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8 Summary

Even though implant-retained overdentures are a proven method of treatment for edentulous patients, based on the available evidence, no preferred treatment concept can be defined for the edentulous maxilla. In general, patients more often encounter problems with mandibular dentures compared to maxillary dentures, possibly due to the morphology and more advantageous denture bearing area of the maxilla. The rate of residual ridge resorption was found to be almost twice more pronounced in the edentulous mandible than in the maxilla after wearing dentures for 5 years (Kovacic et al. 2010). The less pronounced maxillary ridge resorption was discussed to be due to the palate serving as resistance to forces being transmitted through the denture to the denture bearing area (Tallgren 1972). When patients start to experience problems with their maxillary dentures in terms of insufficient stability and retention, there usually is pronounced alveolar ridge resorption. Hence, the only way to enhance function and quality of life for these patients is by means of dental implants.

The improvement of masticatory function of patients with mandibular implant overdentures resulted in 1.5 – 3.6 times fewer chewing strokes as compared to patients with conventional dentures (Geertman et al. 1994).

In the posterior maxilla, placing implants usually is hindered due to an insufficient bone quantity and the need for complex bone grafting, which would impair the patient's morbidity. Overall, there is a low prevalence of dental implants (2- 4%) with the main refusal reasons to implant surgery being fear of surgical risks and costs (Ellis et al. 2011; Walton & MacEntee 2005; Zitzmann et al. 2007). Consequently, placing implants in the anterior maxilla without extensive grafting procedures as well as less invasive implant treatment methods are needed to offer edentulous patients more alternatives for enhanced prosthesis retention, function and well-being.

From a recent systematic review on removable and fixed implant-supported prostheses in edentulous jaws it was concluded that more research should be performed on less than 4 implants in the maxilla (Kern et al. 2016). In addition, the authors stated the necessity for more clinical studies focusing on patients' benefits with respect to quality of life, psychological aspects and financial considerations

(Kern et al. 2016).

Therefore, the general aim of this PhD research was to assess both the clinical performance of maxillary implant overdentures retained by 2 implants in edentulous patients and the patient satisfaction up to 4 years after treatment.

In chapter 3 of this thesis, a within-subject prospective clinical trial is described, comparing maxillary conventional dentures and implant overdentures. Twenty-one edentulous patients encountering problems with their existing maxillary dentures were included. First, patient satisfaction of the existing dentures was assessed by means of the Oral Health Impact Profile (OHIP-20E) questionnaire and additional questions on cleaning ability, general satisfaction, speech, comfort, esthetics, stability, and chewing ability. Then the existing dentures were evaluated on quality and function and corrected in 9 patients, whereas in 12 patients' new dentures were indicated and provided. The new dentures following an adaptation period of 2 months were evaluated by filling in the same questionnaires as above. Thereafter, all patients received two implants in the canine area of the maxilla and two ball anchors retaining the overdentures. Again, patient satisfaction was determined 2 months following insertion of the implant overdentures. There was a significant improvement of patient satisfaction with implant overdentures for all domains compared to old conventional dentures ($P < 0.05$).

The fabrication of new conventional dentures improved patient satisfaction for certain parameters (physical pain, psychological disability, handicap, cleaning ability, comfort and esthetics). Consequently, only the aspects functional limitation, psychological discomfort, physical and social disability, general satisfaction, speech, stability and chewing ability were statistically superior for implant overdentures in comparison ($P < 0.05$). From this study, it was concluded that maxillary overdentures retained by 2 implants and ball anchors significantly ameliorated the quality of life of edentulous patients in the short-term.

The retention of an overdenture is an essential criterion for a patient to be satisfied and feel comfortable when speaking and functioning. Interestingly, the coverage of the tuberosities seems to play a more important role for retention than the coverage of the palate (Orstavik & Floystrand 1984). A study on maxillary overdentures retained by 4 splinted implants did not find a significant impact on patient satisfaction

if overdentures were with or without palatal coverage (de Albuquerque Junior et al. 2000).

Whether reducing the palatal coverage in overdentures retained by only 2 unsplinted implants would influence patient satisfaction was addressed in chapter 4 of this thesis. The same patient group as in chapter 3 received overdentures with palatal coverage for 2 months, which were retained by 2 implants and ball anchors. Thereafter, patients filled in OHIP-20E questionnaires and the additional issues cleaning ability, general satisfaction, speech, comfort, esthetics, stability, and chewing ability were inquired. Subsequently, the palatal coverage was reduced by the technician to the limits of the metal frame and overdentures were polished. The patients wore these overdentures for another 2 months before answering the same questionnaires. The comparison of the 2 overdenture designs yielded equal patient satisfaction for all OHIP domains. Patients were significantly more satisfied with esthetics and taste ($P < .01$) for overdentures with reduced palatal coverage. In conclusion, palatal coverage of maxillary overdentures on 2 implants did not affect patient satisfaction. It is hence worthwhile to consider the reduction of the palatal coverage in individual patients for a beneficial perception of esthetics, taste, phonetics and gag reflex.

Numerous systematic reviews investigated the question of how many implants are optimal to retain a maxillary overdenture (Gallucci et al. 2009; Kern et al. 2016; Klemetti 2008; Rocuzzo et al. 2012; Sadowsky 2007; Slot et al. 2010). Due to insufficient and weak evidence, no explicit statement could be drawn.

From the clinician's perspective, survival of implants and prostheses, marginal bone levels and biological and technical complications are crucial for the success of a therapy. It is well known, that implant loss occurs most frequently within the first year, as so-called early failures, i.e. before implant osseointegration (Esposito et al. 1998). In contrast, less than 50% are late failures, i.e. implant loss after an established but not preserved osseointegration. For this reason, chapter 5 investigated implant survival rates, bone loss and biological and technical complications of 2 maxillary implants retaining overdentures at 1 year. The new or adjusted dentures served as templates both for the execution of a cone-beam computed tomography (CBCT) scan (NewTom 5G, QR, Verona, Italy) and for the fabrication of a surgical guide. For this

reason, denture duplicates with barium sulfate were made, which were modified according to the digital implant planning (coDiagnostiX, Dental Wings Inc. Montreal, Canada). The implants were, if possible, placed in canine position. Minor guided bone regeneration not compromising implant stability was allowed. Two diameter reduced titanium-zirconia implants were inserted to preserve as much autologous bone around the implant (Roxolid® Tissue Level, 3.3 mm diameter, Regular Neck, Institut Straumann AG, Basel, Switzerland). Since implant healing mode (trans- or submucosal) is not impairing implant survival, both modes were allowed in the present study (Astrand et al. 2002; Ericsson et al. 1997). After 3 and 5 months of healing (depending on whether bone grafting was performed or not), ball anchors were mounted, and implant overdentures were delivered. Follow-up visits were executed at 1, 2, 4, and 8 weeks following implant insertion and 2, 4, and 12 months following overdenture insertion (baseline). Intraoral radiographs were taken at implant loading and 1 year in a standardized way with individually designed holders.

At a mean follow-up of 1.1 years (range 1.0-1.7 years), nineteen patients (1 dropout) with 38 implants were evaluated. The implant survival rate amounted to 97.3% with 1 implant lost. There was significant bone loss at 1 year (mean 0.7 mm, SD = 1.1 mm; median: 0.48 mm, IQR = 0.56 mm). More than 2 mm bone resorption was apparent around 8% of the implants. Overall 13 soft tissue events occurred during the observation period: mucosa overgrowth around 11 implants (29%) in 8 patients, 1 pain spot and 1 recession. Technical events comprised 4 minor and 2 major overdenture tooth fractures and 6 rebasings. Despite a large number of events and increased bone loss, the 1-year implant survival rate was high. On the basis of these results, 2 maxillary implants as retention for overdentures cannot be recommended as routine procedure until longer follow-up and more studies on this topic are available. Never the less, this treatment might be a suitable minimally invasive alternative for selected patient cases.

An important issue was considered in the present thesis, namely the pre-treatment assessment of patient satisfaction, which has a significant impact on the post-treatment assessment. The included patients rated their upper dentures before receiving implant therapy. An evidence-based review on PROMs in implant research concluded that many studies present only post-treatment assessments and thereby the benefit of a treatment cannot be evidenced (McGrath et al. 2012). Retrospective

assessment reveals more about the recovery from an event, especially if reported with short follow-up and has the limitation of a recall bias effect (Locker et al. 2004). It was therefore recommended to assess PROMs with a follow-up of a year or longer (McGrath et al. 2012).

In chapter 6 the progression of patient satisfaction was compared from baseline to 1 and 4 years and, whether the initial benefit of the implant treatment would persist over time.

Following the evaluation of the palatal coverage (chapter 4), the patients could choose which design they favored. Two thirds (16 patients) chose for a reduced palatal coverage, while one third (5 patients) asked for palatal closure.

At 4 years, patients rated social disability the best and functional limitation the worst. Patient satisfaction did not change significantly for not any OHIP domain at 1 and 4 years compared to baseline, thus the benefit of maxillary overdentures retained by 2 implants remained unchanged.

To be able to propose the minimum of 2 implants for maxillary edentulous patients, the clinical performance of this treatment has to be evaluated over a few years. Chapter 7 thus examined implant survival, peri-implant bone loss and incidence of biological and technical events at 4 years. Fifteen patients (10 men, 5 women) were available for a mean follow-up of 4 years (range 3.6 – 4.2 years). There were 6 implant failures in 5 patients (3 men, 2 women). One patient lost both implants subsequently. The Kaplan Meier implant survival rate resulted in 75%. There was significant marginal bone loss at 4 years compared to baseline (mean mesial 0.9 mm, SD 1.5 mm; mean distal 1.0 mm, SD 1.3 mm; median mesial 0.8 mm, median distal 0.6 mm; IQR mesial 1.7 mm, distal 1.3 mm). Mucositis was detected around one implant. No other biological complications were evident at 4 years.

With regard to technical complications occurring from 1 year until the last follow-up of 4 years, 17 matrices were mobile in 10 patients (9 men, 1 woman). In total, 30 metal springs of the matrices were lost or broken in 7 patients and had to be replaced. One complete matrix was lost in 1 patient and was renewed.

Three fractures of overdenture teeth were detected in 2 patients and 2 rebasings were needed in 2 patients. For this reason, overdentures were sent to the lab.