Patient-Reported Outcomes of Maxillary Edentulous Patients Wearing Overdentures Retained by Two Implants from Insertion to 4 Years

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Purpose: This cohort study evaluated patient satisfaction for maxillary implant-retained overdentures (IODs) on two implants up to 4 years and assessed the treatment effect over time. Materials and Methods: Patients encountering problems with their conventional dentures were included and received maxillary IODs on two titanium-zirconium implants and ball anchors in the canine area. Patient satisfaction was assessed using the oral health impact profile (OHIP-20E) questionnaires both for dentures and IODs. Two months after insertion of IODs (baseline), the patients chose the preferred overdenture design with full or reduced palatal coverage. OHIP-20E questionnaires were followed according to the individual choice at 1 and 4 years, and outcomes were compared with baseline. Results: Sixteen out of 21 patients were evaluated at a mean follow-up of 4 years (range: 2.4 to 4.8 years). There was no significant difference in the OHIP domains for IODs at 1 year (OHIP-total-1y: 9.5, SD: 13.0) and 4 years (OHIP-total-4y: 14.2, SD: 19.1) compared with baseline (OHIP-total-BL: 12.4, SD: 14.7). Patients were most satisfied with social disability both for IODs (OHIP-SDL: 6.0, SD: 7.6; OHIP-SDL: 3.4, SD: 5.4; OHIP-SDL: 5.7, SD: 9.5) and dentures (OHIP-CD-ol: 28, SD: 29.7; OHIP-CD-n: 25.4, SD: 28.67). Patients were least satisfied with functional limitation both for IODs (OHIP-FL: 6.0, SD: 7.6; OHIP-FL: 3.4, SD: 5.4; OHIP-FL: 5.7, SD: 9.5) and dentures (OHIP-CD-ol: 28, SD: 29.7; OHIP-CD-n: 25.4, SD: 28.67). Conclusion: Patient satisfaction with maxillary IODs on two implants did not change from baseline to 4 years and was high at 4 years of function. Int J Oral Maxillofac Implants 2019;34:481–488. doi: 10.11607/jomi.6980

Keywords: dental implants, dental prosthesis, edentulous, implant-supported, jaw, maxilla, overdenture, patient-reported outcomes, patient satisfaction, quality of life

To evaluate whether or not an implant-retained overdenture (IOD) is a successful treatment, clinicians usually assess the survival rates of implants and IODs, peri-implant bone loss, and biologic, technical, and esthetic outcomes. However, for a comprehensive appraisal of the treatment, the patient’s satisfaction is of major importance in addition to the clinician’s evaluation.1,2 The assessment of patient-reported outcome measures (PROMs) by means of questionnaires has gained high importance in clinical investigations and should be considered, since patients and dentists often rate the same parameters differently.3,4 In a study comparing the assessment of esthetics and phonetics using visual analog scales (VAS) from patients and clinicians for maxillary IODs, the evaluation was better from the clinicians’ perspective.5 Hence, the patients were more critical, and the results indicate that the clinician’s objective assessment does not necessarily represent the patient’s subjective satisfaction.5 It is a premise, though, that the patient is satisfied primarily to obtain treatment success with an overdenture.6

For the patient to be satisfied with a denture, several parameters are of relevance. These include retention, stability, phonetics, mastication, and esthetics.7–10

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However, the expectations of a patient to a treatment are also of major concern. Furthermore, the patient’s perception of the prosthetic outcome may be influenced by the initial intraoral conditions and health situation.

Oral health is part of patient satisfaction and influences the quality of life (QoL). Oral health–related quality of life (OHRQoL) is a more comprehensive evaluation than patient satisfaction alone. Thereby, different aspects of life being affected by oral health, such as the ability to function, psychological status, social factors, pain, and discomfort are determined. Furthermore, the changes of oral health induced by a dental treatment can be measured. The oral health impact profile (OHIP) is an acknowledged questionnaire for the assessment of the OHRQoL and the impact of the prosthetic treatment on the quality of life. The 20-item form OHIP-EDENT is specifically designed for edentulous patients to assess their satisfaction with the prosthetics.

OHIP parameters comprising chewing ability and function significantly improved with maxillary IODs compared to conventional dentures. These results were based on evaluations at 2 months. It was previously stated that patients develop confidence with removable appliances within 2 to 4 weeks. A time period of 2 months was therefore defined as an adequate adaptation period for assessment of patient satisfaction with new dentures.

Interestingly, patients’ responses may change with time as a result of a changed perception of the same parameters. This phenomenon, referred to as a response shift, shows how OHIP domains that might have been of significance to the patient's QoL before a treatment may not be as significant to the patient at a later date. This shift may be due to an adaptation to different circumstances, such as an altered health condition. It can also be caused by external factors, such as adaptation to a treatment being known as a significant treatment effect.

The fact that patients might reply in a different way to PROMs over time is especially of significance in within-subject repeated measures trials, where the effectiveness of a new treatment is tested within the same patient group.

A previous study reported improved VAS ratings from patients for phonetics and comfort at 2 and 6 years compared to the baseline scores with insertion of maxillary IODs supported by two to six implants and a bar. The authors speculated that the improved satisfaction goes along with additional adaptation to the new situation. There was no information on patient satisfaction before the implant treatment, which reflects a cross-sectional investigation, not a comparison before and after the treatment.

To incorporate the aforementioned treatment effect, the impact of the treatment should be accounted for when assessing patient satisfaction with different treatment options. For this reason, patient satisfaction should be determined for the original situation, ie, prior to commencement of treatment, as well.

The goal of a successful treatment is that the patient stays satisfied over time. Most studies present the outcomes at a certain time. To determine whether the treatment effect of IODs is stable, PROMs should be monitored over time.

There is a trend that patients become edentulous at an older age, which asks for less-invasive treatment opportunities. Furthermore, it was concluded in a systematic review that more research should be performed on less than four implants in the edentulous maxilla.

The aim of the present prospective within-subject trial was to evaluate the PROMs using OHIP parameters at 4 years of insertion of maxillary overdentures retained by two implants and to compare the changes of the scores over time, ie, to the previously published ones at insertion (baseline) and 1 year.

It was hypothesized that patient satisfaction with maxillary overdentures on two implants would be stable over time.

MATERIALS AND METHODS

The present study was designed as a within-subject prospective cohort investigation. The local ethical committee (Medisch Ethische Toetsingscommissie van Vrije Universiteit Medisch Centrum Amsterdam) approved the study protocol, and informed written consent was obtained from all patients.

Patients

Patients who were dissatisfied with their conventional maxillary dentures were included in the present study. Patients were consecutively recruited and clinically examined for whether they would comply with the inclusion criteria. Thereafter, a cone beam computed tomography (CBCT) scan (NewTom 5G, QR) was performed to assess whether the bone conditions in the canine area would allow for implant placement. In the case of sufficient bone for implant placement, patients were definitively included. The treatment was executed at the Academic Center for Dentistry Amsterdam (ACTA), The Netherlands, by one experienced clinician (A.Z.). The study procedure was previously published in detail. The inclusion criteria, in short, were: patients edentulous in the maxilla encountering problems with the existing dentures; good general health condition; both smokers and nonsmokers.
The exclusion criteria were: patients in need of major bone grafting procedures; patients having more than four mandibular abutments (teeth or implants); patients with fixed prostheses; patients with immediate maxillary dentures; bruxism; systemic disorders in general and in the area of planned implant placement; and lack of compliance. Consequently, included patients were wearing conventional dentures, removable partial dentures retained by a maximum of four teeth, or overdentures retained by a maximum of four implants in the mandible.

Treatment Procedure
The original dentures were evaluated for function and esthetics. If required, adjustments in terms of rebasing and relining of the existing dentures were performed in nine patients. In 12 patients, adjustments would not have been sufficient, and new conventional dentures were fabricated. In this way, all patients were provided with sufficient dentures according to proven standards. The adjusted or new dentures served as reference for the virtual implant planning and the surgery. Two reduced-diameter implants (Roxolid, 3.3 mm diameter, Institut Straumann) were inserted in the canine area of the maxilla (corresponding to the canine position of the maxillary denture) using guided surgery (coDiagnostiX, Dental Wings). Implant lengths were 10 and 12 mm, with the exception of one implant that was 8 mm. Following the healing period of 2 to 4 months, implant impressions were performed using the perforated maxillary denture as impression tray. In this way, the intermaxillary relation was simultaneously registered. The dental technician modified the maxillary dentures to IODs with an incorporated metal frame and full palatal coverage. Two titanium matrices were indirectly fixed to the overdenture base. The retentive anchors (Retentive anchor abutment, Institut Straumann) were fitted to the implants with a defined torque. A balanced, lingualized occlusion without anterior contacts in habitual occlusion was achieved. The patients were instructed on proper overdenture handling and oral hygiene measures. During the time of converting the maxillary denture to an IOD, patients were wearing a provisional maxillary denture, which was previously fabricated as a duplicate of the existing one.

The IODs were worn for 2 months. Thereafter, the dental technician reduced the palatal coverage until the metal frame in all patients, and the altered maxillary IODs were worn for another 2 months. The influence of the palatal coverage on patient satisfaction was assessed in another study. Subsequently, each patient selected the overdenture design of preference. Seventeen patients chose to continue wearing the IOD with reduced palatal coverage; four patients preferred an IOD with full palatal coverage. The IODs were sent for modification to the in-house dental lab at the day of the clinical visit. Further follow-ups were performed yearly at 1, 2, 3, and 4 years of IOD insertion.

Patient-Reported Outcomes
Patient-reported outcomes were achieved for existing (old) dentures prior to any adjustment (CD<sub>n</sub>) and for new conventional dentures (CD<sub>n</sub>) to assess the pretreatment satisfaction (previously published). In addition, PROMs were assessed for IODs to assess the satisfaction following implant treatment, and the changes were statistically analyzed over time. For that purpose, patients responded to OHIP-20E questionnaires in the Dutch language at the time of study inclusion and 2 months following insertion of new dentures. The same OHIP questionnaires were used 2 months following insertion of maxillary IODs with palatal coverage and 2 months following insertion of IODs with reduced palatal coverage. Thereafter, the patients chose the preferred overdenture design, and OHIP-20E questionnaires were answered by the patients for IODs either with full or reduced palatal coverage according to the individual choice at 1 year and at 4 years.

The questionnaires used VAS with a horizontal line of 100 mm. On the left end, the anchor word “never” represented 100% satisfaction, and on the right end, the anchor word “always” represented 0% satisfaction. Consequently, higher millimeter values represented reduced patient satisfaction. Each patient expressed per question the individual appraisal of satisfaction by placing a vertical stripe on the horizontal line. The stripe was then measured in millimeters. The 20 questions accounted for the seven OHIP domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap.

The results of the OHIP questionnaires for IODs were statistically evaluated for the three time points: 2 months (IOD<sub>2</sub>), 1 year (IOD<sub>12</sub>), and 4 years (IOD<sub>48</sub>). Statistical Analysis
The pairwise Wilcoxon signed rank test was applied for the comparison of OHIP scores at the different time points: baseline (IOD<sub>2</sub>) (ie, 2 months following insertion), 1 year (IOD<sub>12</sub>), and 4 years (IOD<sub>48</sub>) following insertion of maxillary IODs. The patients were grouped at baseline according to the preferred overdenture design (IODs with full or reduced palatal coverage) for the statistical evaluation and proper comparison of patient satisfaction with the two different IOD designs over time.

At the 4-year follow-up, the OHIP scores were compared by means of the Wilcoxon rank sum test for overdentures with full and reduced palatal coverage. The statistical significance was set at P ≤ .05.
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The Wilcoxon signed-rank and rank sum tests were calculated with the R software (https://www.R-project.org/).

Mean OHIP scores were illustrated descriptively per domain for each patient according to the treatment (conventional old dentures, conventional new dentures, and IODs at baseline, 1, and 4 years).

RESULTS

One hundred forty patients were clinically examined for whether they would be suitable for the study. From these, 40 potential candidates received a CBCT scan. Finally, 21 patients (6 women, 15 men) were definitely included in the study. Sixteen patients (6 women, 10 men) were evaluated at a mean follow-up of 4 years (range: 2.4 to 4.8 years). Two patients were followed-up at 2.4 and 2.5 years; all remaining patients were controlled at more than 4 years following insertion of IODs.

The mean age of the patients at study inclusion was 63 years (range: 52 to 81 years).

There were five patient dropouts in total (one patient was abroad and not able to attend the follow-up visit; one patient chose to withdraw from the study; one patient received new overdentures within another study by his dentist, and thus, only the implants were followed-up, not the overdenture anymore; and two patients had implant failures).

Twelve patients (five women, seven men) chose an IOD with reduced palatal coverage (an illustration of a patient example is shown in Figs 1 to 3), whereas four patients (one woman, three men) chose closed palatal coverage. With regard to the opposing arch, 10 patients (four women, six men) had bar-retained overdentures on two implants, one patient (woman) had a bar-retained overdenture on three implants, one patient (man) had a ball-retained overdenture on two implants, three patients (men) had conventional dentures, and one patient (woman) had a removable partial denture retained by three teeth.

The mean OHIP scores with standard deviation for maxillary IODs at baseline (IOD2), 1 year (IOD12), and 4 years (IOD48) are shown in Table 1.

There were no significantly different OHIP values for any domain at baseline compared with 1 year and 4 years. From baseline to 1 year, there was a trend for an increase in patient satisfaction for functional limitation.

Table 1  Mean Values (mm) and SDs of OHIP Domains for Maxillary Implant-Retained Overdentures at Baseline, 1 year, and 4 years

<table>
<thead>
<tr>
<th>Domain</th>
<th>BL–1y</th>
<th>1y–4y</th>
</tr>
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<tbody>
<tr>
<td>Functional limitation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychological discomfort</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical disability</td>
<td></td>
<td></td>
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<tr>
<td>Psychological disability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social disability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Handicap</td>
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</tr>
</tbody>
</table>

BL = baseline (n =15); 1y = 1 year (n = 16); 4y = 4 years (n = 16).
Lower values correspond to higher patient satisfaction.

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Fig 1  Occlusal view of two maxillary implants retaining an overdenture at 4 years. Mucosa impressions are visible from the overdenture with reduced palatal coverage.

Fig 2  Occlusal view of a maxillary overdenture with reduced palatal coverage at 4 years.

Fig 3  Basal view of a maxillary overdenture with reduced palatal coverage at 4 years.
physical disability, psychological disability, social disability, and handicap (evident as decreasing values).

From 1 year to 4 years, there was a slight decrease in patient satisfaction for all seven OHIP domains (apparent by increasing values). Still, patient satisfaction was higher at 4 years (lower OHIP scores) compared with baseline for physical disability, psychological disability, social disability, and handicap.

The lowest values, ie, the greatest patient satisfaction, were found for social disability at all follow-ups (OHIP at baseline: 6.0, SD: 7.6 mm; at 1 year: 3.4, SD: 5.4; at 4 years: 5.7, SD: 9.5). The highest values, ie, the lowest patient satisfaction, were evident for functional limitation at all follow-ups (OHIP at baseline: 20.6, SD: 18.9 mm; at 1 year: 17.6, SD: 18.4; at 4 years: 24.7, SD: 23.8).

The comparison of IODs with full and reduced palatal coverage at 4 years revealed no significant differences for all OHIP domains (Table 2). There was a trend for a greater patient satisfaction with full palatal coverage for psychological discomfort, physical disability, psychological disability, social disability, and handicap (smaller values).

Figures 4a to 4g illustrate the progress of patient satisfaction for each OHIP domain subdivided into different prosthesis types (old conventional dentures, new conventional dentures, IODs in the course of time) per patient. The mean OHIP scores with standard deviation for old and new conventional dentures have been previously published.18

<table>
<thead>
<tr>
<th>Functional limitation</th>
<th>Physical pain</th>
<th>Psychological discomfort</th>
<th>Physical disability</th>
<th>Psychological disability</th>
<th>Social disability</th>
<th>Handicap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean IOD_0</td>
<td>23.9</td>
<td>12.4</td>
<td>23.4</td>
<td>14.1</td>
<td>14.6</td>
<td>7.3</td>
</tr>
<tr>
<td>SD IOD_0</td>
<td>22.1</td>
<td>15.8</td>
<td>27.8</td>
<td>21.8</td>
<td>21.2</td>
<td>10.6</td>
</tr>
<tr>
<td>P value</td>
<td>.86</td>
<td>.49</td>
<td>.67</td>
<td>.90</td>
<td>.31</td>
<td>.34</td>
</tr>
<tr>
<td>Mean IOD_1</td>
<td>27.3</td>
<td>16.6</td>
<td>18.0</td>
<td>11.9</td>
<td>1.1</td>
<td>1.0</td>
</tr>
<tr>
<td>SD IOD_1</td>
<td>31.9</td>
<td>14.2</td>
<td>33.4</td>
<td>20.1</td>
<td>1.4</td>
<td>1.3</td>
</tr>
</tbody>
</table>

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DISCUSSION

Even though there were no significant differences in patient satisfaction with maxillary IODs at 1 and 4 years compared with baseline, there was an improved OHRQoL with regard to physical, psychological, and social disability and handicap at 1 and 4 years.

Consequently, the treatment effect of maxillary IODs was stable until 4 years, and the hypothesis could be confirmed.

From 1 year to 4 years, the patient satisfaction slightly decreased for all OHIP subgroups. Social disability was rated best at all follow-up visits, whereas functional limitation showed the poorest patient satisfaction at all visits.

Patient satisfaction improved with maxillary IODs in contrast with conventional dentures, indicating a positive treatment effect of implants on patient satisfaction.

There is less scientific evidence for maxillary implant-retained overdentures compared with mandibular ones in general and with regard to PROMs. For this reason, it was chosen to evaluate patient satisfaction for maxillary overdentures exclusively.

Diameter-reduced implants were used to avoid major bone grafting procedures. It remains unclear whether this affected the outcomes of patient satisfaction.

Another limiting factor in the present study was the unequal distribution of patients wearing overdentures with open and reduced palatal coverage, which was due to a previous question that was addressed in another study.

Overall Patient Satisfaction

In the present study, the patients did not have a special preference to the treatment, which might have had a positive impact on the highly rated patient satisfaction in general. Compared with conventional dentures, the patients perceived IODs as a significant benefit for all OHIP domains.

Significantly improved OHIP domains were also reported for maxillary IODs on three implants in a similar study compared with conventional dentures.

The attitude and expectation of patients toward a treatment influences their perception of satisfaction. A previous study found more speech problems in edentulous patients who were planned for a maxillary fixed reconstruction on implants but received an IOD compared with those who were planned for and received an IOD. Patients wishing for a fixed reconstruction tend to be less satisfied with removable appliances on implants than those with no preference. It is known that the magnitude of improvement in OHRQoL is influenced by whether the patient receives the treatment of choice or not. Patients preferring maxillary IODs showed the highest satisfaction compared with those who received new conventional dentures instead.

Potential Influencing Factors

In addition, the period of edentulism is of relevance. Patients who have been edentulous for a longer period tend to be more satisfied with an IOD in contrast to patients who have been edentulous for a short time.

Since the present patients were edentulous for several years, the high patient satisfaction is explicable.

The results of the present study and others indicate that the number of implants does not appear to affect patient satisfaction when the patients were wearing conventional dentures before. Furthermore, patient satisfaction with maxillary IODs does not seem to be impaired by the attachment system either.

On the other hand, patient satisfaction with implant prostheses might be impaired with the occurrence of prosthetic complications. In the present study, there were several complications up to 1 year. This finding confirms the common observation that complications occur most often in the first year.

A higher incidence of mechanical problems for maxillary IODs without palatal coverage was described. In the present study, allocation to the overdenture design (with full or reduced palatal coverage) was not randomized, and the numbers of patients were not equally distributed. The comparison of OHIP parameters between the two overdenture designs, therefore, gives only a trend and should be interpreted with caution, especially considering that patients choosing closure of the palate named an enhanced perception of retention as a reason.

In the present study, only patients with a maximum of four mandibular abutments were included to prevent a harming effect of antagonistic teeth on the two implants in the maxilla (and, consequently, on IODs). A review article concluded that antagonistic teeth might negatively affect implant survival for maxillary IODs.

A recent study did not find a detrimental effect of antagonistic teeth when six maxillary implants were connected with a bar, even up to 5 years.

The degree of satisfaction should be evaluated critically, because the patients might have systematically overestimated it. This would create a ceiling effect, which was discussed as a disadvantage of PROMs. An initial enthusiasm of the patients when assessing the IODs cannot be precluded. The present 4-year follow-up might have reduced the bias in assessing patient satisfaction. On the other hand, a longer follow-up would be preferable to attain more reliable results.

It is assumable that the occurrence of pathologies or complications would have a detrimental effect on the patient’s satisfaction with IODs.
Patient Satisfaction from Baseline to 1 Year and 4 Years
There were no significant differences in OHIP-20 scores for maxillary IODs on three implants at 1 and 2 years compared with baseline. This result is in agreement with the present findings and indicates an insignificant change of patient satisfaction over a short time. Interestingly, the number of patients preferring a reduced palatal coverage (77%) at 2 years was similar to the present results (75%) at 4 years.33

A systematic review on patient satisfaction with IODs supports improvements seen after 1 year to be stable for the first 5 years, despite a slight decrease. Unfortunately, only three studies on maxillary IODs were included, whereby these outcomes can mainly be applied for mandibular IODs. A slight decrease of OHIP parameters from 1 year to 4 years was also evident in the present study. This might be due to the adaptation of the patient to the treatment. Besides, wear occurs with time, which might necessitate adjustments and reduce retention and stability of IODs.

The fact that physical, psychological, and social disability and handicap improved at 1 year and 4 years compared with baseline points to an enhanced well-being with maxillary IODs on two implants. This might be the result of adaptation, a safer feeling with regard to overdenture retention, and gain in confidence.

Social Disability
The OHRQoL monitors the outcomes of clinical interventions and thereby enables the evaluation of the patient’s responsiveness to change. An adequate adaptation period should be taken into account when assessing PROMs, which was accounted for in the present study. Accordingly, the patients were likely to be familiar with their maxillary IODs and less limited in social abilities, represented in the highly rated scores for social disability.

Functional Limitation
The finding that functional limitation was rated worst at all follow-up visits shows that some difficulty of chewing was apparent with maxillary IODs on two implants. However, function did not worsen until 4 years, and the scores at 4 years (24.7, SD: 23.8) indicate a rather high patient satisfaction of 75%. This might derive from the fact that patients develop confidence with oral rehabilitation after 2 to 4 weeks, especially with removable appliances.19

The comparison with full (27.3, SD: 31.9) and reduced (23.9, SD: 22.1) palatal coverage revealed no significant difference for functional limitation at 4 years. Surprisingly, the patients rated function slightly less satisfactory with a full palatal coverage of the IOD. One might assume a better retention and stability of the overdenture when the palate is fully covered. On the contrary, it was found that stability and choice of food were not altered by reduction of the palatal coverage in IODs on four implants.17

While evidence supports the use of implants in the mandible to improve the oral health status, the standard of care can still not be defined for the edentulous maxilla. According to the results of a systematic review, the use of two implants in the maxilla does not compromise patient satisfaction. Considering the continuous population growth, the number of elderly patients will likely increase in the future and thus probably the need for IODs with a minimal number of implants.

CONCLUSIONS
Within the limitations of this study, considering an unequal distribution of two overdenture designs (with full and reduced palatal coverage), as well as a rather small number of patients, maxillary implant-retained overdentures on two implants appeared to have a stable treatment effect over a 4-year period.

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