Maxillary overdentures on dental implants
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Costs and cost-effectiveness of maxillary four-implant overdentures on bars or locators

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Costs and cost-effectiveness of maxillary four-implant overdentures supported by bars or locators
Submitted
Abstract

Objectives The purpose of this study is to estimate the costs and to evaluate the cost-effectiveness of four-implant maxillary overdentures on bars or locators in a Dutch setting.

Material and methods Two cost-effectiveness ratios were used, i.e. cost per OHIP-49NL point gained and cost per Mixing Ability Index (MAI) point gained. To assess uncertainty one-way sensitivity and probabilistic sensitivity analyses (OSA and PSA, respectively) were performed.

Results The total costs, calculated by using opportunity costs, were €6312 (range: €5516 - €6893) and €4160 (range: €3676 - €4644) per patient for the bar and locator overdenture treatment, respectively. Cost-effectiveness was €113/OHIP for the bar attachment system and €83/OHIP for the locators. Cost-effectiveness was €2570/MAI for the bars and €1623/MAI for the locators.

In the OSA the incremental cost-effectiveness ratio proved to be very sensitive to change in OHIP scores for both treatment options. The PSA showed that the bar overdenture is always more expensive and more effective in about two thirds of the simulations with respect to OHIP outcomes.

Conclusions This study showed that the total costs and cost-effectiveness ratios for maxillary four-implant overdentures with locators are lower than for bars. Although bar overdentures, in the base case, are more favourable when regarding the OHIP outcome, the PSA showed that for a significant part of the simulations this is not the case. Interpretation of these outcomes is hampered by the absence of formal willingness to pay thresholds for these specific outcome measures used.
Introduction
Various attachment systems have been successfully used with implant overdentures (1). Dental practitioners and technicians select a system based on their experience and the scant available literature. These systems can be classified as connected and non-connected, amongst others as bars or locators (Zest Anchors, Inc., Escondido, California, USA) attachments. The bar system is often regarded as the gold standard and has proven to be a reliable attachment system (2). However, the initial costs of the newer locator system seem to be lower and the locators are easier to handle (3,4). Adopting the locator system could be a way to reduce health care costs in general. As a matter of fact, health care costs do seem to rise every year (The Netherlands Bureau for Economic Policy Analysis as part of the “Centraal Plan Bureau”, CPB). This raise has two causes. First, along with increased life expectancy the total number of elderly increases as well. In general, elderly need more care, ergo healthcare expenditures rise. In addition, the proportion of the Dutch population paying for health care will be relatively smaller, therefore the impact of the aging population even increases. The raise in retirement age may only partly offset this increasing financial burden. In addition, over the years the number of treatment options and also diagnostic options rose, enabling treatment of more and more complex illnesses. Many new treatment options have proven to be more expensive, although cost reductions due to downstream savings of innovative treatments are sometimes claimed (5). This increasing demand, the associated costs, the limited funds available, and the intention to maintain affordable healthcare for everyone requires an efficient use of available resources (6).

By applying cost-effectiveness analysis (CEA) to the use of the bar or locator system, insight can be provided into whether the costlier treatment option offers sufficient added value to the patient to outweigh additional costs. In case of similar effectiveness, it could help health care insurance companies in deciding which therapies to reimburse and which not, to control expenditures.

A CEA is an appropriate technique to use when the outcomes of the different procedures being considered can be expressed in common units (6). In dentistry, unfortunately, universal use of such common units is still grossly lacking. Authors use various outcome measures for CEAs. For
example quality-adjusted prosthesis years (7), general satisfaction scores (8), oral health related quality of life (OHRQoL) (9) and mixing ability (10). Mostly, because these universal outcome measures for CEAs in dentistry are lacking, outcome measures already available from randomized controlled trials (RCTs) are pragmatically used.

The research question for the present study concerns what the costs of a four-implant maxillary overdenture supported by bars or locators are and which option would reflect the most cost-effective option.

**Material and methods**
From a recent RCT with one year follow up, the clinical, functional and patient related outcomes of the two systems (bar or locators) for maxillary overdentures in edentulous patients with mandibular overdentures were known. The locator system was slightly inferior to the bar system, with respect to patient-based outcomes. The clinical outcomes were also slightly inferior and statistically significantly different, but the outcomes for the locator system were well within an acceptable range, still making the locator system a reliable treatment option that could be considered. The initial costs of the newer locator system seem to be lower.

A cost study was performed for the bar overdenture treatment and the locator overdenture treatment. It was chosen to use opportunity costs to represent the actual cost price of the treatment. Additionally, also the total costs when using the Dutch tariffs, were reported. A CEA was performed with the parameters that were available. The score on the oral health related impact profile (OHIP-49NL) (11) was used as an oral health related quality of life outcome measure. Additionally the score on the Mixing Ability Index (MAI) (12,13) was used as a functional outcome measure.

**Patient population**
All patient data was retrieved from a RCT comparing two different attachment systems, namely bars and locators, to support four-implant maxillary overdentures in patients presenting with complaints regarding the retention and/or stability of their maxillary overdenture. The Medical Ethical Committee of the University Medical Centre Groningen approved the trial (METc 2013.025, ABR NL43293.042.13) and all subjects gave written informed-consent prior to inclusion.
This RCT (inclusion January 2013 until January 2016) included 50 fully edentulous patients. All patients were referred to the Department of Oral and Maxillofacial Surgery (University Medical Centre Groningen, the Netherlands) because of complaints regarding the retention and/or stability of their maxillary overdenture. Under local anaesthesia, all patients received four implants in the maxilla to support overdentures. After a healing period of three months, an experienced prosthodontist provided the patients with maxillary overdentures supported by a bar attachment system (Figure 1.) or locators (Figure 2.). Randomization was done by means of sealed envelopes. Patient-based and functional outcome measures were among the parameters of evaluation before and after 1 year of function.

Figure 1. Intra-oral view of the bar attachment system for a four-implant maxillary overdenture.

Effect measures
One year after being provided with the maxillary overdenture, the OHIP-49NL (11) and the MAI (12,13) were used to assess the effect of both treatments. The OHIP-49NL is a widely used validated questionnaire assessing oral health related quality of life (OHRQoL). The total score for the OHIP-49NL ranges from 0 to 196, with a higher score representing a lower OHRQoL.
In determining the MAI, patients have to chew with 20 strokes on a wax tablet (diameter 20 mm), consisting of two 3 mm layers of a blue and a red wax. The level of color mixing was analyzed and used to determine the chewing efficiency. The MAI has no unit of measurement and ranges from about 5 until 30 (respectively a fully mixed and pristine tablet) Again, a higher number reflects a worse situation for the patient.

**Costs**

As a first step to assess the cost-effectiveness, the costs of both treatments were determined. Costs were estimated by calculating the opportunity costs of the different procedures.

Opportunity costs refer to the benefit that a patient could have received, but was given up, to take another course of action. Stated differently, the opportunity cost of investing in a healthcare intervention are measured by the health benefits that could have been achieved had the money been spent on the next best alternative intervention.

The Dutch guidelines for economic evaluation of health care interventions were used (14,15). These guidelines aid researchers and policy makers to perform and evaluate costing studies in economic evaluations. It provides reference prices for various health care services and provides
methodological descriptions for costing studies. Using this manual increases the quality of and comparability between studies. For the current study only direct healthcare costs were used, because in the current case those costs are the most important costs for decision making. The term direct cost refers to all costs due to resource use that are completely attributable to the use of a health care intervention or illness. Direct costs in our case include the cost of the defined intervention, all follow-up costs for medication and health care interventions.

It was assumed that the implants were placed by an oral surgeon in hospital setting and that the overdenture was made by a general dentist in a private practice setting. We assumed that radiographic images in the hospital setting were made by the assistant of the oral surgeon and that radiographic images in private practice settings were made by the dentist and assistant. Based on this data, the costs of both treatments were calculated by multiplying the time costs of health care professionals involved by the time spend. Costs of laboratory work were based on the fabrication costs of a scan-prosthesis for the cone beam computer tomography, surgical guide, and all the necessities for fabrication of the superstructure and definitive overdenture. To reflect uncertainty around the opportunity costs, a 25% margin around the established total time requirements of the professionals and a 10% margin around the costs for the prosthodontics lab were assumed. Within this range, a uniform distribution was assumed.

Because all resource use occurred in the same year (2017) discounting was not applicable.

Cost-effectiveness was analysed by using the cost price calculated with opportunity costs. Next, as a scenario the total costs using the tariff structure-based costs in 2017 were also added. Usually this would be a private person, but could also be the health care insurer. In the Netherlands maxillary overdenture treatment is mostly paid for by the health care insurer and are therefore interesting to know. The costs were only given for a complete view of the costs and were not used for further analysis.

Cost-effectiveness
Based on effectiveness outcomes of the performed RTC two measures
of cost-effectiveness were applied, viz. costs per OHIP-49NL point gained and costs per MAI point gained. To calculate the cost-effectiveness ratio (CER), the cost of a treatment was divided by the change in score for that treatment, i.e. change in OHIP score or MAI score, using the following formula:

\[
\text{CER} = \frac{\text{Costs of treatment}}{\text{Change in OHIP/MAI score}}
\]

When the difference in effectiveness was significantly different a comparison between the two treatment options was made by calculating the incremental cost-effectiveness ratio (ICER). The ICER was estimated by the following formula:

\[
\text{ICER} = \frac{\text{Costs of bar system} - \text{costs of locator system}}{\text{Improvement OHIP score bar system} - \text{Improvement OHIP score locator system}}
\]

In layman terms it reflects the cost of additional gain in OHIP score for the bar system versus the locator system.

**Sensitivity analysis and cost-effectiveness acceptability curve**

A one-way sensitivity analysis was performed to gain insight in the impact of individual parameters on the deterministic cost-effectiveness outcomes. Uncertainty in the deterministic value for the €/OHIP and €/MAI was assessed in a probabilistic sensitivity analysis (PSA). During a PSA the ICER is re-estimated many (in our case a thousand) times, with the values of the individual parameters being varied based on their assigned distribution. The spread in the results gives insight in the level of uncertainty and, for example, 95% confidence intervals can be constructed. For all the parameters, a beta-Pert distribution was used, with the underlying beta-distribution being based on the mean and lower and upper 95% confidence interval range values. On basis of the PSA results, a cost-effectiveness acceptability curve (CEAC) was made. The CEAC shows the probability that the treatment is cost-effective, for a range of willingness to pay thresholds.

**Statistical analysis**

The data was analysed with Microsoft Office Excel (2016).

**Results**

**Patient population**

Fifty patients were included with a mean age of 60.1±8.6 years (range
37.5–75.0) in the locator group and of 63.8±5.4 (range: 53.0–72.6) in the bar group. 23 patients in the locator group and 24 patients in the bar group were available for the 1-year evaluation.

Effect measures
The mean gain in Oral Health related Quality of life (OHIP-49NL) was 56.0±32.8 for the bar group and 50.3±44.7 for the locator group. This difference between the groups was statistically significant (p = 0.036). The mean improvement in chewing ability as assessed with the MAI was 2.5±3.4 for the bar group and 2.6±3.4 for the locator group. For the MAI there was no significant difference between the groups.

Costs
Using the opportunity costs, the total costs for the bar overdenture treatment are €6312 (range: €5516 - €6893) and for the locator overdenture treatment are €4160 (range: €3676 - €4644) (Table 1a). Using the Dutch tariffs, the total costs for the bar overdenture treatment are €7679 (range: €7208 - €7936) and for the locator overdenture treatment are €5486 (range: €5326 - €5645) (Table 1b). For all further analyses only the total costs calculated by the opportunity cost were used.

Cost-Effectiveness
The CER for the bar overdenture is €113/OHIP and €2570/MAI. The CER for the locator overdenture is €83/OHIP and €1623/MAI. The ICER was €380/OHIP. Because the locator overdenture treatment was dominant for the MAI outcome, no ICER was calculated. There is no significant difference in MAI outcome between the two options and the locator treatments is cheaper, so an ICER for this outcome would make no sense.

One-way sensitivity analysis and probabilistic sensitivity analyses
In the one-way sensitivity analysis, the ICER showed to be very sensitive to the gain in OHIP score per treatment option. A 10% range in the actual OHIP score for the locators resulted in an ICER of €201/OHIP - €3161/OHIP for the high and low OHIP value, respectively. The ICER showed to be even more sensitive for the OHIP gain of the bar attachment system, €192/OHIP - €18863/OHIP for the low and high OHIP gain value respectively. These
results show that when further studies show that the OHIP gain for the bar overdenture versus the locator overdenture is lower than we assumed, the ICER will become very high when cost difference between both treatments remain the same.

The impact of laboratory costs of the bar and locator system showed to be small. 10% reduction in the lab costs of the locator increased the ICER up to €408/OHIP, 10% increase of these cost lowered the ICER to €352/OHIP. Sensitivity analysis on the lab cost of the bar system resulted in ICERs of €445/OHIP and €314/OHIP for 10% reduction and 10% increase in the price of the production of the bar system, respectively.
Table 1b. Costs from a payer perspective for the bar- and locator overdenture.

<table>
<thead>
<tr>
<th>Cost parameter, payer perspective</th>
<th>Price (2017)</th>
<th>Range</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tariff oral surgeon</td>
<td>€2003.31</td>
<td>No uncertainty range, these are fixed prices.</td>
<td>University Medical Centre Groningen, Department of Oral and Maxillofacial surgery</td>
</tr>
<tr>
<td>Tariff dentist</td>
<td>Bar: €661.33 locator: €619.88</td>
<td>No uncertainty range, these are fixed prices.</td>
<td>University Medical Centre Groningen, Dental School, Department of Fixed</td>
</tr>
<tr>
<td>Invoice laboratory work</td>
<td>Bar: €3746.06 locator: €1594.58</td>
<td>10% range Bar: €3275.24-€4003.08 locator: €1435.12-€1754.04</td>
<td>Dental laboratory Gerrit van Dijk, Groningen, The Netherlands</td>
</tr>
<tr>
<td>Purchase price implants</td>
<td>€1268.00</td>
<td>Fixed price</td>
<td>Nobel Biocare AB, (25)</td>
</tr>
<tr>
<td>Total costs (tariff)</td>
<td>Bar: €7678.70 locator: €5485.77</td>
<td>Bar: €7207.88 - €7935.72 locator: €5326.31 - €5645.23</td>
<td></td>
</tr>
</tbody>
</table>

Additionally, a PSA was performed to assess the uncertainty of the deterministic values of the €/OHIP. In figure 3 the results of the reestimation of the ICER is shown. The red dot represents the mean value, the other dots are the results of the PSA, showing the uncertainty of the mean value.

The graph shows that for all simulations the costs of the bar system exceeds the costs of the locator system. However, the gain in OHIP points for the bar system is not always higher than the gain for the locator system, as almost 30% of the simulations had a negative incremental OHIP gain, i.e. in these cases the costs of the locators were lower and the locator systems performed better regarding the OHIP gain.

As a result of the CEAC it can be said that the with respect to the OHIP outcome there is a probability of 95% that the bar overdenture is cost-effective when payers are willing to pay a maximum of €135/OHIP and for the locator overdenture this is €109/OHIP (Figure 4).
Figure 3. PSA plot to compare costs of the bar and locator system for the OHIP-49NL effect measure. The red dot represents the mean value.

Figure 4. A cost-effectiveness acceptability curve for the €/OHIP-point threshold

For the MAI outcome, these values are €4000/MAI for the bar overdenture and €2600/MAI for the locator overdenture (Figure 5).
Discussion

Nowadays the gold standard for maxillary overdenture treatment is the use of bars as an attachment system. These bars are expensive and cheaper options, such as locators, are available. However the effectiveness of these options is lower than that of the bar system. In this study it was observed that a maxillary overdenture on bars costs more than a maxillary overdenture on locators. However, the locator overdenture is more cost-effective regarding oral health related quality of life.

The first part of the research question in this study was about the costs of a four-implant maxillary overdenture supported by bars or locators. To answer this question the cost price, calculated using opportunity costs, was mentioned. For policy purposes, study comparability is enhanced by adopting opportunity costs as a norm. For this study only direct healthcare costs were considered. For overdenture treatment the direct healthcare costs are most important, because hardly any indirect healthcare costs or non-healthcare costs are involved for both treatments. Additionally, exact indirect healthcare and the non-healthcare costs were not recorded for the individual patients in this study, and therefore no appropriate estimation could be made.
Besides the cost price with opportunity costs, also the total costs using the Dutch tariffs were mentioned to give insight into the costs of the treatments for the Dutch reimbursement system/patient. These tariff costs for the maxillary overdenture treatment are higher than the opportunity costs. This was also seen for an implant supported removable partial denture in the study of Jensen et al. (10) An explanation for this could be the difficulty of estimating the total opportunity costs. Costs for the laboratory work and implants are the same for both perspectives, so the cause of the difference in total costs lies in the difference between opportunity costs for the labour time of the health care professionals involved and the tariffs for these actions. When looking at table 1a and 1b, it is seen that the biggest difference in costs between the two perspectives is the difference in costs of the oral surgeon, assistant and overhead costs. An explanation for higher tariff costs for the oral surgeon is that the tariffs include integral costs, including capital charges, consisting of a fee for medical specialists and hospital expenses. So, in a hospital setting, the tariff costs not only included the hourly wage for the surgeon but also costs like; costs for secretaries, cleaners, scientists, directional board, and for macro budgeting and income policies. These costs were not considered in our cost estimation for the societal perspective, because no appropriate estimation could be made due to lack of information, explaining the difference.

The second part of the research question was about cost-effectiveness. The CER for the bar overdenture is €113/OHIP and €2570/MAI. The CER for the locator overdenture is €83/OHIP and €1623/MAI. Another study also done in the Netherlands(10) reported an ICER for an implant supported removable partial denture in comparison with a conventional partial denture. The CERs for the implant supported partial denture only can be calculated and was €132/OHIP (€2480 for the implant supported partial denture divided by 18.8 points difference in OHIP outcome). This calculated CER is in the same range as the CERs of the current study; however no clear comparisons can be made between the two, because of the different baseline characteristics of these patient groups.

In the absence of clear common units in dentistry, for this study the OHIP-49NL and MAI were used respectively as a subjective and objective outcome measure. The OHIP-49NL is a validated instrument (11) that measures oral health related quality of life. The MAI is an objective way
to measure chewing function. With these two outcomes a wide range of dentistry related outcome measures is covered.

It is reported that a generic instrument, like the Short Form-36, would be a better outcome measure for economic evaluations (16). With a generic instrument the quality of life can be measured to value the effect of treatments between different illnesses. When you add a time parameter also the quality adjusted life years (QALYs) can be calculated. QALYs are the gold standard to value health care effects for cost-effectiveness studies as this metric makes it possible to compare two health technologies with each other without common outcomes, such as a lifesaving treatment versus a non-lifesaving treatment (16). However in dentistry oral health related quality of life measures seem to provide more easily interpretable results than health related quality of life measures and should be preferred when assessing treatment effects in typical dental patients (17). For the assessment of oral health related quality of life, it is suggested that the OHIP (a disease-specific measure) can discriminate between clinically disparate groups, while the SF-36 (a generic-specific measure) does not. (18) The OHIP can measure the impact of oral conditions on functional and psycho-social well-being and is likely to be effective in identifying patients who may benefit from implant-related procedures.

In the one-way sensitivity analysis one parameter is varied (in the current study 10% higher or lower) to assess the effect on the outcome (the ICER comparing the bar and locator overdenture). In the current study it was found that changes in the OHIP outcome for the locator, but even more for the bar overdenture, had the biggest impact on the ICER. The laboratory costs did not influence the ICER much. This is explainable, because the denominator in the fraction for the ICER is the difference in OHIP outcome, which is very small (about 6). When we change the outcome for the OHIP for one of the groups this denominator almost doubles or gets close to zero and has a big influence on the outcome this way.

In the probabilistic sensitivity analysis, the uncertainty of the deterministic values is assessed. For the OHIP outcome about two thirds of the point estimations are in the northeast quadrant, meaning more costs for the bar overdenture but also more gains for the change in OHIP score. Meaning that for the other approximately one third of the simulations for bar
overdentures more money is spent, but the health benefits regarding satisfaction are the same or lower than when these patients were provided with a locator system. A decision should be carefully made, whether one is willing to pay the additional amount of money while for approximately one third of the simulations the bar attachment system is not cost-effective.

The CEAC shows that with a probability of 95% the bar overdenture is cost-effective when payers are willing to pay a maximum of €135/OHIP and for the locator overdenture this is €109/OHIP. For the MAI outcome, these values are €4000/MAI for the bar overdenture and €2600/MAI for the locator overdenture. When the willingness to pay thresholds are lower, the probability that the treatment options are cost-effective decreases. Because no willingness to pay thresholds for these outcomes are known in the Netherlands, no conclusions can be drawn.

Limitations
The answers to our research question are subject to uncertainty due to various factors. Firstly, for calculating the opportunity costs we did not consider any treatment errors like, re-implantations due to implants not osseointegrating or more than one try in session for the fabrication of the denture. This would raise the total opportunity costs for the bar and locator overdenture. However probably, the cost would rise equally for both treatment types, because it is likely that treatment errors will occur equally for both treatment types.

Secondly, to calculate the total opportunity costs only the primary costs are included. In this study we did not consider any aftercare costs. Ideally, the time horizon of a cost-effectiveness study should cover the entire period over which the interventions may influence either clinical or economic outcomes. For the current study this means that aftercare costs will need to be considered. There are a few studies known about aftercare comparing the bar and locator attachment system. Two studies report less aftercare for locator systems (19,20). One study reports that aftercare for the locator system was frequent but easy to handle. All studies focus on mandibular overdentures instead of maxillary overdentures. Not much is known about aftercare for maxillary overdentures with a locator system in comparison to the bar system. Further cost-effectiveness studies about this topic should focus more on the long-term outcomes, because aftercare could be of
influence on the clinical and economical outcomes. Thirdly, we assumed that implants were placed by an oral and maxillofacial surgeon under local anaesthesia. In practice, also implant dentists could be placing implants, lowering the total costs. A factor that could be raising the total costs is the fact that it is possible that patients need bone augmentations prior to implant placement under general anaesthesia. Like for the first limitation, it is likely that this uncertainty is similar for both treatment types. Meaning that this fact is altering the conclusion about costs, but not about cost-effectiveness.

**Conclusion**

The total costs (using opportunity costs) for the bar overdenture treatment are €6312 (range: €5517 - €6893) and for the locator overdenture treatment are €4160 (range: €3676 - €4644).

The CER for the bar overdenture is €113/OHIP and €2570/MAI. The CER for the locator overdenture is €83/OHIP and €1623/MAI.

Although bar overdentures, in the base case, are more favourable when regarding the OHIP outcome, the PSA showed that for a significant part of the simulations this is not the case. Changes in OHIP outcomes had the biggest impact on the ICER. It must be noticed that the choice for a particular treatment option cannot only be based on cost-effectiveness; clinical performance should also be taken into account.

Further cost-effectiveness studies about this topic should focus on the long-term outcomes, because aftercare could be of influence on the patient centred, functional and economical outcomes. Furthermore, the development of a way to translate OHIP scores to QALY scores and willingness to pay thresholds will aid the cost-effectiveness research in dentistry.
References


