Transmandibular implant versus intramobile cylinder implants: a randomized, prospective clinical trial


Abstract. A randomized, controlled clinical trial was conducted to compare two different implant treatment modalities for edentulous patients with severely resorbed mandibles. In one modality (the IMZ® group), two intramobile cylinder implants were placed, connected by a Dolder bar and provided with an overdenture, and in the other (the TMI group), a transmandibular implant with a triple bar and cantilever extensions was placed, likewise provided with an overdenture. The conditions of the overdentures, the peri-implant tissues, and the implants were evaluated. Orthopantomograms were taken for radiologic evaluation. An overall complication scale which took account of all aspects was devised to compare the results. The follow-up period was 2-4 years, with a mean follow-up of 3 years. The condition of dentures and oral hygiene aspects were comparable for both groups. The complication rate in the TMI group was significantly higher than that in the IMZ group. The scores on the complication scale resulted in a significant difference between the TMI and the IMZ groups (Wilcoxon, $P = 0.0044$).

Osseointegrated implants have been used successfully over the years to create better conditions for prosthetic treatment. Many studies have been published, reporting success rates ranging from 75 to 100%, with a maximum follow-up of 24 years. Only a few studies have compared different implant systems, but, to the best of our knowledge, such a comparison has never been made in a prospective, randomized clinical trial. Randomization means that treatment is assigned according to a balanced allocation method. This allows a comparison to be made between two or more implant systems and permits evaluation of a possible difference in the rate of success. Complications may be assessed on the basis of differences in treatment result rather than differences in patient selection.

This study presents the 2-4-year follow-up results, with a mean of 3 years, of a randomized clinical trial of two different implant systems in severely atrophic mandibles with a bone height less than or equal to 15 mm, measured on a lateral head plate. Emphasis has been placed on the complications that required surgical intervention during the follow-up period and on the final clinical results.

Material and methods

This randomized clinical trial compares two different implant treatment modalities: the transmandibular implant (TMI) (Figs. 1 and 2) and two solitary endosseous IMZ® implants (Figs. 3 and 4) connected by a Dolder bar, both provided with an overdenture.

To be selected, patients had to have severe problems with their dentures and meet the seven criteria listed in Table 1. The patients had to be suitable for both procedures. The patients were informed about both treatment modalities and consented to both. The patients were given the option of withdrawing their cooperation at any time. After agreement by the patient, the treatment was selected by a randomizing computer program using the criteria listed in Table 2. In this way, two comparable groups were formed. The patients were then informed of the type of implants with which they would be treated.

Sixty-five patients were selected. Of these, six (two in the TMI and four in the IMZ group) refused to participate after they had...
The image of two Implants.

FIG. 1: Radiographic view of two Implants.

FIG. 2: Radiographic view of a modified ELX system.

FIG. 3: Clinical view.
pantomogram, was scored on a four-point scale (0–3), where 0 represents no bone loss; 1, bone loss less than one-third of the length of the implant or post; 2, bone loss more than one-third and less than half of the length of the implant or post; and 3, bone loss more than half the length of the implant or post.

To assess the clinical performance of the two implant systems, an inventory of the problems and complications that can occur after placement of the implants had to be made. Subsequently, a scale had to be constructed on which to assess all these problems and complications. Each problem and complication that can occur after placement was awarded a score on the scale expressing the severity of the problem or complication in relation to the performance of the implant system. Evaluating the clinical implant results in this way enabled a comparison to be made of the two different implant systems. The clinical and radiographic data for the entire period were thus classified according to the scale presented in Table 3. A score of 0 indicated no complications or problems and a score of 1, minor problems that did not require intervention or could be easily treated, such as hyperplasia or a sensory disturbance with no hindrance to the patient. Score 2 represented a complication with a reasonable chance of recovery or stabilization of the situation, such as a fractured or mobile implant. Score 3 was given in the case of a serious complication that could lead to failure of the implant system, such as the loss of one implant or bone loss more than half of the length of the implant. Score 4 signifies that the implant treatment had failed (IMZ) or that two or more posts had been removed (TMI).

Results

Patient satisfaction

The degree of patient satisfaction with maxillary and mandibulary dentures is shown in Table 4. Most patients were either satisfied or highly satisfied with their dentures. All patients, including those who were not completely satisfied with their dentures and had had complications, stated that they would undergo the operation again.

Dentures

All the lower dentures were extended to the retromolar pad and were partially tissue-borne. Twenty-four of the TMI patients and all 29 IMZ patients had three occlusal contacts on each side. Only one patient had four occlusal contacts on each side. The remaining patients all had two occlusal contacts on each side. Eighteen patients (nine TMI and nine IMZ) had occlusal contact anteriorly in maximum occlusion. The articulation was without interference and bilateral in 47 patients. In the other 10 patients, either there was no bilateral articulation and/or occlusal interference was present.

Superstructure

The TMI patients had five bars, three connecting the posts and two distal cantilevers. Two patients had only three bars because of missing posts. There were 141 bars in all. In 111 of these 141, there was contact only on the lateral sides of the bar. In the remaining 30, there was contact on top of the bar. Two patients had contact on a post.

The IMZ patients had one Dolder bar. Fifteen patients had contact on the lateral sides of the bar. Fourteen patients had contact on top of this bar.

After removal of the superstructure, fractured posts were found in two patients and one or two mobile posts in four patients in the TMI group. Two TMI patients were found to have non-fitting superstructures (Fig. 5) when an attempt was made to replace them. No mobility of the IMZ implants was noticed after removal of the superstructure, and all the superstructures fitted passively when replaced.
In the IWZ group, a significantly higher number of complications were recorded compared to the WZ group. The main complications were infection, wound dehiscence, and delayed union.

### Table 1: Complications Recorded in Follow-Up Period

<table>
<thead>
<tr>
<th>Complication</th>
<th>IWZ (12)</th>
<th>WZ (9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Wound dehiscence</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Delayed union</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 1: Complications recorded in follow-up period.

- Infection: more common in the IWZ group, possibly due to the higher number of bone grafts used.
- Wound dehiscence: occurred in a patient with a history of smoking.
- Delayed union: patient was non-compliant with follow-up appointments.

### Complications

1. **Infection**: More cases in the IWZ group.
2. **Wound dehiscence**: Occurred in a patient with a history of smoking.
3. **Delayed union**: Patient was non-compliant with follow-up appointments.

### Per-implant Issues

- **Fig. 6**: Radiograph showing bone grafts at the site of implant.
- **Fig. 7**: Radiograph showing bone grafts at the site of implant.

The results of the radiographic examination indicated good bone healing at the site of implantation.
Discussion

Of the patients, 85% were satisfied or very satisfied with their new dentures. All stated that they would undergo the operation again if necessary. This probably implies that their situation had improved as compared to the situation before treatment. In part, this reflects the improved prosthetic care. The patient who did not know whether he was satisfied with his dentures stated that his initial temporomandibular joint problems had not improved.

All dentures were partially tissue-borne distally to the implants. Most of the bars provided retention to the denture only. Support directly on top of the Dolder bar was found in just five bars. It has recently,4,13 been recommended that the denture on the TMI should be tissue-borne only on the retromolar pad. The remaining support should come from on top of the Dolder bar. This is intended to enhance the possibility of bone apposition distal to the lateral posts. It is also said that mobility and fractures of the posts can be prevented with this protocol4. This suggestion had not been made at the time the study was started, and it was decided not to change the prosthetic protocol during the study. New studies will have to show the results of these changes.

In both groups, approximately 30% of the patients had good oral hygiene. Another 30% in both groups had a maximum score of 1 for one or more items. Although the superstructure of the TMI is more complicated, it does not seem to affect oral hygiene.

The radiographic results seem to indicate that the amount of bone loss was less with the TMI implants, although more complications were seen. An explanation could be that in cases involving a fractured post or a slightly mobile post, bone loss was not necessarily evident on an orthopantomogram. Only a severe mobility problem was linked to a clear radiolucency along the entire post (Fig. 6). With the IMZ implants, the bone loss was usually crater-like; therefore, it presented itself more clearly over a shorter distance.

It is not yet known whether the pain noticed at the TMI posts is a precursor of future fractures or mobility of the posts. However, the two patients who initially presented themselves with pain around implants were found to have fractured and/or mobile posts at a later stage. It seems logical to assume that the pathology had already been present but on a subclinical level.

Five of the 12 mobile posts were discovered in the first two TMI patients with complications. Because nonfitting superstructures and mobile posts were noticed in patients who reported pain and submental abscesses, the superstructures were removed routinely. Subsequently, six fractured posts and seven of the 12 mobile posts were discovered during these regular checkups. It was hoped that the early detection of the nonfitting superstructure and subsequent alteration of the superstructure would prevent further mobility and fractures of posts. However, one fractured and two mobile posts were detected in two patients in whom we had changed the superstructures. It is not clear why the superstructure did not fit after a period of time. All superstructures were placed 1 day postoperatively with a passive fit. Some superstructures were repeatedly nonfitting after alteration. The removal of the superstructure is not only important but seems essential if mobile and fractured posts are to be discovered at an early stage.

Screening for complications shows that the TMI patients had more complications than the IMZ patients (Wilcoxon, P=0.0044). However, the TMI patients had four posts as opposed to the two implants in the case of the IMZ patients. Therefore, it is likely that the possibility of complications is higher for the patients in the TMI group than for those in the IMZ group. However, it is hardly possible to correct for this disparity between these two groups in this study. It would be advisable in future studies to use equal numbers of implants or posts. As the oral hygiene in both groups was comparable, the difference in the complication rate cannot be attributed to this factor. Because the two groups of patients were highly comparable on the basis of the criteria listed in Table 2, the reasons for the complications seem to be implant-related rather than patient-related.

In conclusion, it may be stated that in this study the complication rate was significantly higher with TMI as compared to endosteal IMZ implants. From these early results, it seems advisable to use endosteal implants in the atrophic mandibles with a bone height of less than or equal to 15 mm. If the bone height is not sufficient for endosseous implants, the TMI implant may still be considered.

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References


Address:
J. M. Kwakman
Department of Oral and Maxillofacial Surgery
University Hospital Nijmegen
PO Box 9101
6500 HB Nijmegen
The Netherlands