General discussion and conclusions
In the PhD research described in this thesis, the performance of maxillary overdentures supported by four dental implants, with regard to patient satisfaction, masticatory performance, impact of implant dehiscences at surgery, clinical and radiographic outcome, costs and choice of attachment system was studied. In general, it can be said that a four-implant maxillary implant overdenture, supported by either a locator attachment system or a bar attachment system, is a good treatment option for patients with complaints about stability and retention of their conventional denture. The various parameters involved will be discussed below.

**Patient satisfaction**
Patients are very satisfied with maxillary overdenture treatment as reflected by the outcomes of satisfaction questionnaires and general satisfaction scores found in the systematic review and our randomized controlled trial (Chapter 2 and 4). The satisfaction scores derived from our randomized controlled trial are comparable to earlier reported studies on maxillary overdentures (1,2). Moreover, there was no difference in experienced satisfaction between a maxillary overdenture on locators or bars, except for two parameters (general satisfaction score and total OHIP-49NL score). Post-treatment, the general satisfaction score for the locator group was 8 (Q1-Q3: 7-9) and for the bar group it was 9 (Q1-Q3: 8-10). Additionally the total OHIP-49NL score for the locator group was also significantly higher (36.6±36.7) than that of the bar group (18.4±17.5), indicating a better oral-health quality of life for the bar group. When combining all three satisfaction measures (denture complaints questionnaire, OHIP-49NL, general satisfaction score) it can be concluded that both treatment options significantly improve patient satisfaction, but with a higher overall experienced satisfaction by patients treated with a maxillary overdenture on bars. The separate items for the denture complaints questionnaire and the separate items for the OHIP-49NL did not differ significantly, however, but again a trend for better scores for the bar overdenture was observed. Nevertheless, the amount of improvement with regard to satisfaction is similar (but not the same) for both groups, making the locator overdenture still a good treatment option to improve patient satisfaction.

**Function**
Patients with maxillary overdentures can mix food better than patients
without maxillary overdentures, regardless of the type of attachment system. On a masticatory performance questionnaire, patients receiving maxillary overdentures on bars or locators reported an improvement in masticatory performance after treatment, which means that both the patients’ objective and subjective results show that they can chew better after maxillary overdenture treatment with either bars or locators (Chapter 5).

To our knowledge no other study has measured the effect of maxillary overdenture treatment on mastication making a direct comparison not possible. However, studies of patients receiving mandibular implant overdentures with maxillary conventional dentures (3–8) reported that masticatory performance had improved after treatment, both objectively and subjectively which is in line with the results of the present study.

There is no significant difference between a bar and a locator maxillary overdenture with regard to objective masticatory performance as measured by a mixing ability test (Chapter 5). This is in line with other literature comparing mandibular overdentures on bar attachments or locator attachment systems (5,9). However, subjective results for masticatory performance post-treatment are significantly different between bar or locator overdentures. Patients with locator overdentures felt an improvement in mastication, but this improvement is smaller than the improvement reported by patients with bar overdentures. The biggest difference between the groups is seen for the reported ability to chew hard foods. It must be noticed that all patients with a locator maxillary overdenture not only had locators to support the maxillary overdenture on four implants, but also locators for the mandibular overdenture on two implants. It has been reported that the stability of a mandibular overdenture with a bar attachment system is better than that with a solitary attachment system (10). The design of the pivoting locator male allows a resilient connection. When using two implants, this results in a non-rigid connection. When using more than two implants the denture cap will have no possibility to move over the male anymore. The smaller improvement for the ability to chew hard foods seen after overdenture treatment with locators might be influenced by the non-rigid connection of the mandibular overdenture.
Dehiscences
Placing implants with a dehiscence of the implant surface in the maxilla to support a maxillary overdenture does not result in worse per-implant health and implant survival when the implants are placed with primary stability and the dehiscence is covered with autologous bone (harvested from the maxillary tuberosity), anorganic bovine bone and a resorbable membrane (Chapter 3). This eliminates the need for a separate bone augmentation procedure, thus reducing morbidity and speeding up prosthodontic rehabilitation.

The incidence of complications, such as sensory deficits in the lower lip and mental foramen area when using intraoral donor sites, is more significant for the mandibular symphysis and the ramus area than for the maxillary tuberosity (11,12). This observation is in line with the results of the described study in this thesis (Chapter 3), as harvesting from the donor site (the maxillary tuberosity) did not cause complications. Another advantage of choosing the tuberosity as the donor site is that harvesting of bone can be done through the same extended incision as for the insertion of the implants.

Implant survival rate
In this thesis the implant survival rates for maxillary overdentures on bars and locators were determined (Chapter 4). There was no difference between the bar and locator overdentures with regard to implant survival. In two systematic reviews it was found that implant survival for a four-implant overdenture and a bar is higher than that of an overdenture with solitary attachments (13,14). Even though there was no statistical significant difference between the locator and bar group, the implant survival rate tended to be higher in the bar group, which is in line with the findings of the two reviews. However, the solitary attachment systems included in these reviews did not include locators, but only ball attachment systems.

When comparing the survival rates to other studies, the implant survival rate for the bar group seemed to be a bit higher than the reported survival rates in two systematic reviews (13,14), but lower than an earlier study done by the same team using a similar treatment protocol with wider implants (2). The implant survival for the locator group is similar to other
Bone loss was significantly higher around implants supporting an overdenture with the locator system (chapter 4). The mean loss of peri-implant marginal bone was 0.58±0.71mm for the locator group and 0.31±0.47mm for the bar group after 12 months. There is not much literature about maxillary four-implant overdentures on locator abutments, however, the observed amount of bone loss does not deviate much from the few other studies on maxillary overdentures on locator abutments (15,17). Also the amount of bone loss for the bar overdentures observed in this study is comparable to earlier reports (2). The found difference between the groups is 0.3±0.1 mm, with a 95% confidence interval from 0.1 - 0.4 mm. So there is only a chance of 5% that the true population difference is higher than 0.4 mm, putting this finding in perspective with regard to clinical relevance.

The cause of the difference between locator and bar in the present study might be found in the fact that the implants are not splinted when using locator abutments. Recently, in vitro studies revealed that stress levels in surrounding bone tissues were significantly higher for four-implant maxillary overdentures with a solitary attachment system when compared to a bar system (18,19). For the mandibular overdenture more research can be found about this topic. In one study the relation between stress levels and marginal bone loss were measured and the effects of bone stress levels may explain why unsplinted implants supporting a mandibular overdenture show more marginal bone loss compared to splinted implants (20).

Although the marginal bone loss for the locator group was higher, the amount of bone loss in patients treated with locators is still within a healthy range. It was suggested that bone loss ≥2 mm, compared to initial radiographs at delivery of the overdenture and in combination with bleeding on probing, should be interpreted as a ‘red flag’ for the clinician to critically evaluate if any peri-implantitis treatment is indicated in the individual case (21). The found marginal bone loss in the locator group is 1.62 mm smaller than the proposed ‘red flag’ margin. Also, marginal bone loss should always be assessed in combination with bleeding and/or suppuration on probing and pocket depth (22,23).
Clinical outcome
For both the locator and bar overdenture very low indices for plaque, calculus, gingiva, and bleeding were found at all follow-up visits. The clinical outcomes are comparable to the other studies about maxillary overdentures (2,24). The mean peri-implant probing depths were 3.7 mm for the locator overdenture and 4.1 mm for the bar overdenture, which is comparable to other studies (2,25). Implants were surrounded with healthy peri-implant soft tissues, probably due to the strict oral hygiene regime to which patients were subjected.

Cost-effectiveness
Achieving high value for patients is a major goal of health care delivery in general and subsequently also for dental care. Here, ‘value’ is defined as the health outcomes per monetary unit spent (26). Since a uniform strategy is lacking in dentistry, the opportunity costs were chosen as a way to calculate costs, as recommended by various authors (27,28).

For the study reported in Chapter 6 the direct health care costs were taken into account, since these costs are the main costs for overdenture treatment and therefore the most important. Besides analysing costs, quality assessment is the other prerequisite to determine the value of a treatment. Because there is hardly any information about common units in dentistry, for this study the OHIP-49NL and mixing ability index (MAI) were chosen respectively as a subjective and objective outcome measure. The OHIP-49NL is a validated instrument that measures Oral Health Related Quality of Life (29). The MAI is an objective way to measure chewing function. With these two outcomes a wide range of dentistry related outcome measures is covered.

The cost-effectiveness ratio (CER) and incremental cost-effectiveness ratio (ICER) are statistics used in cost-effectiveness analysis to summarise the cost-effectiveness of a health care intervention. It is defined by the difference in costs, divided by the difference in effect. It represents the average (incremental) cost associated with 1 additional unit of the measure of effect. The cost-effectiveness ratio (CER) for the bar overdenture is €113 per OHIP-point gained and €2570 per MAI-point gained. The CER for the locator overdenture is €83 per OHIP-point gained and €1623 per MAI-point gained. Another study also done in the Netherlands (30) 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 can be calculated and was €132/OHIP (€2480 for the implant supported partial denture divided by 18.8 points difference in OHIP outcome) and €1305/MAI (€2480 divided by 1.9 points difference in MAI outcome). These calculated CERs are in the same ballpark 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 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 about 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 then when these patients were given a locator system. A decision about which attachment system to use should be made carefully. 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, should be kept in mind when making the decision.

There is no significant difference in MAI outcome between the two treatment options and the locator treatments is cheaper, so an ICER for the MAI outcome would make no sense. The underlying goal of cost-effectiveness research is to allow clinicians and policymakers to make more rational decisions regarding clinical care and resource allocation. From 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.

The choice for a particular treatment option, especially in dentistry, cannot only be based on cost-effectiveness, as clinical performance is another important factor as well.
Recommendations for further research

In this PhD-study different aspects of maxillary overdenture treatment were evaluated during 1 year. Both treatment options (bar or locator attachments) have been found to be successful, with minimal, but important differences. One year is a relatively short period of time and therefore it is important to follow the patients in this study group during the next years, leading to 5- and 10-year results.

It has to be assessed whether the aftercare of the various approaches also will be comparable on the long run. Aftercare for implant-supported overdentures is an important issue (31). Differences in the amount of aftercare not only nuance the conclusion about whether a locator or bar overdenture treatment is better, but will also influence the cost-effectiveness. With regard to cost-effectiveness analyses in dentistry, universal outcome measures are lacking, outcome measures already available from randomized controlled trials (RCTs) are pragmatically used. Additionally, willingness to pay thresholds for these outcome measures are not known. It would aid future research when general outcome measures and thresholds for cost-effectiveness analyses in dentistry would be set.

The locator system has evolved with the early 2016 launch of the next generation locator R-Tx™ Removable Attachment system. This second version of the locator attachment system has changed on various aspects as compared to the first version. The second version has an altered abutment design and a titanium carbon nitride coating, possibly having an effect on marginal bone loss, denture stability properties and/or wear and aftercare. Secondly, modifications to the denture attachment housing allow the housing to pivot up to 30° over the seated nylon retention inserts to treat a maximum of 60° convergence/divergence between implants. And also the system utilizes only one set of retention inserts with straightforward retention values (zero, low, medium and high). All of these aspects could have an influence on the treatment outcome for maxillary overdentures using locator abutments. It would be advantageous to compare the treatment outcomes of maxillary overdentures using the first or second locator abutment.

Besides choosing another attachment system, clinical and financial advantages can also be established by using fewer implants. A study
comparing the treatment outcome of a four- with a two-implant maxillary overdenture has not yet been published and should be explored. A two-implant overdenture will especially be advantageous for patients that are medically compromised and patients that cannot undergo general anaesthesia required for bone augmentation procedures. Placing two implants will lower post-operative morbidity and make overdenture treatment available for more patients. This treatment option should first be assessed in a randomized controlled trial including relatively healthy patients.

**Conclusion**
The findings of the studies described in this thesis show that 12 months after overdenture placement, there is no difference between a maxillary four-implant overdenture on bars and a maxillary four-implant overdenture on locators with regard to implant survival, objective masticatory performance and clinical indices, while the bar overdenture performed better with regard to marginal bone loss and overall patient satisfaction. Also it was found that initial costs for the bar overdenture were higher and cost-effectiveness was lower in comparison with the locator overdenture.

The specific conclusions are:

- from a systematic review it appeared that treating complete denture wearers with implants to support their denture improves their chewing efficiency, increases maximum bite force and it clearly improves satisfaction.

- even when implants are placed with a dehiscence two thirds of the buccal implant surface, favourable peri-implant health can be achieved after five years, provided these dehiscences are covered with autologous bone, anorganic bone and a resorbable membrane.

- the findings of a randomized clinical trial show that 12 months after overdenture placement (maxillary overdenture on four implants retained by bars opposed by a mandibular overdenture) patients with a bar attachment system had significantly less peri-implant marginal bone loss and were more satisfied than those who were given maxillary overdentures retained by locators. Clinical indices, scores on separate items of the denture complaints questionnaire and scores on separate items of the OHIP-NL49 did not differ between the two groups, however.
• maxillary implant overdentures improve mixing ability and patient-reported masticatory performance. Regarding patient-reported masticatory performance a post-treatment difference is seen between maxillary overdentures with locator attachments or a bar attachment system, in favour of the bar attachment system.

• up to one year after implant treatment, for maxillary four-implant overdentures the total costs of locator attachment system are lower than the total costs for the bar attachment system. The cost-effectiveness ratios are lower for the locator overdenture with regard to OHIP-49NL and MAI outcomes. Although bar overdentures, in the base case, are more favourable with regard to the OHIP score, the probabilistic sensitivity analysis showed that for a significant part of the simulations the locator overdenture is more favourable. Changes in OHIP outcomes had the biggest impact on the ICER.

• in two clinical reports the use of planning software for determining the available space is described. Prosthetic planning software can be very advantageous to determine available space and consequently make a definitive choice about the appropriate a attachment system for overdenture treatment.

Practical implication
When treating a patient with problems of the maxillary conventional denture due to lack of retention or stability or due to hypersensitive gagging reflex, either a maxillary four-implant overdenture on bars or locators is a treatment option that will improve the situation for the patient. However, if bone loss and patient satisfaction are the most important aspects to value treatment success, then, based on this thesis, it cannot be justified that a maxillary four-implant overdenture together with a locator attachment system should be the system of first choice. The maxillary four-implant overdenture on bars performs better with regard to marginal bone loss and patient satisfaction. When other aspects are taken into account the maxillary overdenture on locators is not inferior to the maxillary overdenture on bars.
References


