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Wittneben Matter, Julia-Gabriela Charlotte

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An illustration showing a cross-section of a human jawbone. In the center, a dental implant with a threaded top is embedded in the bone. Below the implant, a white, tooth-like crown is attached. On either side of the implant, there are natural teeth with white crowns and pink gums. The background is a light brown, textured surface representing the jawbone.

# **Esthetics in Implant Prosthodontics**

**Julia-Gabriela Wittneben**

VRIJE UNIVERSITEIT

**Esthetics in Implant Prosthodontics**

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door

Julia-Gabriela Charlotte Wittneben

geboren te Baden- Baden, Duitsland

promotoren: prof.dr. D. Wismeijer

prof.dr. U. Brägger

overige leden:

dr. Y. Liu

prof.dr. F. Lambert

prof.dr. G. O. Gallucci

prof.dr. M. S. Cune

prof.dr. M. M. Bornstein

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## **PREFACE**

The rehabilitation of edentulous spaces with dental implants and fixed restorations in the anterior maxilla, further to be referred to as the “esthetic zone”, is considered an advanced or complex procedure and requires predictable backward-driven treatment planning including the evaluation of prosthetic and surgical risk factors. Risk factors in respect to the final esthetic treatment outcome are often present. The peri-implant mucosa and the future crown is often also visible during smile and speech. Rehabilitation of implant sites in the esthetic zone aiming for a prosthetic pleasing result is therefore challenging as ideal overall esthetic outcomes are dependent of both- pink (soft tissue) and white (hard tissue) esthetics. Objective esthetic indices are needed to determine the final esthetic outcome of these pink and white esthetics thus making the treatment outcomes and results of clinical studies comparable when discussing and publishing these within the scientific community.

The most popular used objective esthetic index for clinical studies focusing on the outcome of the peri-implant mucosa surrounding an implant crown – the Pink Esthetic Score (PES) was first published by Furhauser (Furhauser), followed by a modification of PES and a development of the White Esthetic Score (WES) which describes the esthetic of the implant crown itself by Belser (Belser 2009). Different other indices have been described in the literature and have also been compared with PES/WES regarding the reproducibility, reliability, validity and precision (Tettamanti 2016, Lanza 2017, Hof et al 2018, Arunyanak 2017).

Another indication for the use of an objective esthetic index can be the description of esthetic failures in the literature. On the base of an objective index esthetic failures can be differentiated between pink- tissue failures and white- tissue failures (Fuentalba et al 2015).

The implementation of a provisional prosthetic phase can optimize the final esthetic outcome of the pink esthetics- the peri-implant mucosa- surrounding the future implant crown. The evolution of dental materials, abutment designs and digital technologies made it possible that implant abutments can be fabricated from high-strength ceramic materials like zirconium dioxide which then can be implemented within the prosthetic implant workflow (Guess PC). These have shown to have esthetic advantages for the

white esthetics (Jung RE, Zembic A, Linkevicius T). These abutments can be either prefabricated/stock or individualized using digital technologies.

Focusing on patient's perception, the esthetic zone is the site of most concern, high expectation and attention when being restored with implant born restorations.

Controlled clinical trials have shown that the respective overall implant survival and success rates are similar to those reported for other indications (Adell 1981, Buser 2009/ 2011/2012/ 2013a+2013b, Chappuis 2018, Wittneben 2014).

However, clinical studies that actually measure treatment success, including the critical and systematic assessment of outcomes with implant supported prostheses in the esthetic zone as well as objective esthetic parameters and patient reported outcome measurement (PROMs) are still scarce.

### **Aim and outline of thesis**

The aim of this thesis is to investigate factors influencing the final esthetic outcome (provisional phase, abutment selection, vertical growth of the adjacent teeth) of implant supported prosthesis using objective esthetic parameters and including patient's perception of the total treatment.

To achieve this, aim the following research questions were focused on:

- A) Does the use of a provisional phase within the implant prosthetic workflow lead to a long-term esthetic benefit on final implant crowns and mucosa in the esthetic zone? A randomized controlled clinical trial was performed with 1-year (Chapter 1) and 3-year results (Chapter 2) using objective esthetic parameters.
- B) In the current literature, numerous indices used to qualitatively assess esthetics have been described. However, studies comparing the indices and their reproducibility are scarce. Which is the most reproducible and reliable esthetic index for the evaluation of single implant supported crowns and their surrounding mucosa (Chapter 3).
- C) The final esthetic outcome is also influenced by the selection of the implant abutment and the type of veneering ceramic. Which implant prosthetic workflow has the better esthetic outcome? A randomized prospective multicenter clinical trial was performed in two university centers to compare the overall clinical performance between individualized CAD/CAM abutments veneered with the



hand layered technique and prefabricated zirconium dioxide abutments veneered with pressed ceramics to restore implants inserted in single-tooth gaps in the anterior maxilla. One year (Chapter 4) and three-year results (Chapter 5) are presented.

- D) Vertical eruption of anterior maxillary teeth adjacent to single implant-supported crowns has been reported. This can influence the final long-term esthetic result. Is there continuous vertical tooth eruption next to single dental implants in the adult patients? A prospective clinical study was performed (Chapter 6).
- E) Patients perceptions using Patient Reported Outcome Measures (PROMS) are often included in clinical studies today. How satisfied are patients regarding the esthetic outcome of implant supported compared to tooth supported fixed dental prosthesis focusing on partially edentulous sites (Chapter 7) and single crowns (Chapter 8).

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# Chapter 1

Esthetic outcome of implant supported crowns with and without peri-implant conditioning using provisional fixed prosthesis – A randomized controlled clinical trial

**Published:**

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*Clin Implant Dent Relat Res. 2016 Dec;18(6):1153-1162.*

## **ABSTRACT**

**Background:** Achieving an optimal esthetic result using dental implants is challenging. Fixed implant-supported provisional crowns are often used to customize the emergence profile and to individualize the surrounding peri-implant soft tissue.

**Purpose:** The objective of this study is to evaluate whether the use of a provisional implant-supported crown leads to an esthetic benefit on implants that are placed in the esthetic zone. The null hypothesis is that there is no-difference between the two study groups.

**Material and methods:** 20 single implants (Bone Level, Straumann AG, Basel, Switzerland) were inserted in consecutive patients. After reopening, a randomization process assigned them to either cohort group 1: a provisional phase with soft tissue conditioning using the "dynamic compression technique" or cohort group 2: without a provisional. Implants were finally restored with an all-ceramic crown. Follow-up examinations were performed at 3 and 12 months including implant success and survival, clinical and radiographic parameters.

**Results:** After one year all implants successfully integrated, mean values of combined modPES and WES were 16.7 for group 1 and 10.5 for Group 2. This was statistically significant. Mean bone loss after one year was -0.09 and -0.08 for groups 1 and 2 respectively, without being statistically significant.

**Conclusion:** A provisional phase with soft tissue conditioning does improve the final esthetic result.

## INTRODUCTION

Clinical studies show adequate survival rates for the use of endosseous implants and implant-supported restorations over long-term periods<sup>1, 2</sup> in partially edentulous patients. However, achieving a successful treatment outcome in the esthetic zone is challenging. Detailed treatment planning and the evaluation of pre-existing risk factors determine the complexity of the case. An optimal esthetic implant restoration is defined as a combination of a visually pleasing prosthesis and surrounding peri-implant soft tissue architecture<sup>3</sup>. Even after a successful surgical intervention including the correct 3-dimensional position of the implant platform<sup>4</sup> and a successful build-up of the facial bone wall<sup>5</sup> the prosthetic finalization is demanding. Using implants placed at the level of the bone crest offers customization of the prosthetic margin position and design, the emergence profile and individual position of the zenith of the mucosa. Here, fixed implant-supported provisional restorations are used to condition the mucosa in order to finalize the soft tissue architecture prior to obtaining a final impression.

Different clinical methods of soft tissue conditioning with the use of a provisional restoration have been described in the literature<sup>6-8</sup>. In the present clinical trial, patients within the provisional-group were treated with the "dynamic compression technique"<sup>3</sup>, which is a method that relies on a combination of initial pressure and subsequent modification (reduction) of the provisional. In the beginning, pressure is added in several steps and it "squeezes" the soft tissue laterally to guide it in the right position and then it is important to strategically reduce the provisional by undercontouring - especially in the papillary region- to allow the tissue to fill in the created space<sup>3</sup>. There are currently no published randomized clinical trials comparing patient treatment outcomes with and without the use of a provisional restoration in the esthetic zone. In order to adequately test the hypothesis that the use of a provisional crown increases the esthetic result obtained, a blind randomized clinical study was performed.

The aim of this investigation is to objectively determine whether the use of a provisional implant supported crown leads to an esthetic benefit on implants that have been placed in the esthetic zone. The null hypothesis is that there is no difference between the two study groups.

# **MATERIALS AND METHODS**

## **Patient Cohort**

20 patients were consecutively admitted to this clinical study for the rehabilitation of a single edentulous gap in the anterior maxilla (tooth position: FDI: 13, 12, 11, 21, 22, 23). Ethical approval was gained from the Kings College London Ethical Committee, BDM/11/12-56 and written and informed consent was obtained from all the patients. Patients were treated by the same clinician who performed all surgical and prosthetic procedures (DF). The fabrication of the dental laboratory work was performed by one dental technician (AB).

All eligible patients were enrolled in a comprehensive multidisciplinary examination including medical and dental history. Prior to treatment, radiographic documentation with a peri-apical radiograph was undertaken (only a peri-apical was taken rather than a CBCT due to reduced radiation dose, the bite blocks were prepared at this stage for the customization of these peri-apicals). Intraoral photographs were taken. Irreversible hydrocolloid impressions (DEHP, UK) were obtained to produce articulated diagnostic casts. In order to evaluate the complexity of the case and the existing risk factors, the "ITI Esthetic Risk Assessment" was obtained from each case<sup>9</sup>. Periodontal parameters such as probing pocket depth (PPD) and recession of the gingival margin (REC) were recorded at six sites with a manual probe (UNC-15) using a light force (25 gm). The width of the buccal and oral keratinized gingival tissues was measured with a UNC-15 periodontal probe on the mid-buccal aspect of the alveolar mucosa/gingiva of the adjacent teeth and edentulous area.

## **Screening and eligibility criteria**

The subjects were evaluated for initial study eligibility during the screening visit. Those subjects who appear eligible according to the inclusion/exclusion criteria were asked to sign an informed consent form and were enrolled into the study.

All of the following criteria must be met for inclusion in the study:

### **General inclusion criteria**

- Males and females above the age of 25..
- Absence of uncontrolled or untreated periodontal disease.

- Absence of untreated carious lesions.
- Patient in good medical and psychological health as documented by self assessment.
- Patient's availability for follow-up.

#### **Local inclusion criteria**

- A single tooth replacement required in the incisor or canine region.
- Presence of both adjacent teeth.
- Presence of adequate native bone.

#### **General exclusion criteria**

If any of the following criteria are met, the subject must be excluded from the study:

- Patients who had any known diseases (not including controlled diabetes mellitus), infections or recent surgical procedures within 30 days of study initiation.
- Female patients who were pregnant or lactating.
- Patients who were on chronic treatment (i.e., two weeks or more) with any medication known to affect the oral status (e.g., phenytoin, dihydropyridine, calcium antagonists, cyclosporine) within one month of the baseline visit.
- Patients who were on concomitant anticoagulant therapy of warfarin (coumadine), clopidogrel, ticlopidine or once daily aspirin of more than 81 mg.
- Patients who knowingly had HIV or hepatitis.
- Physical handicaps that would interfere with the ability to perform adequate oral hygiene.
- Patients who had undergone administration of any investigational drug within 30 days of study initiation.
- Alcoholism or chronic drug abuse causing systemic compromise.
- Heavy smokers (>10/cigarettes per day).
- Patients suffering from a known psychological disorder.
- Patients with limited mental capacity or language skills such that study information could not be understood, informed consent could not be obtained, or simple instructions could not be followed.
- Patients with BOP > 30% at the completion of the pre-treatment phase.

#### **Local exclusion criteria**

- Inadequate bone availability.
- History of local radiation therapy.

- Presence of severe oral lesions.
- Presentation with an endodontic lesion in the neighboring areas to the experimental procedure.

## **Patient entry (informed consent, patient registration, and randomization)**

The patient was given a study information leaflet and informed written consent was signed by the patient and the clinician. Patient data was recorded on an Excel database and randomization was performed following entry into the trial and completion of the surgical phase. Therefore the randomization process occurred after the surgical phase.

## **Surgical Intervention**

Implant surgery was performed at six to eight weeks following tooth extraction in accordance with an early implant placement protocol<sup>5</sup>. Systemic antibiotics (single dose: 3g Amoxicillin per-orally) were administered to all patients 1 hour prior to the procedure followed by 500mg of Amoxicillin eight hourly for the first postoperative week.

Implants placed at the level of the bone crest (Bone Level Implant type RC) with a chemically modified, sandblasted and acid-etched surface (SLActive®, Straumann AG, Basel, Switzerland) were placed in a correct 3-dimensional position. Simultaneous contour augmentation was performed with locally harvested autogenous bone chips to cover the exposed implant surface on the facial aspect, followed by a superficial layer of deproteinized bovine bone mineral and covered with a collagen membrane (DBBM, Bio-Oss® and Bio-Gide®, Geistlich Pharma, Wolhusen, Switzerland). Following a period of between 12-16 weeks of healing, access to the implant was achieved by means of a crestal “D shaped” incision, not extending to the adjacent papilla. The 2mm healing cap was changed to a 4mm conical healing cap for a further week of soft tissue healing.

Paracetamol (1g every six hours per-orally) and ibuprofen (400mg every eight hours per-orally) were prescribed for pain control upon patient discretion. All patients were instructed to refrain from tooth brushing in the operated area and rinse with 0.2% chlorhexidine-digluconate mouthwash, three times per day, for one week. To avoid post-operative infection, all patients received systemic antibiotics: Amoxicillin 500mg every eight hours for the 1<sup>st</sup> post-operative week. Patients with penicillin allergy will be



prescribed 500 mg of erythromycin every six hours for the 1<sup>st</sup> post-operative week.

## **Randomization process**

Following successful surgical treatment the patient was then randomly assigned to either cohort. Sealed cards were constructed by a third party and the patient was assigned to either cohort.

**Cohort Group 1:** After the reopening procedure, a screw-retained implant-supported provisional crown was inserted, performing soft tissue conditioning with the dynamic compression technique. After six months of this provisional phase, a definitive implant-supported crown was inserted.

**Cohort Group 2:** After the reopening procedure, a final impression was obtained and an implant-supported crown was fabricated and inserted directly (without an implant-supported provisional phase).

## **Prosthetic Phase**

Patient cohort group 1 received a laboratory fabricated screw-retained provisional crown which was inserted and torqued to 15 N/cm. Peri-implant soft tissue conditioning occurred utilizing the dynamic compression technique<sup>3</sup>, with compression of the tissues followed by sequential reduction of the provisional restoration. The provisional crowns were left in situ for 6 months. A customized impression coping was constructed by removing the provisional crowns and replacing onto the initial cast. A light bodied fast setting addition silicone impression (Honigum, DGM, Germany) was taken of the apical half of the provisional restoration. The provisional restoration was replaced in the patient's mouth to prevent soft tissue collapse. Open tray impression copings were inserted onto the cast with notable voids present between coping and silicone index. Bis-acrylic temporary crown and bridge material (Luxatemp, DMG, Germany) was injected into the space created in order to customize the impression coping and accurately record the emergence profile of the provisional. An open tray polyether impression (Impregum, Espe, Germany) was taken using a customized individual tray, followed by an irreversible hydrocolloid impression of the provisional in situ (DEHP, UK).

Abutments were fabricated via a CAD/CAM system (CARES, Straumann AG, Basel, Switzerland) made of zirconium dioxide and all ceramic screw-retained single crowns were fabricated in the same dental laboratory.

The crown was torqued to 35Ncm, Teflon was used as a spacer and composite resin placed in the screw access cavity. Occlusion was evaluated in static and dynamic movements following the mutually protective occlusion concept<sup>10</sup>. Oral hygiene instructions were given.

Patients of cohort group 2 were treated without a fixed implant supported provisional phase and, therefore, a closed tray impression was taken in polyether (Impregum, Espe, Germany) using a stock tray. The final all ceramic screw-retained implant crown was fabricated the same way as patients in cohort group 1.

### **Follow-up examinations**

After completion of therapy, follow-up examinations were performed of all 20 patients. Patients were seen after 3 months and 12 months after baseline (Fig. 1, Fig. 2). Implant success and survival were assessed at baseline, 3 and 12 months post baseline visit. A surviving implant is defined as an implant in place at the time of follow-up.

A particular implant will be deemed a success if all of the following success criteria (according to Buser et al.<sup>11</sup> and Albrektsson et al.<sup>12</sup>) apply:

- Absence of persisting subjective discomfort such as pain, foreign body perception and or dysaesthesia (painful sensation)
- Absence of a recurrent peri-implant infection with suppuration (where an infection is termed recurrent if it is observed at two or more follow-up visits after treatment with systemic antibiotics)
- Absence of implant mobility on manual palpation
- Absence of any continuous peri-implant radiolucency

### **Clinical parameters**

- Modified pink esthetic score (modPES): assessing the peri-implant soft tissue based on 5 variables (mesial and distal papilla, curvature of the facial mucosa, level of the facial mucosa, root convexity/soft tissue color and texture at the facial aspect of the implant site). Each variable is graded by the use of a score (0, 1 and 2)<sup>13,14</sup>(table 1)

- White esthetic score (WES): evaluates the visible part of the implant restoration itself with five parameters: general tooth form, outline/volume of the crown, color, surface texture, translucency and characterization by a score of 0, 1, 2<sup>13</sup>(table 1)

Post operative intraoral photographs were taken using a Nikon D90 (Nikon, Japan) AF-S Micro Nikkor 105mm lens with side flashes.

The modPES and WES assessments after one year follow-up were completed by two experienced specialist prosthodontists, one of which has used this index previously in published studies (Fig 1, Fig. 2). The examiners were blinded regarding the groups (they did not know if the implants were previously restored with a provisional phase or not). The assessment was completed at two different sessions at a 1-week interval. The scores between the two observers were correlated and where differences were present, a discussion between the observers resulted in an agreed score. If an agreement could not be reached, the lower score was taken.

### **Radiographic parameters**

- DIB values (distance from the implant shoulder to the first bone-to-implant contact, in mm) measured on periapical radiographs as the average of the obtained mesial and distal values<sup>15</sup>.

### **Statistical Analyses**

Statistical analyses of the modPES and WES results were divided into the two cohorts. Mean and median values were produced for each group with relevant standard deviations. All of the results were then tabulated from highest to lowest combined scores. The Mann U Whitney test was used to assess the statistical data produced.

## **RESULTS**

No patients were lost to the study or fulfilled any early exit conditions. Demographic data is summarized in table 2, all of the patients were medically fit and none were tobacco smokers. The randomization process placed cases D, E, F, I, K, N, P, Q, S and T into group 1 (with provisional restoration) (Fig. 1) and A, B, C, G, H, J, L, M, O, and R into group 2 (without provisional phase) (Fig. 2).

### **Evaluation of biologic parameters**

All of the implants achieved primary stability and there were no post-operative complications noted. Osseointegration occurred in all cases and was tested at the impression stage by means of torque testing the implants to 35 Ncm. Clinically, there was no evidence of infection or suppuration around the healed implant sites.

### **Evaluation of the esthetic parameters**

The implant positions consisted of 10 central incisors, 5 lateral incisors and 5 canines. The one-year photographic review of each completed implant crown is illustrated in figures 1 and 2.

The individual modPES and WES scores for each implant are listed in table 3. ModPES and WES scores were all significant different between group 1 and 2 ( $p < 0.05$ ) except for color ( $p = 0.0508$ ) and surface texture ( $p = 0.0544$ ). Combined modPES and WES scores are shown in histogram - figure 3.

### **Statistical evaluation**

Mean values of combined modPES and WES are 16.7 for group 1, with a standard deviation (SD) of 2.06. Group 2 has a mean combined modPES and WES of 10.5, with a SD of 3.31.

### **Z-ratio**

The Z-Score is 3.5151. The p-value is 0.00044. The result is significant at  $p \leq 0.05$ .

### **U-value**

The U-value is 3. The critical value of U at  $p \leq 0.05$  is 23. Therefore, the result is significant at  $p \leq 0.05$ .

It is therefore possible to reject the null hypothesis at the  $p \leq 0.05$  level.

### **Radiographic Findings**

The standardized radiographs did not reveal any peri-implant radiolucency of the implants during the treatment process and as such the success criteria was fully met. Only one of the cases could not be analyzed due to the poor quality of the initial radiograph. The mean bone loss around the implants following one year of loading was -0.08mm with a SD of 0.15. The maximum measured bone loss was -0.35mm (table 4).

The mean bone loss associated with group 1 was -0.09 (SD 0.1568) and group 2 was -0.08 (SD 0.1536). This was not statistically significant.

## **DISCUSSION**

In esthetic sites the implementation of a distinct provisional phase is a commonly used treatment concept<sup>3, 6-8, 16</sup>. Dental professionals are trained to utilize provisional restorations upon natural teeth and implants in daily clinical practice. Fixed implant-supported provisionals are used as a diagnostic tool to evaluate the position of the future incisor edge, the profile view, the prosthetic shape, shade and occlusion. In addition a provisional restoration is an excellent communication tool between the patient, clinician and the dental technician.

In esthetic sites, dental implant designs to be placed at the bone level are commonly used, they offer a larger degree of individualization of the emergence profile and position of the final crown margin. In such cases a provisional phase is commonly used in order to condition and shape the peri-implant soft tissue architecture, including the mucosa and the emergence profile, the papillae, the cervical soft tissue margin and the finalization of the position of the gingival zenith position.

In esthetic sites using bone level implants a provisional phase is recommended. However, it is the clinician's choice whether to restore the implant directly after implant placement or to implement a provisional restoration. With the choice to restore a bone level implant directly, only a rough estimation of the mucosa and emergence profile is possible and in addition, the high pressure added on that site during insertion of the restoration will result in an unknown and unpredictable esthetic outcome of the surrounding soft tissue.

Applying a provisional restorative phase is time and cost intensive as it requires the

fabrication of an implant-supported provisional and adding extra chair time to modify step-by-step the provisional during this treatment phase. Therefore, the question is if this additional provisional treatment step will provide a significant clinical benefit in respect to the final esthetic outcome.

To date there are no randomized clinical trials published that adequately determine whether a provisional phase increases the esthetic result to a clinically relevant degree. In order to test the hypothesis that the use of a provisional crown increases the final esthetic outcome, a blind, randomized, clinical study was performed, where the final esthetic outcomes of both the peri-implant mucosa and the implant-supported crown were compared, assessed by the pink / white esthetic scores PES/WES<sup>13, 14</sup>. Numerous other esthetic indices exist evaluating the peri-implant soft tissues of implant-supported restorations such as the implant crown aesthetic index (ICAI)<sup>17</sup>, the papilla index<sup>18</sup>, the Copenhagen index score<sup>19</sup>, the complex esthetic index<sup>20</sup>, and the peri-implant and crown index (PICI)<sup>21</sup>. In today's literature the pink esthetic score PES<sup>14</sup> and the PES/WES<sup>13</sup> are frequently used for esthetic evaluations of single implant crowns<sup>21</sup>. An investigation that compared the three different esthetic indices for the evaluation of single implant supported crowns, including the reproducibility of the indices concluded that the two indices PES/WES and PICI are to be recommended for clinical use and that the PES/WES index is the most user-friendly one<sup>21</sup>. Both indices PES/WES and PICI were the most reproducible esthetic indices which were not influenced by different observers and resulted in similar outcomes in the overall esthetic evaluation<sup>21</sup>.

A clinical study published by Jemt et al.<sup>18</sup> reported a total of 63 single-implant restorations where the soft tissue was either allowed to heal to provisional resin crowns (n = 25) placed at the time of second-stage surgery, or to healing abutments (n = 38) before final crown insertion<sup>18</sup>. Results obtained 2 years post-crown insertion indicated that the use of provisional crowns may restore soft tissue contour faster than healing abutments alone, but the papillae adjacent to single-implant restorations presented similar volume in both groups after 2 years in function<sup>18</sup>. In the paper published by Jemt et al.<sup>18</sup>, the papilla index was used for the esthetic evaluation. Extracting the data of the papilla presence in the PES score of the present study, the papilla was ranked being completely filled on the mesial aspect in the cohort group with a provisional phase and partially filled without a provisional restoration. In contrast, the distal papilla was a partial fill in both phases, with a mean value of 1.4 with a provisional phase and

0.6 without a provisional phase.

Focusing on the results of the radiographic evaluation of Jemt's investigation, (a positive value was indicative of bone loss, compared to this study where a negative value indicates bone loss,) the mean marginal bone loss at the implants was 0.9 mm after 1 year, and no differences were observed between the 2 groups<sup>18</sup>. The present study shows a mean marginal bone loss between insertion of the final crown and 1 year follow up data with group 1: -0.09 mm and group 2: -0.08 mm which was also not statistically significant.

The results of the present clinical study demonstrate a significant improvement of the final esthetic outcome when using a provisional implant-supported crown during implant therapy. Therefore, the null hypotheses can be rejected. This randomized controlled trial shows a statistically significant higher PES and WES score using a fixed implant-supported provisional compared with the cohort group where the implants were restored directly without a provisional phase.

It can be concluded that the use of a fixed implant-supported provisional crown leads to an esthetic benefit on implants that have been placed in the esthetic zone.

## **CONCLUSIONS**

**Within the limitations of this study design, the following conclusions can be resumed:**

- Patient cohort group with a fixed implant-supported provisional restoration shows statistically significant higher PES and WES scores compared with the cohort group where the implants were restored directly without a provisional phase.
- Mean marginal bone loss between insertion of final crown and 1- year follow up was with group 1: -0.09 mm and group 2: -0.08 mm. This was not statistically significant.

# TABLES

**TABLE 1: Overview modified pink and white esthetic score**

modPES			
Parameter	Absent	Incomplete	Complete
Mesial papilla	0	1	2
Distal papilla	0	1	2
	Major Discrepancy	Minor Discrepancy	No Discrepancy
Curvature of facial mucosa	0	1	2
Level of facial mucosa	0	1	2
Root convexity/soft tissue color and texture	0	1	2
Maximum total modPES score			10
WES			
Parameter	Major Discrepancy	Minor Discrepancy	No Discrepancy
Tooth form	0	1	2
Tooth volume/outline	0	1	2
Color (hue/value)	0	1	2
Surface texture	0	1	2
Translucency	0	1	2
Maximum total WES score			10

**TABLE 2: Demographic data**

Male	Female	Mean Age	Min Age	Max Age	Central Incisors	Lateral Incisors	Canines
9	11	51.4	26	72	10	5	5



**TABLE 3: 1-year results pink and white esthetic score**

Score	1-year results			Group 1		Group 2		p-value
	0	1	2	Mean	Median	Mean	Median	
Mesial Papilla	3	9	8	1.8	2	0.7	1	0.0001
Distal Papilla	5	10	5	1.4	1	0.6	1	0.0352
Curvature of facial mucosa	0	6	14	2	2	1.4	1	0.0017
Level of facial mucosa	0	9	11	1.8	2	1.3	1	0.0239
Root convexity, soft tissue colour & texture	2	10	8	1.7	2	0.9	1	0.0004
<b>Total modPES</b>	<b>10</b>	<b>44</b>	<b>46</b>	<b>8.7</b>	<b>9</b>	<b>4.9</b>	<b>5.5</b>	<b>0.0001</b>
Tooth Form	0	12	8	1.6	2	1.2	1	0.0739
Tooth outline	1	16	3	1.3	1	0.9	1	0.0419
Color (Hue/Value)	3	10	7	1.5	1.5	0.9	1	0.0508
Surface Texture	0	6	14	1.9	2	1.5	1.5	0.0544
Translucency & Characterization	2	8	10	1.7	2	1.1	1	0.0453
<b>Total WES</b>	<b>6</b>	<b>52</b>	<b>42</b>	<b>8</b>	<b>9</b>	<b>5.6</b>	<b>7</b>	<b>0.0036</b>

**TABLE 4: Radiographic parameter (dib) of the 20 implants analyzed after one year**

Case	A	B	C	D	E	F	G	H	I	J
Bone remodeling (mm)	-0.19	-0.12	0.00	<b>-0.09</b>	<b>0.19</b>	<b>-0.21</b>	-0.21	-0.35	<b>0.00</b>	-0.07
Case	K	L	M	N	O	P	Q	R	S	T
Bone remodeling (mm)	<b>No data</b>	0.05	0.20	<b>-0.06</b>	-0.05	<b>-0.08</b>	<b>-0.18</b>	0.00	<b>-0.09</b>	<b>-0.34</b>

## LEGENDS OF FIGURES

**Fig. 1:** Clinical pictures of all implant-supported crowns of group 1 after one year follow up. These implants were all restored with a fixed implant-supported provisional crown with peri- implant conditioning prior to finalization.

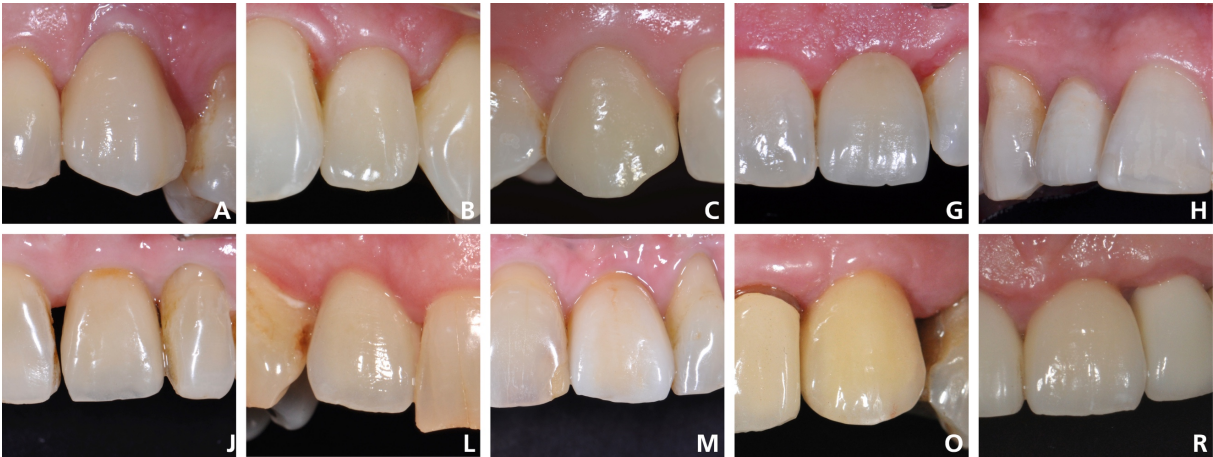
**Fig. 2:** Clinical pictures of all implant-supported crowns of group 2 after one year follow up. Here an implant-supported crown was fabricated after the reopening procedure and inserted directly (without an implant-supported provisional phase).

**Fig. 3:** One- year results combined pink and white esthetic score

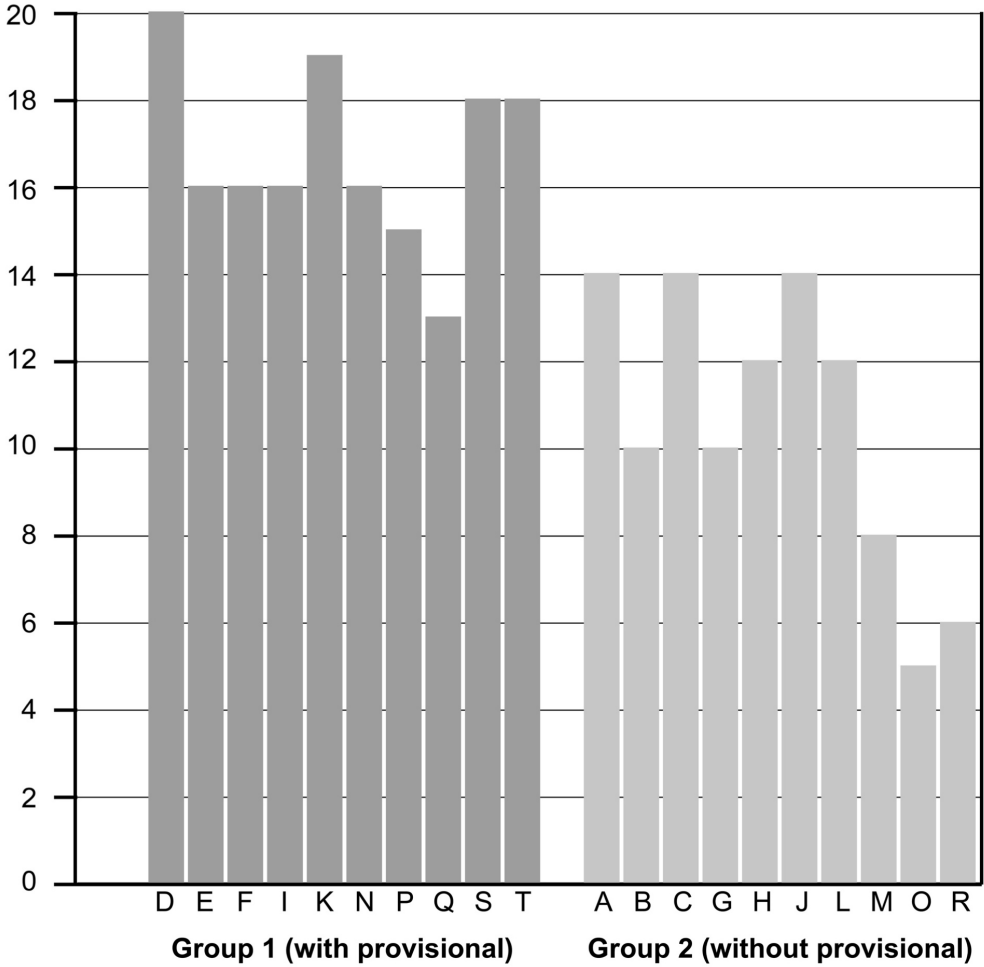
**FIGURE 1**



**FIGURE 2**



**FIGURE 3 – 1-YEAR RESULTS COMBINED PINK AND WHITE ESTHETIC SCORE**



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# Chapter 2

Influence of the Fixed Implant- Supported Provisional Phase on the Esthetic Final Outcome of Implant- Supported Crowns – 3- year results of a Randomized Controlled Clinical Trial.

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## **ABSTRACT**

**Objectives:** The aim of this investigation was to evaluate whether the use of a provisional implant-supported crown improves the final esthetic outcome of implant crowns that are placed within esthetic sites.

**Material and Methods:** Twenty endosseous implants were inserted in sites 13 to 23 (FDI) in 20 patients. Following the reopening procedure, a randomization process assigned them to either cohort group 1: a provisional phase with soft tissue conditioning using the "dynamic compression technique" or cohort group 2: without a provisional phase. Screw-retained all ceramic crowns were inserted. Clinical follow-up appointments were completed at 36 months evaluating clinical, radiographic outcomes and implant success and survival.

**Results:** After three years all implants survived; one implant-supported crown was excluded from the study due to adjacent tooth failure replaced with a further implant supported crown. ModPES scores were significantly different between groups 1 and 2 ( $p=0.018$ ); WES scores were not statistically different between both groups ( $p=0.194$ ). Mean values of combined modPES and WES were 15.6 for group 1, with a standard deviation (SD) of 3.20. Group 2 had a mean combined modPES and WES of 12.2, with a SD of 3.86. Mean bone loss after three year was -0.05 and -0.04mm for groups 1 and 2 respectively, without being statistically significant.

**Conclusion:** Fixed implant-supported provisionals improve the final esthetic outcome of the peri-implant mucosa.

## INTRODUCTION

Rehabilitation of the partially edentulous patient using implant borne fixed reconstructions show high survival over long-term periods.<sup>1</sup> The single edentulous space in the esthetic zone presents one of the most frequently used indications for a dental rehabilitation using endosseous implants.

In the anterior maxilla many risk factors are often present as a thin buccal bone wall, often combined with a thin tissue biotype and the visibility of the peri- implant mucosa and the future crown during smile and speech. The rehabilitation of esthetic sites aiming a prosthetic pleasing result is often challenging as ideal overall esthetic outcomes are dependend of both- pink and white esthetics.<sup>2</sup> To achieve predictable and long-term stable outcomes backward-driven treatment planning including the evaluation of prosthetic and surgical risk factors is essential.<sup>3, 4</sup>

Different soft tissue conditioning techniques have been described in the literature; the “dynamic compression technique” was used in the present clinical cohort study.<sup>5</sup>

The provisional phase has the goal to finalize the peri-implant mucosa prior to final impression. Especially in anterior sites, when placing implants at the bone level an implementation of a provisional phase are recommended. However it requires additional treatment time and costs. In order to adequately test the hypothesis that the use of an implant supported provisional influences the overall final esthetic outcome, a blind randomized clinical trial was conducted.

The one-year results of the present study were previously published and showed statistically significant results for the modified pink esthetic (modPES) and white esthetic (WES) indices, presenting an improvement of the final esthetic outcome for the cohort group including a provisional phase.<sup>6</sup>

The aim of this randomized clinical trail was to determine whether the use of a provisional implant supported crown leads to a continued esthetic benefit on implant crowns that have been inserted in the anterior zone. The null hypothesis is that there is no difference between the two study groups.

# MATERIALS AND METHODS

## Patient Cohort

Twenty patients with a single edentulous gap in the anterior maxilla (FDI 13-23) were included according to the inclusion and exclusion criteria. Ethical approval was gained from the Kings College London Ethical Committee, BDM/11/12-56 and written and informed consent was signed from all the patients. Surgical and prosthetic procedures were performed by the same clinician (DF), dental laboratory work by one dental technician (AB).

## Screening and eligibility criteria

The subjects were evaluated for initial study eligibility during the screening visit. Those subjects who appear eligible according to the inclusion/exclusion criteria were asked to sign an informed consent form and were enrolled into the study. Inclusion and exclusion criteria are presented in table 1.

## Clinical procedures

Details of the clinical procedures were previously published within the 1-year follow up data of the present study.<sup>6</sup>

All patients received a platform switched implant with a chemically modified, sandblasted and acid-etched surface (Bone Level Implant, RC, SLActive®, Straumann AG, Basel, Switzerland) using the early implant placement concept and simultaneous contour augmentation.<sup>7,8</sup> Randomization was performed after the surgical phase using sealed envelopes, which were fabricated, by a third party and the patient was assigned to either cohort 1 or 2:

**Cohort Group 1:** After the reopening procedure, a screw-retained implant-supported provisional crown was inserted, performing soft tissue conditioning with the dynamic compression technique.<sup>9</sup> After six months of this provisional phase, a customised impression coping was used and a definitive implant-supported crown was inserted.

**Cohort Group 2:** After the reopening procedure, a final impression was obtained and an implant-supported crown was fabricated and inserted directly (without an implant-supported provisional phase).



The final screw-retained implant supported crowns were made with individualized CAD/CAM abutments (CARES, Straumann AG, Basel, Switzerland) made of zirconium dioxide and veneered with all ceramic. The crown was torqued to 35 Ncm, teflon was inserted as a spacer and composite resin placed in the screw access cavity. The mutually protective occlusion concept was implemented.<sup>10</sup> Oral hygiene instructions were explained in detail.

## **Follow-up examinations**

Clinical follow-up exams were obtained of all 20 subjects. They were evaluated after 3 and 12 and 36 months after baseline (Fig.1, Fig. 2). Baseline was defined as insertion of the implants. Implant success and survival were documented at baseline, 3 and 12 and 36 months post baseline visit. A surviving implant is defined as an implant in place at the time of follow-up.

A particular implant will be deemed a success if all of the following success criteria (according to Buser et al. 1991<sup>11</sup> and Albrektsson et al. 1986<sup>12</sup>) apply:

- Absence of persisting subjective discomfort such as pain, foreign body perception and or dysaesthesia (painful sensation)
- Absence of a recurrent peri-implant infection with suppuration (where an infection is termed recurrent if it is observed at two or more follow-up visits after treatment with systemic antibiotics)
- Absence of implant mobility on manual palpation
- Absence of any continuous peri-implant radiolucency

## **Clinical parameters**

- Modified pink esthetic score (modPES): evaluation of the peri-implant soft tissue based on 5 variables (mesial and distal papilla, curvature of the facial mucosa, level of the facial mucosa, root convexity/soft tissue color and texture at the facial aspect of the implant site). Each variable is graded by the use of a score 0, 1 and 2.<sup>13, 14</sup>
- White esthetic score (WES): assess the visible part of the implant restoration itself with five parameters: general tooth form, outline/volume of the crown, color, surface texture, translucency and characterization by a score of 0, 1, 2.<sup>13</sup>

ModPES and WES assessments were obtained after three-year follow-up by two experienced specialist prosthodontists, both have used this index previously in published studies (Fig. 1, Fig. 2). The examiners were blinded regarding the groups (they did not know if the implants were previously restored with a provisional phase or not). The assessment was completed at two different sessions at a 1-week interval. The scores between the two observers were correlated and where differences were present, a discussion between the observers resulted in an agreed score. If an agreement could not be reached, the lower score was taken.

### **Radiographic parameters**

Every radiograph was calibrated using the software “Image J” from NIH that measures the distances between the threads of the implant and calibrated to the known inter-thread distance of the implant. The distance from the implant shoulder to the first bone-to-implant contact (DIB) was measured in millimeters on peri-apical radiographs as the average of the obtained mesial and distal values.<sup>15</sup>

### **Statistical Analyses**

Statistical analyses of the modPES and WES results were divided into the two cohorts. Mean and median values were produced for each group with relevant standard deviations. All of the results were then tabulated from highest to lowest combined scores. The Mann U Whitney test was used to assess the statistical data produced.

## **RESULTS**

In table 2 an overview of the demographic statistics is given, all of the subjects were in good medical condition and nonsmokers. Randomization divided cases D, E, F, I, K, N, P, Q, S and T into group 1 (including an implant-supported provisional within the prosthetic workflow) (Fig. 1) and A, B, C, G, H, J, L, M, O, and R into group 2 (without an implant-supported provisional) (Fig. 2).

All patients completed the three-year clinical follow-up.

### **Survival and success of the implants and crowns**

Primary stability was achieved, no post-operative complications, no evidence of infection or suppuration around the healed implant sites were documented up to three years. In one case a recession exposing the abutment part of the zirconia substructure

was noted after 36 months and one crown had porcelain chipping after 24 months, which was not replaced. The prosthetic success rate was 95% and survival rate was 100%. The implant survival was 100%.

### **Esthetic parameters**

Table 3 presents the individual modPES and WES scores.

The modPES scores for mesial and distal papillae were significant higher in group 1 comparing to group 2. Mean total modPES score are 8.1 for group 1 and 5.5 for group 2, concluding total modPES scores which significant different between groups 1 and 2 ( $p=0.018$ ).

WES scores were not statistically different between both groups ( $p=0.194$ ). An overview of the combined modPES and WES scores are presented in a bar chart in figure 3.

Mean values of combined modPES and WES are 15.6 for group 1, with a standard deviation (SD) of 3.20. Group 2 has a mean combined modPES and WES of 12.2, with a SD of 3.86. The Z-score of the Z-ratio is 1.837. The p-value is 0.032. The result is significant at  $p<0.05$ .

### **Radiographic Findings**

Standardized radiographs were used. Two cases could not be analyzed due to difficulties in identifying the exact position of bone due to superimposition of the silicone matrix. The mean bone loss around the implants at the three- year follow up was -0.04mm with a SD of 0.17mm. Mean bone loss of group 1 was -0.05mm (SD 0.21) and group 2 was 0.04mm (SD 0.17) (table 4) without being statistically significant.

## DISCUSSION

The mucosa profile of a dental implant crown differs compared to a natural tooth configuration. An implant-supported provisional can modify the mucosa and emergence profile of the peri-implant soft tissue architecture, it also improves the formation of the interdental papillae. During the implant- prosthetic workflow the clinician can decide between different treatment options before finalizing the implant supported crown: 1.) vague assumption of the emergence profile defined by the dental technician, and insertion with potentially high pressure towards the fragile implant mucosa; or 2.) a step-wise conditioning of a fixed implant-supported provisional combined after a customized impression transfer of the individualized soft tissue. In an investigation by Wittneben et al. 2016<sup>5</sup>, mucosa profile changes were analyzed digitally before and after soft tissue conditioning with a fixed implant provisional using the “dynamic compression technique”. Analyzing the volume changes within the mucosa and emergence profile before and after soft tissue conditioning with an implant-supported provisional- a significant difference was documented. The change was more than doubled compared to the initial profile of the healing abutments.<sup>5</sup> Therefore, the implementation of a distinct provisional phase was recommended.

The findings of the present randomized clinical trial underline these outcomes. These two treatment options were compared in the present trial and the esthetic outcome clinically documented. Previously published results of the one-year and the present three-year data confirm a statistically significant difference in the esthetic outcome of the modPES ratings.<sup>6</sup> ModPES index is evaluating the surrounding peri-implant mucosa and the cohort group implementing a fixed provisional phase had a statistical significant better esthetic outcome compared to the workflow without provisionalization. The use of the PES/WES index is highly recommended for clinical studies, as it represents the most frequently used esthetic index for implant supported crowns, one of the most reproducible index and the most user- friendly esthetic index.<sup>16</sup> In the present clinical trial the modPES results were stable over three years. Cohort group including provisionalization presented mean data of 8.7 out of 10 (maximum) after one year and 8.1 after three years.<sup>6</sup> Cohort group without a provisional phase mean value was 4.9 after one year and 5.5 after three years.<sup>6</sup> A randomized clinical trial focusing on the esthetic and clinical performance of implant supported all ceramic single crowns used a similar implant prosthetic workflow compared to the present clinical trial. Both of their cohort groups used single bone level implants in esthetic sites

implementing a fixed implant supported provisional phase using the dynamic compression technique and finalizing the crowns with all ceramic abutments.<sup>2</sup> The mean modPES results were here 7 and 7.65, similar to the results of the cohort group 1 in the present investigation.<sup>2</sup>

However, no other randomized clinical trial focusing on the implementation of implant supported provisionals within the prosthetic workflow is published.

Jemt et al.<sup>17</sup> investigated in a clinical trial 63 single-implant crowns where the soft tissue was either allowed to heal to provisional resin crowns (n = 25) placed at the time of second-stage surgery, or to healing abutments (n = 38) before finalization of the crown.<sup>17</sup> The data indicated that the use of provisional crowns may restore soft tissue contour faster than healing abutments alone, but the papillae adjacent to single-implant crowns showed similar volume in both groups after 2 years.<sup>17</sup>

The results of the present randomized clinical trial confirm stable peri- implant soft tissue and overall esthetic outcomes also after 3 years in function. A significant improvement of the peri- implant soft tissue outcomes was shown when a provisional implant supported crown was used within the workflow. Therefore, the null hypotheses can be rejected.

Data of the WES index results were not statistically significant different between both groups after three years. At the one year follow up the WES data were statistically different in favor to the group implementing a provisional phase. It was assumed that a provisional might help to determine the final crown design and therefore improving the final esthetic outcome of the crown itself. However this could not be confirmed with the three year data.

Focusing on the marginal bone loss there was no statistically significant difference between Group 1 and Group 2 and less mean bone loss compared to the one year data (tab. 4).

Although the use of an implant-supported provisional and soft tissue conditioning phase requires more chair time and therefore more costs (average 4 clinical appointments over 145 days<sup>5</sup>), it is recommended for implants placed in esthetic sites as it improves the overall final esthetic outcome.

The limitations of the present clinical study were the small sample size- however still showing significant results- and overall being the only randomized clinical trial to date- testing the influence of the provisional phase on the final esthetic results to a clinically relevant degree.

## **CONCLUSIONS**

**The following conclusions can be resumed:**

- Patient cohort group including a fixed implant-supported provisional crown showed statistically significant higher modPES scores compared with the cohort group without provisionalization.
- Mean marginal bone loss between time of delivery of final crown and 3- year follow up was: group 1: 0.05 mm; group 2: 0.04mm, without being statistically significant.

## **ACKNOWLEDGMENTS**

Straumann Group, Basel, Switzerland has provided financial support for the material (implant prosthetic components) and patient treatment for this investigation.

## **CONFLICT OF INTEREST**

There is no conflict of interest from any of the authors in respect to the present investigation.

# TABLES

**TABLE 1: Inclusion and exclusion criteria**

<b>General inclusion criteria</b>	<b>General exclusion criteria</b> If any of the following criteria are met, the subject must be excluded from the study:
Males and females above the age of 25.	Patients who had any known diseases (not including controlled diabetes mellitus), infections or recent surgical procedures within 30 days of study initiation.
Absence of uncontrolled or untreated periodontal disease.	Female patients who were pregnant or lactating.
Absence of untreated carious lesions.	Patients who were on chronic treatment (i.e., two weeks or more) with any medication known to affect the oral status (e.g., phenytoin, dihydropyridine, calcium antagonists, cyclosporine) within one month of the baseline visit.
Patient in good medical and psychological health as documented by self assessment.	Patients who were on concomitant anticoagulant therapy of warfarin (coumadine), clopidogrel, ticlopidine or once daily aspirin of more than 81 mg.
Patient's availability for follow-up.	Patients who knowingly had HIV or hepatitis.
	Physical handicaps that would interfere with the ability to perform adequate oral hygiene.
	Patients who had undergone administration of any investigational drug within 30 days of study initiation.
	Alcoholism or chronic drug abuse causing systemic compromise.
	Heavy smokers (>10/cigarettes per day).
	Patients suffering from a known psychological disorder.
	Patients with limited mental capacity or language skills such that study information could not be understood, informed consent could not be obtained, or simple instructions could not be followed.
	Patients with BOP > 30% at the completion of the pre-treatment phase.
<b>Local inclusion criteria</b>	<b>Local exclusion criteria</b>
A single tooth replacement required in the maxillary incisor or canine region.	Inadequate bone availability.
Presence of both adjacent teeth.	History of local radiation therapy.
Presence of adequate native bone.	Presence of severe oral lesions.
	Presentation with an endodontic lesion in the neighboring areas to the experimental procedure.

**TABLE 2: Demographic data**

Male	Female	Mean Age	Min Age	Max Age	Central incisors	Lateral Incisors	Canines
9	10	53.4	28	74	9	5	5

**TABLE 3: Three-year results mod pink and white esthetic scores**

Score	3-year results			Group 1		Group 2		p-value
	0	1	2	Mean	Median	Mean	Median	
Mesial Papilla	2	10	7	1.6	2	1	1	0.04746
Distal Papilla	4	6	9	1.6	2	0.9	1	0.03593
Curvature of facial mucosa	0	9	10	1.7	2	1.2	1	0.0951
Level of facial mucosa	0	7	12	1.8	2	1.4	1	0.10204
Root convexity, soft tissue colour & texture	4	8	7	1.4	2	0.9	1	0.0951
<b>Total modPES</b>				<b>8.1</b>	<b>9</b>	<b>5.5</b>	<b>3</b>	<b>0.01876</b>
Tooth Form	1	11	7	1.4	1	1.2	1	0.32636
Tooth outline	0	14	5	1.3	1	1.2	1	0.40517
Color (Hue/Value)	1	7	11	1.7	2	1.3	1.5	0.15386
Surface Texture	0	8	11	1.7	2	1.4	1	0.18406
Translucency Characterization &	0	11	8	1.4	1	1.4	1	0.45224
<b>Total WES</b>				<b>7.5</b>	<b>7</b>	<b>6.6</b>	<b>8</b>	<b>0.19489</b>



**TABLE 4: Radiographic parameters – bone level changes (dib) after 1 and 3 years**

Case	A	B	C	D	E	F	G	H	I	J
Bone remodeling (mm) after 1 year	-0.19	-0.12	0.00	-0.09	0.19	-0.21	-0.21	-0.35	0.00	-0.07
Bone remodeling (mm) after 3 years	-0.03	0.00	0.00	0.00	0.18	-0.58	-0.17	-0.22	0.00	-0.08
Case	K	L	M	N	O	P	Q	R	S	T
Bone remodeling (mm) after 1 year	NA	0.05	0.20	-0.06	-0.05	-0.08	-0.18	0.00	-0.09	-0.34
Bone remodeling (mm) after 3 years	NA	NA	0.20	0.02	0.07	0.01	NA	-0.00	-0.08	0.01

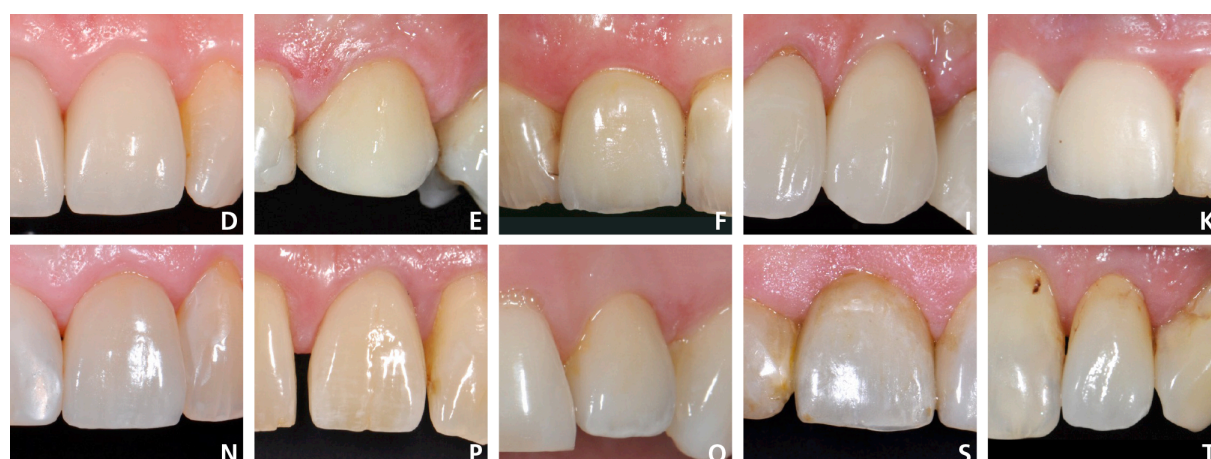
## LEGENDS OF FIGURES

**Figure 1:** Clinical pictures of all implant-supported crowns of group 1 after three year follow up. These implants were all restored with a fixed implant-supported provisional crown with peri- implant conditioning prior to finalization.

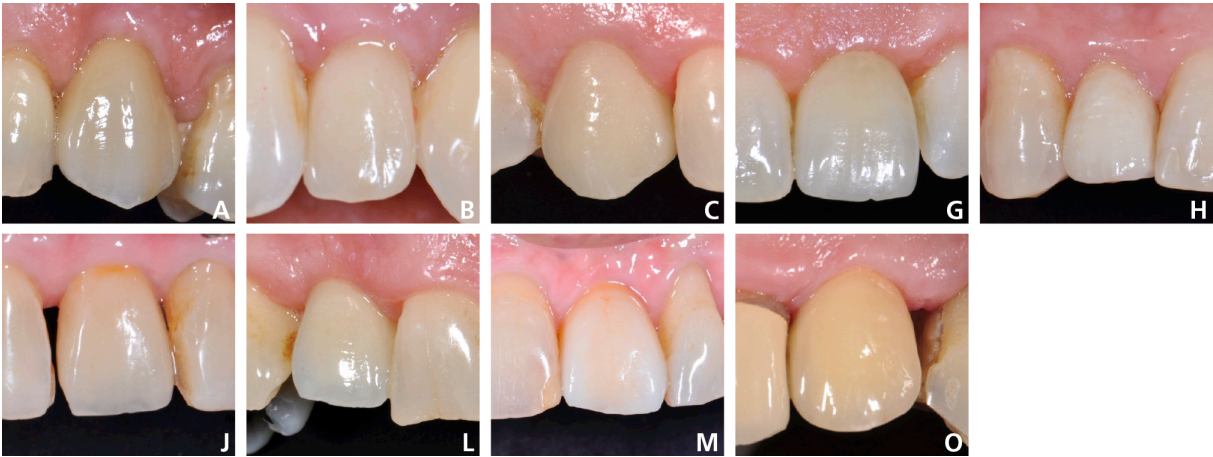
**Figure 2:** Clinical pictures of all implant-supported crowns of group 2 after three year follow up. Here an implant-supported crown was fabricated after the reopening procedure and inserted directly (without an implant-supported provisional phase).

**Figure 3:** Three- year results combined pink and white esthetic score

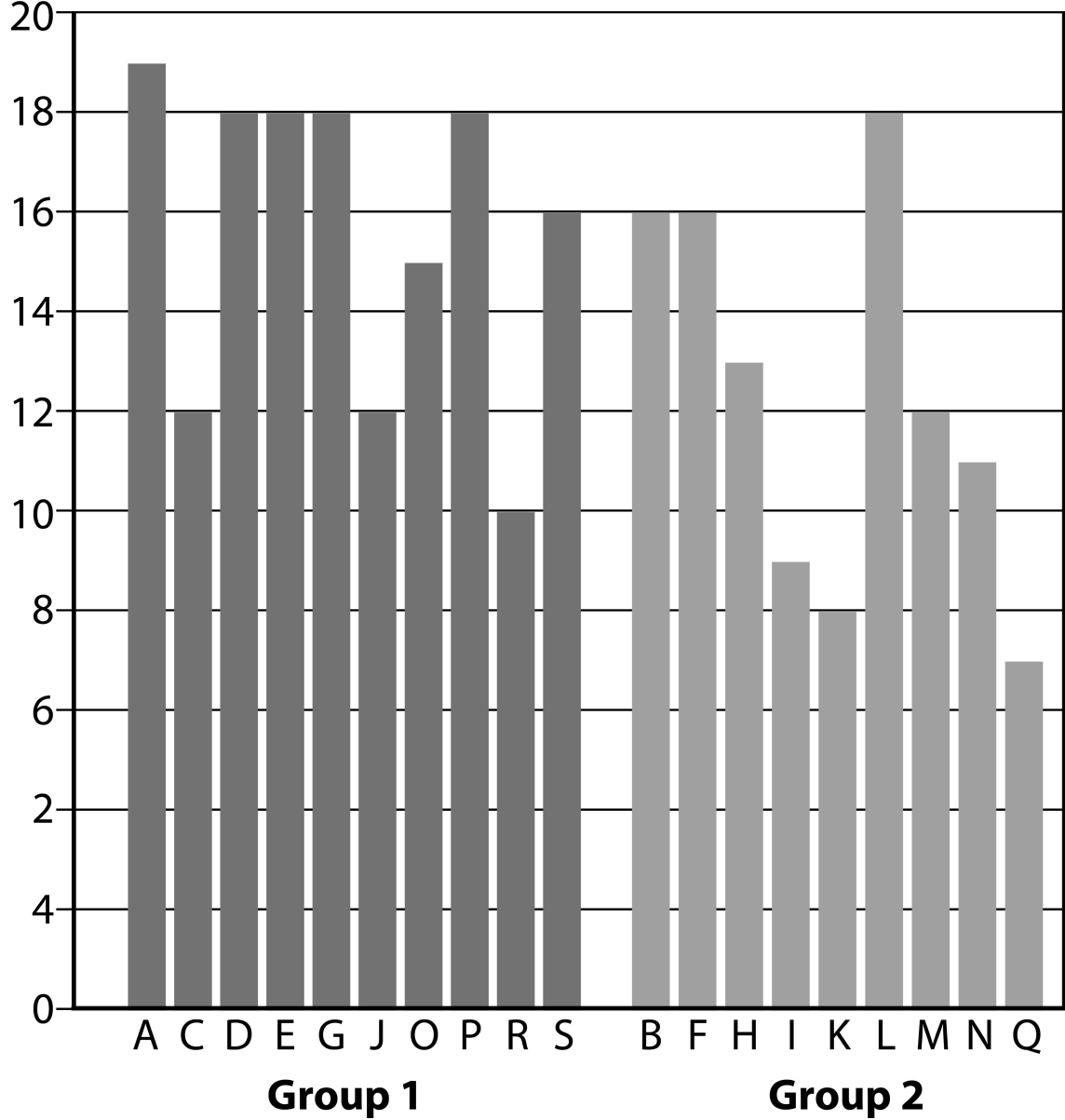
**FIGURE 1**



**FIGURE 2**



**FIGURE 3**



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# Chapter 3

## Esthetic Evaluation of Implant Crowns and Peri-Implant Soft Tissue in the Anterior Maxilla: Comparison and Reproducibility of Three Different Indices.

**Published:**

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## ABSTRACT

**Background:** A successful implant reconstruction with optimal esthetics consists of a visually pleasing prosthesis and complete and healthy surrounding soft tissue. In the current literature, numerous indices used to qualitatively assess esthetics have been described. However, studies comparing the indices and their reproducibility are scarce.

**Purpose:** The aim of this study was to compare three different esthetic indices for the evaluation of single implant supported crowns.

**Material and Methods:** A total of 10 prosthodontists (P), 10 orthodontists (O), 10 general dentists (G) and 10 lay people (L) independently performed the same assessment using 30 photographs and corresponding casts with three different esthetic indices (Peri-implant and Crown Index (PICI), Implant Crown Aesthetic Index (ICAI), "Pink Esthetic Score/ White Esthetic Score (PES/WES)) and repeated the evaluations four weeks later.

**Results:** The PES/WES and the PICI showed significantly higher esthetic scores (pink, white, total) and clinical acceptance compared to the ICAI in all four groups and in both assessments. The highest intraobserver agreement was achieved using the PES/WES and the least with the ICAI. The mean Kappa per group ranged from 0.18 (group L with ICAI) to 0.63 (group G with PICI).

**Conclusion:** In comparison to the ICAI, the PES/WES and PICI were more reproducible. Therefore PES/WES and PICI seem to be more suitable as esthetic indices for single implant crowns.

**Keywords:** esthetic, aesthetic, dental implant, implant supported crown, PES/WES, PICI, ICAI, ICA, esthetic index, implant crown, white, pink

## INTRODUCTION

The use of endosseous dental implants represents a treatment modality with high survival rates of both implants and their prosthetic reconstructions<sup>1-3</sup>. The goal of achieving an optimal esthetic outcome with implants located in the esthetic zone remains a major challenge in implant dentistry. An ideal esthetic implant restoration is defined as a combination of a visually pleasing prosthesis and healthy, harmoniously scalloped surrounding peri-implant soft tissues<sup>4</sup>. In clinical studies esthetic indices for the peri-implant mucosa and the implant-supported restoration have been used to evaluate objectively the esthetic outcome and to compare the data to those of other studies<sup>5-9</sup>.

In 1999, Jemt introduced a papilla index, based on the level of the interproximal mucosa adjacent to single-implant reconstructions. This index represents so far the most frequently used one for esthetic evaluations<sup>10,11</sup>. To evaluate both the peri-implant mucosa and the implant-supported crown, another index using visual analogue scales was introduced<sup>12</sup>. Numerous other indices for the evaluation of the peri-implant soft tissue and the implant supported restoration were proposed in later investigations, as for example the implant crown aesthetic index<sup>13</sup>, the subjective esthetic score<sup>14</sup>, the pink / white esthetic scores PES/WES<sup>15</sup>, the complex esthetic index<sup>16</sup> and the Copenhagen index score<sup>17</sup>.

In the current literature, the pink esthetic score PES<sup>18</sup> and the PES/WES<sup>15</sup> are frequently used for esthetic evaluations of single implant crowns<sup>8,9,19-27</sup>.

Despite of the frequent use of numerous indices for the esthetic evaluation of implant-supported reconstructions in the anterior region, there is no universally accepted or recommended index available in the current literature<sup>11</sup>. Furthermore, studies comparing different esthetic indices are scarce<sup>25</sup>. Nevertheless, objective simple esthetic indices for the peri-implant mucosa and the reconstruction have been recommended to be used routinely in investigations<sup>28</sup>. The use of objective indices as for example the PES, was recommended in a recent consensus statement<sup>29</sup>. In the present study PES/WES and the ICAI index were chosen because both indices describe the white and pink esthetics aspects at the same time- meaning the esthetic outcome of the implant-supported crown and the surrounding peri-implant mucosa. Both indices are used in clinical investigations and comprise a three-point scoring system.

The aim of this study was to compare three esthetic indices and to assess the influence of the examiner's dental specialty compared with the views of lay people and the patients themselves. Examiners conducted an esthetic evaluation of photographs and casts of single implant-supported crowns that had been obtained at the time of insertion (t0) and 12 months (t12) later. In addition, the reproducibility of these esthetic indices was assessed and the level of clinical acceptance determined.

## **MATERIALS AND METHODS**

### **Patients**

Photographs and study casts that were obtained from patients who had a single maxillary incisor gap replaced by a single-implant crown. The final reconstructions were screw-retained and placed on a RC bone level implant (Straumann, Basel) four to six months after surgery. The patients were free from active periodontal or dental disease, and had a full set of records including photos and casts taken at both the insertion (t0) and at the 12-month (t12) follow-up appointment. At the time of this study, the crowns had been in place for at least 12 months and did not demonstrate any mechanical or biological complications. The included patients had been recruited previously in the context of a prospective study that is still ongoing and was approved by the standing ethical committee for clinical studies of the Canton of Bern, Switzerland.

### **Participants**

Four separate groups of ten examiners each carried out the assessments of the patients' photos and casts utilising the esthetic indices described below. Specialist prosthodontists (P), specialist orthodontists (O) and general dental practitioners (G) were recruited by emails sent to different departments at the Universities of Bern and Geneva and to local dental practitioners. The lay people (L) were all adults aged  $\geq 18$  who were neither undergoing nor had ever undergone implant treatment. The authors did not participate as examiners.

### **Indices**

Three indices were evaluated and used in this study (table 1): the "Pink Esthetic Score/ White Esthetic Score (PES/WES)"<sup>15</sup>, the "Implant Crown Aesthetic Index (ICAI)"<sup>13</sup> and a new index termed the "Peri-implant and Crown Index (PICI)", which was introduced by the authors.

The PES/WES<sup>15</sup> was used to evaluate the pink (PES) and white (WES) esthetics of single-implant reconstructions by comparison with the contra-lateral tooth comprising five *pink* and five *white* criteria (table (tab.) 1).

Similarly, the ICAI<sup>13</sup> was used to evaluate the pink and white esthetics of single-implant reconstructions in comparison to the adjacent and contra-lateral teeth. Five *white* and four *pink* criteria were assessed and scored as listed in tab. 1.

Finally, the new “Peri-implant and Crown Index (PICI)” was created for this study to evaluate the pink and white esthetic characteristics by means of visual analogue scales in comparison to the appearance of the contralateral tooth. The PICI includes three *pink*, three *white* and three *subjective overall* criteria (tab. 1). For the pink and white esthetics, the far left of the visual analogue scale would state that the implant reconstruction would be completely different to the contra-lateral tooth whereas the far right would state that the implant crown was identical to the contra-lateral tooth. The scale measured 100mm in length and in a second step two authors independently measured the participant’s mark to provide a score. Any mark lying between two millimetre points was rounded to the nearest one. For the three subjective overall categories, the same scale was used ranging from “not esthetic at all” at the left to “very esthetic” at the right end.

At crown insertion t0, each patient had marked on a visual analogue scale the degree of satisfaction with the appearance of the crown, the mucosa and the overall appearance that was subsequently compared to the three subjective overall categories of the PICI.

### **Data Gathering**

Photographs and study casts of the 15 patients obtained at t0 and t12 were rendered anonymous and randomised in order. This generated 30 cases for evaluation by the participants. The examiners received the 30 cases, an information sheet with instructions regarding each index and data sheets for each index. Lay people received identical instructions as the dental professionals. They were blinded regarding the presence of two time points (t0, t12) and merely advised that some cases may look similar. They were also not aware of the other groups of examiners in the study. The information sheet also instructed the participants to completely score all cases for each index before taking a break and to complete all indices within three days. The order of completion of the indices was PICI, ICAI and PES/WES followed by a questionnaire



related to the examiners experience, age and which index they felt was the easiest and fastest to complete. In order to evaluate the reproducibility of the indices, the participants repeated the same process four weeks later. The order of the cases was reversed and the order of the indices maintained.

The scores collected from each participant were dichotomised as clinically acceptable or not clinically acceptable according to thresholds that were set prior to data collection (tab. 1). The ICAI and PES/WES thresholds were set as described in the original papers<sup>13,15</sup>. For the ICAI a score of >4 was defined as clinically unacceptable whereas for PES/WES a score of <12 was used as clinically unacceptable. For the PICI, the arbitrary score of 360 was determined as the threshold and anything superior to this value was defined clinically acceptable.

Two authors (ST, CM) independently reviewed and transferred the data into an excel spreadsheet. Any difference in the data set was evaluated and agreed upon by discussion.

### **Outcomes**

Outcomes assessed within the study related directly to the aims described in the introduction:

- External validity of the indices was assessed by comparison of the index scores to each other
- Calculation and comparison of the number of clinically acceptable cases for each group, index and round
- Intraobserver agreement
- Interobserver agreement and comparison to the patient's assessments
- Assessment of esthetic changes observed within 12 months
- Final questionnaire: identification of the easiest to use and least time consuming esthetic index

### **Statistical Analyses**

All analyses were performed with the statistical software "R": version 2.15.1. To compare the three esthetic indices, the individual esthetic score scales were converted to percentage scales according to table 1. For all 40 candidates and each index, a mean white, pink and total esthetic percentage-score comprising all 30 cases was calculated and statistically assessed.

Cohen's Kappa (with squared weights) and the Kappa rating according to Landis and

Koch<sup>30</sup> was used to measure the indices' reproducibility. In addition, nonparametric ANOVAs for longitudinal data were first performed in a global and in case of significances in a post-hoc context<sup>31</sup>. All analyses were carried out in an explorative way. Hence no correction for multiple testing was applied. P-values lower than 0.05 were considered as significant. P-values between 0.05 and 0.1 were considered as 'borderline'.

## RESULTS

The comparison of the three different indices revealed lower esthetic ratings with the use of the ICAI compared to the PICI and the PES/WES for the pink, white and overall esthetic outcome. The mean values and standard deviations of the relative esthetic scores expressed as percentages per index, groups and assessments are presented in tab. 2. Nonparametric ANOVA showed statistically significantly higher relative pink, white and total esthetic scores for the PES/WES and the PICI compared to the ICAI in all four groups and in both assessments (tab. 3). Between the PES/WES and the PICI, no statistically significant differences were found for the relative pink, white and total esthetics in three groups (P, G, L), which was confirmed in the repetition of the assessments. Significant differences between the PES/WES and the PICI were only found in the first assessments of the group of orthodontists for the white and total esthetic scores.

The number of clinically acceptable cases per group, index and round are presented in tab. 4. The ICAI showed the lowest clinical acceptance in all four groups and in both assessments. Statistical analyses showed always significantly lower numbers of clinically acceptable cases using the ICAI compared to the PICI and PES/WES except in the first round of the orthodontists group with the PICI (tab. 4). Between the PICI and the PES/WES no significant differences were found except in the first round of the group of orthodontists.

Poor to almost perfect intra-observer agreement between the first and the second assessment was observed for each index (tab. 5) across all 40 examiners. The highest agreement was achieved using the PES/WES where 31 examiners came up to moderate to almost perfect agreement (Kappa 0.41-1). The least agreement was obtained using the ICAI with which only 15 examiners showed moderate to almost perfect agreement (Kappa 0.41-1). The orthodontists showed the lowest and the general dentists the highest mean Kappa score in comparison to the other three groups

(tab. 6). Non-parametric ANOVA showed significantly higher esthetic results in the second assessment of the orthodontists using the PICI, ICAI and PES/WES confirming the lower Kappa values compared to the other three groups. In contrast, the prosthodontists and general dentists showed no significant differences between the first and the second assessments, whereas in the lay group, only one significant difference (pink esthetics with ICAI) was found.

Between the four groups, no significant differences in inter-observer agreement were found concerning the mean relative esthetic score of the PICI, ICAI and PES/WES, which was confirmed in the second assessment (tab. 2).

The mean patient satisfaction with the pink, white and the overall esthetics at t0 was always higher compared to scores from the four groups (tab. 7) and each patient consistently reported higher esthetic ratings compared to the ratings of the 40 participants of the survey.

Investigation of esthetic changes using the PICI and PES/WES showed an improvement in pink and total esthetics from t0 to t12 in three groups (O,P,G,) (tab. 8). The orthodontists were the only group in which significantly higher pink and total esthetic scores at the follow-up t12 were observed with the use of all three indices. In contrast to the other three groups the lay people rated better pink and total esthetic scores at the baseline t0 than at t12, using the ICAI index.

Observers' preferences among the different indices showed no significant differences using  $\text{CHI}^2$  tests but significant differences between their perceived speed of completion, favoring PES/WES as the fastest index ( $p=0.003$ ).

## DISCUSSION

Implementation of evidence based treatment concepts in every day clinical practice highlights the importance of including objective esthetic outcomes in clinical studies. Esthetic indices are an excellent communication tool in order to present and compare results from data of clinical investigations. Studies implementing indices for both the pink and white esthetic criteria, as for example the PES/WES and ICAI, are scarce<sup>25</sup>. The PES/WES and ICAI comprise a three-point scoring system whereas visual analogue scales are less limiting and offer a wider range for evaluation. To assess the patients' satisfaction, visual analogue scales are widely used<sup>5,7,8,12,15,22,32</sup> but these are rarely used for the assessments by dental professionals<sup>12,21</sup>. The present study was designed to compare two esthetic indices that are already established in the literature, and a new index targeting similar criteria but using visual analogue scales for evaluation.

The outcome of the comparison of all three indices showed significantly higher pink, white and total esthetic outcomes for the PES/WES and the PICI compared to ICAI, which was confirmed by the repetition of the assessments (tab. 3). Hartog et al.<sup>25</sup> evaluated in a randomized clinical trial, the esthetic outcome of implants with different neck designs and used PES/WES and ICAI. With the use of the ICAI, lower white and pink esthetic scores were reported compared to the PES/WES, resulting in a smaller number of clinically acceptable cases. These findings were confirmed in the present study and may be due to the scoring system used in the ICAI where any single major deviation results in a clinically unacceptable case. Furthermore, the ICAI is more dependent on the observers' opinion because 8 out of 9 criteria must be in harmony with the adjacent tooth in addition to the contralateral tooth. In a similar study, Hartlev et al.<sup>21</sup> investigated the esthetic outcome after immediate placement and provisionalization of implants but used a combination of PES<sup>18</sup> and WES<sup>15</sup> and visual analogue scales for the clinicians. A strong correlation between the professional visual analogue scale ratings and the PES and WES was found, which was also observed in the present study.

Gehrke et al.<sup>33</sup> published a study that aimed at measuring the reproducibility of the ICAI and assessed the influence exerted by the examiner's degree of dental specialization (3 general dentists; 3 oral maxillofacial surgeons; 3 orthodontists; 3 postgraduate students; 3 lay people). Here the ICAI resulted in poor to moderate intra- and interexaminer agreement and the orthodontists showed the lowest reproducibility.

This was confirmed in the present study with kappa scores that showed the least intraobserver agreement with the use of the ICAI and for the orthodontists compared to the other indices and groups (tab. 5, 6). In another study Cho et al.<sup>32</sup> evaluated the same aim but were using the PES/WES (2 periodontists, 2 prosthodontists, 2 orthodontists, 2 senior dental students). No significant differences in inter-observer agreement were observed for the total PES/WES between the four groups. This is in agreement with the present study, where no significant differences in inter-observer agreement were found concerning the mean relative esthetic score, which was confirmed with each index and in both assessments. Most agreement between the first and second assessment of Cho et al.<sup>32</sup> was obtained by the orthodontists (substantial to almost perfect), which is in contrast to the present study where the orthodontists showed the lowest intra-observer agreement (tab. 6). The reproducibility of visual analogue scales was investigated by Esposito et al.<sup>34</sup> (2009) using a group of 10 clinicians. Weighted Kappa showed a wide range from -0.1 to 0.87 which is in accordance with the present study (0.05- 0.95).

In the present investigation, the orthodontists were the only group that reported a significantly higher pink and total esthetic score at the follow-up t12 compared to t0 with the use of all three indices. These findings are in agreement with Luo et al.<sup>35</sup>. In their study, two orthodontists evaluated single implants in the esthetic zone using the PES<sup>18</sup> at crown placement and 3 months later and showed a significant improvement of the mean PES.

It is well established that the opinions of dentists and patients often differ; as demonstrated on numerous occasions when assessing implant esthetics<sup>12</sup>. A total of 41 implant-supported crowns were re-evaluated by the patients and 5 prosthodontists and the reproducibility of this method was evaluated by 3 randomly selected cases where the evaluation was repeated. The patients reported a higher esthetic outcome than the prosthodontists. The patients were highly satisfied with median values up to 100%. However the assessment by the prosthodontists revealed a significantly lower degree of satisfaction. Later investigations confirmed these findings<sup>5,8,15,20,22</sup>. In the present study, each patient evaluated his satisfaction with the appearance of the crown, the mucosa and his overall satisfaction at the time of insertion using visual analogue scales (tab. 7). A possible explanation why the mean patient satisfaction was higher than the one evaluated by the group of layperson could be that the patient went through the dental treatment and also had a comparison of the before and after picture

in his mind- having therefore a more subjective biased opinion in comparison to the layperson who only had the final result present without knowing the history and using an index (PICI). All of the other 4 groups reported lower VAS scores (lower subjective overall criteria of the PICI): the orthodontists having the lowest and the laypersons the highest satisfaction rates within the groups (tab. 7). This demonstrates that the dental profession is arguably too critical with regard to esthetics. However different dental specialties are equally critical.

Within the limitations of this study, it can be concluded that the use of esthetic indices offers clinicians increased insight into the esthetic outcome of clinical cases in daily dental practice, while also providing a tool to discuss and compare findings of clinical studies. An index should be both reproducible and repeatable. Thus it should be globally applicable among many clinicians with different backgrounds. The conclusion of the present investigation is that the PICI, ICAI and PES/WES are esthetic indices not influenced by different observers. The PES/WES showed the highest reproducibility and the ICAI the lowest, paired with significantly inferior clinical acceptance. Therefore the use of ICAI may be questionable, which was also concluded by Gehrke et al.<sup>33</sup>. PES/WES and PICI are reproducible esthetic indices providing similar relative esthetic scores. The PES/WES was rated as the fastest and easiest index to use. PES/WES and PICI can be recommended for clinical us

## **CONCLUSIONS**

Following the results of the present investigation these conclusions can be summarized:

- PES/WES and PICI are reproducible esthetic indices that are not influenced by different observers and present similar outcomes in the overall esthetic evaluation. They are recommended for clinical use.
- PES/WES is the most user-friendly esthetic index
- The use of ICAI index may be questionable as it has the lowest reproducibility with significantly lower clinical acceptance in all four groups and in both assessments.
- Patients were more satisfied with the esthetic outcome (pink, white and overall esthetics) of their implant reconstruction than any other observer group.
- An improvement of the pink and overall esthetic appearance between t0 and t12 was apparent in three groups (O,P,G) when applying PICI and PES/WES. The orthodontists rated statistically significantly higher esthetic scores between t0 and t12 with all three indices, whereas the general dentists only when using the PICI score.

## **ACKNOWLEDGEMENTS**

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## **CONFLICT OF INTEREST**

The clinical photographs and casts are obtained from an ongoing study which is financially supported by a research grant from Institut Straumann AG, Basel, Switzerland.

## LEGENDS OF FIGURES

**Figure 1:** Case with single-implant crown at position 11 at the 12 month appointment which was rated with high esthetics. The mean esthetic rated by the 40 observers in the first assessment was 468.6 for PICI, 2.9 for ICAI and 16.8 for PES/WES on their original scales.



**Figure 2:** Case with single-implant at position 21 at the 12 month appointment which was rated with low esthetics. The mean esthetic rated by the 40 observers in the first assessment was 240.8 for PICI, 23.4 for ICAI and 7.5 for PES/WES on their original scales.





# TABLES

**TABLE 1:** Criteria of the three esthetic indices and calculation of relative esthetics

	<b>PICI</b> (new index)	<b>ICAI</b> (Meijer H et al. 2005) <sup>13</sup>	<b>PES/WES</b> (Belser U et al. 2009) <sup>15</sup>
<b>criteria of the peri-implant mucosa (pink esthetic)</b>	papillae zenith root convexity	labial margin papillae contour of the labial surface colour and surface	mesial papilla distal papilla facial curvature level of facial mucosa root convexity & color
<b>criteria of the implant crown (white esthetic)</b>	shape color characterization	width length labial convexity color / translucency surface	tooth form outline / volume color (hue/value) surface texture translucency & characterization
<b>subjective overall criteria</b>	crown mucosa overall (crown & mucosa)	none	none
<b>reference tooth</b>	contralateral tooth	contralateral & adjacent tooth	contralateral tooth
<b>scores per criteria</b>	100mm visual analogue scale	0 (no deviation) 1 (small deviation) 5 (large deviation)	2 (no deviation) 1 (small deviation) 0 (large deviation)
<b>overall score</b>	0-600 points	0-45 points	0-20 points
<b>Threshold of clinical acceptability</b>	≥ 360 points	< 5 points	≥12 points
<b>calculation to percentage scale</b>	0 points = 0% 300 points = 50% 600 points = 100%	0 points = 100% 2.5 points = 50% 5 points = 0%	0 points = 0 % 10 points = 50% 20 points = 100%

**TABLE 2:** Mean relative esthetics in percentage (standard deviation in percentage) for each index, group and assessment. O = orthodontists, P = prosthodontists, G = general dentists, L = lay people, 1 = first assessment, 2 = second assessment

group	PICI		
	pink	white	total
O1	56.25 (8.97)	63.03 (10.56)	59.64 (7.90)
O2	62.12 (11.50)	70.12 (9.89)	66.12 (10.29)
P1	59.58 (18.01)	72.71 (12.07)	66.14 (13.69)
P2	63.82 (16.88)	72.26 (11.53)	68.08 (13.82)
G1	63.00 (15.53)	71.13 (15.64)	67.07 (15.45)
G2	62.47 (17.97)	69.76 (13.61)	66.11 (15.69)
L1	61.37 (13.00)	70.47 (11.67)	65.92 (11.86)
L2	63.96 (11.40)	73.89 (10.33)	68.92 (10.19)

group	PES/WES		
	pink	white	total
O1	61.10 (8.26)	72.63 (10.48)	66.87 (8.02)
O2	66.13 (11.71)	76.20 (10.28)	71.17 (7.30)
P1	60.87 (18.60)	71.30 (11.08)	66.08 (11.58)
P2	61.53 (17.46)	73.13 (11.04)	67.33 (12.66)
G1	56.40 (14.81)	70.17 (15.75)	63.30 (14.70)
G2	59.30 (18.34)	69.23 (13.23)	64.27 (13.23)
L1	62.23 (12.68)	73.70 (11.07)	67.97 (9.43)
L2	61.53 (12.25)	75.13 (10.02)	68.33 (9.38)

group	ICAI		
	pink	white	total
O1	43.20 (8.63)	48.67 (12.22)	15.93 (8.42)
O2	45.47 (14.44)	54.07 (14.63)	22.00 (13.31)
P1	36.93 (17.50)	45.33 (20.48)	16.60 (18.35)
P2	39.00 (15.08)	47.33 (22.81)	17.80 (18.36)
G1	41.20 (15.43)	46.60 (21.44)	20.47 (16.06)
G2	43.07 (15.77)	48.07 (18.90)	19.87 (15.77)
L1	49.87 (17.65)	52.53 (16.98)	24.80 (16.14)
L2	42.13 (21.34)	54.93 (19.20)	23.93 (17.79)

**TABLE 3:** p-values generated by comparison of the three esthetic indices to each other relating to pink, white and total esthetic and clinical acceptance . p-values < 0.05 were considered as significant different. O = orthodontists, P = prosthodontists, G = general dentists, L = lay people, 1 = first assessment, 2 = second assessment

group	PICI vs. ICAI			
	pink	white	total	acceptance
O1	0.01	0.004	<0.0001	<b>0.38</b>
O2	0.004	0.003	<0.0001	<b>0.052</b>
P1	<0.0001	<0.0001	<0.0001	<0.0001
P2	0.001	0.004	<0.0001	0.01
G1	<0.0001	<0.0001	<0.0001	0.002
G2	<0.0001	<0.0001	<0.0001	0.001
L1	0.008	0.001	<0.0001	0.01
L2	0.002	0.0008	<0.0001	0.005

group	PICI vs. PES/WES			
	pink	white	total	acceptance
O1	0.13	<b>0.002</b>	<b>0.02</b>	<b>&lt;0.0001</b>
O2	0.33	0.101	0.33	0.43
P1	0.8	0.62	0.97	0.39
P2	0.54	0.72	0.85	0.92
G1	0.23	0.92	0.4	0.64
G2	0.14	0.8	0.3	0.18
L1	0.72	0.26	0.53	0.72
L2	0.52	0.48	0.92	0.72

group	ICAI vs. PES/WES			
	pink	white	total	acceptance
O1	<0.0001	<0.0001	<0.0001	<0.0001
O2	<0.0001	<0.0001	<0.0001	<0.0001
P1	<0.0001	<0.0001	<0.0001	<0.0001
P2	<0.0001	<0.0001	<0.0001	<0.0001
G1	<0.0001	<0.0001	<0.0001	0.0003
G2	<0.0001	<0.0001	<0.0001	<0.0001
L1	<0.0001	<0.0001	<0.0001	<0.0001
L2	<0.0001	<0.0001	<0.0001	<0.0001

**TABLE 4:** Number of cases which were clinically acceptable (standard deviation) for each index, group and round. O = orthodontists, P = prosthodontists, G = general dentists, L = lay people, 1 = first assessment, 2 = second assessment

group	PICI	ICAI	PES/WES
O1	14.6 (5.82)	12.1 (6.19)	22.0 (4.52)
O2	20.9 (7.92)	14.2 (7.33)	24.4 (4.09)
P1	18.8 (8.90)	10.0 (8.63)	21.1 (7.31)
P2	21.0 (10.31)	10.9 (7.64)	21.6 (8.07)
G1	18.9 (9.72)	12.4 (7.69)	18.3 (9.39)
G2	19.7 (10.53)	12.3 (7.62)	18.1 (8.24)
L1	20.8 (6.96)	13.5 (6.70)	22.0 (4.50)
L2	22.5 (5.44)	13.1 (8.12)	22.0 (5.23)

**TABLE 5:** Classification of Kappa Scores by Landis and Koch 1977: distribution of the 40 observers for each index

	PICI	ICAI	PES/WES
<b>Intraobserver agreement</b>			
poor (<0):	0	3	1
slight (0-0.2):	7	13	1
fair (0.21-0.4):	6	9	7
moderate (0.41-0.6)	16	4	14
substantial (0.61-0.8)	9	8	12
almost perfect (0.81-1)	2	3	5

**TABLE 6:** Mean (min; max) weighted kappa scores per group and index

index	orthodontists (O)	prosthodontists (P)	general dentists (G)	lay people (L)
PICI total	0.31 (0.05; 0.62)	0.49 (0.18; 0.74)	0.63 (0.33; 0.95)	0.46 (0.16; 0.72)
ICAI total	0.19 (-0.13; 0.67)	0.39 (-0.06; 1.00)	0.55 (0.33; 1.00)	0.30 (0.00; 0.73)
PES/WES total	0.51 (0.21; 0.82)	0.58 (0.23; 0.87)	0.56 (0.00; 0.90)	0.53 (0.12; 0.83)

**TABLE 7:** mean patients satisfaction at baseline t0 with the pink, white and overall esthetic and the corresponding subjective overall categories (PICl) for each group

	<b>pink esthetic</b>	<b>white esthetic</b>	<b>overall esthetic</b>
<b>patients satisfaction</b>	90.81	92.86	94.17
<b>orthodontists</b>	54.48	58.66	57.16
<b>prosthodontists</b>	60.92	70.29	68.57
<b>general dentists</b>	60.29	69.54	65.22
<b>lay people</b>	64.91	70.31	66.69

**TABLE 8:** Changes in pink and total esthetics from t0 to t12 in percentage (p-value) for each group and index during the first assessment. p-values < 0.05 were considered as significant different.

	<b>pink esthetics in % (p-value)</b>		
	<b>PICl</b>	<b>ICAI</b>	<b>PES/WES</b>
<b>orthodontists</b>	<b>3.59 (0.02)</b>	<b>7.46 (0.008)</b>	<b>4.6 (0.01)</b>
<b>prosthodontists</b>	<b>2.39 (0.04)</b>	-0.27 (0.47)	2.13 (0.11)
<b>general dentists</b>	<b>3.9 (0.02)</b>	<b>4.8 (0.03)</b>	2.66 (0.07)
<b>lay people</b>	1.94 (0.38)	<b>-4.27 (0.049)</b>	0.6 (0.92)

	<b>total esthetics in % (p-value)</b>		
	<b>PICl</b>	<b>ICAI</b>	<b>PES/WES</b>
<b>orthodontists</b>	<b>2.03 (0.03)</b>	<b>3.07 (0.003)</b>	<b>2.2 (0.04)</b>
<b>prosthodontists</b>	0.58 (0.20)	-1.2 (0.27)	0.77 (0.45)
<b>general dentists</b>	<b>1.94 (0.02)</b>	1.2 (0.65)	1.34 (0.23)
<b>lay people</b>	0.5 (1)	<b>-5.34 (0.01)</b>	-1.8 (0.23)

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# Chapter 4

## Esthetic and Clinical Performance of Implant-Supported All-Ceramic Crowns Made with Prefabricated or CAD/CAM Zirconia Abutments.

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## ABSTRACT

**Background:** Patients' esthetic expectations are increasing and the options of the prosthetic pathways are currently evolving.

**Purpose:** The objective of this randomized multicenter clinical trial was to assess and compare the esthetic outcome and clinical performance of anterior maxillary all-ceramic implant crowns based either on prefabricated zirconia abutments veneered with pressed ceramics or on CAD/CAM zirconia abutments veneered with hand build-up technique. The null hypothesis was that there is no statistically significant difference between the two groups.

**Material and methods:** 40 implants were inserted in sites 14-24 (FDI) in 40 patients in two centers, the Universities of Bern and Geneva, Switzerland. After final impression, 20 patients were randomized into Group A restored with a one-piece screw retained single crown made of a prefabricated zirconia abutment with pressed ceramic as the veneering material using the cut-back technique, or Group B using an individualized CAD/CAM zirconia abutment (CARES® abutment, Institut Straumann AG, Basel, Switzerland) with a hand build-up technique. At baseline, 6 months and 1 year clinical, esthetic and radiographic parameters were assessed.

**Results:** Group A exhibited one drop-out patient and one failure resulting in a survival rate of 94.7% after one year, in comparison to 100% for Group B. No other complications occurred. Clinical parameters presented stable and healthy peri-implant soft tissues. Overall, no or only minimal crestal bone changes were observed with a mean DIB (distance from the implant shoulder to the first bone-to-implant contact) of -0.15 mm (Group A) and 0.12 mm (Group B) at 1 year. There were no significant differences at baseline, 6 months and 1 year for DIB values between the two groups. PES (pink esthetic score) and WES (white esthetic score) values at all three examinations indicated stability over time for both groups and pleasing esthetic outcomes.

**Conclusion:** Both implant supported prosthetic pathways represent a valuable treatment option for the restoration of single implant crowns in the anterior maxilla. (ClinicalTrials.gov NCT02905838)

**Keywords:** Esthetic dentistry, Clinical studies/trials, Fixed and removable prosthodontics, Implant Dentistry/Implantology, Oral Implants/Implantology, Prosthetic Dentistry/Prosthodontics



## INTRODUCTION

Reconstruction of the single edentulous space using an endosseous implant and a single crown is a validated treatment option with high survival rates of the implant and the crown (Buser et al. 2012; Cooper et al. 2016; Jung et al. 2012; Wittneben et al. 2014). In the visible anterior maxilla, the prosthetic perfection is often challenging as ideal overall esthetic outcomes of the pink and white esthetics have to be achieved. The pink esthetics focus on the outcome of the peri-implant soft tissue and the white esthetics on the visually pleasing outcome of the crown itself (Belser et al. 2009; Furhauser et al. 2005). The type of the abutment chosen may influence the outcome of both pink and white esthetics. Through the evolution of dental materials, components and the overall prosthetic workflow, “whitish” and resistant ceramic materials as zirconium dioxide can be used. Compared to metal abutments, this material offers advantages with respect to an improved soft tissue condition to avoid “grayish” discoloration of the mucosa, which is especially important in situations with a thin tissue biotype (Ishikawa-Nagai et al. 2007; Jung et al. 2007).

Prefabricated or customized zirconium dioxide abutments are available. In order to use a standardized abutment, the implant has to be placed in a preferably ideal prosthetic position. The indication to use standard abutments is limited, depending on the position of the implant in the vertical dimension. If the implant is placed too deep, they cannot be used, especially not for screw retained reconstructions, as they do not provide enough support for the veneering ceramic. According to the manufacturer, a maximum of 2mm directly veneered ceramic should be used on top of the prefabricated abutment when using screw retention.

Individualization of an implant abutment is advantageous. The abutment can be designed via a wax-up exactly matching the ideal support for the final crown for screw retained crowns or individualization of the final marginal finish line for cemented crowns. Also, the profile of the mucosa at the emergence of the crown in the transition zone can be individualized according the achieved result during the provisional phase (Buser et al. 2013a).

The purpose of this randomized prospective multicenter clinical trial was to compare the overall clinical performance during one year - including the esthetic outcome - between individualized CAD/CAM abutments veneered with a hand build-up technique and prefabricated zirconium dioxide abutments veneered with pressed ceramics to restore implants inserted in single-tooth gaps in the anterior maxilla.

# **MATERIALS AND METHODS**

## **Patient cohort and clinical procedures**

Forty subjects were recruited from two centers, the Universities of Bern (20 patients) and Geneva (20 patients), Switzerland. The recruitment period ran from August 2009 to 2012. Sample size was calculated according to previously published investigations with similar indication. No data on the primary endpoint were available as basis for a power calculation. Participants were recruited from the same patient population that had previously received dental implant treatment and a screw retained implant-supported provisional restoration for soft tissue conditioning using the dynamic compression technique (Buser et al. 2013a). All patients had received a dental implant (Bone Level Implant 4.1 mm diameter, length 8 or 10 or 12 mm, Institut Straumann AG, Basel, Switzerland) with the use of contour augmentation (Buser et al. 2013a; Buser et al. 2013b) in a single edentulous space with one missing maxillary anterior tooth in sites 14-24 (FDI). After the provisional phase and final impression, one-piece screw retained single crowns were fabricated using two different zirconium dioxide abutments and two different veneering ceramic techniques. The patients were randomly assigned to either Group A or B by the use of a sealed envelope, which had been prepared by an independent person. Each study center had a separate randomization schedule to ensure that treatments were balanced between centers. Ethical approval was provided by the Ethics Committee of the State of Bern (approval no. 061/10). The informed consent document was written in accordance with the "Declaration of Helsinki".

## **Screening and eligibility criteria**

The subjects were evaluated for initial study eligibility during the screening visit.

### **Inclusion Criteria**

All of the following criteria had to be met for inclusion in the study:

1. Subjects must have voluntarily signed the informed consent form before any study-related action
2. Males and females with at least 18 years of age
3. Single tooth gaps in the anterior maxilla position 14-24 (FDI)
4. Successfully osseointegrated single tooth implant inserted at least 16 weeks after tooth extraction
5. Full mouth plaque index according to O'Leary  $\leq 25\%$

6. Implant axis compatible with transocclusal screw retention (screw access palatal of incisal edges)

### **Exclusion Criteria**

If any of the following criteria were met, the subject had to be excluded from the study.

### **Surgical exclusion criteria**

1. Systemic disease that would interfere with dental implant therapy
2. Any contraindications for oral surgical procedures
3. History of local irradiation therapy
4. Patients who smoke >10 cigarettes per day or tobacco equivalents or chew tobacco
5. Subjects who had undergone administration of any investigational device within 30 days of enrolment in the study
6. Conditions or circumstances, in the opinion of the investigator, which would prevent completion of study participation or interfere with analysis of study results, such as history of non-compliance
7. Physical or mental handicaps that would interfere with the ability to perform adequate oral hygiene
8. Pregnant or breastfeeding women

### **Dental Exclusion Criteria**

9. Existing implants in the adjacent position
10. Removable dentures or un-restored tooth gaps in the opposing dentition
11. Patients with inadequate oral hygiene or unmotivated for adequate home care
12. Probing pocket depth of  $\geq 4$  mm on one of the teeth immediately adjacent to the dental implant site
13. Lack of primary stability of the implant
14. Inappropriate implant position for the prosthetic requirements
15. Major simultaneous augmentation procedures
16. Insufficient stability of the implant

### **Prosthetic Exclusion Criteria**

17. Screw access position located too close to the planned incisal edge
18. Need of angled abutment due to prosthetic malposition of the implant
19. Height of the abutment is less than 65% of the height of the complete restoration
20. Severe bruxing or clenching habits

## **Laboratory procedures**

**Group A:** Implant-supported single crown was fabricated using a prefabricated stock abutment made of yttrium oxide partially stabilized tetragonal zirconia polycrystalline (Y-TZP) (Anatomic IPS e.max Abutment, straight, color M1, Ivoclar, Liechtenstein) and pressed ceramic (fluorapatite glass-ceramic, IPS e.max ZirPress, Ivoclar, Liechtenstein) using the cut-back technique and hand veneered with a thin layer of fluorapatite veneering ceramic (fluorapatite veneering ceramic, IPS e.max Ceram, Ivoclar, Liechtenstein).

**Group B:** Implant-supported single crown was fabricated using an individualized CAD/CAM abutment made of Y-TZP (CARES® Abutment, Institut Straumann AG, Basel, Switzerland) and hand build-up veneering ceramic technique (fluorapatite veneering ceramic, IPS e.max Ceram, Ivoclar, Liechtenstein).

All implant-supported crowns were fabricated in the same dental laboratory by the same dental technician (Dominique Vinci, Geneva, Switzerland). The implants were placed by experienced oral surgeons in a prosthetic ideal position.

## **Insertion of the all-ceramic crowns**

The final all-ceramic crowns were inserted by experienced prosthodontists 4-6 months after surgical placement of the implants and torqued to 35 Ncm. Occlusion was evaluated in static and dynamic movements following the mutually protective occlusion concept (Kim et al. 2005). Oral hygiene instructions and motivation were given in detail to all patients included.

## **Follow-up examinations**

Patients were seen at baseline, 6 months and 12 months, and the clinical and radiographic parameters were assessed by the same examiners. Baseline was defined one week after insertion of the final all-ceramic implant-supported crown. Primary outcome was PES/WES esthetic index; secondary outcomes were radiographic findings (crestal bone level changes (DIB)); cast analysis; implant success and survival; mechanical complications and survival of implant-supported prosthesis and clinical parameters.

## **Clinical Peri-implant Measurements**

At 4 sites per implant (mesial/distal/buccal/oral; except KM: buccal side only), the following clinical parameters were evaluated at baseline, 6 and 12 months post baseline:

- Modified pink esthetic score (mod PES) (Belser et al. 2009; Furhauser et al. 2005).
- White esthetic score (WES) (Belser et al. 2009)
- Presence/absence of plaque (mod PI): will be evaluated according to criteria of the Plaque Index (PI)(Silness and Loe 1964) adapted for oral implants(Mombelli et al. 1987)
- Pocket probing depth (PPD)
- Modified Sulcus Bleeding Index (mSBI) (Lang et al. 1986)
- Keratinized mucosa (KM) in mm

## **Evaluation of Presence of Technical/ Mechanical Complications and Failures**

The presence/absence of technical/mechanical complications had to be recorded. A prosthetic failure was defined as an event leading to the loss of the reconstruction and the need to renew the entire implant-supported crown, or, the explantation/loss of the implant and therefore also the loss of the implant-supported restoration.

## **Implant Success and Survival Rate**

Implant success and survival was assessed at the screening visit, baseline, 6 and 12 months post baseline. A surviving implant was defined as an implant in place at the time of follow-up. Implants were graded as a success according to the success criteria published by Buser *et al.* (1991)(Buser et al. 1991) and Albrektsson et al. (1986)(Albrektsson et al. 1986) which are defined:

- Absence of persisting subjective discomfort such as pain, foreign body perception and or dysaesthesia (painful sensation)
- Absence of a recurrent peri-implant infection with suppuration (where an infection is termed recurrent if it is observed at two or more follow-up visits after treatment with systemic antibiotics)
- Absence of implant mobility on manual palpation
- Absence of any continuous peri-implant radiolucency.

### **Cast Analysis**

Dental impressions were taken at the baseline, 6 and 12 months follow-up visits to produce stone casts of the maxilla. The casts were photographed with a standardized technique including a millimeter grid as a reference in the picture. With these photographs, the length of the mid-facial height of the implant crown (IC) and the corresponding height of the contra-lateral tooth crown (TC) were both measured to identify changes in crown height, indicating an absence or presence of mucosal recession. This cast analysis technique has been previously used in clinical studies (Buser et al. 2009; Buser et al. 2013a).

### **Esthetic Parameters**

The modPES and WES assessments at the baseline, 6 and 12 months follow-up examinations were completed by two experienced prosthodontists, one of which has used this index previously in two published clinical studies. The examiners were blinded regarding the group allocation.

### **Radiographic Parameters**

Standardized periapical radiographs were obtained at: baseline, 6 and 12 months. The distance from the implant shoulder to the first bone-to-implant contact (DIB) was measured (mm) at the mesial and distal aspect of the implants (Weber et al. 1992) by one experienced clinician. The change in crestal bone height in relation to the reference points on the implant over the observation time was calculated.

### **Statistical Analysis**

First, the data was analyzed descriptively by computing means and standard deviations for all factors and levels of interest.

Then, differences between the two groups and the two centers (Bern and Geneva) were analyzed performing a two-way ANOVA for repeated measures among three time points. Because of sample size considerations the chosen ANOVA was a nonparametric one according to Brunner and Langer. The p values of all main effects and interactions were corrected for multiple testing using Holm's method.

In case of a significant effect, post-hoc tests were then done performing Wilcoxon-Mann-Whitney tests without correction for multiple testing due to the explorative nature of this further analysis.

The level of significance was set to 0.05. All calculations were done with R, version 3.3.1 (The R Project for Statistical Computing, Vienna, Austria, [www.r-project.org](http://www.r-project.org)).

## **RESULTS**

### **Clinical Performance**

One patient in the patient pool from the University of Geneva was lost even before completion of the treatment, and therefore was considered as a drop out. Therefore one drop-out patient in Group A and one failure (fracture of the ceramic crown) resulted in a survival rate of 94.7% for Group A, whereas the survival rate for Group B was 100% (table (tab.) 1). No complications occurred during the entire observation time (tab. 1). An overview of the individual tooth positions (FDI) of the implant crowns are listed in tab. 1.

### **Clinical Findings**

Overall, patients exhibited good oral hygiene, documented by a mean mPI of 0.15 (Group A) and 0.14 (Group B) at 1 year (tab. 2). The peri-implant soft tissues appeared healthy overall as documented by a low mean mSBI of 0.21 (Group A) and 0.18 (Group B) at the 1-year examination (tab. 2). The mean PDs at 1 year were 3.04 and 3.08, respectively. All implants showed a keratinized mucosa on the facial aspect with a mean KM of more than 3.6 mm.

Analysis of variance concluded no statistical significant effect within the groups or centers at the three time points.

### **Radiographic Findings**

Detailed results are shown in Figure (fig.) 1. For the radiographic parameters, there was no significant difference between the two centers. Overall, no or only minimal crestal bone loss was observed with a mean DIB of -0.15 mm (Group A) and 0.12 mm (Group B) at 1 year (range -2.3 to 3.2 mm). There were no significant differences at baseline, 6 months, and 1 year for DIB values between the two groups. Over the observation periods, the DIB values showed no significant changes for both groups calculated by ANOVA.

### **Esthetic Outcomes**

Detailed results are given in Table 3. The esthetic outcomes were pleasing overall

throughout the study period. The PES and WES values at all three examinations also indicated stability over time for both groups. At the 1-year examination, the analysis revealed mean PES values of 7 (Group A) and 7.65 (Group B). The WES exhibited values of 8.28 (Group A) and 8.50 (Group B). No discoloration of the peri-implant mucosa was visible. Analysis of variance showed that there was no statistically significant changes over the observation periods.

### **Cast Analysis**

Detailed results are shown in table 4. Focussing on outcomes of IC no statistically significant effect of group or center was found over the observation periods.

Regarding the outcomes of TC interactions between the two center and groups were significant ( $p = 0.04$ ) and therefore pairwise comparisons between every pair combinations of the two centers and two groups were performed using post-hoc tests (Wilcoxon-Mann-Whitney-Tests). Within group A the center effect was statistically significant ( $p = 0.01$ ). Center effect was also statistically significant between group B ( $p = 0.03$ ) comparing Geneva and Bern.

Within the center Geneva there was a significant difference between group A and B ( $p = 0.01$ ).

## **DISCUSSION**

Due to its better mechanical properties, yttrium oxide partially stabilized tetragonal zirconia polycrystalline (Y-TZP) has overtaken alumina as the preferred ceramic abutment material (Manicone et al. 2007; Zarone et al. 2011). It has high flexural strength values and fracture toughness with the advantage of being able to initiate a unique phase transformation toughening mechanism, which can improve its mechanical strength and reliability (Chevalier 2006; Christel et al. 1989; Guess et al. 2012; Nakamura et al. 2010).

Zirconiumdioxid is a material which is characterized by a dense, monocystalline homogeneity with low corrosion potential and good radiopacity (Manicone et al. 2007). It represents an excellent biocompatible material, which is less prone to plaque accumulation compared to titanium (Degidi et al. 2006; Hisbergues et al. 2009; Rimondini et al. 2002; Scarano et al. 2004).

Influenced by the esthetic advantage of a white color material, less mucosa shine-through, biocompatibility, radio-opacity, insolubility in water environment, soft tissue



integration at least as good as titanium, and less plaque adhesion, it can be concluded that the use of zirconium dioxide abutments in the anterior maxilla is advantageous (Cooper et al. 2015; Nakamura et al. 2010; Nothdurft et al. 2014) but still not as strong as titanium ones. However, different new abutment types are available, and differences in their clinical performance should be identified.

In this investigation, all zirconia abutments were internally connected to an implant and with a one-piece design. In a master thesis by Schnider (Schnider 2016), 50 implant screw retained single crowns with CAD/CAM fabricated zirconium dioxide internally connected one-piece abutments in the anterior and premolar region were retrospectively analyzed after 1.1 - 3.8 years. The analyzed restorations presented no technical and biological complications and failures, resulting in a 100% survival rate (tab. 1). To date, only few investigations present results on internally connected zirconia abutments comparing two different abutment types.

The present randomized controlled prospective trial aimed to compare the overall clinical performance including the esthetic outcome between individualized CAD/CAM Y-TZP abutments veneered with a hand build-up technique and prefabricated Y-TZP abutments veneered with pressed ceramics in the anterior maxilla after one year. With respect to the findings of this investigation, the null hypothesis stating that both prosthetic pathways would provide similar clinical performance and esthetic outcomes cannot be rejected.

Both prosthetic pathways showed excellent clinical performance in the esthetic zone. No mechanical/technical or biological complications occurred during this observation period, except for one failure, which was a ceramic fracture (incisal edge) resulting in the fabrication of a new crown occurring in Group A. Furthermore, one drop out was seen in the same group resulting in a survival rate of 94.75% (tab. 1). Group B exhibited no failures and no complications exhibiting survival rate of 100% after one year. Available clinical studies about internally connected zirconia abutments in the literature confirm this successful performance, and also present high survival rates (Canullo 2007; Ekfeldt et al. 2011; Hosseini et al. 2013; Lops et al. 2013; Nothdurft et al. 2014). In vitro investigations have shown the presence of wear at the interface between titanium implants connected with one-piece zirconia abutments which might theoretically lead to the development of a titanium tattooing (Stimmelmayer et al. 2012; Taylor et al. 2014). In the present clinical investigation, no tattooing or screw loosening was observed after one year- however this time period might not be long enough for

clinical observation of the tattooing effect.

Besides the survival rates being similar in both groups, also the esthetic scores were not statistically different, and the clinical parameters and cast analysis did not show any differences. PES/WES Index (Belser et al. 2009; Furhauser et al. 2005; Gehrke et al. 2008) was used in the present investigation, as it is the most reproducible esthetic index, which is not influenced by different observers and therefore recommended for clinical use (Tettamanti et al. 2016). The present PES/WES results can be compared (tab. 4) with published data from a study by Buser et al. 2011 re-evaluating 20 implant-supported single crowns using the same treatment approach (Buser et al. 2011). Here, similar results were obtained with a mean PES value of 8.10 and mean WES of 8.65 resulting in a total mean score of 16.75.

Crestal bone level of both groups represented almost no bone loss. In both groups, the peri-implant bone levels remained very stable (mean DIB of -0.15 mm in Group A), and 0.12 mm in Group B) at 1 year (fig. 1). Again, these results are comparable with the study by Buser et al. 2011 presenting a mean crestal bone loss of 0.18 mm after 3 years, and to another study also using platform switching implants with the same treatment approach exhibiting a mean bone loss of 0.66 mm after 6 years (Buser et al. 2013b).

Limitations of this study are the short duration of observation, and the limited patient number. However, it can be concluded that both zirconia abutment types - individualized or prefabricated - are a valuable treatment option for single screw retained implant-supported crowns.

## **ACKNOWLEDGMENTS**

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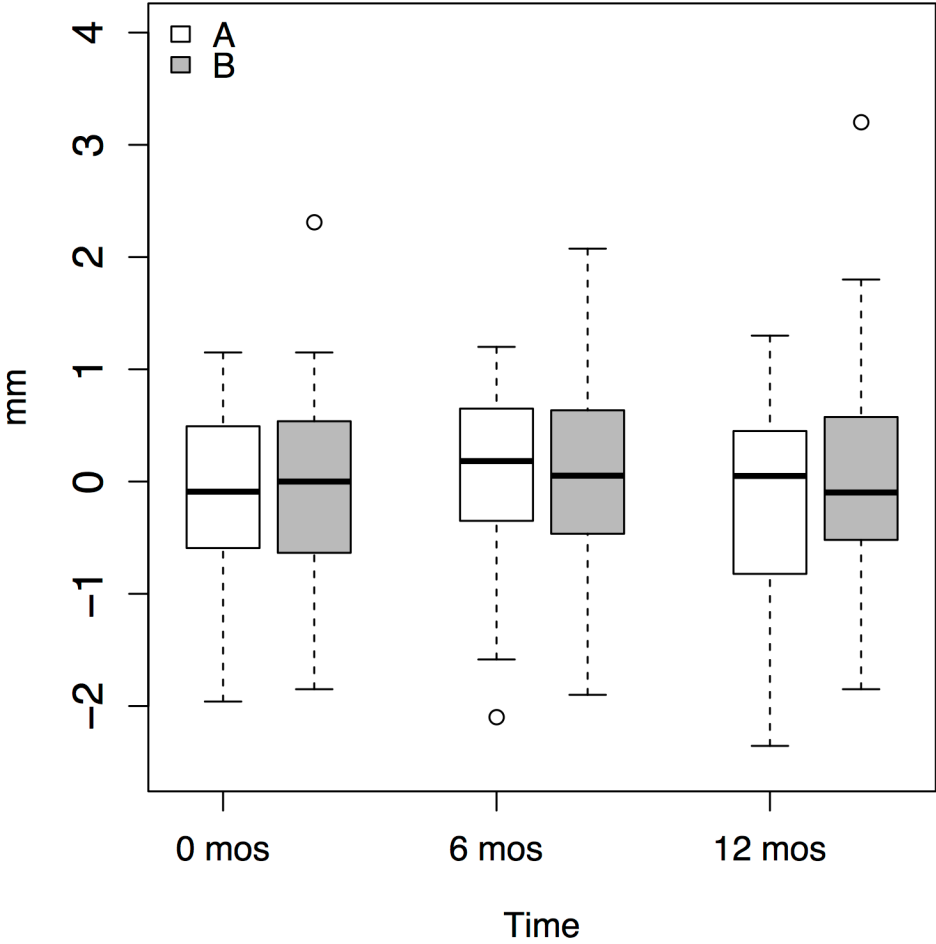
## **CONFLICT OF INTEREST**

There is no conflict of interest from any of the authors in respect to the present investigation.

# TABLES AND FIGURES

## LEGEND OF FIGURE

**Figure 1:** Box plots showing radiographic parameters (DIB) of the implants analyzed for baseline, 6 months and 1 year comparing prefabricated stock abutment versus individualized CAD/CAM abutment.



**TABLE 1:** Overview of failure, complication, survival and success rates after one year comparing prefabricated abutments versus individualized CAD/CAM abutments and individual tooth positions of evaluated implant crowns

	<b>Prefabricated Abutment</b>	<b>CAD/CAM Abutment</b>
Enrolled	n = 20	n = 20
Under exposure	n = 19	n = 20
Drop out	n = 1	n = 0
Failure	n = 1	n = 0
Complications	n = 0	n = 0
Survival (%)	94.7%	100%
Success (%)	94.7%	100%
<b>Tooth Position Maxilla (FDI 14-24):</b>		
1. Quadrant First Premolar (14)	n = 0	n = 0
1. Quadrant Canine (13)	n = 0	n = 1
1. Quadrant Lateral Incisor (12)	n = 2	n = 1
1. Quadrant Central Incisor (11)	n = 7	n = 9
2. Quadrant Central Incisor (21)	n = 8	n = 6
2. Quadrant Lateral Incisor (22)	n = 0	n = 2
2. Quadrant Canine (23)	n = 1	n = 0
2. Quadrant First Premolar (24)	n = 1	n = 1

**TABLE 2:** Overview of clinical parameters of the implants (mean  $\pm$  standard deviation) up to a follow-up of 1 year comparing prefabricated stock abutment versus individualized CAD/CAM abutment.

Definitions: mPI = modified plaque index; mSBI = modified sulcus bleeding index; PPD = probing depth; KM = keratinized mucosa.

Exam	mPI	mSBI	PPD (mm)	KM (mm)
<b>Baseline</b>	PA: 0.14 ( $\pm$ 0.24)	PA: 0.18 ( $\pm$ 0.20)	PA: 3.05 ( $\pm$ 0.60)	PA: 3.84 ( $\pm$ 1.49)
	IA: 0.10 ( $\pm$ 0.29)	IA: 0.08 ( $\pm$ 0.20)	IA: 2.64 ( $\pm$ 0.53)	IA: 4.10 ( $\pm$ 1.15)
<b>6 months</b>	PA: 0.89 ( $\pm$ 1.04)	PA: 0.13 ( $\pm$ 0.20)	PA: 3.07 ( $\pm$ 0.99)	PA: 3.47 ( $\pm$ 1.26)
	IA: 0.62 ( $\pm$ 0.26)	IA: 0.10 ( $\pm$ 0.17)	IA: 2.92 ( $\pm$ 0.26)	IA: 4.22 ( $\pm$ 1.13)
<b>1 year</b>	PA: 0.15 ( $\pm$ 0.23)	PA: 0.21 ( $\pm$ 0.23)	PA: 3.04 ( $\pm$ 0.89)	PA: 3.67 ( $\pm$ 1.27)
	IA: 0.14 ( $\pm$ 0.21)	IA: 0.18 ( $\pm$ 0.24)	IA: 3.08 ( $\pm$ 0.57)	IA: 4.35 ( $\pm$ 1.28)

**TABLE 3:** Mean Pink Esthetic Score (PES) and White Esthetic Score (WES) values and total PES/WES of the implant-supported single crowns at the three time points analyzed (mean value) baseline, 6 months and 1 year comparing PA = prefabricated abutment versus IA = individualized CAD/CAM abutment.

<b>Pink Esthetic Score (PES)</b>						
Timepoint	Mesial Papilla	Distal Papilla	Curvature labial Mucosa	Level labial Mucosa	Root convexity Soft tissue colour and texture	Mean PES
<b>Baseline</b>						
PA	1.53	1.26	1.47	1.26	1.05	<b>6.53<sup>a</sup></b>
IA	1.65	1.30	1.80	1.65	1.35	<b>7.75<sup>a</sup></b>
<b>6 months</b>						
PA	1.47	1.29	1.47	1.47	1.24	<b>6.94</b>
IA	1.67	1.33	1.78	1.61	1.22	<b>7.67</b>
<b>1 year</b>						
PA	1.61	1.22	1.44	1.44	1.28	<b>7.00</b>
IA	1.65	1.30	1.75	1.60	1.30	<b>7.65</b>
<b>White Esthetic Score (WES)</b>						
Timepoint	Tooth Form	Tooth Volume/	Color	Surface Texture	Translucency	Mean WES
<b>Baseline</b>						
PA	1.63	1.47	1.47	1.84	1.84	<b>8.26</b>
IA	1.70	1.70	1.45	1.80	1.85	<b>8.50</b>
<b>6 months</b>						
PA	1.59	1.53	1.53	1.71	1.88	<b>8.24</b>
IA	1.72	1.72	1.50	1.72	1.78	<b>8.44</b>
<b>1 year</b>						
PA	1.67	1.50	1.50	1.72	1.89	<b>8.28</b>
IA	1.70	1.60	1.55	1.80	1.85	<b>8.50</b>

Timepoint	Total PES & WES
<b>Baseline</b>	
PA	<b>14.79</b>
IA	<b>16.25</b>
<b>6 months</b>	
PA	<b>15.18</b>
IA	<b>16.11</b>
<b>1 year</b>	
PA	<b>15.28</b>
IA	<b>16.15</b>

**TABLE 4:** Results of the cast analysis measuring the length of the implant crown and contralateral tooth crown (mm; mean  $\pm$  SD) at baseline, 6 months and 1 year; comparing PA= prefabricated abutment versus IA: individualized CAD/CAM abutment.

Exam	n	Implant Crown (IC)	Tooth Crown (TC)	$\Delta$ IC-TC
<b>Baseline</b>	PA: 20	PA: 10.09 ( $\pm$ 1.11)	PA: 9.43 ( $\pm$ 1.34)	PA: 0.66 ( $\pm$ 0.61)
	IA: 20	IA: 10.30 ( $\pm$ 1.60)	IA: 9.94 ( $\pm$ 1.55)	IA: 0.36 ( $\pm$ 0.61)
<b>6 months</b>	PA: 20	PA: 10.09 ( $\pm$ 1.17)	PA: 9.53 ( $\pm$ 1.24)	PA: 0.56 ( $\pm$ 0.42)
	IA: 20	IA: 10.26 ( $\pm$ 1.77)	IA: 9.91 ( $\pm$ 1.65)	IA: 0.35 ( $\pm$ 0.60)
<b>1 year</b>	PA: 20	PA: 10.21 ( $\pm$ 0.98)	PA: 9.68 ( $\pm$ 1.25)	PA: 0.53 ( $\pm$ 0.58)
	IA: 20	IA: 10.39 ( $\pm$ 1.43)	IA: 10.08 ( $\pm$ 1.32)	IA: 0.31 ( $\pm$ 0.64)

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# Chapter 5

Esthetic and Clinical Performance of  
Implant-Supported All-Ceramic Crowns  
Made with Prefabricated or CAD/CAM  
Zirconia Abutments – 3- year results of a  
Randomized Multicenter Study.

**Published:**

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## ABSTRACT

**Objective:** The aim of this randomized multicenter clinical trial was to evaluate and compare the performance of anterior all-ceramic implant crowns based either on prefabricated zirconia abutments veneered with pressed ceramics or on CAD/CAM zirconia abutments veneered with the hand build-up technique. The null hypothesis was that there is no statistically significant difference between the two study groups.

**Material and methods:** Forty implants were inserted in sites 14-24 (World Dental Federation (FDI)) in two centers, the Universities of Bern and Geneva, Switzerland. 20 patients each were randomized into either Group A and restored with one piece single crown made of a prefabricated zirconia abutment with pressed ceramic, or Group B using an individualized CAD/CAM zirconia abutment with the hand layered technique. After 3 years clinical, esthetic and radiographic parameters were assessed.

**Results:** Group A exhibited one drop-out patient and one failure resulting in a survival rate of 89% after three years and two failures for Group B (90%). Clinical parameters presented healthy peri-implant soft tissues. Overall, no crestal bone level changes were observed (mean DIB of 0.13 mm (Group A) and 0.24 mm (Group B)). There were no significant differences at baseline, 6 months and 1 and 3 years for DIB values between the two groups. PES and WES values evaluated at all three time points indicated stability over time for both groups and pleasing esthetic outcomes.

**Conclusions:** Both implant supported prosthetic pathways represent a valuable treatment option for the restoration of implant crowns in the anterior maxilla.

(ClinicalTrials.gov # NCT02905838)

## INTRODUCTION

Rehabilitation of the single tooth gap with the use of dental implants in the anterior maxilla is challenging. Often risk factors in respect to the final esthetic outcome are present as e.g. thin buccal soft tissue, thin buccal bone plate, high smile line, high patient expectations, pre-existing soft tissue condition and scars. However, in respect of patient's perception, it is the site of most concern and attention. Through the evolution of implant designs and dental materials today it is possible to achieve an ultimately pleasing esthetic outcome with long term success (Buser, Chappuis, Bornstein, et al., 2013; Buser, Chappuis, Kuchler, et al., 2013; Buser et al., 2012; Buser et al., 2011; Chappuis et al., 2018; Wittneben et al., 2014).

The choice of material and type of implant abutments can influence the final esthetic outcome. Therefore, its selection is one of the most aspects within the implant prosthetic workflow. For many years, implant abutments were only available as prefabricated, predesigned stock parts. The introduction of the UCLA (University of California, Los Angeles) custom abutment in 1988 was at that time revolutionary (Lewis, Beumer, Hornburg, & Moy, 1988). These gold custom abutments represented the state of the art in implant prosthodontics because they permitted the retention of a prosthesis directly inside the implant without the use of a transmucosal abutment in addition they were able to compensate for "non-ideally" inserted implants. Due to the casting technique there were more technical challenges and limitations plus higher pricing of gold, the color of the material and an animal study reporting on soft tissue recessions and crestal bone loss (Abrahamsson, Berglundh, Glantz, & Lindhe, 1998) their use has decreased. Composite resin materials are only recommended to be used for temporary abutments e.g. to support a fixed implant supported provisional crown. A RCT (Randomized Controlled Trial) has shown that in terms of oral hygiene and mucosal inflammation, titanium was superior to reinforced composite resin. More plaque accumulation was detected on composite resin surfaces resulting in mucosal inflammation in comparison to titanium (Kanao et al., 2013).

Another alternative abutment material is ceramic-reinforced polyetheretherketone (PEEK). PEEK is a polycyclic, aromatic, thermoplastic polymer with a low density and good biocompatibility (Ramenzoni, Attin, & Schmidlin, 2019). The most characteristic feature of PEEK abutments is their low modulus of elasticity. In a recent in vitro study mechanical property were compared with different abutment materials (Atsu, Aksan, & Bulut, 2019). The ceramic-reinforced PEEK abutments restored with monolithic lithium

disilicate crowns showed similar strengths ( $602.93 \pm 121.03$  N) to the zirconium abutments tested ( $623.9 \pm 97.4$  N), however fracture strength was significantly higher with titanium ( $787.8 \pm 120.9$  N). The study conclusion was there is need for further in vitro and clinical investigations to determine the long-term performance of ceramic-reinforced PEEK abutments.

Alumina abutments were the first generation of ceramic abutments. In direct comparison to titanium, Alumina has lower survival rates as shown in an RCT by Andersson (Andersson et al., 2001) and weaker mechanical properties compared to zirconia (Zembic, Kim, Zwahlen, & Kelly, 2014). Nowadays Yttrium oxide partially stabilized tetragonal zirconia polycrystalline (Y-TZP) has taken over from alumina as the preferred ceramic abutment material due to its superior mechanical properties (Manicone, Rossi Iommetti, & Raffaelli, 2007; Zarone, Russo, & Sorrentino, 2011). This material is able to initiate a unique phase transformation toughening process which can improve its mechanical strength and reliability (Chevalier, 2006; Christel, Meunier, Heller, Torre, & Peille, 1989; Guess, Att, & Strub, 2012; Nakamura, Kanno, Milleding, & Ortengren, 2010) combined with low corrosion potential and good radiopacity (Manicone et al., 2007).

Today the materials most recommended for abutment selection regarding biocompatibility and mechanical strength are titanium and zirconium dioxide. However zirconium dioxide is less prone to plaque accumulation compared to titanium (Degidi et al., 2006; Hisbergues, Vendeville, & Vendeville, 2009; Rimondini, Cerroni, Carrassi, & Torricelli, 2002; Scarano, Piattelli, Caputi, Favero, & Piattelli, 2004). In an RCT Study comparing titanium and zirconia abutments with a follow-up time of 5 years no statistically or clinically relevant differences were observed (Zembic, Bosch, Jung, Hammerle, & Sailer, 2013).

Blue-greyish shimmering of titanium abutments may influence the final esthetic outcome especially in clinical situations with a thin tissue biotype (Ishikawa-Nagai, Da Silva, Weber, & Park, 2007; Jung, Sailer, Hammerle, Attin, & Schmidlin, 2007). Studies have stated that if the mucosa thickness exceeds 2mm light reflection of soft tissue covering titanium or zirconium dioxide is no longer noticeable with the human eye (Ishikawa-Nagai et al., 2007; Jung et al., 2007; van Brakel et al., 2011). Overall, a meta-analysis by Linkevicius et al. comparing titanium and zirconia abutment material regarding the outcome of soft peri-implant tissue concluded that the zirconium dioxide abutments had a significantly better color response of the peri-implant mucosa and a

superior esthetic outcome measured by the pink esthetic score (PES) (Linkevicius & Vaitelis, 2015).

Evolution of dental materials, component design and digital technologies made it possible that high-strength ceramics like zirconium dioxide can be used. Zirconium dioxide abutments can be either prefabricated designed or customized using CAD/CAM (Computer Aided Design/ Computer Aided Manufacturing) technology.

The aim of this randomized prospective multicenter clinical trial was to compare the overall clinical performance -up to three years- between individualized CAD/CAM abutments veneered with the hand layered technique and prefabricated zirconium dioxide abutments veneered with pressed ceramics to restore implants inserted in single-tooth gaps in the anterior maxilla.

## **MATERIALS AND METHODS**

### **Patient cohort**

Forty subjects with a single tooth gap in the anterior maxilla in sites 14-24 (FDI) were included according to the inclusion and exclusion criteria. Patients were recruited from two centers, the Universities of Bern (20 patients) and Geneva (20 patients), Switzerland. Ethical approval was obtained by the Ethics Committee of the State of Bern (approval no. 061/10) and the informed consent document was written and signed in accordance with the "Declaration of Helsinki".

Prior to the randomization process subjects received a dental implant (Bone Level Implant 4.1 mm diameter, length 8 or 10 or 12 mm, Institute Straumann AG, Basel, Switzerland) with the use of contour augmentation (Buser, Chappuis, Bornstein, et al., 2013; Buser, Chappuis, Kuchler, et al., 2013; Chappuis et al., 2018). Soft tissue conditioning was performed using the dynamic compression technique (Wittneben, Buser, Belser, & Bragger, 2013) with a screw-retained implant-supported provisional crown. Screw-retained single crowns were fabricated using two different zirconium dioxide abutments types and two different veneering ceramic techniques after the provisional phase. Patients were randomly assigned to either Group A or B using a sealed envelope technique, which had been carried out by an independent person.

## **Screening and eligibility criteria**

The subjects were evaluated for initial study eligibility during the screening visit prior to the prosthodontic treatment.

### **Inclusion Criteria**

The subjects were evaluated for initial study eligibility during the screening visit. All of the following criteria had to be met for inclusion in the study:

7. Subjects must have voluntarily signed the informed consent form before any study-related action
8. Males and females of at least 18 years of age
9. Single tooth gap in the anterior maxilla position 14-24 (FDI)
10. Successfully osseointegrated single tooth implant inserted at least 16 weeks after tooth extraction
11. Full mouth plaque index according to O'Leary  $\leq 25\%$
12. Implant axis compatible with transocclusal screw retention (screw access palatal of incisal edges)

### **Exclusion Criteria**

If any of the following criteria were met, the subject had to be excluded from the study.

#### **Surgical exclusion criteria**

21. Systemic disease that would interfere with dental implant therapy
22. Any contraindications for oral surgical procedures
23. History of local irradiation therapy
24. Patients who smoke  $>10$  cigarettes per day or tobacco equivalents or chew tobacco
25. Subjects who had undergone administration of any investigational device within 30 days of enrolment in the study
26. Conditions or circumstances, in the opinion of the investigator, which would prevent completion of study participation or interfere with analysis of study results, such as history of non-compliance
27. Physical or mental handicaps that would interfere with the ability to perform adequate oral hygiene
28. Pregnant or breastfeeding women



## **Dental Exclusion Criteria**

29. Existing implants in the adjacent position
30. Removable dentures or un-restored tooth gaps in the opposing dentition
31. Patients with inadequate oral hygiene or unmotivated for adequate home care
32. Probing pocket depth of  $\geq 4$  mm on one of the teeth immediately adjacent to the dental implant site
33. Lack of primary stability of the implant
34. Inappropriate implant position for the prosthetic requirements
35. Major simultaneous augmentation procedures
36. Insufficient stability of the implant

## **Prosthetic Exclusion Criteria**

37. Screw access position located too close to the planned incisal edge of the restoration
38. Need of angled abutment due to prosthetic malposition of the implant
39. Height of the abutment is less than 65% of the height of the complete restoration
40. Severe bruxing or clenching habits

## **Laboratory procedures**

**Group A:** One piece implant-supported single crown was manufactured using a prefabricated stock abutment made of yttrium oxide partially stabilized tetragonal zirconia polycrystalline (Y-TZP) (Anatomic IPS e.max Abutment, straight, color M1, Ivoclar, Liechtenstein) and pressed ceramic (fluorapatite glass-ceramic, IPS e.max ZirPress, Ivoclar, Liechtenstein) using the cut-back technique and hand veneered with a thin layer of fluorapatite veneering ceramic (fluorapatite veneering ceramic, IPS e.max Ceram, Ivoclar, Liechtenstein).

**Group B:** One piece implant-supported single crown was manufactured using an individualized CAD/CAM abutment made of Y-TZP (CARES® Abutment, Institut Straumann AG, Basel, Switzerland) and the hand layered veneering ceramic technique (fluorapatite veneering ceramic, IPS e.max Ceram, Ivoclar, Liechtenstein).

One dental technician (Dominique Vinci, Geneva, Switzerland) fabricated all crowns in the same dental laboratory.

## **Clinical procedures**

All implants were placed with prosthetic backward planning and therefore screw retention and standardized abutments were possible in all cases. The final one piece all-ceramic crowns with internal connection were inserted by experienced prosthodontists 4 - 6 months after surgical placement of the implants and the retaining screw torqued to 35 Ncm. Details of the clinical procedures were previously published within the 1-year follow up data of the present study (Wittneben et al., 2017).

## **Follow-up examinations**

Re-examination was performed at baseline, 6 and 12 and 36 months- clinical and radiographic assessments were obtained. The definition of baseline was one week after insertion of the final implant-supported crown. Data up to 1- year are previously published (Wittneben et al., 2017).

## **Clinical Peri-implant Measurements**

The following clinical parameters were obtained at baseline, 6 and 12 and 36 months post baseline (4 sites per implant (mesial/distal/buccal/oral) except KM: buccal side only):

- Modified pink esthetic score (mod PES) (Belser et al., 2009; Furhauser et al., 2005).
- White esthetic score (WES) (Belser et al., 2009)
- Presence/absence of plaque (mod PI): were evaluated according to criteria of the Plaque Index (PI)(Silness & Loe, 1964) adapted for oral implants (Mombelli, van Oosten, Schurch, & Land, 1987)
- Pocket probing depth (PPD)
- Bleeding on probing (BOP)(Lang, Joss, Orsanic, Gusberti, & Siegrist, 1986)
- Keratinized mucosa (KM) in mm

## **Evaluation of Presence of Technical/ Mechanical Complications and Failures**

The presence/absence of technical/mechanical complications was documented at baseline, 6, 12 and 36 months post baseline. A prosthetic failure was defined as an event leading to the loss of the implant-supported crown and the need to renew the entire restoration, or, the explantation/loss of the implant and therefore also the loss of the implant-supported crown.

### **Implant Success and Survival Rate**

Implant success and survival was evaluated at the screening visit, baseline, 6, 12 and 36 months post baseline. A surviving implant was defined as an implant in place at the time of follow-up. Implants were graded as a success according to the success criteria published by Buser et al. (Buser, Weber, Bragger, & Balsiger, 1991) and Albrektsson et al. (Albrektsson, Jansson, & Lekholm, 1986).

### **Cast Analysis and Radiographic Assessment**

Details on the stone cast fabrication, standardized photograph measurement and radiographic assessment with standardized radiographs have been published in the 1-year follow up data of the present study (Wittneben et al., 2017). Dental impressions and standardized radiographs were taken at the baseline, 6, 12 and 36 months follow-up visits.

### **Esthetic Parameters**

The modPES and WES index was registered by two experienced prosthodontists at the baseline, 6, 12 and 36 months follow-up examinations. The clinicians were blinded regarding the group distribution.

### **Statistical Analysis**

First, data were analyzed descriptively computing means, medians and standard deviations for all factorial combinations of interest.

Then, differences between the two groups and between IC and TC values were analyzed performing Wilcoxon-Mann-Whitney tests. Wilcoxon's signed-rank tests were used in order to compare every pair of the three different time levels among fixed group levels.

No correction for multiple testing was applied due to the explorative nature of this study. The level of significance was set to 0.05. All calculations were done with R, version 3.3.3 (The R Project for Statistical Computing, Vienna, Austria).

# RESULTS

## Clinical Performance

A total of 39 patients were seen at the 3-year follow up. One patient was lost even before completion of the treatment (drop out) in Group A. A fracture of the ceramic crown within the veneering ceramic occurred after one year in Group A (one failure). After three years one patient was unsatisfied with the esthetic outcome and the crown was redone (esthetic failure) and one crown had chipping on the incisal edge within the veneering ceramic leading to a renewal explaining both failures in Group B. Resulting in a survival rates of 89% for Group A and 90% in Group B. No complications were observed (tab. 1). Focusing on the inserted implants – no complications and failures were observed within 3 years.

## Clinical Findings

After three years patients presented with good oral hygiene, documented by a mean mPLI of 0.21 (Group A) and 0.20 (Group B) (tab. 2). Surrounding peri-implant mucosa remained stable over the three year follow up- analysed by mSBI of 0.31 (Group A) and 0.24 (Group B) and PPD of 3.04 (Group A) and 2.83 (Group B). Keratinized mucosa was present on the buccal site of 3.59mm (Group A) and 4.11mm (Group B), respectively (tab. 2). Statistically significant differences between time points was identified for mPLI at baseline and 6 months; 6 and 12 months and between 6 and 36 months for both Groups (tab. 3). No significant differences between time points were documented for mSBI, PPD and KM except for Group B KM at baseline compared to 12 months follow-up (tab. 3).

## Esthetic Outcomes

Both esthetic scores- PES and WES data presented stability and pleasing esthetic outcomes over the 3 year period (tab. 4). Mean PES values exhibited data of 7.76 (Group A) and 7.32 (Group B) after 36 months. WES index scored high with values of 8.88 for Group A and 8.56 for Group B after 3 years (tab. 4).

There was a significant difference between time points baseline and 3 years regarding the PES values which improved in Group A over time (tab. 5).

## **Cast Analysis**

Implant crown length compared to the natural contralateral tooth revealed that no recessions had occurred over the time period of three years. Detailed results are presented in table 6. Significant differences in the length of the implant crown were documented between baseline versus 36 months ( $p= 0.004$ ) and 6 versus 36 months ( $p=0.001$ ) (tab. 7). Delta IC-TC was statistically significant different between 12 and 36 months (0.0589) (tab. 7).

## **Radiographic Findings**

Figure 1 illustrates box plots presenting radiographic data (DIB) of the implants analyzed for baseline, 6, 12 and 36 months in comparison.

After 3 years of follow-up no crestal bone loss was observed with a mean DIB value of 0.13mm for Group A and 0.24 for Group B (tab. 8). There were no statistically significant differences between both groups and also no influence of time effects could be identified (tab. 9).

## **DISCUSSION**

The objective of this randomized controlled prospective multicenter study was to compare the overall clinical performance between individualized CAD/CAM Y-TZP abutments veneered with a hand build-up technique and prefabricated Y-TZP abutments veneered with pressed ceramics in the anterior maxilla after a follow-up period of 3 years. The aim was also to evaluate both prosthetic pathways, as the individualized CAD/CAM abutment requires more time and effort to manufacture and the hand-layered ceramic technique more experience for the technician compared to the workflow with a stock abutment and pressed ceramics. The null hypothesis stating that both prosthetic pathways would provide similar clinical performance and esthetic outcomes cannot be rejected.

After 3 years both implant-prosthetic pathways showed good clinical results. No technical or biological complications were observed. One drop out in Group A resulted in 39 patients, which were seen at the 3 year follow-up. After 3 years both groups exhibited one failure each due to ceramic fracture/major chipping event and Group B one additional esthetic failure occurred. These crowns had to be replaced. Similar survival rates were observed with Group A (89%) and Group B (90%) (tab. 1).

In a retrospective study by Schnider et al. (Schnider, Forrer, Bragger, & Hicklin, 2018),

50 bone level type implants were restored with one piece screw retained implant crowns with individualized CAD/CAM Y-TZP abutments – after a follow up time of 1.1-3.8 years no technical or biological complications neither failures occurred.

In a prospective study by Zembic et al. 31 zirconia abutments were examined at 11 years (Zembic, Philipp, Hammerle, Wohlwend, & Sailer, 2015). The following technical complications occurred: two abutment screws loosened and three crowns exhibited minor chipping. The cumulative success rate was 96.3% for zirconia abutments.

In the present study high PES/WES results proved stability of the esthetic outcome over 36 months in both groups. In Group A a significant improvement of the total PES/WES value was observed between baseline versus 36 months ( $p=0.02$ ) and 6 months versus 36 months ( $p=0.04$ ). In Group B the total PES/WES was statistically significant smaller between baseline and 6 month ( $p=0.03$ ). Concluding a mean PES/WES score after 3 years of 16.64 (Group A) and 15.88 (Group B). These results are comparable to a study by Buser et al. where 41 single implants were placed in the anterior maxilla and after a follow-up time of 5-9 years the PES/WES score was 14.37 (Buser, Chappuis, Bornstein, et al., 2013).

In the present RCT no recession occurred. Peri- implant parameters (mod PI, PPD, BOP, KM) documented stability of the peri- implant soft tissue when comparing baseline to 3 years follow-up. In a RCT comparing zirconia CAD/CAM versus stock abutments like in the present study plaque accumulation, PPD, bleeding tendency and gingiva index were generally small and none of them statistically significant (Schepke, Meijer, Kerdijk, Raghoobar, & Cune, 2017). This is coherent with the data of the present trial.

Focusing on the data of PPD and comparing it to a meta-analysis from Linkevicius et al PPD values are comparable to his included studies focusing on zirconia abutments (Linkevicius & Vaitelis, 2015). Linkevicius could show no statistically significant differences between zirconia and titanium abutments regarding soft tissue parameters. He speculated that on a zirconia abutment the adherence of cells to the abutments might reduce PPD around implants over time (Linkevicius & Vaitelis, 2015).

Regarding the hard tissue, no crestal bone changes were observed, presenting a DIB of 0.13 (Group A) and 0.24 (Group B) at the 3 year follow up visit. No statistical significant difference was documented between the individual time points. These outcomes were confirmed presenting some bone opposition (0.06-0.11mm) after one year in the above mentioned clinical trial by Schepke U. (Schepke et al., 2017).

The results of the present investigation conclude both prosthetic pathways showed good clinical performance in the esthetic zone. Available clinical studies about internally connected zirconia abutments in the literature confirm this successful outcome, and also present high survival rates (Canullo, 2007; Ekfeldt, Furst, & Carlsson, 2011; Hosseini, Worsaae, Schiodt, & Gotfredsen, 2013; Lops, Bressan, Chiapasco, Rossi, & Romeo, 2013; Nothdurft, Nonhoff, & Pospiech, 2014).

After 3 year post insertion the individualized abutment with the more cost and time intensive manufacturing process did not prove to be superior compared to the stock abutment with pressed ceramics. However a total of 2 major chipping events – leading to a renewal of the crowns- in 40 patients after 3 years not unexpected, as chipping has been reported to be the most frequent technical complication and has been reconfirmed with the present investigation (Gherlone et al., 2014; Wittneben et al., 2014). Stronger veneering ceramic materials fabricated by digital veneering might decrease chipping events in the future (Tezulas, Yildiz, Kucuk, & Kahramanoglu, 2019).

Limitations of this study might be the duration of observation, and the limited patient number. However, it can be concluded that both zirconia abutment types - individualized or prefabricated - are a valuable treatment option for single screw retained implant-supported crowns.

## **ACKNOWLEDGMENTS**

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## **CONFLICT OF INTEREST**

There is no conflict of interest from any of the authors in respect to the present investigation.

## TABLES AND FIGURE

**TABLE 1:** Overview of Groups A and B including failures, complications, survival and success analysis after three years (A = prefabricated stock abutment; B = individualized CAD/CAM abutment).

	Group A	Group B
Enrolled	n = 20	n = 20
Under exposure	n = 19	n = 20
Drop out	n = 1	n = 0
Failure	n = 1	n = 2
Complications	n = 0	n = 0
Survival (%)	89%	90%
Success (%)	89%	90%



**TABLE 2:** Clinical parameters of the implants (mean [median]  $\pm$  standard deviation) up to a follow-up of 3 year (A = prefabricated stock abutment; B = individualized CAD/CAM abutment). Statistically significant differences between the gingival parameter scores are marked with the same letters; mPLI = modified plaque index; mSBI = modified sulcus bleeding index; PPD = probing depth; KM = keratinized mucosa.

Exam	mPLI	mSBI	PPD (mm)	KM (mm)
<b>Baseline</b>	A: 0.14 [0.00] ( $\pm$ 0.24)	A: 0.18 [0.25] ( $\pm$ 0.20)	A: 3.05 [3.00] ( $\pm$ 0.60)	A: 3.84 [3.00] ( $\pm$ 1.49)
	B: 0.10 [0.00] ( $\pm$ 0.29)	B: 0.08 [0.00] ( $\pm$ 0.20)	B: 2.64 [2.75] ( $\pm$ 0.53)	B: 4.10 [4.00] ( $\pm$ 1.15)
<b>6 months</b>	A: 0.89 [0.50] ( $\pm$ 1.04)	A: 0.13 [0.00] ( $\pm$ 0.20)	A: 3.07 [3.00] ( $\pm$ 0.99)	A: 3.47 [3.00] ( $\pm$ 1.26) <sup>a</sup>
	B: 0.62 [0.50] ( $\pm$ 0.26)	B: 0.10 [0.00] ( $\pm$ 0.17)	B: 2.92 [3.00] ( $\pm$ 0.26)	B: 4.22 [4.00] ( $\pm$ 1.13) <sup>a</sup>
<b>1 year</b>	A: 0.15 [0.00] ( $\pm$ 0.23)	A: 0.21 [0.12] ( $\pm$ 0.23)	A: 3.04 [3.00] ( $\pm$ 0.89)	A: 3.67 [3.50] ( $\pm$ 1.27)
	B: 0.14 [0.00] ( $\pm$ 0.21)	B: 0.18 [0.00] ( $\pm$ 0.24)	B: 3.08 [3.00] ( $\pm$ 0.57)	B: 4.35 [4.00] ( $\pm$ 1.28)
<b>3 years</b>	A: 0.21 [0.00] ( $\pm$ 0.33)	A: 0.31 [0.25] ( $\pm$ 0.34)	A: 3.04 [2.67] ( $\pm$ 0.79)	A: 3.59 [3.00] ( $\pm$ 1.16)
	B: 0.20 [0.00] ( $\pm$ 0.24)	B: 0.24 [0.25] ( $\pm$ 0.29)	B: 2.83 [2.67] ( $\pm$ 0.61)	B: 4.11 [4.00] ( $\pm$ 1.05)

**TABLE 3:** Clinical parameters: Tests for main effect of time (baseline vs. 6m vs. 12m vs. 36 m) within groups (p-values). Stars (\*) indicating significant findings. One star (\*) for p values being less than 0.05, two stars (\*\*) for p values < 0.01 and three stars (\*\*\*) for p < 0.001.

Group A (p-values)	mPLI	mSBI	PPD	KM
BL vs. 6m	0.0001***	0.5708	0.6051	0.1677
BL vs. 12m	0.5716	0.6078	0.3517	0.5713
BL vs. 36m	0.3929	0.0664	0.9434	0.7584
6m vs. 12m	0.0005***	0.2270	0.9773	0.5807
6m vs. 36m	0.0021**	0.0459*	0.6355	0.5228
12m vs. 36m	0.6049	0.2376	0.3622	0.8915

Group B (p-values)	mPLI	mSBI	PPD	KM
BL vs. 6m	0.0001***	0.5827	0.1642	0.6662
BL vs. 12m	0.3951	0.1138	0.0279*	0.0279*
BL vs. 36m	0.1775	0.0773	0.5062	0.7762
6m vs. 12m	0.0002***	0.3405	0.3371	0.2882
6m vs. 36m	0.0003***	0.0807	0.4201	0.6662
12m vs. 36m	0.2760	0.5519	0.0831	0.1471

**TABLE 4:** Mean [Median] PES and WES values and total PES/WES of the implant-supported single crowns at four time points analyzed (mean value)

<b>Pink Esthetic Score (PES)</b>						
<b>Timepoint</b>	<b>Mesial Papilla</b>	<b>Distal Papilla</b>	<b>Curvature labial Mucosa</b>	<b>Level labial Mucosa</b>	<b>Root convexity Soft tissue colour and</b>	<b>Mean PES</b>
<b>Baseline</b>						
A	1.53 [2.00]	1.26 [1.00]	1.47 [1.00]	1.26 [1.00]	1.05 [1.00]	<b>6.53<sup>a</sup> [6.00]</b>
B	1.65 [2.00]	1.30 [1.00]	1.80 [2.00]	1.65 [2.00]	1.35 [1.00]	<b>7.75<sup>a</sup> [8.50]</b>
<b>6 months</b>						
A	1.47 [2.00]	1.29 [1.00]	1.47 [2.00]	1.47 [2.00]	1.24 [1.00]	<b>6.94 [7.00]</b>
B	1.67 [2.00]	1.33 [1.00]	1.78 [2.00]	1.61 [2.00]	1.22 [1.00]	<b>7.67 [8.00]</b>
<b>1 year</b>						
A	1.61 [2.00]	1.22 [1.00]	1.44 [1.50]	1.44 [1.50]	1.28 [1.00]	<b>7.00 [7.00]</b>
B	1.65 [2.00]	1.30 [1.00]	1.75 [2.00]	1.60 [2.00]	1.30 [1.00]	<b>7.65 [8.00]</b>
<b>3 years</b>						
A	1.71 [2.00]	1.53 [2.00]	1.59 [2.00]	1.47 [2.00]	1.47 [1.00]	<b>7.76 [8.00]</b>
B	1.78 [2.00]	1.33 [1.50]	1.67 [2.00]	1.50 [2.00]	1.44 [1.00]	<b>7.32 [9.00]</b>

<b>White Esthetic Score (WES)</b>						
<b>Timepoint</b>	<b>Tooth Form</b>	<b>Tooth Volume/</b>	<b>Color</b>	<b>Surface Texture</b>	<b>Translucency</b>	<b>Mean WES</b>
<b>Baseline</b>						
A	1.63 [2.00]	1.47 [1.00]	1.47 [1.00]	1.84 [2.00]	1.84 [2.00]	<b>8.26 [9.00]</b>
B	1.70 [2.00]	1.70 [2.00]	1.45 [1.00]	1.80 [2.00]	1.85 [2.00]	<b>8.50 [9.00]</b>
<b>6 months</b>						
A	1.59 [2.00]	1.53 [2.00]	1.53 [2.00]	1.71 [2.00]	1.88 [2.00]	<b>8.24 [9.00]</b>
B	1.72 [2.00]	1.72 [2.00]	1.50 [1.00]	1.72 [2.00]	1.78 [2.00]	<b>8.44 [9.00]</b>
<b>1 year</b>						
A	1.67 [2.00]	1.50 [1.50]	1.50 [1.50]	1.72 [2.00]	1.89 [2.00]	<b>8.28 [9.00]</b>
B	1.70 [2.00]	1.60 [2.00]	1.55 [2.00]	1.80 [2.00]	1.85 [2.00]	<b>8.50 [9.00]</b>
<b>3 years</b>						
A	1.76 [2.00]	1.41 [1.00]	1.71 [2.00]	2.00 [2.00]	2.00 [2.00]	<b>8.88 [9.00]</b>
B	1.72 [2.00]	1.56 [2.00]	1.56 [2.00]	1.89 [2.00]	1.83 [2.00]	<b>8.56 [9.00]</b>

Timepoint	Total PES & WES
<b>Baseline</b>	
A	<b>14.79 [15.00]</b>
B	<b>16.25 [18.00]</b>
<b>6 months</b>	
A	<b>15.18 [15.00]</b>
B	<b>16.11 [18.00]</b>
<b>1 year</b>	
A	<b>15.28 [16.00]</b>
B	<b>16.15 [18.00]</b>
<b>3 years</b>	
A	<b>16.64 [17.00]</b>
B	<b>15.88 [17.50]</b>

**TABLE 5:** PES, WES values and total PES/WES: Test of main effect in between time points within groups (p-values)

Group A (p-values)	mean PES	mean WES	total PES/WES
BL vs. 6m	0.5160	0.4098	1.0000
BL vs. 12m	0.2895	1.0000	0.4327
BL vs. 36m	0.0401*	0.2815	0.0176*
6m vs. 12m	0.4821	0.5862	0.2815
6m vs. 36m	0.0628	0.0559	0.0353*
12m vs. 36m	0.1653	0.1744	0.0886

Group B (p-values)	mean PES	mean WES	total PES/WES
BL vs. 6m	0.0477*	1.0000	0.0305*
BL vs. 12m	0.4840	1.0000	0.4840
BL vs. 36m	0.8368	0.2815	0.5881
6m vs. 12m	0.2652	0.3458	0.1290
6m vs. 36m	0.7055	0.5602	0.2531
12m vs. 36m	0.8369	0.6410	0.5848

**TABLE 6:** Cast analysis regarding the length of the IC and contralateral TC (mm; mean [median]  $\pm$  SD; A = prefabricated stock abutment; B = individualized CAD/CAM abutment.

Exam	IC	TC	$\Delta$ IC-TC
<b>Baseline</b>	A: 10.09 [9.96] ( $\pm$ 1.11)	A: 9.43 [9.00] ( $\pm$ 1.34)	A: 0.66 [0.50] ( $\pm$ 0.61)
	B: 10.30 [10.23] ( $\pm$ 1.60)	B: 9.94 [9.94] ( $\pm$ 1.55)	B: 0.36 [0.22] ( $\pm$ 0.61)
<b>6 months</b>	A: 10.09 [9.93] ( $\pm$ 1.17)	A: 9.53 [9.21] ( $\pm$ 1.24)	A: 0.56 [0.60] ( $\pm$ 0.42)
	B: 10.26 [10.23] ( $\pm$ 1.77)	B: 9.91 [10.39] ( $\pm$ 1.65)	B: 0.35 [0.37] ( $\pm$ 0.60)
<b>1 year</b>	A: 10.21 [10.00] ( $\pm$ 0.98)	A: 9.68 [9.50] ( $\pm$ 1.25)	A: 0.53 [0.46] ( $\pm$ 0.58)
	B: 10.39 [10.27] ( $\pm$ 1.43)	B: 10.08 [10.41] ( $\pm$ 1.32)	B: 0.31 [0.15] ( $\pm$ 0.64)
<b>3 years</b>	A: 10.46 [10.50] ( $\pm$ 1.25)	A: 9.61 [9.80] ( $\pm$ 1.33)	A: 0.85 [0.88] ( $\pm$ 0.67)
	B: 10.46 [10.32] ( $\pm$ 1.58)	B: 9.97 [10.15] ( $\pm$ 1.38)	B: 0.49 [0.32] ( $\pm$ 0.72)

**TABLE 7:** Cast analysis: Test on time effect (p-values)

Comparison (p-values)	IC	TC	$\Delta$ IC-TC
BL vs. 6m	0.7209	0.7725	0.9356
BL vs. 12m	0.1633	0.1036	0.0895
BL vs. 36m	0.0004***	0.3391	0.0589
6m vs. 12m	0.1122	0.1100	0.3387
6m vs. 36m	0.0012**	0.2133	0.0671
12m vs. 36m	0.0127*	0.8934	0.0017**

**TABLE 8:** Radiographic parameters (DIB) of the implants analyzed over the course of 3 years (A = prefabricated stock abutment; B = individualized CAD/CAM abutment).

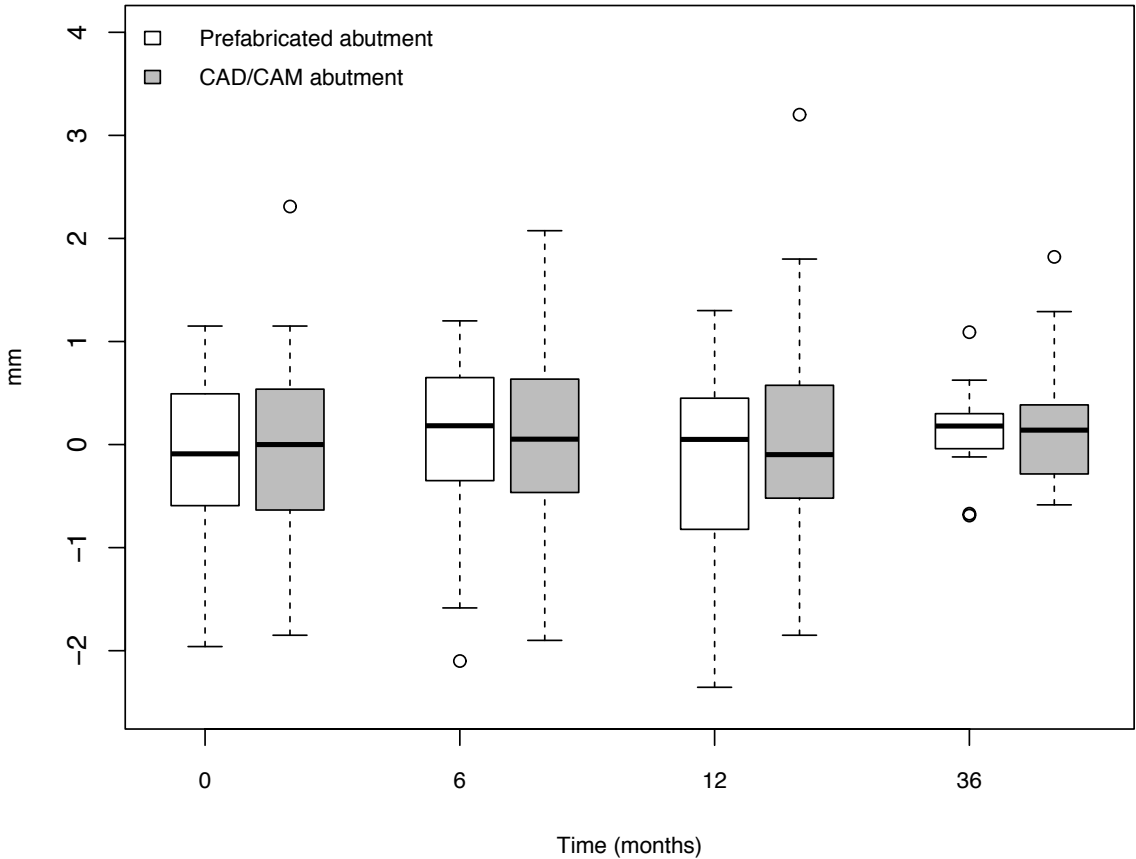
<b>Exam</b>	<b>0 mos</b>	<b>6 mos</b>	<b>12 mos</b>	<b>36 mos</b>
<b>Mean</b>	A: -0.15	A: -0.04	A: -0.15	A: 0.13
	B: -0.06	B: 0.09	B: 0.11	B: 0.23
<b>Median</b>	A: -0.09	A: 0.18	A: 0.05	A: 0.18
	B: 0.00	B: 0.05	B: -0.09	B: 0.14
<b>Maximum</b>	A: 1.15	A: 1.20	A: 1.30	A: 1.09
	B: 2.31	B: 2.07	B: 3.20	B: 1.82
<b>Minimum</b>	A: -1.96	A: -2.10	A: -2.35	A: -0.69
	B: -1.85	B: -1.90	B: -1.85	B: -0.58
<b>STD</b>	A: 0.94	A: 0.88	A: 1.01	A: 0.42
	B: 0.94	B: 0.89	B: 1.08	B: 0.68
<b>p (A versus B)</b>	0.77	0.98	0.78	0.83

**TABLE 9:** Radiographic parameters (DIB) of the implants: Comparison of time effects of both groups (p-values).

<b>Comparison (p-values)</b>	<b>Group A</b>	<b>Group B</b>
BL vs. 6m	0.9321	0.8313
BL vs. 12m	0.6435	0.1712
BL vs. 36m	0.2891	0.6191
6m vs. 12m	0.8971	0.0691
6m vs. 36m	0.3778	0.9780
12m vs. 36m	0.7764	0.9058

# LEGEND OF FIGURE

**Figure 1:** Box plots showing radiographic parameters (DIB) of the implants analyzed for baseline, 6, 12 and 36 months (A = prefabricated stock abutment; B = individualized CAD/CAM abutment)



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# Chapter 6

Vertical eruption of anterior maxillary teeth adjacent to single implant supported crowns after 3 years follow-up

**Accepted:**

*Wittneben JG, Kensuke I, Brägger U, Buser D, Schimmel M, Wismeijer D.*

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## **ABSTRACT**

**Objectives:** The aim of this prospective clinical trial was to evaluate the possible vertical eruption of anterior maxillary teeth which were adjacent to single implant crowns after a 3 years follow-up period.

**Material and Methods:** Thirty single dental implants were inserted in sites 14-24 (FDI). The range of patient age was 23-79 years and mean age at one week after insertion of the final implant-supported crown was 48.4 years. After final impression taking, each implant was restored with a one-piece screw retained all ceramic single crown. The vertical changes of 60 anterior maxillary teeth which were adjacent to the implant were evaluated measuring periapical radiographs and cast models after baseline, 6, 12 and 36 months.

**Results:** Global ANOVA Test showed statistically significant differences for the outcomes DPC ( $p<0.001$ ), crown length distal ( $p=0.001$ ) and mesial ( $p=0.03$ ), incisal edge to edge ( $p<0.001$ ). Among those outcomes, significant differences between the four time points could be identified.

**Conclusions:** Continuous vertical tooth eruption next to a single dental implant was observed in the adult patient.

**Clinical Implications:** Even in adult patients, vertical eruption changes of anterior maxillary teeth adjacent to single implant crowns may occur and can compromise the esthetic result over time.

## **INTRODUCTION**

Rehabilitation of a single edentulous gap with an implant- supported crown is a common treatment procedure, presenting high survival rates for the implants and crowns.<sup>1-3</sup> However, regarding the vertical position implants behave like ankylosed teeth as they do not follow the changes of the alveolar process such as continuous eruption of adjacent teeth.<sup>4-7</sup> An osseointegrated implant does not adapt to eruptive growth changes. This has been well documented in patients provided with implant-supported crowns at a young age in which changes in the occlusal plane associated with infraocclusion of the implant supported crown has been observed.<sup>5,6</sup> Even in adult patients, this phenomenon has been described, compromising the esthetic outcome with the implant supported reconstruction.<sup>8</sup> Facial growth of the child, and even of the adolescent, as well as the continuous eruption of the adjacent anterior teeth at older age, create a significant risk of a less favorable esthetic and/or functional outcome over time. Even after full emergence of teeth and termination of facial growth, teeth exhibit a continuous eruption, at probably a reduced rate but, for a considerable period and following individual patterns.<sup>9</sup> A study by Jemt et al. 2006 has shown that permanent anterior teeth adjacent to single implant- supported crowns showed a significant increase in clinical crown height compared to a population of dentate persons in a follow-up study of more than 15 years.<sup>10</sup> Another investigation differentiated between “young and mature adolescence” evaluating the tooth eruption process adjacent to implant supported crowns. Both groups exhibited major vertical steps after one year of insertion.<sup>11</sup>

The aim of the present prospective clinical trial was to evaluate the vertical eruption changes of anterior maxillary teeth which were adjacent to single implant crowns after a follow up of 3 years.

## **MATERIAL AND METHODS**

After at least 16 weeks of healing after tooth extraction, 30 endosseous implants were placed in 28 patients in a university setting in Switzerland. Implants (Bone Level Implant 4.1 mm diameter, length 8 or 10 or 12 mm, Institute Straumann AG) were placed with the use of contour augmentation in a single edentulous space with one missing maxillary anterior tooth in sites 14-24 (FDI (Federation Dentaire Internationale)).<sup>12,13</sup> After the provisional phase using a fixed screw retained implant supported provisional and final impression taking, one-piece screw retained single all

ceramic crowns were fabricated. The final all ceramic crowns were inserted by experienced prosthodontists 4-6 months after surgical placement of the implants and torqued to 35 Ncm. None of the patients received orthodontic therapy prior to implant placement. Occlusion was evaluated in static and dynamic movements following the mutually protective occlusion concept.<sup>14</sup> Oral hygiene instructions and motivation were given in detail to all patients included. Ethical approval was provided by the Ethics Committee of the State of Bern (approval no. 061/10). The informed consent document was written and signed by the patients in accordance with the "Declaration of Helsinki". Inclusion and exclusion criteria were the same as used in a previously published prospective clinical study by Wittneben et al.<sup>15</sup>

Patients were seen at the follow up appointments at baseline, 6, 12 and 36 months. Clinical and radiographic parameters were assessed and impression taken for the fabrication of the cast models. Baseline was defined one week after insertion of the final all ceramic implant-supported crown.

### **Radiographic analysis**

Intraoral standardized radiographs were taken at baseline, 6, 12, and 36 months follow-up period. The radiographs were taken using the long-cone parallel technique. The individual holders were fabricated with acrylic for each patient having the radiograph taken in the same angle. The films were used either the conventional intraoral radiographic film (F-speed, Kodak Insight) or the digital intraoral radiographic film (Image plate, Duerr Dental). The conventional intraoral radiographic films were scanned by photo scanner (Epson perfection 1660 PHOTO Scanner, Epson Seiko Corporation) and the digital intraoral radiographic films were scanned by the image plate scanner (VistaScan Combi Plus, Duerr Dental). The radiographic analysis was performed using ImageJ software (developed by the National Institutes of Health; available at <http://rsb.info.nih.gov/ij/download.html>). To compensate the anatomic magnification and distortion in the films, the linear dimensions of the digitized images were calibrated. This was achieved by setting the scale in the image to the known distance between two implant threads (0.8 mm).

After calibration, the implant axis and the implant platform lines were drawn at a right angle. The implant platform line was passed through the widest point of the implant neck. The location of the cement-enamel junction (CEJ) was determined by two experienced clinicians and agreed upon discussion for each individual case. The

distance from the CEJ to the platform line was measured at a right angle (eruption distance).

Mean distance from implant platform line to CEJ (MD) and eruption distance (ED) was measured (Fig 1). After measuring the distance, MD and ED were compared in each following up radiograph.

### **Cast analysis**

Impressions were taken at baseline, 6, 12, and 36 months period to produce the cast models of the maxilla. The casts were photographed with a standardized technique using a millimeter grid as reference. The longest height of the implant crown and 60 neighboring natural teeth were measured on these digital pictures to identify potential changes in crown height or mucosal recessions (Fig. 2). Moreover, gingival zeniths were marked on implant position and neighboring natural teeth position. The distance between these zenith points were measured to identify mucosal level changes.

### **Statistical analysis**

The following outcomes were analyzed in n= 30 implants, n= 60 adjacent teeth: DPC (distance from implant platform line to CEJ position) measured with standardized radiographs; crown length of the adjacent tooth measured on the mesial and distal sites, implant crown length, gingival level mesial and distal, incisal edge to edge (Elongation distance) from casts. All of them were measured at baseline, 6, 12 and 36 months. In order to test for possible differences between the different time points a repeated measures ANOVA (analysis of variance) was performed. Because of sample size considerations a nonparametric model was chosen according to Brunner and Langer.<sup>16</sup>

In case of a significant result post-hoc Wilcoxon signed-rank tests were further performed in order to compare each pair of time points.

P values less than 0.05 were considered statistically significant and all p values were corrected for multiple testing using Bonferroni-Holm's method.

All results were calculated with R, 3.3.3 (R Core Team 2013. R: A language and environment for statistical computing. R Foundation for Statistical Computing, <http://www.R-project.org>).

## RESULTS

The present investigation evaluated 28 patients (20 men and 8 women) including 30 implants and 60 adjacent teeth for the 36-month follow-up period. The range of patient age was 23-79 years (mean age at baseline was 48.4 years). An overview of the individual tooth positions (FDI) of the implant- supported single all ceramic crowns are listed in table 1. Most implants were placed in the central incisor position (n=20). All implants were stable and no signs of peri-implantitis throughout the study period.

### Descriptive Statistics

Mean and median values of DPC presented a slight increase over the 3 year follow up period (table 3, figure 3). The natural adjacent tooth crown length measured on 30 distal sites had increased significantly between baseline and one year follow up. After 36 months the values were similar to the baseline data (table 5). 30 mesial sites however did not show an increase in length (table 6). Median and mean values of the data focusing on the incisal edge to edge positions increased from 0.166 (mean) at baseline to 0.347 (mean) at 36 months (table 9, figure 5).

### Time Effect

A detailed overview is given in tables 2, 3, 7, 8 and figures 3, 4, 5. Global ANOVA test showed statistically significant differences for the outcomes DPC ( $p < 0.001$ ), crown length distal ( $p = 0.001$ ) and mesial ( $p = 0.03$ ), incisal edge to edge ( $p < 0.001$ ) (table 2). Among those outcomes, significant differences between the four time points could be identified.

DPC data presented significant elongation over the 3-year period, illustrated in box plot figure 3 and table 3. The data show a statistically significant difference between follow up times baseline and 6 months; baseline and 12 months; baseline and 36 months; 6 and 12 months and 6 and 36 months.

The natural tooth crown length after 12 months was statistically significantly elongated compared to baseline ( $p < 0.001$ ) and after 6 months ( $p = 0.044$ ) and compared to 36 months ( $p < 0.001$ ) (table 8).

Vertical eruption of the Incisal edge to edge positions was continuously documented over the 36 months, shown in figure 5. A clinical situation is presented in figures 6 A+B, showing pictures of a patient at baseline (6A) and after 36 months (6B).



## DISCUSSION

Within the limitation of the small sample size, follow-up of 36 months only, possible methodological errors within the measurements that may have occurred- the present data were prospective in design and, therefore, a true comparison could be obtained within the different follow-up times.

DPC values are reliable as the implant is ankylosed within the bone and if the CEJ position of the adjacent teeth changed within the time points. Statistically significant differences were identified between follow up times baseline and 6 months; baseline and 12 months; baseline and 36 months; 6 and 12 months and 6 and 36 months.

Overall the differences were statistically different for the outcomes DPC ( $p < 0.001$ ), crown length distal ( $p = 0.001$ ) and mesial ( $p = 0.03$ ), incisal edge to edge ( $p < 0.001$ ) between the four time points. Although the mean age of the patients was 48.4 years the adjacent teeth did change in their vertical position. These findings were confirmed by the cast analysis. Here the crown length of the adjacent teeth mesially and distally were statistically significant different between time points baseline and 12 months; 6 months and 12 months; 12 months and 36 months. The incisal edge to edge position of the adjacent teeth compared to the implant measured with the cast models was statistically different between all timepoints.

The assumption that continuous tooth eruption next to a single dental implant exists even in the adult patient could be substantiated by the data of the present investigation and is in accordance with previous published studies.<sup>6,7,11,17-19</sup> All implants in the present study were inserted in the maxilla. A study by Ghislanzoni et al. reporting on vertical changes in the maxilla during a 10-year period detected a trend for eruption especially in the anterior region (+0.3 mm on average).<sup>20</sup> Another retrospective study concluded that the eruption rate was three times higher for the younger age group (< 30 years) compared to the older (> 30 years) patient group.<sup>21</sup> The maxilla moves during growth in three planes- in anteriorposterior, transversal and vertical directions.<sup>22</sup> The growth pattern in the vertical direction is influenced by the periodontal ligament which adapts to tissue remodeling and can continue until late adolescences.<sup>23</sup> An explanation could be that the vertical eruption of natural teeth is attributed to the continuous activity of the periodontal ligament whereas activity of the bone in the adult patients might be only related to bone modeling processes.<sup>24</sup> Patient individual factors might also interfere and influence the process of eruption of teeth adjacent to implants as for example periodontal or orthodontic pre-treatment phases.

However, differences in the incisal edge positions or infraocclusion is visible and represents a major esthetic impairment in the esthetic zone. Patients' perception has been reported in an investigation by Andersson et al. where patients seemed to pay less attention to the degree of infraposition in their esthetic assessment and were more satisfied with the esthetic result than compared to the clinicians.<sup>25</sup>

## CONCLUSION

Within the limitations of this RCT it can be concluded that:

- Continuous vertical tooth eruption next to a single dental implant crown was observed in the adult patient.

## TABLES

**TABLE 1: Distribution of implant positions**

Tooth position maxilla (FDI)	Number
1. Quadrant First Premolar (14)	0
1. Quadrant Canine (13)	1
1. Quadrant Lateral Incisor (12)	4
1. Quadrant Central Incisor (11)	13
2. Quadrant Central Incisor (21)	7
2. Quadrant Lateral Incisor (22)	2
2. Quadrant Canine (23)	1
2. Quadrant First Premolar (24)	2

**TABLE 2: overview of p-values for the time effect in the global anova test**

Outcome	Statistic	Degrees of Freedom	p value
DPC	15.67	2.12	< 0.001
Distance Implant-Tooth (mesial)	0.29	2.17	1.00
Distance Implant-Tooth (distal)	0.06	2.26	1.00
Crown Length (distal)	3.81	2.87	0.001
Implant Crown Length	3.51	2.64	0.11
Crown Length (mesial)	2.97	2.71	0.03
Gingival Level (distal)	0.90	2.57	0.43
Gingival Level (mesial)	1.92	2.92	0.13
Incisal Edge to Edge	14.17	2.56	< 0.001

**TABLE 3: DPC (distance from implant platform line to CEJ position)- Descriptive statistics (millimeters)**

Time Point	Median	Mean	Standard Deviation	Minimum	Maximum
BL	4.95	5.07	1.38	1.09	7.75
6M	5.12	5.21	1.41	1.20	7.77
12M	5.19	5.31	1.37	1.70	7.83
36M	5.21	5.38	1.37	1.65	7.82
BL to 36M change	0.29	0.31	0.29	-0.09	0.92

**TABLE 4: DPC (distance from implant platform line to CEJ position)- p values depending on time points**

Comparison	0 month	6 months	12 months
6 months	0.012	–	–
12 months	< 0.001	0.013	–
36 months	< 0.001	0.005	0.065

**TABLE 5: Natural Tooth crown length Distal (millimeters)**

Time Point	Median	Mean	Standard Deviation	Minimum	Maximum
BL	8.96	8.78	1.14	6.46	10.80
6M	8.94	8.83	1.26	6.25	11.03
12M	9.27	9.11	1.27	6.54	11.82
36M	8.72	8.71	1.19	6.61	11.21
BL to 36M change	0.02	-0.08	0.56	-1.42	1.07

**TABLE 6: Natural Tooth crown length Mesial (millimeters)**

Time Point	Median	Mean	Standard Deviation	Minimum	Maximum
BL	9.77	9.76	1.50	7.15	13.01
6M	9.45	9.71	1.39	7.00	12.60
12M	9.96	10.05	1.24	7.98	13.01
36M	9.65	9.68	1.43	6.93	13.00
BL to 36M change	0.01	-0.05	0.64	-1.66	1.18

**TABLE 7: Global ANOVA Test**

Factor	Statistic	Degrees of Freedom	P value
Distal/Mesial	16.04	1.00	<0.001
Time	4.75	2.84	0.003
Interaction Distal/Mesial : Time	0.48	2.54	0.663

**TABLE 8: p values in comparison of time effects  
(for pooled distal and mesial measurements, n=60)**

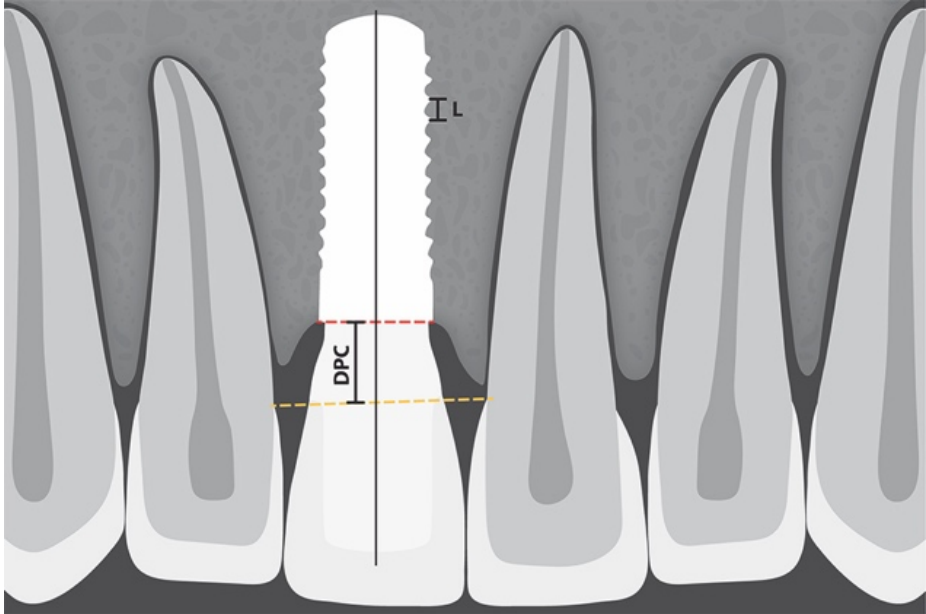
P values for comparisons	6M	12M	36M
BL	0.180	<0.001	0.775
6M	–	0.044	0.268
12M	–	–	<0.001

**TABLE 9: Descriptive statistics incisal edge to edge (millimeters)**

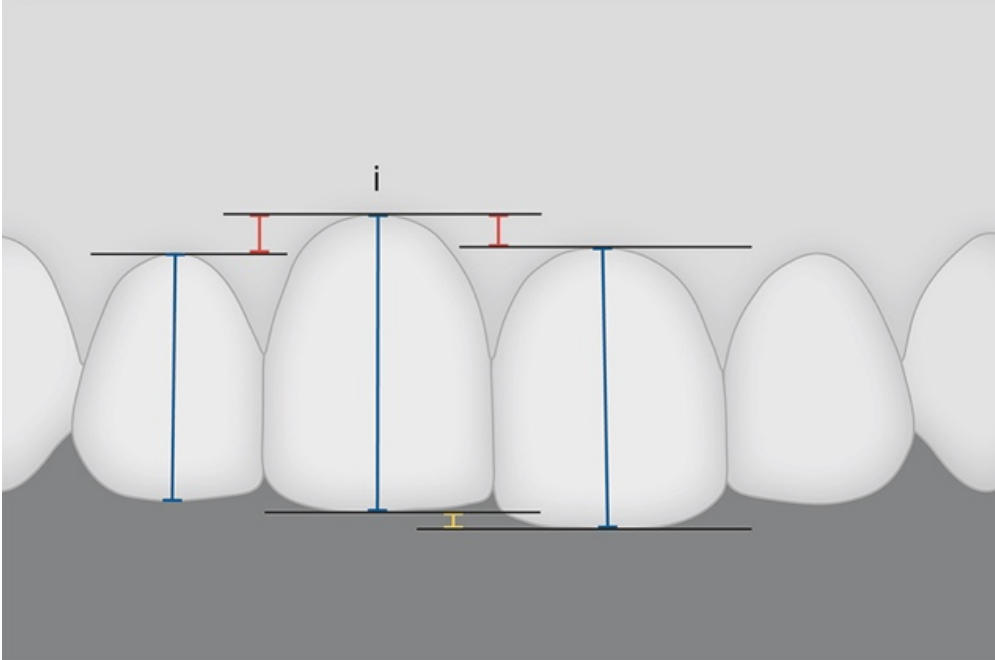
Time Point	Median	Mean	Standard Deviation	Minimum	Maximum
BL	0.15	0.16	0.46	-0.63	2.23
6M	0.20	0.14	0.17	-0.40	0.38
12M	0.22	0.28	0.39	-0.43	2.14
36M	0.27	0.34	0.43	-0.41	2.39
BL to 36M change	0.16	0.18	0.16	-0.02	0.54

**LEGEND OF FIGURE**

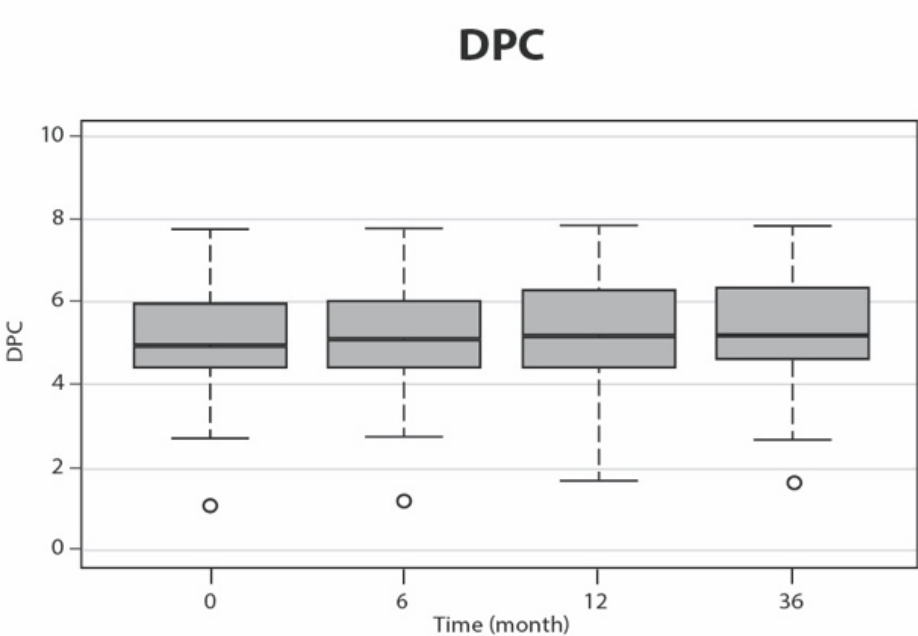
**Figure 1:** The known distance between two implant threads (=L; one thread pitch is 0.8mm) were calibrated. Implant platform line (red line) and the cement-enamel junction line (CEJ line: yellow line) were crossed the implant axis (black line) in a right angle. Distance from platform line to CEJ (DPC) was measured.



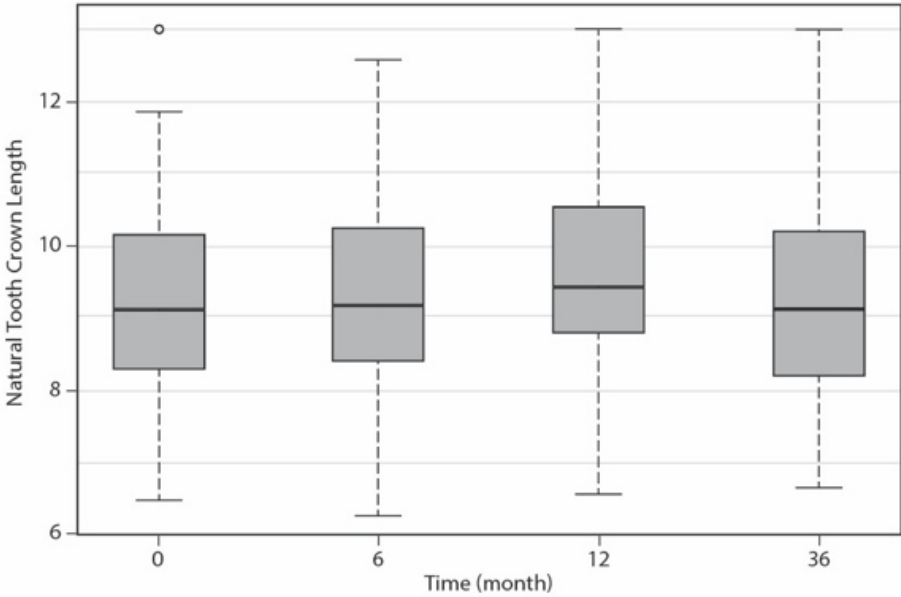
**Figure 2:** Cast analysis: crown length is measured from gingival zenith position to the incisal edge. Gingiva/Mucosal level distance was measured from adjacent natural tooth zenith to the implant mucosa zenith. Incisal edge gap was measured between lowest incisal edge position of the implant crown (i) and adjacent teeth.



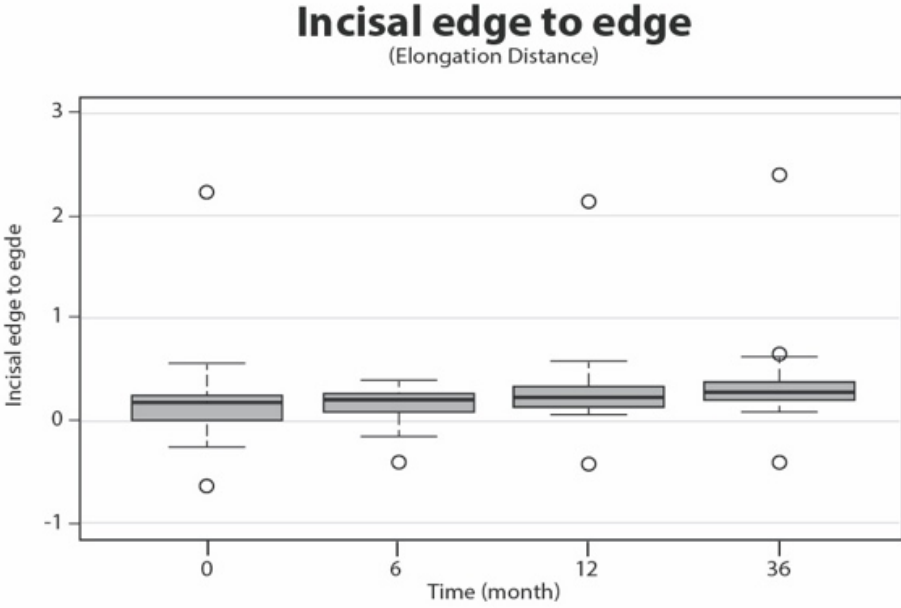
**Figure 3:** DPC Data in relation to follow up time



**Figure 4:** Natural tooth crown length in relation to follow up time



**Figure 5:** Incisal edge to edge data in relation to follow up time



**Figure 6A and 6B:** Clinical example: Implant supported single crown position 21I and adjacent natural tooth 11 with vertical elongation after baseline (6A) and 3 years (6B).





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# Chapter 7

## Patient-reported Outcome Measures focusing on Esthetics of Implant- and Tooth-supported Fixed Dental Prostheses – A Systematic Review and Meta-Analysis.

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## ABSTRACT

**Objectives:** The aim of this systematic review and meta-analysis was to summarize the existing evidence on patient-reported esthetic outcome measures (PROMs) of implant-supported, relative to tooth-supported fixed dental prostheses.

**Material and Methods:** In April 2017, two reviewers independently searched the Medline (PubMed), EMBASE, and Cochrane electronic databases, focusing on studies including patient-reported esthetic outcomes of implant- and tooth-supported fixed dental prostheses (FDPs). Human studies with a mean follow-up period of at least one year, a minimum of ten patients, and English, German, or French publication were included. For the comparison of subgroups random-effects meta-regression for aggregate-level data was used.

**Results:** The systematic search for implant-supported prostheses focusing on patient-reported outcomes identified 2675 titles which were screened by two independent authors. 50 full-text-articles were analyzed, and finally, 16 publications (including 19 relevant study cohorts) were included. For tooth supported prostheses, no studies could be included. A total of 816 implant-supported reconstructions were analyzed by patients. Overall esthetic evaluation by the patients' visual analogue scale (VAS) rating was high in implant-supported FDPs (median 90.3; min-max: 80.0-94.0) and the surrounding mucosa (median: 84.7; min-max: 73.0-92.0). Individual restorative materials, implant neck design (i.e. tissue or bone level type implants), and the use of a fixed provisional had no effect on patients' ratings of the definitive implant supported FDPs.

**Conclusions:** Esthetics is an important patient-reported measure, which lacks in standardized methods; however, patients' satisfaction was high for implant- supported FDPs and the surrounding mucosa.

## INTRODUCTION

In the field of fixed prosthodontics, various assessment methods have been used to evaluate the esthetic outcome. A distinction is made between objective and subjective criteria. Objective criteria are said to be neutral and free of any value by the evaluating person, resulting in reproducible measurements regardless of the person performing the evaluation, whereas subjective criteria always include an influence by the judging person (De Bruyn, Raes, Matthys, Cosyn, 2015).

Objective indices are particularly suitable for the comparison of treatment outcomes in clinical studies (Meijer, Stellingsma, Meijndert, Raghoobar, 2005) or their application for clinical dental education (Lang, Zitzmann, Working Group 3 of the VIII European Workshop on Periodontology, 2012a). Various indices have been introduced for esthetic assessments (Belser et al., 2009; Fürhauser et al., 2005; Jemt, 1997; Meijer et al., 2005). However, even with those objective criteria, 100% exact reproducibility is rare. This even applies to the pink esthetic score/white esthetic score (PES/WES) (Belser et al., 2009), an objective index demonstrating the highest repeatability among all objective esthetic indices (Tettamanti et al., 2016). However, the results vary with different examiners (den Hartog, Raghoobar, Stellingsma, Vissink, Meijer, 2011). Even the same person reevaluating a situation at a second time point might report a non-identical result (Schropp, Isidor, 2007).

As the influence of individual grading may vary among examiners, comparing the results of subjective evaluations is a very difficult task. The amount of grading depends on several factors, for example on the level of clinical training of each examiner (Gehrke, Degidi, Lulay-Saad, Dhom, 2009; Meijer et al., 2005). Comparing the judgment of the esthetic treatment outcome of lay persons and dental professionals, the ratings of lay persons are higher (Belser et al., 2009; Chang, Odman, Wennström, Andersson, 1999; Meijndert, Meijer, Stellingsma, Stegenga, Raghoobar, 2007). But there are many more factors influencing the individual perception of esthetics, such as social environment, education, or cultural background.

Patient-reported outcome measures (PROMs) are among the most frequently used subjective assessments in clinical investigations. Compared to earlier studies, the use of PROMs in general medicine has emerged, leading to a paradigm shift to “patient-

centered care” (Marshall, Haywood, Fitzpatrick, 2006). This trend can also be observed in dental medicine (Buck, Newton, 2001; Derks, Håkansson, Wennström, Klinge, Berglundh, 2015; McGrath, Lam, Lang, 2012b). Taking into account that patient satisfaction is one of the major goals in every medical discipline, this evolution seems logical (De Bruyn et al., 2015).

One such PROM, which has moved to the forefront of dental medicine, is patients’ estimation of the esthetic outcome after prosthodontic treatment. Pleasing esthetics in reconstructive dentistry is defined by the harmonic appearance of natural and adjacent restored teeth and soft tissue (Belser, Buser, Higginbottom, 2004; Belser, Schmid, Higginbottom, Buser, 2004). The scientific literature reflects this phenomenon, as the majority of studies treating esthetic aspects of implant dentistry have been published in the last decade (Cosyn, Thoma, Hämmerle, De Bruyn, 2017).

In partially edentulous patients demanding a fixed rehabilitation, the choice between tooth- or implant-supported fixed dental prostheses (FDPs) needs to be made. To obtain an overview with respect to the most esthetic treatment preference according to patients, the aim of the performed literature screening was to extract PROM data from clinical studies by means of a systematic review protocol.

Today, various assessment methods exist in the form of scales or questionnaires used to acquire these data (Buck, Newton, 2001; McGrath et al., 2012b). However, a standardized approach for the evaluation of PROMs is still lacking. Therefore, the results of studies using different assessment methods are hardly comparable. One of the most widely used assessment methods for PROMs in dentistry are visual analogue scales (VAS), but their application has also been criticized (Schabel, McNamara, Franchi, & Baccetti, 2009; Torrance, Feeny, Furlong, 2001). But at least a high number of studies using VAS for PROM evaluation can be expected. Therefore, the aim of this systematic review and meta-analysis was to analyze the esthetic results of implant-supported relative to tooth-supported FDPs according to patient-reported outcomes assessed by VAS. The results should improve understanding of patient demands in esthetic treatment and patient satisfaction with treatment outcomes. Furthermore, the influence of restoration material, implant type, and provisional phase on PROMs, focusing on implant- and tooth-supported FDPs were analyzed.

# MATERIAL AND METHODS

## Definition of terms

### Patient reported outcome measures (PROMs)

In dental medicine the term “patient reported outcome measures” (PROMs) was introduced in the 8th European Workshop on Periodontology. These essentially include ‘subjective’ reports of patients’ perceptions of their oral health status and its impact on their daily life or quality of life, reports of satisfaction with oral health status, and/or oral health care and other nonclinical assessments (Cosyn et al., 2017; Lang, Zitzmann, Working Group 3 of the VIII European Workshop on Periodontology, 2012b; McGrath, Lam, Lang, 2012a).

### Visual analogue scale (VAS)

A visual analogue scale (VAS) is an instrument used to quantify a subjective experience (e.g. treatment outcome). Commonly used VAS are lines of 10 cm, labeled with worst experience (worst treatment outcome) at one end, and best experience (best treatment outcome) on the other end, without any further markings. Patients are instructed to mark the line according their actual feeling. The clinician measures the distance of the mark from the beginning of the line and calculates a percent value according to the position of the marking.

## Study Protocol

The study protocol for this systematic review was registered in the PROSPERO database. It was set in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement (Moher, Liberati, Tetzlaff, Altman, PRISMA Group, 2009). The focused leading question was set according to the P.I.C.O. model for clinical questions. The four criteria according to the P.I.C.O. model were as follows:

*Population:* Partially edentulous patients

*Intervention:* Implant-supported FDPs

*Comparison:* Tooth-supported FDPs

*Outcome:* Patient-reported outcomes (PROMs), measured with VAS

The resulting P.I.C.O. question was: ‘In partially edentulous patients, what are the esthetic results of implant-supported compared to tooth-supported fixed dental prostheses using patient-reported outcomes’.

## Eligibility Criteria

For the systematic literature searches, an overview of the inclusion and exclusion criteria was provided in Tables 1a and 1b.

Inclusion and exclusion criteria were as follows:

### Inclusion

- Human clinical studies (randomized controlled trials, controlled trials, prospective studies, retrospective studies, case series)
- Partially edentulous patients
- Tooth- or implant-supported FDPs
- Documentation of PROMs by VAS
- Number of patients per study arm or cohort  $\geq 10$
- Mean follow-up period  $\geq 1$  years
- Publication in English, German, or French

### Exclusion

- *In vitro* or animal studies
- Removable partial dentures
- Edentulous patients
- Fully dentate patients
- Insufficient documentation PROMs
- Fewer than 10 patients in relevant study arm/cohort
- Mean follow-up period less than 1 year
- Combined tooth-implant-supported restorations
- Studies not written in English, German, or French

## Search strategy and study selection

For the initial electronic search in the MEDLINE (via PubMed), EMBASE, and COCHRANE libraries, a systematic search term for an initial search was developed (Table 1a). All libraries were scanned for related literature without using any filters. Furthermore, reference lists of related articles with similar topics were systematically screened, and potentially relevant articles were added to the results of the electronic search. After eliminating duplicates, the titles of the remaining articles were checked for adequacy, according to the inclusion criteria. Irrelevant titles (e.g. *in vitro* studies) were excluded. If the relevance of a study was indecisive according to the title, it was



included for abstract screening. If the abstract was also inconclusive, the study was included for full-text screening, resulting in a selection of eligible full texts. After reviewing the full texts, irrelevant articles were excluded, and data from the remaining articles were extracted whenever possible. Study selection and data extraction were performed independently for each step by two reviewers (JW, SA). Disagreement regarding the inclusion of specific articles was solved by discussion. If multiple relevant study arms or cohorts were identified in the same study, data from each group were recorded separately (e.g. different restoration materials). This resulted in a higher number of study populations than indicated by the number of included studies.

After data extraction, no study for the comparison group (tooth-supported FDPs) could be identified. Therefore, a second systematic search of the literature was done, exclusively looking for articles on tooth-supported FDPs. It was performed as outlined above. The applied systematic search strategies can be seen in Tables 1a and 1b.

For data extraction, the study form included the following parameters: authors, year of publication, study design, type of support (tooth/implant), type of retention (screw/cement), mean follow-up, type of FDP, planned number of patients, actual number of patients, mean age, age range, setting, total failure of FDPs, PROMs mucosa, PROMs restoration, restoration material, implant type, implant brand, abutment material, abutment type, and provisional restoration.

## **Risk of bias analysis**

Quality assessment was performed by both authors according to the Cochrane risk of bias tool (Higgins, Green, 2009) for included randomized controlled trials (RCTs) and the Newcastle-Ottawa-Scale (NOS) (Wells et al., 2013) for included observational studies.

The Cochrane risk of bias tool is a domain-based evaluation, in which critical assessments are performed independently for each domain. These domains are “selection bias”, “performance bias”, “detection bias”, “attrition bias”, “reporting bias”, and “other biases”. The assigned judgment for each domain can be “high risk”, “low risk”, or “unclear risk” of bias.

The NOS is a quality assessment tool for nonrandomized trials, for their inclusion in a systematic review and meta-analysis. The quality of included studies was assessed according to three major domains: selection of the study groups, comparability of the study groups and ascertainment of either exposure or outcome of interest. Each domain can be awarded with a certain number of stars, resulting in a maximum number of nine stars. The final judgment of the included studies according to the NOS can be “Good”, “Fair”, or “Poor” quality.

## **Statistical analysis**

Means, standard errors and the 95%-confidence intervals of PROMs of study combinations were estimated by random-effects meta-regression for aggregate-level data. The same method was used to compare the mean outcome of groups of studies. The statistical analysis was performed using Stata 14.2 and significance level set at 0.05.

## **Synthesis of results**

Study data was extracted whenever the study met the inclusion criteria, and PROMs regarding esthetic results assessed by VAS were reported. It was carefully controlled that data was only extracted, if 0 represented the worst treatment outcome (poor esthetics) and 100 the best treatment outcome (perfect esthetics) according to the VAS. PROMs were subdivided into two domains whenever possible: mucosa and FDP. Data was extracted separately for those two domains. When studies described more than one result for any of the two domains, only the most general one was extracted. For example, when a study reported both PROMs according to the general esthetics of the restoration, and according to the color of the restoration, only data according to general esthetics were extracted. Whenever PROMs were not reported according to VAS or a comparable rating system, studies were not included for data extraction.

The primary outcome of the meta-analysis was to compare the esthetic results of implant- vs. tooth-supported fixed dental prostheses (FDPs) according to patients. Secondary outcomes were the influence of restoration material, implant type, and provisional phase on PROMs. As described above, additional data was acquired during the data extraction process; however, these data could not be analyzed due to reporting heterogeneity, incomplete data (pooled results), or missing data.

## RESULTS

Two systematic literature searches were performed. Part one represented studies reporting on patient-related outcomes regarding implant-supported FDPs. Through this search, 2675 titles were retrieved (initial search) which were screened independently by two authors (SA, JW) to assess their suitability for inclusion (Figure 1). A consensus was obtained following discussion for the abstract search (329 abstracts). A total of 50 full-text articles were evaluated according to the inclusion and exclusion criteria. A total of 37 were found to qualify for inclusion in the data extraction, and finally, 16 studies including 19 relevant study cohorts were eligible for inclusion in the review (Figure 1). The same systematic review process was performed for part two – patient-reported outcomes on tooth-supported FDPs (Figure 2). Here 5915 titles were obtained from the initial search, the abstract search included 188 studies, and from these, 17 full-text articles were selected. Eight studies qualified for inclusion for data extraction. At the end no study reporting on tooth supported FDPs could be included. Therefore, it was not possible to perform a meta-analysis for the primary outcome, i.e. the esthetic outcome of tooth- vs. implant-supported FDPs according to PROMs. Nevertheless, sufficient data was available for implant-supported FDPs to perform meta-analyses for the secondary outcomes.

### Description of included studies

An overview of the excluded and included studies is given in Tables 2a and 2b. Means and standard deviations of the outcome of the individual studies formed the basis for the statistical analysis. Results of the quality assessment are presented in Tables 3a and 3b.

The study designs of the included studies were: two randomized clinical trials, eight prospective cohort studies, four retrospective and two cross-sectional studies (Table 4). Most studies were carried out in a university setting. In two studies reporting on implant supported FDPs, multiple (a total of five) relevant study cohorts could be identified, the data of which were recorded separately. Various restorative materials (porcelain-fused-to-metal vs. all-ceramic),(Gallucci, Grütter, Nedir, Bischof, Belser, 2011) and various implant designs (machined neck vs. rough neck vs. scalloped neck)(den Hartog et al., 2013) were examined in these cohorts.

A total of 816 implant-supported FDPs were evaluated by the patients by means of VAS. Of these FDPs 745 (91.3%) were single crowns, 12 (1.5%) were bridges and 2

studies pooled results from bridges and single crowns (n= 59 (7.2%)). The FDPs were supported by bone level or soft tissue level type implants, 48.4% and 39.5% respectively. In 12.1%, the implant type was not reported (Table 4).

Only 20 FDPs were screw-retained (2.5%), 532 (65.2%) cement-retained, and in 6 studies, both retention types were used (23.7%). Porcelain-fused-to-metal (PFM) was used in 131 (16.1%), veneered zirconium dioxide in 232 (28.4%) and lithium disilicate in 24 FDPs (2.9%). In 212 restorations, the type of material was not reported (Table 4).

The implant abutments used in these included studies were predominantly made of titanium (n= 365 (44.7%)), titanium and zirconium dioxide (n= 133 (16.3%)), aluminium oxide (n= 10 (1.2%)), gold (n= 10 (1.2%)) and all-ceramic not further described (n= 67(8.2%)). For 185 FDPs, the abutment material was not reported (Table 4).

In the cohorts included in this review, 385 (47.2%) FDPs were made with standardized abutments, 160 with customized abutments, both types were used in 86 restorations, and the abutment type was not reported in 185 FDPs (Table 4).

A total of 324 (39.7%) FDPs had a fixed provisional prior to insertion of the final crown or bridge and 200 (24.5%) did not. Implants documented in these studies were placed in the anterior and posterior region. In three cohorts (292 FDPs), it was not reported whether a provisional phase was performed within the prosthetic workflow (Table 4). Details on the individual VAS scores and the descriptive data are given in Table 4.

## **Patient- reported VAS**

### **VAS mucosa score**

Data extracted from 19 cohorts focusing on implant-supported FDPs showed that only 7 reported on the esthetic outcome of the peri-implant soft tissue surrounding the reported FDP(s), as evaluated by the patients using VAS ratings. In 12 cohorts, this information was missing. The mean result of the “VAS mucosa score” was 84.7 (median 86.7; min-max 73.0 - 92.0) (unweighted data) (Table 5).

### **VAS FDP score**

A total of 16 studies (19 cohorts) reported on the patient evaluations focusing on the final esthetic outcome of the implant supported FDPs. The mean VAS was 88.9 (median 90.3; min-max 80.0 - 94.0) (Table 5). The mean VAS values extracted by descriptive data are listed in detail in Table 4. For inclusion of the retrieved data into the statistical analysis (random-effects meta-analysis), only studies that reported the

standard deviation of the VAS could be considered. Standard deviation of the VAS was reported only for few studies on implant supported FDPs. An overview of the study cohorts, that were included into the meta-analysis is presented in table 6. The VAS values of the individual study cohorts, their weight and their estimated treatment effect are given in Figures 3 and 4.

### **Influence of restorative material/ implant type/ provisional phase on the outcome of VAS FDP**

Only studies reporting the standard deviation could be considered for inclusion of the retrieved data into the statistical analysis (Table 7).

In implant supported FDPs, mean patient ratings varied between 93.3 (95% CI = 78.8 – 100) (veneered zirconium dioxide) and 85.2 (95% CI = 70.5 - 99.9) (PFM + gold). The differences according to the applied restorative materials were not statistically significant ( $p = 0.616$ ) (Table 7). Patients reported slightly higher VAS ratings in FDPs supported by tissue level type implants (mean = 92.5; 95% CI = 88.8 - 96.2) compared to bone level type implants (mean = 89.2; 95% CI = 86.1 - 92.4). However, the difference was not statistically significant ( $p = 0.128$ ) (Table 7). Presence of a provisional phase did not improve the esthetic outcome according to patients' VAS ratings (90.3 vs. 90.0;  $p = 0.909$ ) (Table 7).

## **DISCUSSION**

Within the limitations of this systematic review patients' satisfaction was high for implant- supported FDPs and the surrounding mucosa.

No influence on the PROMs results were identified among the used dental materials for FDPs, the presence of a provisional phase within the implant-prosthetic workflow or the type of dental implant used.

The primary goal of any prosthodontic procedure is to satisfy the patient receiving a dental treatment. Although the assessment of the patient is subjective and difficult to quantify, it has gained interest in recent years, a fact also observed in clinical studies. De Bruyn stated in his systematic review about the current use of patient centered/reported outcomes that half of the relevant literature (300 of 635) were studies published in the last six years. His study, therefore, concluded a growing interest in PROMs by the scientific community (De Bruyn et al., 2015).

Various terminology has been used in scientific studies, such as patient satisfaction,

patient-centered outcomes, patient-reported outcomes, and patient-reported outcome measures (Cosyn et al., 2017; Lang et al., 2012a; McGrath et al., 2012b).

Patients' expectations are increasing and with respect to rehabilitation with fixed implant- or tooth-supported FDPs, treatments result in proportionally higher costs compared to removable prostheses. In the era of modern implantology, many surgical and prosthetic workflows are possible today with the goal of achieving the best possible esthetic outcome. These advances substantially increase costs, resulting in even more critical patients from an esthetic point of view (Cosyn et al., 2017). However, it has been shown that patients are less critical than clinicians when judging esthetics (Cosyn et al., 2013; Cosyn, Eghbali, De Bruyn, Dierens, & De Rouck, 2012; Hartlev et al., 2014; Meijndert et al., 2007). In an early study by Chang et al in 1999, a total of 41 implant-supported crowns were evaluated by patients and prosthodontists (Chang et al., 1999). Patients were highly satisfied with their implant-supported crowns with mean VAS values of 100; however, the assessment by prosthodontists revealed a significantly lower degree of satisfaction. This finding was confirmed in a study from Tettamanti et al. 2016, in which patients assessed their reconstruction with respect to pink esthetics, white esthetics, and overall esthetics using visual analogue scales. The same procedure was performed using a new "peri-implant and crown index (PICI)". Orthodontists, prosthodontists, general dentists, and lay people evaluated pink and white characteristics using visual analogue scales (100mm length) in comparison to the contralateral tooth. The patients were asked the same questions; a comparison of the patient-related outcomes and PICI was obtained. The overall esthetic assessments of patients was 94.17%, followed by prosthodontists 68.57%, lay people (66.69%) and general dentists (65.22%), with orthodontists being the most critical (57.16%) (Tettamanti et al., 2016).

In this systematic review, the patient-reported outcome of 816 FDPs evaluated by patients in the implant-supported group revealed a mean VAS value of 90 (Table 4).

Dueled et al. 2009 performed a clinical study reporting on 129 patients with tooth agenesis rehabilitated with implant or tooth-supported FDPs. Improved esthetic outcomes were obtained for the implant-supported group and a positive but not significant correlation was observed between the professional and patient perception of the esthetic outcome (Dueled, Gotfredsen, Trab Damsgaard, & Hede, 2009). The patients were more satisfied with the overall outcome than the professional clinician (Dueled et al., 2009).

## **Influence of restoration material**

In a prospective study with a 3-year follow-up, implants were restored either with all-ceramic or metal-ceramic crowns (Hosseini, Worsaae, Schiodt, & Gotfredsen, 2013). Patient-reported outcomes and esthetic evaluations by clinicians were assessed and no correlation could be identified between the professional and patient-reported esthetic outcome. Patient's evaluations regarding the esthetic outcome showed no statistically difference of all-ceramic and metal-ceramic restorations (Hosseini et al. 2013). In the present review the same findings were obtained. VAS ratings of the patients showed no influence of the material choice of the reconstructions.

## **Influence of implant type**

Implants featuring the abutment connection at the crestal bone level to replace single edentulous spaces are preferably indicated in the esthetic zone. With a bone level implant design, the clinician has more prosthetic freedom to determine the location of the final mucosal zenith position and to individualize the emergence profile and, therefore, the peri-implant mucosa. Clinical studies have presented acceptable esthetic outcomes (Buser et al., 2013; Buser et al., 2011; Santing, Raghoobar, Vissink, den Hartog, & Meijer, 2013; Wittneben et al., 2017). Consequently, an enhancement of the overall esthetic outcome would be hypothesized. However, in this review, the patient-reported outcomes regarding VAS FDP scores were higher for patients with soft tissue level implants compared to those with bone level type implants however this was not statistically significant (Table 4).

## **Influence of provisional phase implementation**

The implementation of a distinct provisional phase is a commonly used treatment concept for implants placed in the esthetic zone (Cho, Shetty, Froum, Elian, & Tarnow, 2007; Furze, Byrne, Alam, & Wittneben, 2016; Parpaiola, Sbricoli, Guazzo, Bressan, & Lops, 2013; Priest, 2005; Wittneben, Buser, Belser, & Brägger, 2013). The aim of a provisional phase is to condition and shape the peri-implant soft tissue, including the individualization of the mucosa and emergence profile, the papillae, the cervical soft tissue margin and the finalization of the position of the gingival zenith. A randomized clinical trial by Furze et al. showed that this provisional phase with soft tissue conditioning does improve the final esthetic result (Furze et al., 2016). 20 patients received bone level implants in the esthetic zone and after reopening, using a

randomization process to assign each to either cohort group 1 (provisional phase present) or cohort group 2 (without provisional phase). Implants were finally restored with an all-ceramic crown. The mean values of combined modPES and WES were 16.7 for group 1 and 10.5 for Group 2, which concluded a statistically significant difference. In the present study there was no statistically significant difference with the use of provisional restorations on implant supported FDPs according to PROMs. From the limited available data implant supported provisional restorations were located in both-posterior and anterior sites and therefore a conclusion cannot be stated focusing on esthetic sites.

### **Limitations of the study**

In general, systematic reviews lack in homogeneity among materials used for FDPs across clinical studies, regardless of the type of support. Unfortunately, in the present review no studies could be identified to be included focusing on tooth supported FDP in partially edentulous patients.

The perception of a patient might be influenced by their expectations and experience but represents the value of a reconstruction evaluated by the patient him- or herself. Esthetics is an important PROM and, therefore, it is commonly included in clinical studies. However, the limitation of the information given by the patients is that non-standardized questions are frequently used with varying scoring methods. This lack of standardization method in the assessment of PROMs (McGrath et al., 2012b) was the reason why only studies using VAS ratings were included here. Another limitation in performing the assessment is the validity and reliability of the “ad-hoc” approach.(Cosyn et al., 2017) For the use of future investigations, standardized questions related to the final esthetic outcome should be used and patient responses collected without the clinician performing the treatment being present to minimize influencing factors.



## **CONCLUSION**

Within the limitations of this systematic review it can be concluded that:

- The esthetics of implant supported FDPs are highly rated by patients (VAS=90.0; 87.9 - 92.2).
- No studies were found that reported on PROMS focusing on tooth supported FDPs in partially edentulous patients.
- The appearance of the mucosa surrounding the implant supported FDPs was highly rated (VAS=84.7; min. 73.0 – max. 92.0) by PROMs.
- Implant neck design i.e. tissue or bone level has no influence on esthetic ratings by the patients: 92.5 vs. 89.2.
- PROMs ratings were higher with patients having soft tissue level implants compared to the ones with bone level type implants however without being statistically significant ( $p= 0.128$ ).
- Individual restorative materials had no influence on ratings of PROMS focusing on the esthetics of implant supported FDPs.
- The use of a provisional restoration had no effect on esthetic ratings of the definitive restorations on implant supported FDPs evaluated by PROMs.

## **ACKNOWLEDGEMENTS**

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## TABLES AND FIGURES

**TABLE 1a:** Systematic search strategy- implant supported reconstruction

<b>Focused question (PICO)</b>	In partially edentulous patients, what are the esthetic results of implant-supported compared to tooth-supported fixed dental prostheses using patient-reported outcomes	
<b>Search Strategy</b>	<b>Population</b>	#1 “partially edentulous” OR edentulous OR jaw OR “partially edentulous” OR “partial edentulism” OR edentulous [Mesh Term]
	<b>Intervention exposure</b> <b>or</b>	#2 implant OR crown OR reconstruct* OR FPD OR implant crown* OR Implant bridge* OR “implant supported prosthesis” OR “implant supported crown”
	<b>Comparison</b>	#3 “tooth supported prosthesis” OR tooth supported OR bridge* OR fixed partial denture* OR FPD* OR crown
	<b>Outcome</b>	#4 esthetic OR evaluation OR esthetic* OR VAS OR questionnaire* OR “patient related” OR “patient reported outcome” OR “patient opinion” OR “patient perception” OR “patient report”
	<b>Search combination</b>	#1 AND #2 AND #3 AND # 4
<b>Database search</b>	<b>Electronic</b>	PubMed, Cochrane Central Register of Controlled Trials (CENTRAL)
	<b>Journals</b>	Clinical Oral Implants Research, International Journal of Oral Maxillofacial Implants, Clinical Implant Dentistry and Related Research, Implant Dentistry, Journal of Implantology, Journal of Periodontology, Journal of Clinical Periodontology
<b>Selection criteria</b>	<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>• Human clinical studies (randomized controlled trials, controlled trials, prospective studies, retrospective studies, case series)</li> <li>• Partially edentulous patients</li> <li>• Tooth or implant-supported FDPs</li> <li>• Documentation of PROMs</li> <li>• Number of patients/ study arm or cohort ≥ 10</li> <li>• Mean follow-up period ≥ 1 years</li> <li>• Publication in English, German or French</li> </ul>
	<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• <i>In vitro</i> or animal studies</li> <li>• Removable partial dentures</li> <li>• Edentulous patients</li> <li>• Fully dentate patients</li> <li>• Insufficient documentation PROMs</li> <li>• Fewer than 10 patients in relevant study arm/cohort</li> <li>• Mean follow-up period less than 1 year</li> <li>• Publications not written in English</li> <li>• Combined tooth-implant-supported restorations</li> <li>• Studies not written in English, German or French</li> </ul>

**TABLE 1b:** Systematic search strategy, exclusively looking for tooth supported restorations

<b>Focused question (PICO)</b>	In partially edentulous patients, what are the esthetic results of implant-supported compared to tooth-supported fixed dental prostheses using patient reported outcomes'	
<b>Search Strategy</b>	<b>Population</b>	#1 "partially edentulous" OR edentulous OR jaw OR "partially edentulous" OR "partial edentulism" OR edentulous [Mesh Term]
	<b>Intervention exposure</b> or	#2 tooth supported prosthesis" OR bridge* OR fixed partial denture* OR FPD OR SC OR crown OR crown [Mesh Term] OR fixed partial denture [Mesh Term]
	<b>Comparison</b>	
	<b>Outcome</b>	#3 esthetic OR evaluation OR esthetic* OR VAS OR questionnaire* OR "patient related" OR "patient reported outcome" OR "patient opinion" OR "patient perception" OR "patient report"
	<b>Search combination</b>	#1 AND #2 AND #3
<b>Database search</b>	<b>Electronic</b>	PubMed
	<b>Journals</b>	Clinical Oral Implants Research, International Journal of Oral Maxillofacial Implants, Clinical Implant Dentistry and Related Research, Implant Dentistry, Journal of Implantology, Journal of Periodontology, Journal of Clinical Periodontology
<b>Selection criteria</b>	<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>• Human clinical studies (randomized controlled trials, controlled trials, prospective studies, retrospective studies, case series)</li> <li>• Partially edentulous patients</li> <li>• Tooth-supported FDPs</li> <li>• Documentation of PROMs</li> <li>• Number of patients/ study arm or cohort ≥ 10</li> <li>• Mean follow-up period ≥ 1 years</li> <li>• Publication in English, German or French</li> </ul>
	<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• <i>In vitro</i> or animal studies</li> <li>• Removable partial dentures</li> <li>• Edentulous patients</li> <li>• Fully dentate patients</li> <li>• Insufficient documentation PROMs</li> <li>• Fewer than 10 patients in relevant study arm/cohort</li> <li>• Mean follow-up period less than 1 year</li> <li>• Publications not written in English</li> <li>• Combined tooth-implant-supported restorations</li> <li>• Studies not written in English, German or French</li> </ul>

**TABLE 2a:** Excluded studies during data extraction.

<b>Author (year)</b>	<b>Reason for exclusion</b>
<b>Implant supported (n = 21)</b>	
Andersson, Bergenblock, Fürst, Jemt, 2013	Insufficient data
Andersson, Emami-Kristiansen, Högström, 2003	Follow up less than 1 year
Avivi-Arber, Zarb, 1997	Insufficient data
Baracat, Teixeira, Dos Santos, Da Cunha, Marchini, 2011	Insufficient data, no report on the amount or type of fixed reconstruction
Batisse, Bessadet, Decerle, Veyrune, Nicolas, 2014	Insufficient data
Bianchi, Sanfilippo, 2004	Insufficient data
Carollo, 2003	Insufficient data
Chang et al., 1999	Repeated study
Gibbard, Zarb, 2002	Insufficient data
Kourkouta, Dedi, Paquette, Mol, 2009	Insufficient data
Meijndert et al., 2007	Insufficient data
Moghadam et al., 2012	No report on the amount or type of fixed reconstruction
Santing et al., 2013	Not especially asked for aesthetic outcome
Schropp, Isidor, Kostopoulos, Wenzel, 2004	Insufficient data
Schropp, Isidor, 2007	Insufficient data
Sherif, Susarla, Hwang, Weber, Wright, 2011	Insufficient data
Tymstra et al., 2011	Insufficient data
Tymstra, Meijer, Stellingsma, Raghoobar, Vissink, 2010	Insufficient data
Vanlioğlu, Kahramanoğlu, Yıldız, Ozkan, Kulak-Özkan, 2014	PROMs not reported (email written to author- no response)
Vermynen, Collaert, Lindén, Björn, De Bruyn, 1999	Insufficient data
Vilhjálmsón, Klock, Størksen, Bårdsen, 2011	Insufficient data
<b>Tooth supported (n = 8)</b>	
Nicolaisen, Bahrami, Schropp, Isidor, 2016	Insufficient data
Ohlmann et al., 2014	Insufficient data
Rimmer, Mellor, 1996	Insufficient data
Vanoorbeek, Vandamme, Lijnen, Naert, 2010	Insufficient data
Shi, Li, Ni, Zhu, 2016	Insufficient data
Alshiddi, BinSaleh, Alhawas, 2015	Insufficient data
Bömicke et al., 2017	Fully dentate patients
Nejatidanesh et al., 2016	Fully dentate patients

**TABLE 2b:** Included studies/ cohorts (n=19 cohorts, n=16 studies)

Author (year)	Total N of FDPs	Total N of patients.	mean follow-up (years)	Outcome Mucosa	Outcome FDP	SD FDP
<b>Implant supported (n=19):</b>						
Bonde, Stokholm, Schou, Isidor, 2013	46	42	10.0	82.0	91.0	15.0
Boronat-Lopez, Carrillo, Peñarrocha, Peñarrocha-Diago, 2009	12	12	1.0	NA	83.0	
Chang et al., 1999	21	20	3.0	NA	94.0	7.0
Chang, Wennström, 2013	32	32	7.5	NA	91.8	14.8
Cosyn et al., 2012	46	44	2.5	92.0	94.0	6.0
Covani, Canullo, Toti, Alfonsi, Barone, 2014	47	47	5.0	73.0	80.5	11.3
De Rouck, Collys, Cosyn, 2008	30	30	1.0	NA	93.0	
den Hartog et al., 2013 (1)	31	31	1.5	86.7	88.0	11.0
den Hartog et al., 2013 (2)	31	31	1.5	87.1	89.0	10.0
den Hartog et al., 2013 (3)	31	31	1.5	83.9	91.0	8.0
Eckfeldt, Fürst, Carlsson, 2011	40	25	3.0	NA	90.0	
Gallucci et al., 2011 (1)	10	10	2.0	NA	91.8	5.9
Gallucci et al., 2011 (2)	10	10	2.0	NA	91.8	10.0
Hartlev et al., 2014	54	54	2.8	88.0	83.0	
Hof et al., 2014	60	60	4.1	NA	80.0	
Kolinski et al., 2014	59	37	3.0	NA	89.2	9.4
Spies, Patzelt, Vach, & Kohal, 2016	24	24	2.6	NA	90.3	13.0
Tey, Phillips, Tan, 2016	NA	206	5.2	NA	85.2	14.5
Nejatidanesh, Moradpoor, & Savabi, 2016	232	121	5.9	NA	93.3	5.2
<b>total (n=19)</b>	<b>816</b>	<b>867</b>	<b>4.3</b>	<b>:</b>	<b>:</b>	<b>:</b>

\*number of ratings

**TABLE 3a:** Quality assessment of included studies according to NOS

Author (year)	Selection	Comparability	Outcome	Quality
Bonde et al., 2013	4	2	2	good
Boronat-Lopez et al., 2009	3	1	1	fair
Chang et al., 1999	4	2	3	good
Chang & Wennström, 2013	4	1	3	good
Cosyn et al., 2012	4	2	2	good
Covani et al., 2014	4	2	3	good
De Rouck et al., 2008	4	1	2	good
Eckfeldt et al., 2011	4	1	3	good
Hartlev et al., 2014	4	2	1	fair
Hof et al., 2014	4	1	3	good
Kolinski et al., 2014	4	1	1	fair
Spies et al., 2016	4	1	1	fair
Tey et al., 2016	4	1	2	good
Nejatidaneh et al., 2016	4	1	3	good

**TABLE 3b:** Quality assessment for included randomized clinical trials, according to Cochrane risk of bias tool

Author (year)	Random Sequence	Allocation Concealment	Blinding	Blinding (Outcome)	Outcome Data	Selective Reporting	Other Biases
den Hartog et al., 2013	+	+	0	+	+	+	+
Gallucci et al., 2011	+	+	+	+	+	+	+

**TABLE 4:** Characteristics of study cohorts related to implant supported FDPs and patient-reported outcomes (PROMS) (n=19 cohorts, n=16 studies)

		no. of studies (%)	Total Nof reconstruction (%)	Total N of patients (%)	Outcome mean	Outcome min-max	PROMS mean unweighted	PROMS mean weighted
all study cohorts		19 (100)	816 (100)	867 (100)	88.9	80.0-94.0	88.9	88.0
Studydesign	RCT	5 (26.3)	113 (13.8)	113 (13.0)	90.3	88.0-91.8	90.3	89.8
	Prospective	8 (42.1)	293 (35.9)	266 (30.7)	88.0	80.5-94.0	88.0	87.3
	Retrospective	4 (21.1)	332 (40.7)	412 (47.5)	87.1	80.0-93.3	87.1	87.1
	Cross sectional	2 (10.5)	78 (9.6)	76 (8.8)	92.9	91.8-94.0	92.9	93.1
Setting	Private practice	3 (15.8)	286 (35.0)	381 (43.9)	87.2	83.0-93.3	87.2	87.5
	University	13 (68.4)	410 (50.2)	404 (46.6)	88.9	80.0-94.0	88.9	88.1
	Multicenter	1 (5.3)	59 (7.2)	37 (4.3)	89.2	-	89.2	89.2
	Specialist clinic	2 (10.5)	61 (7.5)	45 (5.2)	92.0	90.0-94.0	92.0	91.8
Type of Implant	Bone Level Implant	11 (57.9)	395 (48.4)	390 (45.0)	87.7	80.0-94.0	87.7	86.7
	Soft Tissue Level Implant	5 (26.3)	322 (39.5)	209 (24.1)	92.2	90.3-94.0	92.2	93.0
	NA	3 (15.8)	99 (12.1)	268 (30.9)	88.1	85.2-90.0	88.1	86.2
Brand	Straumann	3 (15.8)	252 (30.9)	141 (16.3)	92.3	91.8-93.3	92.3	93.1
	Nobel	9 (47.4)	350 (42.9)	343 (39.6)	89.2	80.0-94.0	89.2	88.1
	Astra	1 (5.3)	32 (3.9)	32 (3.7)	91.8	-	91.8	91.8
	Defcon	1 (5.3)	12 (1.5)	12 (1.4)	83.0	-	83.0	83.0
	Avantblast							
	TSA							
	Sweden	1 (5.3)	47 (5.8)	47 (5.4)	80.5	-	80.5	80.5
	Martina							
	Ziraldent	1 (5.3)	24 (2.9)	24 (2.8)	90.3	-	90.3	90.3
	Straumann, Nobel, Biomet 3i	1 (5.3)	0 (0.0)	206 (23.8)	85.2	-	85.2	85.2
Screw/cement retention	NA	2 (10.5)	99 (12.1)	62 (7.2)	89.6	89.2-90.0	89.6	89.5
	Screw	2 (10.5)	20 (2.5)	20 (2.3)	91.8	91.8-91.8	91.8	91.8
	Cement	9 (47.4)	532 (65.2)	414 (47.8)	90.1	80.5-94.0	90.1	90.1
	Both	6 (31.6)	193 (23.7)	384 (44.3)	87.2	80.0-91.0	87.2	85.7
Type of reconstruction	NA	2 (10.5)	71 (8.7)	49 (5.7)	86.1	83.0-89.2	86.1	87.7
	of SC	16 (84.2)	745 (91.3)	612 (70.6)	89.5	80.0-94.0	89.5	89.0
	FPD	1 (5.3)	12 (1.5)	12 (1.4)	83.0	-	83.0	83.0
	Both	2 (10.5)	59 (7.2)	243 (28.0)	87.2	85.2-89.2	87.2	85.8
Restoration material	PFM	5 (26.3)	131 (16.1)	131 (15.1)	88.0	80.5-93.0	88.0	87.2
	PFM+all ceramic	2 (10.5)	100 (12.3)	98 (11.3)	88.5	83.0-94.0	88.5	87.9
	PFM+Gold	1 (5.3)	-	206 (23.8)	85.2	-	85.2	85.2
	All ceramic+acrylic	4 (21.1)	117 (14.3)	97 (11.2)	91.7	90.0-94.0	91.7	91.4
	Veneered Zirconia and monolithic Zirconia	1 (5.3)	232 (28.4)	121 (14.0)	93.3	-	93.3	93.3
	Lithium disilicate (emax)	1 (5.3)	24 (2.9)	24 (2.8)	90.3	-	90.3	90.3
	NA	5 (26.3)	212 (26.0)	190 (21.9)	87.4	80.0-91.0	87.4	86.4

Abutment	Standardized/ prefabricated		6 (31.6)	385 (47.2)	269 (31.0)	92.2	90.3-94.0	92.2	92.5
	Individualized		6 (31.6)	160 (19.6)	160 (18.5)	88.7	80.5-91.8	88.7	87.0
	Both		2 (10.5)	86 (10.5)	69 (8.0)	92.0	90.0-94.0	92.0	92.6
	NA		5 (26.3)	185 (22.7)	369 (42.6)	84.1	80.0-89.2	84.1	84.4
Abutment material	Titanium		5 (26.3)	365 (44.7)	254 (29.3)	89.8	80.5-93.3	89.8	90.4
	Titanium Zirconium dioxide	+	4 (21.1)	133 (16.3)	118 (13.6)	89.5	88.0-91.0	89.5	89.5
	Titanium ceramic	+	1 (5.3)	46 (5.6)	44 (5.1)	94.0	-	94.0	94.0
	Gold		1 (5.3)	10 (1.2)	10 (1.2)	91.8	-	91.8	91.8
	Aluminium oxide ceramic - no further spec		1 (5.3)	10 (1.2)	10 (1.2)	91.8	-	91.8	91.8
	NA		2 (10.5)	67 (8.2)	62 (7.2)	92.5	91.0-94.0	92.5	92.0
	NA		5 (26.3)	185 (22.7)	369 (42.6)	84.1	80.0-89.2	84.1	84.4
Provisional Phase loaded on implants	Yes		11 (57.9)	324 (39.7)	302 (34.8)	89.3	83.0-93.0	89.3	88.8
	No		5 (26.3)	200 (24.5)	178 (20.5)	89.9	80.5-94.0	89.9	89.2
	NA		3 (15.8)	292 (35.8)	387 (44.6)	86.2	80.0-93.3	86.2	86.9



**TABLE 5:** No. of reconstructions, patients, mean follow-up, patient-reported outcome, studies on implant supported FDPs (n=19 cohorts, n=16 studies)

	<b>data reported in n cohorts</b>	<b>data missing</b>	<b>mean</b>	<b>sd</b>	<b>median</b>	<b>min-max</b>
N of reconstructions	19	0	45.3	49.1	31.5	10-232
Actual N of pts	19	0	45.6	46.0	31.0	10-206
Mean follow up (years)	19	0	3.4	2.4	2.8	1.0-10.0
VAS mucosa	7	12	84.7	6.0	86.7	73.0-92.0
VAS crown/bridge	19	0	88.9	4.5	90.3	80.0-94.0

**TABLE 6:** Patient-reported outcomes for cohorts of implant FDPs including standard deviation (sd) – n = 14

	<b>Total N of pats. (%)</b>	<b>mean VAS crown/bridge</b>	<b>sd</b>	<b>95%-CI</b>
Bonde et al., 2013	42 (6.1)	91	15	86.3 - 95.7
Chang et al., 1999	20 (2.9)	94	7	90.7 - 97.3
Chang & Wennström, 2013	32 (4.7)	91.8	14.8	86.5 - 97.1
Cosyn et al., 2012	44 (6.4)	94	6	92.2 - 95.8
Covani et al., 2014	47 (6.9)	80.5	11.3	77.2 - 83.8
den Hartog et al., 2013 (1)	31 (4.5)	88	11	84 - 92
den Hartog et al., 2013 (2)	31 (4.5)	89	10	85.3 - 92.7
den Hartog et al., 2013 (3)	31 (4.5)	91	8	88.1 - 93.9
Gallucci et al., 2011 (1)	10 (1.5)	91.81	5.94	87.6 - 96.1
Gallucci et al., 2011 (2)	10 (1.5)	91.8	10.04	84.6 - 99
Kolinski et al., 2014	37 (5.4)	89.2	9.4	86.1 - 92.3
Spies et al., 2016	24 (3.5)	90.3	13	84.8 - 95.8
Tey et al., 2016	206 (30.0)	85.2	14.5	83.2 - 87.2
Nejatidanesh et al., 2016	121 (17.6)	93.3	5.2	92.4 - 94.2
<b>total*</b>	<b>686 (100)</b>	<b>90.0</b>	<b>1.00**</b>	<b>87.9 - 92.2</b>

\* estimation by random-effects meta-regression

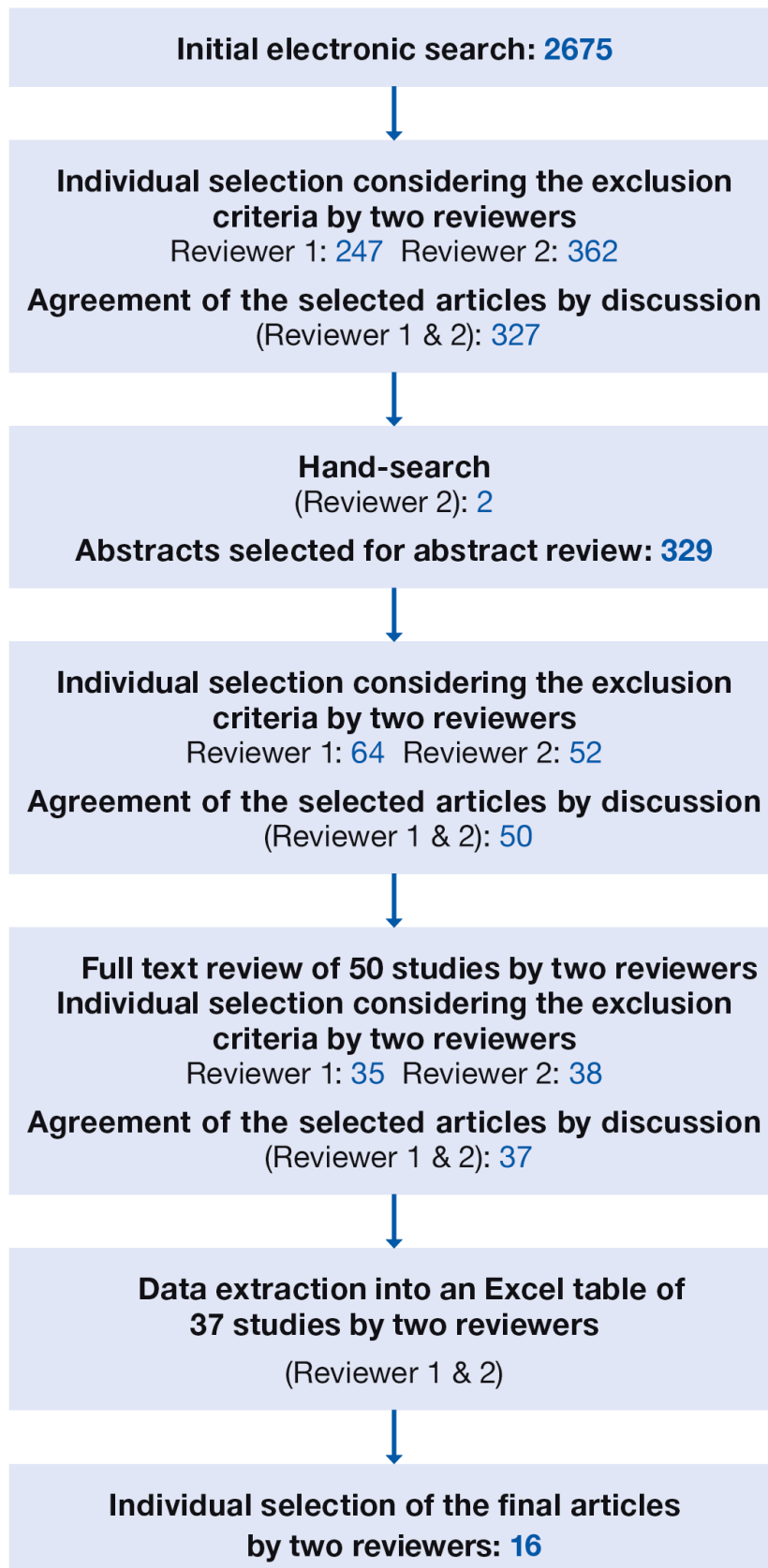
\*\* estimated standard error

**TABLE 7: Patient-reported outcomes - implant supported study cohorts - comparison of groups (estimation by random-effects meta-regression)**

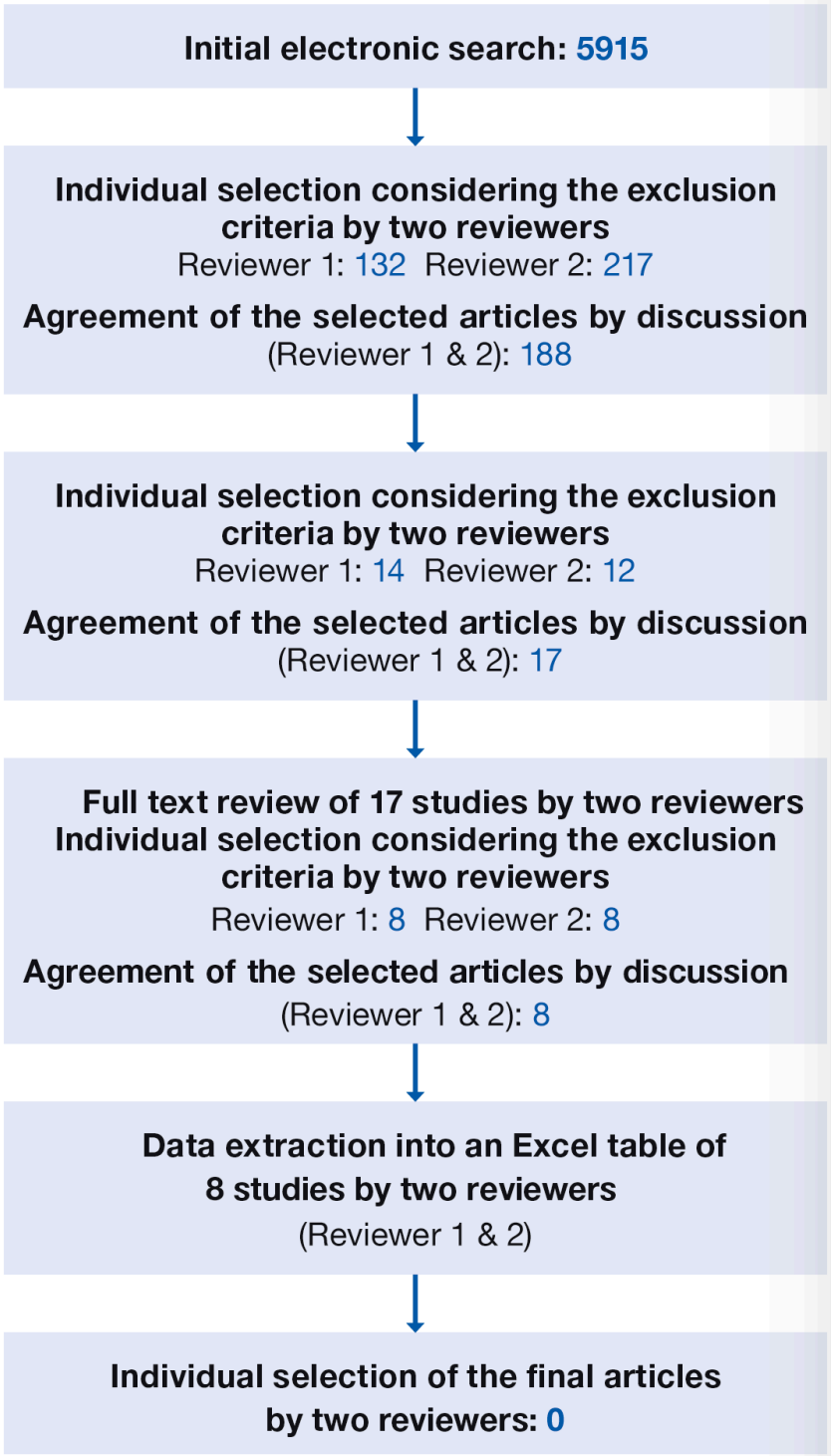
		studies	patients	mean VAS	standard error	95%-CI	p-value
restoration material	PFM	3	89	87.8	2.87	78.7 - 96.9	0.616
	All ceramic	3	72	92.4	2.95	83.0 - 100	
	Veneered Zirconiumdioxide	1	121	93.3	4.54	78.8 - 100	
	Lithiumdisilicate (emax)	1	24	90.3	5.24	73.6 - 100	
	PFM + ceramic	1	44	94.0	4.61	79.3 - 100	
	PFM + gold	1	206	85.2	4.63	70.5 - 99.9	
implant type	Bone Level Implant	7	234	89.2	1.39	86.1 - 92.4	0.128
	Soft Tissue Level Implant	5	209	92.5	1.63	88.8 - 96.2	
provisional phase	Yes	8	206	90.3	1.46	87.0 - 93.6	0.909
	No	4	153	90.0	1.95	85.6 - 94.4	

## FIGURES

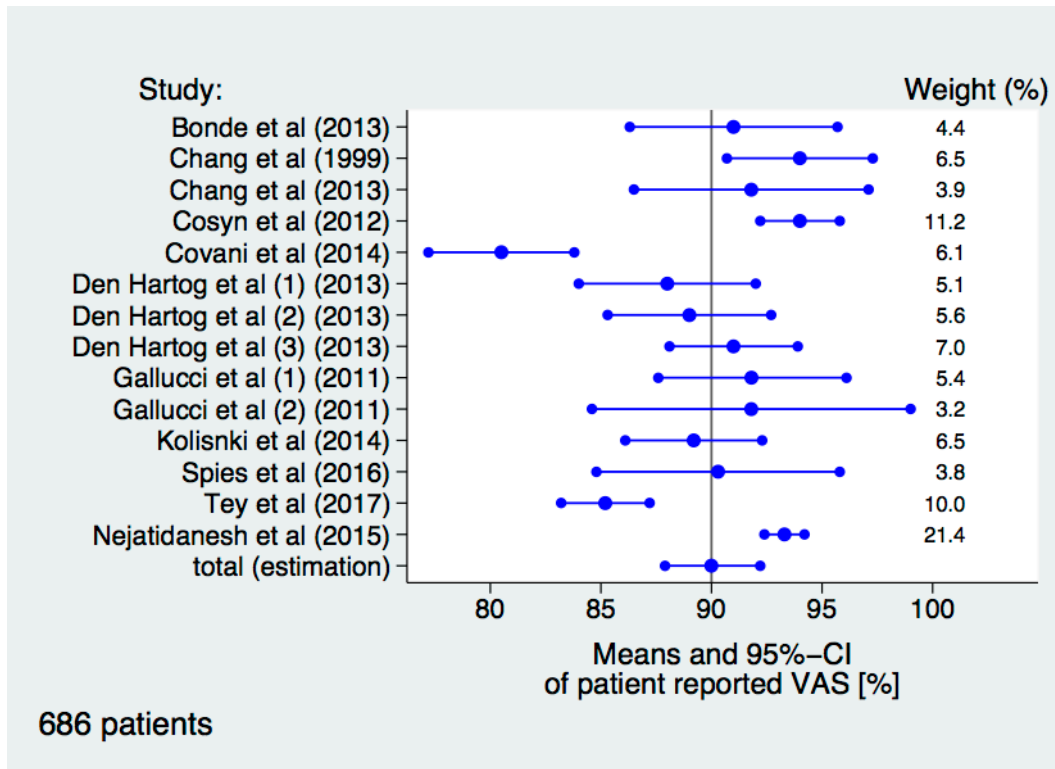
Figure 1: Flow diagram describing the search design implant supported group



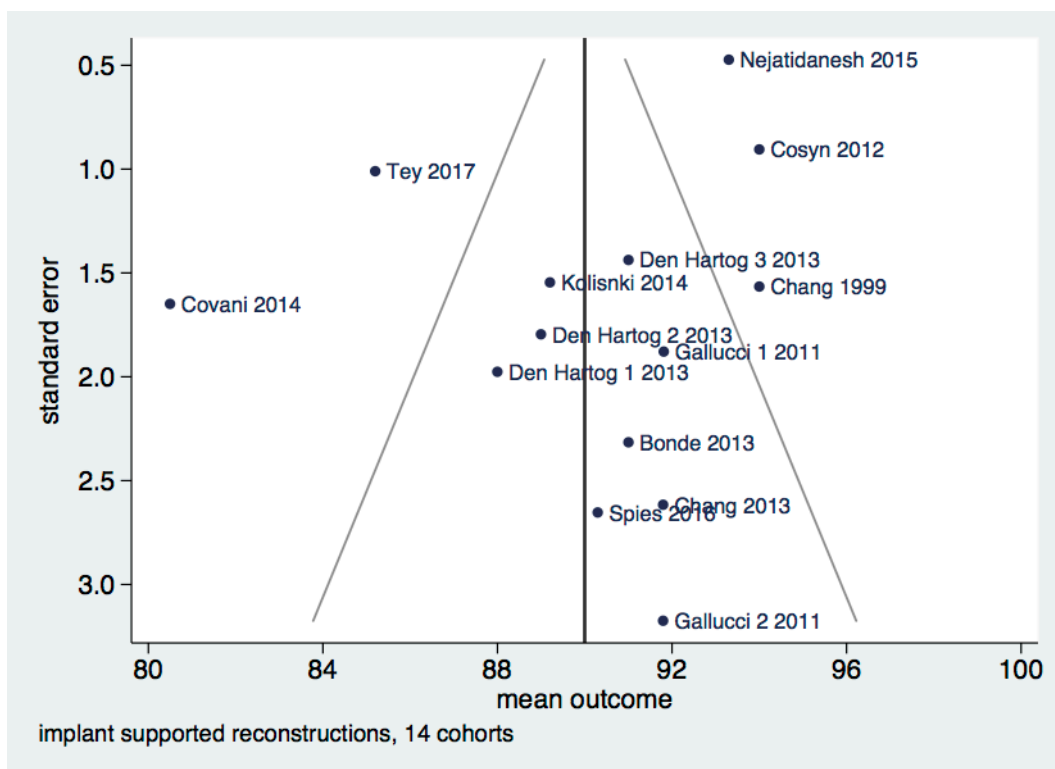
**Figure 2:** Flow diagram describing the search design tooth supported group



**Figure 3:** Patient reported outcomes, implant supported group (only data with standard deviation)



**Figure 4:** Funnel plot of included study cohorts, reporting on implant-supported reconstructions (n= 14)



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# Chapter 8

Patient-reported Outcome Measures  
focusing on the Esthetics of Implant-  
compared to Tooth-supported Single  
Crowns – A Systematic Review and Meta-  
Analysis.

**Submitted (under review):**

*Wittneben JG, Wismeijer D, Shahdad S, Brägger U, Abou-Ayash S.*

*Clinical Implant Dentistry and Related Research*

## ABSTRACT

**Background:** Patient-Reported Outcome Measures (PROMs) are used for subjective evaluations in clinical investigations.

**Purpose:** The present meta-analysis aimed to summarize the evidence of PROMs on the esthetic outcome in implant-supported, relative to tooth-supported single crowns (SCs).

**Material and Methods:** Two reviewers independently searched the EMBASE, Medline (PubMed), and Cochrane electronic databases. They focused on clinical studies reporting patient-reported esthetic evaluations of implant- or tooth-supported single crowns (SCs) by means of visual analogue scales (VAS). The main inclusion criteria were a minimum follow-up of one year, and a minimum number of ten patients, reported in English, German, or French. Random-effects meta-regression for aggregate-level was data used for comparison of studies.

**Results:** Eighteen studies including 23 relevant study cohorts were eligible for inclusion in the meta-analysis. PROMs data of 1122 implant-supported SCs evaluated by 903 patients revealed a mean VAS score of 89.5% (80.0- 94.0%). 201 patients evaluated the esthetic outcome of 486 tooth-supported SCs with a mean score of 94.4% (92.3- 96.0%). VAS ratings of patients regarding their perception of esthetics did not show any difference among different dental materials for the crowns or type of implant used.

**Conclusions:** Patients are highly satisfied with the esthetic outcome of their implant- and tooth-supported crowns.

## INTRODUCTION

In the recent years, Patient-Reported Outcome Measures (PROMs) have been frequently used for subjective assessments in clinical investigations in general medicine and dentistry leading to a paradigm shift to “patient-centered care”<sup>1-4</sup>. In dental medicine, PROMS include ‘subjective’ reports of patients’ perceptions of their oral health status and its’ impact on their daily life or quality of life, reports of satisfaction with oral health status, and/or oral health care and other nonclinical assessments<sup>5-7</sup>. These reports can be acquired either by self-administered questionnaires or by patient interviews. Today, different assessment questionnaires exist to evaluate patient reported outcomes.<sup>2,3</sup> They can be divided into generic or condition-targeted questionnaires that are applied either independent of the patients’ conditions, or in patients with a certain disease. Furthermore, questionnaires can be uni- or multi-dimensional, focusing on single or multiple constructs<sup>8</sup>.

Pleasing esthetics in reconstructive dentistry is defined by the harmonic appearance of natural and adjacent restored teeth and soft tissue<sup>9,10</sup>. The measure of esthetic outcome after prosthodontic treatment using PROMs is increasingly being used as a tool for evaluating patient satisfaction<sup>7</sup>. Usually, visual analogue scales (VAS), numerical rating scales (NRS), or Likert scales are applied, evaluating esthetics from a patient’s point of view. However, due the lack of a standardized approach for the evaluation of PROMs, the outcome of investigations using different assessments are difficult to be compared.

Occasionally, patients may seek and clinicians decide to extract an esthetically displeasing tooth with an intention of replacing it with an implant-supported single crown (SC), assuming the latter will achieve a better esthetic outcome. It has to be admitted, the choice to keep or to extract an esthetically displeasing tooth is mostly not only made based on esthetics, but rather on factors influencing the long-term treatment outcome such as the amount of sound tooth structure, endodontic- and periodontic conditions, the available amount of bone or localized soft tissue conditions. However, the expected esthetic treatment outcome plays an important role in this decision-making process.

A meta-analysis extracting PROMs data from clinical studies was used to obtain an overview focusing on the esthetic treatment preference of patients. The outcome of the present study should improve understanding of patient demands in esthetic treatment and patient satisfaction with treatment outcomes. The current systematic

review and meta-analysis aimed to determine the esthetic result of an implant-supported SC compared to a SC on a natural tooth according to PROMs assessed by VAS. Furthermore, the influence of the restoration material and implant type on PROMs was evaluated.

## **MATERIAL AND METHODS**

### **Definition of terms**

#### **Patient-reported outcome measures (PROMs)**

As mentioned above, PROMS are used to evaluate patients' subjective opinions, for example on a treatment outcome or the health status. However, in current literature, there is some disagreement on the use of the term PROMS <sup>11</sup>. Some authors differentiate between the terms PROMs and PROs for "patient-reported outcomes". According to them, PROMs are only the instruments (e.g. questionnaires) that are used for measuring PROs <sup>12</sup>. To be consistent with another publication of the same group <sup>13</sup>, the term PROMs as it is used in the present study includes both, the instruments, as well as the actual patient-reported outcomes.

#### **Visual analogue scale (VAS)**

Visual analogue scales (VAS) are instruments intended to measure subjective experiences (e.g. treatment outcome). VAS are straight lines of a predefined length (usually 10cm), labeled with worst experience (worst treatment outcome) at one end, and best experience (best treatment outcome) on the other end with no markings in between. Patients themselves mark the line according to their subjective feelings about a proposed question. Afterward, the area of the mark from the beginning of the line is measured by a clinician and a percent value focusing on the position of the marking is calculated.

### **Study Protocol**

In accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement the study protocol was defined <sup>14</sup>. The research question according to the P.I.C.O. model was set as follows:

*Population:* Fully, or partially dentate patients

*Intervention:* Implant-supported SCs



*Comparison:* Tooth-supported SCs

*Outcome:* Patient-reported outcomes (PROMs) on esthetics, measured by VAS

The resulting P.I.C.O. question was: 'What are the esthetic results of implant-supported SCs compared to tooth-supported SCs in fully or partially dentate patients according to PROMs?'

## **Eligibility Criteria**

An overview of the inclusion and exclusion criteria focusing on both systematic literature reviews - is provided in Table 1.

Inclusion and exclusion criteria were defined:

### **Inclusion**

- Human clinical studies (randomized controlled trials, controlled trials, prospective studies, retrospective studies, case series)
- Partially edentulous patients
- Fully dentate patients
- Tooth- or implant-supported SCs
- Documentation of PROMs by VAS
- Number of patients per study arm or cohort  $\geq 10$
- Mean follow-up period  $\geq 1$  years
- Publication in English, German, or French

### **Exclusion**

- *In vitro* or animal studies
- Removable partial dentures
- Tooth or implant-supported bridges
- Completely edentulous patients
- Insufficient documentation PROMs
- Fewer than 10 patients in relevant study arm/cohort
- Mean follow-up period less than 1 year
- Combined tooth-implant-supported restorations
- Studies not written in English, German, or French

## **Search strategy and study selection**

First an initial electronic search was done in the MEDLINE (via PubMed), EMBASE, and COCHRANE libraries, after developing a systematic search term (Table 1). The libraries were searched without applying any filters. Additionally, related articles' reference lists were analyzed systematically, to identify matching publications. Afterwards, duplicates were eliminated, and the titles of the remaining articles were checked for adequacy. Titles not matching the criteria (e.g. animal studies) were excluded. In case that relevance of an article could not be verified by the title, it was included for the screening of the abstract. The same procedure was done for abstract screening, and possibly eligible abstracts were included for full-text screening. After the full-text screening, irrelevant articles were excluded, and data extraction from the remaining full-texts was done whenever possible. The whole procedure was done by two reviewers (JW, SA) separately. When there was a disagreement between the two reviewers concerning article relevance, it was solved by discussion. In the case that multiple relevant study arms or cohorts were identified in the same investigation, data from each group were recorded separately (e.g. different restoration materials). The outcome was a higher number of study populations than indicated by the number of included studies.

For data extraction, the study form included the following parameters: authors, year of publication, study design, type of support (tooth/implant), type of retention (screw/cement), mean follow-up, planned number of patients, actual number of patients, mean age, age range, setting, total failure of SCs, PROMs mucosa, PROMs restoration, restoration material, implant type, implant brand, abutment material, abutment type, and provisional restoration.

## **Risk of bias analysis**

For included randomized controlled trials (RCTs), quality assessment was obtained separately by both authors using the Cochrane risk of bias tool <sup>15</sup>. For included observational studies, the Newcastle-Ottawa-Scale (NOS) <sup>16</sup> was used.

The Cochrane risk of bias tool uses separate domains, evaluating the risk of bias. These domains are "selection bias", "performance bias", "detection bias", "attrition bias", "reporting bias", and "other biases". The assigned judgment for each domain can be "high risk", "low risk", or "unclear risk" of bias.

The NOS is a quality assessment tool for nonrandomized studies, using three three

major domains for the evaluation: selection of the study groups, comparability of the study groups and ascertainment of either exposure or outcome of interest. Each domain can be awarded a certain number of stars, resulting in a maximum number of nine stars. The final judgment of the included studies according to the NOS can be “Good”, “Fair”, or “Poor” quality.

## **Statistical analysis**

Means, standard errors and the 95%-confidence intervals of PROMs of study combinations were calculated by random-effects meta-regression for aggregate-level data. To compare the mean outcome of groups of studies the same method was used. Statistical analysis was completed using Stata 14.2 and significance level set at 0.05.

## **Synthesis of results**

Data extraction of the individual studies was performed whenever PROMs according to the esthetic results of SCs measured by VAS were reported, and the study met the inclusion criteria. When the VAS value of 100 did not represent the best and 0 the worst treatment outcome, data was not extracted. Whenever possible PROMs were subdivided into the two categories single crown and mucosa and data was subsequently recorded separately. When studies described various PROMs, as for example color, shape, and general esthetics, only data according to the most general result were extracted.

The primary outcome of the meta-analysis was to compare patient-reported esthetic outcomes of implant- vs. tooth-supported SCs. Secondary outcomes were to analyze the influence of restoration material, implant type, and provisional phase according to patients. As described above, additional data was acquired during the data extraction process; however, these data could not be analyzed due to reporting heterogeneity, incomplete data (pooled results), or missing data.

## RESULTS

The systematic literature search was completed as described above. A total number of 2015 titles were retrieved (initial search) and screened independently by two authors (SA, JW) to assess their suitability for inclusion (Figure (Fig.) 1). A consensus was obtained following discussion for the abstract search (360 abstracts). A total of 69 full-text articles were evaluated according to the inclusion and exclusion criteria, of which 53 were found to qualify for inclusion in the data extraction process, and finally, 18 studies including 23 relevant study cohorts were eligible for inclusion in the review (Fig. 1).

### Description of included studies

Excluded and included studies are listed in Tables 2a and 2b. Quality assessment of the individual studies is illustrated in Tables 3a and 3b.

Study cohorts focusing on the implant-supported crowns were designed the following: seven cohorts from randomized clinical trials, seven from prospective, four from retrospective and two from cross-sectional studies (Table 4). The tooth-supported SC study cohorts were carried out in one prospective and one retrospective designed study. The majority of the included studies were performed in a university environment. Two investigations in the implant-supported group and in one study in the tooth-supported group multiple cohorts could be identified, the data of which were included in the present meta-analysis separately.

A total of 1122 implant-supported and 486 tooth-supported crowns were assessed by the patients using VAS. An equal distribution of the location of tooth supported crowns was documented presenting 50.4% of crowns located in anterior sites and 49.5% in posterior. Focusing on the individual location of implant-supported crowns 62.5% were inserted in anteriorly and 37.5% in posterior sites.

Bone level type implants supported 34.1% of the crowns and soft tissue level type implants 28.7%. In 37.2%, the implant type was not reported (Table 4).

Twenty implant-supported crowns were screw-retained (1.8%), 581 (51.8%) cement-retained, and both retention types were used in 41.3%.

The implant-supported SCs were made of veneered zirconium dioxide (20.7%), porcelain-fused-to-metal (PFM) was used in 119 (10.6%), PFM in combination with gold (24.1%) and all ceramic not further described 10.4%. In 23.2% of the crowns on implants, the type of material was not reported (Table 4).

The implant abutments extracted in these included studies were predominantly made of titanium (n= 365 (32.5%)), titanium and zirconium dioxide (n= 133 (11.9%)), aluminium oxide (n= 10 (0.9%)), gold (n= 10 (0.9%)) and all-ceramic not further described (n= 67(6.0%)). For 491 crowns (43.8%), the abutment material was not described in the studies (Table 4).

In the cohorts included in this review, 385 (34.3%) crowns were made with standard stock abutments, 160 with customized abutments, both types were used in studies reporting on 86 crowns, and the abutment type was not reported in 491 crowns (Table 4).

A total of 360 (32.10%) implant-supported crowns had a provisional prior to insertion of the final crown whereas a provisional was not used in 200 (17.8%). However, in the majority of the crowns (562 crowns), studies did not provide details of whether a provisional phase was implemented. Individual VAS scores and descriptive data in detail are presented in Table 4.

Tables 7- 9 illustrate the characteristics of tooth supported cohorts in detail. Individual mean values of VAS including min-max values, weighted mean and standard deviation are presented. 486 single tooth supported crowns were included. In respect to the material choice, 396 were veneered zirconium dioxide and 90 were lithium disilicate crowns (Table 8). The majority of crowns were inserted in a university clinic (66.7%) and 33.3% in a private practice setting (Table 8).

## **Patient-reported VAS scores**

### **VAS mucosa score**

Only 7 cohorts out of 20 reported on the esthetic outcome of the peri-implant soft tissue around the final implant-supported crown, assessed by patients utilizing VAS ratings. Mean outcome of the “VAS mucosa score” was 84.7% (median 86.7%; min-max 73.0-92.0%) (unweighted data) (Table 5).

None of the studies focusing on tooth-supported single crowns reported VAS results regarding the esthetic outcome of the soft tissues.

### **VAS crown**

In the present meta-analysis 16 studies (20 cohorts) documented patient evaluations including the final esthetic outcome of the implant-supported crowns. The mean VAS

was 89.5% (median 91.0% (min-max 80.0- 94.0%)) (Table 5). An overview of mean VAS values extracted by descriptive data is presented in Table 4. In order to perform a random-effects meta-analysis only cohorts that reported the standard deviation of the VAS could be included. The Standard deviation of the VAS was reported for all studies focusing on tooth supported- but only for few studies on implant-supported crowns (Tables 6 and 9).

Mean VAS crown rating of the tooth-supported crowns was 94.4% (Table 7). Characteristics of individual descriptive data are summarized in Table 8.

### **VAS tooth- versus implant-supported crowns**

Mean values of the esthetic evaluations by the patients (VAS crown) was higher in studies with tooth-supported (94.4%) versus implant-supported (90.0%) crowns, however not being statistically significant ( $p = 0.05$ ) (Table 10). An overview of both groups is illustrated in funnel plots (Fig. 2, Fig. 3).

### **Influence of restoration material/ implant type/ provisional phase on the outcome of VAS crown**

Table 11 and 12 are reporting on the results of the random-effects meta-regression in detail, were only studies including standard deviation could be considered for inclusion of this analysis. Focusing on implant-supported crowns the type of restoration material, type of the implant (bone level versus soft tissue level) and the implementation of a provisional phase did not have a statistically significant effect (Table 11).

In regard to tooth-supported crowns, the comparison of VAS values with respect to the restoration material concluded no statistical significance among the ceramic materials (Table 12).

## DISCUSSION

The purpose of the present systematic review and meta-analysis was to assess the PROMs of implant- and tooth- supported single crowns, and compare them to each other. Patient reported outcomes focusing on the esthetic zone were higher for crowns supported by teeth than implants, however not being statistically significant different. The different dental materials or the type of dental implant used did not have a significant influence on the evaluations of the patients. These findings presented that patient's esthetic perspective is similar -no matter if the crown is placed on a natural tooth or an implant.

In the present meta-analysis, patient-reported outcomes of 889 implant-supported SCs evaluated by 685 patients (mean VAS value 90%; 95% CI: 87.9-92.2%), and 486 tooth-supported SCs evaluated by 201 patients (mean VAS value 94.4%; 95% CI: 90.2-98.6%) were analyzed. Comparing the two sets of VAS scores, a statistically significant difference could not be observed ( $p = 0.050$ ). However, the ratings of implant-supported SCs were slightly lower compared to tooth-supported SCs.

Visual Analogue Scales (VAS) for assessing PROMs remains one of the most widely used methods in dentistry due to their ease of use, however, their application has also been criticized<sup>17,18</sup>. The major point of criticism is, that patients tend to avoid the end of the scales, which represent the best or worst possible outcome, especially in comparison to categorized rating scales<sup>19</sup>. Even though VAS and NRS are directly related<sup>20</sup>, it has been demonstrated that the results of VAS tend to be higher compared to NRS<sup>21</sup>. Therefore, the decision was made to focus only on a single outcome measure, not to add a confounding factor, as the amount of confounding factors in systematic reviews is always high. Consequently, the present study only focused on VAS, as the literature screening before the actual systematic search revealed that VAS was the most widely applied PROM.

The statistical analysis just barely missed to show a statistically significant difference between the two groups, using the routinely applied level of significance of  $p < 0.05$ . However, the question if the difference that was found might be clinically relevant remains. To answer this question, the current results were also analyzed in terms of the minimal clinically important difference (MCID). The MCID is widely applied to overcome the shortcomings of study results, purely based on p-values, especially in the field of PROMs. It is defined as the minimum change or difference, that is important for the patient<sup>22</sup>. In the current literature there are MCIDs described for various PROMs

measured by VAS, but not for esthetic outcomes. Nevertheless, the MCIDs related to VAS, that can be found are about 10mm (10%) or even higher <sup>23–25</sup>. Regarding the present study, the upper value of the 95% CI comparing implant- and tooth-supported SCs was 8.66, which means that the threshold of the MCID was not reached. It has to be noted that assuming an MCID of 10 mm to be applicable for analyzing the esthetic outcomes measured by VAS is only an estimate, that is not based on studies on esthetics. However, focusing on the statistical analyses and the MCID in combination, facilitates the interpretation of the current results. The demonstrated differences might not only be statistically but also clinically irrelevant.

### **Influence of restoration material**

In the present review, the VAS assessments of the patients presented no influence of the material selection for the crowns. This finding has been previously corroborated in a prospective study evaluating implants restored either with all- ceramic or metal-ceramic crowns after 3-years <sup>26</sup>. Patient's esthetic evaluations was not statistically different between all-ceramic and metal- ceramic restorations. Furthermore, esthetic evaluations by clinicians were also documented, and no correlation was reported between the professional and patient-reported esthetic outcome.

### **Influence of implant type**

Bone level design implants with the abutment connection at the crestal bone level are preferred by a vast majority of clinicians when replacing teeth in the esthetic zone. It is perceived that it offers the clinician greater prosthetic freedom to determine the location of the mucosal zenith and individualize the emergence profile to achieve high pink esthetics <sup>27–30</sup>.

In a retrospective study revealing the clinical outcome of 50 single implant crowns on bone level implants restored with all ceramic abutments and hand- layered ceramic patient satisfaction after 2.3 years was high presenting a mean esthetic satisfaction score of 9.5 out of 10 <sup>31</sup>. However, in this systematic review, the patient-reported outcomes were higher for soft tissue level implant design compared to those with bone level type implants, the difference was not statistically significant ( $p= 0.128$ ) (Table 11). This outcome was confirmed by focusing only on implant supported crowns placed in the anterior region (Table 11). Apart from the studies included in this systematic review, similar results have previously been reported in other studies describing esthetic



outcomes of tissue level design implants<sup>32-34</sup>.

## **Limitations of the study**

Surprisingly, in the present meta-analysis, only 2 studies could be identified on the tooth- supported SCs that could be included in this systematic review, therefore the results should be interpreted with caution.

In general, patients included in this study did not have a choice of treatment – tooth versus implant supported. Here it has be considered that losing a tooth and replacing by an implant usually adds to an esthetic comprise associated with tooth removal (e.g. previous inflammation, previous endodontic surgery, lack of buccal bone plate, loss of soft tissue). However, in the present investigation the VAS evaluation regarding the esthetic outcome of the patients was not statistically significant between both groups. Due to the lack of standardization in the method of assessment of PROMs<sup>3</sup>, only studies that used VAS as a scale of measure were included in this review to allow direct comparison and data for meta-analysis. This is likely to have excluded some studies especially in the tooth-supported group.

Given that there is a growing interest in patient reported outcomes in healthcare, future studies should be designed using validated and standardized questions and their responses collected by investigators who are not involved in the treatment to avoid bias. Furthermore, these assessments should be carried out before treatment, immediately after completion of treatment and repeated at regular follow-up intervals to truly gauge the patient's perception of treatment outcome from an esthetic point of view.

## CONCLUSION

Within the limitations of this meta-analysis it can be concluded that:

- Patients are highly satisfied with the esthetic outcome of their implant- and tooth- supported crowns and mucosa around implants.
- Patients' perception of esthetics focusing on SC was slightly higher when supported by teeth than implants, however without being statistically significantly different ( $p= 0.050$ ).
- VAS ratings of patients regarding their perception of esthetics did not show any difference among different dental materials and type of implant used for the crowns in both groups, implant- and tooth-supported.
- The inclusion of a provisional phase within the implant prosthetic workflow did not improve the esthetic outcome according to the VAS rating of the patients ( $p= 0.911$ ).

## ACKNOWLEDGEMENTS

The authors express their gratitude to biostatistician Mrs. Hiltrud Niggemann for conducting the statistical analysis. No financial funding was obtained.

## FIGURE LEGENDS

**Figure 1:** Flow diagram describing the systematic search

**Figure 2:** Funnel plot of included study cohorts focusing on implant supported single crowns

**Figure 3:** Funnel plot of included study cohorts reporting on tooth supported single crowns

# TABLES

**TABLE 1: Systematic search strategy**

<b>Focused question (PICO)</b>	What are the esthetic results of implant-supported SCs compared to tooth-supported SCs in dentate patients, according to PROMs?	
<b>Search Strategy</b>	<b>Population</b>	#1 fully OR partially OR dentate OR jaw
	<b>Intervention exposure</b> <b>or</b>	#2 implant OR crown OR reconstruct* OR FPD OR implant crown* OR „implant-supported prosthesis“ OR „implant-supported crown“
	<b>Comparison</b>	#3 tooth-supported OR fixed partial denture* OR crown
	<b>Outcome</b>	#4 esthetic OR evaluation OR esthetic* OR VAS OR questionnaire* OR "patient-related" OR "patient-reported outcome" OR "patient opinion" OR "patient perception" OR "patient report"
	<b>Search combination</b>	#1 AND #2 AND #3 AND # 4
<b>Database search</b>	<b>Electronic</b>	PubMed, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL)
	<b>Journals</b>	Clinical Oral Implants Research, International Journal of Oral Maxillofacial Implants, Clinical Implant Dentistry and Related Research, Implant Dentistry, Journal of Implantology, Journal of Periodontology, Journal of Clinical Periodontology
<b>Selection criteria</b>	<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>• Human clinical studies (randomized controlled trials, controlled trials, prospective studies, retrospective studies, case series)</li> <li>• Partially edentulous patients</li> <li>• Fully dentate patients</li> <li>• Tooth- or implant-supported SCs</li> <li>• Documentation of PROMs by VAS</li> <li>• Number of patients per study arm or cohort ≥ 10</li> <li>• Mean follow-up period ≥ 1 years</li> <li>• Publication in English, German, or French</li> </ul>
	<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• <i>In vitro</i> or animal studies</li> <li>• Removable partial dentures</li> <li>• Tooth-or implant supported bridges</li> <li>• Completely edentulous patients</li> <li>• Insufficient documentation PROMs</li> <li>• Fewer than 10 patients in relevant study arm/cohort</li> <li>• Mean follow-up period less than 1 year</li> <li>• Combined tooth-implant-supported restorations</li> <li>• Studies not written in English, German, or French</li> </ul>

**TABLE 2a: Excluded studies during data extraction.**

<b>Author (year)</b>	<b>Reason for exclusion</b>
Alshiddi et al (2015) <sup>35</sup>	insufficient data
Amorfini et al (2017) <sup>36</sup>	follow up less than 1 year
Andersson et al (2003) <sup>37</sup>	follow up less than 1 year
Andersson et al (2013) <sup>38</sup>	insufficient data
Avivi-Arber et al (1997) <sup>39</sup>	insufficient data
Baracat (2011) <sup>40</sup>	insufficient data, no report on the amount or type of fixed reconstruction
Batisse (2014) <sup>41</sup>	insufficient data
Bianchi (2004) <sup>42</sup>	insufficient data
Boardmann et al (2016) <sup>43</sup>	insufficient data
Boronat-Lopez (2009) <sup>44</sup>	no single crowns
Branzén et al (2015) <sup>45</sup>	insufficient data
Carollo (2003) <sup>46</sup>	insufficient data
Cosyn et al (2016) <sup>47</sup>	proms not reported (email written to author)
Dogan et al (2017) <sup>48</sup>	not especially asked for aesthetic outcome
Edelhoff et al (2008) <sup>49</sup>	insufficient data
Gibbard/Zarb (2002) <sup>50</sup>	insufficient data
Kourkouta et al (2009) <sup>51</sup>	insufficient data
Meijndert et al (2007) <sup>52</sup>	insufficient data
Moghadam et al (2012) <sup>53</sup>	no report on the amount or type of fixed reconstruction
Näpänkangas et al (1997) <sup>54</sup>	insufficient data
Nicolaisen MH et al (2016) <sup>55</sup>	insufficient data
Ohlmann B et al (2014) <sup>56</sup>	no exact value given
Rimmer/Mellor (1996) <sup>57</sup>	insufficient data
Santing et al (2013) <sup>30</sup>	not especially asked for aesthetic outcome
Schropp et al (2004) <sup>58</sup>	insufficient data
Schropp/Isidor (2007) <sup>59</sup>	insufficient data
Sherif et al (2011) <sup>60</sup>	insufficient data
Shi et al (2016) <sup>61</sup>	not especially asked for aesthetic outcome
Tymstra et al (2010) <sup>62</sup>	insufficient data
Tymstra et al (2011) <sup>63</sup>	insufficient data
Vanlioglu et al (2014) <sup>64</sup>	proms not reported (email written to author)
Vanorbeek et al (2010) <sup>65</sup>	insufficient data
Vermynen et al (2003) <sup>66</sup>	insufficient data
Vilhjalmsson et al (2011) <sup>67</sup>	insufficient data

**TABLE 2b: Included studies/ cohorts (n=23 cohorts, n=18 studies)**

Author (year)	Total N of SCs	Total N of patients	mean follow-up (years)	Mucosa (%)	Crown (%)
Implant supported cohorts (n=20):				Pat. reported VAS (%) mean	Pat. reported VAS (%) mean
Bonde et al (2013) <sup>68</sup>	46	42	10.0	82.0	91.0
Chang et al (1999) <sup>69</sup>	21	20	3.0	NA	94.0
Chang et al (2013) <sup>70</sup>	32	32	7.5	NA	91.8
Cosyn et al (2012) <sup>71</sup>	46	44	2.5	92.0	94.0
Covani et al (2014) <sup>72</sup>	47	47	5.0	73.0	80.5
De Rouck et al (2008) <sup>73</sup>	30	30	1.0	NA	93.0
De Rouck et al (1) (2009) <sup>74</sup>	24	24	1.0	NA	93.0
De Rouck et al (2) (2009) <sup>74</sup>	25	25	1.0	NA	91.0
Den Hartog et al (1) (2013) <sup>75</sup>	31	31	1.5	86.7	88.0
Den Hartog et al (2) (2013) <sup>75</sup>	31	31	1.5	87.1	89.0
Den Hartog et al (3) (2013) <sup>75</sup>	31	31	1.5	83.9	91.0
Eksfeldt et al (2011) <sup>76</sup>	40	25	3.0	NA	90.0
Gallucci et al (1) (2011) <sup>77</sup>	10	10	2.0	NA	91.8
Gallucci et al (2) (2011) <sup>77</sup>	10	10	2.0	NA	91.8
Hartlev et al (2014) <sup>78</sup>	54	54	2.8	88.0	83.0
Hof et al (2014) <sup>79</sup>	60	60	4.1	NA	80.0
Kolisnki et al (2014) <sup>80</sup>	58	36	3.0	NA	89.2
Nejatidanesh et al (2015) <sup>81</sup>	232	121	5.9	NA	93.3
Spies et al (2016) <sup>82</sup>	24	24	2.6	NA	90.3
Tey et al (2017) <sup>83</sup>	270	206	5.2	NA	85.2
total (n=20)	1122	903	4.2		
Tooth supported cohorts (n=3):					
Bomicke et al (1) (2017) <sup>84</sup>	90	45	3.1	NA	95.0
Bomicke et al (2) (2017) <sup>84</sup>	72	21	2.7	NA	96.0
Nejatidanesh et al (2015) <sup>81</sup>	324	135	5.1	NA	92.3
total (n=3)	486	201#	4.4		

**TABLE 3a: Quality assessment of included studies according to NOS**

Author (year)	Selection	Comparability	Outcome	Quality
Bömicke et al. <sup>84</sup>	3	1	2	good
Bonde et al. <sup>68</sup>	4	2	2	good
Chang et al. <sup>69</sup>	4	2	3	good
Chang et al. <sup>70</sup>	4	1	3	good
Cosyn et al. <sup>71</sup>	4	2	2	good
Covani et al. <sup>72</sup>	4	2	3	good
De Rouck et al. <sup>73</sup>	4	1	2	good
Eksfeldt et al. <sup>76</sup>	4	1	3	good
Hartlev et al. <sup>78</sup>	4	2	1	fair
Hof et al. <sup>79</sup>	4	1	3	good
Kolinski et al. <sup>80</sup>	4	1	1	fair
Spies et al. <sup>82</sup>	4	1	1	fair
Tey et al. <sup>83</sup>	4	1	2	good
Nejatidanesh et al. <sup>81</sup>	4	1	3	good

**TABLE 3b: Quality assessment for included randomized clinical trials, according to Cochrane risk of bias tool**

Author (year)	Random Sequence	Allocation Concealment	Blinding	Blinding (Outcome)	Outcome Data	Selective Reporting	Other Biases
den Hartog et al. <sup>75</sup>	+	+	0	+	+	+	+
De Rouck et al. <sup>74</sup>	+	0	-	-	+	+	+
Gallucci et al. <sup>77</sup>	+	+	+	+	+	+	+

**TABLE 4: Characteristics of study cohorts related to implant supported crowns and patient-reported outcomes (PROMS) evaluated by Visual Analogue Scale (VAS)**

		no. of cohorts (%)	Total Nof crowns (%)	Total N of patients (%)	VAS mean (%)	VAS min-max (%)	VAS mean (%) unweighted	VAS mean (%) weighted
all studies		20 (100)	1122 (100)	903 (100)	89.5	80.0-94.0	89.5	88.3
Studydesign	RCT	7 (35.0)	162 (14.4)	162 (17.9)	90.8	88.0-93.0	90.8	90.4
	Prospective	7 (35.0)	280 (25.0)	253 (28.0)	88.7	80.5-94.0	88.7	87.5
	Retrospective	4 (20.0)	602 (53.7)	412 (45.6)	87.1	80.0-93.3	87.1	87.1
	Cross sectional	2 (10.0)	78 (7.0)	76 (8.4)	92.9	91.8-94.0	92.9	93.1
Implant	Bone Level Implant	10 (50.0)	383 (34.1)	378 (41.9)	88.1	80.0-94.0	88.1	86.8
	Soft Tissue Level Implant	5 (25.0)	322 (28.7)	209 (23.1)	92.2	90.3-94.0	92.2	93.0
	NA	5 (25.0)	417 (37.2)	316 (35.0)	89.7	85.2-93.0	89.7	87.1
Screw/cement	Screw	2 (10.0)	20 (1.8)	20 (2.2)	91.8	91.8-91.8	91.8	91.8
	Cement	11 (55.0)	581 (51.8)	463 (51.3)	90.4	80.5-94.0	90.4	90.3
	Both	6 (30.0)	463 (41.3)	384 (42.5)	87.2	80.0-91.0	87.2	85.7
	NA	1 (5.0)	58 (5.2)	36 (4.0)	89.2	-	89.2	89.2
Setting	Private practice	3 (15.0)	556 (49.6)	381 (42.2)	87.2	83.0-93.3	87.2	87.5
	University	14 (70.0)	447 (39.8)	441 (48.8)	89.7	80.0-94.0	89.7	88.6
	Multicenter	1 (5.0)	58 (5.2)	36 (4.0)	89.2	-	89.2	89.2
	Specialist clinic	2 (10.0)	61 (5.4)	45 (5.0)	92.0	90.0-94.0	92.0	91.8
Restoration material	PFM	4 (20.0)	119 (10.6)	119 (13.2)	89.3	80.5-93.0	89.3	87.6
	PFM+all ceramic	2 (10.0)	100 (8.9)	98 (10.9)	88.5	83.0-94.0	88.5	87.9
	PFM+Gold	1 (5.0)	270 (24.1)	206 (22.8)	85.2	-	85.2	85.2
	All ceramic	4 (20.0)	117 (10.4)	97 (10.7)	91.7	90.0-94.0	91.7	91.4
	Veneered	1 (5.0)	232 (20.7)	121 (13.4)	93.3	-	93.3	93.3
	Zirconiumdioxide	1 (5.0)	24 (2.1)	24 (2.7)	90.3	-	90.3	90.3
	VZ+MZ	1 (5.0)	24 (2.1)	24 (2.7)	90.3	-	90.3	90.3
NA	7 (35.0)	260 (23.2)	238 (26.4)	88.7	80.0-93.0	88.7	87.5	
Brand	Straumann	3 (15.0)	252 (22.5)	141 (15.6)	92.3	91.8-93.3	92.3	93.1
	Nobel	11 (55.0)	399 (35.6)	392 (43.4)	89.7	80.0-94.0	89.7	88.6
	Astra	1 (5.0)	32 (2.9)	32 (3.5)	91.8	-	91.8	91.8
	Sweden	1 (5.0)	47 (4.2)	47 (5.2)	80.5	-	80.5	80.5
	Martina	1 (5.0)	24 (2.1)	24 (2.7)	90.3	-	90.3	90.3
	Ziraldent	1 (5.0)	24 (2.1)	24 (2.7)	90.3	-	90.3	90.3
	Straumann, Nobel, Biomet	1 (5.0)	270 (24.1)	206 (22.8)	85.2	-	85.2	85.2
	3i	1 (5.0)	24 (2.1)	24 (2.7)	90.3	-	90.3	90.3
NA	2 (10.0)	98 (8.7)	61 (6.8)	89.6	89.2-90.0	89.6	89.5	
Abutment material	Titanium	5 (25.0)	365 (32.5)	254 (28.1)	89.8	80.5-93.3	89.8	90.4
	Titanium + Zirconiumdioxide	4 (20.0)	133 (11.9)	118 (13.1)	89.5	88.0-91.0	89.5	89.5
	Titanium + ceramic	1 (5.0)	46 (4.1)	44 (4.9)	94.0	-	94.0	94.0
	Gold	1 (5.0)	10 (0.9)	10 (1.1)	91.8	-	91.8	91.8
	Aluminium oxide	1 (5.0)	10 (0.9)	10 (1.1)	91.8	-	91.8	91.8
	ceramic - no further spec	2 (10.0)	67 (6.0)	62 (6.9)	92.5	91.0-94.0	92.5	92.0
	NA	6 (30.0)	491 (43.8)	405 (44.9)	86.9	80.0-93.0	86.9	85.3

Abutment	Standardized/ prefabricated	6 (30.0)	385 (34.3)	269 (29.8)	92.2	90.3-94.0	92.2	92.5
	Individualized	6 (30.0)	160 (14.3)	160 (17.7)	88.7	80.5-91.8	88.7	87.0
	Both	2 (10.0)	86 (7.7)	69 (7.6)	92.0	90.0-94.0	92.0	92.6
	NA	6 (30.0)	491 (43.8)	405 (44.9)	86.9	80.0-93.0	86.9	85.3
Prov. loaded on implants	Phase Yes	12 (60.0)	360 (32.1)	338 (37.4)	90.2	83.0-93.0	90.2	89.5
	No	5 (25.0)	200 (17.8)	178 (19.7)	89.9	80.5-94.0	89.9	89.2
	NA	3 (15.0)	562 (50.1)	387 (42.9)	86.2	80.0-93.3	86.2	86.9



**TABLE 5: No. of SCs, patients, mean follow-up, patient-reported outcome, studies on implant supported SCs (n=20 cohorts, n=16 studies)**

	data reported in n cohorts	data missing	mean	sd	median	min-max
N of SCs	20	0	56.1	68.4	31.5	10-270
Actual N of pts	20	0	45.2	44.6	31.0	10-206
Mean follow up (years)	20	0	3.3	2.4	2.7	1.0-10.0
VAS (%) crown	20	0	89.5	4.2	91.0	80.0-94.0
VAS (%) mucosa	07	13	84.7	6.0	86.7	73.0-92.0

**TABLE 6: Patient-reported outcomes for cohorts of implant-supported SCs including standard deviation (sd) – n = 14**

	Total N of patient (%)	mean VAS crown (%)	sd (%)	95%-CI
Bonde et al. <sup>68</sup>	42 (6.1)	91	15	86.3 - 95.7
Chang et al. <sup>69</sup>	20 (2.9)	94	7	90.7 - 97.3
Chang et al. <sup>70</sup>	32 (4.7)	91.8	14.8	86.5 - 97.1
Cosyn et al. <sup>71</sup>	44 (6.4)	94	6	92.2 - 95.8
Covani et al. <sup>72</sup>	47 (6.9)	80.5	11.3	77.2 - 83.8
den Hartog et al. (1) <sup>75</sup>	31 (4.5)	88	11	84 - 92
den Hartog et al. (2) <sup>75</sup>	31 (4.5)	89	10	85.3 - 92.7
den Hartog et al. (3) <sup>75</sup>	31 (4.5)	91	8	88.1 - 93.9
Gallucci et al. (1) <sup>77</sup>	10 (1.5)	91.81	5.94	87.6 - 96.1
Gallucci et al. (2) <sup>77</sup>	10 (1.5)	91.8	10.04	84.6 - 99.0
Kolinski et al. <sup>80</sup>	36 (5.3)	89.2	9.4	86.0 - 92.4
Spies et al. <sup>82</sup>	24 (3.5)	90.3	13	84.8 - 95.8
Tey et al. <sup>83</sup>	206 (30.0)	85.2	14.5	83.2 - 87.2
Nejatidanesh et al. <sup>81</sup>	121 (17.7)	93.3	5.2	92.4 - 94.2
<b>total*</b>	<b>685 (100)</b>	<b>90.0</b>	<b>1.00**</b>	<b>87.9 - 92.2</b>

\* estimation by random-effects meta-regression

\*\* estimated standard error

**TABLE 7: Overview of data about SCs, patients, mean follow-up, patient-reported outcome of tooth-supported cohorts (n=3 cohorts, n=2 studies )**

	data reported in nr cohorts	data missing	mean	sd	median	min-max
N of SCs	3	0	162.0	140.6	90.0	72-324
Actual N of pts*	3	0	67.0	60.1	45.0	21-135
Mean follow up (years)	3	0	3.6	1.3	3.1	2.7-5.1
VAS crown (%)	3	0	94.4	1.9	95.0	92.3-96.0

\*number of reported outcomes

**TABLE 8: Characteristics of tooth supported cohorts (n=3 cohorts, n=2 studies)**

		no. of studies (%)	Total N of crowns (%)	Total N of patients (%) <sup>*</sup>	VAS mean <sup>*</sup> (%)	VAS min-max (%)	mean (%) weighted
all studies		3 (100)	486 (100)	201 (100)	94.4	92.3-96.0	93.3
Studydesign	Prospective	2 (66.7)	162 (33.3)	66 (32.8)	95.5	95.0-96.0	95.3
	Retrospective	1 (33.3)	324 (66.7)	135 (67.2)	92.3	-	92.3
Implant	NA	3 (100)	486 (100)	201 (100)	94.4	92.3-96.0	93.3
Screw/cement	Cement	1 (33.3)	324 (66.7)	135 (67.2)	92.3	-	92.3
	NA	2 (66.7)	162 (33.3)	66 (32.8)	95.5	95.0-96.0	95.3
Setting	Private practice	1 (33.3)	324 (66.7)	135 (67.2)	92.3	-	92.3
	University	2 (66.7)	162 (33.3)	66 (3.8)	95.5	95.0-96.0	95.3
Material	Veneered Zirconiumdioxide	2 (66.7)	396 (81.5)	156 (77.6)	94.2	92.3-96.0	92.8
	Lithiumdisilicate (emax)	1 (33.3)	90 (18.5)	45 (22.4)	95.0	-	95.0

\* unweighted mean

**TABLE 9: Patient-reported outcome of tooth supported cohorts - mean, sd and 95%-CI (n=3 cohorts, n=2 studies)**

	Total N of patients (%)	mean VAS crown (%)	sd (%)	95%-CI
Bomicke et al. (1) <sup>84</sup>	45 (22.4)	95.0	8.0	92.6 - 97.4
Bomicke et al- (2) <sup>84</sup>	21 (10.4)	96.0	5.0	93.7 - 98.3
Nejatidanesh et al. <sup>81</sup>	135 (67.2)	92.3	5.9	91.3 - 93.3
total*	201 (100) <sup>#</sup>	94.4	1.97 <sup>**</sup>	90.2 - 98.6

#number of reported outcomes

\* estimation by random-effects meta-regression

\*\* estimated standard error

**TABLE 10: Patient-reported outcomes - implant supported comparison to tooth supported study cohorts (estimation by random-effects meta-regression)**

	cohorts	patients	mean	standard error	95%-CI	p-value
Tooth (1)	3	201	94.4	1.97	90.2 - 98.6	
Implant (2)	14	686	90.0	1.00	87.9 - 92.2	
Difference (tooth minus implant)			4.3	2.2	-0.0001257 -8.66	p=0.0500067

**TABLE 11: Patient-reported outcomes - implant supported study cohorts - comparison of groups (estimation by random-effects meta-regression)**

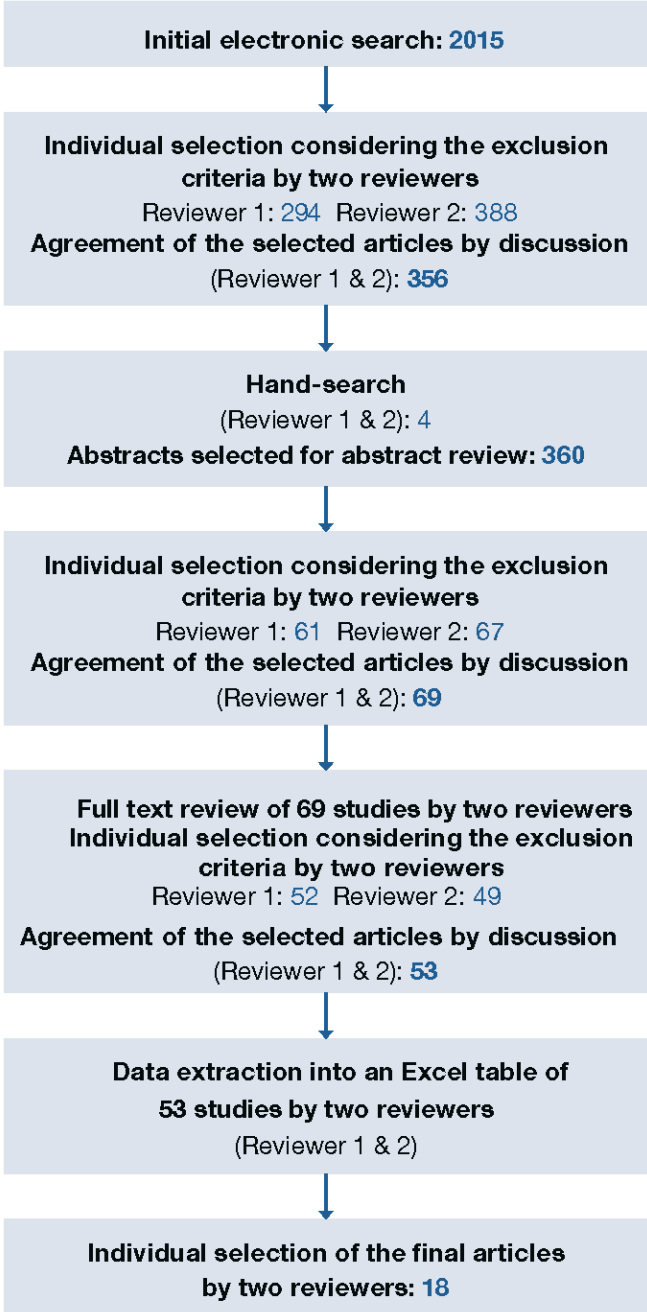
		studies	patients	mean VAS (%)	standard error	95%-CI	p-value
restoration material	PFM	3	89	87.8	2.87	78.7 - 96.9	0.616
	All ceramic	3	72	92.4	2.95	83.0 - 100	
	Veneered Zirconiumdioxide	1	121	93.3	4.54	78.8 - 100	
	Lithiumdisilicate (emax)	1	24	90.3	5.24	73.6 - 100	
	PFM + ceramic	1	44	94.0	4.61	79.3 - 100	
	PFM + gold	1	206	85.2	4.63	70.5 - 99.9	
	provisional phase	Yes	8	205	90.3	1.46	
	No	4	153	90.0	1.95	85.6 - 94.4	
implant type ALL	Bone Level Implant	7	234	89.2	1.39	86.1 - 92.4	0.128
	Soft Tissue Level Implant	5	209	92.5	1.63	88.8 - 96.2	
<b>Anterior (FDI 15-25)</b>	Bone Level Implant	6	192	89.2	1.89	84.3 - 94.0	0.232
	Soft Tissue Level Implant	3	64	92.6	0.95	88.5 - 96.6	

**TABLE 12: Patient-reported outcomes - tooth supported cohorts- restoration material (estimation by random-effects meta-regression) (n=3 cohorts, n=2 studies)**

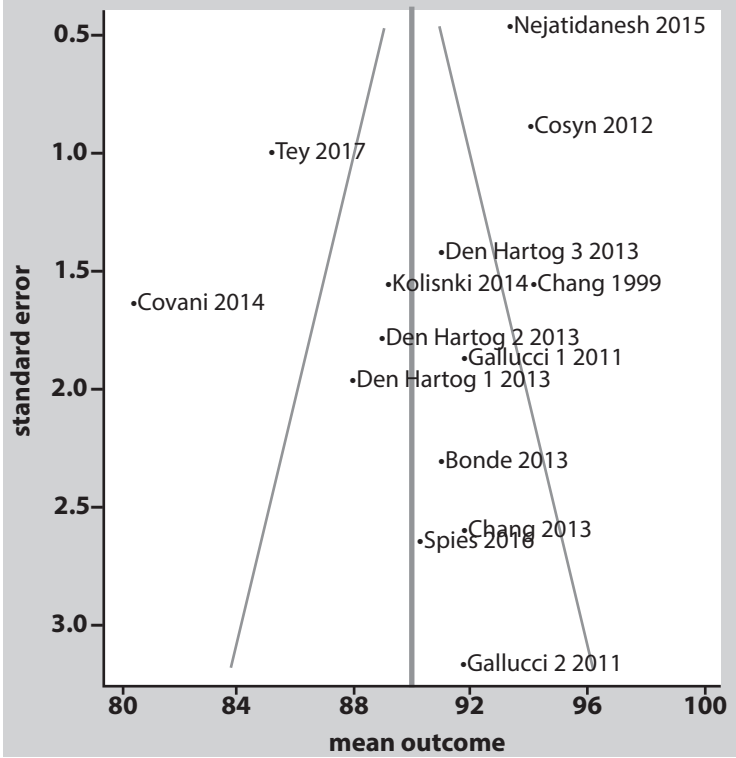
	studies	patients	Mean VAS	standard error	95%-CI	p-value
Zirconium dioxide (1)	2	156	94.0	1.85	90.4 - 97.6	p=0.768
Lithium disilicate (emax) (2)	1	45	95.0	2.75	89.6 - 100.4	

# FIGURES

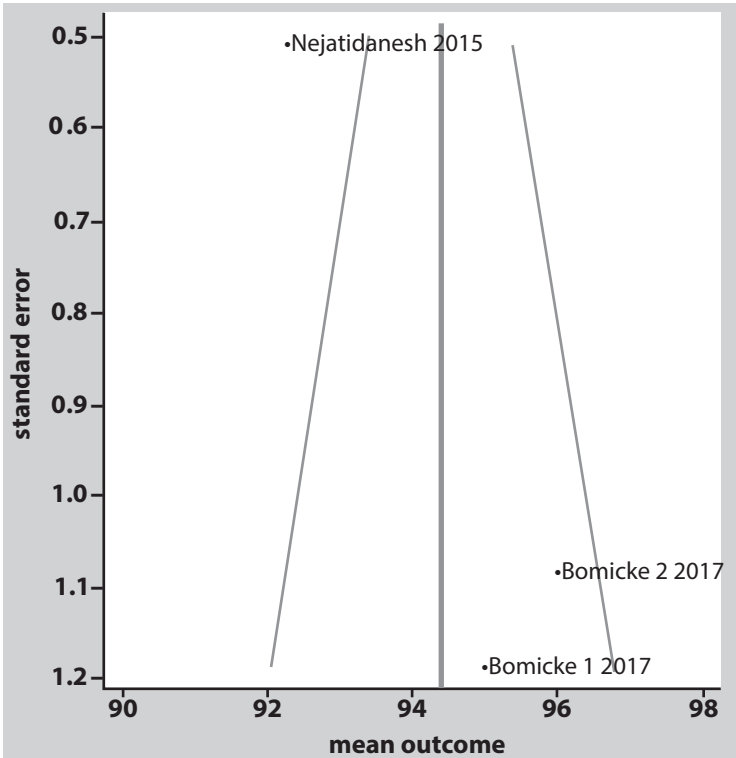
Figure 1: Flow diagram describing the systematic search



**Figure 2:** Funnel plot of included study cohorts focusing on implant supported single crowns



**Figure 3:** Funnel plot of included study cohorts reporting on tooth supported single crowns



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# Chapter 9

## Summary and general discussion

In times of social media and selfie-hypes, patients' expectations concerning dental treatment are increasing.

Achieving a prosthetic ideal esthetic outcome using implants in esthetic sites is often challenging. Pink and white esthetics are influenced by the prosthetic workflow. This thesis aimed to investigate factors influencing the final esthetic outcome (provisional phase, abutment selection, vertical growth of the adjacent teeth) of implant supported prosthesis using objective esthetic parameters and including patient's perception of the final treatment.

The first prosthetic treatment approach after the reopening procedure of a two-stage implant in esthetic sites is the fabrication of a fixed implant supported provisional. After the removal of the healing abutment the mucosa profile is only a small round emergence profile. When using bone level type implants in esthetic sites the emergence and mucosa profile should be conditioned to finalize the peri-implant soft tissue architecture around the future crown (Wittneben et al 2013). With a volumetric calculation using optical scanning of the mucosa profile before and after soft tissue conditioning it was shown that the change was more than double compared to the initial profile of the healing abutments (Wittneben et al. 2016). However, the supplemental use of a fixed implant supported provisional is cost- and time intensive. The time investment of the conditioning phase is described with an average of 4 clinical appointments over 145 days (Wittneben et al 2016). The aim of the randomized clinical trial in **chapters 1 and 2** was therefore to determine whether the use of a fixed implant-supported provisional crown leads to an esthetic benefit on implant crowns in the esthetic zone up to three years (Furze et al 2016 and 2019).

After one- year patient cohort group including a fixed implant- supported provisional crown showed statistically significant higher modPES (modified pink esthetic score) and WES (white esthetic scores) compared with the cohort group without provisionalization. After three years modPES index was still significantly higher, especially in the papillae sites in the group including a provisional phase, however after three years the WES index was no longer statistically significant different.

The RCT also concluded up to three years that the mean marginal bone loss between time of delivery of final crown and 3- year follow up was: group 1: 0.05mm; group 2: 0.04mm, without being statistically significant. The provisional phase had no impact on the crestal bone changes. Summarizing from **chapter 1 and 2** it is recommended to use a fixed implant supported provisional in esthetic sites using the «dynamic compression technique» (Wittneben et al 2013) as it improves the overall final esthetic outcome significantly (Furze et al 2016, Furze et al 2019).

An ideal esthetic outcome of implant supported restorations is a combination of pink and white esthetics. The pink esthetic is defined on the outcome of the peri-implant soft tissue and the white esthetic on the esthetic outcome of the crown itself (Belser et al. 2009b; Furhauser et al. 2005). This is evaluated using esthetic indices.

In order to qualitatively assess esthetics in clinical studies and to be able to compare the results among the existing literature the aim of the study in **chapter 3** was to compare three esthetic indices. Next to PES/ WES index we also used the peri-implant and crown (PICI) index, a new esthetic index which was introduced and also compared within the study. This new esthetic index is using a visual analogue scale (VAS) for the evaluation of esthetics- this is advantageous as many clinical studies are also including patient perception of the final esthetic outcome evaluated with VAS.

This way the esthetic outcome can then be statistically compared with the patient perception and the expert opinion measured both with VAS.

The reproducibility of the three esthetic indices was evaluated and the level of clinical acceptance described. We aimed to assess the influence of the examiner's dental specialty compared with the views of lay people and the patients themselves.

The conclusion is that PES/WES and PICI are reproducible esthetic indices that are not influenced by different observers and present similar outcomes in the overall

esthetic evaluation. Both are recommended for clinical studies (Tettamanti et al 2016). The use of ICAI index may be questionable as it has the lowest reproducibility with significantly lower clinical acceptance in all four groups and in both evaluations (Tettamanti et al 2016).

One of the most influencing aspects regarding the esthetic outcome of the future implant crown appearance within the prosthetic workflow remains the choice of abutment. Different prosthetic workflows are available to finalize an implant supported crown. The evolution of ceramic materials, development of implant components and CAD/CAM (Computer Aided Design/ Computer Aided Manufacturing) processing have made it possible that high-strength ceramic materials like zirconium dioxide can be manufactured.

Zirconium dioxide is a material which is characterized by a dense, monocrystalline homogeneity with low corrosion potential and good radiopacity (Manicone et al. 2007). As an abutment material zirconium dioxide has advantages such as excellent biocompatibility, less prone to plaque accumulation compared to titanium (Degidi et al. 2006; Hisbergues et al. 2009; Rimondini et al. 2002; Scarano et al. 2004), less mucosa shine-through, a soft tissue adhesion which is at least as good as titanium (Cooper et al. 2015; Ishikawa-Nagai et al. 2007; Jung et al. 2007; Nakamura et al. 2010; Nothdurft et al. 2014; van Brakel et al. 2012) and the overall „whitish“ appearance.

Zirconium dioxide abutments can be either made of a standard premanufactured design or individualized using CAD/CAM processing technology. The aim of the randomized multicenter clinical trial presented in **chapters 4 and 5** was to compare the overall clinical performance -up to three years- between individualized CAD/CAM abutments veneered with the hand layered technique and prefabricated zirconium dioxide abutments veneered with pressed ceramics to restore implants inserted in single-tooth gaps in the anterior maxilla (Wittneben 2017, Wittneben 2020).

After three years Group A (prefabricated zirconia abutment with pressed ceramic) exhibited one drop-out patient and one failure resulting in a survival rate of 89% after and two failures for Group B (individualized CAD/CAM zirconia abutment with the hand layered ceramic) (90%) (Wittneben 2020).

Clinical parameters documented healthy peri-implant soft tissues. No crestal bone level changes were assessed (mean DIB of 0.13 mm (Group A) and 0.24 mm (Group

B)). There were no significant differences at baseline, 6 months and 1 and 3 years for DIB values between the two groups. PES/WES index presented pleasing esthetic outcomes evaluated at all three time follow-ups. After three years it was concluded that both implant supported prosthetic workflows represent a valuable treatment option for the restoration of implant crowns in the esthetic zone (Wittneben 2020).

Another factor influencing the long-term success of the final esthetic outcome focusing on implant supported crowns is the vertical eruption of neighboring natural teeth in the anterior maxilla. Therefore, the aim of the prospective clinical trial presented in **chapter 6** was to evaluate the possible vertical eruption of anterior maxillary teeth which were adjacent to single implant crowns up till 3 years after implant restoration. Vertical changes of 60 anterior maxillary teeth which were adjacent to 30 implant crowns were assessed by measuring periapical radiographs and casts after baseline, 6, 12 and 36 months. The range of patient age was 23-79 years and mean age at one week after insertion of the final implant-supported crown was 48.4 years. It was concluded that continuous vertical tooth eruption next to a single dental implant was observed with statistically significant findings in the adult patient. Which means that age cannot protect us from vertical growth of natural teeth, this may be disadvantageous for the long-term stability of the final esthetic outcome and should be communicated with patients in order to lower patient expectations.

The aim of achieving the most pleasing esthetic outcome in the field of implant prosthodontics naturally should include patient's perception. Today Patient Reported Outcome Measures (PROMS) are commonly used in clinical studies. The final aim of this thesis was therefore to determine how satisfied the patients are regarding the esthetic outcome of implant supported compared to tooth supported bridges focusing on partially edentulous sites in **chapter 7** and single crowns (SC) in **chapter 8**.

A systematic review and meta-analysis identified 16 publications (19 study cohorts) in **chapter 7** for implant-supported prostheses focusing on patient-reported outcomes on implants, however for tooth supported prostheses, no studies could be included. Of 816 implant-supported reconstructions which were evaluated by patients the overall esthetic assessment by the patients' visual analogue scale (VAS) rating was high in implant-supported FDPs (median 90.3; min-max: 80.0-94.0) and the surrounding mucosa (median: 84.7; min-max: 73.0-92.0) (Wittneben et al 2018).

Focusing on single crowns a systematic review and meta-analysis included 18 studies (23 relevant study cohorts) in **chapter 8**. PROMs data of 1122 implant-supported SCs assessed by 903 patients revealed a mean VAS value of 89.5% (80.0-94.0%). 201 patients evaluating the esthetic outcome of 486 tooth-supported SCs with a mean of 94.4% (92.3- 96.0%).

Patients' perception on esthetics focusing on crowns supported by teeth and implants just failed being statistically significant different.

In conclusion of both meta-analysis it can be stated that patients are highly satisfied with the esthetic outcome of their implant- and tooth- supported restorations.

It may be interpreted that patients are more satisfied with the overall esthetic outcome in comparison to the high expectations of the professional clinician treating the patient. Which is a good sign because it should be aimed that the clinician has higher standards in order to achieve the perfect esthetic outcome and the patient finally will be greatly satisfied with the treatment. However, achieving a perfect esthetic result is still challenging: it is time consuming, cost intensive and needs more education for the treating clinician and usually more risks are involved. Concepts which are easier, faster and less cost intensive are aimed to be investigated in the future. However first we need to address how to achieve the ultimate esthetic outcome and which factors influence the result before we can start inventing easier concepts.

Overall this thesis was able to present real factors influencing significantly the esthetic outcome of implant support reconstructions which were assessed by two randomized clinical studies (one multicenter study) plus a prospective study. Objective indices were evaluated to be suitable for clinical investigations and a new esthetic index introduced. Patient perception data was extracted from the existing evidence via two meta-analysis.

Focusing of the aim of future studies the esthetic outcome on long term results of hard and soft tissues changes around implants should be investigated and also to create faster and less complex treatment concepts aiming to achieve the same esthetic outcome and precision.



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# Appendices

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# About the author

PD Dr. med. dent. Wittneben, MMedSc (born 26<sup>th</sup> of June 1979) is a Swiss and German citizen with two daughters (Emilia and Naomi) living in Basel, Switzerland.

Since 2008 she is a Senior Lecturer and Research Associate at the Department of Reconstructive Dentistry and Gerodontology at the University of Bern, Switzerland. She is a part-time faculty member at the Harvard School of Dental Medicine, Department for Restorative Dentistry and Biomaterials Sciences in Boston, USA.

She received her degree and doctorate from University of Witten/Herdecke in Germany. PD Dr. Wittneben completed a three-year postgraduate specialization training in Prosthodontics at Harvard School of Dental Medicine and holds a Master of Medical Science from Harvard University.

She was awarded with the Joseph L. Henry Award for "Overall Achievement in Clinical and Research Training and Contribution to the University" from Harvard University.

2011 she was appointed Visiting Assistant Professor at both Harvard and Tufts University, Boston USA.

PD Dr. Wittneben actively participates in research related to prosthodontics, CAD/CAM and implant supported prosthetics and is publishing in international peer reviewed journals. She is the author of the 6th ITI Treatment Guide Book focusing on extended edentulous spaces in the esthetic zone, which has been translated into 8 languages.

She is a Fellow and Speaker of the International Team for Implantology (ITI) and a member of the European Association for Osseointegration (EAO), American College of Prosthodontists (ACP), the Swiss Dental Association (SSO) and Swiss Society of Reconstructive Dentistry (SSRD).