroimplantaires entre les deux groupes. Aucun des patients n’a rapporté d’ennuis sensoriels au niveau de la levre ou du menton. Aucune différence dans la satisfaction n’a été observée entre les deux groupes. En ce qui concerne le maintien, une nécessité plus importante d’intervention au niveau des prothèses était constatée dans le groupe A tandis que
Zusammenfassung

Hybridprothesen im Unterkiefer getragen von 2 oder 4 endossealen Implantaten. Eine prospektive Studie über 5 Jahre


Material und Methoden: An der Studie nahmen 60 zahnlose Patienten mit einer Unterkieferhöhe zwischen 12 und 18 mm teil. 30 Patienten wurden mit einer Hybridprothese getragen von 2 IMZ Implantaten versorgt (Gruppe A), und 30 Patienten erhielten eine Hybridprothese auf 4 IMZ Implantaten [Gruppe B]. Standardisierte klinische und radiologische Parameter wurden 6 Wochen nach Eingliederung der Rekonstruktion und nach 1, 2, 3, 4 und 5 Jahren funktioneller Belastung ausgewertet. Die prothetische und chirurgische Nachsorge wurde während der Beobachtungsperiode aufgezeichnet.


Resumen

Objetivo: La intención de este estudio fue prospec-tivo comparativo de 5 años fue evaluar los resultados del tratamiento (índice de supervivencia, condiciones de los tejidos duros y blandos perimplantarios, satisfacción del paciente, mantenimiento postquirúrgico y postprotesico) de sobredentaduras mandibulares soportadas por 2 o 4 implantés.

Material y Métodos: Participaron 60 pacientes edentulos con una altura mandibular entre 12 y 18 mm. Se trataron 30 pacientes con una sobredentadura soportada por 2 implantes IMZ [grupo A] y 30 pacientes se trataron con una sobredentadura soportada por 4 implantes IMZ [grupo B]. Se evaluaron parámetros clínicos y radiológicos a las 6 semanas tras conclusión del tratamiento protésico y tras 1, 2, 3, 4 y 5 años de carga funcional. Se tomó nota del mantenimiento protésico y quirúrgico durante el periodo de evaluación.

Resultados: Se perdió un implante [grupo A] durante el periodo de cicatrización. No hubo diferencias significativas respecto a ninguno de los parámetros clínicos y radiográficos estudiados de los tejidos perimplantarios entre los grupos. Ninguno de los pacientes informó sobre molestias sensoriales en el labio o la región del mentón. No se observaron diferencias entre los grupos respecto a la satisfacción. Respecto al mantenimiento, hubo una tendencia a una mayor necesidad de intervenciones prostéticas en el grupo A, mientras que las correcciones en los tejidos blandos se circunscribieron al grupo B.

Conclusions: No hay diferencias en el estado clínico y radiográfico de los pacientes tratados con una sobredentadura en 2 o 4 implantes durante un periodo de evaluación de 5 años. Los pacientes de ambos grupos estaban satisfechos con sus sobredentaduras.


