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Single-tooth implant treatment in the maxillary aesthetic region

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Single-tooth implant treatment in the maxillary aesthetic region

A decade of treatment

C.M. Meijndert

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**Single-tooth implant treatment
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A decade of treatment**

C.M. Meijndert

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Single-tooth implant treatment in the maxillary aesthetic region. A decade of treatment

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1

General introduction

Single tooth replacement in the aesthetic region has been part of implant dentistry for a number of decades. Since its introduction, a variety of implant systems, surgical and prosthetic techniques, and loading protocols have been used (Den Hartog et al., 2008; Esposito et al., 2010; Jung et al., 2012; Lang et al., 2012; Benic et al., 2014; Slagter et al., 2014; Van Nimwegen et al., 2019.) Most studies have only reported on the 1-year survival rate for single tooth implants and crowns. The few studies with a longer follow-up demonstrated that the 5- and 10-year survival rate of implants are 97.2% and 95.2%, respectively. The 5- and 10-year survival rate of single crowns are 96.3% and 89.4% respectively (Jung et al., 2012). Implant design, however, is subject to continuous development to achieve better or faster osseointegration of the implant, to improve the connection between the implant and abutment, and to optimise the aesthetics by facilitating the prosthetics. A specific implant design and prosthetic construction might not be used today anymore and therefore might cause restrictions when comparing the results of the former implant designs and prosthetic rehabilitation with the more recent designs and prosthetic constructions.

Healed sites with extended resorption

Implant treatment was, at least in former days, not always part of the initial restorative treatment plan after tooth extraction. After tooth extraction, the alveolus undergoes a series of physiologic events that can, without extra precautions, lead to progressive resorption of the alveolar ridge. Predominantly of the buccal bony wall, this could lead to severe recession of the mucosa (Araújo et al., 2019). This so-called ‘physiologic collapse’ can make the site unfit for implant placement (Buser et al., 2004; Chen & Buser, 2009; Jung et al., 2018). These unfavourable circumstances often require extensive pre-implant local ridge augmentation surgery to obtain enough bone for implant placement and a satisfying soft tissue display. This often means that placement and restoration of the implant needs to be postponed (Kuchler & Von Arx, 2014).

Healed sites with limited resorption

Luckily, the extended resorption of the alveolar ridge does not always occur after a tooth extraction. Thus, leaving enough bone for implant placement after healing. When needed, e.g. in cases where the implant can be placed with sufficient initial stability, but parts of the implant shoulder remain uncovered, or where the buccal bone wall is thin (less than 2mm in thickness), a simultaneous local augmentation procedure can be performed with autologous bone and/or a bone substitute (xenograft, allograft,

hydroxyapatite) (Campana et al., 2014). The augmented site can be covered with a membrane and a mucosa graft when needed.

Post-extraction sites with a buccal bone defect

When considering implant therapy for replacement of a single tooth, it is advisable to start planning before the failing tooth is extracted. One of the techniques that is used to avert the risk of post-extraction alveolar ridge resorption is alveolar ridge preservation. (Jung et al., 2018). The goal is to reduce the dimensional changes that occur after tooth extraction, by applying a bone graft and/or a bone substitute in the extraction socket, so that the implants can be placed in a prosthetically ideal position (Jung et al., 2018; Wessing et al., 2018). Alveolar ridge preservation does not stop the resorption process, but it can slow down the degree of alveolar alterations before implant placement (Chappuis et al., 2018; Tonetti et al., 2019). This is particularly important in the aesthetic region. The alveolar bone supports the peri-implant mucosa, and the peri-implant mucosa is essential for a good aesthetic outcome. Therefore it can be assumed that alveolar ridge preservation has a beneficial effect on the aesthetic outcome (MacBeth et al., 2017; Jung et al., 2018; Chappuis et al., 2018).

Post-extraction sites without a buccal bone defect

Nowadays, immediate implant placement after tooth extraction is frequently advocated for. This approach is less time consuming than the conventional procedure and leads to increasing patient contentment (Joshi & Gupta, 2015). Studies have shown that immediate implant placement and restoration after tooth extraction has a comparable outcome to that of conventional implant placement and restoration protocols when the conditions are favourable (Esposito et al., 2017; Slagter et al., 2014). A key condition for the success of the immediate implant placement and restoration approach is primary stability (Papaspnyridakos et al., 2014). Primary stability limits micromovement and allows osteogenic cells to adhere to the implant surface, leading to osseointegration (Rodrigo et al., 2010). However, it is influenced by a number of factors such as the quality and quantity of the bone, surgical techniques, and the micro and macro design of the implants (Rao & Gill, 2012; Smeets et al., 2016). But when primary implant stability is achieved, and a bony defect of the buccal bone plate is absent, or present as small solitary defects at most, immediate non-occlusal provisionalization is possible (Slagter et al., 2014; Van Nimwegen et al., 2018).

Implant design

Originally, most of the implant designs were cylindrical with parallel walls to enable a maximum contact area with the surrounding bone. In addition to the cylindrical shaped implant, a tapered shaped implant design was introduced that resembles a more natural root shape. An alleged benefit of a tapered implant design is improved primary stability compared to parallel-walled implants. Which is achieved due to the self-tapping property combined with under-drilling during the osteotomy (Sugiura et al., 2019; Atieh et al., 2018). Furthermore, it is said that there is less risk of bone fenestrations in bony undercut cases, especially at the apical part of the tapered implants, as is often present with maxillary alveolar processes (Atieh et al., 2018).

A more detailed aspect of the implant design is the implant-abutment connection. To respect the biological width, the implant-abutment interface of some brands were initially placed at tissue level, away from the bone crest (Buser et al., 1990). Later on, there was a shift from tissue level to bone level implants. Bone level implants allow the practitioner to create a natural emergence profile with individually designed abutments, to fit each individual patient. Such a natural emergence profile can enhance the aesthetic outcome, which is particularly important in the aesthetic zone (Chappuis et al., 2016; Siebert et al., 2018). However, inherent to this approach is that the microgap between the implant and abutment is located at bone level. The microgap between the implant and abutment can be a source of bacterial colonisation and the presence of an abundance of bacteria can trigger an inflammatory response. This in turn, will lead to bone resorption around the implant (Romanos et al., 2016; Yu et al., 2020).

Implant-abutment connection

Various connection types have been developed in an effort to reduce the microgap between the implant and abutment, and thereby to minimize crestal bone resorption (Koutouzis, 2019). This bone resorption can potentially affect the stability of the mid-buccal mucosa and thus affect the aesthetic outcome, which is particularly harmful in the aesthetic zone (Fürhauser et al., 2005; Belser et al., 2009; Jemt, 1997).

A clear distinction can be made between external and internal implant-abutment connections. The external connections have been used successfully for many years, but are more susceptible to complications such as abutment screw loosening (Gracis et al., 2012), bacterial leakage (Steinebrunner et al., 2005) and peri-implant bone loss (Koo et al., 2012) compared to internal connections. Within the internal connection category, there are various geometric variations (Koutouzis, 2019). The internal implant geometry can be parallel-walled or conical/tapered, and is equipped with a platform

switch or a platform match. It has been suggested that an internal implant-abutment connection with a conical configuration is the most stable connection, with less bacterial leakage than the other configurations (Zipprich, 2018). This might lead to less bone loss compared to a non-conical connection (Schmitt, et al., 2014).

Because the aesthetic outcome of restorations in the aesthetic region is of major importance, it is important to assess if an implant-abutment connection has any influence on the clinical, radiographic and aesthetic outcome of an implant restoration. So far, only Vetromilla et al. (2019) performed a systematic review on implant abutment connections in the aesthetic region. They concluded from the Pink and White Esthetic Scores that the internal hexagon performed better aesthetically, but they were not able to quantify their observations. Additionally, they did not distinguish between platform-switched and platform-matched connections. According to Caricasulo et al. (2018), the presence of a platform switch might be an important contributing factor in reducing peri-implant bone loss. Thus, when studying the outcome of different connection types, analysing platform switched connections separately from platform matched connections might be a determining factor (Hsu et al., 2017; Caricasulo et al., 2018).

General aim and outline of the thesis

The general aim of this thesis was to assess the outcomes of treating a single missing tooth in the aesthetic region with an implant, hereby assessing the short and long term outcome. The patients in the various studies described in this thesis had different grades of alveolar bone resorption. A variety of dental implant designs within the portfolio of one implant brand were applied.

The specific aims were:

- to assess the 10-year clinical, radiographic, aesthetic, and patient centred outcomes of a tissue level implant system placed in augmented sites comparing three different augmentation techniques (**Chapter 2**);
- to assess the 5-year clinical, radiographic, aesthetic, and patient centred outcomes of a bone level cylindrical implant system in healed sites (**Chapter 3**);
- to assess the 1-year clinical, radiographic, aesthetic, and patient centred outcomes of a bone level tapered implant system in unassisted healed sites (**Chapter 4**);
- to assess the 1-year clinical, radiographic, aesthetic, and patient centred outcomes of a bone level tapered implant system in preserved healed sites (**Chapter 5**);
- to assess the 1-year clinical, radiographic, aesthetic, and patient centred outcomes of a bone level tapered implant system in post-extraction sockets (**Chapter 6**);

- to review the literature systematically regarding the influence of the implant-abutment connection configuration to gain insight into the effect of different implant-abutment interface designs on peri-implant bone level changes, implant loss and mid-buccal mucosa changes around single implants in the aesthetic region (**Chapter 7**).

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Chapter 1

- Vetromilla, B. M., Brondani, L. P., Pereira-Cenci, T., & Bergoli, C. D. **(2019)** Influence of different implant-abutment connection designs on the mechanical and biological behavior of single-tooth implants in the maxillary esthetic zone: A systematic review. *The Journal of Prosthetic Dentistry*, 121(3), 398–403.e3.
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2

Single implants in the aesthetic region preceded by local ridge augmentation

a 10-year randomized controlled trial

*This chapter is an edited version of the manuscript:
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implants in the aesthetic region preceded by local ridge augmentation; a 10-year
randomized controlled trial. Clin. Oral. Implants. Res. 2017; 28: 388-395.*

Abstract

Aim: The aim of this randomized controlled trial was to assess the 10-year effects of three different augmentation techniques (augmentation with chin bone, augmentation with chin bone plus a membrane and augmentation with a bone substitute plus a membrane) for implant supported restorations in the maxillary aesthetic region regarding clinical and radiographic parameters, and patient-centred outcomes.

Materials and methods: Ninety-three patients (44 male/49 female, mean age 33 years) requesting single tooth replacement and presenting with a horizontal bone deficiency were included. After augmentation, 93 implants were placed. Clinical variables, standardized radiographs and photographs and patient questionnaires were analysed to assess the impact of the various augmentation techniques 1 month (T_1), 12 months (T_{12}) and 120 months (T_{120}) after final crown placement.

Results: The 10-years implant survival was 95.7% and did not differ between the groups, nor were significant differences observed in the other treatment outcomes assessed. Peri-implant bone loss was low, being 0.48 ± 1.19 mm (mesial) and 0.30 ± 1.24 mm (distal) at T_{120} . Mid-buccal marginal gingival recession at T_{120} was minor, being 0.32 ± 0.83 mm. Mean overall patient satisfaction at T_{120} was 8.6 with 98.6% of the patients satisfied.

Conclusions: Clinical, radiographic, aesthetic and patient centred outcomes were very favourable after 10 years and did not differ between the groups with different bone augmentation techniques.

Introduction

Single tooth replacement in the aesthetic region has been part of implant dentistry for a number of decades. Since its introduction many implant systems, surgical and prosthetic techniques, and loading protocols have been used (Den Hartog et al., 2008; Esposito et al., 2010; Jung et al., 2012; Lang et al., 2012; Benic et al., 2014; Slagter et al., 2014). Yet, most reported survival rates of single tooth implants and crowns are restricted to one year. From a systematic review of Jung et al. (2012) it can be learned that 5 and 10 years' survival of implants supporting a single crown was 97.2% and 95.2%, respectively. The 5- and 10-years' survival rate of the single crowns themselves were 96.3% and 89.4%, respectively. It must be noted, however that this meta-analysis was not limited to single tooth replacement specifically in the aesthetic region.

The goal of dental implant therapy in the aesthetic region is to achieve successful tissue integration and predictable and aesthetic acceptable soft tissue contours, thus re-establishing both function and aesthetics. Favourable results should not just be a short-term result, but also be present after a long-term follow-up. Yet, a follow-up of ≥ 10 years of dental implants in the aesthetic region is limited to the studies of Jemt (2008), Gotfredsen (2012), Schropp & Isidor (2015) and Kuchler et al. (2016). Jemt studied 38 patients with 47 Branemark system implants (Nobel Biocare, Gothenburg, Sweden). Implant survival rate was 100%; crown survival rate was 77%. Gotfredsen studied 20 patients with 20 Astra Tech ST implants (Astra Tech AB, Mölndal, Sweden). Implant survival rate was 100%; crown survival rate was 90%. Schropp and Isidor (2015) studied 44 patients with 44 Osseotite implants (Biomet/3i, Palm Beach Gardens, FL, USA). Implant survival rate was 93.2%; crown survival rate was not reported. Kuchler et al. (2016) studied 17 patients with 17 Straumann Plus implants (Institut Straumann AG, Basel, Switzerland). Implant survival rate was 100%; crown survival rate was not reported. Only the latter study reported on hard and soft tissues as well as patient centred outcomes.

Due to post-extraction resorption of the alveolar process or because of bone loss as a result of periodontal disease or trauma, it is not uncommon that insufficient bone volume is available to place implants in the anterior region and to obtain favourable aesthetics. Thus, pre-implant local ridge augmentation is commonly needed in these cases. Jung et al. (2013) presented 12–14 years' outcomes of implants placed simultaneously with guided bone regeneration using resorbable and non-resorbable membranes. Fifty-eight patients, treated with 222 Branemark implants (Nobel Biocare, Gothenburg, Sweden) were evaluated. Implant surgery was performed without an augmentation

procedure or with an augmentation procedure with demineralized bovine bone mineral in combination with either a collagen (CM) or an expanded polytetrafluoroethylene (e-PTFE) membrane. Implant survival was 94.6% in the control group, 91.9% in the CM group and 92.6% in the e-PTFE group, without any significant differences. It must be noted that implants were positioned in both the anterior and posterior region of maxilla and the mandible and with a variety of superstructures. Kuchler & Von Arx (2014) showed in their systematic review on horizontal ridge augmentation prior to implant placement in the anterior maxilla that different methods are available to create the basis needed for reliable implant placement. Survival rates of implants, with an up to 4 years follow-up, placed in such reconstructed areas is ranging from 93.5% to 100%. No such data are available for long-term implant survival specifically for single-tooth replacement in the aesthetic region.

To date, limited long-term studies are available on dental implants in the maxillary aesthetic region and no long-term studies are available comparing the long-term results of different augmentation procedure techniques with regard to the changes in hard and soft peri-implant tissues in a randomized clinical trial. Therefore, the aim of this randomized controlled trial was to assess the 10-year effects of three different augmentation techniques (augmentation with chin bone, augmentation with chin bone plus a Bio-Gide® membrane and augmentation with Bio-Oss® plus a Bio-Gide® membrane) for implant-supported restorations in the maxillary aesthetic region regarding clinical and radiographic parameters, and patient-centred outcomes.

Materials and Methods

Patient selection

Ninety-three consecutive patients, fulfilling the selection criteria, were selected from the Department of Oral and Maxillofacial Surgery in Groningen (University Medical Center Groningen, Groningen, the Netherlands) and from the Department of Oral and Maxillofacial Surgery in Drachten (Nij Smellinghe Hospital, Drachten, the Netherlands). All patients (44 men, 49 women, mean age at time of implant surgery 33.3 ± 13.0 years) had a single tooth diastema in the anterior region of the maxilla. The planned treatment site had to show a horizontal bone deficiency, making a bucco-palatinal local ridge augmentation necessary to obtain sufficient bone volume for reliable placement of a dental implant. Study design with in- and exclusion criteria, together with 1-year results, has been reported in detail by Meijndert et al. (2007, 2008).

Study groups

To reconstruct the local bone defects, three treatment modalities were applied:

- Chin bone;
- Chin bone combined with a resorbable Guided Bone Regeneration membrane (Bio-Gide®, Geistlich, Wolhusen, Switzerland);
- Bio-Oss® spongiosa granules (0.25–1.0 mm, Geistlich, Wolhusen, Switzerland) in combination with a Bio-Gide® GBR membrane.

Patients were randomly assigned to one of the three treatment groups using a balancing procedure aiming at an equal distribution of variables that may interfere with the outcome of the study, being age, gender and location of the single-tooth defect (Zielhuis et al., 1990) (**Table 1**). The study was approved by the Medical Ethical Committee; written informed consent was obtained from all patients.

Table 1. Characteristics of the study group at the start of the study.

	Chin bone (gr1)	Chin bone + Bio-Gide® (gr2)	Bio-Oss® + Bio-Gide® (gr3)	Total
Number of participants	31	31	31	93
Mean age in years at the time of implant surgery (range)	33.3 (18-59)	34.6 (18-63)	32.2 (18-63)	33.3 (18-63)
Gender (male/female)	15/18	16/15	15/16	44/49
Tooth gap position (I₁/I₂/C/P₁)	21/7/1/2	21/7/1/2/	21/9/0/1	62/24/2/5

Surgical and restorative procedures

All augmentation procedures were performed under local anaesthesia. In groups 1 and 2, monocortical chin bone grafts were harvested and fixed on the perforated receptor site with a titanium screw. In group 2, the chin bone graft was covered by a Bio-Gide® GBR membrane. In group 3, Bio-Oss® spongiosa granules were placed on the perforated cortical bone of the receptor site and were also covered with a Bio-Gide® GBR membrane. Three months after the augmentation procedure with chin bone (groups 1 and 2) and 6 months after augmentation with Bio-Oss® (group 3), Straumann Standard Plus implants (Institut Straumann AG, Basel, Switzerland) were placed. All implants had a standard body diameter of 4.1 mm and were uncovered 6 months after insertion. An impression was taken during the surgical procedure at the time the implant was placed. A temporary crown was custom made in the laboratory by the dental technician. The temporary crown consisted of a titanium temporary post (RN synOcta®

post; Institute Straumann AG, Basel, Switzerland) and veneering composite (Solidex, Shofu, Tokyo, Japan). On the day of uncovering of the implants, the temporary crown was placed to allow healing of the peri-implant mucosa against a tooth-shaped form. The temporary crowns were screwed directly onto the implant and tightened to 15 Ncm using a torque control device. One month later, a final crown was constructed. The final crown consisted of an abutment (RN synOcta® 1.5 mm abutment; Institute Straumann AG, Basel, Switzerland), a cast-on gold coping for contouring of an ideal emergence profile and adaptation of the margin to the mucosal contour (gold coping; Institute Straumann AG, Basel, Switzerland) and a porcelain crown with a zirkoniumoxide core (Procera®, NobelBiocare, Gothenburg, Sweden). The synOcta® abutment was screwed directly onto the implant with a tightening force of 35 Ncm, the gold coping was screwed onto the abutment with a tightening force of 15 Ncm and the porcelain crown was cemented onto the gold coping.

Clinical and radiographic examinations

Clinical assessments were performed at 1 month (T_1), 12 months (T_{12}) and 120 months (T_{120}) after placement of the final crown using Plaque index (Mombelli et al., 1987), Bleeding index (Mombelli et al., 1987) and Gingiva index (Löe & Silness, 1963). At T_{120} pocket probing depth (Quirynen et al. 1991) was assessed using a clickprobe with standard probing pressure of 0.2–0.25N (Click-Probe®, KerrHawe Dental Corporation, Bioggio, Switzerland) which is equivalent to the electronic periodontal probe with standardized probing pressure of 0.25 ± 0.025 N used at T_1 and T_{12} (ParoProbe®, Estrad BV, Nieuwleusen, the Netherlands). Radiographic examination was performed using standardized intraoral radiographs. Marginal bone level (MBL) was measured mesially and distally at 1 month, 12 months and 120 months after final crown placement. At the same time points, colour slides were taken from the implant-supported crown and surrounding soft tissues. Mid-buccal and approximal marginal gingival level (MGL) was measured to the nearest 0.1 mm.

Evaluation of aesthetics and patient satisfaction

Aesthetics of implant crown and surrounding mucosa was assessed using the Implant Crown Aesthetic Index (ICAI). This index rates anatomic form, colour and surface characteristics of the crown and surrounding mucosa using a penalty system for minor and major deviations (Meijer et al., 2005). Assessment was done on colour slides of evaluation period T_{12} and T_{120} and was performed by the same prosthodontist who was trained with the index and blinded for the applied treatment procedure (**Figs 1, 2 and 3**).

Figure 1. 10-years' result of a patient from Chin bone group; implant-supported restoration in position 11.

Figure 2. 10-years' result of a patient from Chin bone + Bio-Gide® group; implant-supported restoration in position 11.

Figure 3. 10-years' result of a patient from Bio-Oss® + Bio-Gide® group; implant-supported restoration in position 11.

Patient satisfaction was rated using a questionnaire in which patients had to state their opinion through multiple choice questions (Meijndert et al., 2007, 2008). A distinction was made between the appearance of the crown and the appearance of the mucosa 12 months and 120 months after final crown placement. In addition, overall satisfaction was scored by means of a Visual Analogue Scale (range 0–10).

Data analysis

For a description of all collected clinical data, Plaque index, Bleeding index and Gingiva index were calculated as median and inter quartile range. Overall between-group comparison was calculated using the non-parametric Kruskal-Wallis test. If statistical significance was found, the Mann–Whitney U tests was applied to relate an observed significant difference to a specific group. Pocket probing depths and marginal bone and mucosa levels were normally distributed and described as means and standard deviations. Overall significance level between groups was calculated using the One-way ANOVA, followed by the independent t- test to relate an observed significant difference to a specific group. Significance between the follow-up periods was calculated using a paired samples t-test. ICAI and satisfaction questionnaire were not normally distributed. Therefore an overall analysis was conducted with a Kruskal–Wallis test. Significance between the two reviewed follow-up periods was calculated using the Wilcoxon signed rank test. All analyses and calculations were processed in SPSS (IBM SPSS Statistics Data Editor; version 20.0; SPSS Inc., Chicago, IL, USA) using a significance level of $P = 0.05$.

Results

Patients

Of the 93 initially placed implants, 4 implants were lost in 10 years. Two implants failed to osseointegrate and were lost within 6 months after placement. Both patients originated from the Bio-Oss® + Bio-Gide® membrane group. The other 2 implants were removed after 2 and 6 years due to soft tissue recession and resorption of bone buccally of the implant, causing an undesirable aesthetic result. Both patients originated from the Chin Bone + Bio-Gide® membrane group. All 4 patients received a new implant, were seen for routine inspections, but were excluded from further analyses. At the 1 month' and 12 months' follow-up, all patients were present for evaluation. At the 120 months' evaluation 17 patients were lost to follow-up due to moving to another part of the country or changing address without notice. The assumption was made

that non-attendance was independent of treatment result and patient satisfaction. Dropout was distributed over the treatment groups as follows: 2 non-attendance in the group with chin bone, 2 implant loss and 5 non-attendance in the group with chinbone and membrane, and 2 implant loss and 10 non-attendance in the group with a bone substitute and membrane.

Clinical outcomes

After 10 years, implant survival rate for the total group was 95.7% and did not differ significantly between the groups (group chin bone with implant survival rate of 100%; group chin bone and membrane and group bone substitute and membrane both with an implant survival rate of 93.5%). During the 10 years' follow-up, in 9 patients new final crowns had to be made due to porcelain chipping. No loosening of the cemented crowns took place, nor loosening of the screw of the abutments. Together with 2 patients who suffered from implant loss after 2 and 6 years (and crown loss as a consequence), this results in a 10-years crown survival rate of 87.9%. Plaque index, Bleeding index and Gingiva index scored within the healthy spectrum in all groups (**Table 2**). Mean pocket probing depths were calculated for the buccal, palatal and approximal site (mesial and distal site combined) and are presented in **Table 3**. Mean pocket probing depth was within 4 mm at T_{120} . There was no significant difference between the 3 treatment modalities, although the group with a bone substitute and membrane tended to have deeper pockets than both chin bone groups. This became apparent at the buccal site at T_{120} where probing depth was significantly deeper in this group compared with the chin bone groups ($P = 0.002$).

Marginal bone level and marginal gingiva level

Mean marginal bone level change was calculated separately for the mesial and distal side of the implant and is depicted in **Table 4**. In 10 years, total marginal bone loss at the mesial side was 0.48 ± 1.19 mm and at the distal side 0.30 ± 1.24 mm, with no significant differences between the groups. Whereas 72 patients were seen at the 10-years' follow-up, marginal gingival level could not be evaluated for all patients. As the incisal edge of the implant crown was used as a reference line for measurement, patients in whom a new crown was made during follow-up ($n = 9$) had to be excluded for comparison of marginal gingival levels. Mean mesial, buccal and distal gingiva level changes were calculated separately and are depicted in **Table 5**. In 10 years total marginal gingiva level change at the mesial side was a gain of 0.53 ± 0.89 mm, a loss of 0.30 ± 0.78 mm at the buccal side and a gain of 0.45 ± 0.90 mm at the distal side, with no significant differences between the groups.

Table 2. Clinical variables. Median, first and third inter quartile ranges of Plaque index (scores 0-3), Bleeding index (scores 0-3), and Gingiva index (scores 0-3) at T₁, T₁₂ and T₁₂₀ of treatment group Chin bone, Chin bone + Bio-Gide® and Bio-Oss® + Bio-Gide®.

	Chin bone (gr1)	Chin bone + Bio- Gide® (gr2)	Bio-Oss® + Bio- Gide® (gr3)	Significance level between groups*	Total of the groups
T ₁					
Plaque index	n=31 1 [0;1]	n=31 0 [0;1]	n=29 0 [0;1]	p _{overall} = 0.02 gr1-gr2 p=0.02 gr1-gr3 p=0.01	n=91 0 [0;1]
Bleeding index					
Gingiva index	1 [0;2] 0 [0;0] n=31	1 [1;2] 0 [0;0] n=31	2 [1;2] 0 [0;1] n=29	p _{overall} = 0.21 p _{overall} = 0.81	1 [1;2] 0 [0;1] n=91
T ₁₂					
Plaque index	1 [0;1] 2 [1;2] 0 [0;1] n=29	0 [0;1] 2 [1;2] 0 [0;1] n=24	0 [0;1] 2 [1;2] 0 [0;1] n=19	p _{overall} = 0.16 p _{overall} = 0.22 p _{overall} = 0.99	0 [0;1] 2 [1;2] 0 [0;1] n=72
T ₁₂₀					
Plaque index	0 [0;0] 1 [0;2] 0 [0;0.5]	0 [0;1] 1 [0;2] 0 [0;0]	0 [0;1] 1 [0;2] 0 [0;0]	p _{overall} = 0.77 p _{overall} = 0.67 p _{overall} = 0.31	0 [0;0.8] 1 [0;2] 0 [0;0]

* Overall between-group comparison was calculated using the Kruskal-Wallis test. If statistical significance was found, the Mann-Whitney U tests was applied to relate an observed significant difference to a specific group.

Table 3. Pocket probing depth. Mean $\pm$ standard deviation of pocket probing depth (ppd) in mm at T₁, T₁₂ and T₁₂₀ of treatment group Chin bone, Chin bone + Bio-Gide® and Bio-Oss® + Bio-Gide®.

	Chin bone (gr1)	Chin bone + Bio- Gide® (gr2)	Bio-Oss® + Bio- Gide® (gr3)	Significance level between groups*	Total of the groups
T₁	n=31	n=31	n=29		n=91
Buccal ppd	2.7 $\pm$ 1.2	2.9 $\pm$ 0.9	3.3 $\pm$ 1.4	p _{overall} = 0.13	3.0 $\pm$ 1.2
Palatinal ppd	2.6 $\pm$ 1.0	2.6 $\pm$ 1.1	2.8 $\pm$ 1.4	p _{overall} = 0.76	2.7 $\pm$ 1.2
Approximal ppd	3.9 $\pm$ 1.2	3.5 $\pm$ 1.2	4.2 $\pm$ 1.6	p _{overall} = 0.13	3.9 $\pm$ 1.3
T₁₂	n=31	n=31	n=29		n=91
Buccal ppd	3.2 $\pm$ 1.2	2.9 $\pm$ 1.0	3.6 $\pm$ 1.3	p _{overall} = 0.08	3.2 $\pm$ 1.2
Palatinal ppd	2.7 $\pm$ 0.9	3.1 $\pm$ 1.1	3.3 $\pm$ 1.4	p _{overall} = 0.13	3.0 $\pm$ 1.2
Approximal ppd	4.3 $\pm$ 1.4	4.4 $\pm$ 1.3	4.1 $\pm$ 1.0	p _{overall} = 0.58	4.3 $\pm$ 1.3
T₁₂₀	n=29	n=24	n=19		n=72
Buccal ppd	2.8 $\pm$ 1.0	2.8 $\pm$ 1.0	3.9 $\pm$ 1.7	p _{overall} = 0.009 gr1-gr3 p=0.03 gr2-gr3 p=0.03	3.1 $\pm$ 1.3
Palatinal ppd	3.2 $\pm$ 0.9	3.7 $\pm$ 1.1	3.8 $\pm$ 1.7	p _{overall} = 0.22	3.5 $\pm$ 1.2
Approximal ppd	3.9 $\pm$ 1.4	3.5 $\pm$ 1.0	4.3 $\pm$ 1.7	p _{overall} = 0.22	3.9 $\pm$ 1.4

* Overall significance level between groups was calculated using the One-way ANOVA. When a p-value < 0.05 was found, the independent t- test was used to relate an observed significant difference to a specific group.

Table 4. Bone level change. Mean change ± standard deviation of peri-implant marginal bone level (MBL) in mm, between $T_{1,}$ and T_{120} of treatment group Chin bone, Chin bone + Bio-Gide® and Bio-Oss® + Bio-Gide®.

	Chin bone (gr1)	Chin bone + Bio- Gide® (gr2)	Bio-Oss® + Bio- Gide® (gr3)	Significance level between groups *	Total of the groups
T_1 - T_{12}	n=31	n=31	n=29		n=91
MBL mesial of implant	-0.23 ± 0.81	-0.08 ± 0.90	-0.11 ± 0.49	$p_{\text{overall}} = 0.73$	-0.14 ± 0.76
MBL distal of implant	-0.08 ± 0.36	-0.15 ± 0.48	-0.17 ± 0.57	$p_{\text{overall}} = 0.69$	-0.14 ± 0.47
T_1 - T_{120}	n=29	n=24	n=19		n=72
MBL mesial of implant	-0.16 ± 0.91	-0.74 ± 1.20	-0.64 ± 1.46	$p_{\text{overall}} = 0.19$	-0.48 ± 1.19
MBL distal of implant	-0.28 ± 1.23	-0.24 ± 1.05	-0.37 ± 1.47	$p_{\text{overall}} = 0.92$	-0.30 ± 1.24
T_{12} - T_{120}	n=29	n=24	n=19		n=72
MBL mesial of implant	0.17 ± 1.05	-0.55 ± 1.08	-0.66 ± 1.45	$p_{\text{overall}} = 0.04$ gr1-gr2 p=0.03 gr1-gr3 p=0.05	-0.30 ± 1.24
MBL distal of implant	-0.29 ± 1.07	-0.06 ± 0.98	-0.31 ± 1.41	$p_{\text{overall}} = 0.73$	-0.23 ± 1.15

* Overall significance level between groups was calculated using the One-way ANOVA. When a p-value < 0.05 was found, the independent t-test related an observed significant difference to a specific group.

Table 5. Mucosa level change. Mean change $\pm$ standard deviation (in mm) of marginal gingiva level (MGL) between T_1 , T_{12} and T_{120} of treatment group Chin bone, Chin bone + Bio-Gide® and Bio-Oss® + Bio-Gide®.

	Chin bone (gr1)	Chin bone + Bio- Gide® (gr2)	Bio-Oss® + Bio- Gide® (gr3)	Significance level between groups*	Total of the groups
T_1 - T_{12}	n=31	n=31	n=29		n=91
MGL mesial of implant	0.22 $\pm$ 0.45	0.19 $\pm$ 0.43	0.30 $\pm$ 0.51	$p_{\text{overall}} = 0.68$	0.24 $\pm$ 0.46
MGL buccal of implant	-0.02 $\pm$ 0.32	-0.06 $\pm$ 0.39	-0.12 $\pm$ 0.52	$p_{\text{overall}} = 0.65$	-0.06 $\pm$ 0.42
MGL distal of implant	0.27 $\pm$ 0.76	0.17 $\pm$ 0.48	0.32 $\pm$ 0.72	$p_{\text{overall}} = 0.66$	0.25 $\pm$ 0.66
T_1 - T_{120}	n=26	n=18	n=17		n=61
MGL mesial of implant	0.56 $\pm$ 0.84	0.27 $\pm$ 1.10	0.82 $\pm$ 0.60	$p_{\text{overall}} = 0.17$	0.53 $\pm$ 0.89
MGL buccal of implant	-0.10 $\pm$ 0.68	-0.46 $\pm$ 1.00	-0.47 $\pm$ 0.79	$p_{\text{overall}} = 0.24$	-0.31 $\pm$ 0.32
MGL distal of implant	0.45 $\pm$ 1.03	0.19 $\pm$ 1.13	0.79 $\pm$ 0.67	$p_{\text{overall}} = 0.18$	0.46 $\pm$ 0.99
T_{12} - T_{120}	n=26	n=18	n=17		n=61
MGL mesial of implant	0.28 $\pm$ 0.82	0.11 $\pm$ 1.09	0.51 $\pm$ 0.76	$p_{\text{overall}} = 0.40$	0.29 $\pm$ 0.90
MGL buccal of implant	-0.08 $\pm$ 0.61	-0.50 $\pm$ 0.89	-0.41 $\pm$ 0.85	$p_{\text{overall}} = 0.16$	-0.30 $\pm$ 0.78
MGL distal of implant	0.27 $\pm$ 0.90	-0.02 $\pm$ 0.93	0.53 $\pm$ 0.80	$p_{\text{overall}} = 0.17$	0.25 $\pm$ 0.90

* Overall significance level between groups was calculated using the One-way ANOVA. When a p -value < 0.05 was found, the independent t-test related an observed significant difference to a specific group.

Aesthetic index and patient satisfaction

Mean scores of the ICAI were calculated at T_{12} and T_{120} (**Table 6**). The mean total ICAI penalty score after 10 years was 5.8 with 59% of all cases rated as acceptable. There were no significant differences between the groups. The only significant diminution was found in the appreciation of the crowns ($P = 0.001$). Percentage of acceptable results decreased from 90% at T_{12} to 82% at T_{120} . Patients who received a new implant crown between T_{12} and T_{120} were included in this assessment. Mean scores of the patient satisfaction questionnaires were calculated at T_{12} and at T_{120} (**Table 7**). Mean total overall satisfaction after 10 years was 8.6 with no significant difference between the groups and no significant difference with the overall satisfaction score after 1 year. Patients were least happy with the mucosal aspects of the implant site. Only 59.7% of the patients were completely satisfied with the mucosa at T_{120} .

Discussion

Ten-year results of single tooth replacement with implant-supported restorations in the aesthetic region showed stable and healthy peri-implant tissues and satisfied patients. No relevant differences could be observed between an augmentation technique with chin bone, with chin bone plus a Bio-Gide® membrane (Bio-Gide®: Geistlich, Wolhusen, Switzerland) or with Bio-Oss® (Bio-Oss®: Geistlich, Wolhusen, Switzerland) plus a Bio-Gide® membrane.

Implant survival rate of the total group after 10 years was 95.7%. Kuchler et al. (2016) presented 10-year results of the same implant system as used in the present study. Implant survival rate in their study was 100%. Other studies in the aesthetic region showed 100% (Jemt, 2008; Gotfredsen, 2012) and 93.2% (Schropp & Isidor, 2015). Percentages in these studies are hard to compare, because other implant systems were used and different surgical procedures were performed, e.g. direct placement, augmented sites and non-augmented sites. Nevertheless, implant survival rates are high after a long-term follow up and comparable to the survival rate in the current study. Crown survival rate was 87.9%, which is also comparable to the results reported in the literature (Jemt, 2008; Gotfredsen, 2012). Comparison with the study of Jung et al. (2013), with different augmentation procedures in a variety of regions, learned that long-term implant survival is high and independent on specific augmentation procedures. The results are also not different (with respect to implant survival as well as marginal bone loss) with a control group in which no augmentation procedure was performed. No studies were found with which the specific augmentation procedures in the aesthetic region could be compared.

Table 6. Aesthetic assessment. Mean penalty scores, minimum and maximum values of the Implant Crown Aesthetic Index and percentage of acceptable penalty results (acceptable scores 0-4) at T₁₂ and T₁₂₀ of treatment group Chin bone, Chin bone + Bio-Gide® and Bio-Oss® + Bio-Gide® .

	Chin bone (gr1)	Chin bone + Bio- Gide® (gr2)	Bio-Oss® + Bio- Gide® (gr3)	Significance level between groups*	Total
T₁₂					
Total	4.3 (0-13) 65%	5.2 (1-14.5) 61%	4.7 (1-14) 65%	p _{overall} =0.47	4.7 (0.5-14.5) 66%
% acceptable results					
Crown (range)	1.2 (0-5) 90%	1.4 (0-6) 97%	1.2(0-5.5) 93%	p _{overall} =0.21	1.3 (0-6) 90%
% acceptable results					
Mucosa (range)	3.1 (0-11) 81%	3.8 (1-11) 65%	3.6 (0-8.5) 72%	p _{overall} =0.25	3.5 (0-11) 70%
% acceptable results					
T₁₂₀					
Total (range)	4.9 (1-14) 62%	6.5 (2-17) 50%	5.3 (1-13) 42%	p _{overall} =0.21	5.5 (1-17) 59%
% acceptable results					
Crown (range)	1.9 (0-6) 86%	2.0 (0-6) 75%	1.5 (0-5) 84%	p _{overall} =0.49	1.9 (0-6) 82%
% acceptable results					
Mucosa (range)	3.0 (1-11) 83%	4.4 (1-12) 67%	3.8 (0-11) 86%	p _{overall} =0.17	3.7 (0-12) 74%
% acceptable results					
Significance level between follow-up periods**					
Mean total score	p=0.31	p=0.08	p=0.64		p=0.051
Mean crown score	p=0.06	p=0.052	p=0.36		p=0.004
Mean mucosa score	p=0.76	p=0.36	p=0.93		p=0.69

*Overall significance was calculated with the Kruskal–Wallis test.
**Significance between two follow-up periods were calculated with the Wilcoxon signed rank test.

Table 7. Patient satisfaction. Mean $\pm$ standard deviation scores of the overall satisfaction score, crown satisfaction score and mucosa satisfaction score expressed in the questionnaire at T12 and T120 of the treatment group Chin bone, Chin bone + Bio-Gide® and Bio-Oss® + Bio-Gide®.

	Chin bone (gr1)	Chin bone + Bio-Gide® (gr2)	Bio-Oss® + Bio-Gide® (gr3)	Significance level between groups*	Total
T₁₂					
Overall score	8.5 (1.0) 100%	8.4 (1.1) 100%	8.7 (1.0) 100%	$p_{\text{overall}} = 0.62$	8.5 (1.0) 100%
% acceptable result[‡]					
Crown score	0.1 (0.2) 80%	0.1 (0.3) 77.4%	0.0 (0.1) 90%	$p_{\text{overall}} = 0.39$	0.08 (0.2) 82.4%
% acceptable result					
Mucosa score	0.4 (0.4) 43.3%	0.4 (0.4) 41.9%	0.2 (0.3) 46.7%	$p_{\text{overall}} = 0.42$	0.3 (0.4) 42.9%
% acceptable result					
T₁₂₀					
Overall score	8.6 (1.2) 96.4%	8.6 (1.3) 100%	8.6 (1.1) 100%	$p_{\text{overall}} = 0.97$	8.6 (1.2) 98.6%
% acceptable result[‡]					
Crown score	0.1 (0.2) 75%	0.1 (0.2) 70.8%	0.1 (0.3) 85%	$p_{\text{overall}} = 0.99$	0.1 (0.2) 76.4%
% acceptable result					
Mucosa score	0.2 (0.3) 64.3%	0.4 (0.4) 41.7%	0.2 (0.3) 75%	$p_{\text{overall}} = 0.20$	0.3 (0.3) 59.7%
% acceptable result					
Significance level between follow-up periods**					
Overall score	$p = 0.61$	$p = 0.89$	$p = 0.48$		$p = 0.88$
Crown score	$p = 0.99$	$p = 0.79$	$p = 0.20$		$p = 0.55$
Mucosa score	$p = 0.06$	$p = 0.56$	$p = 0.34$		$p = 0.10$

‡ Percentage of acceptable results expresses the percentage of patients rated ≥ 6 on the Visual Analogue Scale. Overall score: possible score 0-10 based on a VAS-scale; crown index score: possible score 0-1; mucosa index score: possible score 0-1. Score is ranked acceptable when: overall score = 6-10; crown score = 0; mucosa score = 0.

* Overall significance was calculated with the Kruskal-Wallis test.

**Significance between two follow-up periods were calculated with the Wilcoxon signed rank test.

Plaque index, Bleeding index and Gingiva index scores were at the healthy end of the spectrum. Apparently, method of augmentation has no influence on the short and long-term clinical outcome of the treatments applied in this study. Probing depth at the buccal site was at all evaluation periods significantly deeper in the group with a bone substitute compared to the chin bone groups. An explanation for this phenomenon could not be found in the literature. A reason could be that the bone substitute has not fully been converted into bone over time and that the periodontal probe penetrates the substitute material. The electronic Paro-Probe® was not available anymore for the 10-years' evaluation. The Paro-Probe® has a standardized probing pressure of 0.25N. In the search for a probe with a comparable standardized pressure force and a comparable flexibility of the tip, the Click-Probe® has been chosen as a reasonable alternative. Nevertheless, there could be a slight difference and this change in device is a possible limitation.

Mean marginal bone loss after 10 years for the total group was 0.48 mm at the mesial side of the implant and 0.30 mm at the distal side, with no significant differences between the groups. Jemt (2008) reported a mean marginal bone loss of 0.66 mm and Gotfredsen (2012) reported mean bone loss of 0.75 mm after 10 years. These numbers are well in line with the present study. It seems that healthy peri-implant soft tissues are accompanied by limited peri-implant bone loss.

Mean marginal gingival levels appeared to be very stable during the 10-year evaluation period. Mean mid-buccal recession of marginal mucosa was 0.3 mm, whereas approximal mucosa levels increased 0.5 mm. No significant differences between the groups were calculated. Only in the study of Schropp & Isidor (2015) marginal approximal gingiva levels were evaluated over 10 years, although using different parameters. Also in this study a gain in papilla height was found. Combining the results of marginal bone and gingival levels, it appears that a very stable situation was reached after finalizing the treatment. It seems that this is comparable with situations in which not a bone augmentations is needed. However, it is not known what the resorption rate of the augmentation materials was during the subsequent healing periods.

The overall score of the ICAI at T_{120} was 5.8, with an acceptable result for 59% of the patients. At T_{12} this was respectively 4.8 and 66%. In none of the mentioned 10-year studies an aesthetic rating system was used. Mucosa scored less favourable than the crown, this is probably related to the initial situation: all patients presented with a large bone deficiency, making a bucco-palatinal local ridge augmentation necessary. It is known that the need for a bone augmentation procedure influences the aesthetic result negatively (Santing et al., 2013). The slight progression of gingival recession resulted

in a number of patients with a visible titanium border of the implant cervically of the crown. The scores of the ICAI at T_{120} was 5.8, with an acceptable result in only 59% of the patients. It appears that ICAI has a very stringent scoring system with penalty points for small deviations from the ideal situation. Also in other studies, in which ICAI was used, low levels of acceptable results were found: 66.7% for mucosa and 75% for crowns in the study of Santing et al. (2013); 56.5% for mucosa and 62% for crowns in the study of Den Hartog et al. (2013). In contrast with the slightly diminishing results of the aesthetic index, overall patient satisfaction was 8.6 (on a scale from 0 to 10), with 98.6% of the patients satisfied at the 10-year evaluation, which favourable score is in line with the literature (Gotfredsen, 2012; Schropp & Isidor, 2015). Apparently, patients are very satisfied with single tooth replacements by implant restoration in the aesthetic zone, notwithstanding the fact that professionals experience implant treatment in the aesthetic region rather challenging and are not always satisfied.

At the T_{120} months' evaluation 19 patients were lost to follow-up due to moving to another part of the country or changing address without notice. Drop-out was unevenly distributed over the treatment groups (2 non-attendance in the group with chin bone, 7 non-attendance in the group with chinbone and membrane, and 10 non-attendance in the group with a bone substitute and membrane). The assumption was made that non-attendance was independent of treatment result and patient satisfaction. However, drop-out could have had an effect.

Few long-term studies on dental implant treatment in the aesthetic region are available. Moreover, different evaluation parameters are used and patient centred outcomes are not always present. Therefore, it is difficult to get insight in the true long-term clinical performance of dental implants and dental implant restorations and to compare different clinical procedures. Since volume of soft tissue and underlying bone buccal of dental implants is of most importance in the aesthetic region, investigators should strive to include evaluation of these tissues in studies. Buccal bone is also not an item in the present study. Standardized analysis of radiographs made with cone beam computer tomography could possibly help to get information on buccal bone, although it is recognized that presently insufficient resolution and metallic artifacts influence detection of small changes in bone volume (Kuchler et al., 2016).

Conclusion

Pre-implant augmentation of a defect in the anterior region with chin bone, chin bone plus a Bio-Gide® membrane or Bio-Oss® plus a Bio-Gide® membrane are all proper techniques resulting in favourable clinical and radiographic 10-years' outcomes and satisfied patients. From this 10-year randomized controlled trial on single tooth replacement with implant restorations in the aesthetic region can be concluded that no relevant differences with respect to clinical, radiographic, aesthetic and patient centred outcomes could be observed. If a bone augmentation is needed, professionals can consider factors as morbidity, costs and treatment time for each individual patient, without having impact on the outcome.

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3

Performance of bone level implants with conical connections in the anterior maxilla

a 5-year prospective cohort study

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Abstract

Aim: To assess clinical, radiographic and aesthetic outcomes, and satisfaction of patients treated with single implant restorations in the maxillary aesthetic region 5 years after final restoration.

Material and methods: Sixty patients (29 male/31 female, mean age 37 years) with a single missing tooth in the anterior maxilla (39 central incisors/10 lateral incisors/5 cuspids/6 first premolars) received a bone-level implant with conical connection. In 29 patients, a bone augmentation procedure was necessary before implant placement (autogenous bone grafts mixed with spongiosa granules). All implants (12 with 3.3 mm diameter/ 48 with 4.1 mm diameter) were loaded after 3 months of submerged healing. The restoration consisted of an individually designed full-zirconia abutment veneered with porcelain. Follow-up with clinical and radiographic assessment was conducted until 60 months after placement of the final restoration. Aesthetic outcome of the restoration was determined with the Pink Esthetic Score–White Esthetic Score (PES-WES). Patient satisfaction was assessed with a VAS scale and satisfaction questionnaire.

Results: Fifty patients completed the 5-year follow-up. Implant survival was 100%, restoration survival 98%. Mean bone level change was -0.13 ± 0.66 mm with a median (IQR) pocket probing depth of 2.75 [2.25; 3.25]. The mean PES and WES scores were 6.6 ± 1.7 and 7.8 ± 1.5 , respectively. Patient satisfaction was high (92.1 ± 7.8 on 100 mm VAS scale). There were no differences between patient groups with or without a bone augmentation procedure.

Conclusion: Bone-level implants with a conical connection are a reliable treatment option in single-tooth replacements in the maxillary aesthetic zone.

Introduction

The maxillary anterior region is an aesthetically high demanding region. For implant restorations, optimal pre-treatment conditions, careful surgical procedures and reliable implant materials are required (Roccuzzo et al., 2018). Failing or missing teeth often coincide with deficiencies of the hard and soft tissues. Depending on the severity of these deficiencies, the end result of the treatment can be compromised (Sanz-Sánchez, et al., 2018). To prevent such a compromised outcome, a bone augmentation procedure prior to implant placement is often needed to reconstruct the defect.

Over time there has been a shift in the use of tissue-level implants to bone-level implants. Bone-level implants can enable the practitioner to create a natural emergence profile with individually designed abutments, which is particularly useful in the aesthetic zone (Chappuis et al., 2016; Siebert et al., 2018). A satisfying treatment outcome should be durable and stay stable for many years. Stability of the peri-implant soft and hard tissues are essential for long lasting implant success (Schwartz-Arad et al., 2005). There is evidence that an internal conical implant-abutment connection with platform-switching is efficient in maintaining stable biological aspects. The tighter conical seal between the implant and the abutment reduces bacterial leakage and thus reduces bone loss around implants compared to a non-conical connections (Schmitt et al., 2014). The reviews of Gracis et al.(2012), Goiato et al.(2015) and Palacios-Garzón et al.(2018) indicated that short-term results of this connection are favorable, but longer follow-up periods are needed to confirm the results over the long term.

Five-year and ten-year results of single-tooth replacements have been published, but specific data on single bone level implants in healed sites in the anterior maxilla with an internal conical abutment connection are limited to the studies of Palmer, Gotfredsen, Pieri, Berberi, and Cooper (Palmer et al., 2000; Gotfredsen, 2004; Pieri et al., 2013; Berberi et al., 2014; Cooper et al., 2014) . All authors reported high implant survival rate between 98% and 100% and marginal bone loss <0.5mm after 5 years. All the cited studies reported on the 5-year outcome of the same bone level implant system (Astra Tech Implant System, Dentsply Implants, Mölndal, Sweden). However, Gao (Gao et al., 2017) published a 3-year study with another type of bone level implants (Straumann Bone Level Implant System, Institute Straumann AG, Basel, Switzerland). Although this study had a shorter follow-up period, the results were comparable (100% implant survival and 0.07 ± 0.48 mm bone loss).

No studies with 5-year results of the latter bone level implant system (Straumann Bone Level Implant System) have been published, and none of the published studies

included a full-scale assessment of bone level change and the effects on soft tissue, aesthetics and patient satisfaction.

Therefore, the objectives of this prospective study were to report the clinical, radiographic and aesthetic outcomes, including biological and technical complications, and satisfaction of patients treated with single bone level implant restorations with a conical connection, with a follow-up of 5 years.

Materials and Methods

Study design

The study was designed as a single cohort, prospective clinical case series with a follow-up of 5 years. The manuscript was organized according to the STROBE guidelines. Recruitment of patients, implant treatment and follow-up took place at the Department of Oral and Maxillofacial Surgery of the University Medical Centre Groningen (UMCG), the Netherlands. The Medical Ethical Committee of the UMCG reviewed and approved the study protocol (METC 2009.057). Written informed consent was obtained from all eligible patients before enrolment. Details of the study design and the results of the one year follow-up were described by Santing and colleagues (Santing et al., 2013).

Patients

Sixty patients (29 males, 31 females; mean age 37 years) matched the inclusion criteria and were enrolled in the study (**Table 1**). These criteria included a single tooth diastema in the maxillary anterior region which had to be missing for at least 3 months prior to implant placement. Patients who smoked or were periodontally unhealthy (indicated by bleeding on probing combined with pockets ≥ 4 mm) were excluded from the study. These 60 patients had 39 missing central incisors, 10 missing lateral incisors, 5 missing cuspids and 6 missing first premolars.

Twenty-nine patients had a large bone defect and were augmented in a separate session before placing an implant. The nature of the defects was mainly horizontal. Autogenous bone grafts for guided bone regeneration (GBR) were harvested from the retromolar ramus area and mixed with spongiosa granules (0.25-1.0 mm, Geistlich Bio-Oss®, Geistlich Pharma AG, Wolhusen, Switzerland). This 1:1 mixture was placed in the defect and a membrane (Geistlich Bio-Gide®, Geistlich Pharma AG) was placed to cover the augmented area. The wound was subsequently sutured with vertical and horizontal

Table 1. Characteristics of the study group at the start of the study.

Mean age $\pm$ SD in years at implant placement	36.9 $\pm$ 15.1
Sex (male/ female)	29/31
Implant location (I₁/I₂/C/P₁)	39 / 10 / 5 / 6
Implant diameter (3.3/4.1mm)	12 / 48
Implant length (12/14mm)	16 / 44
Augmentation before implant placement, n	29

mattresses (4-0 vicryl, Johnson & Johnson Gateway, Piscataway, USA) (Raghoobar et al., 2009; Santing et al., 2013). The implants were placed three months thereafter (12 implants with 3.3 mm diameter and 48 implants with 4.1 mm diameter). This resulted in a population of 60 patients which could be divided in two subgroups and allowing to determine whether augmentation therapy influences the outcome compared to non-augmented sites.

Implant placement

All patients were scheduled to receive a bone level implant with conical connection (Straumann Bone Level Implant System, Institute Straumann AG, Basel, Switzerland). Individual surgical templates were provided to place the implants in the optimal position. In cases where parts of the implant shoulder remained uncovered, or where the buccal bone wall was thin (less than 2mm in thickness), a local augmentation procedure was performed with autogenous bone chips collected during implant bed preparation and anorganic bovine bone (Geistlich Bio-Oss®, Geistlich Pharma AG), covered with a Geistlich Bio-Gide® membrane (Geistlich Pharma AG). The wound was closed with Ethilon 5-0 nylon sutures (Johnson & Johnson Gateway, Piscataway, NJ, USA). All surgical interventions were performed under prophylactic antibiotics (amoxicillin 500 mg, three times daily, or clindamycin 300 mg, four times daily for 7 days in case of amoxicillin allergy) and patients were instructed to rinse with 0.2% chlorhexidine mouthrinse twice for 7 days. Implants integrated unloaded submucosally for 3 months. A removable partial denture was worn during this healing phase, but did not interfere with treated implant site.

Prosthetic phase

After the healing phase of 3 months, the implants were uncovered and a healing cap was placed for one week. A titanium-based provisional crown (temporary abutment

(SynOcta® Titanium Post for Temporary Restorations, Institut Straumann AG, Basel, Switzerland) and composite resin (Solidex, Shofu, Higashiyama-Ku, Kyoto, Japan) was then made and screwed onto the implant (torqued to 35Ncm) and patients were given oral hygiene instructions. The patients received a final restoration three months later: an individually designed full-zirconia abutment, without a titanium interface, with a porcelain crown, either cemented or screwed onto the implant, depending on the position of the screw access hole. Twenty-seven restorations were cement-retained and 33 restorations were screw-retained. In case of a cemented restoration, a zirconia coping was veneered with porcelain (E.max Ceram, Ivoclar Vivadent, Liechtenstein) and cemented with glass ionomer cement (Fuji Plus; GC Europe, Leuven, Belgium). In case of a screw-retained restoration, porcelain (E.max Ceram) was directly fused to the abutment. Abutment screws were torqued to 35 Ncm.

Outcome measures

Clinical, radiographic and patient centred variables were collected before implant placement (T_0), 1 month (T_1), 1 year (T_{12}) and 5 years (T_{60}) after loading with the final restoration. Outcome measures were change in peri-implant marginal bone level, survival rate of the implant and crown, clinical variables, aesthetic outcome and patient satisfaction.

Figure 1. Method of measuring peri-implant bone level on an intraoral radiograph. A line was drawn from the implant shoulder to the first bone-to-implant contact on the mesial and distal side. The length of the implant body was used for calibration.

- *Bone level change* was recorded on standardised radiographs according to the method developed by Meijndert and colleagues (Meijndert et al., 2004). Measurements were done by a trained observer with a high intra-rater reliability score (ICC 0.98 [0.96-0.98] with 95% CI). A line was drawn from the implant shoulder to the first bone-to-implant contact on the mesial and distal side (Figure 1). Mean change was calculated with the least favourable change of the mesial and distal site to avoid an underestimation of the bone level change. A negative value indicates bone loss.
- *Survival of the implant and crown* was assessed as positive when the implant or crown was present, immobile, and no progressive bone loss, infection or fracture leading to removal was reported.
- *Clinical variables* were assessed using the Modified Plaque Index (Mombelli et al., 1987), Modified Sulcus Bleeding Index (Mombelli et al., 1987) and Papilla Index (Jemt, 1997). The pocket probing depth was measured to the nearest 1 mm using a periodontal Click-probe® with a standard pressure of 0.2-0.25N (KerrHawe Dental Corporation, Bioggio, Switzerland).
- *Aesthetic outcome*, using the modified Pink and White Esthetic Score (PES-WES) (Belser et al., 2009), was assessed by an experienced prosthodontist who was trained with the index and blinded for the applied treatment procedures.
- *Peri-implant mucositis and peri-implantitis* were assessed according to the definition composed at the Seventh European Workshop on Periodontology (Lang & Berglundh, 2011) describing peri-implant mucositis as: bleeding on probing and/or suppuration but <2mm radiographic bone loss. Peri-implantitis was described as bleeding on probing and/or suppuration in combination with radiographic bone loss ≥2mm.
- *Patient satisfaction* was determined with a self-administered 5-point Likert-type questionnaire (Den Hartog et al., 2013) focussing on the colour and form of the crown and the colour and form of the peri-implant mucosa, ranging from very dissatisfied (score 1) to very satisfied (score 5). Specific questions were:
 - How satisfied are you with the form of the crown on the implant?
 - How satisfied are you with the colour of the crown on the implant?
 - How satisfied are you with the form of the gums around the implant?
 - How satisfied are you with the colour of the gums around the implant?
- *Overall satisfaction* was noted on a 100mm VAS-scale ranging from 'very dissatisfied' at the outer left side to 'very satisfied' at the outer right side.

Statistical methods

Statistical analysis was performed to determine if there was an association between the obtained measurements. A statistical software package was used (IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp).

Normality of the data was checked with the Shapiro Wilk test before determining the statistical test. Papilla index, plaque index and bleeding index, being ordinal variables, were presented as medians and interquartile range. Pocket probing depth, being not normally distributed, was presented as median and interquartile range. Bone level change and aesthetic evaluation, being normally distributed, were presented as means and standard deviations.

Inter-group comparison (augmented versus not augmented) of non-parametric data (pocket depth, bone level change, PES, WES and VAS score of patient satisfaction) was calculated using the Mann-Whitney U test. Inter-group comparison of ordinal data (Papilla Index) was analysed using the Chi-square test. The null-hypotheses was that there was no difference in bone level change between the two subgroups. The between-time interval comparison for non-parametric continuous and ordinal data was calculated using the Wilcoxon signed-rank test.

Results

Patients

A total of 50 patients (23 male, 27 female, mean age at time of inclusion was 37 years old) were available for evaluation after 5 years (T_{60}) of which 23 had been subjected to pre-implant reconstructive surgery. Ten patients had dropped out of the study because they either moved to another country ($n=5$) or moved without leaving an address ($n=5$). The assumption was made that not attending the evaluation was independent of the clinical or the radiographic condition as well as that it was independent of the patients' satisfaction. Statistical analysis was done on the evaluated 50 patients.

Implant and crown survival

No implants were lost during the 5-year follow-up (implant survival 100%). At the time of this follow-up 24 patients showed signs of peri-implant mucositis and one patient was diagnosed with peri-implantitis. That patient was referred for treatment when this was diagnosed at the T_{60} follow up. Crown survival was 98% (one crown fractured within the first year in function). In addition to this was the observation of porcelain chipping of

two crowns at the T_{60} follow-up, but these patients wished no repair or replacement. During the 5-years follow-up period, no loosening of crowns and/or abutment screws were encountered.

Peri-implant bone level change

Primary outcome measure was peri-implant bone level change (**Table 2**). Mean bone level change at T_{60} was minor, being -0.13 ± 0.66 mm. Bone level change was comparable between the augmented and non-augmented group ($p=0.53$, Mann-Whitney U-test, **Table 3**). Since the latter was based on a subgroup calculation, a post-hoc group size determination was performed. It appeared that 428 participants should be needed in each group to calculate a significant difference, so it seems to be justified to mention that there is not a clinically relevant difference between the two subgroups.

Table 2. Mean bone level change (mm $\pm$ SD) from one month after crown placement (T_1) to 5 years after crown placement (T_{60}).

Mean change T_1 - T_{60}	-0.13 ± 0.66	n = 50
Implant bone loss	n	%
0-0.5 mm	44	88
0.6-1.0 mm	5	10
1.1-1.5 mm	0	0
1.6-2.0 mm	0	0
>2.0 mm	1	2

Largest change of mesial or distal site was used.

Clinical parameters

A summary of the clinical parameters is shown in **Table 4**. Plaque was hardly present at the implant restorations. Thirteen patients had probing depths ≥ 5 mm at the implant site. Of these 13 implants, 10 showed bleeding on probing (score 1-2), but minor peri-implant bone loss (0-0.5 mm). One patient showed severe bleeding on probing (score 3) and >2 mm bone loss on the peri-apical radiograph and was subsequently referred for peri-implantitis treatment. Calculations in **Table 3** show a statistically significant deeper probing depth in the augmented group. The patient diagnosed with peri-implantitis belonged to the augmented group.

Table 3. Difference between the subgroups augmented and non-augmented at 5 years after crown placement (T_{60}).

	With pre-implant augmentation (n=23)	Without pre-implant augmentation (n=27)	P-value CI 95% p < 0.05
Bone level change T_1 - T_{60} (mean $\pm$ SD)	-0.23 $\pm$ 0.91	-0.06 $\pm$ 0.30	p= 0.50 [†]
Pocket probing depth (mm) (median, IQR)	3.25 [2.50 ; 3.25]	2.50 [2.25 ; 3.00]	p= 0.037 [†]
Papilla Index (median,IQR)	2.5[2.0;2.5]	2.5[2.0;2.5]	p=0.24 [‡]
Patient satisfaction VAS score	92.1 $\pm$ 8.2	92.2 $\pm$ 7.6	p=0.92 [†]
Mean PES	6.0 $\pm$ 1.5	7.2 $\pm$ 1.6	p=0.01*
Mesial papilla	1.22 $\pm$ 0.52	1.30 $\pm$ 0.54	p=0.59
Distal papilla	0.78 $\pm$ 0.52	1.19 $\pm$ 0.48	p=0.008
Curvature facial mucosa	1.78 $\pm$ 0.42	1.85 $\pm$ 0.36	p=0.53
Level of facial mucosa	1.13 $\pm$ 0.69	1.59 $\pm$ 0.57	p=0.015*
Root convexity/soft tissue color and texture	1.04 $\pm$ 0.71	1.22 $\pm$ 0.80	p=0.36

[†] = Mann Whitney U test
[‡] = Pearson Chi-Square test
* = Statistical significant different

Table 4. Clinical variables: pocket probing depth, papilla index, plaque index score and bleeding index score at 5 years after crown placement T₆₀ (n=50).

PPD at implant site (median, IQR)			
Mesial	3.00 [2.00 ; 3.00]		
Buccal	3.00 [2.00 ; 3.00]		
Distal	3.00 [3.00 ; 4.00]		
Palatinal	2.00 [2.00 ; 3.00]		
Total of all sites	2.75 [2.25 ; 3.25]		
Papilla index (median, IQR)			
Mesial	2.5 [2.0;3.0]		
Distal	2.0 [2.0;3.0]		
Plaque (median, IQR)	0.0 [0.0;0.0]		
Bleeding (median, IQR)	0.0 [0.0;0.0]		
Bleeding score	n	%	
0	25	50	
1	11	22	
2	13	26	
3	1	2	

Aesthetic rating and patient satisfaction

A summary of the aesthetic evaluation and the patient satisfaction score is shown in **Table 5**. Mean PES at T_{12} was 6.9 ± 1.8 and had not significantly decreased at T_{60} (6.6 ± 1.7 , $p=0.30$, Wilcoxon Signed Rank test). Also the WES score hardly showed changes between T_{12} and T_{60} (from 7.5 ± 1.7 to 7.8 ± 1.5 , $p=0.21$ Wilcoxon Signed Rank test). Between group comparison revealed a statistically significant better PES for the non-augmented group ($p=0.01$, Mann Whitney U test) but no statistical significant different WES ($p=0.30$, Mann Whitney U test). Mean patient satisfaction was rated at 92.1 ± 7.8 on a 0-100 VAS scale and comparable between augmented and non-augmented subjects ($p=0.92$, Mann Whitney U test).

Table 5. Aesthetic evaluation by means of PES and WES score, and patient satisfaction outcome of a questionnaire and a 0-100 VAS-scale, 5 years after crown placement (T_{60}) (n=50).

Total score	mean $\pm$ SD	% score ≥ 6
PES	6.6 ± 1.7	74%
WES	7.8 ± 1.5	92%
Overall VAS score	73.1 ± 7.4	
Patient satisfaction	N of satisfied patients [†]	% satisfied patients of total
Colour of the crown	46	92.0%
Form of the crown	46	92.0%
Colour of the mucosa	41	82.0%
Form of the mucosa	36	72.0%
Overall VAS score	92.1 ± 7.8	

[†] = Measured on a 5-point scale. Score 4 and 5 denote 'satisfied' and 'very satisfied', respectively, and were found acceptable.

Discussion

Bone level implants with conical connection presented with a good clinical performance in the maxillary anterior region and a high patients satisfaction after 5 years in function. Implant survival was 100% and crown survival 98%. Irrespective of the need for a pre-implant surgical bone augmentation procedure, the change in bone level was minor in both subgroups. The null-hypothesis that there was no difference in change of bone level between the subgroups could not be rejected. Regarding the 5-year results of solitary bone level implants with a conical implant-abutment connection in the healed anterior maxilla, the outcomes of the studied implant type are in line with the results from other studies. The mean marginal bone level change of the authors who conducted comparable studies all remained substantially under the 0.5 mm bone loss. (Palmer et al., 2000; Gotfredsen, 2004; Pieri et al., 2013; Berberi et al., 2014; Cooper et al., 2014). Although a different implant system was used in the afore mentioned studies (Astra Tech Implant System), bone level change reported in the present study is similar to results from the other cited studies mentioned previously.

A statistically significant difference was found between the pocket probing depths of the augmented group (3.25 [2.50 ; 3.25]) and the non-augmented group (2.50 [2.25 ; 3.00]; $p=0.04$). A possible explanation could be that inherent to a bone augmentation procedure soft tissues heal differently on a surface of a newly applied material, being a mixture of autologous bone and a bone substitute. It must be noted, however, that the difference in probing depth is very small and not clinically relevant. The clinical parameters in our study - pocket probing depth, plaque score, bleeding score and Gingiva Index - are comparable to those reported by Gotfredsen, Pieri and Cooper (Gotfredsen, 2004; Pieri et al., 2013; Cooper et al., 2014).

In the present study, no incidences were associated with the implant-abutment connection. Previous studies have reported soft tissue complications associated with abutment screw loosening (Krishnan et al., 2014; Goodacre et al., 2018; Pjetursson et al., 2018). The absence of connection-related complications in this study suggests a strong fixation and tight seal of a conical connection. This was also appointed by Palmer and co-workers (Palmer et al., 2000).

PES and WES scored high and the level of acceptance (6 or higher) was exceeded in 74% for PES and 92% for WES. During the T60 assessment of the WES, the aesthetic outcome of 56% ($n=28$ of 50) of the patients was assessed as poor because the incisal edge was in infraposition compared to the contra-lateral tooth. At the 1-year follow-up, only 26% ($n=16$ of 60) patients got a poor judgement on this item. Having the same

observer, this would imply that there was a change in position of the surrounding dentition relative to the implant crown. This change in position has been confirmed in the literature and addressed in a systematic review by Papageorgiou and colleagues (Papageorgiou et al., 2018). It is thought that eruption of teeth is most prone in adolescents and young adults and that this development decreases to a clinically insignificant proportion in the second decade of life (Fudalej et al., 2007). However, this was not supported by studies of Bernard et al (Bernard et al., 2004) and Huanca Ghislazoni et al (Huanca Ghislazoni et al., 2017) who studied continued eruption of natural teeth next to dental implants and found no correlation between age and infraposition of the implant crown. Nevertheless, clinicians need to be aware that long-term adverse effects of dental implants among natural teeth can be observed in terms of infraposition.

Patient satisfaction was rated high in our study. Patients were more satisfied with the crown than with the form of the peri-implant mucosa. This is in contrast to the augmented population described by Pieri et al. (2013), who reported equal satisfaction between the crown and the surrounding mucosa. Gotfredsen (2004) reported high patient satisfaction on crown aesthetics, but no specific data on the satisfaction of the soft tissues.

The mean PES in the present study was high, with a higher score in the non-augmented group. On the contrary, Pieri et al. (2013) reported slightly higher PES scores for his population with augmented patients but had no comparison group. The additional surgical procedure in the augmented group could have negatively affected the aesthetic outcome due to scarring of the mucosa, which may underlie the lower PES score. Nevertheless, the patient satisfaction scores and professional rating in both groups remained high at the T60 follow-up evaluation.

A limitation of the study is that both patients needing and not needing an augmentation procedure were included in the study. A non-randomized controlled clinical trial would have been a better study design to explore a possible significant difference between the two subgroups. Another limitation of this study is that 10 patients (17% of the initial group) were lost to follow-up. Results of these patients could differ from the group which were seen for evaluation.

Conclusion

This prospective cohort study showed that peri-implant tissues were healthy, marginal bone loss was minor, patient satisfaction was high and aesthetic outcome was favourable. Thus, a bone level implant with conical connection is a reliable treatment option in single tooth replacement in the maxillary aesthetic zone.

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4

Bone level tapered implants in the maxillary aesthetic zone

*a one-year prospective case series
in healed sites*

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Abstract

Aim: To assess the clinical, radiographic and aesthetic performance of bone level tapered implants placed in healed sites in the maxillary aesthetic zone during a one-year follow-up.

Material and methods: Thirty participants (15 male, 15 female, mean age 38 years) with a single tooth diastema that had healed without an alveolar ridge preservation procedure, for at least 3 months, received a bone level tapered implant. Buccal bone augmentation procedures were performed at implant placement if the buccal bone wall was less than 2 mm. A provisional restoration was connected after a healing phase of 3 months. A definitive restoration was placed 3 months after the provisional restoration. Implant stability, peri-implant hard and soft tissue health, esthetics and patient-centered outcomes were recorded.

Results: All the placed implants demonstrated good stability immediately after implant placement. A buccal bone augmentation procedure was needed in 77% of the cases. The median implant stability quotient value was 73 [68;76] at implant placement and had increased to 79 [76;81] when the definitive restoration was inserted ($p<0.005$). All the patients attended the follow-up 1 year after placement of the definitive restoration and none had lost an implant. The mean marginal bone loss was 0.07 ± 0.10 mm; mid-buccal mucosa level recession was 0.14 ± 0.40 mm; and the median Pink Esthetic Score and White Esthetic Score were 6 [4;7 interquartile range] and 8 [7;8.3 interquartile range], respectively. The participants' mean overall satisfaction was 90.1 ± 6.5 on a 0-100 Visual Analogue Scale. No complications occurred.

Conclusion: It can be concluded from a 1-year follow-up that treatment with the bone level tapered implant system resulted in good implant stability, healthy peri-implant hard and soft tissues, satisfying esthetics and good patient-centered outcomes.

Introduction

There is a wide range of implant designs that can be used for single-tooth replacement. One of these designs is an implant with a tapered body. Compared to a parallel-walled implant body, tapered implants have the alleged clinical benefits of, for example, less risk of apical bone fenestrations due to bony undercuts, which are commonly seen in the maxillary alveolar process (Buser et al., 2004), and improved primary stability compared to parallel-walled implants (Atieh et al., 2018; Sugiura et al., 2019).

When the alveolus is left to heal without bone preservative measures after a tooth is extracted, the buccal bone wall is subject to progressive physiologic resorption (Araújo et al., 2019). The resorption pattern can lead to a deficient labial bone wall and can compromise proper soft tissue support (Merheb, 2014; Araújo et al., 2015; Chappuis et al., 2017). Techniques have been described to avert this ‘physiologic collapse’ of the alveolar ridge, such as socket preservation, either with or without immediate implant placement (Jung et al., 2018; Araújo et al., 2019). It is particularly important to preserve the alveolar processes in the aesthetic region. The alveolar bone supports the mucosa and this determines a great deal of the aesthetic outcome of an implant restoration (Buser et al., 2004). Although recommendations are manifest, implant treatment is not always part of the restoration plan at the time of tooth extraction, and immediate implant placement or alveolar ridge preservation is therefore not carried out. It has been demonstrated that if implant treatment does become an option at a later stadium, guided bone regeneration, to augment the deficient bone wall, successfully increases the contour of bone and soft tissues (Chappuis et al., 2018; Wessing et al., 2018).

Different brands of tapered implants are available. The results of placing these implants in the aesthetic region are good regarding implant survival, bone level change and aesthetic outcome, both in preserved and in non-preserved sites (Den Hartog et al., 2013; Cosyn et al., 2015; Slagter et al., 2016). In 2015, a new line of tapered implants was launched (Straumann Bone Level Tapered implant, Institut Straumann AG, Basel, Switzerland). This implant is equipped with the successful characteristics established by previous studies (Smeets et al., 2016; Hsu et al., 2017), such as SLActive surface and platform switching with a conical implant/abutment connection, but it also has a tapered body which means it is more applicable for challenging anatomical sites and for enhanced primary stability in soft bone or extraction sockets.

To the best of our knowledge, only a few studies have published about the use of this BLT implant system (Caiazzo et al., 2019; Levine et al., 2019; Pariente et al., 2020). Of these, only one describes placement specifically in the anterior maxilla. However,

the study has a short follow-up of 6 months, and does not describe implant stability, aesthetics or patient-reported outcomes (Caiazzo et al., 2019). Therefore, a full-scale assessment on the performance of the Straumann Bone Level Tapered implant system in healed sites in the maxillary aesthetic area is lacking.

The purpose of this one-year, prospective, observational case series was to perform a full-scale assessment of clinical, radiographic, aesthetic and patient-reported outcomes of single bone level tapered implants in healed sites in the maxillary aesthetic zone using the new Straumann implant.

Materials and Methods

Study design

The study was designed as a prospective clinical case series with 30 participants. Recruitment and inclusion of participants in need of single-implant treatment took place at the Department of Oral and Maxillofacial surgery of the University Medical Center Groningen, the Netherlands, from January 2016 until December 2017. The research protocol was approved by the Medical Ethics committee of the UMCG (METc 2015.517). The study was registered in the Dutch trial register (Trial ID: NL8755). Informed consent was signed by all the participants prior to treatment. This manuscript was constructed according to the STROBE guidelines for cohort studies (Von Elm et al., 2014).

Participants

The inclusion criteria were:

- the treatment site is in the anterior maxilla (central incisors, lateral incisors, cuspids and first premolars);
- a single tooth diastema (healed unassisted for at least 3 months) with sufficient bone volume for implant placement;
- the presence of natural teeth on both sides of the planned implant site;
- at least 18 years of age at the time of treatment;
- the patient is capable of understanding and giving informed consent.

Participants were excluded when there was:

- presence of active clinical periodontal disease as expressed by probing pockets
- depths ≥ 4 mm combined with bleeding on probing in the natural dentition other than the affected tooth;

- smoking;
- a history of radiotherapy to the head and neck region;
- use of bisphosphonates less than 10 years ago.

Surgical phase

One day before implant placement, the participants started antibiotic therapy (amoxicillin 500mg, 3 times daily for 7 days, or clindamycin 300 mg, 4 times daily for 7 days in case of an amoxicillin allergy) and a 0.2% chlorhexidine mouth rinse, twice daily for 7 days. Although it acknowledged that implant placement in healed sites probably does not require antibiotic therapy, it was expected that a substantial number of patients would need a local bone augmentation because of limited thickness of the buccal bone wall. For this reason antibiotics were prescribed for all included patients. All the participants' surgeries were performed by the same, experienced, surgeon (GMR). After administering local anaesthesia, a mid-crestal incision with a divergent relieving incision was made at the distal side for a small muco-periosteal flap elevation. The implant position was dictated by a (semi-guided) surgical template and the implant bed was prepared following the manufacturer's drilling guidelines. All the participants received a Straumann Bone Level Tapered implant (SLActive®, Roxolid®, Ø 3.3mm and 4.1mm, Institut Straumann AG, Basel, Switzerland) according to the pre-operative planning. The implants were placed 3 mm apically of the prospective gingival margin of the future restoration. The reason for this was to take fully advantage of the biologic width to create a natural emergence profile with individually designed abutments. Next to this, the implants were placed somewhat palatally of the center of the former tooth root to have at least 2 mm of buccal bone thickness, whether or not reached with an additional bone augmentation procedure. When the bone wall thickness facially to the implant was < 2 mm, a local bone augmentation was performed with a 1:1 mixture of xenogenic bone (Cerabone®, Botis Biomaterials GmbH, Zossen, Germany) and autologous bone chips collected during implant bed preparation, which was covered with a collagen membrane (Jason®, Botis Biomaterials GmbH, Zossen, Germany) and secured with interrupted sutures (5-0 ethilon, Johnson&Johnson Gateway, Piscataway, USA). Wound healing and suture removal were checked after two weeks. A partial removable denture (RPD) was provided to wear until the day of abutment connection.

Prosthetic phase

The implants were uncovered three months after insertion, with the use of a soft-tissue punch technique. An open tray impression was made with a vinylpolysiloxane

precision impression material (Provil Novo, Medium fast set, Kulzer Mitsui Chemical Group, Germany). The impression was sent to the dental laboratory to make a screw-retained provisional restoration, that avoided centric and eccentric contact with the antagonist teeth, and which was placed the same day.

The provisional restoration consisted of a platform-switched titanium stock abutment with an acrylic resin crown and was torqued to 25 Ncm. Three months later, an impression was made for the construction of a definitive crown. The definitive porcelain fused to zirconia restorations were cemented onto individualized zirconium abutments with a platform-switched, internal conical connection (zirconium CARES® abutment, Institut Straumann AG, Basel, Switzerland) or were designed as screw-retained restorations with a titanium base (Variobase® for single crowns AS, Institut Straumann AG, Basel, Switzerland). In both cases, the screws were tightened to the implant with a torque of 35 Ncm. For screw-retained restorations the inclination of the implant is crucial. In the beginning of the study, therefore, definitive restorations were cement-retained with a separate zirconia abutment and a porcelain-veneered core. During the study angulated screw-channels became available with the possibility to have any restoration screw-retained with porcelain-veneered zirconia abutments. After installing both the provisional and the definitive restorations, oral hygiene instructions were given to the patients. All the prosthetic procedures were carried out by the same prosthodontist (HJAM).

Evaluation

The clinical, radiographic, photographic and patient centred outcomes were assessed before implant placement (T_{pre}), one month after definitive restoration placement (T_1) and 12 months after definitive restoration placement (T_{12}) by the same observer (CMM).

Outcome measures

- *Implant survival*: defined as the percentage of implants that are in place and functional at the time of follow-up.
- *Marginal bone level change* was measured on standard peri-apical radiographs with individually fitting aiming devices (Meijndert et al., 2004) by a trained observer (CMM). The distance from the implant shoulder to the first bone to implant contact was taken on the mesial and the distal side of the implant.
- At implant placement, it was noted if the thickness of the labial bone wall was insufficient, i.e. <2 mm (Grunder et al., 2005), and if additional augmentation was needed.

- *Implant stability*, analysed by measuring the initial fixation (Implant Stability Quotient: ISQ) using an Osstell™ mentor device (Integration Diagnostics AB, Gothenburg, Sweden) (Sim & Lang, 2010; Sennerby & Meredith, 2008) immediately after implantation and right before placing the definitive restoration.
- *Probing depth*. The implant was probed at four sites (mesial, distal, mid-buccal, mid-palatinal) and the depth was measured to the nearest 1 mm using a periodontal Click-probe® with a standard pressure of 0.2-0.25N (KerrHawe Dental Corporation, Bioggio, Switzerland).
- *Clinical variables*. Modified Plaque index (Mombelli et al., 1987), Modified Sulcus Bleeding Index (Mombelli et al., 1987), Gingiva Index (Löe, 1967) and Papilla index (Jemt, 1997).
- *Aesthetic parameters* were assessed with the modified Pink and White Esthetic Scores (PES/WES) (Belser et al., 2009).
- *Mid-buccal gingiva and papilla change* (Zuiderveld et al., 2018) were measured on intra-oral color photographs using a periodontal probe parallel to, and in close proximity to, the axis of the implant crown for calibration (Williams Color-Coded probe; Hu-Friedy Chicago, IL, USA). A horizontal line was drawn between the incisal line of the adjacent teeth (reference line). The distance between the reference line and the mesial and distal papilla and the mid-buccal mucosal margin were measured and analysed (Adobe Photoshop 21.0.3 2020, Adobe Systems Inc., San Jose, USA).
- *Participant satisfaction* was assessed with a questionnaire used by Den Hartog et al. (2013), completed prior to implant placement and one year after definitive crown placement. The questions focussed on the influence of the affected site or the new implant restoration on the patient's self-confidence, function and aesthetics, and were answered on a 5-point scale, ranging from very dissatisfied or strongly disagree (score 1) to very satisfied or totally agree (score 5). The overall satisfaction was measured on a 0-100 Visual Analogue Scale (VAS).
- *Complications*: Any biological and technical complication that occurred during the period prior to, and up to one year after definitive crown placement, were recorded.

Statistical analysis

Statistical analysis was performed to gain insight in data of clinical, radiographic and esthetic outcome scores and difference in patients satisfaction between the pre-operative situation and one year after definitive restoration placement. All the data

was checked for normality using QQ-plots and the Shapiro-Wilk test in order to determine the appropriate statistical method. Ordinal and not-normally distributed continuous data was analysed using the Wilcoxon signed rank test to determine any significance between time intervals. The normally distributed data between the time intervals was calculated with the Paired T-test. Categorical data was analysed with the Mc Nemar’s test. A p-value of 0.05 was considered to indicate statistical significance. A Bonferroni correction was performed to correct for multiple testing. All the analyses were performed using SPSS (PASW Statistics 23.0, SPSS Inc.; IBM Corporation, Chicago, IL, USA).

Results

A total of 30 participants was included in the study. The study population characteristics are depicted in **Table 1**. No participants dropped out or were lost to follow-up.

Table 1. Characteristics of the study group at the start of the study.

Number of participants	30
Mean age mean±SD (range)	38±16 (18-75)
Male/female ratio	15/15
Implant location (I ₁ /I ₂ /C/P ₁)	15/11/2/2
Implant length 10/12/14	3/25/2
Implant diameter 3.3/4.1	11/19

Implant stability

The median implant stability quotient value immediately after implant placement was 73 [68;76] (min 46, max 81) and had increased significantly to 79 [77;81] (min 73, max 85) on the day the definitive restoration was placed (**Table 2**).

Buccal bone thickness at implant placement

Although there was sufficient bone volume in all cases to place the implants with adequate primary stability (manually torqued with a ratchet to at least 35Ncm), the bone thickness of 23 out of 30 cases (77%) was <2 mm facially to the implant. These cases received additional augmentation. One patient lost granules of the augmentation material 2 weeks after implant placement, but no further treatment was needed. All the wounds healed uneventfully.

Implant survival rate

No implants were lost during the follow-up, resulting in a 100% implant survival rate. (Table 2)

Marginal bone level change

Figure 1 shows the radiographic changes from before the treatment to 12 months after definitive crown placement. Implant survival rates and marginal bone level changes are depicted in table 2. The mean marginal bone level changed significantly in the first 7 months after implant placement. Thereafter only little, non-significant change occurred. The peri-implant bone level changes were not normally distributed, so it is appropriate to note the medians and IQR but, to give more insight into the actual change, the bone level changes are also depicted as mean±SD.

Table 2. Survival rate (%), implant stability quotient (ISQ) and bone level change (in mm) from time of implant placement to 12 months after definitive crown placement, measured in mm. n=30.

Survival rate	100%					
Implant stability ISQ	at implant placement		at definitive crown placement		p*	
	73 [68;76]		79 [77;81]		<0.00	
Bone level change (mean±SD)	T ₀ -T ₁	p**	T ₀ -T ₁₂	p**	T ₁ -T ₁₂	p**
Mesial	-0.48±1.13	0.001	-0.54±1.20	0.000	-0.09±0.15	0.68
Distal	-0.55±0.98	0.000	-0.56±0.98	0.002	-0.06±0.15	0.16
Mean of mesial+distal	-0.53±1.02	0.000	-0.51±1.06	0.000	-0.07±0.10	0.66

* Wilcoxon signed rank test. A bonferroni core

** The threshold for significance is p<0.017 due to the Bonferroni correction

T₀ = time of implant placement.

T₁ = one month after definitive crown placement (7 months after implant placement).

T₁₂ = 12 months after definitive crown placement (18 months after implant placement)

Clinical parameters

The bleeding index, gingiva index and mean probing depth scores from the 12 month evaluation are depicted in Table 3. There were no significant differences between T₁ and T₁₂.

Figure 1. Bone level during the course of treatment: a) before implant placement; b) immediately after implant placement; c) 1 month after definitive crown placement; c) 12 months after definitive crown placement.

Table 3. Clinical parameters at 12 months after definitive crown placement. n=30.

Pocket probing depth in mm median [IQR]		
Mesial	4.0 [3.0;5.0]	
Mid-buccal	3.0 [2.0;4.0]	
Distal	4.0 [3.0;5.0]	
Palatinal	3.0 [2.0;3.0]	
Mean of all sites	3.4[2.8;3.9]	
Gingiva index (median,IQR)	0 [0;0]	
Bleeding score (median, IQR)	1 [0;1]	
	n	%
0	14	46.7
1	10	33.3
2	5	16.7
3	1	3.3

Aesthetic evaluation

Figure 2 shows the soft tissue changes from before treatment to 12 months after final crown placement. A summary of the PES/WES outcome is depicted in **Table 4**. There was statistically no significant change in PES or WES between the first month (T_1) and 12 months (T_{12}) after definitive crown placement. The change in mid-buccal mucosa height between T_1 and T_{12} was -0.14 ± 0.40 mm. There was an overall gain in papilla height: $+0.05 \pm 0.60$ mm mesially and $+0.06 \pm 0.53$ mm distally. There was not a significant difference in mid-buccal mucosa level and in papilla height between the first month (T_1) and 12 months (T_{12}) after definitive crown placement.

Figure 2. Soft tissue changes: a) before implant placement (patient had worn a RPD prior to treatment); b) 1 month after definitive crown placement; c) 12 months after definitive crown placement

Table 4. Evaluation of the aesthetic outcome at T_{12} (PES/WES) and mucosa level change from T_1 to T_{12} . $n=30$.

Aesthetic evaluation at T_{12} (median,IQR)		
PES	6 [4;7]	
WES	8 [7;8.25]	
Mucosa level change from T_1 to T_{12} in mm (mean $\pm$ SD)		p^*
Mid-buccal mucosa	-0.14 ± 0.40	0.07
Mesial papilla	$+0.05 \pm 0.60$	0.69
Distal papilla	$+0.06 \pm 0.53$	0.57

* paired T-test

Patient satisfaction

At baseline, which was before implant treatment, 25 patients rated their satisfaction with the removable partial denture as 53.0 ± 23.5 . This score increased significantly after placement of the implant restoration, to a mean score of 90.1 ± 6.5 at the T_{12} follow-up (Table 5). Five participants did not wear any prosthetic construction at baseline and could not answer the questionnaire. They were thus excluded from this part of the analysis.

Complications

Four participants reported mobility of the provisional restoration 2 weeks after placement. The screws could be retightened without further complications. One patient had suffered extensive marginal bone loss during the three months with the temporary restoration so it was removed and the peri-implant region was surgically explored and chemically cleaned using 35% phosphoric acid gel (Hentenaar et al., 2017). The area was augmented with a mixture of autologous bone from the tuberosity region and

deproteinized bovine bone mineral (BioOss®, Geistlich, Wolhusen, Switzerland) and the implant was covered with a collagen membrane (Bio-Gide®, Geistlich, Wolhusen, Switzerland) to heal submerged for 4 months. The definitive crown was placed after uncovering the implant. At the T_{12} follow-up this implant had a peri-implant bone level at the neck of the implant and healthy peri-implant soft tissues.

Table 5. Patient satisfaction was rated on a 0-100 VAS scale and further clarified in a questionnaire. T_{pre} is time prior to implant placement. T_{12} is twelve months after definitive crown placement. Significance levels between T_{pre} and T_{12} .

	T_{pre} n=25*	T_{12} n=30	p
Overall patient satisfaction			
0-100 VAS scale (mean ± SD)	53.0±23.5	90.1±6.5	<0.05 [‡]
Questionnaire, % in agreement			
Wellbeing			
Presence of shame	32.0	0.0	0.008 [‡]
Decreased self-confidence	16.0	3.3	0.25 [‡]
Aware of prosth. visibility	24.0	3.3	0.063 [‡]
Function			
Evade eating with affected zone	60.0	10.0	0.000 [‡]
Decreased chewing ability	52.0	0.0	0.000 [‡]
Influences speech	32.0	3.3	0.016 [‡]
Influences taste	28.0	0.0	0.016 [‡]
Aesthetics			
Satisfied with shape of the RPD/crown	48.0	100	0.000 [‡]
Satisfied with colour of the RPD/crown	68.0	93.3	0.016 [‡]
Satisfied with shape of the mucosa	60.0	86.7	0.016 [‡]
Satisfied with colour of the mucosa	44.0	86.7	0.006 [‡]

* 5 participants did not wear the removable partial denture (RPD) and therefore did not answer the questionnaire. These participants were left out of the statistical analysis.

[‡] paired T-test

[‡]Mc Nemar's test

Discussion

The results of this prospective clinical case series of single bone level tapered implants, placed in unassisted healed sites in the aesthetic region, one year after definitive crown placement, regarding stability, clinical, radiographic, aesthetic and patient-centred outcomes, were favourable.

Comparison of our study's outcomes with others that used the same bone level tapered implant in healed sites is, to the best of our knowledge, limited to two studies: Levine et al. (2019) and Pariente et al. (2020). They used the implant mainly in the posterior region and with other treatment protocols than the current study. Both studies also reported high survival rates (98%) and stable marginal bone levels (0.3 ± 0.46 mm, Levine et al., 2019, and 0.35 ± 0.23 mm, Pariente et al., 2020) after one and two years. In the absence of studies using the same implant brand, comparison can best be made with other implant systems with a tapered design applied to healed sites in the aesthetic region. De Bruyckere (2018) and Cosyn (2015) used the tapered NobelActive® implants (Nobel Biocare, Gothenburg, Sweden) and reported the same range of bone loss as Levine(2019) and Pariente(2020), one year after implant placement (-0.42 ± 0.36 mm, Cosyn et al., 2015, and -0.48 ± 0.4 mm, de Bruyckere et al., 2018). Zuiderveld (2018) used the NobelReplace CC implant (Nobel Biocare, Gothenburg, Sweden) and recorded bone level changes of $+0.06 \pm 0.5$ mm mesially and -0.01 ± 0.4 mm distally in the time from definitive crown placement to 12 months thereafter. The present study's results are in the same range as the mentioned studies and the bone level changes are comparable with the peri-implant bone level changes of the other tapered implants in the aesthetic region, including very little bone loss after the first year in function.

An alleged benefit of a tapered implant design is a good primary stability due to the self-tapping property combined with underdrilling during osteotomy. Therefore, implant stability, was analysed by measuring the initial fixation (Implant Stability Quotient: ISQ). The implant stability quotient was not measured by Levine (2019) or Pariente (2020). Torroella-Saura et al. (2015) and Moroi et al. (2020) compared ISQ values of tapered implants with cylindrical implants. Although different implant brands were used, and mainly in the molar and mandibular region, they noted mean ISQ values at implant placement of 72.9 ± 2.5 (Torroella-Saura et al., 2015) and 60.2 ± 12.4 (Moroi et al., 2020) for the tapered implants, which were higher than for the cylindrical implants. Our study's ISQ at implant placement was 73 [68;76], indicating high implant stability (The Ostell ISQ, 2020) and is comparable to the values measured with other implant brands and in the posterior mandibular region by Torroella-Saura (2015) and Moroi (2020). In addition to knowing this, Pariente (2020) did describe the mean insertion torque (IT) value. Being 34 ± 5.3 Ncm. This can be classified as good primary stability (Kotsakis et al., 2014), even though the majority of the implants were placed in poor type III or IV bone (63.3%). At the time the study protocol was drafted, only little was known about the BLT implant, especially in the anterior zone, so it was decided to be careful when subjecting the study participants to immediate loading without knowing beforehand

what the implant stability would be. Knowing that this implant scores high on both ISQ and IT values might help in considering immediate loading in future patients.

One of the inclusion criteria for our participants was the presence of sufficient bone for implant placement. Despite this, the thickness of the labial bone wall was insufficient in 23 cases (77%) and had to be augmented to achieve a bone wall thickness of at least 2 mm, i.e. placement of tapered implants in sites where physiologic resorption has occurred does not always prevent the need for extra bone augmentation. The need for additional augmentation was also seen in other studies with unassisted healed sites in the aesthetic region. In the Zuiderveld (2019) study, 90% of the cases needed a bone augmentation procedure. If compared with a study with cylindrical implants in the maxillary aesthetic region, Boardman et al.(2016) reported that 90% of the healed site cases needed an additional bone augmentation procedure at implant placement. These percentages are very much alike, leaving the question if a tapered implant design diminishes the need for an additional bone augmentation unanswered. A thin bone wall (<2mm) labial to the implant tends to be more susceptible to resorption, leading to poor soft tissue support, which might lead to aesthetic failure as a consequence(Buser et al., 2017; Cosyn et al., 2017).

The aesthetic outcome in our study was satisfactory, with an acceptable PES score of 6[4;7] (Belser et al., 2009) and small recession to the mid-buccal mucosa (-0.14 ± 0.40 mm) and papillae ($+0.05 \pm 0.60$ mesial and $+0.06 \pm 0.53$ distal). The median value of 6 for PES is rather low in the light that a possible score of 10 can be given for a perfect situation. Apparently, it is rather difficult in these healed sites to achieve an optimum result after physiologic resorption has occurred after removal of the tooth and flap surgery in combination with a local bone augmentation procedure. Comparison of the PES value with a study in which immediate implant placement was used in the maxillary aesthetic region reveals that this is a slightly higher, being a mean value of 6.8 ± 1.5 (Zuiderveld et al., 2018). An explanation could be the flapless surgery in case of immediate implant placement. There was not a significant difference in mid-buccal mucosa level and in papilla height between the first month (T_1) and 12 months (T_{12}) after definitive crown placement, meaning that soft tissues are stable in the first year after definitive restoration placement. The mucosa changes of both the mid-buccal gingiva and the papillae are within the range of that previously found by the other authors (Cosyn et al., 2015; de Bruyckere et al., 2018; Zuiderveld et al., 2019) who also presented minor changes in the soft tissues, indicating that the BLT implant is comparable to the other, more or less equally shaped, implants and accompanied with

stable marginal bone levels, as well as, or maybe because of it, stable peri-implant soft tissues after one year.

The present study's overall patient satisfaction score resembles those mentioned by Zuiderveld et al.(2019) and Lowy et al.(2019): the participants were more satisfied with the end result than the professional observers. Perhaps this is because the patients' pre-treatment situation is still fresh in their minds and express satisfaction as oral wellbeing, function and aesthetics in comparison to the pre-treatment situation, whereas the professionals use an index and might be more critical about the smaller defaults than the participants. However, both are consistent in liking the whites better than the pinks, as can be seen on comparing the answers to the questionnaire with the PES and WES outcomes.

Although this study's overall results were good, two major limitations need to be mentioned and addressed in future research. First, the study did not compare the performance of a tapered implant to the performance of a cylindrical implant, preferable from the same brand, by means of a randomized controlled trial. Comparisons were made with other studies addressing a tapered implant design. Second, although acknowledging the importance of the facial bone thickness, the buccal bone thickness was not measured by means of cone beam computed tomography to monitor the original bone, the augmented bone and its stability over time.

Conclusion

Within the limitations of the study, it can be concluded from a one-year follow-up that treatment with the bone level tapered implant system resulted in good implant stability, healthy peri-implant hard and soft tissues, satisfying esthetics and good patient-centered outcomes.

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5

Alveolar ridge preservation in defect sockets in the maxillary aesthetic zone followed by single-tooth bone level tapered implants with immediate provisionalization

a one-year prospective case series

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Abstract

Aim: To assess clinically, radiographically and aesthetically over one year the performance of a bone level tapered implant in the maxillary aesthetic zone in sites after alveolar ridge preservation.

Material and methods: Thirty patients (16 male, 14 female, mean age 43 years) with a failing tooth and large bone defect after removal, received alveolar ridge preservation. After three months, implants were placed with immediate provisionalization. Definitive restorations were placed after 3 months. The treatment was evaluated one year following the definitive restoration.

Results: All the patients attended the one-year follow-up. One implant was lost (96.7% implant survival rate). The mean Implant Stability Quotient value was 68.9 ± 8.74 at implant placement. The mean marginal bone level change was minor (-0.07 ± 0.12 mm). The mean mid-buccal mucosa changed with $+0.01 \pm 0.45$ mm. The median Pink Esthetic Score and White Esthetic Score after one year were 6 [4;7] and 8 [7;9], respectively. The patients' mean overall satisfaction (0-100 VAS scale) was 86.6 ± 10.3 .

Conclusion: Bone level tapered implants with immediate provisionalization perform well after alveolar ridge preservation in the maxillary aesthetic zone, according to implant stability, clinical, radiographic, aesthetic and patient-centred outcomes.

Introduction

Immediate implant placement is frequently advocated for a single failing tooth in the maxillary aesthetic zone. However, in some cases after tooth extraction, the future implant site is inadequate for primary implant placement (Buser et al., 2004; Chen & Buser, 2009). Examples of inadequate sites for immediate implant placement are large bone deficiencies, severe recession of the mucosa and extensive infection (Jung et al., 2018). Just removing the tooth and let the alveolus heal without extra precautions, can often lead to progressive physiologic resorption of the buccal bony wall (Araújo et al., 2019). A few techniques have been described to avert this ‘physiologic collapse’ of the alveolar ridge after tooth extraction, including alveolar ridge preservation (Jung et al., 2018). Alveolar ridge preservation cannot stop the resorption process, but it can reduce the degree of alveolar alteration (Chappuis et al., 2017; Tonetti et al., 2019). This is particularly important in the aesthetic region where the alveolar bone supports the mucosa, which determines a great deal of the aesthetic outcome of an implant restoration. The Jung et al. (2018) systematic review noted that alveolar ridge preservation has clear advantages in preserving alveolar ridge volume in the aesthetic region.

There is a wide range of dental implant designs, one of which is a tapered implant body. In 2018, Jokstad and Ganeles defined a tapered implant as *a cylindrical implant where the endosseous part narrows in diameter toward the apex* (Jokstad & Ganeles, 2018). A possible benefit of a tapered implant design is improved primary stability compared to parallel-walled implants (Atieh et al., 2018; Sugiura et al., 2019). Improved primary stability is particularly important in low density and soft bone, and in healing extraction sockets. Furthermore, it is said that there is less risk of bone fenestrations in anatomical undercuts at the apical part of tapered implants, as is often present with the maxillary alveolar processes (Atieh et al., 2018). Good results have been achieved with tapered implants in the aesthetic region including implant survival, bone level change and aesthetic outcome, both in preserved and in non-preserved sites (den Hartog et al., 2013; Slagter et al., 2016; Eghbali et al., 2018; Zuiderveld et al., 2018). Various tapered implant brands are available. In 2015, a new line of tapered implants was launched (Straumann Bone Level Tapered implant, Institut Straumann AG, Basel, Switzerland). It has a tapered body, converging from the cervical part towards the apex, and is further equipped with the established characteristics of previous designs of the same manufacturer, such as a SLActive surface (Smeets et al., 2016) and platform switch with conical implant/abutment connection (Hsu et al., 2017). To the best of our

knowledge, only a few studies have reported the use of this newly designed implant system in compromised bone (Caiazoo et al., 2019; Levine et al., 2019; Pariente et al., 2020). However, a full-scale assessment describing parameters such as primary stability, marginal bone level change, change in clinical peri-implant parameters, aesthetic outcome, patient-reported outcomes is lacking.

Therefore, the purpose of this prospective observational case series was to perform a full-scale assessment of clinical, radiographic, aesthetic and patient-reported outcomes of single-tooth bone level tapered implants with immediate provisionalization after alveolar ridge preservation in the maxillary aesthetic zone over a one-year follow-up period.

Materials and Methods

Study design

The study was designed as a prospective clinical case series on 30 consecutive patients requesting implant treatment for a single failing tooth in the maxillary aesthetic zone but for whom immediate implant placement was not possible. Recruitment and inclusion of patients took place at the Department of Oral and Maxillofacial Surgery of the University Medical Center Groningen, the Netherlands, from January 2016 until December 2017. The research protocol was approved by the Medical Ethics committee of the UMCG (METc 2015.517). The trial was registered in the Dutch trial register (Trial ID: NL8755). Informed consent was signed by all the participants prior to treatment. This manuscript was constructed according to the STROBE guidelines for cohort studies (von Elm et al., 2014).

Participants

The inclusion criteria were:

- treatment site in the anterior maxilla (first premolar to first premolar)
- a single failing tooth and in need of ridge preservation prior to implant placement because of a vertical buccal bone wall defect of >5mm of the extraction socket, assessed after tooth extraction by bone sounding technique;
- presence of natural teeth on both sides of the planned implant site;
- at least 18 years of age at the time of treatment;
- the patient is capable of understanding and giving informed consent.

Patients were excluded when there was:

- presence of active clinical periodontal disease as expressed by probing pockets depths ≥ 4 mm combined with bleeding on probing in the natural dentition other than the affected tooth;
- smoking;
- a history of radiotherapy to the head and neck region;
- use of bisphosphonates less than 10 years ago.

Treatment procedures

Participants with a failing tooth and not suitable for immediate implant placement were eligible for this study. They were informed about and consented to the research protocol prior to tooth extraction. All the participants started antibiotic therapy the day before extraction (amoxicillin 500mg, 3 times daily for 7 days, or clindamycin 300 mg, 4 times daily for 7 days in case of an amoxicillin allergy) and a 0.2% chlorhexidine mouth rinse, twice daily for 7 days. After administering local anaesthesia, the tooth was removed as atraumatically as possible using a periosteal elevator and forceps. The socket was cleaned and the granulation tissue was removed. A bone graft, harvested from the maxillary tuberosity or retromolar area, was shaped to fit the labial bone wall defect and inserted in the alveolus. Next, the socket was augmented with a mixture of autologous bone and anorganic bovine bone (Geistlich Bio-Oss®, Geistlich Pharma AG) (Raghoobar et al., 2009). The alveolus was closed with a mucosa graft from the maxillary tuberosity or palate. Wound healing and suture removal was checked two weeks after surgery. The participants wore a removable partial denture during the healing period. The implants were placed 3 months after the augmentation procedure.

One day before implant placement, all the participants started antibiotic therapy (amoxicillin 500mg, 3 times daily for 7 days, or clindamycin 300 mg, 4 times daily for 7 days in case of an amoxicillin allergy) and a 0.2% chlorhexidine mouth rinse, twice daily for 7 days. All the surgeries were performed by the same, experienced, surgeon (GMR). After administering local anaesthesia, a mid-crestal incision with a divergent relieving incision was made next to the distal tooth for a small muco-periosteal flap elevation. The implant position was dictated by a (semi-guided) surgical template and the implant bed was prepared following the manufacturers' surgical guidelines. All the participants received a Straumann Bone Level Tapered (BLT) implant (Institute Straumann AG, Basel, Switzerland) according to the pre-operative planning. The implants were installed 3 mm apically of the prospective gingival margin of the future restoration, with an insertion torque of at least 45 Ncm. If the thickness of the labial

bone wall was <2 mm (Grunder et al., 2005), a 1:1 mixture of autologous bone (from the drills) and bovine bone (Cerabone®, Botiss Biomaterials GmbH, Zossen, Germany) was augmented. The augmented area was covered with a collagen membrane (Collprotect®, Botiss Biomaterials GmbH, Zossen, Germany).

Immediately following implant placement, an implant-level open tray impression was made with a vinylpolysiloxane precision impression material (Provil Novo, Medium fast set, Kulzer Mitsui Chemical Group, Germany) (HJAM). The impression was sent to the dental laboratory which then manufactured a screw-retained provisional restoration. The provisional restoration consisted of a platform-switched titanium stock temporary abutment with an acrylic resin restoration. The participants received the provisional restoration on the day the implant was placed. The screw of the provisional restoration was torqued to 25 Ncm. After 3 months, an impression was made for the construction of a definitive crown. Definitive porcelain fused to zirconia restorations were cemented onto individualized zirconium abutments with a platform-switched, internal conical connection (zirconium CARES[®] abutment) or designed as screw-retained restorations with a titanium base (Variobase[®] for single crowns AS, Straumann AG, Basel). In both cases, the implant screws were tightened with a torque of 35 Ncm. Oral hygiene instructions were given after installing both the provisional and the definitive restorations.

Evaluation

Clinical, radiographic, photographic and patient-centred outcomes were assessed before implant placement (T_{pre}), one month after definitive restoration placement (T_1) and 12 months after definitive crown placement (T_{12}). All the assessments were done by the same observer (CMM).

Outcome measures

At removal of the failing tooth, the size of the labial bone wall defect was measured and the origin of the donor bone (donor site), used to preserve the alveolar ridge, was noted.

- *At implant placement*, it was noted if the thickness of the labial bone wall was insufficient, being <2 mm (Grunder et al., 2005), and additional augmentation was needed.
- *Implant stability*. Implant stability was analysed by measuring the initial fixation (Implant Stability Quotient: ISQ) using an Osstell™ mentor device (IntegrationDiagnostics AB, Gothenburg, Sweden) (Sim & Lang, 2010; Sennerby

& Meredith, 2008). Implant stability was measured immediately after implantation and just before placement of the definitive restoration.

- *Implant survival*. was defined as the percentage of the implants that are in place and functional at the time of follow-up.
- *Marginal bone level change*. The bone level was measured by a trained observer (CMM) on standard peri-apical radiographs with individually fitting aiming devices (Meijndert et al., 2004). The distance from the implant shoulder to the first bone to implant contact was taken on the mesial and distal side of the implant. Only the bone level changes apical from the implant shoulder were taken into account. Any bone that was depicted above the implant shoulder was given a value of 0.00 mm.
- *Probing depth*. The implant and the adjacent teeth were probed at four sites (mesial, distal, buccal, palatal). The probing depth was measured to the nearest 1 mm using a periodontal Click-probe® with a standard pressure of 0.2-0.25N (KerrHawe Dental Corporation, Bioggio, Switzerland).
- *Clinical variables*. Modified Plaque index (Mombellie et al., 1987), Modified Sulcus Bleeding Index (Mombellie et al., 1987), Gingiva Index (Löe, 1967)
- *Aesthetic parameters* according to the modified Pink and White Esthetic Score (PES/WES) (Belser et al., 2009).
- *The mid-buccal mucosa and papilla change* (Zuiderveld et al., 2018) were measured on intra-oral colour photographs using a periodontal probe parallel to the axis of the implant crown for calibration (Williams Color-Coded probe; Hu-Friedy Chicago, IL, USA). A horizontal line was drawn between the incisal line of the adjacent teeth (reference line). The distance between the reference line and the mesial and distal papilla and the mid-buccal mucosal margin were measured and analysed (Adobe Photoshop 21.0.3 2020, Adobe Systems Inc., San Jose, USA).
- *Participant satisfaction* was assessed with a questionnaire used by Den Hartog et al.(2013) prior to implant placement and one year after definitive crown placement. The questions focussed on the influence of the affected site or the new implant restoration on the patient self-confidence, function and aesthetics, and had to be answered on a 5-point scale, ranging from very dissatisfied (score 1) to very satisfied (score 5). The overall satisfaction was measured on a 0-100 Visual Analogue Scale (VAS).
- *Complications*: Any biological and technical complication that occurred from surgery up to one year after definitive crown placement, were recorded.

Statistical analysis

All the data was checked for normality using QQ-plots and the Shapiro-Wilk test in order to determine the appropriate statistical method. Ordinal and not-normally distributed continuous data was analysed using the Wilcoxon signed rank test to determine any significance between time intervals. The normally distributed data was analysed using the Paired T-test to determine any significance between time intervals. The McNemar's test was used for the questions in the questionnaire. A p-value of 0.05 was considered to indicate statistical significance. All the analyses were performed using SPSS (PASW Statistics 23.0, SPSS Inc.; IBM Corporation, Chicago, IL, USA).

Results

A total of 30 participants was included. The characteristics of the study population are depicted in **Table 1**. No patients dropped out or were lost to follow-up.

Table 1. Characteristics of the study group at the start of the study

Number of participants	30
Mean age in years mean±SD (range)	43±16 (18-74)
Sex (male/female)	16/14
Labial bone wall defect in mm , mean (range)	8.6 (5-12)
Implant location (I ₁ /I ₂ /C/P ₁)	24/5/1/0
Implant length, mm (10/12/14)	0/19/11
Implant diameter, mm (3.3/4.1)	4/26

Labial bone wall defect

In all cases the defect of the labial bone wall after removing the tooth was U-shaped. Five participants had also a fistula at the labial mucosa. The origin of the bone (donor site) to preserve the alveolar ridge was the maxillary tuberosity in 14 cases and the retromolar area in 16 cases. The choice for the retromolar area was made in case wisdom teeth were present in the maxilla. When maxillary wisdom teeth are present, usually, less bone can be harvested in these areas.

Insufficient labial bone wall thickness at implant placement

In all cases there was enough bone volume after alveolar ridge preservation to insert the implant with sufficient primary stability. The thickness of labial bone wall at implant placement was <2 mm in 10 cases. In 5 of these cases the alveolar ridge preservation was previously done with bone from the maxillary tuberosity, whereas in the other 5 cases bone was harvested from the retromolar area.

Implant stability

Mean implant stability immediately after implantation was 68.9 ± 8.74 ISQ and 80.2 ± 2.73 ISQ just before placement of the definitive restoration.

Survival rate

One patient lost the implant two months after placement. This resulted in an implant survival rate of 96.7%. The patient was excluded from further analysis (**Table 2**).

Table 2. Survival rate (%) and bone level change from 1 month (T_1) to 12 months (T_{12}) after definitive restoration placement measured in mm, with the median [IQR] and mean $\pm$ SD depicted in the parentheses.

Implant loss, n (survival rate %)		1 (96.7%)
Bone level change		
Mesial		0.00 [-0.04;0.00] (-0.07 $\pm$ 0.16)
Distal		0.00 [-0.02;0.00] (-0.06 $\pm$ 0.14)
Mesial+distal		0.00 [-0.08;0.00] (-0.07 $\pm$ 0.12)

Peri-implant bone level change

The main results are depicted in Table 2. There was statistically no significant changes from T_1 to T_{12} (**Figure 1**). The peri-implant bone level changes were not normally distributed, so only the medians and IQR were calculated. To give more insight in the actual change, bone level changes are also depicted in mean $\pm$ SD. The mean bone level change was -0.07 ± 0.16 mm on the mesial side and -0.06 ± 0.14 on the distal side.

Figure 1. Bone level a) prior to implant placement (3 months after preservation). b) 1 month after definitive restoration placement. c) 12 months after definitive restoration placement

Clinical parameters

The Bleeding-index, Gingiva-index and probing depth scores are depicted in **Table 3**. There were no significant differences in the parameters between the T_1 and T_{12} follow-up periods.

Table 3. Clinical parameters at 1 month (T_1) and 12 months (T_{12}) after definitive crown placement (n=29)

	T_1	T_{12}	Significance
Pocket probing depth in mm (mean$\pm$SD)			
Mesial side	3.7 $\pm$ 1.7	3.9 $\pm$ 1.7	p= 0.56
Mid-buccal side	3.2 $\pm$ 1.0	3.0 $\pm$ 1.0	p=0.26
Distal side	4.1 $\pm$ 1.6	4.3 $\pm$ 1.7	p=0.42
Palatal side	3.4 $\pm$ 1.2	3.2 $\pm$ 1.2	p=0.29
Mean of all sides	3.4 $\pm$ 1.1	3.6 $\pm$ 1.1	p=0.35
Bleeding index (median [IQR])	1 [0;2]	0 [0;2]	p=0.25
Gingiva index (median [IQR])	0 [0;0]	0 [0;0]	p=0.56

Aesthetic evaluation

Aesthetics were evaluated using the modified PES/WES index and mucosa level (**Figure 2**). A summary of the outcomes is depicted in **Table 4**. At T_{12} median PES was 6 [4;7] and median WES was 8 [7;9]. There were no significant differences between the T_1 and T_{12}

follow-up periods. The mid-buccal mucosa remained stable between the 1st month and the 12th month after definitive restoration placement ($+0.01 \pm 0.45$, $p=0.91$).

Figure 2. Soft tissue changes. a) pre-implant situation b) 1 month after definitive restoration placement c) 12 months after definitive restoration placement

Table 4. Evaluation of the aesthetic outcome at T_{12} (PES/WES) and mucosa level change from T_1 to T_{12} ($n=29$).

Aesthetic evaluation at T_{12} (median [IQR])	
PES	6 [4 ;7]
WES	8 [7;9]
Mucosa level changes from, mm (mean $\pm$ SD)	
Mid-buccal mucosa	$+0.01 \pm 0.45$
Mesial papilla	$+0.13 \pm 0.55$
Distal papilla	$+0.17 \pm 0.54$

Patient satisfaction

At baseline, before surgery, the patients gave an overall satisfaction score of 54.9 ± 21.0 on the VAS scale (**Table 5**). This score increased significantly after the definitive implant restoration was placed, up to a mean score of 86.6 ± 10.3 at the T_{12} follow-up ($p<0.001$). Items of function and presence of shame improved significantly between T_{pre} and T_{12} .

Complications

One patient lost the implant during the osseointegration period. A specific reason for this could not be found. This patient was successfully treated again after a healing period of 3 months. Other complications were minor: 4 participants reported they had lost some bone granules from the applied augmentation at the routine check-up two

weeks after surgery (no further treatment was necessary) and 2 participants reported mobility of the provisional restoration 2 weeks after placement (the screws could be retightened again without further complications). There were no complications after the definitive restorations were placed.

Table 5. Patient satisfaction was rated on a 0-100 VAS scale and further clarified through a questionnaire. T_{pre} is time prior to implant placement. T_{12} is twelve months after definitive crown placement.

	T_{pre} n=28*	T_{12} n=29
Overall patient satisfaction		
0-100 VAS scale (mean $\pm$ SD)	54.9 $\pm$ 21.0	86.6 $\pm$ 10.3
Questionnaire, % in agreement		
Wellbeing		
Presence of shame	21.4	0
Decreased self-confidence	21.4	0
Aware of prosth. visibility	21.4	6.9
Function		
Evade eating with affected zone	67.9	31.0
Decreased chewing ability	57.1	6.9
Influences speech	60.7	0
Influences taste	64.3	0
Aesthetics		
Satisfied with shape of the RPD/crown	85.7	75.9
Satisfied with colour of the RPD/crown	96.4	96.6
Satisfied with mucosal shape	92.3	100
Satisfied with mucosal colour	88.5	96.6

* 2 patients did not wear the partial denture and have therefore not answered the questionnaire

Discussion

This 1-year prospective case series reports the results of solitary Straumann Bone Level Tapered (BLT) implants in the aesthetic zone placed 3 months after alveolar ridge preservation and in combination with immediate provisionalization. Apart from one implant being lost in the early stages of osseointegration, there was a good primary

stability at implant placement of all implants, marginal bone loss was minor, peri-implant soft-tissues were stable and patients and professionals were satisfied with the aesthetic results.

To the best of our knowledge, only the Caiazzo et al. (2019) pilot study has published information on the Straumann BLT implant in the aesthetic region. However, they only reported the changes in buccal bone thickness and had a 6 month follow-up. Two other studies, though, focussed on Straumann BLT implants in the molar regions. Levine et al. (2019) noted a survival rate of 98.3% and a marginal bone level change of -0.3 ± 0.46 mm after one year, which is slightly higher than that described by us (-0.07 ± 0.12 mm). However, baseline measurements were made immediately after implant placement, in contrast to our baseline measurement, which was 4 months after implant placement. Pariente et al. (2020) described that most bone loss occurs in the 3 months after implant surgery. Here, the mean bone loss during the first year after implant placement was 0.35 ± 0.23 mm, of which 0.28 ± 0.19 mm in the first 3 months. This could explain the difference in results between our and the above mentioned studies.

The implant stability quotient was measured in neither the study of Levine et al. (2019), nor the study of Pariente et al. (2020). Moroi et al. (2020) studied implant stability of tapered implants versus cylindrical implants, but these implants were from a different brand and mostly placed in the posterior region. They found a mean ISQ value of 60.2 ± 12.41 at implant placement and 66.6 ± 9.00 at definitive crown placement for the tapered implants. These values were higher than for the cylindrical implants, being 54.7 ± 7.92 and 64.0 ± 5.78 ISQ at respectively implant placement and definitive crown placement. The rationale to use tapered implants is the claimed less risk of bone fenestrations in anatomical undercuts at the apical part of tapered implants, as often is present with the maxillary alveolar processes. And also, in the literature it is claimed that a tapered implant design has the possible benefit of improved primary stability compared to parallel-walled implants. However, the question was if this is also true in relatively soft bone as is the case in alveolar ridge preservation sites, because initial implant stability measurements in the maxillary aesthetic region were not performed. This is the reason why implant stability has been added as outcome measure in the present study. In the present study the mean ISQ values were high, being respectively 68.9 ± 8.74 and 80.2 ± 2.73 , indicating good implant stability at both evaluation time points for this new implant design in the maxillary aesthetic region in sites in which alveolar ridge preservation has been performed.

In the literature waiting times to place implants after alveolar ridge preservation differ from 3-6 months (Avila-Ortiz et al., 2019). A long waiting time gives the risk of

significant ridge alterations and resorption of the applied augmentation (Buser et al., 2004; Chappuis et al., 2017). A short healing time gives the risk of placing the implant in soft bone, thus not reaching enough initial implant stability. In the present study, it was chosen to have a healing time of 3 months after alveolar ridge surgery, following the protocol of previous studies on alveolar ridge preservation at the same department in which good results were reached (Slagter et al., 2016; Zuiderveld et al., 2019).

The thickness of labial bone wall at implant placement was insufficient in 10 cases (33.3%) and had to be augmented to achieve a labial bone wall thickness of at least 2 mm. The insufficient thickness could not be attributed to type of bone used for the alveolar ridge preservation, as the origin of augmented bone was evenly distributed between maxillary tuberosity and retromolar area. Apparently, placement of tapered implants in sites in which alveolar ridge preservation has been executed does not prevent the need for an extra bone augmentation at the labial side of the implant in all cases. This was also seen in other studies with alveolar ridge preservation in the aesthetic region. In Zuiderveld et al. (2019) in 45% of the cases an extra bone augmentation procedure was needed and in Lai et al. (2020) this was the case in 26.3%.

In the absence of studies with the same implant brand and design, comparisons can best be made with other implant systems with a tapered design, applied in the aesthetic region. Eghbali et al. (2018) presented 1 year results of alveolar ridge preservation and connective tissue grafts. In this study the implants (NobelActive implant system, Nobel Biocare AB, Goteborg, Sweden) were placed 4 months after alveolar ridge preservation and a provisional restoration combined with a connective tissue grafts were performed 3 months later. Implant survival after one year was 100%. Favourable clinical and aesthetic outcome were reported. The mean marginal bone loss was 0.53 mm and the mid-facial recession amounted 0.05 mm at 1 year. In the Zuiderveld et al. (2019) study, the NobelReplace CC implant system (Nobel Biocare AB, Goteborg, Sweden) was used in the maxillary aesthetic region, again after ridge preservation. After a one-year follow-up, the implant survival was 100%, and the change in marginal bone level was $+0.03 \pm 0.4$ mm mesially and $+0.13 \pm 0.5$ mm distally. These changes are minor and are comparable to those in the present study.

The aesthetic outcome is of particular interest for restorations in the aesthetic zone. Aesthetics can be evaluated by professionals with the PES/WES score (Belser et al., 2009) and by patients with questionnaires (Kanas & Rogers, 2010). Our median PES/WES score was 6/8 after one year. This is in line with Zuiderveld et al. (2019) who noted a mean PES/WES score of 6.6/8.7 after one year. The present study's overall patient's satisfaction score was also very much alike with the satisfaction scores mentioned by

Zuiderveld et al. (2019). It is remarkable that PES was rated lower than the WES by the professional although mucosa was better evaluated than the crown by the patients. This is probably due to the fact that professionals rate other items as important than patients. In both our and Zuiderveld's study (2018) patients are more satisfied with the end result than the professional observers. This phenomenon has been recorded before, showing little correlation between the professional's opinion and the patient's opinion about the aesthetics (Meijndert et al., 2007). Hence, it is not justified to leave out one of them in evaluating the aesthetic outcome. Nonetheless, the overall satisfaction with the implant restorations was high for both patient and professional. As is in accordance with other reports on single implants in the aesthetic zone (Slagter et al., 2016; Zuiderveld et al., 2018).

The question is if peri-implant bone level and midbuccal mucosa level will remain stable in sites in which alveolar ridge preservation has been performed. The aforementioned study by Eghbali et al. (2018) also presented 5-year results and reported a peri-implant bone loss of 0.47mm which is remarkably stable compared to 1 year. Next to this, only a small extra recession, being 0.07 mm, of the midbuccal mucosa level took place. If the implant system in the present study acts the same as the one used in the study of Eghbali et al. (2018), prognosis is good towards 5 years results. However, despite both implant systems are tapered, one cannot automatically assume that both results will be the same. Both implants systems have their specific characteristics and surface topography. Therefore, it is worthwhile to extend the follow-up time of the present study to at least 5 years.

Conclusion

Within the limitations of this case series, it can be concluded that the Straumann Bone Level Tapered implant system, applied in the maxillary aesthetic region after alveolar ridge preservation and in combination with immediate provisionalization, is accompanied with a high survival rate, stable marginal bone levels and soft tissue levels, good aesthetic outcomes and high patient satisfaction one year after implant placement.

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6

Immediate placement and restoration of a new tapered implant system in the aesthetic region

a report of three cases

*This chapter is an edited version of the manuscript:
Meijndert CM, Raghoobar GM, Vissink A, Meijer HJA. Immediate Placement and
Restoration of a New Tapered Implant System in the Aesthetic Region: A Report of Three
Cases. Case Rep. Dent. 2020; 25; 7632692.*

Abstract

Aim: To assess the clinical, radiographic, aesthetic and patient centred outcomes of a tapered implant system applied for an immediate implant placement and restoration approach in single tooth replacement of anterior maxillary teeth.

Material and Method: Three cases were treated with a new bone level tapered implant. All patients were treated with the same strategy involving flapless extraction and implant placement with simultaneous augmentation. Implants were provisionally restored with a screw-retained restoration at the day of surgery. Definitive restoration was fabricated after 3 months. Follow-up was one year after definitive restoration.

Results: At the 1 year follow-up, the implants were stable and no complications had occurred. Peri-implant bone levels had increased with a mean value of 0.24 ± 0.30 mm between definitive restoration placement and 1 year of follow-up. Clinical outcome scores showed healthy soft tissues. Mean Pink and White Esthetic scores were rated 7.0 and 7.3, respectively. Mean patient satisfaction had improved from 55.7 (pre-treatment) to 90.0 (1 year follow-up) on a 0-100 VAS scale.

Conclusion: Immediate implant placement and restoration with the new tapered bone level implant system is accompanied by good initial clinical and radiographic results as well as high patient satisfaction.

Introduction

Implant placement and restorative procedures have evolved into a procedure that can be performed immediately after tooth extraction. This approach is less time consuming than the conventional procedure and leads to increasing patient contentment (Joshi & Gupta, 2015). This is especially beneficial in an aesthetically sensitive area like the anterior maxilla. Studies have shown that this procedure has an outcome comparable to the conventional implant placement and restoration protocols (Esposito et al., 2017; Slagter et al., 2014).

One of the key conditions for the success of an immediate implant placement and restoration approach is primary stability (Papaspnyridakos et al., 2014). Primary stability limits micro movement and allows osteogenic cells to adhere to the implant surface, leading to osseointegration (Rodrigo et al., 2010; Smeets et al., 2016). Factors that influence primary stability are the quality and quantity of bone, surgical techniques and implant design (Rao & Gill, 2012). If osseointegration is achieved, the next challenge is to maintain stable peri-implant hard and soft tissues. This too has been a topic of research. Amongst others, to reduce peri-implant bone resorption, improvements have been made at the implant-abutment connection by platform switching and by using an internal connection type (Pozzi et al., 2014). An internal conical connection is presumed to be accompanied by less peri-implant bone loss compared to either an external connection or a straight internal connection (Koutouzis, 2019, Caricauslo et al., 2018).

A new implant line has recently been presented by Straumann. The bone level implant is equipped with a deep cutting thread design and internal conical implant-abutment connection for high primary stability and minimal bone loss in fresh extraction sockets.

The aim of this case series study is to describe three cases with a failing tooth in the aesthetic region (p1-p1), that were treated with this implant system following an immediate implant placement and restoration protocol.

Materials and Methods

Study design

This report describes a prospective case series with a follow-up of one year. Recruitment of patients, implant treatment and follow-up took place at the Department of Oral and Maxillofacial Surgery of the University Medical Centre Groningen, the Netherlands.

Patients

Patients were eligible if they met the inclusion criteria; >18 year of age, adequate oral hygiene, non-smoking, no medical and general contraindications for the surgical procedure (ASA score $\geq$ III, Smeets et al. 1998), no periodontal pathology in the remaining dentition, indicated by bleeding on probing combined with pockets $\geq$ 4 mm. An intra-oral radiograph and a cone beam computer tomography (CBCT) were made to determine whether it was likely to expect that the implant would gain sufficient initial stability immediately after tooth removal. Recommendations of Buser et al. (2017) were followed concerning immediate implant placement, being: a fully intact facial bone wall at the extraction site with a thick wall phenotype (> 1 mm), a thick gingival phenotype, no acute infection at the extraction, and sufficient volume of bone apical and palatal of the extraction site to allow implant insertion in a correct 3D position with sufficient primary stability.

Three patients were included; two presented with an irreparable resorption defect in the root of the right central incisor and one patient was referred for replacement of a fractured left central incisor. One case is presented to illustrate. See **figure 1**. After detailed explanation of benefits and risks of possible treatment options, the patients chose an implant supported restoration to replace the failing central incisor. Written informed consents were obtained from the patients before enrolment. All patients were treated following the same immediate placement and restoration protocol as described below.

After inclusion

After inclusion an alginate impression was made and sent to the dental lab where a plaster model was fabricated. An open impression tray was printed based on a scanned version of the plaster cast and a surgical drilling template was manually produced according to the ideal position of the future crown. The preferred implant position was planned so that the restoration could be screw retained.

Figure 1. Initial situation before treatment of one of the included patients. Note the intact facial bone wall, having at least a thickness of 1 mm in the cervical region.

Surgical procedure

Patients started prophylactic antibiotic treatment one day before the surgery (Amoxicillin 500 mg, three times daily for 7 days) and twice a day a 0.2% chlorhexidine mouth rinse (Corsodyl; GlaxoSmithKline, Utrecht, the Netherlands). After administering local anaesthesia (Ultracaine D-S Forte; Aventis Pharma Deutschland GmbH, Frankfurt am Main, Germany), the periodontal fibers were separated from the tooth after which the affected tooth could be carefully removed without raising a flap. The alveolus was carefully inspected and cleaned of residual granulation tissue. The manufacturers drilling protocol was followed starting with the needle drill marking site of implant insertion as dictated by the (semi-guided) drilling template (**Figure 2a**). The surgeon ensured that the implant was positioned slightly palatal to the axis of the original root, for sufficient initial stability and ensuring a buccal bone thickness of at least 2 mm in the cervical region. The final implant drill was placed in the osteotomy as a space maintainer during augmentation of the gap between the drill and buccal wall. A 1:1 mixture of autologous bone (residual bone chips collected from the burs during osteotomy) and anorganic bovine bone (Geistlich Bio-Oss®, Geistlich Pharma AG) was used (**Figure 2b**). Next, the final drill was carefully removed and the implant (Straumann BLX implant, Strauman AG, Basel, Switzerland (**Figure. 3**)) was placed 3 mm apical to the most apical aspect of the prospective clinical crown. The implant was torqued to 45 Ncm. An implant-level open tray impression was made with a vinylpolysiloxane precision impression material (Provil Novo, Medium fast set. Kulzer Mitsui Chemical Group, Germany). The impression was sent to the dental lab for manufacturing the provisional restoration. A healing abutment was placed on the implant. A sterile re-absorbable gelatin sponge haemostat (Cutanplast®, Mascia Brunelli, Milan, Italy) was applied to seal the graft

material from the time of placement of the healing abutment until placement of the provisional restoration.

Figure 2. Sugical phase. a surgical template in place. b bone graft mixture added around the final drill. c. restoration at the same day as the implant placement.

Prosthetic procedure

At the end of the same day, the healing abutment was replaced by the provisional restoration (**Figure 2c**). The provisional consisted of a screw-retained, platform switched titanium stock abutment with an acrylic resin crown. The crown was under-contoured to allow the gingiva to regrow for better aesthetics at final crown stage. The temporary crown was torqued to 25Ncm and left to heal for 3 months. It was checked that there was no contact with antagonistic teeth during articulation. A CBCT was made to check the correct implant position (**Figure 4a**).

Figure 3. Straumann BLX implant RB. Roxolid® implant material with SLActive® surface. Full tapered core with bi-directional cutting threads, chipflute for redistribution of bone chips, microthreads on the implant neck to reduce stress at cortical bone. Conical implant abutment connection (TorxFit™). Courtesy of Straumann AG.

Two weeks after implant placement and temporary provisionalization, the patients were recalled for check-up (**Figure 4b**). None of the patients reported pain at the time of recall and only one patient reported having a bruised feeling at the day of implant surgery and one patient reported to have lost a few granulation particles but no major dehiscence was present.

After a 3 months healing period, an open tray implant level impression was made with a polyether precision impression material (Impregum Penta; 3 M ESPE, St. Paul, USA) for the purpose of a definitive restoration. The definitive restoration consisted of a titanium base with zirconium structure and porcelain crown. When the restoration was completed and patients were satisfied the crown was placed and tightened to 35Ncm torque and oral hygiene instruction were given. Patients were followed for 12 months after final crown placement (**Figure 4c,4d**).

Figure 4. A control CBCT at the day of implant placement. b Temporary crown 2weeks after placement. c, d: radiographic and clinical image 12 months after definitive crown placement

Follow-up

Recall was at 1 month (T_1) and 12 months (T_{12}) after the final restoration was placed. On these follow-up appointments, x-rays were made and clinical variables were measured. Bone level change was measured on a peri-apical radiograph on the mesial and distal side of the implant by drawing a line from the implant shoulder to the first bone to implant contact point. Change in midbuccal gingiva level was measured by drawing a (horizontal) line from the top of the midbuccal zenith of both natural lateral incisors and a second (vertical) line was drawn, perpendicular from the horizontal line to the mid buccal zenith of the tooth/implant crown. The length of this vertical line was measured (see figure 5). A periodontal probe was held close to, and parallel to the long axis of the implant crown, and was used as a calibration (Zuiderveld et al., 2018).

Table 1. Clinical, radiographic and patient centred outcomes.

	Mesial bone level change (mm) $T_1 - T_{12}^*$	Distal bone level change (mm) $T_1 - T_{12}^*$	Mean mid buccal gingiva level change (mm) T_{pre} to T_{12}	Mean pockets at T_{12} (mm)	Bleeding score at T_{12}	VAS-score patient satisfaction		PES		WES	
						T_{pre}	T_{12}	T_{pre}	T_{12}	T_{pre}	T_{12}
Case 1	0.00	0.00	+1.74	2.3	1	58	92	4	8	3	7
Case 2	+ 0.30	0.00	+0.73	3.5	2	56	87	8	8	6	7
Case 3	+ 0.11	+1.05	+0.32	2.3	0	53	91	na	5	na	8
Mean	0.24 ± 0.15	0.35 ± 0.61	0.93 ± 0.73	2.7	1	55.7	90.0	6.0	7.0	4.5	7.3

T_{pre} = situation before treatment, T_{12} = 12 months after definitive crown placement
na = not applicable

* positive value indicates that bone level was increased towards the implant shoulder. zero indicates bone depicted at or above the implant shoulder at both T_1 and T_{12} .
‡ positive value indicate an incisal displacement of the mid buccal zenith.

Clinical variables, being the bleeding score (modified Sulcus Bleeding index (Mombelli et al., 1987) and pocket probing depth (using the Clickprobe with standard pressure of 0.2-0.25N of KerrHawe Dental Corporation, Bioggio, Switzerland) were scored. Patient satisfaction was scored on a 0-100 mm VAS-scale. Aesthetic outcome was rated on intra-oral photographs using the modified Pink and White Esthetic Score (PES-WES) (Belser et al., 2009).

Results

Results of the outcome measures are depicted in **table 1**. No biological or technical complications had occurred during the whole follow-up time, all implants were stable and patients were very satisfied with the final result (survival rate 100%).

The peri-implant characteristics of the patient of case 1 started with a gross deviation in midbuccal zenith of 2.24 mm more apical compare to the contralateral incisor. This was improved at the T_{12} measurements, but a slight mismatch of 0.69 mm remained (**figure 5**). This did not bother the patient therefore no further treatment was initiated. Clinical assessment showed one isolated bleeding on probing at the disto-buccal implant site. Pocket probing measured at this site was 3 mm. Radiographs showed high attachment of the bone to the implant up to the implant shoulder.

Figure 5. An improvement (1.74 mm) of mid buccal zenith after one year compared to the situation before treatment

The peri-implant tissue of patient case 2 showed moderate peri-implant inflammation expressed by a confluent red line on probing, redness and slight edema of the gingiva sulcus. Pockets were ≤ 4 mm. Inflammatory signs were also detected at the neighbouring teeth showed by bleeding on probing and slight redness and edema of the sulcular borders and pockets ≤ 3 mm. Patient was pregnant at the time of T_{12} follow-up.

The patient described in case 3 started with no crown to score for PES/WES, therefore PES/WES was not rated prior to treatment. The patient was very satisfied with aesthetic and functional abilities at the 12-month follow-up. Bleeding on probing was not detected. The peri-apical radiograph showed good maturation of bone with minimal change in bone level.

Overall, implant survival rate was 100%. Mean bone level increased with 0.24 ± 0.30 mm. Mean PES score improved from score 4.0 at T_{pre} to 7.0 at T_{12} , WES improved from 3 at T_{pre} to 7.3 at T_{12} , patient satisfaction improved from 55.7 at T_{pre} to 90.0 T_{12} on the VAS scale. No technical or biological complications occurred up to 1-year follow up.

Discussion

This case series presents the results of three patients that were treated with the new Straumann BLX tapered bone level implant, immediately after tooth extraction.

After 15 months in function, both patient reported outcome and aesthetic score were much improved compared to the pre-treatment situation. The three patients presented with satisfying hard and soft peri-implant tissues.

Radiographic images 12 months after definitive crown placement (the implants were 15 months in function at this time) show a mean bone level change of $+0.24 \pm 0.30$ mm, which implies a bone 'gain'. De Bruyn et al. (2012) reported a bone change of +1.3 mm after 1 year in an immediate implant placement group. They attributed this bone gain to healing of the extraction socket. It is not unlikely that a similar mechanism applies here. The implant is also equipped with features that, in other studies, have shown to be favourable in the preservation of cortical bone around the implant. For example a platform switch (Hsu et al., 2017; Strietzel et al., 2015) and a conical implant-abutment connection (Mishra et al., 2017; Caricasulo et al., 2018;). There is not much known about the effect of the connection configuration on the aesthetic outcome in the anterior region. Cooper et al. (2019) compared three different connection configurations in the anterior region. They found the least bone loss in the conical connection group but found no statistical significant difference in the papillae level change or the PES score. They stated that more research on the effect of implant-abutment interface design is needed. This is also acknowledged by Barwacz et al. (2016).

The three studied patients in this report presented with satisfying improvements as expressed in a PES score of 7.0 and patient questionnaire score (VAS-scale score) of

90.0. This is in line with other studies on immediate placement and provisionalisation protocols, where PES scores of 7.5 ± 1.6 (Meijer et al., 2019) and 6.8 ± 1.5 (Zuiderveld et al., 2018) were published on immediate implant placement protocols. All patients reached the threshold of clinical acceptability (score ≥ 6) (Belser et al., 2009).

One patient was pregnant at the final follow-up and showed signs of inflammation around the implant and other natural teeth. There is a connection between increased plasma levels during pregnancy and gum disease (Chapple et al., 2018). Because the same inflammatory signs were present at the neighbouring teeth, it can be assumed that the marginal peri-implant soft tissues are affected due to the pregnancy hormones.

The initial results of this implant are favourable. However, this is a report of three patients followed for a short period of time. Studies with larger population and a longer follow-up are needed to view the stability of the facial hard and soft tissues in the long-term, as various studies have shown that hard and soft tissue alterations can be observed after many years in function (Kan et al., 2011; Cosyn et al., 2018; Raes et al., 2018).

Conclusion

Within the limitations of this study, it can be concluded that immediate implant placement and provisionalisation using this implant has the potential to result in favourable clinical, radiographic, aesthetic and patient satisfaction outcomes.

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Chapter 6

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7

The effect of implant-abutment connection on peri-implant bone levels around single implants in the aesthetic zone

a systematic review and a meta-analysis

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Abstract

Aim: To systematically review literature about the effect of different implant-abutment interface designs on peri-implant bone level changes, implant loss and mid-buccal mucosa changes around single implants placed in the anterior maxilla.

Methods: A detailed search was carried out in Pubmed, EMBASE, Cochrane, Scopus, Open Grey and African journals Online (until December 1, 2020). Eligible prospective studies were divided according to the internal implant-abutment configuration: i) platform switched conical (PS-conical), ii) platform switched parallel (PS-parallel) and iii) platform matched parallel (PM-parallel). Risk of bias was assessed with RoB 2.0 and ROBINS-I. A meta regression analysis was carried out primarily on the pooled peri-implant bone level changes and secondly on implant loss and mid-buccal mucosa level change. The manuscript complied with the PRISMA guidelines and was registered in the PROSPERO database (ID: 225092).

Results: A total of 5,513 hits gave 44 eligible articles for the analyses. Bone level change did not differ significantly between the PS-conical and PS-parallel connections, their bone losses were significantly lower compared to the PM connections, only the PS-conical has significant lower implant losses than the PM connections. Mid-buccal mucosa level change was comparable between the three connection configurations. Moderate to high risk of bias was detected in the included studies.

Conclusions: The performance of PS-conical and PS-parallel connection configurations are comparable and are accompanied with significantly less bone loss compared to PM-parallel connection configurations. All 3 connection types demonstrated mid-buccal mucosa changes that were small and did not differ significantly amongst the types.

Introduction

The range of implants used in restorative dentistry has become increasingly sophisticated and, simultaneously, more complex (Buser et al., 2017). The variation has become so large, that it is difficult for clinicians to choose between the available components (Shafie & White, 2014). One of these components is the implant-abutment connection configuration. A clear distinction can be made between external and internal implant-abutment connections. The external connection is used successfully for many years, but it is more susceptible to complications, such as abutment screw loosening (Gracis et al., 2012), bacterial leakage (Steinebrunner et al., 2005) and peri-implant bone loss (Koo et al., 2012), compared to the internal connection. The internal connection category has more geometric variations (Koutouzis, 2019). For example, the internal implant geometry is parallel-walled or conical/tapered. The parallel-walled connection types are often equipped with various indexing/anti-rotational features like an octagon or a hexagon, and exist with a platform switch or a platform match. A conical/tapered connection type implicates a cone-in-cone or has a conical portion in the inner cervical part, with or without indexing features in the apical part (Shafie & White, 2014).

All the previous mentioned variations were developed in an effort to reduce mechanical failure (Ceruso et al., 2017) and to minimize crestal bone resorption (Koutouzis, 2019). It is presumed that the long-term survival and success of implant treatment can be affected by peri-implant crestal bone resorption (Schwartz-Arad et al., 2005). This bone resorption can affect the stability of the mucosa, and may therefore affect the aesthetic outcome, which makes the implant-abutment connection particularly interesting in the aesthetic zone (Jemt, 1997; Furhauser et al., 2015; Belser et al., 2009). Eliminating, or at least reducing the amount of bacterial leakage could have a positive influence on peri-implant tissue stability, and thus on the aesthetic outcome. It has been suggested that an internal implant-abutment connection with a conical configuration is the most stable connection, with less bacterial leakage, than the other configurations (Zipprich et al., 2018).

In 2018, Caricasulo et al. (2018) performed a systematic review with a meta-analysis, on the difference between conical, internal and external connection configurations. They concluded that significantly less bone loss occurs with conical and internal connections compared to external connections. Although they did not distinguish between platform switching and platform matching, they concluded, after performing an additional analysis, that a platform switch might be of more importance in preserving peri-implant bone levels than the connection configuration itself. The finding that

platform switching might have a positive effect on preserving peri-implant bone levels was also mentioned by Hsu et al. (2017). However, Caricasulo (2018) and Hsu (2017) did not focus specifically on the aesthetic region or on a possible effect on the aesthetic outcome.

Vetromilla et al. (2019) did perform a systematic review on implant abutment connections in the aesthetic region. They concluded from the PES/WES that the internal hexagon performs better aesthetically, but were not able to quantify their observations. Additionally, they did not distinguish between platform-switched and platform-matched connections, but this might be a noteworthy nuance when considering Caricasulo's (2018) outcome.

Since the aesthetic outcome of a restoration in the aesthetic region is so important, it would be interesting to know if the implant abutment connection can contribute to achieving the best possible results. So far, to the best of our knowledge, a systematic review with a meta-analysis of the effect of solely internal connections in the aesthetic region, distinguishing between platform switching and –matching, is not available.

Therefore, the aim of our systematic review was to determine whether the type of implant connection configuration, i.e. platform switched conical connections (PS-conical), platform switched parallel connections (PS-parallel) or platform matched parallel connections (PM-parallel), has a significant impact on peri-implant bone changes, whether an implant-abutment connection influences implant survival, and whether the stability of the mid-buccal mucosa level, as a factor determining the aesthetic outcome, is influenced by the connection configuration.

Materials and Methods

Research protocol

This systematic review was conducted following the Cochrane Handbook for systematic reviews and was reported according to the PRISMA Statement guidelines 2009 (Moher et al., 2009). The protocol of this systematic review was entered under the PROSPERO registration number: ID: 225092. The research question was formulated by means of a PICO:

P - single titanium implants in the maxillary aesthetic region

I - conical implant-abutment connections

C - parallel walled implant-abutment connections with and without a platform switch

O - peri-implant bone level change

The primary outcome is peri-implant bone level change and the secondary outcome are implant loss and mid-buccal mucosa level change.

Information sources

We conducted a literature research of the following databases: PubMed, Cochrane Library EMBASE Scopus, Open Grey and African journals Online. According to the syntax rules of each database, key words and their combinations were used to identify studies published until December 2020. No time restrictions were applied (**Table 1**).

Table 1. Description of the search strings per search bank

Pubmed	1673 hits
("Dental Implants, Single-Tooth"[Mesh] OR (implant*[tiab] AND (single[tiab] OR solitary[tiab]))) AND ("Maxilla"[Mesh] OR "Esthetics, Dental"[Mesh:NoExp] OR esthetic*[tiab] OR aesthetic*[tiab] OR anterior[tiab] OR maxilla*[tiab] OR incisor*[tiab] OR front*[tiab]) AND ("Alveolar Bone Loss"[Mesh] OR bone[tiab]) AND ("Clinical Trial" [Publication Type] OR "Cohort Studies"[Mesh] OR "Case Reports" [Publication Type] OR "Observational Study" [Publication Type] OR "Treatment Outcome"[Mesh:NoExp] OR "Comparative Study" [Publication Type] OR random*[tiab] OR trial[ti] OR outcome*[tiab] OR cohort[tiab] OR follow-up[tiab] OR followup[tiab] OR prospectiv*[tiab] OR longitudinal*[tiab] OR case ser*[tiab])	
Embase	1539 hits
('single tooth implant'/exp OR (implant* AND (single OR solitary)):ab,ti) AND ('maxilla'/exp OR 'esthetics'/exp OR (esthetic* OR aesthetic* OR anterior OR maxilla* OR incisor* OR front*):ab,ti) AND ('alveolar bone loss'/exp OR bone:ab,ti) AND ('clinical study'/exp OR 'observational study'/exp OR 'cohort analysis'/exp OR 'comparative study'/exp OR 'treatment outcome'/de OR trial:ti OR (random* OR outcome* OR cohort OR 'follow-up' OR followup OR prospectiv* OR longitudinal* OR 'case ser*'):ab,ti)	
Cochrane	527 hits
(implant* AND (single OR solitary)) AND (esthetic* OR aesthetic* OR anterior OR maxilla* OR incisor* OR front*) AND (bone)	
Scopus	1626 hits
(TITLE-ABS-KEY (implant* AND (single OR solitary))) AND (TITLE-ABS-KEY (dental OR tooth OR teeth OR crown*)) AND (TITLE-ABS-KEY (esthetic* OR aesthetic* OR anterior OR maxilla* OR incisor* OR front*)) AND (TITLE-ABS-KEY (bone)) AND(TITLE-ABS-KEY ("clinical trial*" OR prospectiv* OR cohort* OR "case report*" OR "case stud*" OR observational* OR "follow-up" OR followup OR random* OR outcome* OR longitudinal* OR "case ser*" OR "clinical stud*" OR "controlled stud*"))	
Open Grey	24 hits
single implant	
African journal Online	145 hits
dental AND implant AND single AND maxilla AND bone	

The following study criteria were handled:

Inclusion criteria:

- Human subjects included in the studies should be ≥ 18 years of age;
- Titanium, bone level implants;
- Implants supporting single crowns placed in the anterior region of the maxilla (second premolar to second premolar);
- Only healed sites (at least 3 months healing time after extraction);
- Follow-up of at least 1 year after implant placement;
- Detailed information on bone level changes measured on peri-apical radiographs;
- Randomized clinical trials or prospective clinical studies with a minimum sample of 10 participants per study-group.

Exclusion criteria:

- External implant-abutment connections;
- No details of the implant type;
- Did not report bone level changes;
- Bone level measurements obtained with cone beam computer tomography (CBCT) or orthopantomograms;
- Animal studies, in vitro studies, retrospective studies, reviews.

Study selection

Two reviewers (C.M.M., H.J.A.M.) independently screened the results from the electronic searches, according to the inclusion and exclusion criteria, in two rounds. Articles were first screened by title and abstract. In case of disagreement or doubt, the study was moved to the next round (full text assessment). The Cohen's κ and percentage of agreement were calculated to determine the measure of agreement between the two reviewers. Any disagreement regarding the inclusion was resolved by a consensus discussion. In case of persistent disagreement, an external independent reviewer (G.M.R) with experience in implant dentistry could be consulted.

Quality assessment

Methodological quality and risk of bias were assessed using the Cochrane risk of bias tool (RoB 2.0) (Sterne et al., 2019) for randomised controlled trials and the ROBINS-1 tool (Sterne et al., 2016) for prospective clinical non-randomised trials by the same two reviewers (C.M.M., H.J.A.M.), independently. Any disagreement was resolved by consensus between the reviewers.

Data extraction

Following a pre-specified form, the following data were extracted cooperatively by C.M.M. and H.J.A.M.: authors, year of publication, study design, follow-up time, type of implant, type of implant-abutment connection, number of implants, number of implant failures, bone level changes and, if available, additional data on the mid-buccal mucosa level changes. It was decided to group the studies according to the properties of the internal configuration. When an implant connection was fully or partially conical/tapered along the inner wall of the implant body and the corresponding portion of the abutment, the implant was classified as conical and placed in the 'platform switched conical' group (PS-conical). Any connection where the inner portion of the implant and abutment was parallel-walled were classified based on the presence or absence of a platform switch and were placed accordingly into either the 'platform switch parallel' (PS-parallel) or 'platform matched parallel' group (PM- parallel).

Statistical analysis

Inter-observer agreement was calculated with IBM SPSS Statistics 20 (SPSS, Chicago, Illinois, USA). Publication bias was assessed by plotting the log odds ratio against its standard error. Pooling of bone loss, implant survival and mid buccal mucosa changes was performed by using the software Comprehensive Meta-Analysis, Version 3.3.070 (CMA, Biostat, Englewood, NJ 07631, USA). A random effects model was used on the pooled outcomes. To analyse sources of heterogeneity between studies, a meta-regression analysis (random effects model) was performed on the connection types, i.e., PS-conical, PS-parallel and PM-parallel.

Results

Study identification and selection

The study selection procedure is summarised in **figure 1**. A total of 5,513 publications was identified after the electronic and hand search, up to the 1st of July 2020. After discarding the duplicates from the output, a total of 2,395 publications underwent title abstract selection whereupon 2,071 did not meet the inclusion criteria. A total of 324 articles remained for full-text analysis and, of these, 281 did not meet the in- and exclusion criteria, or they were a follow-up of an earlier study. A last update was done on the 1st of December 2020 and, of the 111 new results, 1 was suitable for analysis. A total of 44 publications was finally included for data extraction. There was substantial

agreement between the two reviewers' judgements, $\kappa=0.76$, (93.9% agreement) at title/abstract selection. At full text selection, this agreement was also substantial, $\kappa=0.75$, (91.4% agreement). There was no need to consult the third reviewer in any of the study selection phases.

Figure 1. Study identification and selection process.

Description of the selected studies

The search results yielded 24 non-randomised clinical trials (nRCTs) and 20 randomised clinical trials (RCTs). The studies' median follow-up was 1 [1;5] year (ranging from 1-10 years). Detailed data from the included studies is listed in **Table 2**. If an article reported data on two groups, but the same connection type was used, the groups were pooled. When an article reported data from two groups with different connection types, the groups were viewed separately. Consequently, a total of 31 groups (1105 implants) had PS-conical connections, 5 groups (124 implants) had a PS-parallel connection, and 12 groups (356 implants) had a PM-parallel connection.

Table 2. Characteristics and outcomes of the included studies.

First author et al.,	publication year	Follow-up time (years)	Study type	Implant type	no of implants	Annual implant loss (%)	Annual bone level change in mm (mean±sd)	Annual mid-buccal level change in mm. (mean±sd)
Kemppainen et al.	1997	1	RCT	Astra Tech ST	35	2	-0.14±0.10	nr
Palmer et al.	2000	5	Prosp. study	Astra Tech ST	14	0	0.02±0.10	nr
Cooper et al.	2001	1	Prosp. study	Astra Tech ST	53	4	-0.40±0.51	0.34±0.94
Norton	2004	1	Prosp. study	Astra Tech ST	11	4	-0.55±0.49	nr
Cooper et al.	2007	3	Prosp. study	Astra Tech ST	43	2	-0.14±0.32	0.17±0.47
Goffredsen	2012	10	Prosp. study	Astra Tech ST	10	0	-0.09±0.04	nr
Vanlioglu et al.	2012	5	Prosp. study	Astra Tech OsseoSpeed	10	0	-0.05±0.01	nr
Bashutski et al.	2013	1	RCT	Astra Tech OsseoSpeed	24	8	-0.53±0.51	nr
Grandi et al.	2013	1	Prosp. study	JD Evolution	24	4	-0.60±0.51	nr
Berberi et al.	2014	5	Prosp. study	Astra Tech OsseoSpeed	20	0	-0.04±0.03	nr
Cooper et al.	2014	5	Prosp. study	Astra Tech OsseoSpeed	49	0	0.02±0.26	0.08±0.21
Vanlioglu et al.	2014	1	Prosp. study	Straumann Bone Level implant	55	0	-0.10±0.08	nr
Cosyn et al.	2015	1	Prosp. study	Nobel Active	50	0	-0.48±0.46	0.06±0.60
Esposito et al.	2015	1	RCT	Mega Gen, EZ Plus	46	0	-0.27±0.14	nr
Raes et al.	2015	2	Prosp. study	Astra Tech OsseoSpeed	85	2	0.02±0.45	0.10±0.45
Hsu et al.(a)	2016	1	RCT	SuperLine Dentium	13	0	-0.21±0.56	-0.38±0.49
Slagter et al.	2016	1	RCT	Nobel Active	20	0	-0.65±0.46	nr
Yildiz et al.	2016	1	Prosp. study	Straumann Bone Level implant	29	7	0.08±0.82	nr
Allen et al.	2017	2	Prosp. study	Straumann Bone Level implant	20	0	-0.41±0.26	nr
De Bruyckere et al.	2018	1	RCT	Nobel Active	42	0	-0.60±0.69	-0.18±0.33
Eghbali et al.	2018	5	Prosp. study	Nobel Active	32	0	-0.09±0.08	-0.02±0.07
Jonker et al.	2018	1	RCT	Straumann Bone Level implant	43	2	-0.42±0.55	nr
Raes et al.	2018	8	Prosp. study	Astra Tech OsseoSpeed	18	0	-0.06±0.24	nr
Zuiderveld et al.	2018	1	RCT	Nobel Replace CC	40	0	-0.02±0.11	-0.11±1.19
Cooper et al.(a)	2019	3	RCT	Astra Tech OsseoSpeed	45	0	-0.04±0.17	0.07±0.23
Friberg et al.	2019	1	Prosp. study	Nobel Parallel CC	22	2	-0.41±0.36	nr
Heydecke et al.	2019	3	Prosp. study	Nobel Replace CC	90	0	-0.29±0.17	nr
Hosseini et al.	2019	5	Prosp. study	Astra Tech EV	33	0	-0.02±0.07	0.07±0.11
Meijndert et al.	2019	5	Prosp. study	Straumann Bone Level implant	50	0	-0.03±0.13	nr
Zuiderveld et al.	2019	1	Prosp. study	Nobel Replace CC	40	0	0.05±0.44	-0.04±0.28
Wittneben et al.	2020	3	RCT	Straumann Bone Level implant	39	0	-0.10±0.17	nr

P5-conical

Table 2. (Continued)

	First author et al.,	publication year	Follow-up time (years)	Study type	Implant type	no of implants	Annual implant loss (%)	Annual bone level change in mm (mean±sd)	Annual mid-buccal level change in mm. (mean±sd)
P5-parallel	Canullo et al.	2013	2	RCT	Sweden&Martina Premium SP	20	0	-0.17±0.20	nr
	Canullo et al.	2016	5	RCT	Sweden&Martina Premium SP	30	0	-0.09±0.07	0.08±0.11
	Canullo et al.	2018	5	Prosp. study	Sweden&Martina Premium SP	22	0	-0.06±0.06	nr
	Cooper et al.(b)	2019	3	RCT	Biomet 3i, NanoTite Certain Prevail	32	5	-0.35±0.17	0.10±0.23
	Lowy et al.(a)	2019	1	RCT	BioHorizons Tapered Plus	20	0	-0.05±0.21	0.10±0.70
	Raghoobar et al.	2009	1	RCT	Nobel Replace Groovy	45	0	-0.54±0.13	-0.63±1.63
PM-parallel	Fu et al.	2014	1	RCT	Tapered Screw-Vent	26	0	-1.28±0.91	nr
	Felice et al.	2015	1	RCT	Dentsply Friadent, XIVE S plus	23	0	-0.19±0.10	nr
	Meloni et al.	2015	1	RCT	Nobel Replace Tapered	30	0	-0.87±0.19	nr
	Den Hartog et al.	2016	5	RCT	Nobel Replace Tapered Groovy	27	1	-0.03±0.10	nr
	Guarnieri et al.	2016	3	Prosp. study	BioHorizons Tapered Internal	13	0	-0.14±0.07	-0.01±0.04
	Hsu et al.(b)	2016	1	RCT	Zimmer dental, Tapered Screw-Vent	13	0	-0.74±0.47	nr
	Den Hartog et al.	2017	5	RCT	Nobel Tapered Groovy	54	0	-0.25±0.20	nr
	Gjelvold et al.	2017	1	RCT	BioHorizons Tapered Internal	50	2	-0.63±0.54	0.21±0.46
	Cooper et al.(c)	2019	3	RCT	Nobel Speedy Replace	34	5	-0.34±0.17	nr
	Lowy et al.(b)	2019	1	RCT	BioHorizons Internal	20	0	-0.65±0.59	0.50±0.90
	Gjelvold et al.	2020	1	Prosp. study	BioHorizons Tapered Internal	21	2	-0.4±0.41	-0.02±0.36

Risk of bias

ROBINS-1 was used on the prospective non-randomised trials and the domain with a high risk of bias was 'bias due to confounding'. Low risk of bias was detected in 'bias due to deviations from intended interventions' and in 'bias in selection of the reported result'. Five studies had a high risk of bias on at least one domain (20.8%), 15 studies had a moderate risk of bias on at least one domain (62.5%), and 4 studies had a low risk of bias (16.7%). See **supplementary figure 1**.

RoB-2.0 was applied to the RCTs and a high risk of bias was seen in the domain 'bias due to deviations from intended interventions'. Low risk of bias was detected in the domain 'bias due to missing outcome data'. Eighteen studies had a high risk of bias on at least 1 domain (90%), and the remaining two studies had low risk of bias (10%). See **supplementary figure 2**.

Publication bias

The funnel plot showed no studies on the lower right part of the plot, indicating a possibility of publication bias. See **supplementary figure 3**.

Quantitative synthesis

i. Bone level change

All the study groups reported bone level changes ($n=48$). The pooled bone level change per year for all the groups was -0.24 mm (95% CI: -0.27 to -0.20). In the PS-conical group, it was -0.16 mm (95% CI: -0.19 to -0.13), while in the PS-parallel group it was -0.14 mm (95% CI: -0.3 to -0.06) and in the PM-parallel group it was -0.48 mm (95% CI: -0.63 to -0.32).

A meta-regression analysis revealed that the differences in bone change per year were statistically significant between the two platform switched and the platform matched group; PS-conical vs. PM-parallel ($p=0.00$), PS-parallel vs. PM-parallel ($p=0.00$). The difference between the conical and parallel platform switched groups ($p=0.52$) was not significant. The Forest plots of the random effects meta-analysis are depicted in **figures 2-4**.

Figure 2. Forest plots for random effects meta-analysis of studies evaluating bone level change in the PS-Conical group

ii. Implant loss

Forty-seven study groups reported on implant survival. The percentage of pooled implant loss per year was 0.19 (95% CI: 0.16-0.21) with 0.13 (95% CI: 0.10-0.16) in the PS-conical group, 0.22 (95% CI: 0.12-0.33) in the PS-parallel group, and 0.73 (95% CI: 0.55-0.91) in the PM-parallel group.

A meta-regression analysis revealed a significant statistical difference in implant loss between the PS-conical and the PM-parallel groups. There was no statistical difference found when PS-conical vs. PS-parallel ($p=0.79$) and PS-parallel vs. PM-parallel ($p=0.10$) were analysed. Forest plots of the random effects meta-analysis are depicted in **supplementary figure 4**.

Figure 3. Forest plots for random effects meta-analysis of studies evaluating of bone level change in the PS-parallel group

Figure 4. Forest plots for random effects meta-analysis of studies evaluating of bone level change in the PM-parallel group

iii. Mid-buccal mucosa level changes

Twenty study groups reported changes in mid-buccal mucosa level, viz., 12 in the PS-conical group, 3 in the PS-parallel group, and 5 in the PM-parallel connection group. The groups' pooled mid-buccal mucosa level change per year was 0.05 mm (95%CI: 0.01 to 0.08), composed of 0.04 mm (95%CI: -0.02 to 0.09) in the PS-conical group, 0.08 mm (95%CI: 0.05 to 0.12) in the PS-parallel group, and 0.04 mm (95%CI: -0.08 to 0.16) in the PM-parallel group. A meta-regression analysis revealed no statistically significant difference between the three groups. Forest plots of the random effects meta-analysis are depicted in **supplementary figure 5**.

Discussion

The results of this systematic review reveal a relationship between the type of implant-abutment connection configuration and peri-implant bone loss around implants placed in the anterior region of the maxilla. The PS-conical and PS-parallel connection configurations are comparable with less peri-implant bone loss than PM-parallel connections. The presence of a platform switch seems to have more influence on bone loss than the internal connection configuration itself.

In the present review, PS-conical and PS-parallel connection configurations result in significantly less peri-implant bone loss than the PM-parallel connections. Although the Caricasulo (2018), Vetromilla (2019) and Yu (2020) studies confirmed that the least amount of bone loss occurs with conical connections, only Caricasulo (2018) researched the effect of platform switching. They found 0.30 mm more bone loss on applying PM connections than the PS-conical connection (significant), and that the PS-parallel only resulted in 0.05 mm more bone loss than the conical connections (not significant). This is in agreement with our study's outcome where there is no significant difference between the platform switched (PS) connection, but the difference with the platform matched (PM) is significant. Both Vetromilla (2019) and Yu (2020) did not look into the effect of platform switching which might explain why Yu (2020) found a significant difference between the conical and the non-conical group and why Vetromilla (2019) found fairly high amounts of bone loss in the internal-connection group (0.7 mm). This is closer to the 0.52 mm bone loss we found in our PM groups than to the 0.14 mm bone loss in our PS groups. Hsu et al. (2017) did compare platform-switching with platform-matching. They concluded that platform switched connections are accompanied with less peri-implant bone loss than the platform matched connections. Comparing the results of previous authors (Hsu et al., 2017; Caricasulo et al., 2018; Vetromilla et al., 2019; Yu et al., 2020) with the present review reveals that platform-switching plays an important protective role in preserving the level of peri-implant bone. Perhaps, supported by the Caricasulo (2018) results, it can even be cautiously stated that the presence of a platform switch has more influence on bone level change than the presence or absence of a conical component in the connection.

According to our study, in contrast to bone level change platform switching seems to have little influence on the mid-buccal mucosa level. However, it must be noted that this is based on 3 PS-parallel groups and 5 PM-parallel groups, compared to 12 PS-conical groups. This uneven distribution might affect the statistical power of the meta-analysis. When searching for studies that compared implant abutment connections in

the aesthetic region, only 1 RCT (Cooper et al., 2019) was set up in the anterior maxilla and reported no statistically significant differences between the 3 connection types concerning mid-buccal mucosa changes. The overall mid-buccal retractions in both the PS-conical, PS-parallel and PM-parallel groups were small and the differences were negligible.

Although there are statistically significant differences between the abutment connection configurations, all three types' clinical and radiographic results are good. All the reported bone loss, implant loss and mid-buccal mucosa level change results are within the range of what is deemed acceptable. However, long term stability is important, especially the durability of an aesthetically good result, hence the authors favoured the internal connections with a platform switch over the connections with a platform match. Yet, the included studies only had a relatively short follow-up (mostly 1 year) and since the tissues around implants change continuously, albeit only a little, it would be useful to re-evaluate the previous statement when more long-term studies are available.

Strength and limitations

The strength of this meta-analysis is the broad and detailed literature search in multiple databases. A limitation to this study is that the quality of the reporting in the included studies was weak and the median follow-up time was short (1 [1;5] year). Also, the meta-analysis was done for variables that can be measured in many ways (in particular bone level change and mucosa level change) and are subject to confounding factors (such as surgical and restoration protocol and implant geometry) and was thus subject to heterogeneity, which means that the outcome must be viewed with caution. Another limitation is the decision to calculate annual bone loss, annual implant loss and annual mucosa change rates which, although good for comparability purposes, resembles a linear relation that assumes that the same quantity of bone, implants or mucosa is lost every year. Yet, in real life, most remodelling takes place in the first year, and only a few changes in the years thereafter. We accepted this limitation in order to perform a meta-analysis and this approach is commonly accepted in the dental implant literature, but one should still interpret the results with caution.

Recommendations for future research

Due to a lack of well-designed RCTs and high quality studies, additional well designed studies are needed to be able to truly rate the effect of different implant-abutment connections in the aesthetic zone. We therefore encourage efforts to come to a

consensus on how to measure and report clinical and radiographic variables, as well as aesthetic ratings, accurately and homogenously.

Conclusion

The performance of conical and parallel connection configurations with a platform switch is comparable regarding peri-implant bone loss and implant loss when applied to solitary implant restorations in the aesthetic zone. Parallel walled platform matched connections showed the most bone level change and implant loss. None of the connection configurations is significantly better at preserving the mid-buccal mucosa levels.

	Risk of bias domains							
	D1	D2	D3	D4	D5	D6	D7	Overall
Palmer et al. 2000	+	-	+	+	+	-	+	-
Cooper et al. 2001	-	-	+	+	+	-	+	-
Norton 2004	-	+	+	+	+	-	+	-
Cooper et al. 2007	-	-	+	+	+	-	+	-
Gotfredsen 2012	✗	+	-	+	+	-	+	✗
Vanlioglu et al. 2012	+	+	+	+	+	-	+	-
Grandi et al. 2013	+	✗	✗	+	+	-	+	✗
Berberi et al. 2014	+	+	+	+	+	+	+	+
Cooper et al. 2014	-	-	+	+	+	-	+	-
Vanlioglu et al. 2014	+	+	+	+	+	+	+	+
Cosyn et al. 2015	-	+	+	+	+	+	+	-
Raes et al. 2015	+	+	+	+	-	+	+	-
Guarnieri et al. 2016	+	✗	+	+	+	-	+	✗
Yildiz et al. 2016	-	-	-	+	+	-	+	-
Allen et al. 2017	-	+	+	+	+	-	+	-
Canullo et al. 2018	+	+	+	+	+	+	+	+
Eghbali et al. 2018	+	+	+	+	+	+	+	+
Raes et al. 2018	+	+	+	+	-	+	+	-
Friberg et al. 2019	✗	+	+	+	+	+	+	✗
Heydecke et al. 2019	+	+	+	+	-	-	+	-
Hosseini 2019	✗	+	-	+	+	-	+	✗
Meijndert et al. 2019	+	+	+	+	-	-	+	-
Zuiderveld et al. 2019	+	+	+	+	+	-	+	-
Gjelvold et al. 2020	-	+	+	+	+	-	+	-

Domains:
D1: Bias due to confounding.
D2: Bias due to selection of participants.
D3: Bias in classification of interventions.
D4: Bias due to deviations from intended interventions.
D5: Bias due to missing data.
D6: Bias in measurement of outcomes.
D7: Bias in selection of the reported result.

Judgement
✗ Serious
- Moderate
+ Low

Supplementary 1. Visualization risk-of-bias assessments ROBINS-1 for prospective non-randomised trials

		Risk of bias domains					
		D1	D2	D3	D4	D5	Overall
Study	Kemppainen et al. 1997	-	-	+	X	-	X
	Raghoobar et al. 2009	+	X	+	-	+	X
	Bashutski et al. 2013	-	X	+	+	+	X
	Canullo et al. 2013	+	+	+	+	+	+
	Fu et al. 2014	-	X	+	-	X	X
	Esposito et al. 2015	+	X	+	+	+	X
	Felice et al. 2015	+	X	+	+	+	X
	Meloni et al. 2015	+	X	+	+	+	X
	den Hartog et al. 2016	+	X	+	X	+	X
	Hsu et al.2016	-	X	+	-	+	X
	Slagter et al. 2016	-	X	+	+	+	X
	Canullo et al. 2017	+	+	+	+	+	+
	den Hartog et al. 2017	+	X	+	X	+	X
	Gjelvold et al. 2017	+	X	+	-	+	X
	Witneben et al. 2017	+	X	+	+	+	X
	De Bruyckere et al. 2018	+	X	+	-	+	X
	Jonker et al. 2018	+	X	+	+	+	X
	Zuiderveld et al. 2018	+	X	+	+	+	X
	Cooper et al. 2019	+	X	+	X	+	X
	Lowy et al. 2019	+	X	+	-	+	X
Domains:							Judgement
D1: Bias arising from the randomization process							X High
D2: Bias due to deviations from intended intervention.							- Some concerns
D3: Bias due to missing outcome data.							+
D4: Bias in measurement of the outcome.							
D5: Bias in selection of the reported result.							

Supplementary 2. Visualization risk-of-bias assessment RoB-2.0 for randomised controlled trials

Supplementary 3. Funnel plot of standard error by log odds ratio.

Supplementary 4. Forest plots for random effects meta-analysis of studies evaluating implant loss in the PS-Conical group

Forest plots for random effects meta-analysis of studies evaluating implant loss in the PS-parallel group

Forest plots for random effects meta-analysis of studies evaluating implant loss in the PM-parallel group

Supplementary 5. Forest plots for random effects meta-analysis of studies evaluating mid-buccal mucosa level change in the PS-Conical group

The effect of implant-abutment connections on peri-implant bone level change

Forest plots for random effects meta-analysis of studies evaluating mid-buccal mucosa level change in the PS-parallel group

Forest plots for random effects meta-analysis of studies evaluating mid-buccal mucosa level change in the PM-parallel group

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8

General discussion and conclusions

The general aim of the research described in this thesis was to assess the outcomes of treating a missing tooth in the aesthetic region with an implant, following short and long term outcome up to a decade of treatment. Patients treated in the various studies in this thesis had different grades of alveolar bone resorption, and requested implant therapy for one missing or failing tooth. A variety of dental implant designs within the portfolio of one implant brand were applied. In general it can be said that the implant survival rates in the studies described in this thesis were high, the peri-implant bone levels were stable, the peri-implant soft tissues were healthy and the aesthetic outcomes were satisfying, in both the healed and post-extraction sites.

Peri-implant bone level change

Tissue-level implants

In the longest running study described in this thesis (10 years), a tissue level implant was used in augmented healed sites. Tissue level implants were initially designed to respect the biological width. The results in this study showed minor bone loss after 10 years (0.48 mm), which is comparable to the marginal bone loss reported by other 10-year studies of the aesthetic region (0.66 mm, Jemt, 2008; 0.75 mm Gotfredsen, 2012). These favorable outcomes confirm the efficiency of this concept (**Chapter 2**). A disadvantage of a tissue level implant, especially when it is applied in the aesthetic region, is that it leaves little opportunity to design a personalised emergence profile for each abutment. The silver metal collar of the implant 'may' become visible around the gum line, which is a concern in the aesthetic region. Placing a tissue level implant deeper to overcome the risk of a visible metal collar was proven not to be a solution: the polished part in contact with the peri-implant bone led to crestal bone resorption and did not result in better coverage of the implant neck with mucosa (Hämmerle et al., 1996; Buser & Von Arx, 2000). In an attempt to overcome this limitation, there has been a shift from using tissue level implants to using bone level implants.

Bone level implants

The bone level implants used by the studies described in this thesis were placed in healed sites and showed negligible marginal bone loss after 5 years (0.13 mm) (**Chapter 3**). The more recent bone level implants (with a tapered implant body) that were placed in healed sites were also accompanied by negligible marginal bone loss after 1 year in function (-0.07 mm) (**Chapters 4 and 5**). Comparable results were reported in the

literature (after 1 year: -0.10 mm, Vanlioglu, 2014; after 5 years: -0.12 mm, Hosseini et al., 2020; -0.19 mm, Berberi et al., 2014) but, in other studies, the marginal bone loss was slightly higher (after 1 year: -0.48 mm, De Bruyckere et al., 2018; -0.3 mm, Levine et al., 2019; after 5 years: -0.43 mm, Canullo et al., 2018; -0.47 mm, Eghbali et al., 2018). This discrepancy in marginal bone loss between studies might, amongst others, be related to the timing of the baseline measurement. The most marginal bone loss, probably as a result of bone remodeling, occurs in the first few months after implant placement (Pariente et al., 2020). When measuring the baseline after completing the prosthetic phase, for example in a delayed or conventional restoration protocol, the initial bone healing part is left out of the calculations. Another reason that could explain the discrepancy in bone loss between studies could be the implant abutment connection configuration applied in those studies. They all used platform switched internal conical connections. The fit and tightness of a connection between an implant and abutment can reduce micromovement and bacterial colonization at the interface, and hereby reducing bone loss at the crest. An internal, platform switched connection is accompanied by less marginal bone loss than an external or platform matched connection (Hsu et al., 2017; Caricasulo et al., 2018; **Chapter 7**). It has to be mentioned, however, that the 1-year differences in marginal bone loss observed between the various implant abutment connections are probably clinically irrelevant in the short term, but might become clinically relevant after a longer follow-up.

Alveolar ridge preservation – delayed implant placement

When implant treatment is not applicable yet at the time of tooth extraction, it is advised to perform alveolar ridge preservation immediately after tooth extraction (Cosyn et al., 2013; Benic et al., 2014). The studies described in this thesis used autologous bone combined with anorganic bovine bone particles. **Chapter 2** demonstrates that there is no difference in marginal bone level changes with respect to the augmentation material applied to the alveolar reconstructions (autologous chin bone or anorganic bovine bone particles). We learnt from the study described in **chapter 3** that there were no differences in peri-implant marginal bone level changes, either after 1 year, as described by Santing et al. (2013) or after 5 years in function, between the augmented and the non-augmented sites. Apparently, implants placed in healed sites comprised of native bone or of reconstructed bone behaved comparably in this respect, and both conditions were accompanied by satisfying aesthetics.

According to Jung et al. (2018), the goal of alveolar ridge preservation is to avoid further augmentative procedures. Yet, it is important to note that in our and Zuiderveld's

studies, a fair number of the implant shoulders were not covered sufficiently or had a thin facial bone wall thickness at implant placement, leading to a risk of soft tissue recession (Zuiderveld et al., 2019). Hence, alveolar ridge preservation does not rule out entirely that no additional augmentation is needed to achieve a satisfying aesthetic outcome. However, the additional augmentation is usually minor and can be performed with bone scrapes from the osteotomy bur, mixed with a bone substitute, thus avoiding donor site surgery and the associated morbidity.

Alveolar ridge preservation – immediate implant placement

Alveolar ridge preservation is also advised when placing implants in fresh extraction sockets (Jung et al., 2018). The rationale behind combining these two procedures is that alveolar ridge preservation reduces the alveolar ridge resorption and thus avoids soft tissue recession compared to an unassisted healed socket with immediate implant placement. The indication for a treatment is somewhat under debate as some authors pose that bonefill will also occur spontaneously when the horizontal infra-bony defect size is <2mm and the buccal bone wall is intact (Benic et al., 2014; Naji et al., 2020). Considering the aesthetic risk associated with the unpredictability of the resorption patterns, we decided to combine immediate implant placement with alveolar ridge preservation in the aesthetic region (**Chapter 6**). We added a mixture of autologous bone and demineralized bovine bone in the gap between the implant and the facial bone wall. The first results were promising in this small case series, but larger studies with a longer follow-up are needed.

Peri-implant soft tissues

Peri-implant mucosa level change

Peri-implant mucosa level stability is of utmost importance in the aesthetic region. It is aesthetically pleasing when the mucosa around a prosthetic crown is in harmony with the mucosa around the natural neighbouring dentition.

Buser et al. (2004) found that the thickness of the buccal bone at the implant site plays a fundamental role in the aesthetic predictability of the rehabilitation. A buccal bone plate of >1.5mm is less prone to resorption (Zheng et al., 2020) and less prone to mid-buccal mucosa recessions (Farronato et al., 2020). All the studies described in this thesis aimed to have at least 2 mm of bone at the buccal side of the implant during implant placement. This might explain the minor change in mid-buccal mucosa

level observed in the 1, 5 and 10 year follow-up studies (**Chapter 2-6**). However, we did not measure the actual buccal bone thickness during the follow-up appointments. Thus it is important that future studies measure the dimensional changes of the buccal bone and show whether these changes are a reason for mucosa stability or not. Cone beam computer tomographic methods are commonly available now to measure the buccal bone thickness. These methods, however, have their limitations because metallic artefacts limit the visualization quality of the bone around the implants, leading to an underestimation of the bone thickness (Ritter et al., 2014; Vanderstuyft et al., 2019).

Papillae

Changes in the appearance of the papilla can be recorded in mm and/or with an index as described, for example, by Jemt et al. (1997). In general, it can be said that the papilla changes observed in the various studies reported in this thesis were minor throughout the evaluation periods.

There are various theories about the formation of interdental papillae approximal to an implant. Cosyn et al. (2012) performed a multivariate analysis of risk factors for soft tissue recessions in the anterior maxilla and gave, for example, surgery with a ridge reconstruction as a risk factor for interproximal recession. In the study in which we applied extensive reconstructive surgery prior to implant placement (**Chapter 2**), only 20% of the patients scored a full papillae fill in the Implant Crown Aesthetic Index. These less favourable outcomes can be a result of the poor pre-operative state of the site and/or with the reconstructive surgery subsequently needed. According to Jung et al. (2018), the mucosa attachment level at the neighbouring teeth is a predominant factor in the establishment of the papillae. It can be argued that the bone resorption after a tooth extraction causes recession of the mucosa around the neighbouring teeth, resulting in a retraction of the gingiva attachment level at the rootsurface. Reconstructing the alveolar bone with a bone augmentation does not regenerate the cementum at the root surface of neighbouring teeth, and thus does not re-establish the original gingival attachment levels, resulting in an incomplete papilla fill proximal to the implant. Furthermore, when flap elevation is needed to gain access to the site for augmentation, this can also result in disrupted papillary tissue attachments (Jung et al., 2018).

According to Cosyn et al. (2012), other factors that might influence the presence or absence of papillae are: the actual presence of a contact point, the distance from the contact point to the interproximal bone peak (when ≤ 5 mm, increased likelihood of a present papilla) and the tooth-to-implant distance (when ≥ 2.5 mm, increased likelihood

of a present papilla). It must be acknowledged that the papilla fill in the interdental spaces in single-tooth implant treatment does not seem to be depended on peri-implant bone height changes (Rocuzzo et al., 2018). This is in contrast to statements we made previously for the mid-buccal mucosa level, but it emphasizes the complex biology around an implant restoration.

Peri-implant soft tissue health

The gingiva index, pocket probing depth and bleeding upon probing around dental implants are outcomes when evaluating the health of the soft tissue around dental implants. In general, it can be said that all the studies described in this thesis recorded healthy soft tissues at all evaluation periods. Apparently, high patient compliance to the prescribed post-treatment oral hygiene instructions, as is part of a university-based study with a strict protocol, could have played an important role in the observed health of the peri-implant soft tissues. Nonetheless, as reported by Visser et al. (2011), and noted in **Chapter 2**, despite careful instructions on the necessary aftercare after crown placement, 63% of the patients needed supplemental oral hygiene support after 5 years. We realize that the strict protocol followed in the university setting might not be always feasible in general practice. But knowing that, despite the strict protocol, more than half of the patients needed additional instructions stretches even more the importance of the instructions and the aftercare for a long-term stable implant restoration.

Another possible explanation for the good peri-implant health outcome in the studies reported in this thesis, might be, as mentioned before, at least in part due to the implant-abutment connections used. All the bone level implants were equipped with a platform switched conical connection, which has the smallest microgap between the components, thus resulting in the least amount of micromovement and bacterial leakage (Zipprich et al., 2018; Ivanovski et al., 2018).

Implant-abutment connection

Over time, there has been a shift in the use of tissue level implants to bone level implants in the aesthetic region. A microgap at the connection between the implant and abutment is inherent in a bone level design, thus affecting the benefit of an uncompromised biological width, possibly leading to more peri-implant bone loss. This can potentially reflect poorly on the aesthetic outcome due to insufficient soft tissue support. A systematic review of the literature was performed to gain insight

into the available evidence for the question whether the implant abutment connection configuration (i.e., conical connections, platform switched parallel connections (PS-parallel) or platform matched parallel connections (PM-parallel)) could have an effect on the stability of the peri-implant tissues and implant loss (**Chapter 7**).

All the studies described in this thesis, except the tissue level implant in **chapter 2**, had a platform switched conical connection at bone level. These studies showed negligible marginal bone loss after 1 and 5 years (0.07 mm after 1 year, 0.13 mm after 5 years). The annual bone loss was comparable with annual bone loss calculated in the meta-analysis of the PS-conical and PS-parallel groups (**Chapter 7**) which also included other brands of implants (PS-conical: 0.16 mm; PS-parallel: 0.14 mm annual marginal bone loss). These findings indicate that the implant abutment connection contributes to keeping the peri-implant tissues stable, despite the different neck designs, different surface structures of the implant and abutments, and that it is used for various treatment indications, also with different loading protocols applied in the various studies included in the review.

The reason for the good results observed for conical connections may be their claimed biomechanical advantages: several in-vitro studies demonstrated how conical abutments could minimize the microgap (Schmit et al., 2014) and reduce micromovements during loading, compared to platform matched or external implant-abutment connections (Zipprich et al., 2018). However, these favourable circumstances do not explain why the peri-implant bone loss was comparable between the conical and PS-parallel groups. Apparently, the effect of the smaller microgap in conical connections (Schmitt et al., 2014; Zipprich et al., 2018) does not contribute enough to have a clinically noticeable effect on bone loss, implant loss and mid-buccal mucosa level change, compared to the PS-parallel connections.

Both the conical and PS-parallel groups maintained their bone levels significantly better than the platform matched group. This outcome is in line with the results reported by Caricasulo et al. (2018) and Hsu et al. (2017). It is shown that no connection type can completely eliminate the gathering of bacteria (Zipprich et al., 2018), but moving the microgap inwards, away from the bone crest, seems to contribute to a significant reduction in the amount of bone loss. However, one should view this with caution as there does not seem to be any consensus on this yet (Schwarz et al., 2014), also because the majority of the studies included in our study had a short follow-up (1 year). A possible risk factor in the long term could be a loss of torque value between implant and abutment under mechanical stress (occlusal loading) (Coppede et al., 2009). Since

the tissues around implants change continuously, albeit only a little, it would be useful to re-evaluate the previous statement when more long-term studies are available.

Aesthetic outcome and patient satisfaction

The professionals in the different studies used various indices to rate the aesthetics: the Implant Crown Aesthetic Index (ICAI) developed by Meijer et al. (2005) and the Pink Esthetic Score/ White Esthetic Score (PES/WES) developed by Fürhauser et al. (2005) and Belser et al. (2009).

It is still under debate whether there is an ideal index that reflects the patients' judgment. A systematic review assessing the value of aesthetic indices concluded that clinicians are more critical of aesthetic outcomes than patients. Moreover, it was noted that there is a need for a comprehensive and practical index to assess the aesthetic outcomes for single-tooth implant restorations in the aesthetic zone (Arunyanak et al., 2017).

In the studies described in this thesis, independent of what index was used, it appeared that the professionals rarely gave a 100% satisfaction score. This means that, despite the surgical and prosthetic procedures applied, the implants used, and whether the procedures were carried out by experienced professionals, it is still difficult to achieve a perfect result, one that is completely in harmony with the surrounding pink and white tissues. A favorable outcome of the 5- and 10-year studies is that the aesthetic results appeared to be stable throughout the years. This could mean that the satisfying aesthetics results achieved in the short-follow-up studies (**Chapters 4-6**) have good prospects for future aesthetic stability.

In line with the conclusion stated in the Arunyanak et al. (2017) systematic review, it can be concluded from the studies described in this thesis that patients are much more satisfied than the professionals. In fact, the patients rated the aesthetics very highly, not only at the 1-year evaluation time points, but also after 5 years and 10 years. It could be that the professional scoring indices are too strict for evaluating small deviations from the ideal situation, deviations that are of minor importance for patients, or are not noticed at all. In fact, while the professionals only rate the end product, the patients also take the initial situation into account when assessing how satisfied they are with the end result. As long as there are no better aesthetic indices, it is not justified to leave out either the professional or the patient judgment in evaluating the aesthetic outcome.

Strengths and limitations

Considering the results of all the studies described in this thesis, some strengths can be mentioned. As far as reasonably applicable, all the patients were treated under the same surgical and post-surgical conditions. Except for half of the patients in the tissue level study, all the patients were treated in the same university setting, by the same experienced surgical and prosthetic team. All the patients were included under the same criteria (periodontally healthy and non-smoking; single tooth replacement with neighbouring natural teeth) and the interventions were performed under a prophylactic antibiotic and chlorhexidine mouth rinse regime.

Some limitations have to be addressed with respect to comparison of the different studies. Studies with healed sites as well as studies with post-extraction sites are present. In addition the treatment sites exhibited different grades of bone deficiencies. Different implant designs were used which have also been subject to different developments in micro- and macrostructure through time. Finally, the studies in this thesis had different follow-up periods and, as with the 5-year and 10-year studies, had different observers to collect the data during the first year- even though it was calibrated. A direct comparison of the results from the studies is, therefore, not possible.

Future perspectives

The studies described in this thesis evaluate a decade of treatment with Straumann implants in the aesthetic region. During these years, the manufacturer developed various implant components to meet the changing demands of the market following the advancing insights from research. The outcomes are favourable, from the oldest up to the most recent implant designs. However, the more recent implant designs (for example the tapered implants) were only evaluated for 1-year. To ensure the successfulness of these implants, long term evaluation is needed.

When writing this thesis, it repeatedly emerged that the studies could not be properly compared with other studies available, due to the various measuring methods and reporting of the data outcomes. Implant survival and bone level change are often reported but important parameters, such as aesthetic outcome and patient centred outcome of a treatment, are forgotten. Forthcoming is a need to implement a uniform set of methods to evaluate and report aesthetic outcomes and patient satisfaction.

Although the studies described in this thesis, as well as the other studies in the literature, report satisfying results for single-tooth replacement in the aesthetic zone, this treatment is a complex procedure influenced by numerous factors such as pre-treatment status, surgical techniques (flap/flapless, hard/soft tissue augmentation, placement protocol), implant characteristics (surface properties, thread and neck design, abutment connection configuration) and patient characteristics ((micro) biological and oral hygiene). More insight will be gained through further research and continuous evaluation of innovations leading to a high quality restoration that is functional, stable and aesthetically pleasing in the short and long term.

Conclusions

Based on the various studies described in this thesis, the following specific conclusions can be drawn:

- Pre-implant augmentation of a bone defect in the anterior region with either chinbone or a demineralised bovine bone substitute, followed by tissue level implant treatment, results in favourable 10-year clinical, radiographic and aesthetic outcomes, and satisfied patients (**Chapter 2**);
- Bone level parallel-walled implants result in favourable 5-year results, for single tooth replacement in the maxillary aesthetic zone, with respect to clinical, radiographic, aesthetic and patient centered outcome. (**Chapter 3**);
- Bone level tapered implants in unassisted healed maxillary sites, with a delayed loading protocol, result in favourable outcomes with respect to implant stability, and clinical, aesthetic, radiographic and patient-centred outcomes (**Chapter 4**);
- Bone level tapered implants, applied in the maxillary aesthetic region after alveolar ridge preservation, and in combination with immediate provisionalization, are accompanied with a high survival rate, stable marginal bone levels and soft tissue levels, good aesthetic outcomes and high patient satisfaction 1 year after implant placement (**Chapter 5**);
- Immediate implant placement and provisionalization using an implant system with self-cutting edges has the potential to result in favourable clinical, radiographic, aesthetic and patient satisfaction outcomes (**Chapter 6**);
- The performance of conical and parallel platform-switched connection configurations, when applied to solitary implant restorations in the aesthetic zone is comparable with regard to peri-implant bone loss (**Chapter 7**);

- Parallel walled platform matched connections do not perform less good as conical and parallel platform-switched connections to prevent peri-implant bone loss (**Chapter 7**);
- None of the different connection configurations was significantly better at preserving the mid-buccal mucosa levels (**Chapter 7**);
- The presence of a platform switch might be of more importance than the connection configuration itself (**Chapter 7**).

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Addendum

Summary

Samenvatting

Dankwoord

Curriculum vitae

Summary

Single tooth replacement in the aesthetic region has been part of implant dentistry for a number of decades. Since its introduction, many implant systems, surgical and prosthetic techniques, and loading protocols have been used. The goal of dental implant therapy in the aesthetic region is to achieve successful tissue integration, with predictable and aesthetically acceptable hard and soft tissue contours, thus re-establishing both function and aesthetics. The results should not just be a short term achievement, but should remain stable in the long term. Therefore, the general aim of this thesis was to assess the outcomes of implant treatment for a missing tooth in the aesthetic region in both shortterm and longterm follow-up. The patients in the various studies described in this thesis had different grades of alveolar bone resorption, and requested implant therapy for one missing or failing tooth. Different implant designs were applied, the choice being based on the best suitable Straumann implant system (ITI dental implant system) available at the time.

In the study described in **chapter 2**, we aimed to assess the 10-year effects of three different augmentation techniques (augmentation with chin bone, augmentation with chin bone plus a membrane, and augmentation with a bone substitute plus a membrane) for implant-supported restorations in the maxillary aesthetic region. The clinical and radiographic parameters, as well as the patient-centred outcomes, were noted. Ninety-three participants (44 male/49 female, mean age 33 years) requesting single tooth replacement, and presenting with a horizontal bone deficiency, were included. Six months after the augmentation with either of the three augmentation techniques, tissue level implants were placed. All 93 implants were provisionalized after 6 months of submerged healing. Clinical variables, standardized radiographs and photographs, and patient questionnaires were analysed to assess the impact of the various augmentation techniques one month (T_1), 12 months (T_{12}) and 120 months (T_{120}) after final crown placement. The ten-year implant survival was 95.7% and did not differ between the groups, neither were there significant differences observed in the other assessed treatment outcomes. Peri-implant bone loss was low, viz. 0.48 ± 1.19 mm (mesially) and 0.30 ± 1.24 mm (distally) at T_{120} . The mid-buccal marginal gingival level loss was 0.32 ± 0.83 mm at T_{120} . The mean overall satisfaction was 8.6 (on a scale from 0-10) at T_{120} , with 98.6% of the patients being satisfied. It was concluded that the clinical, radiographic, aesthetic and patient-centred outcomes were very favourable after 10 years and did not differ between the groups with different bone augmentation techniques.

In **chapter 3** we describe a study assessing the clinical, radiographic and aesthetic outcomes, and the satisfaction of patients treated with single implant restorations in the maxillary aesthetic region five years after the final restoration. Sixty patients (29 male/31 female, mean age 37 years) with a missing anterior tooth in the maxilla received a bone level implant with a conical connection. In 29 patients, a bone augmentation procedure was necessary before implant placement (autogenous bone grafts mixed with spongiosa granules). All the implants were loaded after 3 months of submerged healing. The restoration consisted of an individually designed full-zirconia abutment veneered with porcelain. Follow-ups, including clinical and radiographic assessments, were conducted up to 60 months after the final restoration. The aesthetic outcome of the restoration was determined with the Pink Esthetic Score/White Esthetic Score (PES/WES). Patient satisfaction was assessed with a VAS scale and satisfaction questionnaire. Fifty patients completed the 5-year follow-up. The implant survival was 100% and the restoration survival was 98%. The mean bone level change was -0.13 ± 0.66 mm, with a median (IQR) pocket probing depth of 2.75 [2.25; 3.25]. The mean PES and WES scores were 6.6 ± 1.7 and 7.8 ± 1.5 , respectively. The patient satisfaction was high (92.1 ± 7.8 on 100 mm VAS scale). There were no differences between patients with or without a bone augmentation procedure. It was concluded that bone level implants with a conical connection are a reliable treatment option for single tooth replacements in the maxillary aesthetic zone.

Bone level tapered implants have an advantage in terms of stability and less need for additional bone augmentation procedures in the healed sites, which might be advantageous for the maxillary aesthetic zone. In the study described in **chapter 4**, the clinical, radiographic and aesthetic performance of bone level tapered implants placed in healed maxillary aesthetic sites was assessed during a one-year follow-up. Thirty participants (15 male, 15 female, mean age 38 years) with a single tooth diastema, that had healed without assistance for at least 3 months, received a bone level tapered implant. Buccal bone augmentation procedures were performed at implant placement if the buccal bone wall was less than 2 mm. A provisional restoration was connected after a healing phase of 3 months. A definitive restoration was placed 3 months after the provisional restoration. All the placed implants demonstrated good stability. A buccal bone augmentation procedure was needed in 77% of the cases. The median implant stability quotient value was 73 [68;76] at implant placement and had increased to 79 [76;81] when the definitive restoration was inserted ($p < 0.005$). All the patients attended the follow-up one year after the definitive restoration was placed and none had lost an implant. The mean marginal bone loss was 0.07 ± 0.10 mm, mid-buccal mucosa level

recession was 0.14 ± 0.40 mm, and the median PES and WES were 6 [4;7] and 8 [7;8.3], respectively. The participants' mean overall satisfaction was 90.1 ± 6.5 on a 0-100 VAS. We can conclude that bone level tapered implants perform well in anterior maxillary healed sites, with respect to implant stability, based on clinical, aesthetic, radiographic and patient centred outcomes during a one-year follow-up.

The performance of bone level tapered implants in the maxillary aesthetic zone was also evaluated clinically, radiographically and aesthetically after one year in sites where alveolar ridge preservation was applied (**Chapter 5**). Thirty patients (16 male, 14 female, mean age 43 years) with a failing tooth and a large bone defect after tooth removal, received alveolar ridge preservation. After three months, implants were placed with immediate provisionalization. The definitive restorations were placed after 3 months. All the patients attended the one-year follow-up. One implant was lost (96.7% implant survival rate). The mean Implant Stability Quotient value was 68.9 ± 8.74 at implant placement. The mean marginal bone level change was minor (-0.07 ± 0.12 mm). The mean mid-buccal mucosa change was $+0.01 \pm 0.45$ mm. The median PES and WES were 6 [4;7] and 8 [7;9], respectively, after one year. The patients' mean overall satisfaction (0-100 VAS scale) was 86.6 ± 10.3 . It can be concluded that bone level tapered implants, with immediate provisionalization, perform well after alveolar ridge preservation in the maxillary aesthetic zone, with respect to implant stability, and clinical, radiographic, aesthetic and patient-centred outcomes.

The alleged benefit of tapered implants, compared to cylindrical implants, is the enhanced primary stability in soft bone and in extraction sockets. The tapered shape and self-cutting threads, combined with under drilling the implant bed during the osteotomy, make this implant type suitable for challenging sites. In the case report described in **chapter 6**, the clinical, radiographic, aesthetic and patient centred outcomes of a new implant system designed for an immediate implant placement and restoration approach, to replace a single tooth in the anterior maxillary region, was assessed. Three cases were treated with a bone level tapered implant. All the patients were treated with the same strategy involving flapless extraction and implant placement with simultaneous augmentation. The implants were provisionally restored with a screw-retained restoration at the day of the surgery. A definitive restoration was fabricated after three months. At the one year follow-up after the definitive restoration, the implants were stable and no complications had occurred. The peri-implant bone levels had increased with a mean value of 0.24 ± 0.30 mm between definitive restoration placement and the 1 year follow-up. The clinical outcome scores showed healthy soft tissues. The mean PES and WES were 7.0 and 7.3, respectively. The mean patient

satisfaction had improved from 55.7 (pre-treatment) to 90.0 (1-year follow-up) on a 0-100 VAS scale. We can conclude that immediate implant placement and restoration with the new tapered bone level implant system is accompanied by good initial clinical and radiographic results as well as high patient satisfaction.

A common denominator amongst all the studies was the stability and health of the peri-implant tissues. The implant abutment connection became of interest as it is located in the critical zone that guards the 'inside' from the 'outside' environment. In vitro studies have suggested that there is a microgap in each connection type (internal, external, platform switched, platform matched, parallel and conical configurations), but that the conical connection shows the smallest microgap. The microgap can harbour peri-implant pathogens with the potential of inducing inflammation in the peri-implant tissues. Clinical trials have suggested that dental implants with a conical implant-abutment configuration are accompanied by less peri-implant bone loss than non-conical configurations. Therefore, a systematic review of the literature was performed to assess the effect of different implant-abutment interface designs on peri-implant bone level changes, implant loss and mid-buccal mucosa changes around single implants placed in the anterior maxilla (**chapter 7**). Eligible prospective studies were divided according to the internal implant-abutment configuration: i) platform switched conical (PS-conical), ii) platform switched parallel (PS-parallel) and iii) platform matched parallel (PM-parallel). A detailed search was carried out in Pubmed, EMBASE, Cochrane, Scopus, Open Grey and African journals Online (until December 1, 2020). Risk of bias was assessed with RoB 2.0 and ROBINS-I. A meta regression analysis was carried out primarily on the pooled peri-implant bone level changes followed by implant loss and mid-buccal mucosa level change. The manuscript complied with the PRISMA guidelines and was registered in the PROSPERO database (ID: 225092). A total of 5,513 hits gave 44 eligible articles for the analyses. The bone level change and implant loss did not differ significantly between the PS-conical and PS-parallel connections, and their bone losses were significantly lower than with PM connections, but only the PS-conical had significantly lower implant losses than the PM connections. The mid-buccal mucosa level changes were comparable between the three connection configurations. Moderate to high risk of bias was detected in the included studies. The conclusion is that the performance of PS-conical and PS-parallel connection configurations are comparable, with significantly less bone loss compared to PM-parallel connection configurations, but all 3 lead to small mid-buccal mucosa changes which did not differ significantly between the groups.

The main research outcomes are discussed in **chapter 8**. In general it can be concluded that single tooth replacement in the aesthetic region of the maxilla results in stable peri-implant hard and soft tissues, favourable aesthetic outcomes, and high patient satisfaction, both in the short and in the long term follow-up, when the pre- and post-implant placement conditions are properly dealt with.

Samenvatting

Restauratieve tandheelkunde richt zich op het functioneel en esthetisch herstel van (ontbrekende) tanden en kiezen. Het ontbreken van gebitselementen kan op verschillende manieren worden opgelost. Eén van die manieren is implantaattherapie. Bij implantaattherapie wordt een implantaat in het kaakbot verankerd om vervolgens te dienen als een pijler voor het bevestigen van een kroon of een brug, of voor het ondersteunen van een volledig kunstgebit. Het doel van implantaattherapie in de esthetische regio is het bereiken van zowel een succesvolle integratie van het implantaat in het kaakbot als een fraaie esthetische contour van harde en zachte weefsels rondom het implantaat.

Sinds de introductie van implantaten in de restauratieve tandheelkunde is een groot aantal implantaatsystemen, chirurgische technieken en prothetische materialen ontwikkeld. Inmiddels is de implantaattherapie een alom aanvaarde behandelmethode geworden. Het overkoepelende doel van het in dit proefschrift beschreven onderzoek was om de korte en lange termijn uitkomsten van enkeltandsvervanging met behulp van implantaten in de esthetische regio van de bovenkaak te objectiveren.

In de in **hoofdstuk 2** beschreven studie worden de 10-jaars resultaten van het plaatsen van een tissue-level implantaat geanalyseerd. Bij het tissue-level implantaat ligt de verbinding tussen het abutment en het implantaat op tandvleesniveau. De gedachte die hieraan ten grondslag ligt, is dat de randspleet tussen het abutment en het implantaat, de plek waar bacteriën zich bij voorkeur kunnen nestelen, zich niet op botniveau bevindt en er minder botverlies zal optreden. Drieënnegentig patiënten (44 mannen en 49 vrouwen, gemiddelde leeftijd 33 jaar) met een ontbrekende voortand en een uitgebreid botdefect van de kaak in de esthetische regio van de bovenkaak werden geïnccludeerd. Om een implantaat in deze regio van de kaak te kunnen plaatsen, moest eerst het defect worden opgebouwd met eigen bot of kunstbot. Het doel van de studie was het verkrijgen van een antwoord op de vraag of het uitmaakt welk augmentatiemateriaal en welke chirurgische methode het beste kunnen worden toegepast voor het verkrijgen van een goede peri-implantaire gezondheid en een fraai esthetisch resultaat. Het tekort aan bot was opgebouwd middels augmentatie met alleen kinbot, augmentatie met kinbot bedekt met een membraan, of augmentatie met een botsubstituut bedekt met een membraan. Na een genezingsperiode van 3-6 maanden werd het implantaat geplaatst. Zes maanden later werd het implantaat vrijgelegd en een tijdelijke kroon geplaatst. Drie maanden later werd deze tijdelijke kroon vervangen door de definitieve kroon. Vooraf aan de behandeling en 1 maand (T_1),

12 maanden (T_{12}) en 120 maanden (T_{120}) na de plaatsing van de definitieve kroon werd de gezondheid van peri-implantaire weefsels beoordeeld, en werden gestandaardiseerde röntgenfoto's en lichtfoto's gemaakt om veranderingen van het botniveau en het tandvlees te kunnen beoordelen. Tevens werd de tevredenheid van patiënten over het behandelresultaat met behulp van vragenlijsten geanalyseerd. Tien jaar na het plaatsen van de definitieve kroon bleken nog 72 van de 93 patiënten te kunnen deelnemen aan het vervolgonderzoek. De 10-jaars overleving van het implantaat was 95,7%: 4 implantaten waren verloren gegaan. De implantaatoverleving verschilde niet tussen de drie onderzochte groepen, noch werden er significante verschillen waargenomen in andere behandeluitkomsten. Het peri-implantair botverlies na 10 jaar was gering, namelijk gemiddeld 0,48 mm mesiaal en 0,30 mm distaal. De recessie van de mid-buccale gingiva was zeer gering, namelijk gemiddeld 0,32 mm. Ook waren vrijwel alle patiënten (98,6%) tevreden met het eindresultaat. Dit bleek uit een gemiddelde score van 8,6 op een schaal van 0-10. Geconcludeerd werd dat ook op lange termijn het zowel klinische en röntgenologische beeld als de esthetische uitkomst en patiënttevredenheid zeer gunstig waren. De uitkomsten van de drie onderzochte augmentatiestrategieën waren vergelijkbaar.

In **hoofdstuk 3** wordt een studie beschreven waarin de 5-jaars resultaten na het plaatsen van een bone-level implantaat werden geanalyseerd. Bone-level implantaten worden op botniveau geplaatst en hebben als voordeel dat er meer vrijheid is voor het creëren van een individueel vormgegeven abutment. Door het abutment een kleinere diameter te geven dan het implantaatplatform, verschuift de randspleet (en de bacteriën) weg van de botrand (platform switching). Dit moet het botverlies als reactie op bacteriën tegen gaan. In 60 patiënten (29 mannen en 31 vrouwen, gemiddelde leeftijd 37 jaar) met een solitair ontbrekend gebitselement in de esthetische zone van de bovenkaak werd een bone-level implantaat geplaatst. Bij 29 van de 60 patiënten was te weinig bot aanwezig om een implantaat te plaatsen. Bij deze patiënten werd eerst een bottransplantatie met autoloog bot en een botsubstituut verricht. Na een helingsperiode van 3 maanden werd het implantaat geplaatst. In alle patiënten werden de implantaten drie maanden na het plaatsen vrijgelegd en voorzien van een tijdelijke kroon. Hierbij werd een implantaat abutment verbinding met platform switching gebruikt. Drie maanden later werd de definitieve kroon geplaatst. Voorafgaand aan de behandeling, en 1 maand, 12 maanden en 60 maanden na plaatsing van de definitieve kroon werden het klinische en röntgenologische beeld beoordeeld. Daarnaast werd de tevredenheid van de patiënten gemeten met vragenlijsten en het esthetische resultaat beoordeeld op lichtfoto's met behulp van een esthetische index (PES/WES). Vijftig van de 60 patiënten

waren beschikbaar voor de 5-jaar follow-up. Na vijf jaar bedroeg de overleving van het implantaat 100% en de overleving van de kronen 98%. Het gemiddelde botverlies was zeer gering (0,13 mm) en de mediane pocket-sonderingsdiepte was gemiddeld 2,75 mm. De gemiddelde PES- en WES-scores waren, respectievelijk 6,6 en 7,8 op een 10-punts schaal. De patiënttevredenheid was hoog (92,1 op een VAS-schaal van 0-100). De uitkomsten van patiënten bij wie wel of geen augmentatieprocedure was verricht, waren vergelijkbaar. Met andere woorden, het plaatsen van bone-level implantaten is een betrouwbare behandeloptie in de maxillaire esthetische zone voor het vervangen van een solitair gebitselement, ongeacht of er wel of niet eerst een botaugmentatie in de implantaatregio moet worden verricht.

In de **hoofdstukken 2 en 3** beschreven studies werden cilindrische implantaten met parallelle wanden gebruikt. Inmiddels zijn ook implantaten met een taps toelopend ontwerp beschikbaar. Tapse implantaten zouden het voordeel hebben van een verbeterde initiële stabiliteit met minder kans op perforatie van de buccale botwand. In **hoofdstukken 4 en 5** worden twee studies beschreven waarin werd onderzocht hoe het behandelresultaat was van taps toelopende bone-level implantaten voor toepassing bij enkeltandsvervanging in de esthetische regio van de bovenkaak. Voor de studie beschreven in **hoofdstuk 4** werden de klinische, röntgenologische en esthetische resultaten van enkeltandsvervanging in de esthetische regio van de bovenkaak bij 30 patiënten (15 mannen en 15 vrouwen, gemiddeld 38 jaar) na 1 jaar geëvalueerd. Alle implantaten werden geplaatst in een regio waar minimaal drie maanden eerder een gebitselement was verwijderd en was genezen zonder aanvullende maatregelen, zoals een botaugmentatie. Bij de meerderheid van de patiënten (77%) moest tijdens het plaatsen van het implantaat buccaal extra bot worden aangebracht (autoloog + botsubstituut), omdat plaatselijk de dikte van de buccale botlamel minder was dan 2 mm. Na een osseointegratiefase van 3 maanden werden de implantaten vrijgelegd en voorzien van een tijdelijke kroon, drie maanden later gevolgd door de definitieve kroon. De stabiliteit van alle implantaten was goed, de mediane Implantaat Stabiliteit Quotiënt (ISQ) was 73 direct na plaatsing van het implantaat en 79 op het moment van het aanbrengen van de definitieve kroon ($p < 0,005$). Eén jaar na het plaatsen van de definitieve kroon was geen enkel implantaat verloren gegaan (100% overleving), bedroeg het gemiddelde peri-implantaire botverlies 0,07 mm, was de gemiddelde recessie op mid-buccaal mucosaniveau 0,14 mm, en waren de mediane PES en WES waarden respectievelijk 6 en 8. De gemiddelde algemene tevredenheid van de deelnemers was 90,1 op een 100 punts VAS schaal. Geconcludeerd werd dat het taps toelopende

implantaat geschikt was om een reeds ontbrekend element in de esthetische regio van de bovenkaak te vervangen.

In de in **hoofdstuk 5** beschreven studie werd het taps toelopende implantaat ook toegepast in patiënten bij wie na extractie de alveole was opgevuld met (kunst)bot. Deze toepassing werd onderzocht omdat studies hadden uitgewezen dat het resorptie proces sterk kan worden vertraagd wanneer na de extractie de alveole wordt opgevuld. Op deze wijze kan een gunstigere uitgangssituatie worden gecreëerd voor het plaatsing van het implantaat. Dertig patiënten (16 mannen en 14 vrouwen, gemiddelde leeftijd 43 jaar) met een niet te behouden gebitselement in de esthetische regio van de bovenkaak en bij wie een buccaal botdefect na extractie was ontstaan, werden geïncludeerd. In alle patiënten werd eerst de extractie alveole opgevuld met een 1:1 mengsel van autoloogbot en een botsubstituut. Drie maanden later werd een taps toelopend bone-level implantaat geplaatst en op dezelfde dag voorzien van een tijdelijke kroon. Deze kroon werd na drie maanden vervangen door de definitieve kroon. Na een jaar was één implantaat verloren gegaan (96,7% implantaatoverleving). De gemiddelde ISQ waarde was 68,9 ten tijde van het plaatsen van het implantaat en 80,2 ten tijde van het plaatsen van de definitieve restauratie ($p < 0,005$). Eén jaar na het plaatsen van de definitieve kroon was het peri-implantaire botniveau zeer gering afgenomen (0,07 mm) en was het niveau van de mid-buccale mucosaverandering feitelijk niet veranderd (+0,01 mm). De mediane PES en WES na één jaar waren respectievelijk 6 en 8, en de gemiddelde patiënttevredenheid was 86,6 (0-100 VAS-schaal). Met andere woorden, taps toelopende bone-level implantaten kunnen met een goed resultaat direct worden belast in een regio waar na verwijderen van een gebitselement de alveole is gevuld met een mengsel van autoloog bot en een botsubstituut.

De al goede initiële stabiliteit van taps toelopende implantaten werd in een later ontwerp verder verbeterd door het aanbrengen van 'scherper en dieper snijdende' schroefwindingen, zodat het implantaat zichzelf nog beter in het bot kan graven. Deze verandering in het ontwerp van het implantaat zou met name gunstig zijn wanneer een implantaat direct na het verwijderen van een gebitselement in de alveole wordt geplaatst. Wanneer deze methodiek wordt gecombineerd met het direct plaatsen van een kroon, kan tevens het aantal behandelsessies worden verminderd en de totale behandel tijd worden verkort. In de in **hoofdstuk 6** beschreven case reports werden de klinische, röntgenologische, esthetische en patiënt-gerapporteerde uitkomsten van dit nieuwe type implantaat beschreven. Drie patiënten met een niet te behouden gebitselement in de esthetische regio van de bovenkaak werden behandeld met dezelfde strategie, namelijk extractie van het gebitselement, zonder afschuiven

van de mucosa, het plaatsen van het implantaat met gelijktijdige augmentatie van de resterende alveolruimte met autoloog bot en een botsubstituut, en het direct plaatsen van de tijdelijke kroon. Deze tijdelijke kroon werd na drie maanden vervangen door de definitieve kroon. Eén jaar na het plaatsen van de definitieve kroon waren de implantaten stabiel, waren geen complicaties opgetreden, was het peri-implantaire botniveau stabiel, was de peri-implantaire mucosa gezond en de patiënttevredenheid hoog.

Een gemeenschappelijke uitkomst maat van de in de vorige hoofdstukken beschreven onderzoeken was de stabiliteit en gezondheid van peri-implantaire weefsels. Mogelijk ligt de toegepaste implantaat-abutment connectie aan deze gunstige resultaten (mede) ten grondslag. Omdat nog weinig bekend was over het effect van de implantaat-abutment configuratie op het peri-implantaire botniveau en mogelijk effect op de esthetiek werd een systematische literatuurstudie gedaan naar het effect van implantaat-abutmentconfiguraties op het verlies van implantaten, het peri-implantaire botniveau en het mid-buccale mucosaniveau rond solitaire implantaten in de esthetische regio (**hoofdstuk 7**). Er werd gezocht in verschillende online zoekbanken (Pubmed, EMBASE, Cochrane, Scopus, Open Grey en African Journal Online, tot 1 december 2020). Het risico op bias werd beoordeeld met RoB 2.0 en ROBINS-I. De prospectieve studies die aan de inclusiecriteria voldeden werden onderverdeeld naar de interne implantaat-abutment configuratie: i) platformswitch met conische interne configuratie (PS-conisch), ii) platform-switch met parallelle interne configuratie (PS-parallel) en iii) platform-match met parallelle configuratie (PM-parallel). Vierenveertig van de 5.513 gevonden studies kwamen in aanmerking voor nadere analyses. Uit de analyses kwam naar voren dat verandering van botniveau en implantaatverlies niet significant verschilden tussen de PS-conische en PS-parallelle configuraties, maar het botverlies van deze configuraties was wel beiden significant lager dan dat van de PM-configuraties. Ook gingen na toepassing van de PS-conische configuratie significant minder implantaten verloren dan wanneer een PM-configuratie werd toegepast. Het niveau van de mid-buccale mucosa verschild echter niet tussen de drie configuraties. Er werd geconcludeerd dat, hoewel voor beide groepen geldt dat er weinig botverlies optreedt, de toepassing van PS-conische en PS-parallelle configuraties met significant minder botverlies gepaard gaan dan bij de toepassing van PM-parallelle configuraties. Alle drie configuraties vertoonden slechts kleine en vergelijkbare veranderingen in het mid-buccale mucosaniveau.

De belangrijkste onderzoeksresultaten worden in een breder kader besproken in **hoofdstuk 8**. In het algemeen kan worden gesteld dat een solitaire tandvervanging in

het esthetische gebied van de bovenkaak gepaard gaat stabiele peri-implantaire harde en zachte weefsels, gunstige esthetische resultaten en een hoge patiënttevredenheid, zowel op de korte als lange termijn. Een voorwaarde voor een dergelijk gunstige uitkomst is het correct inschatten van de Ausgangssituatie en het daarop aanpassen van de chirurgische en prothetische behandeling.

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Curriculum vitae

Caroliene Cornelia Maria Meijndert was born on the 9th of August 1989 in Siloam Venda, in the north of South-Africa. After finishing MAVO and HAVO at the Gomarus College (2005, 2007), she finished VWO at the Luzac College Groningen (C&M in 2009 and N&G in 2010). Caroliene started to study Dentistry at the University of Groningen in September 2010. In 2016 she applied for an MD/PhD research program at the Graduate School of Medical Sciences of the University of Groningen and commenced the PhD study during the Master program. She graduated for her Masters in Dentistry in July 2017 and continued the MD/PhD program at the department of Oral- and Maxillofacial Surgery of the University Medical Centre Groningen. Next to the research work she worked as a general practitioner in a private practice in Zuidhorn (Dental clinics). Two weeks after the thesis defence, Victor Verhulst and Caroliene Meijndert have planned to marry and to live in Haarlem. She will continue working as a general practitioner in a private practice.