Clinical aspects of a multicenter clinical trial of implant-retained mandibular overdentures in patients with severely resorbed mandibles

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In a multicenter clinical trial treatment, the effects of overdentures on different implant systems in patients with severely resorbed mandibles were compared 1 year after the insertion of new dentures. The implant systems used were the transmandibular implant (TMI), the IMZ (IMZ), and the Bränemark system (BRÅ). Treatment was randomly assigned to 88 patients according to a balanced allocation method. Evaluation included peri-implant and radiographic parameters. According to the Delphi method a Clinical Implant Performance scale (CIP) was constructed based on all conceivable complications of the different implant systems. During the healing period, one IMZ and one BRÅ implant were lost, and one TMI implant was removed after functional loading. The results of the peri-implant and radiographic parameters and the CIP scale revealed no significant differences between the three implant systems. (J Prosthet Dent 1996;75:194-204.)

A high rate of success has been documented for osseointegrated implants that support fixed prostheses in edentulous jaws.1,2 However, reports about implant-retained mandibular overdentures are scarce and have been presented only in recent years.3-8 The results seem to be comparable with those of implant-supported fixed prostheses. Most studies do not report on patients with severely resorbed alveolar ridges. A maximum height of the alveolar ridge as an inclusion criterion is almost never mentioned; only a minimum height is requested for implantation.

Few studies have been published in which different implant systems retaining overdentures were compared. Lack of identical evaluation criteria and differences in selection criteria and patients' characteristics make comparison of studies in which only one implant system is used impossible. The only study design that enables comparison of different implant systems is a clinical trial. In spite of recommendations to perform phase III randomized clinical trials,9-11 this study design is seldom applied.

This study is part of a multicenter randomized clinical trial in which treatment effects of different implant systems that retain mandibular overdentures in patients with severely resorbed mandibles were compared with each other and with a control treatment, namely complete conventional dentures. Patient-related and clinical aspects were evaluated. The results of patient-related aspects were presented in a previous article.12 This study compared clinical and radiographic aspects of different implant systems (retaining mandibular overdentures) in patients with severely resorbed mandibular alveolar ridges 1 year after insertion of the overdentures. The implant systems used were the transmandibular implant (TMI), the IMZ (IMZ), and the Bränemark (BRÅ) systems. Clinical aspects include criteria to evaluate the peri-implant tissues and criteria to evaluate the mandibular overdentures retained by these different implant systems.

MATERIAL AND METHODS
Patient selection and study design

For this clinical trial, edentulous patients with severely resorbed mandibles and persistent problems and who wore conventional complete dentures were selected. Two centers participated in this study, the Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics at the University Hospital Groningen and the Departments of Oral Function and Prosthetic Dentistry and Oral and Maxillofacial Surgery at the University of Nijmegen, The
Netherlands. The criteria for inclusion were: a mandibular symphyseal bone height of 8 to 15 mm as measured on a standardized lateral cephalogram, no history of preprosthetic surgery or implant treatment, and no general medical contraindications for implants or a surgical procedure.

All patients were informed about the different treatment options, possible risks, and the method used for treatment assignment. Written informed consent was obtained from all participating patients.

Treatment was randomly assigned by use of a balancing procedure to aim at an equal distribution of patients over the treatment groups with regard to 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 the present mandibular denture was worn, and the symphyseal bone height of the mandible. The study design is described in full detail in a previous article.

In the period of November 1989 until September 1991, 157 patients were selected and treatment was randomly allocated. Implant-retained overdenture treatment was allocated to 93 patients and complete denture treatment to 64 patients. Because this article deals with clinical aspects of different implant systems, the results of the complete denture group will not be presented. Five patients refused implant treatment; thus the total group consisted of 88 patients at baseline. Table I shows that 58 of these patients were treated with permucosal implants (41 IMZ and 17 Brånemark implants) and 30 with a transmandibular implant. Characteristics of the patients are presented in Table II. The group consisted of 69 women and 19 men and their ages varied from 35 to 84 years, with an average of 64 patients. Because this article deals with clinical aspects of different implant systems, the results of the complete denture group will not be presented. Five patients refused implant treatment; thus the total group consisted of 88 patients at baseline. Table I shows that 58 of these patients were treated with permucosal implants (41 IMZ and 17 Brånemark implants) and 30 with a transmandibular implant. Characteristics of the patients are presented in Table II. The group consisted of 69 women and 19 men and their ages varied from 35 to 84 years, with an average of 54 years.

Treatment procedures

The transmandibular implant (Krønen Medical BV, Beesd, The Netherlands) according to Bosker was inserted in the patient, who was under general anesthesia. The distribution of the lengths of the posts and implants is presented in Table III. The superstructure, which consisted of a triple-bar construction with two cantilever extensions, was placed the day after surgery. For a period of 3 months, the patients were not allowed to eat solid food or wear the mandibular denture. After this period, the fabrication of the new maxillary denture and the mandibular overdenture was started.

In case of permucosal implants according to the IMZ system (Friedrichsfeld AG, Mannheim, Germany) (Fig. 2) and the Brånemark system (Nobelpharma AB, Göteborg, Sweden) (Fig. 3), two implants were inserted interforaminal in the mandible while the patient was 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 3 months, second-stage surgery (abutment connection) was performed and the fabrication of the new maxillary denture and mandibular overdenture began. The overdentures were supported by a single bar clip attachment.

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

Data collection

*Balancing criteria.

<table>
<thead>
<tr>
<th>Table I. Number of participants in the trial</th>
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<td><strong>Center</strong></td>
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</tr>
<tr>
<td>Nijmegen</td>
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<tr>
<td>Groningen</td>
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<td>Total</td>
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<th>Table II. Patient characteristics</th>
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<tr>
<td><strong>Age in years (SD)</strong></td>
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<tr>
<td><strong>Gender</strong></td>
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<tr>
<td>Men (%)</td>
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<tr>
<td>Women (%)</td>
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<tr>
<td>Groningen (%)</td>
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<tr>
<td>Nijmegen (%)</td>
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<td><strong>Edentulous period mandible in years</strong></td>
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<tr>
<td><strong>Edentulous period maxilla in years</strong></td>
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<tr>
<td><strong>Number of mandibular dentures</strong></td>
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<td><strong>Number of maxillary dentures</strong></td>
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<td><strong>Age of present mandibular denture</strong></td>
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<tr>
<td><strong>Age of present maxillary denture</strong></td>
</tr>
<tr>
<td><strong>Mandibular bone height in mm</strong></td>
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</table>

*Balancing criteria.

**Periodontal parameters.** The plaque index (PI) and the bleeding index (BI) according to Mombelli et al. and the gingiva index (GI) according to Loe and Silness were used. Probing depth (PD) was assessed at four locations around each implant or post (mesially, buccally, distally, and lingually) with a Meritt-B periodontal probe (Hu-Friedy, Chicago, Ill.). Keratinized mucosa (KM) was assessed at two sites around each abutment (buccally and lingually) according to the recommendations of Apae et al.

**Radiographic evaluation.** Orthopantomographic radiographs (OPT) were made immediately after surgery and 1 year after insertion of the new dentures. The marginal bone height of the implant was evaluated both mesially and distally. One year after insertion, the radiographs of the new dentures were compared with the radiographs immediately after surgery. These comparative classifica-
tions were rated on a four point scale (0 through 3): 0, no apparent bone loss; 1, reduction of the bone level not exceeding more than a third of the implant length; 2, reduction of the bone level exceeding a third of the implant length but not exceeding half of the implant length; and 3, reduction of the bone level exceeding half of the implant length.

Clinical Implant Performance scale

To compare the results of the different implant systems all surgical, prosthetic, radiographic, and peri-implant complications that occurred from the day the new dentures were fabricated until 1 year after insertion were taken into account. With these data, a clinical implant performance scale (CIP scale) was constructed according to the Delphi method.

The Delphi method is a method to obtain consensus in questions that are issues of uncertainty even to experts described by Milholland et al.\textsuperscript{21} For this study, all conceivable complications that might occur after placement of dental implants were written and presented to six experts. They were asked to rate their anonymous opinion for each complication on a five-point rating scale. When differences in opinion occurred, they were asked to rate their opinion again on the basis of their knowledge of the scores of the other experts. After three rounds there was almost complete agreement (agreement of at least five of the six experts) on 88% of the items. The principles of the Delphi method and the construction of this CIP scale were described by Van Waas et al. (unpublished material).

The CIP scale consisted of a five-point rating scale (0 through 4): 0, success with no complications; 1, minor

Fig. 1. A and B, Transmandibular implant according to Bosker.
complications that do not need intervention or are easily treated; 2, complications with a chance of recovery or stabilization of the present situation; 3, serious complications that may lead to failure of the implant system; and 4, failure of the implant system.

Minor complications (CIP 1) were gingival hyperplasia, relining of maxillary or mandibular denture, readjustment of occlusion and articulation, clip loosening, fracture of a cantilever extension (TMI), coping screw loosening (IMZ/BRA), broken abutment (IMZ/BRA), a slight sensory disturbance of the mental nerve, radiographic score 0 along with PD ≥5.5 mm, radiograph score 1 along with PD <5.5 mm.

Complications with a chance on recovery or stabilization of the present situation (CIP 2) were correction of a non-fitting superstructure, fracture of the superstructure, a severe sensory disturbance of the mental nerve, fracture of one post (TMI), radiograph score 1 along with PD ≥5.5 mm or radiograph score 2 along with PD <5.5 mm.

Serious complications (CIP 3) were scored if one or two posts were mobile (TMI), in case of removal of one post (TMI), a radiograph score 2 along with PD ≥5.5 mm or a radiograph score 3.

Failure of the implant system (CIP 4) was scored in case of removal of two or more posts (TMI) or removal of one or two implants (BRA/IMZ).

**Interobserver agreement**

Before measuring was started, the criteria for the clinical and radiographic parameters were evaluated. In each
center, two observers were selected for the 1-year evaluation. Several times, observers were exchanged between the two centers as a control of the standard protocol. Interob-
servers agreement was determined by means of Cohen's kappa. Kappa represents the observed proportion of non-
chance agreement. The Cohen's kappa for the PI was 0.57, the BI was 0.44, GI 0.54, and KM 0.67.

**Statistical analysis**

Differences between the treatment groups before treat-
ment and between the implant systems at the 1-year evalua-
tion were tested at patient level; namely, the mean pa-
tient values were analyzed. A two-way analysis of variance
(ANOVA) was applied according to treatment and center
to correct for possible confounding followed by multiple comparison.

**RESULTS**

The comparability of all groups was tested before treat-
ment for the variables listed in Table II. No significant dif-
ferences were evident (two-way ANOVA or logistic regres-
sion for gender).

During the healing period before loading, two failures were observed, one Brânemark implant and one IMZ im-
plant. Both implants were successfully replaced after bone healing, and 3 months after replacement they were func-
tionally loaded and remained successfully in function.

During the first year after insertion of the new dentures

Fig. 3. A and B, Two Brânemark implants with bar.
Fig. 4. Plaque index according to Mombelli et al.\textsuperscript{18}: TMI (n = 105), IMZ (n = 82), BRÅ (n = 34) (implants/posts).

Table III. Frequencies of the most length of the transmandibular implant (n 119) and of the implant length of the IMZ (diameter 3.3 mm n = 12; 4.0 mm n 70) and Bränemark implants (diameter 3.75 mm)

<table>
<thead>
<tr>
<th></th>
<th>TMI</th>
<th>IMZ</th>
<th>BRÅ</th>
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<tbody>
<tr>
<td>Post length (in mm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>4</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>10</td>
<td>26</td>
<td>8</td>
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</tr>
<tr>
<td>12</td>
<td>44</td>
<td>10</td>
<td></td>
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<tr>
<td>14</td>
<td>29</td>
<td>34</td>
<td></td>
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<tr>
<td>16</td>
<td>15</td>
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<td></td>
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<tr>
<td>18</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>105</td>
<td>82</td>
<td>34</td>
</tr>
</tbody>
</table>

Peri-implant parameters

The mean scores of two observers for all peri-implant parameters are used in subsequent analyses. Either four posts of the transmandibular implant or two IMZ or two Bränemark implants per patient are presented in Figs. 4 through 9. This means that n = 105 for the TMI group, 82 for the IMZ group and 34 for the BRÅ group. For the testing of differences between the implant systems the number of observations (patients) are 28, 41, and 17 respectively, for the TMI, the IMZ, and the BRÅ groups. The frequency distribution of implants/posts with(out) plaque is illustrated in Fig. 4. The mean values were 0.5 (TMI), 0.5 (IMZ), and 0.6 (BRÅ). The differences between the implant systems were not significant (two-way ANOVA). The corresponding values for the BI for the TMI, IMZ, and BRÅ groups were 0.4, 0.4, and 0.3 respectively, and the differences were not significant (two-way ANOVA) (Fig. 5). The frequency of gingival inflammation around the implants/posts is illustrated in Fig. 6. The mean values were 0.5 (TMI), 0.7 (IMZ), and 0.2 (BRÅ). The differences between the IMZ and the BRÅ groups were significant, and the differences between TMI-IMZ and TMI-BRÅ were not significant (two-way ANOVA). The frequency distributions of the PDs were in the ranges 0 to 3 mm, 3.5 mm to 5 mm, and 5.5 mm or more (Fig. 7). The mean PD (four measurements per implant/post) for the TMI group was 3.0 mm (SD 0.4), 3.7 mm (SD 0.9) for the IMZ group, and 2.5 mm (SD 0.8) for the BRÅ group. Differences between IMZ BRÅ and IMZ-TMI were significant; differences between TMI-BRÅ were not significant (two-way ANOVA). GI and PD showed significant differences among the implant systems,
Fig. 5. Bleeding index according to Mombelli et al.\textsuperscript{18}: TMI (n = 105), IMZ (n = 82), BRA (n = 34) (implants/posts).

Fig. 6. Gingiva index according to L\öe and Silness\textsuperscript{19}: TMI (n = 105), IMZ (n = 82), BRA (n = 34) (implants/posts).

**Table IV.** Frequencies of the bone level reduction (in percentages) 1 year after insertion of the new dentures

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>TMI</td>
<td>105</td>
<td>46</td>
<td>46</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>IMZ</td>
<td>80</td>
<td>59</td>
<td>32</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>BRA</td>
<td>34</td>
<td>32</td>
<td>65</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

0, No apparent bone loss; 1, reduction <\textsuperscript{1}/\textsuperscript{4} of the implant length; 2, reduction \textsuperscript{2}/\textsuperscript{4} of the implant length; 3, reduction >\textsuperscript{3}/\textsuperscript{4} of the implant length.

Table IV shows the bone level changes 1 year after insertion of the new dentures. Of each implant/post, the whereas no center differences were found (two-way ANOVA). The assessments of the width of KM on the buccal and lingual sites (Fig. 8) show that 10% of the posts of the TMI group, 10% of the implants of the IMZ group, and 23% of the BRA group were not surrounded by a zone of KM.

**Radiographic evaluation**

Table IV shows the bone level changes 1 year after insertion of the new dentures. Of each implant/post, the
most unfavorable value of the two measurements was used. No apparent bone loss was reported in 46% of the TMI posts, 69% of the IMZ, and 32% of the BRA implants. Reduction of the bone level exceeding a third of the implant length was reported in 8% of the TMI posts, 8% of the IMZ implants, and 3% of the BRA implants. The mean scores for the TMI group were 1.0 (SD 0.6), for the IMZ group 0.7 (SD 0.8), and for the BRA group 0.9 (SD 0.5). Differences between the three systems were not significant (two-way ANOVA).

Clinical implant performance scale

Only 7% of the TMI patients, 29% of the IMZ patients and 12% of the BRA patients did not have complications (CIP 0) (Fig. 9). Most of the complications were not serious (CIP 1). Peculiar to the TMI group were fracture of a cantilever extension and a slight sensory disturbance of the mental nerve. Loosening of coping screws occurred only in the IMZ group and replacement of the clip only in the BRA group. Gingival hyperplasia was noted in the IMZ and BRA groups; there were other complications that required relining of the maxillary denture and readjustment of occlusion and articulation.

Fracture of a post (CIP 2), correction of a nonfitting superstructure, and a severe sensory disturbance were complications peculiar to the TMI group. A radiograph score 1 along with PD ≥5.5 mm and radiograph score 2 along with PD <5.5 mm were noted in all groups.

Fig. 7. Probing depth: TMI (n = 420), IMZ (n = 328), BRA (n = 136).

Fig. 8. Keratinized mucosa according to Apse et al.20; TMI (n = 210), IMZ (n = 164), BRA (n = 64). 0, no KM; 1, 1 mm or less of KM; 2, between 1 and 2 mm of KM; 3, more than 2 mm of KM.
One mobile post (CIP 3) was noted in the TMI group; other serious complications that occurred in the TMI and the IMZ groups were radiograph score 2 along with PD ≥5.5 mm and a radiograph score 3.

Failure of the implant system (CIP 4) occurred twice in the TMI group. For one patient, two posts were removed; the remaining posts were left in situ and are still supporting the overdenture. One implant was completely removed. No failures were noted in the IMZ and BRA groups.

The mean CIP scores for the different implant systems were: 1.4, SD 1.0 (TMI); 1.1, SD 0.9 (IMZ); and 1.0, SD 0.5 (BRA). The differences between the implant systems were not significant (two-way ANOVA).

DISCUSSION

To our knowledge, this is the first publication of a randomized clinical trial in which different implant systems were compared. Patients were randomly assigned (by a balancing procedure) to the different treatment groups. Comparison of general characteristics at entry indicated that the balancing procedure provided three identical treatment groups. Only in this way can different implant systems be compared.

In this study of patients with severe alveolar bone loss in the mandible, the symphyseal bone height selected was less than 15 mm but more than 8 mm as measured on a standardized lateral cephalogram. Often the symphyseal bone height is higher than the vertical dimension of the alveolar ridge because the mental spine area keeps its height longer than other parts of the alveolar ridge. Because the permucosal implants were inserted in the canine region, the bone height at that point was presumably less than the mean symphyseal bone height of 13.6 mm (Table II). This could explain why the length of the permucosal implants was ≥11 mm for most of the implants (73%). The length of the posts of the transmandibular implant does not account for the height of the mandibular ridge because the posts penetrate the mandible, part of it in the baseplate and sometimes threads towering over the alveolar ridge.

The scores of the plaque, gingiva and bleeding indexes were favorable and seemed to be comparable to other overdenture studies. Comparison with these studies, however, is difficult because different criteria were used. The results revealed no significant differences for the PI and BI among the implant systems. The GI demonstrated significantly better scores for the BRA group than for the IMZ group.

Differences in PD were significant between IMZ-BRA and IMZ-TMI. Conclusions, however, should be drawn with caution because the geometric design of the three implant systems are not comparable. The transmandibular implant has threaded posts, the IMZ implants are cylinders with a smooth surface, and the Bränemark implants are threaded cylinders. The abutments of the IMZ and BRA systems also have different geometric designs; the IMZ abutment and implant body have the same width whereas the BRA abutment is wider than the implant body. Measuring PD along the TMI posts and BRA implants is more difficult than along the IMZ implants, which may be why the mean PD of the IMZ implants was deeper (3.7 mm, SD 0.9) than those of the other systems (TMI 3.0 mm, SD 0.4; BRA 2.5 mm, SD 0.8).

Orthopantomographic radiographs (OPTs) were used for the evaluation of the bone levels because of the difficulty of good parallel positioning of periapical films in patients with severe resorption and a pronounced floor of the mouth. Furthermore, only part of the TMI system can be evaluated with periapical films. In this study, the use of the same method was desired for all implant systems,
and OPTs were made of all patients. The bone level changes were evaluated in proportion to the length of the implant, because absolute measurements (in millimeters) cannot be performed on an OPT and reproducibility with this technique is difficult to achieve.

Small bone defects were detected in 46% of the TMI posts, 32% of the IMZ implants, and 65% of the BRA implants. Comparison of radiographs made directly after surgery and after 1 year of loading revealed some defects, because the tops of the implants were placed flush with the marginal bone level and the tops of the IMZ and the BRA implants were highly polished. Moreover, the first year of functioning includes the bone remodeling phase, and subsequent years will exhibit a much lower rate of bone loss. The results of this study are of the first year of functioning, thus minor bone level changes could be expected. Furthermore, results would have been better if the mean scores were presented instead of the most unfavorable score of each implant/post, because averaging masks greater variations in individual measurements.

The CIP scale was developed for comparative assessments of the different implant systems and included all the complications that occurred. Thus far, studies reported on survival rates and the data of these studies only represent the percentages of implants that have not been removed. The success criteria of Smith and Zarb are much more specific but still have an absolute character of yes or no with respect to success or failure. Albrektsson and Zarb suggested that every implant should be evaluated as part of a four-grade scale that represents (1) success, (2) survival, (3) unaccounted for, and (4) failure. In this study, a scale was constructed that included not only the success criteria of Smith and Zarb and the categories of Albrektsson and Zarb, but all of the complications that occurred, so as to compare the different implant systems.

The differences in the mean scores of the three implant systems were not significant. The TMI group, however, displayed more complications (mainly surgical and prosthetic) than the other implant groups. Two failures occurred: one TMI and two posts of another TMI had to be completely removed. The IMZ group exhibited mainly radiographic complications along with PD >5.5 mm and few surgical and prosthetic complications. The BRA group mainly exhibited minor radiographic complications. However, one IMZ and one BRA implant were removed during the healing period. These failures were not part of the CIP scale because all of the complications that occurred from the day of surgery and after 1 year after insertion were taken into account. The score CIP 3, which means a serious complication that may lead to implant failure, was given to three patients because of a radiograph score 2 along with PD ≥5.5 mm, or a radiograph score 3.

This study is the first attempt at comparison of clinical and radiographic performances of three different implant systems in a clinical trial. The results do not reveal significant differences at the evaluation 1 year after insertion of the new implant-retained overdentures. To assess the clinical differences between the three implant systems in patients with severely resorbed mandibles, long-term evaluation is necessary.

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