# BJÖRN GJELVOLD <br> ON THE CLINICAL OUTCOME OF DIFFERENT SINGLE IMPLANT TREATMENT MODALITIES 



MALMÖ UNIVERSITY

ON THE CLINICAL OUTCOME OF DIFFERENT SINGLE IMPLANT TREATMENT MODALITIES
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# BJÖRN GJelvold <br> ON THE CLINICAL OUTCOME OF DIFFERENT SINGLE IMPLANT TREATMENT MODALITIES 

Malmö University, 2020<br>Faculty of Odontology<br>Department of Prosthodontics<br>Malmö, Sweden

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I may not have gone where I intended to go, but I think I have ended up where I needed to be.

This thesis is number 56 in a series of investigations on implants, hard tissues and the locomotor apparatus originating from the Department of Biomaterials and the Department of Prosthodontics, University of Gothenburg, the Department of Prosthetic Dentistry/Material Sciences the Department of Oral \& Maxillofacial Surgery and Oral Medicine, Malmö University.

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## LIST OF PUBLICATIONS

This dissertation is based on the following publications, which will be referred to in the main text by their Roman numerals. The papers are appended at the end of the thesis.
I. Gjelvold B, Chrcanovic B, Bagewitz IC, Kisch J, Albrektsson T, Wennerberg A. Esthetic and patient-centered outcomes of single implants: A retrospective study. Int J Oral Maxillofac Implants 2017;32(5):1065-1073.
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III. Gjelvold B, Mahmood DJH, Wennerberg A. Accuracy of surgical guides from 2 different desktop 3D printers for computed tomography-guided surgery. J Prosthet Dent 2019;121(3):498-503.
IV. Gjelvold B, Kisch J, Chrcanovic B, Mahmood DJH, Albrektsson T, Wennerberg A. Immediate loading of single implants, guided surgery and digital impression: a nonrandomized study. In press.

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THESIS AT A GLANCE

| I | To retrospectively evaluate the outcome of conventional single <br> implant treatment and the use of narrow diameter dental <br> implants in a young cohort. Focusing on survival, patient <br> satisfaction, clinical and aesthetic outcomes. |  |
| :--- | :--- | :--- |
| II | To evaluate the overall treatment outcome following two <br> different treatment procedures for single dental implants. A <br> randomized clinical trial of immediate and delayed loading of <br> single dental implants with a l-year follow-up | To evaluate the deviation in single dental implant position <br> following the use of surgical guides fabricated from two <br> different desktop 3D printers in a guided surgery procedure. |
| IV | To evaluate the overall treatment outcome of single dental <br> implants installed with the assistance of fully guided surgery, <br> submitted to immediate loading and with the use of intraoral <br> scans to facilitate the workflow. |  |

## ABSTRACT

Today there are several treatment techniques available to replace a missing tooth. Since the beginning of the 1990s, it has become increasingly common to treat individual tooth loss with dental implants. Important patient factors are survival, success, functionality, aesthetics, oral health and quality of life.

The range of indications and possibilities for implant treatment has broadened compared to the originally proposed treatment indications. A variety of methods, components and materials are available today. Improvements of the implant surface have led to shorter healing periods, which has affected the overall treatment time. Methods for computer-assisted implant planning and surgical guides have been developed to improve treatment planning. Several techniques are involved in the manufacturing of implant-supported single crowns, from the traditional plaster models, wax, casting and porcelain veneering to 3 D scanning, computer aided design and manufacturing. It is important that all these treatment modalities are evaluated in a systematic and scientific way to ensure that the treatment given is the best one possible according to the individual conditions that exist.

The general aim of this project was to evaluate the treatment outcome between different treatment modalities for single dental implants. Study I aims to retrospectively evaluate implant survival. Patient reported outcome measures, marginal bone loss (MBL), clinical and esthetic outcomes following conventional single implant treatment. The aim of study II, a prospective randomized clinical study, was to compare the overall treatment outcome following immediate loading (IL) and delayed loading (DL) of single implants. In study

III the aim was to in a vitro setting evaluate the deviation in final dental implant position after the use of surgical guides fabricated from two different desktop 3D printers using a digital workflow. For study IV the aim was to, in a non-randomized study, compare clinical and aesthetic outcomes between immediately loaded single implants placed with and without a fully guided-surgery procedure (DIL).

In study I a total of 85 implants were examined after a mean follow-up time of 7.51 years. The 5 -year implant survival rate was $98.4 \% ~(95 \%$ CI: $96.3 \%-100 \%$ ), with a crown survival rate of 91.8\% (95\% CI: 86.3\%-97.3\%). Overall mean MBL was -0.13 mm. Final and initial total Pink esthetic score (PES) were 9.61 and 11.49 (P <.001) Mean White esthetic score (WES) was 6.48 at final follow-up. Visual analog scale (VAS) score for soft tissue and implant-supported crown aesthetics were 73.5 and 82.1 (maximum score 100). A oral health impact profile-14 (OHIP-14) 14 score of 16.11 was observed at the final follow-up.

Study II and IV found implant survival rates of $100 \%, 96 \%$ and $90.5 \%$ for IL, DL and DIL, respectively, after 1-year. No statistically significant differences were found for MBL, PES, WES and OHIP-14 after 1-year. Statistically significant lower papilla index scores were found for the IL. Overall statistically significant improvement in PES, WES and OHIP-14 were found over time. In the DIL group a moderate correlation between aesthetics and deviation in fixture position was found.

For Study III a statistically significant difference between stereolithography and direct light processing (DLP) was found for deviation at entry point ( $P=.023$ ) and the vertical implant position ( $P=.009$ ). Overall lower deviations were found for the guides from the DLP printer, with the exception of deviation in horizontal implant position.

The results from these studies suggest that good clinical results can be achieved with different treatment modalities for single implants. Positive advantages with immediate loading and guided surgery is primarily seen in the early faces of the treatment procedure only. Care needs to be exerted with technically complicated treatment procedures as the effect on implant survival should not be underestimated.

Further studies have to be performed to evaluate guided surgery and immediate loading to identify possible factors effecting survival.

## POPULÄRVETENSKAPLIG SAMMANFATTNING

Det finns idag flera behandlingstekniker för att ersätta en förlorad tand. Sedan början av 1990-talet har det blivit allt mer vanligt att behandla enstaka tandförluster med tandimplantat. Behandlingen består av att ett titanimplantat som installeras och sedan integreras i benet i det aktuella området. Därefter förses titanimplantatet med en individuellt utformad tand, oftast i ett keramiskt material. Behandlingens ökande popularitet beror delvis på en god långsiktig hållbarhet. Tidigare var det framförallt fokus på behandlingens funktionalitet, men på senare tid har fokus ökat kring det estetiska utfallet samt blivit ett område för ett flertal vetenskapliga publikationer. Även forskning kring implantatbehandlingens påverkan på patientens orala hälsa och livskvalité har blivit allt mer vanligt. Från patientens/samhällets sida har allt högre förväntningar och önskemål om inflytande på behandlingen ökat.

De indikationer som patienter i dag får implantat för har förändrats jämfört med tidigare. Det har tagits fram ett flertal olika behandlingsmetoder, komponenter och material för att ersätta en tand eller tänder med hjälp av implantat. För tandimplantat idag finns det ett stort utbud av både tillverkare och modeller. Förbättringar av implantatytan har medfört kortare inläkningstider, något som har påverkat behandlingstiden. Det har visat sig att även implantat som belastas direkt med en tandersättning efter det kirurgiska ingreppet är möjligt. Kirurgiska tekniker och metoder för att ersätta förlorat ben har förbättrat förutsättningarna för var det är möjligt att placera implantat. Även datorstödda implantatplaneringar och
kirurgiska operationsguider har utvecklats i syfte att kunna bättre planera behandlingen.

Flera tekniker för framställande av den tänkta tandersättning som monteras på implantatet finns i dag. Utvecklingen har gått från arbete med gipsmodeller, vax, gjutning och porslin till 3D scanning, datorstödd design och tillverkning.

Det är viktigt att denna utveckling och förändring utvärderas kontinuerligt på ett systematiskt och vetenskapligt sätt för att säkerställa att den behandling som patienter erhåller blir bästa möjliga efter de individuella förutsättningar som finns. Utvärdering utförs både i form av laboratorie- och kliniska studier. Det kliniska utfallet kan utvärderas utifrån ersättningens överlevnad över tid, estetik, oral hälsa och livskvalité. Många utvärderingstekniker och kriterier har tagits fram för dessa ändamål. Det är viktigt att forskning och utvärdering utförs så standardiserat som möjligt så att resultaten kan jämföras.

Tre av avhandlingens studier har tittat på utfallet för olika behandlingstekniker vid behandling av entandsluckor med tandimplantat. Fokus har varit implantatöverlevnad, mjukvävnad, estetik, oral hälsa och livskvalité. Den första studien undersökte behandlingsutfallet för konventionell implantatbehandling hos en grupp unga patienter. Två studier med vardera ett års uppföljning har utvärderat utfallet för tre olika behandlingstekniker: konventionell behandling, direkt belastning och guidad kirurgi i kombination med direktbelastning. En studie i avhandlingen har fokuserat på att utvärdera hur bra två olika 3D printrar är på att framställa kirurgiska guider.

Avhandlingen visar endast på små skillnader mellan de olika behandlingsteknikerna vad avser benförluster kring implantaten, estetik, oral hälsa och livskvalité. Resultaten visar att det finns en risk för sämre överlevnad vid mer teknisk krävande behandling, så som digital planering med guidad kirurgi i kombination med direktbelastning av implantat, men också att den guidade tekniken kan ha vissa fördelar när det kommer till tandköttets utseende/läkningsprocess i det tidiga skedet av behandlingen. Dock ses ingen skillnad mellan teknikerna efter ett år. 3D printing har potential att kunna framställa kirurgiska guider med hög precision och 3D scanning går även att använda som hjälpmedel för att efter behandlingen utvärdera tandimplantatets position i relation till den datorplanerade positioneringen.

## ABBREVATIONS AND DEFINITIONS

2D
3D
Accuracy

CAD
CAM
CBCT
CMM
DLP
DOP
dzyz
FDI

GI
IOS
MBL
Ncm
OHIP
OHRQoL
PD
PES
Precision

Two-dimensional
Three-dimensional
ISO 5725 definition, involves two components, precision and trueness.
Computer aided design
Computer aided manufacturing
Cone beam computer tomography
Coordinate measuring machine
Direct light processing
Bleeding on probing
Distance between two points in a xyz space
Fédération Dentaire Internationale (FDI) notation system, ISO 3950
Gingival index
Intraoral scanner
Marginal bone loss
Newton centimeter
Oral health impact profile
Oral health related quality of life
Probing depth
Pink esthetic score
Refers to the closeness of agreement between test results.

| PROMs | Patient reported outcome measures |
| :--- | :--- |
| RCT | Randomized controlled trial |
| RMS | Root mean square |
| SLA | Stereolithography |
| Trueness | Refers to the closeness of agreement between the <br> arithmetic mean of a large number of test results <br> and the true or accepted reference value. |
|  | Visual analog scale |
| VAS | White esthetic score |

## INTRODUCTION

## Dental implants

The introduction of titanium implants in dentistry is by far one of the major advances in dentistry in recent time. The implants evolved from experimental research to a predictable treatment for the replacement of missing teeth. Dental implantology has advanced as an established area of research in dentistry, with the 100 most cited papers on implantology being ranked second after periodontology. ${ }^{1}$ Two pioneers of implant dentistry were P.I. Brånemark from the University of Gothenburg and A. Schroeder from the University of Bern, who independently of each other established the scientific basis for modern implant dentistry. P.I. Brånemark operated his first patient in 1965, using the machined surface commercially pure titanium dental implants, see Figure 1.


Figure 1. The machined surfaced commercially pure titanium dental implant used by P.I. Brånemark in human trials since 1965. The design of the depicted implant was introduced during the 1970s.

The possibility to replace missing teeth with implant-supported reconstructions have benefitted many patients worldwide. The use of titanium dental implants were first introduced in edentulous jaws, the range of indications have since then broadened. The dental implant primary function is to act as an anchoring element for a prosthetic restoration, may it be a removable denture or a single tooth restoration. Indications for treatment can be to restore dental aesthetics, chewing, speech, occlusal stability and patient comfort. ${ }^{2}$ Long-term evaluations of dental implants report high success and survival rates from $94 \%$ after 10 years with minimal marginal bone loss (MBL) and $87.8 \%$ after 36 years of follow-up. ${ }^{3,4}$ It has been suggested that a multidisciplinary approach is beneficial for a successful implant treatment outcome for some patient categories. ${ }^{5}$ Patients with congenital absence of teeth is one such group.

Common for today's dental implant systems is that they consist of an implant body that interacts with the bone, a transmucosal component and restorative part. Dental implants can consist of an integrated transmucosal part that protrudes above the crestal bone often referred to as tissue-level. The other variation is the so-called bone-level that is fully inserted into the bone, se Figure 2. For the twopiece implants a separate abutment is connected, either integrated into the implant-supported crown or as a separate abutment. ${ }^{2}$ The implant restoration can be screw- or cement retained, see Figure 3.


Figure 2. A: Implant-supported single crown, B: Tissue-level implant, C: Abutment, D: Bone-level implant


Figure 3. A: Cement retained implant-supported single crown, B: Abutment, C: Screw retained SC, D: Dental implant

Development in dental implant design, supra-construction materials and fabrication techniques have led to a positive impact on the clinical outcome. ${ }^{6}$ The implant body usually has a cylindrical design. The thread design can vary significantly between manufacturers, serving different intended purposes such as improved primary stability, distributing load, bone compression or preservation of cortical bone. ${ }^{7}$ Surface modification of titanium implants has been intensely researched resulting in the development of surfaces that promote bone integration and an earlier bone-to-implant contact percentage. ${ }^{8}$ The move from a turned machined to a moderately rough surface did improve survival rates of implants installed in the maxilla. ${ }^{9}$ A majority of dental implants today have a moderately rough surface.

However, despite the development and increased success of dental implants one should always strive to keep natural teeth and if needed strive to perform the treatment and maintenance needed for them to be maintained. Taking biological and technical complications into considerations, dental implants are not close to the excellent survival rates of natural teeth. ${ }^{10}$ Every clinician should keep in mind that dental implants do not replace teeth, they simply replace missing teeth.

As we continue to replace missing teeth with dental implants, it should be self-evident to be rigorous and to continuously evaluate the process of replacing missing teeth. In the evaluation of different treatment protocols, materials, surfaces and designs we can find
indications of progress and areas for further improvement. Creating a sound scientific foundation is, therefore, of great importance. To improve our understanding of dental implants and the many available treatment modalities we need first to understand the different methods of evaluation.

## Evaluation of dental implants

Several ways of treatment evaluation have been developed ranging from implant survival to patient reported outcome measures.

## Survival and success

The traditional principle of evaluating dental implants concerning success, survival, failure and unaccounted for proposed by Albrektsson et al. ${ }^{11,12}$ is still commonly used, see Table 1.

Table 1. Four-field table

| $\mathbf{8 0 \%}$ | $\mathbf{4 \%}$ <br> Ss=Success |
| :---: | :--- |
| $\mathbf{1 0 \%}$ | U=Unaccounted for |
| Si=Survival | F=Failure |

Success, a defined criteria for marginal bone loss over time, stated as a maximum 1 mm of bone loss during the first year and $<0.2$ mm annually thereafter. In addition absence of implant mobility, peri-implant radiolucency, pain and infection. One should keep in mind that these criteria require a baseline radiograph and subsequent follow-up radiographs. Survival is of a lower order than success and says nothing about the quality of survival. Important parameters in a dental implant cohort are the number of failures and the unaccounted for implants. The higher the number of unaccounted for implants, the higher is the level of uncertainty for all study outcomes.

## Marginal bone loss

Marginal bone loss (MBL) is maybe the most commonly used parameter in dental implantology. The evaluation is dependent on radiographic examinations of the dental implant and the subsequent measurements of the marginal bone levels (see Figure 4).


Figure 4. A: Marginal bone level at fixture installation (baseline). B: Marginal bone level at 5 year follow-up examination (follow-up).

However, there are some aspects that should be kept in mind when reading scientific reports. Implant associated MBL is an evaluation over time and therefore the timespan and baseline are of importance when comparing different results. Consider a hypothetical study with a baseline radiographic evaluation at the time of prosthetic reconstruction and a follow-up examination after 1-year that yields a mean bone loss of 0.1 mm , which by all means is a satisfying result. However, we would be unaware if any bone loss had occurred prior to the time of prosthetic reconstruction. Let us say the mean marginal bone level was 3.0 mm at the prosthetic baseline in contrast to zero mm at fixture installation. This together with information about the surgical protocol would indeed be valuable facts when interpreting the research, Figure 5. Therefore, both accounting for the marginal bone level and MBL is of value.

One should, in addition, pay attention to the measurement reference points. The most commonly used ones are the implant shoulder or the junction between the dental implant and the prosthetic reconstruction. Deliberately using a more apical reference point and only reporting bone loss below that reference point would give us a completely different picture of the same study, see Figure 6.


Figure 5. The same patient as in figure 2, now presenting a more optimistic out-come with the delivery of the prosthetic restoration as baseline. A: Marginal bone level at delivery of the implant-supported single crown (baseline). B: Marginal bone level at the 5 year follow-up (follow-up).


Figure 6. Same patient as in figure 2 with different reference points for measure-ments. A: Baseline. B: Marginal bone level at the 5 year follow-up (follow-up).

Peri-implant soft tissue health
Probing depth (PD) and bleeding on probing (BOP) are clinical parameters commonly used to monitor the health of the peri-implant tissues. ${ }^{13}$

Probing depth needs a baseline measurement for subsequent measurements to be of any clinical value. Bleeding on probing (BOP) is a diagnostic parameter defined as the presence of bleeding after the probing with a periodontal probe into the peri-implant sulcus. The absence of BOP has been suggested by some as a reliable indicator for periodontal stability. ${ }^{13}$ However, mean BOP and PD do not display any correlation with MBL, nor can these indices serve as tools to study peri-implantitis. ${ }^{14}$

The ginigiva index (GI) proposed by Löe et al. ${ }^{15}$ in 1963 is often used to document the status of health or inflammation in peri-implant soft tissue. However, evidence is missing to support any correlation between MBL and GI.

## Peri-implant soft tissue

Besides the evaluation of peri-implant tissue health and MBL, other clinical parameters have been used to evaluate regeneration of the peri-implant soft tissue. The papilla index was proposed by Jemt et al. ${ }^{16}$ in 1997 for the evaluation of recession and regeneration of gingival papilla at single implant sites. The index consists of a five point scale ranging from 0 to 4 . Several factors such as underlying bone support, periodontal biotype, biofilm, tooth morphology and contact points do effect the regeneration of gingival papilla. I addition several treatment techniques has been suggested for conditioning the soft tissue to achieve more predictable or improved results, especially through the use of temporary restorations. ${ }^{17-19}$

The monitoring of soft tissue changes around dental implants has historically been conducted with morphometric analysis, ${ }^{20,21}$ either two-dimensional (2D) or three-dimentional (3D). They are commonly used to monitor changes in papilla and gingival zenith position over time or between two different treatments. 3D analysis could be used to calculate volume changes between two superimposed 3D surfaces. 3D analysis and best-fit alignment will be covered later on.

## Aesthetic evaluation

As treatment outcome progressed along with biological understanding, material development, dental implant design, and treatment protocols the possibility for an improved aesthetic outcome increased, leading to an increased aesthetic focus by the mid-1990s. ${ }^{2}$

Objective parameters such as presence or absence of the papilla, mucosal margin shape, reconstruction colour and shape has been used to evaluate the aesthetic outcome. ${ }^{22,23} \mathrm{~A}$ recent systematic review of the parameters and methods for the professional evaluation of aesthetics found a great diversity in parameters, methods and measuring units. ${ }^{24}$

Aesthetics is a frequent research topic and several are the number of proposed ways to evaluate aesthetics, see Table 2. A reason for this popularity could in part be that aesthetic outcome has been reported to be a motivating factor for at least $20 \%$ of implant patients. ${ }^{25}$ Symmetry in the dental arch is one among several important aspects when patients report aesthetic outcome. ${ }^{26}$ Not only short term aesthetic results should be considered. For certain patient groups, particularly patients treated early in life, a long lasting aesthetic outcome may be of particular importance. Implant infraposition is one of several factors that could impact the long term aesthetic outcome. ${ }^{27-29}$ Fürhauser et al. ${ }^{22}$ introduced the pink esthetic scale (PES) focusing on soft tissue aesthetics. The scale consist of seven variables focusing on dental papilla, shape, color and texture, with a total index score ranging from 0 to 14 . Belser et al. ${ }^{23}$ proposed the pink and white esthetic scale (PES/WES). The WES, for the evaluation of the dental restoration, ranges from 0 to 10 and focuses on five variables to evaluate how well the restoration blends in. To note is that the PES proposed by Belser et al. has a score range from 0 to 10 . Table 2 gives an overview of some commonly used aesthetic scales.

Others have defined (almost) perfect aesthetic outcome as PES $\geq$ 12 and WES $\geq 9$ and aesthetic failure as PES $\leq 7$ and/or WES $\leq 5 .{ }^{30}$

Table 2. The most commonly used dental implant aesthetic indexes
$\left.\begin{array}{llll}\hline \text { Index } & \text { Reference } & \text { Abbreviation } & \text { Score } \\ \hline \text { Fürhauser et al. 2005 } & \text { P2 } & \text { Pink esthetic score } & \text { PES }\end{array}\right] 0-14$.

## Patient reported outcome measures

The objective scales like PES and ICEI do not take into account the patients' perspective. Improving patient satisfaction is of vital importance for many dental treatments and should be in focus when evaluating different treatment protocols for dental implants. ${ }^{34}$ The term PROMs (patient reported outcome measures) is intended to include patients' perceptions on oral health related quality of life (OHRQoL), satisfaction with oral care or oral health and other assessments. ${ }^{35}$ PROMs have generally been underexposed in implant prosthodontics, despite a recent increase in publications on the subject. ${ }^{36}$

The ITI consensus report on the subject comes with a recommendation that PROMs should be included in every clinical study reporting on the outcomes of oral rehabilitation with dental implants. ${ }^{34}$

OHRQoL can be assessed by the oral health impact profile (OHIP) questionnaire, originally developed by Slade and Spencer. ${ }^{37}$ The questionnaire has been adapted and validated in many countries, among those Sweden. ${ }^{38}$ Commonly used in implant dentistry are the OHIP-14 or OHIP-49 questionnaires. In the questionnaires psychological, physical and social impacts on OHRQoL are included. Another questionnaire is the Orofacial Esthetic Scale (OES), developed for the purpose of measuring self-reported orofacial aesthetics in patients with prosthodontic concerns. ${ }^{39}$ The aim of these questionnaires is to provide a standardized assessment method for PROMs that can be used in both research and daily practice.

The use of visual analog scales (VAS) in dentistry originates from the work of Aitken ${ }^{40}$ in the field of phsychology and has been commonly used to evaluate patients' feelings or experience, such as satisfaction, pain and discomfort. The VAS scale consist of a 100 mm line, with one end of the scale consisting with minimal subject experience and the other maximal. The patients then mark their degree of experience. VAS scales have been used in several studies evaluating dental implant restorations and soft tissue. ${ }^{41}$ However, clinicians have been more critical concerning the aesthetic outcome than patients have. There are some issues with the use of VAS scales in research, especially the difficulty to compare results with other studies and therefore there is a need of more standardised approaches. ${ }^{35}$

## 3D measurements

Intraoral scanner (IOS) devices are by definition a 3D scanner used for digital impressions of the oral cavity by optical means and its area of application and availability has increased. ${ }^{42} 3 \mathrm{D}$ scanning is not only an excellent tool for restorative impressions, but serve well for research purposes. Peri-implant soft tissue monitoring and computer guided surgery are some of the other areas where the technology is used besides prosthodontics. ${ }^{21,43}$

Metrology is the science of measurement, 3D measurements or 3D metrology is the utilization of a 3D scanner to acquire a multitude of $\mathrm{X}, \mathrm{Y}, \mathrm{Z}$ coordinates on the surface of a physical object. ${ }^{44}$ These coordinates offers a comprehensive definition of a physical object that is used for measurement. The multitude of measuring points in a $\mathrm{X}, \mathrm{Y}, \mathrm{Z}$ coordinate system makes up a what is referred to as a point cloud. Point clouds are used for many purposes and are often converted into to a polygon mesh that makes up a 3D object. ${ }^{45}$ IOS unites serve to enquire these 3D objects (see Figure 7) as do computer tomography and dental laboratory scanners.


Figure 7. IOS 3D dataset of a maxillary dentition. Capturing tooth and gingiva form.

## Accuracy: precision and trueness

The terms precision and trueness are in research commonly referred to when evaluating IOS systems and their accuracy. Of basic importance is to know the definition of accuracy. In the ISO 5725 definition,
accuracy involves two components, trueness and precision. ${ }^{46}$ With a set of measurements, trueness is the mean value closeness to the actual (true) value. More simply explained, we know that a piece of metal is exactly 100 mm (true/reference value). We measure it 5 times with an mm ruler that results in a mean value of 100.05 mm . The trueness for the mm ruler would then be 0.05 mm . Precision is the closeness of agreement between the set of measurements. According to this definition high trueness and precision is therefore a requirement for high accuracy, see Figure $8 .{ }^{47}$


Figure 8. Illustration of A: Good precision and poor trueness. B: Poor precision and good trueness. C: Good precision and trueness. ${ }^{47}$

Closely linked to the metrology of precision is repeatability and reproducibility. Repeatability practices were introduced by Bland and Altman in 1983.48 and are the closeness of agreement between the results of successive measurements. For establishment of repeatability, the conditions of the experiment must be kept the same. Reproducibility on the other hand refers to the ability to replicate the findings of others.

In clinical research trueness is often and in many cases not possible to measure, this can be because the absolute true value of a patient maxillary arch shape is not possible to measure in a clinical setting. The clinical evaluation of IOS units is one such example. When evaluating IOS and conventional impressions with regard to trueness, there need to be an additional measuring method more accurate than the two to evaluate the trueness of the respective method. Something that is often easier to aquiver in a laboratory study setup. The output from a coordinate measuring machine (CMM), a highly accurate measuring instrument, could and are often used as the true value reference. ${ }^{49}$

## Euclidean distance

Every point that makes up a 3D object is determined by three coordinates ( $\mathrm{X}, \mathrm{Y}, \mathrm{Z}$ ) in what could be referred to as 3D Euclidean space. The distance between two points on a single 3D object or between two different 3D objects is referred to as the Euclidean distance. ${ }^{50}$ The following calculation would therefore be appropriate, see formula 1.

$$
d x y z=\sqrt{\left(x_{1}-x_{2}\right)^{2}+\left(y_{1}-y_{2}\right)^{2}+\left(z_{1}-z_{2}\right)^{2}}
$$

Formula 1. dxyz = distance between two points in a xyz-space (3d space), where X 1 is the first coordinate of the first point, X 2 is the first coordinate of the second point, $y$ second coordinate and $z$ third coordinate.

## Alignment of $3 D$ surfaces

For several examinations and evaluations there is a need to align two models in the same coordinate system. ${ }^{44,45,51}$ Several alignment methods are available for 3D coordinate metrology and will serve different purposes. One method commonly used in dentistry is the best-fit alignment. The alignment process minimizes the distance of every selected measured point to its reference. Root mean square (RMS) is a standard mathematical tool and can be used to determine how the deviation between 3D datasets is different from zero. ${ }^{52} \mathrm{~A}$ low RMS value indicates a high degree of similarity of the superimposed datasets.

## The single missing tooth and dental implants

There are today a variety of therapeutic options available to replace a missing single tooth, removable partial denture, resin-bonded bridge, fixed partial denture and implant-supported single crown (SC), see Figure 9.


Figure 9. A: Fixed dental prosthesis 23 to 25. B: resin-bonded bridge 12. C: Implant-supported SC 25.

The choice of treatment should always be based on clinical and radiographic assessments, as well as on the patient's wishes. Bone volume, aesthetic demands, soft tissue thickness, restored or intact neighbouring teeth, patient hygiene and cost are some of many factors that have an impact on the patient specific treatment of choice. ${ }^{17,53-55}$

Replacing a single missing tooth with titanium implants was described by Jemt et al. ${ }^{56}$ in the early 1990's. Today single implants and implant-supported SCs have in many cases become the treatment of choice due to their excellent long-term functional success. ${ }^{3,57}$ In certain situations single implants are considered the most cost-effective alternative compared to fixed partial dentures. ${ }^{58}$

As we continue to replace single missing teeth with dental implants, the diversity of diagnostic considerations and proposed treatment protocols have increased from a surgical and prosthodontic viewpoint. ${ }^{2,59-62} \mathrm{~A}$ trend towards earlier loading and immediate installation. ${ }^{2}$ There has been a comeback for the ceramic implant and an ever increasing range of restorative materials available. ${ }^{2}$ Particularly in the field of prosthetics there is a trend towards increased digitalization. ${ }^{42}$ Computer aided design (CAD) and computer aided manufacturing (CAM) play a larger role in dentist and laboratory technicians daily work with dental implants. ${ }^{42,63}$ Progress has been made with virtual planning software's used for patient communication as well as treatment planning. All of these accompanied with the use of IOS and three dimensional (3D) printing technology, are impacting and changing our clinical workflows. ${ }^{2,42,64}$

## Implant placement after tooth extraction

The surgery protocol for dental implants originate from the traditional guidelines proposed by Brånemark and co-workers for a successful osseointegration. These guidelines recommended a healing period of 8 to 12 months after tooth extraction prior to fixture installation, followed by a unloaded healing period of 3 to 6 month afterwards. ${ }^{65}$ Historically, Brånemark proposed a submerged post-operative healing of the implant and Schroeder a non-submerged healing. ${ }^{2}$ The latter eliminated the need for a second surgery appointment before the prosthetic reconstruction could be started, less appointments for the patient, but on the other hand making the dental implant more vulnerable to premature or undesirable early loading.

As the research progressed on implant surface modifications and bone integration the proposed initial and postoperative healing periods have been shortened. ${ }^{2}$ There are today several therapeutic approaches available for when to proceed with fixture installation following tooth extraction, aiming to limit bone resorption, shorten treatment time and increase treatment predictability. ${ }^{66,67}$ Table 3 outlines the general agreement of therapeutic approaches according to the consensus report and clinical recommendation of the XV European Workshop in Periodontology. ${ }^{66}$

Table 3. Representation of different options following tooth extraction.

| At tooth extraction | Immediate implant placement | Implant placement 0-1 week | With bone regeneration |
| :---: | :---: | :---: | :---: |
|  |  |  | Without bone regeneration |
|  | Alveolar ridge preservation | Implant <br> placement | With bone regeneration |
|  |  |  | Without bone regeneration |
| After tooth e xtraction | Early soft tissue healing | Implant placement 4-8 weeks | With bone regeneration |
|  |  |  | Without bone regeneration |
|  | Partial bone healing | Implant placement 3-4 months | With bone regeneration |
|  |  |  | Without bone regeneration |
|  | Full bone healing | Implant placement $>4$ months | With bone regeneration |
|  |  |  | Without bone regeneration |

## Timing of loading dental implants

Several therapeutic options are available for when to load a dental implant. According an ITI Consensus report ${ }^{68}$ the protocols were defined as follows:
i. Immediate loading: a restoration is connected to the dental implant in occlusion within 1 week following installation.
ii. Immediate restoration: a restoration is connected to the dental implant and not in occlusion within 1 week following installation.
iii. Early loading: the restoration is connected between 1 week and 2 months after installation.
iv. Conventional loading: a healing period of more than 2 months after installation with no connected restoration.

Conventional loading is often referred to as delayed loading and originally the healing period was 3 months in the mandible and 6 to 8 months in the maxilla. The 5 -year survival rate of single dental implants in a conventional loading protocol generally ranges from $95-100 \% .{ }^{69}$ The immediate or early loading of dental implants usually in combination with immediate installation reports a wide range in survival rates, ranging from $83-100 \%$ with great variation in the follow-up period. ${ }^{67,68}$ The choice of treatment should therefore be taken with careful considerations towards associated risks and patient benefits.

## Immediate loading of single implants

Immediate loading is a treatment concept that could be considered an attempt to meet patients' and/or dentists' desire for a shorter treatment. ${ }^{69}$ Among the first reported attempts there were a focus on edentulous mandibles with either fixed or removable restorations. ${ }^{70}$ The results from these early reports revealed challenges in reaching the success and survival of the conventional protocol. With the introduction of moderately rough implants came an improvement in the results, especially in extraction sockets and immediate installation cases. ${ }^{71}$ For single implants and immediate loading the implant survival has been documented with a variation of between 85.7-100\% with a reported follow-up period ranging from 12-36 months. ${ }^{3,69,72,73}$ It should be stressed that even if high survival rates have been reported in several RCT's, more failures are to be expected following
immediate loading of single implants. ${ }^{69,74,75}$ A recent meta-analysis has reported that immediate loading of dental implants statistically significantly effects the failure rate to a higher level then delayed loading. ${ }^{76}$ However, immediate loading does not seem to have any effect on the occurrence of postoperative infection or MBL. ${ }^{76}$ Sufficient primary implant stability, optimal conditions for a biological stabilisation during initial healing, and the avoidance of eccentric load are the main factors that have been pointed out as important to ensure a positive outcome for immediate loading. ${ }^{77-80}$ An installation torque value of 30 Ncm and above has been suggested necessary for immediate loading. ${ }^{81}$

However there can be other positive effects, like post-operative healing and soft-tissue adaptation. Several publications have focused on the aesthetics, soft-tissue, timing of loading and temporary restorations. ${ }^{17,53,54,82}$ The background assumption is that the immediate loading procedure results in less disturbance of the peri-implant soft tissues than in the conventional two-stage protocol and that the restoration itself helps guide the soft-tissue from an early stage in the procedure ${ }^{83}$ Concerning the patients perspective there are reports, despite increased risk for failure, of positive PROMs outcomes. ${ }^{84}$

New dental implants systems are continuously being introduced by the MedTec industry claiming enhanced design features for increased primary stability and consequently better suited for immediate loading, often with limited scientific evidence. Promoting for dentists and patients the possibility of a speedy recovery, commonly without any scientific evidence.

## Computer-guided surgery

Computer-guided surgery helps the clinician to pre-plan and subsequently install dental implants in an optimal position. ${ }^{85-87}$ Prosthetically driven implant surgery and the obvious advantages of correct implant positioning is certainly some of the main reasons for advances in guided surgery from a professional viewpoint. The technology is commonly utilizing a combination of cone beam computer tomography (CBCT), intraoral scans and a computer software. The computer software's does not only help the clinician to plan the designated site for the dental implant, but brings with it the possibility to visualize or fabricate a prosthetic reconstruction. ${ }^{88}$ As well
as being made use of in dentist-patient or dentist-dental technician communication. Such communication and planning can help give the patient better understanding of the suggested treatment and optimize the treatment plan.

Guided surgery can be divided into two main branches, static and dynamic. ${ }^{64}$ The static approach utilizes a surgical template (surgical guide) for the dental implant to reach the desired position. The dynamic approach, often called navigation, uses a navigational system that allows real-time tracing of the surgeons drill in relation to the patient. The main advantage of this system is that it, contrary to the surgical guide, allows intraoperative changes in implant position. Regarding the fabrication of the static surgical guides, one can distinguish between two fabrication methods: additive manufacturing and the use of mechanical positioning devices. ${ }^{89}$

Within the use of surgical guides there are several types of guides dependent on the type of guide support:
i. Tooth-supported surgical guides.
ii. Mucosa-supported surgical guides.
iii. Bone-supported surgical guides.
iv. Mini implant or pin-supported guides.

In addition, the level of guidance can be controlled. Guided osteotomy preparation ranging from pilot drill to increasing drill diameter with freehand implant placement. The fully guided protocol allow guided osteotomy preparation and implant placement. Depth stops can be used to control the drilling depth and installation depth. ${ }^{64}$

As the accuracy of the treatment protocol is essential to prevent damage to surrounding structures, each step in the process needs to be carefully executed. ${ }^{90}$ The level of accuracy is effected by many factors, such as guide support, level of guidance and number of implants. ${ }^{64,91-100}$ Fully guided implant surgery and tooth supported guides are reported to achieve greater accuracy concerning final implant position compared to other guided surgery protocols. ${ }^{91}$

The guided surgery procedure is not without problems, many factors besides support and level of guidance can affect the accuracy of surgical guides. In each step of the procedure, namely CBCT, intraoral scan, software planning, guide design and fabrication, drilling,
errors may influence the overall accuracy. ${ }^{91,92,96-99,101,102}$ A safety distance should therefore be kept during such procedures to surrounding teeth. The European Association for Osseointegration consensus in 2012, states that a mean system error of 1.2 mm in horizontal and 0.5 mm in vertical deviation could be expected. ${ }^{103}$ Figure 10 displays the most common referred to deviation variables concerning fixture placement with guided surgery. ${ }^{92}$

The development of IOS technology and three-dimensional (3D) printing technology have made computer-guided surgery more accessible and less expensive to the dental practice. ${ }^{104}$ IOS is considered as a valid alternative to conventional impressions for such procedures. ${ }^{105}$


Figure 10. A: Deviation at entry point. B: Deviation at apex. C: Angular deviation. D: Deviation in vertical implant position. E: Deviation in horizontal implant position. F: Rotational deviation of the implant hex.

Desktop 3D-printers have been proved capable of manufacturing surgical guides of high accuracy. ${ }^{106,107}$ Further, 3D printed provisional materials have been considered applicable for intraoral use and the
technology has proved capable of producing interim restorations with a good internal fit. ${ }^{108}$

Combining immediate loading with fully guided surgery, IOS and 3D-printed interim restorations seem a valid option. Studies on immediate loading and guided surgery report possible positive effects on papilla formation, less post-operative pain and swelling compared to absence of guided surgery. ${ }^{109,110}$

## Implant-supported single crowns

Numerous clinical studies and systematic reviews have focused on the implant-supported SCs. ${ }^{57,111-113}$ The reported survival of implant-supported SCs in a systematic review was $94.5 \%$ after 5 years ${ }^{111}$ and in a more recent report $96.3 \%$. ${ }^{57}$ Important to note is that implant-supported single crowns SCs are not problem free. A cumulative soft tissue complication rate of $7.1 \%$ over a 5 -year period has been reported, slightly higher bone loss for cemented reconstruction and technical complications with screw-loosening as the most common ( $8.8 \%$ complication rate after 5 years). ${ }^{57}$

Mainly aesthetic factors have impacted the choice of all-ceramic implant-supported SCs. ${ }^{12}$ Several ceramic material are available and the two most commonly used are the lithium disilicate glass-ceramic and yttria stabilized tetragonal zirconia polycrystal oxide ceramic. Zirconia implant-supported SCs have a reported 5-year estimated survival rate of $97.6 \%$, similar to metal-ceramic implant-supported SCs of $98.37 \%$. ${ }^{12}$ Technical complications as chipping/fracture are reported to be more prevalent in the maxillary dentition, further for ceramic crowns there is a higher prevalence of crown fractures. ${ }^{113}$ The development of full-contour restoration in monolithic zirconia can prevent veneering related fractures. ${ }^{112}$

Implant-supported SCs on titanium bases (Ti-base) that are adhesively cemented have recently increased in use. Figure 11. Contrary to the old CeraOne ${ }^{\circledR}$ (Nobel Biocare, Balsberg, Switzerland) abutment, ${ }^{114}$ Ti-bases are designed in mind to fit a CAD/CAM workflow. ${ }^{115}$ The ti-bases are recommended for extraoral cementation and in such easily controlled for fit and excess cement. Combined with a full-contour zirconia or zirconia with a buccal cut-back for veneering this fits very well with a digital workflow. ${ }^{115}$


Figure 11. A: Implant-supported SC cemented on a titanium base abutment. B: Titanium base. C: Screw retained implant-supported SC, individual designed abutment for veneering. D: Implant.

However, long-term clinical studies on the retention between the titanium base and SC needs to be conducted. Laboratory studies report high pull out strength and zirconia crown on titanium bases are reported to be mechanically stronger then zirconia crowns fixed directly on the dental implant. ${ }^{116}$ Titanium bases have the advantage that a wide variety of CAD/CAM material can be milled to fit. Titanium bases are available for several dental implant systems, both as original and copy components, Figure 12.


Figure 12. A: Elos Accurate $®^{\circledR}$ Hybrid Base ${ }^{\text {TM }}$ Engaging, Elos Medtech. B: Titanium base zirconium abutment, Medentika. C: Titanium base abutment, BioHorizons. D: Variobase ${ }^{\circledR}$, Straumann

As previously mentioned implants-supported SCs are often associated with the occurrence of biological, technical, functional and/or aesthetic complications. ${ }^{57,113}$ Today young patients in need of tooth replacement due to tooth agenesis are often treated with dental implants. ${ }^{117}$ Other reasons for tooth loss can be dental trauma, caries or periodontal disease. Common for them all is that these dental implants and SCs are expected to last a lifetime. This is however of concern as post-treatment complications are not uncommon. ${ }^{111}$ Besides the need to replace SCs due to technical complications, some patients request a replacement due to aesthetic reasons. ${ }^{112}$ However, this is not unexpected, as the appearance of the natural dentition is continuously affected over time by lifestyle, environment and genetics. ${ }^{18}$ As SCs are inert reconstructions not capable of changing with the natural dentition aesthetic problems may arise and can impact satisfaction of the patient. Full-contour restorations with titanium bases can, therefore, be a rational and feasible treatment concept, especially as these types of restorations are reported to be more cost-benefited in a digital workflow. ${ }^{115}$ Advances in the aesthetic characteristics of the ceramic material, such as multi-layered zirconia, will lead to further advances in restoring patients with SCs.

## Dental impression

Dental impressions have been taken by dentists for centuries, ${ }^{119}$ traditionally with an impression material to create a negative imprint. This impression is then used to create a dental stone cast. This stone cast is used to fabricate dental restoration following several different workflows appropriate for the desired restoration. From the use of plaster as an impression material, the materials of today are commonly elastomeric ones (silicone based, polyether and polysulphides). ${ }^{119}$

The use of digital technology for the fabrication of dental restorations including the use of IOS and CAD/CAM has been in development since the 1970s. ${ }^{120}$ Duret presented a concept of how to utilise scanning technology to capture the shape of a tooth preparation and translating the shape into a 3 D morphometric landmark in a computer software and CAD/CAM manufacturing of dental restorations. ${ }^{120}$ Following this the first commercially available IOS was presented as CEREC 1 (Sirona, Bensheim, Germay) in 1985. ${ }^{121}$ Recent development in the area of IOS has widened the market
and improvements in scanner accuracy has broadened the field of indications. ${ }^{51,122-125}$ In the field of prosthodontics several treatment procedures have been suggested for an IOS workflow, in the field of fixed implants prosthodontics, fixed and removable tooth supported prosthodontics. ${ }^{122,123,126}$

Several advantages over conventional impressions have been reported. Central is a higher patient acceptance, reduction in stress and discomfort (Figure 13), ${ }^{127,128}$ and possibility countering both gag reflexes and anxiety. Likewise, IOS can be time-efficient and simplifying the clinical procedure. ${ }^{115,127}$


Figure 13. IOS of patient.

In addition, IOS has been reported to be a preferred way of taking impression for newly educated dentists and they seem to adept to the technology with ease. ${ }^{129}$ Using IOS technology is not without problems, difficulties recording deep margin lines and capturing nonridged soft tissue areas are some of the challenges that clinicians may encounter. Currently conventional impressions seem to be the superior method for long-span restoration, areas with several adja-
cent pontics and narrow alveolar ridges surrounded by non-rigid soft tissues. ${ }^{49,130,131}$

## 3D Printing - additive manufacturing

Additive manufacturing could simply be explained as creating an object out of bricks contrary to subtractive manufacturing were you would chisel a statue out of a rock. Milling a ceramic crown is the prime example of subtractive manufacturing in dentistry. ${ }^{63}$ CAD/ CAM milling and other ways of subtractive manufacturing do have limits concerning what shapes that can be manufactured. ${ }^{132}$ Additive manufacturing does however open up for the manufacturing of complex geometries, but the materials for dental purposes are still somewhat limited. ${ }^{132}$

Additive manufacturing is relatively new in the field of dentistry, but the technology has been around since the 1980s. Charles "Chuck" Hull is often credited as the inventor of additive manufacturing. ${ }^{133}$ The process was named stereolithography (SLA), a technique for the production of solid plastic models by successively applying thin layers of curable material on a build plate. As Hull intended the technology has primarily been used for prototyping ahead of mass production. However, there has been an increase in the utility and availability of additive manufacturing. Today over 135 companies produce systems for additive manufacturing and an increase in the total of systems sold is reported. ${ }^{104}$ In addition, several additive manufacturing technologies have been developed, some of these are fused deposition modelling (FDM), selective laser sintering (SLS), selective laser melting (SLM), drop on demand (DOD), directed energy deposition (DED), direct light processing (DPL) and continuous DLP (CDLP). ${ }^{104}$ In dentistry additive manufacturing is used to produce dental models, temporary restorations, surgical guides, splints and metallic framework for fixed and removable reconstructions. ${ }^{132}$

## HYPOTHESES

1. There is no statistically significant difference between subgroups (male, female, smoker, non-smoker, reason for tooth loss and implant location) with regard to the treatment outcome for anterior single dental implants following a conventional treatment procedure in a young patient cohort.
2. There is no statistically significant difference in the treatment outcome for narrow diameter dental implants compared to wider diameter dental implants used to replace missing single anterior teeth.
3. There is no statistically significant difference in the treatment outcome between delayed loading, immediate loading or immediate loading in combination with guided surgery for single dental implants in the anterior maxilla.
4. There is no statistically significant difference in final implant position following guided surgery installation of single dental implants between surgical guides produced by two different desktop 3D-pinters.

## SPECIFIC AIMS

A. To retrospectively evaluate a cohort of young adults conventionally treated with single dental implants in the anterior dentition, with regard to implant survival, PROMs, MBL, clinical and esthetic outcomes.
B. To prospectively evaluate in a randomized clinical trial the two single dental implants treatment procedures, immediate (IL) and delayed loading (DL), in the anterior maxilla with regard to implant survival, PROMs, MBL, clinical and aesthetic outcomes, during a 1-year follow-up period.
C. To evaluate the overall treatment outcome of a single dental implant treatment procedure involving digitally planned and immediate loaded (DIL) anterior single dental implants, installed with the assistance of guided surgery and with restorations fabricated with the help of intraoral scanning, during a 1 -year follow-up period.
D. To evaluate the deviation in final dental implant position for the single implant guided surgery procedure using surgical guides fabricated from two different desktop 3D printers using a digital workflow.

## MATERIAL AND METHODS

## Study design

## Study I:

Designed as retrospective clinical study investigating treatment outcome in a patient cohort treated at the Centre of Dental Specialist Care in Malmö between the years 2004 and 2011.

## Study II:

Designed as a prospective randomized clinical trial. One group following the delayed loading (DL) protocol and one group submitted to immediate loading (IL). For two independent groups to yield a power of at least $80 \%$ to give a statistically significant result 20 subjects would need to be recruited in each group. To compensate for dropouts, due the 5-year follow-up period, the groups sizes were increased to $25-25$.

## Study III:

Designed as a laboratory study with two independent groups. No previous research was available on which to base the standard deviation estimates. The study was therefore designed as a pilot with a group size of 10 surgical guides for each desktop 3D-printer.

Study IV:
Designed as a prospective clinical trial with the delayed loading group from study II as control. The test group, digital immediate loading (DIL), was planned to have 1-year follow-up period. For two independent groups to yield a power of at least $80 \%$ to give a
statistically significant result 20 subjects would need to be recruited in each group.

## Ethics

Study I,II and IV were clinical trials conducted in accordance with the Helsinki declaration of 1975 as revised in $2000 .{ }^{134}$ The study protocols were submitted to ethical review and approved by the Regional Ethical Review Board in Lund, Sweden. Study I ref.: 2012/318, study II ref.: 2011/125 and study IV ref.: 2015/671. Study II and IV were registered at ClinicalTrials.gov with ID NCT02770846 and NCT04061694.

Prior to any inclusion in the clinical trials all patients were orally and in writing informed about the respective studies and given time to ask any questions about their participation. All patients who agreed to take part in the studies then signed a written informed consent.

## Inclusion and exclusion

## Study I:

Patients selected for inclusion had been treated with one or more single-tooth replacements and had adjacent natural teeth. Treatment had been performed with XiVE® S implants (Dentsply Implants, Mannheim, Germany) at the Centre of Dental Specialist Care, Malmö, Sweden between 2004 and 2011.

Study II and IV:
Inclusion criteria were as follows:

- At least 18 years old.
- In need of a single-tooth replacement of an incisor, canine or pre-molar in the maxilla.
- Signed informed consent.

Exclusion criteria were as follows:

- General health contraindications for oral surgery.
- Inadequate oral hygiene, defined as a full-mouth plaque score of above $25 \%$.
- In need of bone grafting or ridge augmentation

For the immediate loading group in study II and for the patients in study IV it was decided to exclude implants with an insertion torque below 30 Ncm .

In study II patients referred to the Centre of Dental Specialist Care, Malmö between April 2011 and April 2014 were considered for inclusion.

In study IV patients referred to the Centre of Dental Specialist Care, Malmö between November 2016 and February 2018 were considered for inclusion.

## Treatment procedure study I

Surgical procedure
Prior to surgery the treatment plans were discussed in a multidisciplinary group, consisting of a prosthodontist, an oral surgeon, an oral radiologist and an orthodontist. In this group it was decided whether or not narrow-diameter implants would be indicated.

The implants were placed according to a standard two-stage surgical procedure for single implant placement in healed sites. In study I no antibiotics were given before or after surgery. Surgery was performed under local anesthesia (Xylocaine with 2\% adrenaline, Dentsply Pharmaceutical, York, PA, USA). An incision was placed at the mid-crest and a mucoperiosteal flap was raised with a vertical releasing incision.

In cases with insufficient bone and exposed implant surface (20 implants), guided bone regeneration (GBR) procedures were simultaneously performed at implant placement, and these osseous defects were grafted with a natural bone mineral of bovine origin (Bio-Oss®, Geistlich Pharma, Wolhusen, Switzerland) and covered with a collagen membrane (Bio-Gide® Membrane, Geistlich Pharma, Wolhusen, Switzerland). All implants were placed at the crestal level. Postoperatively, the patients were instructed to rinse twice daily with a solution of $0.2 \%$ chlorhexidine for 14 days, to take ibuprofen $400 \mathrm{mg} \times 2$ for 3 days and in case of pain, paracetamol $500 \mathrm{mg} \times 4$ per day. Bone quantity and quality of the treated surgical sites were classified at the time of surgery according to the Lekholm and Zarb classification. ${ }^{55}$

## Prosthetic treatment

The prosthetic treatment was performed at the Centre of Dental Specialist Care, Malmö, Sweden, by seven different prosthodontists. One prosthodontist (the third author) treated $57.0 \%$ of the patients. No temporary implant crowns were used to shape the emergence profile before impression. For the implant impression the open-tray technique was used with polyether impression material (Impregum Penta, 3M ESPE Dental Products, St. Paul, MN, USA), and alginate (Blueprint Creme, Dentsply DeTrey GmbH, Konstanz, Germany) for the antagonistic impression. The occlusal relationship was recorded in a bite registration wax (Alminax, Kemdent, Associated Dental Products Ltd, Wiltshire, England). All materials were used according to manufacturer's guidelines.

After completion of the final restoration the patients' dental hygiene were followed up by a dental hygienist within 6 months. The patients were asked to attend a radiographic follow-up examination after 12 months. Each patient then attended a dental hygiene recall program based on individual needs.

## Treatment procedure study II

## Surgical treatment

For the patients willing to participate in the study, a clinical examination was done prior to randomization. Periapical and panoramic radiographs were used to initially evaluate the implant site. For patients eligible for the study, bone quantity and quality of the treated surgical sites were classified at the time of surgery according to the Lekholm and Zarb 1985 classification. ${ }^{55}$ Patients were assigned to one of the two study groups, IL or DL, using a closed randomization method with sealed envelopes. The surgeon was blinded with regard to treatment group assignment.

All patients were consecutively treated with Tapered Internal implants (BioHorizons, Birmingham, AL, USA), placed in healed bone sites (4 months or more after tooth loss), according to a standardized surgical procedure. All implant sites were free from clinical signs of inflammation. Prophylactic antibiotic therapy was prescribed to all patients (phenoxymethylpenicillin, $500 \mathrm{mg} 8 / 8 \mathrm{~h}$, Kåvepenin, Meda AB , Solna, Sweden), beginning one hour before surgery and extending for seven days. Surgery was performed under local anesthesia (Xylocaine with

2\% adrenaline, Dentsply Pharmaceutical, York, PA, USA). An incision was placed at the mid-crest and a mucoperiosteal flap was raised with a vertical releasing incision. All implants were installed according to the recommendations given by the implant manufacturer. After installation the implant was inspected for the presence of buccal fenestrations or dehiscences. Exposure of more than 1 mm of the implant excluded the patient from the study. Defects $<1 \mathrm{~mm}$ were covered with autogenous bone chips collected during the implant bed preparation, and no membranes were used. Postoperatively, the patients were instructed to rinse twice daily with a solution of $0.2 \%$ chlorhexidine for 14 days and to take analgesics in case of need (paracetamol $500 \mathrm{mg} 6 / 6 \mathrm{~h}$, Alvedon, GlaxoSmithKline AB, Solna, Sweden). Sutures were removed after 2 weeks. All fixture installations were performed at the Centre of Dental Specialist Care, Malmö, Sweden, by the second author (J.K.).


Figure 14. Temporary crown IL (A) Titanium temporary abutment; (B) Temporary crown after polishing; (C) Radiograph of temporary crown; (D) Temporary crown seated and mucosa sutured.

In the IL group, the implants were immediately loaded with a screwretained temporary crown. A titanium temporary abutment (BioHorizons, Birmingham, AL, USA) with a composite crown (Sinfony,

3M ESPE, Maplewood, Minnesota, USA) were used (Figure 14). The provisional restorations were adjusted to a light centric contact and free from eccentric contacts with the opposing teeth before the polishing procedures. The restorations were tightened to 15 Ncm and the mucoperiostal flaps were adapted to the crown before wound closure. The patients were instructed to avoid exerting force on the temporary restoration. In the DL group the patients underwent a two-stage surgery procedure with a minimum healing period of 4 months before a screw-retained temporary crown was fabricated using the same materials as in the IL group. The temporary crown shape and emergence profile were modified until the patients were satisfied with the crown and soft tissue appearance.

## Prosthetic treatment

Prosthetic procedures for definitive crowns were initiated after 2 months in the IL group and after 4-6 months in the DL group from the time of fixture installation. An implant-level impression was performed using a customized impression coping in such a way that the obtained emergence profile from the temporary restorations could be transferred to the definitive restoration, according to the method described elsewhere. ${ }^{18}$ The definitive crown consisted of an individually fabricated zirconia abutment (I-butment, Biomain AB , Helsingborg, Sweden), with a titanium base (Medentica GmbH, Hügelsheim, Germany), being cemented- or screw-retained (Figure 15). The cemented-retained crowns and titanium bases were cemented with a bonding agent (Z-Prime Plus, Bisco, Schaumburg, IL, USA) and dual-curing resin cement (Variolink, Ivolclar-Vivadent, Schaan, Liechtenstein). All crowns were veneered (GC Initial, GC EUROPE N.V., Leuven, Belgium) by the same dental technician. All the clinical prosthetic procedures were accomplished by the first author (B.G.)


Figure 15. (A) Temporary crown; (B) Radiograph of final restoration; (C) Final restoration

## Treatment procedure study IV

Surgical procedure, guide fabrication and temporary restoration
Following the clinical examination, an intraoral scanning of the maxilla and antagonist arch was performed with an IOS (Trios 3, 3Shape A/S, Copenhagen, Denmark). Cone beam computed tomography (CBCT) (ProMax 3D, Planmeca Oy, Helsinki, Finland) of the implant site was acquired. Digital imaging and communications in medicine (DICOM) files obtained from CBCT examination and the intraoral scanning were imported into a guided surgery software (Implant Studio, 3Shape, Copenhagen, Denmark). The dental implant (Tapered Internal, BioHorizons, Birmingham, AL) position was planned virtually and the appropriate implant diameter and length were selected for each individual case. In the same software a predesign of the temporary restorations were performed to help guide the position of the dental implant.

Surgical guides were then designed and fabricated for each case. The surgical guides (E-Shell 600 Clear, Deltamed GmbH, Friedberg, Germany) were made with additive technology, using a digital light processing (DLP) 3D printer (Vida, EnvisonTEC GmbH, Gladbeck, Germany). A master cylinder sleeve (BioHorizons, Birmingham, AL) was incorporated into each surgical guide. The surgical guides were then submitted to sterilization according to the material suppliers' guidelines.

The temporary restorations were designed (Dental Designer, 3Shape, Copenhagen, Denmark) according to the intended dental implant position and then 3D printed (E-Dent 400, EnvisonTEC GmbH , Gladbeck, Germany). The 3D-printed restorations were cemented on a titanium base abutment (BioHorizons, Birmingham, AL ) after polishing.

All implants were placed into healed bone (at least 4 months after tooth loss) in sites that were free from clinical signs of inflammation/ infection. Prior to surgery a single-preoperative dosage of 2 g amoxicillin was administered. Surgery was performed under local anesthesia (Xylocaine with 2\% adrenaline, Dentsply, Mölndal, Sweden). The dental implants were installed using a guided surgery kit (BioHorizons, Birmingham, AL) by one operator, following the drilling protocol supplied by the manufacturer. Mucosal tissue at the implant


Figure 16. 3D printed temporary crown and radiograph of titanium base abutment.
site was removed with a soft tissue punch from the guided surgery kit, no mucoperiosteal flaps were raised. The installation torque was registered for each implant. The implant driver and a torque wrench were used for final adjustments of the dental implant hexagon position. The temporary restorations were immediately mounted onto the dental implants, see Figure 16. The restorations were adjusted to a light centric contact and free from eccentric contacts, and necessary adjustments to proximal contacts points were performed. The restorations were then tightened to 15 Ncm . Postoperatively, the patients were instructed to rinse twice daily with a solution of $0.2 \%$ chlorhexidine for 14 days and to take analgesics in case of need (paracetamol $500 \mathrm{mg} 6 / 6 \mathrm{~h}$, Alvedon, GlaxoSmithKline AB, Solna, Sweden). All patients returned after 14 days for a postoperative check-up.


Figure 17. Final restoration and radiograph

## Definitive Prosthetic procedure

Two months after surgery, an intraoral scanning (Trios 3, 3Shape A/S, Copenhagen, Denmark) was performed using a scan body (Snap scan body, BioHorizons, Birmingham, AL). The final screw-retained single implant crown consisted of a titanium base abutment (BioHorizons, Birmingham, AL) and a zirconia crown (BruxZir, Glidewell Labratories, Newport Beach, CA), see Figure 17. The zirconia crowns were designed with a buccal cutback for veneering (GC Initial, GC EUROPE N.V., Leuven, Belgium). All laboratory procedures were performed by the same team of dental technicians and all clinical prosthetic procedures by the first author (B.G.).

## Clinical evaluations study I,II,IV

 Installation torqueInstallation torque was recorded at fixture installation with a dental drill unit for implant surgery (iChiropro, Bien-Air Dental SA, Bienne, Switzerland)

## Resonance frequency analysis

Resonance frequency analysis (RFA) was performed according to the manufacturer's instructions (Osstell ISQ, Osstell AB, Göteborg, Sweden). In study II the RFA was used to monitor the implant stability between implant installation and completion of the final restoration, to determine if there were any early signs of failure.

## Success and survival

Success and survival of implants were evaluated according to Albrektsson. ${ }^{11,12}$ Both MBL and in the definition stated clinical criteria were considered for success. Implants not fulfilling the success criteria, but not lost, were considered as survivals.

The survival of the implant-supported SCs was assessed and failures were defined as complications leading to crown replacement. Aesthetical reasons for crown replacement were not considered for survival. For the retrospective study patients were asked about complications and all patient records were scrutinized for biological and technical complications.

## Marginal bone loss

Digital intra-oral periapical radiographs (Schick Digital X-ray Sensor, Sirona, Salzburg, Austria) were taken using the long-cone parallel technique. When there were no available digital radiographies from the baseline appointment in study I, the analogue periapical radiographies were scanned at 1200 dpi (Epson Perfection V800 Photo Color Scanner; Nagano, Japan).

The marginal bone level was measured after calibration with the inter-thread distance of the Tapered Internal implants ( 1.00 mm ) and XiVE implants $(0.85 \mathrm{~mm})$. Measurements were taken from the implant-abutment junction to the marginal bone level, at both mesial and distal sides of each implant, and then the mean value of these two measurements was considered. MBL was calculated by comparing bone level measurements from follow-up examinations to the radiographic baseline examination. The Image J software (National Institute of Health, Bethesda, USA) was used for all measurements.

## Change in vertical and horizontal dimensions

Vertical distance was evaluated between the fixture-abutment junction (FAJ) and the cement-enamel junction (CEJ) of the adjacent tooth on the mesial side, see Figure 18, as described by Jemt. ${ }^{135}$ Digital intra-oral periapical radiographs (Schick Digital X-ray Sensor, Sirona, Salzburg, Austria) were taken using the long-cone parallel technique. When there were no available digital radiographies from the baseline appointment in study I, the analogue periapical radiographies were scanned at 1200 dpi (Epson Perfection V800 Photo Color Scanner; Nagano, Japan).

The change from baseline to follow-up examination gives the changes in vertical-tooth relationship. Negative change would indicate implant infraposition.

Plaster models (GC Fujirock, EP, GC Europe N.V., Leuven, Belgium) from the time of prosthesis insertion and from the final follow-up examination where photographed (Nikon D7000, Nikon Corporation, Tokyo, Japan) together with a $1-\mathrm{mm}$ precision ruler. The horizontal distance between the teeth adjacent to the implant-supported crown was measured at baseline and at the final follow-up.


Figure 18. Fixture-abutment junction (FAJ) and Cement-enamel junction (CEJ)

## Gingival index

The gingival index was scored for each implant at the final followup examination, according to Löe and Silness. ${ }^{15}$ Registered for the distal tooth adjacent to the implant site pre-surgery and at the dental implant site on each subsequent follow-up examination.

## Papilla index

The papilla index ${ }^{16}$ at the implant sites were measured from baseline and on each follow-up examination. The index consists of a five point scale ranging from 0 to 4 .

Score 0: No papilla is present.
Score 1: Less than half of the papilla height is present.
Score 2: At least half of the papilla height is present.
Score 3: A complete papilla fill.
Score 4: A hyperplastic papilla.

## Soft tissue changes

The vertical changes in gingival zenith positions were defined as the linear distance from the gingival zenith to the reference line and for papilla levels as the linear distance from the papilla tip to the reference line (Figure 19).

In study II casts were made after receiving and before removing the temporary restoration, at completion of the permanent restoration, and after 3, 6, and 12 months. Study casts were photographed (Nikon D7000, Nikon Corporation, Tokyo, Japan) together with a 1-mm precision ruler. The Image J software (National Institute of Health, Bethesda, USA) were used for all measurements.


Figure 19. Photographic measurements of soft tissue changes. The casts were positioned in front of the camera in a reproducible manner by individual bite impressions. A reference line was used to measure vertical change in mesial papilla $(M)$, distal papilla (D) and the zenith position $(Z)$.

In study IV Change in gingival zenith position and papilla levels were measured from intraoral scanning's acquired at the follow-up visits. The datasets were imported into a 3D-data measurement analysis software (GOM Inspect 2017, build 2017-09-14, GOM Metrology, Braunschweig, Germany) for a best fit alignment and subsequent measurements, see Figure 20.


Figure 20. GOM Inspect intraoral scan soft tissue measurement.

## Pink and white esthetic score

Photographs from the baseline and follow-up appointments were used to register PES, according to Fürhauser et al. ${ }^{22}$ PES consist of 7 variables, each one can be scored 0,1 or 2 . Each variable score is then summarized into a total score, with a range $0-14$, see Table 4 .

Table 4. Pink esthetic score (PES) variables.

| Variables | $\mathbf{0}$ | $\mathbf{1}$ | $\mathbf{2}$ |
| :--- | :---: | :---: | :---: |
| Mesial papilla | Absent | Incomplete | Complete |
| Distal papilla | Absent | Incomplete | Complete |
| $\begin{array}{l}\text { Level of soft- } \\ \text { tissue margin }\end{array}$ | $\begin{array}{c}\text { Major discrepan- } \\ \text { cy }>2 \mathrm{~mm}\end{array}$ | $\begin{array}{c}\text { Minor discrepan- } \\ \text { cy } 1-2 ~ m m\end{array}$ | No discrepancy |
| <1 mm |  |  |  |$]$| Fairly natural |
| :--- |

Photographs from the baseline and follow-up appointments were used to register WES, according to Belser et al. ${ }^{23}$ WES consists of 5 variables, each one can be scored 0,1 , or 2 . Each score is than summarized into a total score, with a range $0-10$, see Table 5.

Table 5. White esthetic score (WES) variables.

| Variables | 0 | 1 | 2 |
| :---: | :---: | :---: | :---: |
| Tooth from | Major discrepancy | Minor discrepancy | No discrepancy |
| Tooth volume/outline | Major discrepancy | Minor discrepancy | No discrepancy |
| Color (hue/value) | Major discrepancy | Minor discrepancy | No discrepancy |
| Surface texture | Major discrepancy | Minor discrepancy | No discrepancy |
| Translucency | Major discrepancy | Minor discrepancy | No discrepancy |

The following definition was used to define aesthetic outcome according to an almost perfect aesthetic outcome or aesthetic failure. Perfect (almost) aesthetic outcome as PES $\geq 12$ and WES $\geq 9$ and aesthetic failure as PES $\leq 7$ and/or WES $\leq 5 . .^{30}$

## Oral Health Impact Profile

The oral health-related quality of life (OHRQOL) was recorded using the Swedish validated version of the short version Oral Health Impact Profile (OHIP-14) questionnaire. ${ }^{38}$ The OHIP-14 captures these four dimensions of oral health: 'psychological impact', 'pain and discomfort', 'behavioral impact' and 'functional limitation'.

The additive score (Add-OHIP-14) was obtained by summation of the response codes for the 14 items. This gives a range from 14-70, were a higher score indicates poor OHRQOL.

## Visual analog scale

The patients' aesthetic satisfaction was assessed, by using a visual analog scale (VAS). The patients marked their satisfaction on a nonnumerical 100 mm line ranging from "not at all satisfied $=0$ " (left) to "very satisfied $=100$ " (right), for each implant. The questions were: "How satisfied are you with the aesthetic result of your treatment?" (VAS), "How satisfied are you with the aesthetic appearance of the soft tissue around your implant-supported crown restoration" (VAS1), and "How satisfied are you with the aesthetic appearance of your implant-supported crown restoration?"(VAS-2). Each response was
given a numerical value by measuring in millimeters the distance from the left end of the line.

In study IV pain and discomfort were scored after the surgery and the impression appointments. The patients marked their decision on a non-numerical 100 mm line ranging from "severe pain and severe discomfort $=0$ " (left) to "no pain and no discomfort $=100$ " (right). Each response was given a numerical value as described above.

## Follow-up appointments studies I, II, IV

Every patient appointment and associated evaluation before, during and after treatment completion is indicated in Table 6. After completion of the final restoration, the patients' dental hygiene was followed up by a dental hygienist within 6 months. Additional dental hygienist check-ups were planned based on the patients' individual needs.

## Laboratory study III

A digital scan (Trios 3, 3Shape, Copenhagen, Denmark) of a maxillary typodont was used to create a 3D model. The model was then digitally manipulated in 3D sculpting-based computer assisted design (CAD) software (Meshmixer 3.2, Autodesk, San Rafael, CA, USA) as follows: the first premolar on the left side was removed and the space was flattened and cropped to a half dental arch. Using an SLA printer (Form 2, Formlabs, Somerville, MA, USA) 20 surgical models were fabricated (Tough Resin V4, Formlabs, Somerville, MA, USA). The models were numbered 1 through 20 and divided into 2 groups: SLA and DLP. Each model was digitally scanned (Trios 3, 3Shape, Copenhagen, Denmark) and radiographed with a CBCT machine (ProMax 3D, Planmeca, Helsinki, Finland). All CBCTs were performed with the same characteristics: voxel size 0.2 mm , exposure factors were $60 \mathrm{kV}, 8.0 \mathrm{~mA}$, and exposure time was 4.065 seconds. A series of axially sliced image data was obtained and exported to digital imaging and communications in medicine (DICOM) format and numbered according to corresponding model. Digital scans and DICOM files were imported into CT-guided surgery software (Implant Studio, 3Shape, Copenhagen, Denmark) for planning and surgery guide design.

Table 6. Study appointments and evaluations. $1=$ Study I, 2 = Study II, 4 = Study IV. * indicates crown impression.

|  |  |  |  |  |  |  |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| Resonance frequency |  | 2,4 |  | 2 |  |  |

For each situation a dental implant (Tapered Internal, BioHorizons, Birmingham, AL, USA), 12 mm in length and 3.8 mm in diameter was selected, resulting in the same drilling protocol. In the guided surgery software, the dental implants were virtually positioned 1 mm above the model surface, as seen in Figure 21.

In the DLP group, 10 surgical guides were fabricated from a photopolymer resin (E-Guide, EnvisionTEC, Dearborn, MI, USA) using a DLP printer (Vida, EnvisionTEC, Dearborn, MI, USA) as seen in Figure 22A. Guide thickness 1.4 mm , offset from teeth to
guide 0.02 mm , offset from sleeve to guide 0.01 mm , according to manufacturing recommendations. In the SLA group, 10 surgical guides were fabricated from a different photopolymer resin (Dental SG Resin, Formlabs, Somerville, MA, USA) using an SLA printer (Form 2, Formlabs, Somerville, MA, USA), as seen in Figure 22B. Guide thickness 2 mm , offset from teeth to guide 0.06 mm , offset from sleeve to guide 0.05 mm , according to manufacturing recommendations. The surgical guides were positioned, printed, and post processed according to the manufacturers' guidelines.


Figure 21 . Guided surgery planning

Master cylinder sleeves (Master Sleeve, BioHorizons, Birmingham, AL, USA) were then incorporated into the surgical guides. The two 3D printers were calibrated prior to guide fabrication.

A visual inspection was performed to evaluate the correct seating of the surgical guides on their respective surgical model. All 20 dental implants were installed using a guided surgery kit (BioHorizons) by one operator (B.G.), following the drill protocol and the implant manufacturer's instruction for fully guided surgery. The implant driver and a torque wrench (BioHorizons) were used to reach the indicated stop position and adjust the implant hexagon to correspond with the indication marking on the surgical guide.


Figure 22. A, Surgical guide DLP (Vida 3D printer and E-guide material). B, Surgery guide SLA (Form 2 3D printer and Dental SG Resin material).

## Deviations in implant position

After implant placement, scan bodies (PEEK Scan Abutments, BioHorizons, Birmingham, AL, USA) were attached onto each dental implant and the models were digitally scanned (Trios 3, 3Shape, Copenhagen, Denmark). The digital scans and the guided surgery planning were separately imported into dental design software (Dental Designer; 3Shape, Copenhagen, Denmark), from which standard tessellation language (STL) datasets were exported with incorporated geometric dental implant structures. Corresponding datasets of the planned and final dental implant position were then imported into 3D data measurement analysis software (GOM Inspect 2017, build 2017-09-14, GOM Metrology, Braunschweig, Germany). To make the superimposition more precise, irrelevant areas beyond the field of interest were not selected for alignment after the primary alignment between the datasets.

Alignments were performed using a best fit algorithm based on the selected surfaces of the neighboring teeth. ${ }^{51}$ Color-coded deviation maps were generated to show the difference between 2 aligned datasets as seen in Figure 23, in addition to the mean deviation (RMS-value).

To identify the central entry point and apex of the dental implant, fitting elements were applied to key geometric surfaces of the dental implant using the Gaussian best-fit approach. The following parameters were calculated: deviation at entry point, measured at the center of the implant (in mm); deviation at apex, measured at the center of the implant apex (in mm); angular deviation (in degrees); deviation in vertical implant position, measured at the center of the implant (in mm ); deviation in horizontal implant position, measured at the


Figure 23. Alignment of datasets, color-coded deviations maps, and mean deviation
center of the implant (in mm); and rotational deviation of the implant hexagon (in degrees). ${ }^{92}$ The parameters are illustrated in Figure 24. The software calculated the distance between the measuring points on the $\mathrm{x}, \mathrm{y}$, and z -axes and the Euclidian distance (dxyz) with the following equation, see formula 2 .
$d x y z=\sqrt{\left(x_{1}-x_{2}\right)^{2}+\left(y_{1}-y_{2}\right)^{2}+\left(z_{1}-z_{2}\right)^{2}}$
Formula 2. $\mathrm{dxyz}=$ distance between two points i a xyz-space (3D space), where $X_{1}$ is the first coordinate of the first point, $X_{2}$ is the first coordinate of the second point, $y$ second coordinate and $z$ third coordinate.


Figure 24. Inspection variables software output. y second coordinate and z third coordinate.

## Statistics

The software used for the statistical analyses was the Statistical Package for the Social Sciences (SPSS) version 25 (SPSS Inc., Chicago, IL, USA). The data were tabulated, and from these measurements mean, standard deviation (SD), minimum and maximum scores were calculated. Kolmogorov-Smirnov test was performed to evaluate the normal distribution of the variables, and Levene's test evaluated homoscedasticity. The performed tests for two independent groups, three or more independent groups, and two dependent groups were Student's t-test or Mann-Whitney test, one way ANOVA (LSD Post Hoc) or Kruskal-Wallis test (Dunn's post hoc test and Bonferroni correction), and paired-samples t-test or Wilcoxon signed-rank test, respectively, depending on the normality. Pearson's chi-squared or Fisher's exact test was performed for categorical variables, depending on the expected count of events in a $2 \times 2$ contingency table. Correlation and linear regression were performed to check the relationship between the variables. Life tables were presented for implants and crowns respectively, with cumulative survival rate (CSR). The $95 \%$ confidence interval (CI) for the survival proportions were calculated by using the $95 \%$ confidence limits of the event rates. The degree of statistical significance was considered $P<0.05$.

## RESULTS

## Clinical studies I, II, IV

Patient cohorts
In study I, the following patients were excluded, out of the 114 of the originally consecutively treated patients between 2004 and 2011: eight patients who had implants incorporated in a fixed partial denture; two patients with implants adjacent to only one natural tooth; eleven patients with implants adjacent to another implant; and six patients with the supraconstruction made at another dental clinic. Thus, 87 patients with a total of 126 implants were included. All patients were healthy but $6 \%$ reported the intake of some type of medication at the time of implant installation. The reasons for medication were not considered a contraindication for surgery by the surgeon. Of the 95 surgical sites with agenesia, 52 sites were from 26 patients presenting bilateral agenesia.

For Study II, a total of 62 patients were initially allocated. Twelve patients were not included in the study for the following reasons: four patients did not want treatment for economic reasons, three patients presented extensive osseous defects that would require a bone graft in order to make the insertion of an implant possible, one patient desired a tooth supported bridge instead of an implant, one patient did not have the required anatomical space for an implant, and three patients decided to leave the study before surgery. The remaining 50 patients were included in the study, 25 randomly allocated to each group. In the IL-group all implants reached the minimum insertion torque of 30 Ncm .
Table 7. Characteristics of patients in studies IIII and IV.

| Variable | Study I | Study II |  | Study IV |
| :---: | :---: | :---: | :---: | :---: |
|  |  | Immediate loading (IL) | Delayed loading (DL) | Digital Immediate loading (DIL) |
| Implant surgery (patient level) |  |  |  |  |
| Mean age $\pm$ SD (min, max), (years) | $20.7 \pm 7.3$ (16.7, 67.7) | $40.8 \pm 13.3$ (19.0, 66.6) | $40.9 \pm 15.5(18.5,76.7)$ | $40.2 \pm 21.0$ (18.2, 72.0) |
| Male/female | 36/51 | 14/11 | 6/19 | 11/10 |
| Smokers/Non-smokers | 15/72 | 2/23 | 6/19 | 1/20 |
| Bruxers/Non-bruxers | - | 2/23 | 0/25 | 3/18 |
| Diabetic/Non-diabetic | 0/87 | 0/25 | 0/25 | 2/19 |
| Orthodontic treatment (Yes/No) | 59/28 | - | - | - |
| Reason for missing tooth (implant level) |  |  |  |  |
| Trauma | 15 (11.9\%) | 15 (60.0\%) | 12 (48.0\%) | 4 (19.0\%) |
| Agenesia | 95 (75.4\%) | 3 (12.0\%) | 4 (16.0\%) | 6 (29.6\%) |
| Advanced caries | 2 (1.6\%) | 5 (20.0\%) | 5 (20.0\%) | 6 (29.6\%) |
| Root resorption | 1 (0.8\%) | 2 (8.0\%) | 2 (8.0\%) | 0 (0\%) |
| Apical destruction | 3 (2.4\%) | 0 (0\%) | 2 (8.0\%) | 4 (19.0\%) |
| Advanced periodontitis | 0 (0\%) | 0 (0\%) | 0 (0\%) | 1 (4.8\%) |
| Ectopic eruption | 6 (4.8\%) | 0 (0\%) | 0 (0\%) | 0 (0\%) |
| Odontoma | 2 (1.6\%) | 0 (0\%) | 0 (0\%) | 0 (0\%) |
| Ankyloses | 1 (0.8\%) | 0 (0\%) | 0 (0\%) | 0 (0\%) |
| Cleft-lip and palate | 1 (0.8\%) | 0 (0\%) | 0 (0\%) | 0 (0\%) |

In study IV, a total of 25 patients were initially allocated. Four patients were not included in the study for the following reasons: one patient did not want treatment due to economic reasons, two patients presented extensive osseous defects prior to the planned treatment, and one patient decided to leave the study before surgery. The remaining 21 patients were included in the study and there were no drop-outs during the treatment. Patient characteristics are presented in Table 7 for study I, II and IV.

## Dental implants

In study I there were 102 dental implants installed in the maxilla and 24 in the mandible. The mean time $\pm$ SD in days between fixture installation and the second-stage surgery (abutment connection) was $142 \pm 65$ (range, $0-512$ ) and $105 \pm 39$ (range, $0-184$ ) for the maxilla ( $\mathrm{n}=102$ ) and mandible ( $\mathrm{n}=23$ ), respectively. Maxillary implants received the definitive crowns after a mean of $225 \pm 111$ (range, 80-719) days after implant surgery, while mandibular implants were reconstructed after a mean of $182 \pm 63$ (range, 87-335) days after implant surgery. Details about implant location in study I are presented in Table 8 and details about implant length and diameter are described in Table 9.

Table 8. Overview of implants according to their location study I.

| Implant n (\%) | $3(2.4)$ | $2(1.6)$ | $16(12.7)$ | $24(19.0)$ | $4(3.2)$ |
| :--- | :--- | :--- | :--- | :--- | :--- |
| Location, FDI* | 15 | 14 | 13 | 12 | 11 |
|  | 21 | 22 | 23 | 24 | 25 |
| Implant n (\%) | $6(4.8)$ | $23(18.3)$ | $18(14.3)$ | $3(2.4)$ | $3(2.4)$ |
|  |  |  |  |  |  |
| Implant n (\%) | $6(4.8)$ | $0(0.0)$ | $1(0.8)$ | $0(0.0)$ | $7(5.6)$ |
| Location, FDI* | 35 | 34 | 33 | 32 | 31 |
| Implant n (\%) | $2(1.6)$ | $3(2.4)$ | $1(0.8)$ | $1(0.8)$ | $3(2.4)$ |

*Fédération Dentaire Internationale (FDI) notation system, ISO 3950

Of the 65 implants with a diameter of $3.0 \mathrm{~mm} 61.5 \%$ were used to replace maxillary lateral incisors. The number of implants per patient ranged from 1 to $4 ; 2$ patients ( $2.3 \%$ ) received 4 implants, 5 patients

Table 9. Overview of Implants according to their length and diameter study.

|  |  | Length |  |  | Total |  |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- |
|  |  | 9.5 mm | 11.0 mm | 13.0 mm | 15.0 mm |  |
| Diameter | 3.0 mm | 0 | 15 | 18 | 32 | 65 |
|  | 3.4 mm | 0 | 1 | 15 | 14 | 30 |
|  | 3.8 mm | 1 | 4 | 7 | 18 | 30 |
| Total | 4.5 mm | 1 | 0 | 0 | 0 | 1 |

( $5.7 \%$ ) received 3 implants, 23 patients ( $26.4 \%$ ) received 2 implants, and 57 patients $(65.5 \%)$ received 1 implant. All fixture installations were performed at the Department of Oral and Maxillofacial Surgery, Malmö University Hospital, Malmö, Sweden, by eight different surgeons. One surgeon treated the majority of the patients ( $74.4 \%$ ).

In study I two patients lost one implant each primarily, before abutment connection. Both were installed in the mandibular left central incisor region. These implants were not replaced; instead these patient were rehabilitated with resin-bonded bridges.

The definitive abutments and SCs are described in Table 10. A total of 15 crowns were screw retained whereas 109 crowns were cemented.

Table 10. Overview of abutments and crown materials.

| Abutments | n | Crown material | N |
| :---: | :---: | :---: | :---: |
| Friadent EstheticBase (Dentsply implants, York, PA, USA) | 98 | Procera Zirconia (Nobel Biocare Holding AG, ZürichFlughafen, Switzerland) | 54 |
| Friadent Cercon Abutment (Dentsply implants, York, PA, USA) | 10 | Procera Alumina (Nobel Biocare Holding AG, ZürichFlughafen, Switzerland) | 38 |
| Friadent AuroBase (Dentsply implants, York, PA, USA) | 12 | Gold alloy, veneered | 12 |
| MedentiCAD (Medentika GmbH , Hügelsheim, Germany) | 3 | Titanium, veneered | 6 |
| Atlantis Abutment (Dentsply implants, York, PA, USA) | 1 | KaVo Everest Zirconia (KaVo Dental GmbH, Biberach/Riß, Germany) | 6 |
|  |  | Ceramill Zi (Amann Girrbach AG, Koblach, Austria) | 5 |
|  |  | Denzir (Denzir AB, Skellefteå, Sweden) | 3 |
| Total | 124 |  | 124 |

In study II twenty-five dental implants were installed in each group (IL and DL). In study IV twenty-one dental implants was installed in the DIL group. Details about implant location are presented in Table 11 and details about implant length, diameter and bone site characteristics are described in Table 12.

As for post-operative complications in study II, one implant was lost 3 months after surgery in the DL group, FDI location 13. Concerning study IV two implants were lost 2-4 weeks after surgery, FDI locations 21 and 24. In study II the patient that lost an implant was a smoker, and the two patients with failed implants from study IV displayed signs of parafunction at the initial examination and in addition one was a smoker.

In the IL group 15 restorations were screw-retained and 10 cemented, in the DL group 15 screw-retained and 9 cemented and in the DIL group all were screw-retained

Table 11. Overview of implants according to their location study II and IV.

| Location, FDI* | $\mathbf{1 5}$ | $\mathbf{1 4}$ | $\mathbf{1 3}$ | $\mathbf{1 2}$ | $\mathbf{1 1}$ |
| :--- | :--- | :--- | :--- | :--- | :--- |
| IL | 4 | 2 | 0 | 2 | 3 |
| Implant n (\%) | $(16.0)$ | $(8.0)$ | $(0.0)$ | $(8.0)$ | $(12.0)$ |
| DL | 3 | 2 | 1 | 1 | 3 |
| Implant n (\%) | $(12.0)$ | $(8.0)$ | $(4.0)$ | $(4.0)$ | $(12.0)$ |
| DIL | 0 | 4 | 0 | 3 | 3 |
| Implant n (\%) | $(0.0)$ | $(19.0)$ | $(0.0)$ | $(14.4)$ | $(14.3)$ |
|  |  |  |  |  |  |
| Location, FDI* | $\mathbf{2 1}$ | $\mathbf{2 2}$ | $\mathbf{2 3}$ | $\mathbf{2 4}$ | $\mathbf{2 5}$ |
| IL | 2 | 3 | 3 | 3 | 3 |
| Implant n (\%) | $(8.0)$ | $(12.0)$ | $(12.0)$ | $(12.0)$ | $(12.0)$ |
| DL | 6 | 2 | 3 | 3 | 1 |
| Implant n (\%) | $(24.0)$ | $(8.0)$ | $(12.0)$ | $(12.0)$ | $(4.0)$ |
| DIL | 5 | 3 | 0 | 3 | 0 |
| Implant n (\%) | $(23.8)$ | $(14.3)$ | $(0.0)$ | $(14.3)$ | $(0.0)$ |

[^0]Table 12. Overview of implant and bone characteristics study II and IV.

| Variable | IL | DL | DIL |
| :--- | :--- | :--- | :--- |
| Implant diameter: $3.8 / 4.6 \mathrm{~mm}$ | $18 / 7$ | $22 / 3$ | $19 / 2$ |
| Implant length: $9 / 10.5 / 12 / 15 \mathrm{~mm}$ | $0 / 16 / 9$ | $2 / 14 / 9$ | $1 / 5 / 15 / 0$ |
| Bone quantity: A/B/C/D/E | $5 / 20 / 0 / 0 / 0$ | $2 / 21 / 2 / 0 / 0$ | $4 / 17 / 0 / 0 / 0$ |

## Resonance frequency analysis

The mean $\pm$ SD Implant Stability Quotient (ISQ) values at fixture installation for IL, DL and DIL were $73.64 \pm 7.78,68.86 \pm 8.36$ and $72.19 \pm 7.32$, respectively ( $P=.033$, Kruskal-Wallis test). Dunn's post hoc test after Kruskal-Wallis test adjusted by Bonferroni of group IL-DL, DL-DIL, and IL-DIL yielded $P=.030, P=.342$ and $P=1.000$ respectively.

At completion of the final restoration the mean $\pm$ SD ISQ values were $74.64 \pm 6.31$ and $73.62 \pm 5.05$ for IL and DL, respectively. It should be noted that completion of the final restoration did occur at different time points for the two groups.

## Installation torque

The mean $\pm$ SD installation torque values at fixture installation for IL, DL and DIL were $34.04 \pm 4.89,30.24 \pm 7.92$ and $41.06 \pm 6.03$, respectively. ( $P<.001$, Kruskal-Wallis test). Dunn's post hoc test after Kruskal-Wallis test adjusted by Bonferroni of group IL-DL, DL-DIL, and IL-DIL yielded $P=.430, P<.001$ and $P=.003$ respectively.

## Follow-up

In study I the patients were invited to attend a final clinical and radiographic follow-up examination as part of the study. The unaccounted for implants in study I represented $32.5 \%(n=41)$, whereas $32.1 \%$ of the patients $(\mathrm{n}=28)$ dropped out from the study, see Figure 25. Reasons for patient drop-outs were: could not or did not want to attend the follow-up examination $(\mathrm{n}=18)$ or it was not possible to get in contact with the patient $(\mathrm{n}=10)$. All patients who did not want to attend the follow-up examination reported that their restoration was still in good function.


Figure 25. Clinical study flowchart

The mean $\pm$ SD (min, max) total follow-up time from the implant surgical date was $7.51 \pm 1.58(3.57,11.06)$ years and $6.9 \pm 1.61$ $(2.94,10.05)$ years after crown insertion.

Concerning study II and IV there were no unaccounted for implants and all patients attended the follow-up visit 1-year after delivery of the final restoration, except for two patients who missed the 6-month follow-up in study II. The clinical trial outline is shown in Figure 26.

## Complications prosthetic restorations

In study I after delivery of the final implant-supported SCs altogether 10 crowns were lost during the follow-up period due to loss of crown retention ( $\mathrm{n}=1$ ), porcelain fracture ( $\mathrm{n}=7$ ) and fracture due to trauma ( $\mathrm{n}=2$ ). Two crowns were replaced shortly after completion due to aesthetical reasons and were not considered as lost. Other complications that did occur but did not lead to crown replacement were: porcelain fracture $(\mathrm{n}=3)$ and re-cemented crown after loss of
crown retention ( $\mathrm{n}=2$ ). The overall rate of technical complications were $12 \%$.

In study II and IV no complications to the implant-supported SCs occurred during the 1-year follow-up period.

## Success and survival

For study I the 5 -year implant CSR was $98.4 \%$ ( $95 \%$ CI: 96.3$100 \%$ ); for life table see Table 13. The 5 -year implant-supported SC CSR was $91.8 \%$ ( $95 \%$ CI: 86.3-97.3\%) ; for life table see Table 14.

In study II the implant survival rates after 1-year were $100 \%$ and $96.0 \%$ for IL and DL, respectively ( $P=1.000$, Fisher's exact test). The implant success rates were $96.0 \%$ and $88.0 \%$ for IL and DL, respectively ( $P=.609$, Fisher's exact test).

Concerning study IV the implant survival rate after 1-year was $90.5 \%$ for DIL, after 1 year. No statistically significant difference in survival rate was found between IL and DIL ( $P=.203$, Fisher's exact test). The implant success after 1 year for the DIL was $85.7 \%$. No statistically significant difference in success was found between IL and DIL ( $P=.318$, Fisher's exact test).

For implant survival no statistically significant correlation were found for bone quantity, implant length, implant diameter, implant site and ISQ value in study II and IV.
Table 13．Life table for implant survival study I．

| Interval start <br> time（years） | Number <br> entering | Number <br> withdrawing |
| :--- | :--- | :--- |

time（years）
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Number of
terminal
events







Proportion
terminating

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Table 14. Life table for crown complications study I.

| Interval start time (years) | Number entering interval | Number withdrawing during interval | Number exposed to risk | Number of terminal events | Proportion terminating | Proportion surviving | Cumulative proportion surviving at end of interval |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 0 | 124 | 16 | 116 | 2 | 0.017 | 0.983 | 0.983 |
| 1 | 106 | 3 | 104.5 | 1 | 0.010 | 0.990 | 0.973 |
| 2 | 102 | 4 | 100 | 0 | 0.000 | 1.000 | 0.973 |
| 3 | 98 | 3 | 96.5 | 1 | 0.010 | 0.990 | 0.963 |
| 4 | 94 | 7 | 90.5 | 2 | 0.022 | 0.978 | 0.942 |
| 5 | 85 | 12 | 79 | 2 | 0.025 | 0.975 | 0.918 |
| 6 | 71 | 27 | 57.5 | 1 | 0.017 | 0.983 | 0.902 |
| 7 | 43 | 21 | 32.5 | 1 | 0.031 | 0.969 | 0.874 |
| 8 | 21 | 13 | 14.5 | 0 | 0.000 | 1.000 | 0.874 |
| 9 | 8 | 6 | 5 | 0 | 0.000 | 1.000 | 0.874 |
| 10 | 2 | 2 | 1 | 0 | 0.000 | 1.000 | 0.874 |

## Marginal bone loss

In study I the mean $\pm$ SD marginal bone level was located on average $0.85 \pm 0.63 \mathrm{~mm}$ below the implant-abutment junction at delivery of the definitive prosthesis. The mean $\pm$ SD (min, max) MBL was -0.19 $\pm 0.60 \mathrm{~mm}(-2.37,1.06 ; \mathrm{n}=90)$ at the final follow-up examination. Negative values represent bone loss. The mean $\pm$ SD (min, max) time between baseline and final radiographies was $5.8 \pm 2.7$ years ( 0.69 , 10.05). Figure 27 shows an example of periapical radiographs of one of the patients included in the study, at baseline and after 9 years. The MBL was compared between different subgroups (maxilla, mandible, male, female, smokers, non-smokers, GBR, non-GBR, agenesia and trauma) with no statistically significant differences between these groups, Table 15. The mean $\pm$ SD MBL (min, max) for implants of $3.0,3.4$, and 3.8 mm of diameter were $-0.20 \pm 0.51 \mathrm{~mm}(-1.61,0.84$; $\mathrm{n}=42),-0.10 \pm 0.67 \mathrm{~mm}(-2.37,0.76 ; \mathrm{n}=22)$, and $-0.28 \pm 0.69 \mathrm{~mm}$ (-2.05, 1.06; n = 26), respectively ( $P=.207$; Kruskal-Wallis test). There was only one 4.5 mm diameter implant used in the cohort.


Figure 27. Patient radiographs at baseline (a) and after 9 years at final follow-up (b).

Table 15. Comparison of marginal bone loss (in millimeters) between different groups. Negative values represent bone loss.

| Group | $\underset{(\min , \max )}{ }$ | N | Group | $\begin{gathered} \operatorname{mean} \pm S D \\ (\min , \max ) \end{gathered}$ | n | $\boldsymbol{P}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Maxilla | $\begin{gathered} -0.24 \pm 0.61 \\ (-2.37,1.06) \end{gathered}$ | 77 | Mandible | $\begin{gathered} 0.07 \pm 0.52 \\ (-1.20,0.84) \end{gathered}$ | 13 | .060* |
| Male | $\begin{gathered} -0.04 \pm 0.44 \\ (-1.04,0.84) \end{gathered}$ | 35 | Female | $\begin{gathered} -0.30 \pm 0.67 \\ (-2.37,1.06) \end{gathered}$ | 55 | .204* |
| Smokers | $\begin{gathered} -0.41 \pm 0.80 \\ (-2.37,0.74) \end{gathered}$ | 13 | Nonsmokers | $\begin{aligned} & -0.16 \pm 0.56 \\ & (-2.05,1.06) \end{aligned}$ | 77 | .291* |
| GBR | $\begin{gathered} -0.12 \pm 0.61 \\ (-1.61,0.84) \end{gathered}$ | 16 | Non-GBR | $\begin{gathered} -0.19 \pm 0.57 \\ (-2.05,1.06) \end{gathered}$ | 69 | .831* |
| Agenesia | $\begin{gathered} -0.19 \pm 0.60 \\ (-2.37,1.06) \end{gathered}$ | 69 | Trauma | $\begin{aligned} & -0.31 \pm 0.67 \\ & (-1.65,0.84) \end{aligned}$ | 11 | .547** |

Concerning studies II and IV the MBL after 12 months for IL, DL and DIL is presented in Table 16, with DIL implants displaying the lowest MBL, with no statistically significant difference between the groups.

The mean $\pm$ SD marginal bone level was located on average for IL, DL and DIL $0.40 \pm 0.45 \mathrm{~mm}, 0.36 \pm 0.47 \mathrm{~mm}$ and $0.28 \pm 0.29$ mm below the implant-abutment junction at implant installation ( $P=.743$, Kruskal-Wallis test).

In study II the mean $\pm$ SD (min, max) MBL for the period 0-6 months for IL and DL were $-0.51 \pm 0.50 \mathrm{~mm}(-1.80,0.57)$ and -0.51 $\pm 0.56 \mathrm{~mm}(-2.04,0.22)$, respectively $(P=.589$, Mann-Whitney test) and from $7-12$ months $-0.07 \pm 0.28 \mathrm{~mm}(-0.37,0.79)$ and $-0.18 \pm$ $0.41 \mathrm{~mm}(-0.37,1.22)$, respectively ( $P=.332$, Mann-Whitney test). In both the IL and DL group there was a statistically significant difference in MBL between $0-6$ months and $7-12$ months ( $P<.001$ and $P<.001$, Wilcoxon signed-rank test).

Considering the entire population in study II and IV the mean $\pm$ SD (min, max) MBL between smokers ( $\mathrm{n}=7$ ) and non-smokers ( n $=61)$ at 12 months was $-0.93 \pm 0.80 \mathrm{~mm}(-2.05,0.00)$ and $-0.52 \pm$ $0.45 \mathrm{~mm}(-2.37,0.44)$, respectively ( $P=.250$, Mann-Whitney test).

## Gingival index

In study I the mean $\pm \mathrm{SD}(\mathrm{min}, \max )$ gingival index score at the final examination was $1.21 \pm 0.54(1,3 ; \mathrm{n}=85)$. Gingival index scores for study II and IV are presented in Table 17, with no statistically significant difference between the groups.
Table 16. MBL at 12 months, gingival index and papilla index.

| Variable | Study II |  | Study IV | $\boldsymbol{P}$ | P |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | IL | DL |  |  |  |  |  |
|  | mean $\pm$ SD (min, max) | mean $\pm$ SD (min, max) | mean $\pm$ SD (min, max) |  | IL-DL | IL-DIL | DL-DIL |
| MBL (mm) | $-0.57 \pm 0.52(-2.05,0.21)$ | $-0.69 \pm 0.57(-2.37,0.18)$ | $-0.40 \pm 0.41$ (-1.17, 0.44) | .189* | .438** | .263** | .070** |
| Gingival index |  |  |  |  |  |  |  |
| Initial appointment | $1.24 \pm 0.52(1,3)$ | $1.36 \pm 0.70(1,3)$ | $1.10 \pm 0.30(1,2)$ | . $383 \dagger$ |  |  |  |
| 3 months follow-up | $1.08 \pm 0.28(1,2)$ | $1.00 \pm 0.00(1,1)$ | $1.05 \pm 0.23$ (1,2) | . $391 \dagger$ |  |  |  |
| 12 months follow-up | $1.12 \pm 0.33(1,2)$ | $1.04 \pm 0.02(1,2)$ | $1.16 \pm 0.37(1,2)$ | . $438 \dagger$ |  |  |  |
| PI, mesial |  |  |  |  |  |  |  |
| Temporary crown | $0.72 \pm 0.79(0,2)$ | $1.62 \pm 0.82(0,3)$ | $1.63 \pm 0.90(0,3)$ | . $001 \dagger$ | . $002 \ddagger$ | . $003 \ddagger$ | $1.000 \ddagger$ |
| Definitive crown | $1.88 \pm 0.97(0,3)$ | $2.29 \pm 0.80(0,3)$ | $2.21 \pm 0.53(1,3)$ | .234* |  |  |  |
| 12 months follow-up | $2.56 \pm 0.51(2,3)$ | $2.63 \pm 0.58(1,3)$ | $2.68 \pm 0.51(2,3)$ | .681* |  |  |  |
| PI, distal |  |  |  |  |  |  |  |
| Temporary crown | $0.72 \pm 0.54(0,2)$ | $1.38 \pm 0.82(0,3)$ | $1.63 \pm 0.60(0,2)$ | <.001 $\dagger$ | .006 $\ddagger$ | <.001 $\ddagger$ | .681\% |
| Definitive crown | $1.24 \pm 0.88(0,3)$ | $2.08 \pm 0.83(0,3)$ | $2.00 \pm 0.58(1,3)$ | . $001 \dagger$ | .002 $\ddagger$ | .014\# | $1.000 \ddagger$ |
| 12 months follow-up | $2.12 \pm 0.67(1,3)$ | $2.25 \pm 0.85(0,3)$ | $2.42 \pm 0.51(2,3)$ | . $357 \dagger$ |  |  |  |

## Papilla index

The results for the papilla index for studies II and IV are presented in Table 16. In both studies a statistically significant higher papilla index score were found for group DL and DIL concerning the mesial sites at temporary crown placement $(P=.002$ and $P=.003)$, distal sites at temporary crown placement $(P=.006$ and $P=<.001)$ and for the distal sites at definitive crown placement $(P=.002$ and $P=.014)$, respectively. A complete papilla fill according to papilla index on both mesial and distal sides for IL, DL and DIL after 12 months was $28.0 \%, 45.8 \%$ and $36.8 \%$, respectively ( $P=.433$, Chi-square test)

## Change in vertical and horizontal dimensions

In study I the mean $\pm$ SD (min, max) change in vertical distance between FAJ and CEJ of the adjacent tooth on the mesial side was $0.13 \pm 0.57 \mathrm{~mm}(-1.28,2.06 ; \mathrm{n}=78)$, where positive values represent increase in the distance. The change in vertical distance was compared between different subgroups (maxilla, mandible, male, female, orthodontic treatment and non-orthodontic treatment) with a statistically significant differences between male and female $(P=$ .010), Table 17. There was a very weak relationship between the patients' age and change in vertical distance $\left(\mathrm{R}=.053, \mathrm{R}^{2}=.003, P\right.$ $=.645$, Pearson correlation). For every 1-year increase of the patients' age, there was a change in vertical distance of 0.004 mm .

Table 17. Comparison of vertical distance (in millimeters) between the fixture/abutment junction (FAJ) and the cement/enamel junction (CEJ) of the adjacent tooth on the mesial side between different groups. Positive values represent increase in the distance.

| Group | Group |  |  | $\boldsymbol{P}$ |
| :---: | :---: | :---: | :---: | :---: |
| mean $\pm$ SD (min, max) | n | mean $\pm$ SD (min, max) | n |  |
| Maxilla | Mandible |  |  |  |
| $0.15 \pm 0.58$ (-1.28, 2.06) | 67 | $-0.02 \pm 0.51(-0.76,0.96)$ | 11 | .272* |
| Male | Female |  |  |  |
| $-0.09 \pm 0.44$ (-1.28, 0.88) | 28 | $0.25 \pm 0.60$ (-0.75, 2.06) | 50 | .010** |
| Orthodontics |  | Non-orthodontics |  |  |
| $0.97 \pm 0.55$ (-1.28, 2.61) | 57 | $0.21 \pm 0.62$ (-0.75, 1.76) | 21 | .424** |

[^1]The mean $\pm \mathrm{SD}(\min , \max )$ change in horizontal distance between the adjacent teeth was $0.01 \pm 0.41 \mathrm{~mm}(-0.68,0.96 ; \mathrm{n}=51)$, where positive values represent increase in the single tooth space.

## Soft tissue changes

In studies II and IV the soft tissue changes for gingival zenith and papilla levels for IL, DL and DIL are presented in Table 18. Statistically significant less soft tissue change was found for the distal papilla at 12 months for DIL compared to IL ( $P=.026$ ), and for gingival zenith at 3 months for DIL compared to DL $(P=.021)$.

## Pink and white esthetic score

Concerning PES and WES outcomes in study I intraoral photographs of 106 out of 126 implants were available for the initial PES. Concerning the final PES and WES, intraoral photographs from one additional patient were included that had recently visited the clinic prior to the final follow-up examination, leading to a total of 86 implants. The mean $\pm$ SD $(\min , \max )$ for initial and final total PES were 9.61 $\pm 2.78(1,14 ; \mathrm{n}=106)$ and $11.49 \pm 2.68(2,14 ; \mathrm{n}=86)$, respectively ( $P<.001$, Wilcoxon signed-rank test). The values of initial and final total PES for male were $9.08 \pm 2.96(4,14 ; \mathrm{n}=37)$ and $10.85 \pm 3.14$ ( 2,$14 ; \mathrm{n}=34$ ), respectively ( $P=.023$, Wilcoxon signed-rank test), and for female they were $9.90 \pm 2.66(1,14 ; n=69)$ and $11.90 \pm 2.28$ ( 2,$14 ; \mathrm{n}=52$ ), respectively ( $P<.001$, Wilcoxon signed-rank test). The difference between male and female for the initial PES was not statistically significant ( $P=.194$, Mann-Whitney test), nor was it for the final PES score ( $P=.140$, Mann-Whitney test).

The mean $\pm$ SD (min, max) total WES was $6.48 \pm 2.35(0,10 ; n$ $=86)$. The values of WES for male and female were $6.12 \pm 2.46(1$, $10 ; \mathrm{n}=34)$ and $6.71 \pm 2.27(0,10 ; \mathrm{n}=52)$, respectively $(P=.244$; Mann-Whitney test).

Concerning only implants of diameter 3.0 mm used to replace missing maxillary lateral incisors the mean $\pm S D$ (min, max) final PES and WES were $12.58 \pm 1.28(9,14 ; \mathrm{n}=34)$ and $7.41 \pm 1.86(2$, 10; $n=34$ ), respectively.

For studies II and IV an overview of PES and WES outcomes for the groups IL, DL and DIL can be found in Table 19, with no statistically significant differences.

There was a statistically significant improvement in PES between initial evaluation and the 12 months follow-up for IL, DL and DIL ( $P=.001, P=.002$ and $P=<.001$ Wilcoxon signed-rank test) and for WES ( $P=.008, P=.001$ and $P=.012$, respectively, Wilcoxon signed-rank test). Patient with improved PES over time presented in Figure 28.

Concerning perfect aesthetics and aesthetic failures, the results for studies I, II and IV are presented in Table 20.


Figure 28. A: Definitive SC placement. B: 1-year follow-up. Improved PES score variables: mesial papilla, distal papilla, soft tissue contour, soft tissue color and soft tissue texture.
Table 18. Soft tissue changes in mm

| Variable | Study II |  | Study IV | P | P |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | IL | DL | DIL |  |  |  |  |
|  | mean $\pm$ SD (min, max) | mean $\pm$ SD ( $\mathrm{min}, \mathrm{max}$ ) | mean $\pm$ SD (min, max) |  | IL-DL | IL-DIL DL-DIL |  |
| Mesial papilla |  |  |  |  |  |  |  |
| Temporary | $0.33 \pm 0.47(-0.85,1,36)$ | $0.24 \pm 0.58$ (-0.21, 1.92) | $0.10 \pm 0.56$ (-0.93, 1,31) | .164† |  |  |  |
| 3 months | $0.24 \pm 0.39$ (-0.46, 1.28) | $0.25 \pm 0.51(-1.05,1.31)$ | $0.18 \pm 0.43$ (-0.22, 1.37) | . $501 \dagger$ |  |  |  |
| 12 months | $0.74 \pm 0.70$ (-0.36, 2.35) | $0.60 \pm 0.58$ (-0.26, 2.40) | $0.37 \pm 0.55(-0.46,1.58)$ | .119† |  |  |  |
| Distal papilla |  |  |  |  |  |  |  |
| Temporary | $-0.01 \pm 0.54(-1.41,0.68)$ | $0.09 \pm 0.74$ (-1.47, 1.34) | $-0.18 \pm 0.57(-2.22,0.48)$ | . $241 \dagger$ |  |  |  |
| 3 months | $0.30 \pm 0.44(-0.47,1.41)$ | $0.24 \pm 0.42$ (-0.33, 1.34) | $0.06 \pm 0.34(-0.44,1.05)$ | .098† |  |  |  |
| 12 months | $0.63 \pm 0.47$ (-0.22, 1.49) | $0.50 \pm 0.60$ (-1.24, 1.71) | $0.24 \pm 0.39(-0.33,1.06)$ | .029 $\dagger$ | 1.000\% | .026* | .183* |
| Gingival zenith |  |  |  |  |  |  |  |
| Temporary | $-0.17 \pm 0.45(-1.00,0.72)$ | $-0.19 \pm 0.60(-1.19,0.71)$ | $-0.10 \pm 0.25(-0.66,0.22)$ | . $929 \dagger$ |  |  |  |
| 3 months | $0.09 \pm 0.31(-0.40,0.65)$ | $0.24 \pm 0.42$ (-0.53, 1.07) | $-0.04 \pm 0.26$ (-0.80, 0.28) | . $026 \dagger$ | . 394 | . 578 | .021\% |
| 12 months | $0.10 \pm 0.38$ (-0.75, 0.92) | $0.32 \pm 0.52$ (-0.54, 1.37) | $-0.02 \pm 0.36$ (-0.87, 0.50) | .147† |  |  |  |

SD - standard deviation
$\ddagger$ Dunn's post hoc test adjusted by Bonferroni correction
Table 19. PES and WES score studies II and IV.

| Variable | Study II |  | Study IV | P* |
| :---: | :---: | :---: | :---: | :---: |
|  | IL | DL | DIL |  |
| PES | mean $\pm$ SD (min, max) | mean $\pm$ SD (min, max) | mean $\pm$ SD (min, max) |  |
| Definitive crown placement | $8.56 \pm 2.27(2,13)$ | $9.42 \pm 2.98(4,14)$ | $8.79 \pm 2.42(2,12)$ | . 338 |
| 3 months follow-up | $9.32 \pm 2.14(3,13)$ | $10.08 \pm 2.52(5,14)$ | $9.68 \pm 2.06(5,12)$ | . 383 |
| 12 months follow-up | $10.36 \pm 2.46$ ( 3,14 ) | $10.67 \pm 2.32$ ( 5,14 ) | $10.53 \pm 2.04(5,13)$ | . 839 |
| WES |  |  |  |  |
| Definitive crown placement | $7.00 \pm 1.41(4,10)$ | $7.00 \pm 1.64(4,10)$ | $7.11 \pm 1.76(4,10)$ | . 941 |
| 3 months follow-up | $7.24 \pm 1.36(4,10)$ | $7.54 \pm 1.74(4,10)$ | $7.26 \pm 1.56(4,10)$ | . 560 |
| 12 months follow-up | $7.76 \pm 1.30(5,10)$ | $7.87 \pm 1.39(5,10)$ | $7.79 \pm 1.36(4,10)$ | . 911 |

[^2]Table 20. Perfect aesthetic outcome, average and aesthetic failure studies I, II and IV. Study I implant level and study II,IV patient level.

| Variable |  | Perfect outcome <br> PES $\geq 12 \&$ WES $\geq 9$ | Average | Aesthetic failure <br> PES $\leq 7$ and/or WES $\leq 5$ |
| :--- | :--- | :---: | :---: | :---: |
| Study I |  | $14.1 \%$ | $80.2 \%$ | $4.7 \%$ |
| Study II | IL | $20.0 \%$ | $64.0 \%$ | $16.0 \%$ |
|  | DL | $16.7 \%$ | $70.8 \%$ | $12.5 \%$ |
| Study IV | DIL | $15.8 \%$ | $68.4 \%$ | $15.8 \%$ |

## PROMs

In study I the mean $\pm$ SD (min, max) Add-OHIP-14 score on patient level was $16.07 \pm 3.29(14,28 ; n=56)$ at the final examination. The mean $\pm$ SD (min, max)VAS for the satisfaction of the soft tissue appearance (VAS-1) and implant-supported SCs appearance (VAS-2) were $73.5 \pm 21.7(18,100 ; \mathrm{n}=82)$ and $82.1 \pm 18.3(10,100 ; \mathrm{n}=82)$, respectively. The values of VAS-1 for male and female were $74.6 \pm 25.5$ (18, $100 ; \mathrm{n}=34)$ and $72.8 \pm 18.8(18,100 ; \mathrm{n}=48)$, respectively $(\mathrm{P}=.180$, Mann-Whitney test), the VAS-2 for male and female were $86.8 \pm 12.4$ $(65,100 ; \mathrm{n}=34)$ and $78.8 \pm 21.1(10,100 ; \mathrm{n}=48)$, respectively $(\mathrm{P}=$ .062, Mann-Whitney test). Out of the 59 attending the final follow-up examination, 56 completed the OHIP-14 questioner and VAS. Figure 29 shows a patient restoration and reported PROMs.


Figure 29. Patient from study I, final follow-up examination. Dental implant in site 13. PES final=13, WES $=10$, VAS- $1=69$, VAS $-2=85$, Add-OHIP-14=15

Concerning only implants of diameter 3.0 mm used to replace missing maxillary lateral incisors, the $\pm$ SD (min, max) Add-OHIP-14, VAS-1 and VAS-2 were $16.87 \pm 3.61(14,25 ; n=31), 73.80 \pm 24.12(18,100$; $\mathrm{n}=31)$ and $79.52 \pm 21.74(10,100 ; \mathrm{n}=31)$, respectively.

In study I the relationship between VAS-1 and final PES score was very weak ( $\mathrm{R}=.187, \mathrm{R} 2=.035, P=.092$; Pearson correlation). The linear regression analysis showed that for every 1 point increase in PES, the VAS- 1 value increased 1.505 points. The relationship between VAS-2 and the WES score was very weak ( $\mathrm{R}=.029$, R 2 $=.001, P=.793$; Pearson correlation). The linear regression analysis showed that for every 1 point increase in WES, the VAS-2 value increased 0.227 point.

The results of PROMs for the studies II and IV are presented in Table 21. In studies II and IV the mean $\pm$ SD Add-OHIP-14 score at the initial appointment for males and females were $22.09 \pm 6.86$ $(\mathrm{n}=31)$ and $25.50 \pm 9.60(\mathrm{n}=40)$, respectively $(P=.172$, Mann-Whitney test). At the final follow-up the mean Add-OHIP-14 score for males and females were $16.52 \pm 3.09(\mathrm{n}=29)$ and $16.08 \pm 3.50$ ( $\mathrm{n}=39$ ), respectively $(P=.406$, Mann-Whitney test). There was an overall statistically significant improvement in OHRQoL, assessed by OHiP-14, between initial appointment and temporary crown for IL, DL and DIL ( $P<.001, P=.002$ and $P=.001$, Wilcoxon signed-rank test). Further for OHIP-14 there was a statistically significant improvement between temporary restoration and 12 months follow-up both for IL, DL and DIL $(P=.005, P=.006$ and $P=$ .041, respectively, Wilcoxon signed-rank test). Statistically significant lower Add-OHIP-14 score was found for DIL in relation to IL after two months with a temporary crown $(P=.024)$. For study II the relationship between VAS and final (12-month) PES score was very weak $(\mathrm{R}=.033, \mathrm{R} 2=.001, P=.825$; Pearson correlation). The linear regression analysis showed that for every 1 point increase in PES, the VAS value increased by 0.141 points. The relationship between VAS and the final (12-month) WES score was very weak $(\mathrm{R}=.061, \mathrm{R} 2$ $=.004, P=.678$; Pearson correlation). The linear regression analysis showed that for every 1 point increase in WES, the VAS value increased by 0.471 points. Relationship VAS and final (12-month) Add-OHIP-14 score was moderate $(\mathrm{R}=.404, \mathrm{R} 2=.163, P=.004$; Pearson correlation). The linear regression analysis showed that for every 1 point increase in Add-OHIP-14, the VAS value decreased 1.225 points.
Table 21.Outcome PROMs study II and IV

| Variable | Study II |  | Study IV | $\boldsymbol{P}$ | $\boldsymbol{P}$ |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | IL | DL | DIL |  |  |  |  |
|  | mean $\pm$ SD (min, max) | mean $\pm$ SD (min, max) | mean $\pm$ SD ( min, max) |  | IL-DL | IL-DIL | DL-DIL |
| Add-OHIP-14 |  |  |  |  |  |  |  |
| Pre-surgery | $26.68 \pm 9.30(15,46)$ | $23.40 \pm 8.64(14,52)$ | $21.57 \pm 7.17(14,35)$ | . $104 \dagger$ |  |  |  |
| Temporary crown | $18.64 \pm 5.32(14,34)$ | $18.67 \pm 9.06(14,57)$ | $15.42 \pm 2.47(14,22)$ | . $028 \dagger$ | $1.000 \%$ | .024* | .204* |
| 12 months follow-up | $16.48 \pm 3.87(14,29)$ | $15.38 \pm 2.58(14,25)$ | $17.10 \pm 3.23(14,24)$ | . $170 \dagger$ |  | . |  |
| VAS |  |  |  |  |  |  |  |
| Pain surgery |  |  | $25.9 \pm 29.8(0,86)$ |  |  |  |  |
| Discomfort surgery |  |  | $21.4 \pm 24.8(0,82)$ |  |  |  |  |
| Pain impression |  |  | $9.9 \pm 10.7(0,38)$ |  |  |  |  |
| Discomfort impression |  |  | $6.3 \pm 17.5(0,26)$ |  |  |  |  |
| Aesthetic pre-surgery |  |  | $34.6 \pm 25.8(0,96)$ |  |  |  |  |
| Aesthetic temporary |  |  | $67.4 \pm 20.1(21,96)$ |  |  |  |  |
| Aesthetic 12 months follow-up | $89.58 \pm 9.5(70,100)$ | $87.93 \pm 11.3(60,100)$ | $88.90 \pm 14.8(47,100)$ | . $791 \dagger$ |  | - |  |

SD - standard deviation, $\dagger$ Kruskal-Wallis test, $\ddagger$ Dunn's post hoc test adjusted by Bonferroni correction
Table 22. Comparison of MBL (negative values mean bone loss), vertical distance (Positive values represent increase in the distance), WES, PES final, VAS-1, VAS-2, and OHIP-14 between implants placed in patients with bilateral and unilateral tooth agenesia (considering only aplasia and excluding implants in mandible and in sites 11 and 21).

[^3]$\begin{array}{cc} & \text { Unilateral agenesia } \\ \mathrm{n} & \text { mean } \pm \text { SD }(\min , \max ) \\ 31 & -0.32 \pm 0.72(-2.37,0.61) \\ 25 & 0.17 \pm 0.56(1.28,-0.75) \\ 38 & 6.75 \pm 1.59(3,10) \\ 38 & 11.15 \pm 2.94(2,14) \\ 36 & 65.5 \pm 24.4(18,95) \\ 36 & 74.9 \pm 24.4(10,100) \\ 36 & 15.3 \pm 2.7(14,25)\end{array}$
$\begin{array}{cc} & \text { Unilateral agenesia } \\ \mathrm{n} & \text { mean } \pm \text { SD }(\min , \max ) \\ 31 & -0.32 \pm 0.72(-2.37,0.61) \\ 25 & 0.17 \pm 0.56(1.28,-0.75) \\ 38 & 6.75 \pm 1.59(3,10) \\ 38 & 11.15 \pm 2.94(2,14) \\ 36 & 65.5 \pm 24.4(18,95) \\ 36 & 74.9 \pm 24.4(10,100) \\ 36 & 15.3 \pm 2.7(14,25)\end{array}$


| $\boldsymbol{P}$ |
| :---: |
| $.023^{*}$ |
| $.063^{*}$ |
| $.280^{*}$ |


4
Mean $\pm$ SD $($ min, max $)$
$0.39 \pm 0.01(0.21,0.63)$
$0.49 \pm 0.17(0.23,0.77)$
$1.25 \pm 0.49(0.52,1.98)$

DLP
Mean $\pm$ SD (min, max)
$0.27 \pm 0.08(0.15,0.36)$
$0.34 \pm 0.14(0.10,0.53)$ $0.99 \pm 0.57$ ( $0.27,1.90$ )

Table 23. Deviation differences in implant positions.
SD - standard deviation, * Mann-Whitney test, ** Student's stest
Variable
Deviation at entry point (mm)
Deviation at apex (mm)
Angular deviation (degrees)
For vertical deviation, positive values represent more coronal position of implant; SD - standard deviation, "Mann-Whitney test

## Deviation from the planned implant position

The mean $\pm$ SD (min, max) deviation at entry point, implant apex, angular deviation, vertical position and horizontal position for DIL were $0.72 \pm 0.36 \mathrm{~mm}(0.18,1.55), 1.09 \pm 0.56 \mathrm{~mm}(0.19,2.27)$, $2.60 \pm 1.53^{\circ}(0.31 .5 .84), 0.48 \pm 0.31 \mathrm{~mm}(0.13,1.17)$ and $0.49 \pm$ $0.30 \mathrm{~mm}(0.10,1.47)$, respectively. The relationship between final PES (12 months) and deviation entry point was moderate ( $\mathrm{R}=.554$, $\mathrm{R}^{2}=.307, P=.014$; Pearson correlation). The relationship between final PES ( 12 months) and deviation vertical position was moderate ( $\mathrm{R}=.515, \mathrm{R}^{2}=.265, P=.024$; Pearson correlation). The relationship between survival and vertical position was moderate $\left(\mathrm{R}=.567, \mathrm{R}^{2}\right.$ $=.321, P=.007$; Pearson correlation). Linear regression analysis showed increased implant deviation negatively affected both PES and survival.

## Agenesia study l

In study I two subgroups with agenesia, bilateral or unilateral agenesia, were further evaluated. Considering only agenesia cases (excluding tooth positions 11,21 and mandible) the comparison of MBL, vertical distance, WES, PES final, VAS-1, VAS-2, and OHIP-14 between implants placed in patients with bilateral and unilateral tooth agenesis are presented in Table 22. A statistical significant difference was found for PES-final score ( $P=.010$ ).

## Laboratory study III

A total of 20 dental implants were placed with no unexpected occurrences during surgical guide fabrication or fixture installation. The mean $\pm$ SD RMS between the points used for the best-fit alignment of the two datasets were for DLP $18.8 \pm 4.0 \mu \mathrm{~m}$ and SLA $18.9 \pm$ $4.3 \mu \mathrm{~m}(P=.739)$. In the DLP group, the lowest mean deviation was found for vertical implant position ( $0.16 \pm 0.11 \mathrm{~mm}$ ) and for the SLA group in horizontal implant position ( $0.16 \pm 0.11 \mathrm{~mm}$ ). The SLA group had the highest mean deviation at the apex $(0.49 \pm 0.17$ $\mathrm{mm})$. For the DLP group, the deviation at the apex was $0.34 \pm 0.14$ mm . Statistically significant differences were found for deviation at entry point ( $P=.023$ ) and for vertical implant position ( $P=.009$ ). A summary of the statistical analysis for deviations in dental implant position between the DLP and SLA group is presented in Table 23.

## DISCUSSION

The three clinical studies and the laboratory study included in the present thesis focused on single dental implant treatment in the anterior dentition, evaluating several factors of clinical relevance, such as survival, success, MBL, aesthetics and PROMs.

In the clinical studies moderately rough dental implants were used and high survival rates are to be expected today. ${ }^{9}$ In the retrospective study I the 5 -year implant CSR was $98.4 \% ~(95 \%$ CI: 96.3-100\%). This finding was similar to what others have reported for implant survival at 5 years: $97.2 \%$ ( $95 \%$ CI: $96.3-97.9 \%$ ). ${ }^{57}$ Success was not reported in the study I, and the reason for this was that no radiographs were available at fixture installation and, therefore, the amount of MBL between fixture installation and delivery of the definitive SCs could not be accounted for.

In study II the implants in the DL group presented a lower survival rate, of $96 \%$, opposed to $100 \%$ for IL implants, due to the early loss of one implant. Further, in the study IV the DIL group lost two implants shortly after fixture installation, resulting in a survival rate of $90.5 \%$. For study II and IV prophylactic antibiotics were used, contrary to none in study I. A recent systematic review, including only RCTs with at least 6 months of follow-up, reported a mean survival rate of $98.2 \%$ for immediate loaded dental implants. ${ }^{75}$ Others have reported similar findings for immediately loaded single implants. ${ }^{77,136}$ The survival outcome for the DIL group (immediate loading and guided surgery) raises some concerns. It is known that immediate loading results in a statistically significant higher risk of implant failure, especially in single implant cases. ${ }^{75,76}$ However, it is common for studies on immediate loading to exclude smokers and
bruxism, considered to be risk factors for early implant loss. ${ }^{137}$ The two patients who lost implants presented signs of parafunction on adjacent teeth, and one of these patients was a smoker. However, excluding these patients would limit the identification of possible risk factors. Moreover, as the IL group in this case was immediately loaded and the same inclusion and exclusion criteria applied, something else may certainly have contributed to implant loss in the DIL group. The DIL group presented statistically significant higher installation torque values than the IL group, with torque values above 30 Ncm for all cases, including the two later failed dental implants. However, as the installation torque for the DIL group was measured during installation with the surgical guide still in place these results should, therefore, be interpreted with caution. There were nonetheless no statistically significant difference in ISQ values between DIL and IL, and implant survival did not correlate with bone quantity, implant length, implant diameter and site. Others have found that higher ISQ values can be correlated to an increase in installation torque, increased implant diameter, bone quality and patient sex. ${ }^{138}$ The statistically significant lower ISQ value at implant installation for the DL group may have been influenced by these factors.

Another possible contributing factor leading to early implant loss, but not evaluated in the present study, is the possible effect of inadequate irrigation during flapless fully guided-surgery, as bone drilling during preparation of the implant site may induce thermal trauma and prejudice the treatment outcome from the early stages of healing. ${ }^{139}$ Furthermore, there was a moderate correlation between survival and vertical deviation in implant position for the implants in the DIL group, suggesting that deviation in implant position can have an effect on implant survival when subjected to immediate loading. The results for deviation in implants position reported for DIL implants were in agreement with previously reported results. ${ }^{91}$

Regarding implant-supported SCs in study I the CSR was $91.8 \%$ ( $95 \%$ CI: 86.3-97.3\%), somewhat lower than Jung et al. reported for implant-supported SCs at 5-years: 96.3\% (95\% CI: 94.2-97.6\%). ${ }^{57}$ Pjetursson et al. reported in a systematic review on the 5 -year survival rates of metal-ceramic and zirconia-supported implant-supported SCs, 98.3\% (95\% CI: 96.8-99.1) and 97.6\% (95\% CI: 94.3-99.0), respectively. ${ }^{112}$ The reason for a lower SC survival in study I was


Figure 30. Porcelain fracture of laterial incisor.
mainly due to porcelain fractures. A possible reason for this can be that the SCs included did not comprise of an even distribution from every location in the dental arch. A total of $37.3 \%$ of the dental implants were in the lateral incisors region in the maxilla, a location more frequent to failure in the study I (Figure 30). For implant-supported SCs higher fracture rates have been reported for posterior teeth opposed to anterior ones, ${ }^{112}$ in contrast to the results in the study I. Zirconia restorations have been associated with a higher risk for porcelain fracture. ${ }^{112}$ In the present study Procera Zirconia and Alumina represented the majority of restoration and stock abutments were mainly used. Inadequate support of the veneering material could be a possible explanation for the lower crown survival in the present study, a factor addressed by other especially concerning the early implant-supported zirconia restorations. ${ }^{112}$

In study I the mean overall MBL was -0.19 mm , with a mean follow-up time of 7 years after SCs insertion. As all implants were placed at the crestal level by the surgeons and the crestal bone on average was located 0.85 mm below the implant collar at baseline (definitive prosthesis delivery), some initial bone loss might have occurred that was not accounted for during the first year. The subgroups (maxilla, mandible, male, female, smokers, non-smokers, GBR, non-GBR, agenesis and trauma) were small and imbalanced, which may explain the lack of statistically significant differences.

Others have however reported that smoking has potential negative effect on treatment outcome. ${ }^{140}$ With regard to implant diameter, 3.0 mm narrow-diameter implants did not seem to lose more bone than wider implants. This is in agreement with other studies that report similar outcomes for narrow implants as compared with standard diameter ones. ${ }^{141,142}$ However, some have suggested a possible negative impact on MBL for narrow-diameter implants due to increased stress values at the implant-bone interface or the use of alloys to increase the implant fracture resistance. ${ }^{142}$ No findings in the study I could be related to this.

Concerning the studies II and IV a mean MBL occurred in all groups during the 1-year observation period. In the study II (IL and DL), in addition to a 1-year evaluation of MBL, the MBL after 6 months was evaluated. A greater percentage of the total MBL did occur during the initial 6 months opposed to the following 6 months across both groups. This greater initial MBL could be related to the bone remodeling process initiated after fixture installation. ${ }^{143}$ The total amount of MBL for both studies II and IV corresponds to the findings of a previous study evaluating immediate loading with the same implant system. ${ }^{136}$ Therefore the lack of statistically significant difference for MBL between groups seems to indicate that immediate loading in the present study did not affect the MBL in relation to delayed loading during the 1 -year of function. Neither does a digital workflow with guided surgery seem to have any negative effect on the marginal bone within this short evaluation period. However, one should keep in mind that a lager sample size and a longer follow-up period could result in a different outcome.

Changes in vertical and horizontal tooth-implant position were evaluated in the study I. The probable reason for the change in vertical position of dental implants and their SCs leading consequently to a infraposition, is the fact that implants behave like ankylosed teeth, and do not follow the changes of the alveolar processes during growth of the jaws. ${ }^{144}$ This remodelling process may continue until late adulthood and is not completely age dependent. ${ }^{24}$ In the study I there was a slight increase in the vertical distance between baseline and follow-up. The correlation with age was however very weak, as may be expected in a cohort consisting of mainly young adults followed for a limited period of time. Others have suggested that the
degree of infraposition is correlated to the shape of the face. ${ }^{27}$ Due to the lack of information of face shape in the present study this was not possible to investigate. Moreover, there was a significant difference ( $P=.010$ ) between males and females regarding infraposition. The patients with an infraposition of more than 1 mm were all females $(\mathrm{n}=5)$. This finding supports previous observations that females seem to present a higher risk for infraposition. ${ }^{27,28}$ In the other subgroups (maxilla, mandible, prior orthodontic treatment, bilateral agenesia and unilateral agenesia) there were no statistically significant differences, probably due to very unbalanced subgroups.

The papilla index and soft tissue changes were evaluated in the studies II and IV. The statistically significant early differences in papilla index, between IL and DL could be explained by the differences in time between implant surgery and definitive crown placement for these two groups. Even differences in flap adaptation and suturing may have played a role as well. Moreover, the DL group may present a higher score due to the reshaping of the emergence profile until patient satisfaction was reached. Others have suggested that such soft tissue conditioning by customizing the shape and contour of a provisional restoration in the aesthetic zone helps the achievement of a better aesthetic outcome. ${ }^{19}$ Statistically significant higher papilla index scores observed for the DIL group could be explained by the less invasive flapless surgery procedure. Similar findings for guided surgery have been reported by others. ${ }^{110}$ Concerning soft-tissue changes at papilla sites, there were no statistically significant differences between the groups, except between the groups IL and DIL for distal papilla at the 12 -month follow-up. The papilla index scores correlated very well with the overall small changes in soft tissue papilla levels for the DIL group and could further be connected to the reported less postoperative swelling following guided surgery. ${ }^{109}$ The present results suggest a positive effect using a custom interim restoration from the day of fixture installation. Combining this with post-healing soft tissue conditioning used in the DL group, as suggested by others, could further help to improve the aesthetic outcome. ${ }^{61}$

It is not possible to conclude with the present results if pre-designed temporary restorations would have had any superior effects on papilla formation compared with temporary restoration fabricated directly after installation. The punch procedure for flapless surgery
in the DIL group result in some loss of keratinized soft tissue and could possibly compromise the aesthetic outcome. However, changes in gingival zenith and PES did not statistically significantly differ between the groups except for gingival zenith between DL and DIL at the 3-month follow-up, however, the mean difference was 0.28 mm and two different measurement methods were used (intraoral scans and plaster casts).

There was an overall tendency of the papilla to gradually increase in height with time, correlating to the changes found in the papilla index score. The gradual improvement in aesthetics and changes in soft tissue shape may be explained by the gradual papillae formation and the healing process of the mucosa over time. ${ }^{145}$ It is expected that a longer follow-up period than the one observed in the present study could result in additional papilla formation. ${ }^{16,135}$

In the present clinical studies, PES and WES were used to evaluate the aesthetic outcome. It is to be expected that the PES will automatically improve in correlation with wound healing and papillae formation, as many of the evaluation parameters are related. An increase in the WES can be related to the soft tissue healing and adaptation, as the perception of the crown shape and counter may change in the areas in close proximity with the soft tissue.

In study I there was a statistically significant increase in PES between baseline and final examination. This may be explained by the maturing and remodeling of the mucosa around dental implants over time, as reported by others. ${ }^{16,21,29,135,146}$ It is worth pointing out that no patients in this cohort received temporary implant restorations for contouring the mucosa before the impression for the final restoration, contrary to the patients in group DL of the study II. These results suggest that good soft tissue aesthetics can be accomplished without the use of intermediate restorations. The general high mean score for PES may partly be explained by the fact that the index uses the contralateral tooth as a reference, which may be a limitation when applied to a cohort with patients having bilateral agenesia. ${ }^{67}$ Cases with bilateral agenesia showed significantly higher final PES ( $P=$ .010) compared to unilateral agenesia patients. This may indicate that an aesthetic scale that does not consider the contralateral tooth would be more appropriate to evaluate such cases. Our WES scores seemed similar to those reported by others in long-term retrospective evaluations. ${ }^{147}$

The studies II and IV had some common aspects, namely all implants were placed in edentulous healed sites and all SCs were of veneered zirconia on ti-bases. As for the aesthetic outcome, no statistically significant difference was found between the groups, except for an improved PES over time as reported in study I. The final PES and WES scores for all three groups are comparable with the findings reported by others. ${ }^{20,148}$ One could, in addition to the present procedures, consider further interventions to improve the aesthetic outcome, as for instance bone augmentation to potentially improve the shape of the alveolar process and soft tissue. ${ }^{62}$ Furthermore, the aesthetic results were comparable to the findings of others concerning aesthetic failures and perfect outcome. ${ }^{30}$ For the DIL group there was a moderate correlation between the degree in implant position deviations and PES, suggesting that increased deviation effects the PES negatively, supporting the finding of others. ${ }^{95}$

Concerning PROMs, OHIP-14 and VAS were assessed before treatment and at follow-up examinations. Due to the retrospective nature of the study I, however only PROMs for the final follow-up examination could be presented. For OHIP-14 a low mean additive score of 16.07 resulted at the final follow-up. In a Swedish study that evaluated OHIP-14, the mean additive score was $22.6 .{ }^{38}$ The low score in the study I might be explained by a generally healthy cohort with good oral status and overall well-functioning prosthetic restorations. Moreover, the patients' satisfaction was high with the aesthetic outcome for both soft tissue appearance and prosthetic restoration. Similar findings have been reported by others. ${ }^{149,150}$ It is important to stress that the patients' opinion on the aesthetics (VAS) is subjective, and some patients were satisfied with the result, even though there was marginal gingivitis in some cases, as seen in the case shown in Figure 31.

Patients with bilateral agenesis had higher satisfaction with the soft tissue appearance and prosthetic restorations, but no statistically significant differences were found between the bilateral and unilateral subgroups. The dental arch symmetry is an important aspect when patients report aesthetic impairment ${ }^{26}$, and arch symmetry may be easier to achieve in cases with bilateral agenesis and in such may have impacted the patients perception concerning the aesthetic outcome. However, there were only a very weak correlation between objective


Figure 31. Patient with single implant in region 23, scoring low PES and WES, but reporting high VAS scores.
aesthetic scales (PES and WES) and patient's satisfaction with the aesthetics. Others have found that factors considered by professionals to be of significance concerning the aesthetic result, may not be of key importance for the patient's. ${ }^{149}$

For the studies II and IV the statistically significant improvement in OHIP-14 between pre-treatment and after receiving a temporary crown for all groups could probably be a result of increased comfort while eating, and the feeling of less insecurity and embarrassment. This improvement occurred earlier in the IL and DIL group than in the DL group, due to the immediate placement of a temporary restoration. As in the study I a low mean additive OHIP-14 score may be explained by generally healthy patients with good oral status and overall well-functioning prosthetic restorations.

Concerning OHIP-14 in the study IV, a statistically significant higher score for the IL group compared to the DIL group was reported. This significant difference did not persist when all three groups were compared. However, there was still a statistically significant lower score for the DIL group at the temporary restoration in comparison to the IL group. No explanation could be found for this finding. We should be careful to assume that patients were generally more satisfied with the temporary restoration in the DIL group, as
there were a notable baseline difference between the groups. The OHIP-14 score improved over time for all evaluated groups.

Patients scored generally high conceding VAS, in agreement with previous findings ${ }^{30,149}$. Reported pain and discomfort were generally low for both the surgical and impression appointment, but equivalent data was lacking for the IL and DL groups. Furthermore, there was a moderate correlation between VAS and OHIP-14, suggesting that low OHRQoL scores affecd the patient's judgment of aesthetics in a negative sense.

There were several limitations in the study I that are important to mention. One important limitation of this study design is that it is not a prospective trial with a strict treatment protocol for all patients. Baseline documentation such as photos, plaster models and x-rays was not available for all patients. Another shortcoming was that a considerable number of patients ( $34.5 \%$ ) were unaccounted for or could not attend the final follow-up. The cohort had a low mean age at fixture installation and young adults may be more prone to changes in their lives (such as, for example, to move to another city in order to begin University studies), decreasing the recall attendance. As with all retrospective studies, the results should be interpreted with caution due to the higher risk of recall bias (a systematic error that occurs when participants do not remember previous events or experiences accurately or omit details). Further, there were no available x-rays at the date of fixture installation, meaning that it was only possible to evaluate MBL and infraposition from the time of prosthetic reconstruction. Concerning the patient-centred outcome, the absence of a baseline assessment for OHRQOL and patient satisfaction made it impossible to learn whether the score had improved after treatment. Moreover, the investigated cohort was overall young, healthy, complying with oral hygiene measurements, and treated by specialists in surgery, orthodontics and prosthodontics. The findings of this study may, therefore, not be applicable to the general population.

One important limitation of the studies II and IV is the short fol-low-up time ( 1 year). Further follow-up appointments would have provided long-term data on the immediate loading protocol and the evaluated implant system. Despite the short follow-up period, it is very important to evaluate patients submitted to these protocols in the early post-treatment period, when the soft tissues are more prone
to most of the expected anatomical changes. Moreover, it is important from the implant perspective, as a great deal of implants fail within one year after installation, regardless of whether a very long follow-up is planned or not. ${ }^{4}$ Further, the very limited positive effects gained for early soft tissue adaption and reported additional positive effects like less chair time and reduced post-operative swelling ${ }^{109,110}$ should be put in perspective to the increased risk of early failure in the present studies. Concerning the measurements of the gingival zenith position and papilla levels, two different measuring techniques were used. As calibrated measurements on photographic images were used for the IL group, and on 3D models for the DIL, these results should be interpreted with caution.

A limitation of the study IV, the non-randomized study including groups DIL and IL, is the possibility of selection bias, particularly related to the inferior implant survival for the DIL group. Selection bias could imply potential systematic differences between characteristics of participants in the two groups, despite that examined patient characteristics were similar between the groups. To minimize this possibility, inclusion of the patients was first completed for the IL group before the DIL group was subsequently included in the study. No patient was especially selected for inclusion in a specific group or study.

In the laboratory study III, the null hypothesis was partially rejected, since significant differences were found in the final dental implant position between the guides fabricated from the two tested desktop 3D printers. An additional intention with this study, in relation to previously discussed clinical studies, was to prepare for the use of surgical guides in the study IV, evaluating both the 3D-printer to be used and the method of measuring implant deviation. A digital scan of a dental implant with an intraoral scan body is commonly used in the fabrication of implant-supported crowns and has been investigated. ${ }^{122,123,126}$ This procedure, in conjunction with data from the guided surgery software, can be used to extract datasets with information about the planned and postoperative dental implant positions. Cristache et al. ${ }^{43}$ used a similar method to compare the datasets from the surgical planning with post-insertion digital scan datasets. In the past, a second CBCT examination of the patient was necessary to identify the postoperative implant position, exposing the
patient to additional radiation. Use of intraoral scan bodies reduces radiographic exposure and is in accordance with recommendations in a recent systematic review. ${ }^{151}$

No statistical significant difference in deviation was found between the two groups for the alignment of planned and final datasets. Bestfit alignment has been commonly used to align datasets and can be used in studies to evaluate the accuracy of digital scans. Ender et al. ${ }^{152}$ reported on the precision of repeated quadrant dental arch silicone impressions ( $18.8 \pm 7.1 \mu \mathrm{~m}$ ) and the Trios3 (3Shape) scanner $(26.1 \pm 3.8 \mu \mathrm{~m})$. Full-arch best-fit alignment might, however, generate systematic errors because of the deviation between two large data distances. ${ }^{124,131}$ The precision and trueness of the intraoral scanner used in the present study have been evaluated. ${ }^{125,131,153}$

In the study III, the DLP and SLA groups presented a low degree of deviation between the planned and postoperative dental implant positions. The findings fall within the mean system error of 1.2 mm for the horizontal and 0.5 mm for the vertical direction established by the European Association for Osseointegration (EAO) consensus in 2012. ${ }^{103}$ For in vitro studies, lower deviations are to be expected, as reported in a recent systematic review with a mean horizontal coronal deviation of $1.10 \pm 0.09 \mathrm{~mm}$ for clinical studies and $0.77 \pm 0.15 \mathrm{~mm}$ for in vitro studies. ${ }^{91}$ These results do not consider the number of dental implants or type of guide support. Lower deviations are to be expected for single dental implants tooth-supported guides, ${ }^{93}$ but a variation in deviation does occur. ${ }^{94-98}$ In comparison, the clinical study IV had a mean horizontal deviation of $0.49 \pm 0.30 \mathrm{~mm}$ and the laboratory study III $0.17 \pm 0.09 \mathrm{~mm}$. In study III, the deviations could in part be explained by the tolerance between the guide tools, length of dental implant, and distance between guide sleeve and implant site. ${ }^{102}$ The high standard deviation for rotational deviation and the indication of data with a wide spread were to be expected as the hexagon position was visually aligned during installation. Further improvement of guided surgery tools may help to reduce such deviations. The higher deviations found in the clinical study were certainly due to clinical factors not present in the laboratory study, such as saliva, soft tissue, patient movement, or humidity in the oral environment. The material used for the surgical models in the study III does not have the same physical properties as bone, enamel, and
soft tissue, meaning that seating of the guide and implant insertion may be different in a clinical setting. Further, individual variations in guide design due to anatomical differences between patients may have affected the results.

In the study III a statistically significant difference was found between the DLP and SLA for deviation at entry point ( $P=0.023$ ) and in vertical implant position $(P=0.009)$, with a lower mean deviation in the DLP group. However, for all deviations values, with the exception of horizontal deviation, the mean results favored the DLP group. An explanation for the statistically significant differences could be that the larger offset values needed for the master cylinder sleeve and between guide and teeth for the SLA printer used could have influenced the mounting of the sleeve and the seating of the surgery guide on the model. In addition, the surgery guides from the SLA printer needed to undergo a longer post-polymerization process than the DLP guides due to a lower degree of photopolymerization during 3D-printing. Handling during the postpolymerization process may have caused minor distortions leading to improper seating of the guide. Factors related to the manufacturing of surgical guides including incorporation of the master sleeve, 3D printer resolution, surface finish of the material, machine reproducibility, offset values, postprocessing, and calibration of a 3D printer can affect the definitive implant position. Further research is recommended before any conclusions can be drawn. With the increased accessibility of desktop 3D printers and the possibility for more in-office production of surgical guides, validation of the workflow is important. The use of a digital scan to confirm the postoperative dental implant position as used in the studies III and IV and another study ${ }^{43}$ could easily be incorporated into guided surgery software and would greatly help in the quality control of the procedure.

A limitation in the study III is that no reference objects were incorporated into the model design. Such objects would have helped in the alignment of the two datasets and the following measurements. ${ }^{107,124,131}$ The use of a high accuracy industrial scanner would further minimize errors from the scanning procedure. However, these types of objects and scanners are not present in a clinical setting.

## CONCLUSIONS

Within the limitations of these studies, the following conclusions could be drawn:
A. Excellent survival rates can be achieved with conventional single implant treatment in young and healthy patients. In addition to satisfactory results concerning patient-centered findings, aesthetics and marginal bone preservation
B. Single implants in the maxilla can present satisfactory results after 1-year regardless of the choice of treatment, be it either immediate loading or delayed loading. With comparable MBL, soft-tissue, aesthetic and patient-centered outcomes.
C. Immediate loading in combination with fully guided surgery might negatively affect the implant survival in comparison to non-guided immediate loading. Care needs to be exerted with technically complicated treatment procedures as the effect on implant survival should not be underestimated. Further evaluation of the procedure is therefore warranted, in order to identify risk factors. Immediate loading, fully guided surgery and a digital workflow appear to have a positive effect on early soft tissue adaption.
D. The two tested desktop 3D printers proved capable of producing surgical guides that resulted in in vitro acceptable levels of deviations with regard to final implant position. The DLP-printer proved more accurate concerning deviations at entry point and vertical implant position in comparison to the SLA-printer.

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## PAPERS I-IV

# Esthetic and Patient-Centered Outcomes of Single Implants: A Retrospective Study 

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#### Abstract

Purpose: The aims of this clinical study were to retrospectively evaluate implant survival, patient satisfaction, and radiographic, clinical, and esthetic outcomes following single-implant treatment. Materials and Methods: Eighty-seven patients, with a total of 126 implants (XiVE S, Dentsply Implants), who received single implant-retained crowns between 2004 and 2011 were retrospectively evaluated. Implant survival, marginal bone levels (MBL), changes in implant/mesial tooth vertical relationship, pink esthetic score (PES), white esthetic score (WES), patient assessment of the esthetics (visual analog scale), and oral health impact profile (OHIP-14) were evaluated. Results: Altogether, 59 patients with a total of 85 implants attended a final clinical and radiographic follow-up examination. The mean ages of males and females at implant placement were 19.78 and 22.58 years, respectively. The mean total follow-up time from the implant surgical date was 7.51 years. The 5-year implant clinical survival rate (CSR) was 98.4\% (95\% Cl: 96.3\%-100\%), and crown CSR was $91.8 \%$ ( $95 \% \mathrm{Cl}: 86.3 \%-97.3 \%$ ). The overall mean change in MBL was -0.19 mm . No significant differences were found between the different implant diameters (3.0, 3.4, and 3.8 mm ) with regard to change in MBL. Mean increase in implant infraposition was 0.13 mm . With regard to esthetics, mean initial and final total PES were 9.61 and 11.49, respectively ( $\mathrm{P}<.001$ ). The mean WES was 6.48 at follow-up. Patients' mean assessment of soft tissue esthetics and implant-supported crown appearance were 73.5 and 82.1 (maximum score 100). At the follow-up examination, the additive OHIP-14 score was 16.11. Conclusion: This retrospective study of XiVE S implants found excellent survival rates and showed good clinical outcomes concerning patient-centered findings, esthetics, and marginal bone preservation. In context, it is important to stress that this study consisted of mostly young patients with agenesis who were treated by experienced clinicians. Int J Oral Maxillofac Implants 2017 (9 pages). doi: 10.11607/jomi. 5495


Keywords: agenesis, esthetics, infraposition, marginal bone level, patient satisfaction, patient-centered outcome, PES, pink esthetic score, single implant, WES, white esthetic score

Replacing a single missing tooth can be a challenge, and clinicians need to consider many factors for an optimal treatment outcome. Restoring the edentulous
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space with a single dental implant was described in the early 1990s by Jemt et al. ${ }^{1}$ Today single implants have become the treatment of choice for many patients due to their excellent long-term functional success. Another potential advantage of the single implant is that the fabrication of a tooth-supported prosthesis requiring substantial tooth removal may be avoided. ${ }^{2}$ After the introduction of moderately rough implant surfaces, further improvements in treatment outcome have been seen. ${ }^{3}$ The use of narrow implants, for example, in sites with missing laterals, has further increased the possibility to avoid tooth-retained constructions. Having said this, there are few long-term follow-up studies published so far. ${ }^{4}$

Particularly in anterior sites, esthetic appearance is important as well as function. Esthetic outcome has been reported to be a motivating factor for at least $20 \%$ of implant patients. ${ }^{5}$ It has been suggested that a multidisciplinary approach is beneficial for a successful implant treatment outcome for some patient categories. ${ }^{6}$ Patients with congenital absence of teeth is one such
category. These patients are often treated early in life, when the esthetic outcome may be of particular concern. In addition, implant infraposition ${ }^{7}$ may disturb the long-term esthetic outcome for these patients. Different esthetic indices have been suggested to evaluate the treatment outcome, such as the white esthetic score (WES) and the pink esthetic score (PES). ${ }^{8,9}$ Several studies have demonstrated the reliability and reproducibility of these indices in esthetic assessments. ${ }^{10-12}$

However, scales such as PES and WES do not take into account the patient's perspective, a key factor in judging the success of the treatment outcome. There is a lack of literature on the subject, despite the increased interest in patient-centered outcomes. ${ }^{13}$ Further, studies reporting esthetic and patient-centered outcomes in young patients are few.

The aims of this clinical study were to retrospectively evaluate implant survival, patient satisfaction, and radiographic, clinical, and esthetic outcomes following single-implant treatment.

## MATERIALS AND METHODS

## Inclusion and Exclusion Criteria

Patients selected for inclusion in this study were in need of one or more single-tooth replacements and had adjacent natural teeth. Treatment was performed with XiVE S implants (Dentsply Implants) at the Centre of Dental Specialist Care, Malmö, Sweden, between 2004 and 2011.

Patients were thoroughly informed about the study. The study was conducted in accordance with the Helsinki Declaration of 1975 as revised in 2000, ${ }^{14}$ and all patients gave a written informed consent. The study protocol was approved by the Regional Ethical Review Board in Lund, Sweden (Ref: 2012/318).

## Patient Population

Of the original 114 patients consecutively treated between 2004 and 2011, the following were excluded: 8 patients who had implants incorporated in a fixed partial denture; 2 patients with implants adjacent to only one natural tooth; 11 patients with implants adjacent to another implant; and 6 patients with the superstructure made at another dental clinic. For the remaining 87 patients with a total of 126 implants, the mean $\pm$ standard deviation (SD) age for males and females at implant placement was $19.78 \pm 3.55$ years (range, $17-38$ years; $n=36$ ) and 22.58 $\pm 10.85$ years (range, 17-68 years; $n=51$ ), respectively. All patients were healthy. There were $6 \%$ who reported the current use of medication, but the implant surgeon did not consider the reasons for the medication use a contraindication for surgery. The use of smoking tobacco and snuff was reported respectively by 15 (17.2\%) and $4(4.6 \%)$ of the patients before treatment. None of the
patients were diabetic. Fifty-nine patients (67\%) had received orthodontic treatment previously. The reasons for missing teeth were agenesis ( $\mathrm{n}=95 ; 75.4 \%$ ), trauma ( $\mathrm{n}=15 ; 11.9 \%$ ), apical infection/endodontic reason ( $\mathrm{n}=$ $3 ; 2.4 \%$ ), advanced caries ( $n=2 ; 1.6 \%$ ), ectopic eruption ( $n=6 ; 4.8 \%$ ), odontoma ( $n=2 ; 1.6 \%$ ), external resorption ( $\mathrm{n}=1 ; 0.8 \%$ ), ankylosis ( $\mathrm{n}=1 ; 0.8 \%$ ), and cleft lip and palate ( $\mathrm{n}=1 ; 0.8 \%$ ). Of the 95 sites with agenesis, 52 sites were from 26 patients presenting bilateral agenesis.

## Surgical and Prosthetic Procedures

Prior to surgery the patients were discussed in a multidisciplinary group, consisting of a prosthodontist, an oral surgeon, an oral radiologist, and an orthodontist. In this group it was decided whether narrow-diameter implants would be indicated.

The implants were placed according to a standard two-stage surgical procedure for single-implant placement in healed sites. No antibiotics were given before or after surgery. Surgery was performed under local anesthesia (Xylocaine 2\% with adrenaline, Dentsply Pharmaceutical). An incision was made at the midcrest, and a mucoperiosteal flap was raised with a vertical releasing incision.

In cases with insufficient bone and exposed implant surface ( 20 implants), guided bone regeneration (GBR) procedures were simultaneously performed at implant placement, and these osseous defects were grafted with a natural bone mineral of bovine origin (Bio-Oss, Geistlich) and covered with a collagen membrane (BioGide Membrane, Geistlich). All implants were placed at the crestal level. Postoperatively, the patients were instructed to rinse twice daily with a solution of $0.2 \%$ chlorhexidine for 14 days, to take ibuprofen 400 mg twice per day for 3 days and, in case of pain, paracetamol 500 mg four times per day. Bone quantity and quality of the treated surgical sites were classified at the time of surgery according to the Lekholm and Zarb classification. ${ }^{15}$ The second-stage surgery (abutment connection) was performed after a mean time $\pm$ SD of $142 \pm 65$ (range, 53 to 512 days) and $105 \pm 39$ days (range, 66 to 184 days) for the maxilla ( $\mathrm{n}=102$ ) and mandible ( $n=24$ ), respectively. Maxillary implants received the definitive crowns at a mean time $\pm$ SD of $225 \pm 111$ days (range, 80-719 days) after implant surgery, while mandibular implants were reconstructed $182 \pm 63$ days (range, 87-335 days) after implant insertion. A total of 15 crowns were screw retained, whereas 109 crowns were cemented. Two patients lost one implant each primarily, before abutment connection. Both were placed in the mandibular left central incisor region. These implants were not replaced; instead, these patients received resin-bonded fixed partial prostheses. Details about implant location are presented in Table 1, and implant length and diameter are described in Table 2. Of the

Table 1 Overview of Implants According to Their Location

| No. of implants (\%) | $3(2.4)$ | $2(1.6)$ | $16(12.7)$ | $24(19.0)$ | $4(3.2)$ | $6(4.8)$ | $23(18.3)$ | $18(14.3)$ | $3(2.4)$ | $3(2.4)$ |
| :--- | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | $\mathbf{1 5}$ | $\mathbf{1 4}$ | $\mathbf{1 3}$ | $\mathbf{1 2}$ | $\mathbf{1 1}$ | $\mathbf{2 1}$ | $\mathbf{2 2}$ | $\mathbf{2 3}$ | $\mathbf{2 4}$ | $\mathbf{2 5}$ |
| Location (FDI) | $\mathbf{3 5}$ | $\mathbf{3 4}$ | $\mathbf{3 3}$ | $\mathbf{3 2}$ | $\mathbf{3 1}$ | $\mathbf{4 1}$ | $\mathbf{4 2}$ | $\mathbf{4 3}$ | $\mathbf{4 4}$ | $\mathbf{4 5}$ |
|  | $6(4.8)$ | $0(0.0)$ | $1(0.8)$ | $0(0.0)$ | $7(5.6)$ | $2(1.6)$ | $3(2.4)$ | $1(0.8)$ | $1(0.8)$ | $3(2.4)$ |
| No. of implants (\%) |  |  |  |  |  |  |  |  |  |  |

65 implants with a diameter of $3.0 \mathrm{~mm}, 61.5 \%$ were used to replace maxillary lateral incisors. The number of implants per patient ranged from 1 to $4 ; 2$ patients ( $2.3 \%$ ) received 4 implants, 5 patients (5.7\%) received 3 implants, 23 patients ( $26.4 \%$ ) received 2 implants, and 57 patients ( $65.5 \%$ ) received 1 implant. All implant placements were performed at the Department of Oral Maxillofacial Surgery, Malmö University Hospital, Malmö, Sweden, by eight different surgeons. One surgeon treated the majority of the patients ( $74.4 \%$ ).

The prosthetic treatment was performed at the Centre of Dental Specialist Care, Malmö, Sweden, by seven different prosthodontists. One prosthodontist (the third author) treated $57.0 \%$ of the patients. No temporary implant crowns were used to shape the emergence profile before impression. For the implant impression, the open-tray technique was used with polyether impression material (Impregum Penta, 3M ESPE), and alginate (Blueprint Creme, Dentsply DeTrey) was used for the antagonistic impression. The occlusal relationship was recorded in a bite registration wax (Alminax, Kemdent, Associated Dental Products Ltd). All materials were used according to the manufacturer's guidelines. The definitive abutments and single crowns are described in Table 3.

After completion of the final restoration, each patient was seen by a dental hygienist within 6 months for dental hygiene follow-up. The patients were asked to attend a radiographic follow-up examination after 12 months. Each patient then attended a dental hygiene recall program based on individual needs.

## Clinical Evaluation

All patients were invited to attend a final clinical and radiographic follow-up examination. The examinations were conducted by the first author, who was not previously involved in the treatment of the patients.

Survival of implants was evaluated according to Albrektsson. ${ }^{16}$

The survival of the implant-supported single crowns was assessed, and complications were defined as incidents leading to crown replacement: (1) loss of crown retention; (2) porcelain fracture; (3) fracture due to trauma. Esthetic reasons for crown replacement were not considered for survival. Patients were asked about complications, and all patient records were scrutinized for biologic and technical complications.

| Table 2 | Overview of Implants According to <br> Their Length and Diameter |  |  |  |  |
| :--- | :--- | :---: | :---: | :---: | :---: |
|  | Length (mm) |  |  |  |  |

## Table 3 Overview of Abutments and

 Crown Materials| Abutments |  |
| :--- | :---: |
| Friadent EstheticBase (Dentsply Implants) | 98 |
| Friadent Cercon Abutment (Dentsply Implants) | 10 |
| Friadent AuroBase (Dentsply Implants) | 12 |
| MedentiCAD (Medentika) | 3 |
| Atlantis Abutment (Dentsply Implants) | 1 |
| Total | 124 |
| Crown materials | 54 |
| Procera Zirconia (Nobel Biocare) | 38 |
| Procera Alumina (Nobel Biocare) | 12 |
| Gold alloy, veneered | 6 |
| Titanium, veneered | 6 |
| KaVo Everest Zirconia (KaVo Dental) | 5 |
| Ceramill Zi (Amann Girrbach) | 3 |
| Denzir (Denzir) | 124 |
| Total |  |

The Gingival Index was scored for each implant at the final follow-up examination, according to Löe and Silness. ${ }^{17}$

The first two authors, who were not involved in the patients' treatment, conducted all evaluations.

## Radiographic and Photographic Evaluations

Reproducible intraoral radiographs were obtained using the long-cone parallel technique at the time of definitive prosthesis delivery (baseline) and at the last/final
follow-up visit. When there were no available digital radiographs from the baseline appointment, the analog periapical radiographs were scanned at 1,200 dpi (Epson Perfection V800 Photo Color Scanner). Digital intraoral radiographs (Schick Digital X-ray Sensor, Sirona) were taken of implants of all patients attending the final follow-up examination. The Image J software (US National Institutes of Health) was used for all measurements.

From the periapical radiographs, the following measurements were performed:

1. Marginal bone level (MBL) was measured after calibration based on the inter-thread distance of the XiVE implants ( 0.85 mm ). Measurements were taken from the implant-abutment junction to the marginal bone level, at both mesial and distal sides of each implant, and then the mean value of these two measurements was considered. Crestal bone loss was calculated by comparing bone-to-implant contact level of the final radiograph with baseline.
2. Vertical distance was evaluated between the implant-abutment junction and the cementoenamel junction of the adjacent tooth on the mesial side, as described by Jemt. ${ }^{18}$

Plaster models (Fujirock, GC Europe) from the time of prosthesis insertion and from the final examination were photographed (Nikon D7000, Nikon Corporation, Tokyo, Japan) together with a 1-mm precision ruler. The horizontal distance between the teeth adjacent to the implant-supported crown was measured at baseline and at the final examination.

## Esthetic Evaluations

Intraoral photographs from the baseline and final followup appointments were used to register PES, according to Fürhauser et al. ${ }^{9}$ Photographs from the final follow-up appointment were used to registerWES, according to Belser et al. ${ }^{8}$ Others have defined the (almost) perfect outcome for PES and WES as PES $\geq 12$ and WES $\geq 9$, respectively, and esthetic failure as PES $\leq 7$ and WES $\leq 5$, respectively. ${ }^{19}$

## Patient-Centered Evaluations

The oral health-related quality of life (OHRQL) was recorded using the Swedish validated version of the Oral Health Impact Profile (OHIP-14) questionnaire. ${ }^{20}$ The additive score is obtained by summation of the response codes for the 14 items. This gives a range from 14 to 70 , where a higher score indicates poor OHRQL. The questionnaires were completed at the final followup examination. Moreover, the patients' satisfaction with the final restoration was assessed with use of a visual analog scale (VAS). The patients marked their satisfaction in a non-numerical $100-\mathrm{mm}$ line ranging from "not at all satisfied $=0$ " (left) to "very satisfied $=$
$100^{\prime \prime}$ (right), for each implant received. They were asked the following questions: (VAS 1)"How satisfied are you with the esthetic appearance of the soft tissue around your implant-supported crown restoration?" and (VAS 2) "How satisfied are you with the esthetic appearance of your implant-supported crown restoration?" Each response was given a numeric value by measuring in millimeters the distance from the left end of the line.

## Statistics

All data were statistically analyzed by one examiner. The software used was the Statistical Package for the Social Sciences (SPSS) version 22 (SPSS Inc). The data were tabulated, and from these measurements mean, SD, and minimum and maximum scores were calculated. The performed tests for two independent groups, three or more independent groups, and two dependent groups were Student $t$ test or Mann-Whitney test, one way ANOVA or Kruskal-Wallis test, and paired-samples $t$ test or Wilcoxon signed-rank test, respectively, depending on the normality. Life tables were presented for implants and crowns respectively, with cumulative survival rate (CSR). The $95 \%$ confidence interval (Cl) for the survival proportions was calculated by using the $95 \%$ confidence limits of the event rates. Correlation and linear regression were performed to check the relationship between the age of patients and change in vertical distance, and VAS 1 and final PES score, and between the VAS 2 and the WES score. The degree of statistical significance was considered $P<.05$.

## RESULTS

## Patients Lost to Follow-up

Patients were invited to attend a final clinical and radiographic follow-up examination as part of the study. The dropouts at this examination represented $32.5 \%$ ( $\mathrm{n}=$ 41) of the implants and $32.1 \%(n=28)$ of the patients. Reasons for patient dropouts were: could not or did not want to attend the follow-up examination ( $\mathrm{n}=18$ ) or it was not possible to get in contact with the patient ( $\mathrm{n}=$ 10). All patients who did not want to attend the followup examination reported that their restoration was still in good function. The mean $\pm$ SD total follow-up time from the implant surgical date was $7.51 \pm 1.58$ years (range, 3.57-11.06 years) and $6.9 \pm 1.61$ years (range, 2.94-10.05 years) after crown insertion.

## Clinical Outcome

The 5 -year implant CSR was $98.4 \% ~(95 \% ~ C I: ~ 96.3 \%-100 \%) ; ~ ;$ see life table (Table 4). Two implants did not survive and were lost before abutment connection. The 5-year crown CSR was $91.8 \%$ ( $95 \% \mathrm{Cl}: 86.3 \%-97.3 \%$ ); see life table (Table 5). Altogether, 10 crowns were lost during the follow-up period due to loss of crown retention $(n=1)$,

Table 4 Life Table for Implant Survival

| Interval start <br> time $(\mathbf{y})$ | No. entering <br> interval | No. withdrawing <br> during interval | No. <br> exposed <br> to risk | No. of <br> terminal <br> events | Proportion <br> terminating | Proportion <br> surviving | Cumulative <br> proportion surviving <br> at end of interval |
| :--- | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 0 | 126 | 8 | 122 | 2 | 0.016 | 0.984 | 0.984 |
| 1 | 116 | 10 | 111 | 0 | 0.000 | 1.000 | 0.984 |
| 2 | 106 | 2 | 105 | 0 | 0.000 | 1.000 | 0.984 |
| 3 | 104 | 6 | 101 | 0 | 0.000 | 1.000 | 0.984 |
| 4 | 98 | 4 | 96 | 0 | 0.000 | 1.000 | 0.984 |
| 5 | 94 | 7 | 90.5 | 0 | 0.000 | 1.000 | 0.984 |
| 6 | 87 | 20 | 77 | 0 | 0.000 | 1.000 | 0.984 |
| 7 | 67 | 36 | 49 | 0 | 0.000 | 1.000 | 0.984 |
| 8 | 14 | 17 | 10 | 0 | 0.00 | 1.000 | 0.984 |
| 10 | 6 | 4 | 4 | 0 | 0.000 | 1.000 | 0.984 |
| 11 | 2 | 2 | 1 | 0 | 0.000 | 1.000 | 0.984 |


| Table 5 | Life Table for Crown Complications |
| :--- | :---: | :---: | :---: | :---: | :---: | :---: | :---: |

porcelain fracture ( $\mathrm{n}=7$ ), and fracture due to trauma ( n = 2). Two crowns were replaced shortly after completion due to esthetic reasons and were not considered as lost. Other complications that did occur but did not lead to crown replacement were porcelain fracture ( $\mathrm{n}=3$ ) and re-cemented crown after loss of crown retention ( $\mathrm{n}=$ 2). The overall rate of technical complications was $12 \%$.

The mean $\pm$ SD Gingival Index score at the final examination was $1.21 \pm 0.54$ (range, $1-3 ; \mathrm{n}=85$ ).

## Radiographic and Photographic Outcomes

The crestal bone was located on average $0.85 \pm 0.63$ mm (range, 0.00 to 3.68 mm ) below the implant collar at delivery of the definitive prosthesis. The mean $\pm$ SD change in MBL was $-0.19 \pm 0.60 \mathrm{~mm}$ (range, -2.37 to $1.06 ; n=90$ ). Negative values represent bone loss. The mean $\pm$ SD time between baseline and final radiographs was $5.8 \pm 2.7$ years (range, 0.69 to 10.05 years). Figure 1 presents a patient's radiographs at baseline and after 9 years at the follow-up examination.

The change in MBL was also compared between different subgroups (maxilla/mandible, men/women, smokers/ nonsmokers, GBR/non-GBR, agenesis/trauma) with no statistically significant differences (Table 6). The mean $\pm$ SD MBL for implants with diameters of 3.0, 3.4, and 3.8 mm were $-0.20 \pm 0.51 \mathrm{~mm}$ (range, -1.61 to $0.84 \mathrm{~mm} ; \mathrm{n}$ $=42$ ), $-0.10 \pm 0.67 \mathrm{~mm}$ (range, -2.37 to $0.76 \mathrm{~mm} ; \mathrm{n}=$ 22), and $-0.28 \pm 0.69 \mathrm{~mm}$ (range, -2.05 to $1.06 \mathrm{~mm} ; \mathrm{n}=$ 26), respectively ( $P=.207$; Kruskal-Wallis test). There was only one $4.5-\mathrm{mm}$-diameter implant used in the cohort.

The mean $\pm$ SD change in vertical distance between implant-abutment junction and cementoenamel junction of the adjacent tooth on the mesial side was $0.13 \pm 0.57$ mm (range, -1.28 to $2.06 \mathrm{~mm} ; \mathrm{n}=78$ ). Positive values represent increase in the distance. The change in vertical distance was also compared between different subgroups (maxilla/mandible, men/women, orthodontic treatment/ non-orthodontic treatment) with no statistically significant differences (Table 7). There was a very weak relationship between the age of patients and change in vertical distance


| Table 6 | Comparison of Marginal Bone Loss |  |  |
| :--- | :---: | ---: | :---: |
|  | (in mm) Between Different Groups |  |  |
| Group | Mean $\pm$ SD $(\min , \max )$ | n | P value |
| Maxilla | $-0.24 \pm 0.61(-2.37,1.06)$ | 77 | $.060^{a}$ |
| Mandible | $0.07 \pm 0.52(-1.20,0.84)$ | 3 |  |
| Men | $-0.04 \pm 0.44(-1.04,0.84)$ | 35 | $.204^{\mathrm{a}}$ |
| Women | $-0.30 \pm 0.67(-2.37,1.06)$ | 55 |  |
| Smokers | $-0.41 \pm 0.80(-2.37,0.74)$ | 13 | $.291^{\mathrm{a}}$ |
| Nonsmokers | $-0.16 \pm 0.56(-2.05,1.06)$ | 77 |  |
| GBR | $-0.12 \pm 0.61(-1.61,0.84)$ | 16 | $.831^{\mathrm{a}}$ |
| Non-GBR | $-0.19 \pm 0.57(-2.05,1.06)$ | 69 |  |
| Agenesis | $-0.19 \pm 0.60(-2.37,1.06)$ | 69 | $.547^{\mathrm{b}}$ |
| Trauma | $-0.31 \pm 0.67(-1.65,0.84)$ | 11 |  |

Negative values represent bone loss.
${ }^{\text {a }}$ Mann-Whitney test.
${ }^{\text {b }}$ Student $t$ test.

| Table 7 | Comparison of Vertical Distance (in mm) Between the Implant-Abutment Junction and the Cementoenamel Junction of the Adjacent Tooth on the Mesial Side Between Different Groups |  |  |
| :---: | :---: | :---: | :---: |
| Group | Mean $\pm$ SD ( $\mathbf{m i n}$, max) | n | value |
| Maxilla | $0.15 \pm 0.58(-1.28,2.06)$ | 67 | . $272{ }^{\text {a }}$ |
| Mandible | $-0.02 \pm 0.51(-0.76,0.96)$ | 11 |  |
| Men | $-0.09 \pm 0.44(-1.28,0.88)$ | 28 | . $010{ }^{\text {b }}$ |
| Women | $0.25 \pm 0.60(-0.75,2.06)$ | 50 |  |
| Orthodontics | $0.97 \pm 0.55(-1.28,2.61)$ | 57 | . $424{ }^{\text {b }}$ |
| Non-orthodontics | $0.21 \pm 0.62(-0.75,1.76)$ | 21 |  |

Positive values represent increase in the distance.
amann-Whitney test.
${ }^{\text {b }}$ Student $t$ test.
$=37$ ) and $10.85 \pm 3.14$ (range, $2-14, \mathrm{n}=34$ ), respectively ( $P=.023$, Wilcoxon signed-rank test), and for women they were $9.90 \pm 2.66$ (range, $1-14, \mathrm{n}=69$ ) and $11.90 \pm 2.28$ (range, $2-14, \mathrm{n}=52$ ), respectively ( $P<.001$, Wilcoxon signed-rank test). The difference between men and women for the initial PES was not statistically significant ( $P=.194$, Mann-Whitney test), nor was it for the final PES score ( $P=.140$, Mann-Whitney test).

The mean $\pm$ SD total WES was $6.48 \pm 2.35$ (range, $0-10 ; \mathrm{n}=86$ ). The values of WES for men and women were $6.12 \pm 2.46$ (range, $1-10 ; n=34$ ) and $6.71 \pm 2.27$ (range, $0-10 ; \mathrm{n}=52$ ), respectively ( $P=.244$, MannWhitney test).

For 3.0-mm-diameter implants used to replace missing maxillary lateral incisors, the final PES and WES were $12.58 \pm 1.28$ (range, $9-14 ; \mathrm{n}=34$ ) and $7.41 \pm 1.86$ (range, $2-10 ; n=34$ ), respectively.

Fig 2 Patient with single implant (maxillary right canine) at final follow-up 7 years after implant placement. PES final $=13$, WES $=10$, VAS1 $=69$, VAS2 $=85$, OHIP- $14=15$.


| Group | Bilateral agenesis |  | Unilateral agenesis |  | $P$ value |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  | Mean $\pm$ SD ( $\mathbf{m i n}$, max) | n | Mean $\pm$ SD ( $\mathbf{m i n}$, max) | n |  |
| MBL ${ }^{\text {b }}$ | $-0.14 \pm 0.47$ (-1.04, 1.06) | 31 | $-0.32 \pm 0.72(-2.37,0.61)$ | 28 | $.654{ }^{\text {d }}$ |
| Vertical distance ${ }^{\text {c }}$ | $-0.04 \pm 0.41$ (0.645, -1.28) | 25 | $0.17 \pm 0.56$ (1.28, -0.75) | 25 | . $136{ }^{\text {e }}$ |
| WES | $7.18 \pm 2.37(1,10)$ | 38 | $6.75 \pm 1.59(3,10)$ | 20 | . $252{ }^{\text {d }}$ |
| PES-final | $12.71 \pm 1.56(7,14)$ | 38 | $11.15 \pm 2.94(2,14)$ | 20 | .010 ${ }^{\text {d }}$ |
| VAS 1 | $78.4 \pm 18.5(33.8,100)$ | 36 | $65.5 \pm 24.4(18,95)$ | 19 | .061 ${ }^{\text {d }}$ |
| VAS 2 | $84.7 \pm 13.1(50.3,100)$ | 36 | $74.9 \pm 24.4(10,100)$ | 19 | $.167^{\text {d }}$ |
| OHIP-14 | $16.3 \pm 3.2(14,24)$ | 36 | $15.3 \pm 2.7(14,25)$ | 19 | . $214{ }^{\text {d }}$ |

aconsidering only aplasia and excluding implants in the mandible and in sites 11 and 21.
${ }^{\text {a }}$ Considering only aplasia and exclud
'Negative values mean bone loss.
cP itive values represent increase in the distance.
c
${ }^{\mathrm{d}}$ Masitive values repre
eStudent $t$ test.

Perfect outcomes for final PES and WES were found in $62 \%$ and $17 \%$ of the cases, respectively. Esthetic failures for final PES and WES were found in $9 \%$ and $30 \%$ of the cases, respectively. Figure 2 presents a patient with a high PES/WES outcome.

## Patient-Centered Outcome

The mean $\pm$ SD additive OHIP-14 score on the patient level was $16.07 \pm 3.29$ (range, $14-28 ; n=56$ ) at the final examination. The mean $\pm$ SDVAS for satisfaction of the soft tissue appearance (VAS 1) and implant-supported crown appearance (VAS 2) were $73.5 \pm 21.7$ (range, $18-100 ; \mathrm{n}=82$ ) and $82.1 \pm 18.3$ (range, $10-100 ; \mathrm{n}$ $=82$ ), respectively. The values of VAS 1 for men and women were $74.6 \pm 25.5$ (range, $18-100 ; \mathrm{n}=34$ ) and $72.8 \pm 18.8$ (range, 18-100; $\mathrm{n}=48$ ), respectively ( $P=$ .180, Mann-Whitney test), and those for VAS 2 for men and women were $86.8 \pm 12.4$ (range, $65-100 ; \mathrm{n}=34$ ) and $78.8 \pm 21.1$ (range, $10-100 ; n=48$ ), respectively ( $P=.062$, Mann-Whitney test). Out of the 59 attending the follow-up examination, 56 completed the OHIP-14 and VAS.

For 3.0-mm-diameter implants used to replace missing maxillary lateral incisors, the OHIP-14, VAS-1 and VAS-2 were $16.87 \pm 3.61$ (range, $14-25 ; \mathrm{n}=31$ ), $73.80 \pm$
24.12 (range, $18-100 ; \mathrm{n}=31$ ), and $79.52 \pm 21.74$ (range, 10-100; $n=31$ ), respectively.

The relationship between VAS 1 and the final PES score was very weak ( $R=0.187, R^{2}=0.035, P=.092$; Pearson correlation). The linear regression analysis showed that for every 1-point increase in PES, the VAS 1 value increased 1.505 points. The relationship between VAS 2 and the WES score was also very weak ( $R=0.029, R^{2}=0.001, P=$ .793; Pearson correlation). The linear regression analysis showed that for every 1 point increase in WES, the VAS 2 value increased 0.227 point.

Considering only agenesis cases (excluding tooth positions 11,21, and mandibular teeth), the comparison of MBL, vertical distance, WES, PES final, VAS 1, VAS 2, and OHIP-14 between implants placed in patients with bilateral and unilateral tooth agenesis are presented in Table 8.

## DISCUSSION

This study reports high survival rates for dental implants, as is expected for moderately rough implants available today. ${ }^{3}$ The 5-year implant CSR was $98.4 \%$ ( $95 \% \mathrm{CI}$ : 96.3\%$100 \%$ ), and crown CSR was $91.8 \%$ ( $95 \% \mathrm{Cl}: 86.3 \%-97.3 \%$ ). Others have reported 5-year implant survival at 97.2\%


Fig 3 Patient with single implant (maxillary left canine) at fina follow-up 10 years after implant placement. PES final $=2$, WES $=3$, VAS1 $=76$, VAS2 $=81$, OHIP- $14=14$.
(95\% CI: 96.3\%-97.9\%) and implant-supported single crown survival at $96.3 \% ~(95 \% \mathrm{Cl}: 94.2 \%-97.6 \%) .{ }^{2}$ The mean overall change in MBL was -0.19 mm . Taking into account that all implants were placed at the crestal level by the surgeons and that the crestal bone on average was located 0.85 mm below the implant collar at baseline (definitive prosthesis delivery), it is suggested that some initial bone loss had occurred that was not accounted for during the first year. The subgroups (maxilla/mandible, men/ women, smokers/nonsmokers, GBR/non-GBR, agenesis/ trauma) were small and imbalanced, which may explain the lack of statistically significant differences. Others have reported that smoking has a potential negative effect on treatment outcome. ${ }^{21}$ With regard to implant diameter, 3.0-mm narrow-diameter implants did not seem to lose more bone than wider implants. This is in agreement with other studies that report similar outcomes for narrow implants as compared with standard diameter ones. ${ }^{4,22}$

The probable reason for the change in vertical position, and consequently implant infraposition, is the fact that implants behave like ankylosed teeth and do not follow the changes of the alveolar processes during growth of the jaws. ${ }^{23}$ This remodeling process may continue until late adulthood and is not completely age dependent..$^{24}$ In the present study there was a slight increase in the vertical distance between baseline and follow-up. The correlation with age was very weak, as may be expected in a cohort consisting of mainly young adults. Others have suggested that the degree of infraposition is correlated to the shape of the face. ${ }^{7}$ Due to the lack of information of face shape in the present study, this was not possible to investigate. Moreover, there was a significant difference ( $P=.010$ ) between males and females regarding infraposition. The patients with an infraposition of more than 1 mm were all females ( $n=5$ ). This finding supports previous observations that females seem to present a higher risk for infraposition., ${ }^{724}$ In the other subgroups (maxilla/mandible, prior orthodontic treatment/non-orthodontic treatment, bilateral/unilateral
agenesis) there were no statistically significant differences, probably due to very unbalanced subgroups.

In the present study, PES and WES were used to evaluate the esthetic outcome. There was a statistically significant increase in PES between baseline and final examinations. This may be explained by the maturing and remodeling of the mucosa around dental implants over time, which was also observed by others. ${ }^{25-27}$ It is worth pointing out that no patients in this cohort received temporary implant restorations for contouring the mucosa before the impression for the final restoration. These results suggest that good soft tissue esthetics can be accomplished without the use of intermediate restorations. The general high mean score for PES and a high proportion of "perfect" outcomes for PES may also be partly due to the fact that the index uses the contralateral tooth as reference, which may be a limitation when applied to a cohort of patients with bilateral agenesis. ${ }^{28}$ Patients with bilateral agenesis showed significantly higher final PES $(P=.010)$ compared to unilateral agenesis patients. This may indicate that an esthetic scale that does not consider the contralateral tooth would be more appropriate for evaluation in these patients. The WES scores in the present study were similar to those reported by others. ${ }^{29}$

With regard to the patient-centered outcomes, OHIP-14 and VAS were used. For OHIP-14, there was a low mean additive score of 16.07 at the final follow-up. In a Swedish study that evaluated OHIP-14, the mean additive score was $22.6{ }^{20}$ The low score in the present study may be explained by a generally healthy cohort with good oral status and overall well-functioning prosthetic restorations. Moreover, the patients' satisfaction was high with the esthetic outcome as well as the prosthetic restoration. It is important to stress that the patients' opinions of the esthetics (VAS) are subjective, and some patients were satisfied with the result even though there was marginal gingivitis, as in the case shown in Fig 3. The dentists' opinions, on the other hand, are objective and based on scales (PES and WES). Patients with bilateral agenesis had higher satisfaction with the soft tissue appearance and prosthetic restorations, but no statistically significant differences were found. The dental arch symmetry is an important aspect when patients report esthetic impairment, ${ }^{30}$ and arch symmetry may be easier to achieve in bilateral agenesis. There was only a very weak correlation between PES-WES and patients' satisfaction with the esthetics. ${ }^{31}$

An important limitation of this study design is that it was not a prospective trial with a strict treatment protocol for all patients. Baseline documentation (photographs, plaster models, and radiographs) was not available for all patients. Furthermore, a considerable number of patients (34.5\%) were unaccounted for or could not attend the final follow-up. The cohort had a low mean age at implant placement, and young adults may be more prone to changes in living situations and therefore
more difficult to recall. As with all retrospective studies, the results should be interpreted with caution due to the higher risk of recall bias. Further, there were no available radiographs at the date of implant placement, meaning that it was only possible to follow MBL and infraposition from the time of prosthetic reconstruction. Concerning the patient-centered outcome, the absence of a baseline assessment for OHRQL and patient satisfaction made it impossible to learn whether the score had improved after treatment. Moreover, the investigated cohort was overall young, healthy, complying with oral hygiene measures, and treated by specialists in surgery, orthodontics, and prosthodontics. The findings of this study, therefore, may not be applicable to the general population.

## CONCLUSIONS

This retrospective study of Xive S implants yields excellent survival rates and reports good clinical outcomes concerning patient-centered findings, esthetics, and marginal bone preservation. In context, it is important to stress that this study consisted of mostly young patients with agenesis that were treated by experienced clinicians.

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# Clinical and radiographic outcome following immediate loading and delayed loading of single-tooth implants: Randomized clinical trial 

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#### Abstract

Background: Immediate loading of single implants is generally considered a reliable procedure. Purpose: The objective of the present prospective randomized clinical study was to compare the overall treatment outcome following immediate loading (IL) and delayed loading (DL) of single implants after 1 year of follow-up.

Materials and Methods: Patients with a missing maxillary tooth (15-25) were randomly assigned to IL or DL. The protocol included implant installation in healed sites, immediate loading, delayed loading, temporary screw-retained restoration, and replacement with a permanent single implant crown. Outcome measures were implant survival, marginal bone level, soft tissue changes, papillae index, pink, and white esthetic score (PES and WES), patient judged aesthetics, and oral health impact profile (OHiP-14).

Results: Implant survival rate was $100 \%$ and $96 \%$ for IL and DL, respectively. Implant success rate was $96 \%$ and $88 \%$ for IL and DL, respectively. Statistically significant lower papilla index scores were found in the IL group at temporary crown and definitive crown placement. An overall statistically significant improvement after 12 months for PES, WES and OHIP-14 was found.

Conclusion: This prospective randomized study showed that single implants in the maxilla can present satisfactory results with respect to either immediate loading or delayed loading after 12 months.

\section*{KEYWORDS} immediate function, immediate loading, implant, implant-supported crown, implant survival, patient satisfaction, randomized controlled trial


## 1 | INTRODUCTION

The main purpose of dental implants is to act as anchoring elements for prosthetic restorations, replacing one or several lost teeth. Replacing a single tooth can be a challenging endeavor with many factors to consider for the clinician and patient alike. The use of single implants has become a predictable and successful treatment option ${ }^{1}$ and in certain situations considered the most cost-effective alternative of other
options when treating gaps. ${ }^{2}$ The high success rates have led to further development of the original delayed loading protocol. Immediate, early and delayed loading protocols have been described for single implants. ${ }^{3}$ Also the term functional (occlusal) or nonfunctional (nonocclusal) immediate loading has been introduced. ${ }^{3}$ Predictable bone integration and high survival rates have been reported for immediate loading of single implants in the anterior maxilla. ${ }^{4}$ However, it should be stressed that although high survival rates have been reported, more failures are to
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be expected following immediate loading of single implants. ${ }^{3}$ Sufficient primary implant stability ${ }^{5}$ and the avoidance of eccentric contacts are some factors that has been pointed out as important, for ensuring positive outcome of single implants.

In addition, soft-tissue and aesthetic outcomes are important, and a number of clinical studies focused on these issues for single-implant restorations in the anterior region. ${ }^{6-10}$ The immediate loading procedure results in less disturbance of the peri-implant soft tissues than the two-stage protocol. A study by Luongo et al. ${ }^{11}$ observed that repeated abutment changes do not alter bone levels, however the effect on softtissue healing and the additional effect from the use of intermediate temporary restoration to shape the implant crown emergence profile remain sparsely documented. Different scales have been developed for soft-tissue and aesthetic evaluations, such as the papilla index, ${ }^{12}$ the Pink Esthetic Score, ${ }^{13}$ and the White Esthetic Score. ${ }^{14}$

Improving patient satisfaction is of vital importance for many dental treatments and should also be in focus when different treatment protocols are evaluated. Changes in oral health-related quality of life (OHRQoL) can be assessed by the Oral Health Impact Profile-14 (OHIP-14). ${ }^{15}$ Other studies have demonstrated an improvement in the OHRQoL between the preoperative and postoperative condition following immediate loading. ${ }^{6,7}$ Patient-centered outcomes before, after and during delayed and immediate loading treatment procedure is scarcely documented. ${ }^{3}$

The purpose of this prospective randomized clinical study was to compare implant survival, patient satisfaction, radiographic, clinical, and aesthetic outcomes following immediate loading (IL) and delayed loading (DL) of single dental implants in the maxillary aesthetic zone, after 1-year of follow-up.

## 2 | MATERIALS AND METHODS

## 2.1 | Patient selection

Prior to patient inclusion a sample size of 50 patients, randomized to either IL or DL, was determined as acceptable to reach the level of required statistical power. Patients of at least 18 years of age in need of one or more single-tooth replacements at the Centre of Dental Specialist Care, Malmö between April 2011 and April 2014 were considered for inclusion in the present study. The single-tooth replacement needed to be an incisor, canine or premolar of maxillae with adjacent natural teeth. Exclusion criteria were general contraindications for oral surgery, patients with inadequate oral hygiene, and need for bone grafting or ridge augmentation at the implant site. For the IL-group it was decided to exclude implants with an insertion torque below 30 Ncm .

Patients were thoroughly informed about the treatment. The study was conducted in accordance with the Helsinki declaration of 1975 as revised in 2000, ${ }^{16}$ and all patients signed a written informed consent. The study protocol was approved by the Regional Ethical Review Board in Lund, Sweden (Dnr 2011/125). ClinicalTrails.gov ID: NCT02770846.

### 2.2 Treatment group procedures

For the patients willing to participate in the study, a clinical examination was done prior to randomization. Periapical and panoramic radiographs were used to initially evaluate the implant site. For patients eligible for the study, bone quantity and quality of the treated surgical sites were classified at the time of surgery according to the Lekholm and Zarb 1985 classification. ${ }^{17}$ Patients were assigned to one of the two study groups, IL or DL, using a closed randomization method with sealed envelopes. The surgeon was blinded with regard to treatment group assignment.

All patients were consecutively treated with Tapered Internal implants (BioHorizons, Birmingham, Alabama), placed in healed bone (4 months or more after tooth loss), according to a standardized surgical procedure. All implant sites were free from clinical signs of inflammation. Prophylactic antibiotic therapy was prescribed to all patients (phenoxymethylpenicillin, $500 \mathrm{mg} 8 / 8$ hours, Kåvepenin, Meda AB, Solna, Sweden), beginning 1 hour before surgery and extending for 7 days. Surgery was performed under local anesthesia (Xylocaine with 2\% adrenaline, Dentsply Pharmaceutical, York, Pennsylvania). An incision was placed at the mid-crest and a mucoperiosteal flap was raised with a vertical releasing incision. All implants were installed according to the recommendations given by the implant manufacturer. After installation, the implant was inspected for the presence of buccal fenestrations or dehiscences. Exposure of more than 1 mm of the implant excluded the patient from the study. Defects $<1 \mathrm{~mm}$ were covered with autogenous bone chips collected during the implant bed preparation, and no membranes were used. Postoperatively, the patients were instructed to rinse twice daily with a solution of $0.2 \%$ chlorhexidine for 14 days and to take analgesics in case of need (paracetamol $500 \mathrm{mg} 6 / 6$ hours, Alvedon, GlaxoSmithKline AB, Solna, Sweden). Sutures were removed after 2 weeks. All fixture installations were performed at the Centre of Dental Specialist Care, Malmö, Sweden, by the second author (J.K.)

In the IL group, the implants were immediately loaded with a screw-retained temporary crown. A titanium temporary abutment (BioHorizons, Birmingham, Alabama) with a composite crown (Sinfony, 3M ESPE, Maplewood, Minnesota) were used (Figure 1). The provisional restorations were adjusted to a light centric contact and free from eccentric contacts with the opposing teeth before the polishing procedures. The restorations were tightened to 15 Ncm and the mucoperiostal flaps were adapted to the crown before wound closure. The patients were instructed to avoid exerting force on the temporary restoration. In the DL group, the patients underwent a two-stage surgery procedure with a minimum healing period of 4 months before a screwretained temporary crown was fabricated using the same materials as in the IL group. The temporary crown shape and emergence profile were modified until the patients were satisfied with the crown and soft tissue appearance. Prosthetic procedures for definitive crowns were initiated after 2 months in the IL group and after 4-6 months in the DL group from the time of fixture installation. An implant-level impression was performed using a customized impression coping in such a way that the obtained emergence profile from the temporary restorations could be transferred to the definitive restoration, according to the method described elsewhere. ${ }^{18}$ The definitive crown consisted of an

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FIGURE 1 Temporary crown IL A, Titanium temporary abutment; B, Temporary crown after polishing; C, Radiograph of temporary crown; D, Temporary crown seated and mucosa sutured
individually fabricated zirconia abutment (I-butment, Biomain AB, Helsingborg, Sweden), with a titanium base (Medentica GmbH, Hügelsheim, Germany), being cemented- or screw-retained (Figure 2). The cemented-retained crowns and titanium bases were cemented with a bonding agent (Z-Prime Plus, Bisco, Schaumburg, Illinois) and dual-curing resin cement (Variolink, Ivolclar-Vivadent, Schaan, Liechtenstein). All crowns were veneered (GC Initial, GC EUROPE N.V., Leuven, Belgium) by the same dental technician. All prosthetic procedures were accomplished by the first author (B.G.).

## 2.3 | Follow-up appointments

After completion of the final restoration, the patients' dental hygiene were followed up by a dental hygienist within 6 months. The patients
were asked to attend a clinical and radiographic follow-up examination at 3,6 , and 12 months after definitive crown placement. The baseline for the radiographic follow-up was the day of the implant surgery, and the baseline for the aesthetic outcomes was the day of the placement of the definitive crown. The examinations were conducted by the same examiner responsible for the prosthetic treatment.

## 2.4 | Hard and soft tissue evaluation

Digital intraoral periapical radiographs (Schick Digital X-ray Sensor, Sirona, Salzburg, Austria) were taken immediately after surgery, and after 6 and 12 months, always using the long-cone parallel technique. The marginal bone level was measured after calibration with the interthread distance of the Tapered Internal implants ( 1.00 mm ).


FIGURE 2 A, Temporary crown; B, Radiograph of final restoration; C, Final restoration


FIGURE 3 Photographic measurements of soft tissue changes. The casts were positioned in front of the camera in a reproducible manner by individual bite impressions. A reference line was used to measure vertical change in mesial papilla (M), distal papilla (D), and the zenith position (Z)

Measurements were taken from the implant-abutment junction to the marginal bone level, at both mesial and distal sides of each implant, and then the mean value of these two measurements was considered. Marginal bone loss (MBL) was calculated by comparing bone-to-implant contact levels to the radiographic baseline examination. The Image J software (National Institute of Health, Bethesda) was used for all measurements.

Furthermore, resonance frequency analysis (RFA) was performed at implant installation and at definitive crown placement according to the manufacturer's instructions (Osstell ISQ, Osstell AB, Göteborg, Sweden). In the present study, the RFA was used to monitor the implant stability between implant installation and completion of the final restoration, to determine if there were any early signs of failure.

The gingival index was scored for each implant at each follow-up examination, according to Löe and Silness. ${ }^{19}$

The papilla index, ${ }^{12}$ gingival zenith and papilla levels around the implant restoration were measured on each follow-up examination. The vertical changes in gingival zenith positions were defined as the linear distance from the gingival zenith to the reference line and for papilla levels as the linear distance from the papilla tip to the reference line (Figure 3). Casts were made after receiving and before removing the temporary restoration, at completion of the permanent restoration, and after 3, 6, 12 months. Study casts were photographed (Nikon D7000, Nikon Corporation, Tokyo, Japan) together with a 1-mm precision ruler. The Image J software (National Institute of Health, Bethesda) were used for all measurements.

## 2.5 | Aesthetic assessment

Intraoral photographs from the aesthetic baseline and follow-up appointments were used to register the pink esthetic score (PES), according to the technique described by others. ${ }^{13}$ Photographs from the final follow-up appointment were used to calculate the white esthetic score (WES). ${ }^{14}$

Cosyn et al. have defined (almost) perfect outcome for PES and WES as PES $\geq 12$ and WES $\geq 9$, respectively, and aesthetic failure as PES $\leq 7$ and WES $\leq 5$, respectively. ${ }^{20}$

## 2.6 | Patient-centered outcome

The OHRQoL was calculated using the Swedish validated version of the Oral Health Impact Profile (OHIP-14) questionnaire. ${ }^{15}$ The additive score is obtained by summation of the response codes for the 14 items. This gives a range from 14 to 70, where a higher score indicates poor OHRQoL. The questionnaires were completed at the beginning of the treatment, on the day when the patients received a temporary crown, and at 6 and 12 months after the definitive crown placement. Moreover, the patients' satisfaction with the final restoration was assessed 12 months after the definitive crown placement, by using a visual analog scale (VAS). The patients marked their satisfaction in a non-numerical 100 mm line ranging from "not at all satisfied $=0$ " (left) to "very satisfied = 100" (right), for each implant. They were asked the following question: (1) "Are you satisfied with the aesthetic result of your treatment?" Each response was given a numerical value by measuring in millimeters the distance from the left end of the line.

## 2.7 | Success and survival

Implant success and survival were evaluated according to Albrektsson. ${ }^{21}$

## 2.8 | Statistics

All data were statistically analyzed by one examiner, who did not take part in any of the clinical procedures. The software used was the Statistical Package for the Social Sciences (SPSS) version 22 (SPSS Inc., Chicago, Illinois). The data were tabulated, and from these measurements mean, standard deviation (SD), minimum and maximum were calculated. Kolmogorov-Smirnov test was performed to evaluate the normal distribution of the variables, and Levene's test evaluated homoscedasticity. The performed tests for two independent groups, three or more independent groups, and two dependent groups were Student's $t$-test or Mann-Whitney test, one way ANOVA or Kruskal-Wallis test, and paired-samples $t$-test or Wilcoxon signed-rank test, respectively, depending on the normality. Pearson's chi-squared or Fisher's exact test was performed for categorical variables, depending on the expected count of events in a $2 \times 2$ contingency table. Correlation and linear regression were performed to check the relationship between the patients' satisfaction (VAS), PES/WES scores and OHIP-14. The degree of statistical significance was considered $P<.05$.

## 3 | RESULTS

A total of 62 patients were initially allocated to the study. Twelve patients were not included in the study for the following reasons: four patients did not want treatment for economic reasons, three patients presented extensive osseous defects that would require a bone graft in order to make the insertion of an implant possible, one patient desired


FIGURE 4 Clinical trial outline of study participants
a tooth supported bridge instead of an implant, three patients decided to leave the study before surgery. The remaining 50 patients were included in the study, 25 randomly allocated to each group. In the ILgroup, all implants reached the minimum insertion torque of 30 Ncm .

There were no drop-outs and all patients attended the follow-up visits, except for two patients who missed the 6-month follow-up. One implant was lost 3 months after surgery in the DL group, resulting in an implant survival rate of $100 \%$ and $96 \%$ for IL and DL, respectively. Implant success rate was $96 \%$ and $88 \%$ for IL and DL, respectively. No complications to the implants or implant supported crowns occurred during the 1-year follow-up period. The clinical trial outline is shown in Figure 4. Details about the patients and treatment specifications at the time of the implant surgery are described in Table 1.

## 3.1 | Hard and soft tissue evaluation

The mean $\pm$ SD Implant Stability Quotient (ISQ) values at fixture installation for IL and DL were $73.64 \pm 7.78$ and $68.86 \pm 8.36$, respectively ( $P<.015$, Mann-Whitney test). At completion of the final restoration the mean $\pm$ SD ISQ values were $74.64 \pm 6.31$ and $73.62 \pm 5.05$ for IL
and DL, respectively. It should be noted that completion of the final restoration did occur at different time points for the two groups. Outcome for MBL, gingiva index and papilla index for IL and DL are shown in Table 2. In both the IL and DL group there were a statistically significant difference in MBL between 0-6 months and 7-12 months ( $P=.000$ and $P=.000$, Wilcoxon signed-rank test) with IL implants displaying the least loss of marginal bone. The mean $\pm$ SD (min-max) MBL between smokers $(n=7)$ and nonsmokers $(n=42)$ at 6 months was $-0.87 \pm$ $0.81 \mathrm{~mm}(-1.99-0.00)$ and $-0.45 \pm 0.45 \mathrm{~mm}(-2.04-0.57)$, respectively ( $P=.424$, Mann-Whitney test). The values at 12 months were $-0.93 \pm 0.80 \mathrm{~mm}(-2.05-0.00)$ and $0.58 \pm 0.48 \mathrm{~mm}(-2.37-0.23)$ for smokers and nonsmokers, respectively ( $P=.408$, Mann-Whitney test).

Soft tissue changes for gingival zenith and papilla levels around the implant restoration for IL and DL are shown in Table 3. The mean distance until mesial and distal papilla reached a complete papilla fill (papilla fill according to the papilla index) for IL and DL were $0.77 \pm$ 0.71 mm and $0.60 \pm 0.74 \mathrm{~mm}$, respectively ( $P=.264$, Mann-Whitney test) at the 12-month follow-up. Patients with a complete papilla fill on both mesial and distal sides in IL and DL after 12 months were $28 \%$ and $46 \%$, respectively ( $P=.244$, Fisher's exact test).
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TABLE 1 Characteristics and treatment specifications of 50 patients treated with a single implant with immediate or delayed loading

| Variable | Immediate loading | Delayed loading | $P$-value |
| :---: | :---: | :---: | :---: |
| Implant surgery |  |  |  |
| Mean age $\pm$ SD (min, max), (years) | $40.8 \pm 13.3$ (19.0-66.6) | $40.9 \pm 15.5$ (18.5-76.7) | .973* |
| Men/women | 14/11 | 6/19 | .021 $\dagger$ |
| Smokers/Nonsmokers | 2/23 | 6/19 | . $247+\dagger$ |
| Bruxers/Nonbruxers | 2/23 | 0/25 | .490†† |
| Diabetic/Nondiabetic | 0/25 | 0/25 | - |
| Reason for missing tooth |  |  |  |
| Trauma | 15 | 12 |  |
| Agenesia | 3 | 4 |  |
| Advanced caries | 5 | 5 |  |
| Root resorption | 2 | 2 |  |
| Apical destruction | 0 | 2 |  |
| Implant diameter: 3.8/4.6 mm | 18/7 | 22/3 |  |
| Implant length: $10.5 / 12 / 15 \mathrm{~mm}$ | 0/16/9 | 2/14/9 |  |
| Bone quantity: $A / B / C / D / E$ | 5/20/0/0/0 | 2/21/2/0/0 |  |
| Bone quality: $1 / 2 / 3 / 4$ | 0/13/12/0 | 0/6/18/1 |  |
| Mean installation torque $\pm$ SD | $34.04 \pm 4.89$ | $30.24 \pm 7.92$ | .062** |
| Prosthetic treatment | mean days $\pm$ SD after im |  |  |
| Abutment connection | - | $140 \pm 3$ |  |
| Definitive prosthesis | $103 \pm 5$ | $228 \pm 59$ |  |
| Screw-retained/cemented | 15/10 | 15/9 |  |

SD, standard deviation.
*Student's $t$-test. ${ }^{* *}$ Mann-Whitney test. $\dagger$ Pearson Chi-squared test. $\dagger \dagger$ Fisher's exact test.

## 3.2 | Aesthetic outcomes

An overview of PES and WES outcomes for IL and DL can be seen in Table 4, with no statistically significant differences between the two loading protocols.

There was a statistically significant improvement in PES between initial evaluation and after 1 year for both IL and DL ( $P=.001$ and $P=.002$, Wilcoxon signed-rank test) and also for WES ( $P=.008$ and $P=.001$, Wilcoxon signed-rank test).

Perfect outcome after 12 months in the IL and DL groups were found for PES in $32.0 \%$ and $37.5 \%$ of the cases and for WES in $28.0 \%$ and $29.2 \%$ of the cases, respectively. Aesthetic failures in the IL and DL groups were found for PES in $16.0 \%$ and $12.6 \%$ of the cases and for WES in $4.0 \%$ and $8.3 \%$ of the cases, respectively.

## 3.3 | Patient-centered outcomes

OHiP-14 and VAS outcome for IL and DL are summarized in Table 5. For both groups, the mean additive OHIP-14 score at the initial appointment for male and female were $21.40 \pm 6.54(n=20)$ and
$27.47 \pm 9.73(n=30)$, respectively ( $P=.018$, Mann-Whitney test). At the final follow-up, the mean additive OHIP-14 score for male and female were $15.7 \pm 2.66(n=20)$ and $16.10 \pm 3.74(n=29)$, respectively ( $P=.929$, Mann-Whitney test). There was an overall statistically significant improvement in OHRQoL, assessed by OHiP-14, between initial appointment and temporary crown placement for IL and DL ( $P=.000$ and $P=.002$, Wilcoxon signed-rank test). The relationship between VAS and final (12-month) PES score was very weak ( $R=0.033, R^{2}=0.001, P=.825$; Pearson correlation). The linear regression analysis showed that for every 1 point increase in PES, the VAS value increased by 0.141 points. The relationship between VAS and the final (12-month) WES score was also very weak ( $R=0.061$, $R^{2}=0.004, P=.678$; Pearson correlation). The linear regression analysis showed that for every 1 point increase in WES, the VAS value increased by 0.471 points.

For both groups, the relationship VAS and final (12-month) additive OHIP-14 score was moderate ( $R=0.404, R^{2}=0.163, P=.004$; Pearson correlation). The linear regression analysis showed that for every 1 point increase in OHIP-14, the VAS value decreased 1.225 points.

TABLE 2 MBL, gingiva index, and papilla index outcomes

| Variable | Immediate loading | Delayed loading | $P$-value |
| :---: | :---: | :---: | :---: |
| MBL (mm) | mean $\pm$ SD (min, max) | mean $\pm$ SD (min, max) |  |
| 0-6 months | $-0.51 \pm 0.50$ ( $-1.80,0.57)$ | $-0.51 \pm 0.56$ (-2.04, 0.22) | .589** |
| 7-12 months | $-0.07 \pm 0.28(-0.37,0.79)$ | $-0.18 \pm 0.41(-0.37,1.22)$ | .332** |
| 0-12 months | $-0.57 \pm 0.52(-2.05,0.21)$ | $-0.69 \pm 0.57(-2.37,0.18)$ | . $468{ }^{*}$ |
| Gingiva Index |  |  |  |
| Initial appointment | $1.24 \pm 0.52(1,3)$ | $1.36 \pm 0.70(1,3)$ | . $648{ }^{* *}$ |
| Temporary crown placement | $1.32 \pm 0.56$ (1, 3) | $1.25 \pm 0.44(1,2)$ | .754** |
| 3 months of definitive crown | $1.08 \pm 0.28(1,2)$ | $1.00 \pm 0.00(1,1)$ | .161** |
| 6 months of definitive crown | $1.04 \pm 0.20(1,2)$ | $1.00 \pm 0.00(1,1)$ | . 328 ** |
| 12 months of definitive crown | $1.12 \pm 0.33(1,2)$ | $1.04 \pm 0.20$ (1, 2) | . 322 ** |
| Papilla index, mesial |  |  |  |
| Temporary crown placement | $0.72 \pm 0.79(0,2)$ | $1.62 \pm 0.82(0,3)$ | <.001** |
| Before temporary crown removal | $1.80 \pm 0.91(0,4)$ | $2.46 \pm 0.66$ (1, 3) | .005** |
| Definitive crown placement | $1.88 \pm 0.97(0,3)$ | $2.29 \pm 0.80(0,3)$ | .121** |
| 6 months of definitive crown | $2.38 \pm 0.65(1,3)$ | $2.43 \pm 0.79(0,3)$ | .544** |
| 12 months of definitive crown | $2.56 \pm 0.51(2,3)$ | $2.63 \pm 0.58(1,3)$ | .533** |
| Papilla index, distal |  |  |  |
| Temporary crown placement | $0.72 \pm 0.54(0,2)$ | $1.38 \pm 0.82(0,3)$ | .003** |
| Before temporary crown removal | $1.28 \pm 0.84(0,3)$ | $2.04 \pm 0.86$ (0,3) | .004** |
| Definitive crown placement | $1.24 \pm 0.88(0,3)$ | $2.08 \pm 0.83$ (0,3) | .002** |
| 6 months of definitive crown | $1.75 \pm 0.85(0,3)$ | $2.13 \pm 0.87(0,3)$ | .113** |
| 12 months of definitive crown | $2.12 \pm 0.67(1,3)$ | $2.25 \pm 0.85(0,3)$ | . 366 ** |

MBL, marginal bone loss (negative values represent bone loss); SD, standard deviation.
*Student's t-test. **Mann-Whitney test.

TABLE 3 Soft tissue changes

| Variable | Immediate loading | Delayed loading | $P$-value |
| :---: | :---: | :---: | :---: |
| Soft tissue changes: mesial papilla (mm) | mean $\pm$ SD (min, max) | mean $\pm$ SD (min, max) |  |
| During temporary crown At change to definitive crown | $\begin{aligned} & 0.35 \pm 0.54(-0.63,1,87) \\ & -0.02 \pm 0.30(-0.72,0.65) \end{aligned}$ | $\begin{aligned} & 0.30 \pm 0.45(-0.36,1,42) \\ & -0.07 \pm 0.34(-0.76,0.47) \end{aligned}$ | $\begin{aligned} & .810^{* *} \\ & .920^{* *} \end{aligned}$ |
| Changes from definitive crown placement |  |  |  |
| 3 months | $0.24 \pm 0.39(-0.46,1.28)$ | $0.25 \pm 0.51(-1.05,1.31)$ | .953* |
| 6 months | $0.45 \pm 0.50(-0.31,1.58)$ | $0.44 \pm 0.47$ (-0.37, 1.42) | .922* |
| 12 months | $0.74 \pm 0.70(-0.36,2.35)$ | $0.60 \pm 0.58(-0.26,2.40)$ | . $522{ }^{* *}$ |
| Soft tissue changes: distal papilla (mm) |  |  |  |
| During temporary crown | $0.04 \pm 0.70(-2.10,1.33)$ | $0.27 \pm 0.57(-1.16,1.13)$ | .224* |
| At change to definitive crown | $-0.05 \pm 0.32(-0.73,0.69)$ | $-0.18 \pm 0.50$ (-1.49, 0.47) | . $646 * *$ |
| Changes from definitive crown placement |  |  |  |
| 3 months | $0.30 \pm 0.44(-0.47,1.41)$ | $0.24 \pm 0.42(-0.33,1.34)$ | .682** |
| 6 months | $0.52 \pm 0.41(-0.12,1.34)$ | $0.37 \pm 0.44(-0.42,1.30)$ | .194** |
| 12 months | $0.63 \pm 0.48$ (-0.22, 1.49) | $0.50 \pm 0.60$ (-1.24, 1.71) | .406* |
| Soft tissue changes: gingival zenith (mm) |  |  |  |
| During temporary crown | $-0.01 \pm 0.55(-1.13,1.47)$ | $0.11 \pm 0.45(-0.69,0.97)$ | . 423 * |
| At change to definitive crown | $-0.16 \pm 0.51(-1.43,0.70)$ | $-0.30 \pm 0.50(-1.37,0.58)$ | . $332{ }^{*}$ |
| Changes from definitive crown placement |  |  |  |
| 3 months | $0.09 \pm 0.31(-0.40,0.65)$ | $0.24 \pm 0.42(-0.53,1.07)$ | .164* |
| 6 months | $0.11 \pm 0.29(-0.31,0.82)$ | $0.30 \pm 0.42(-0.45,1.37)$ | .075* |
| 12 months | $0.10 \pm 0.38(-0.75,0.92)$ | $0.32 \pm 0.52(-0.54,1.37)$ | .088* |

SD, standard deviation, Soft tissue change-positive values represent a gain in soft tissue.
*Student's $t$-test.

| 8 |  |  |
| :--- | :--- | :--- |
| TABLE 4 Aesthetic outcomes |  |  |
| Variable |  |  |
| PES | Immediate loading | Delayed loading |
| Definitive crown placement | $8.56 \pm 2.27(2-13)$ | mean $\pm$ SD (min, max) |
| 3 months of definitive crown | $9.32 \pm 2.14(3-13)$ | $9.42 \pm 2.98(4-14)$ |
| 6 months of definitive crown | $9.75 \pm 2.36(3-14)$ | $10.08 \pm 2.52(5-14)$ |
| 12 months of definitive crown | $10.36 \pm 2.46(3-14)$ | $10.33 \pm 2.68(5-14)$ |
| WES |  | $10.67 \pm 2.32(5-14)$ |
| Definitive crown placement | $7.00 \pm 1.41(4-10)$ |  |
| 3 months of definitive crown | $7.24 \pm 1.36(4-10)$ | $7.00 \pm 1.64(4-10)$ |
| 6 months of definitive crown | $7.50 \pm 1.35(4-10)$ | $7.54 \pm 1.74(4-10)$ |
| 12 months of definitive crown | $7.76 \pm 1.30(5-10)$ | $7.54 \pm 1.62(4-10)$ |

SD, standard deviation.
*Student's $t$-test. ${ }^{* *}$ Mann-Whitney test.

## 4 | DISCUSSION

The aims of the present study were to evaluate implant survival, patient satisfaction, radiographic, clinical, and aesthetic outcomes following immediate loading and delayed loading of single dental implants placed in the maxilla, until 1 year of follow-up. The DL implants presented a lower survival rate $96 \%$, opposed to $100 \%$ for the IL implants, due to the early loss of one implant. The patient who lost an implant was a smoker, considered to be a risk factor for early implant loss. ${ }^{22}$ The survival rate for immediate loading was similar to the ones found in other single-implant studies. ${ }^{5,23}$

Others have found that higher ISQ values can be correlated to an increase in installation torque, increased implant diameter and sex. ${ }^{24}$ The statistically significant higher ISQ value at implant installation for the IL-group may have been influenced by these factors.

Bone resorption occurred in both groups during the observation period. The greater initial bone loss seen in both groups (0-6 months) could be related to the bone remodeling process initiated after fixture installation. ${ }^{25}$ The amount of bone loss correspond the findings of a previous study evaluating immediate loading and the same implant system. ${ }^{23}$ The lack of statistically significant difference for MBL between groups seems to indicate that immediate loading in the present study did not affect the MBL in relation to delayed loading during the 1 year of function. However, it is a matter of debate whether there could be a difference under difference circumstances, such as larger study groups followed by a longer period.

The statistically significant difference in papilla index between groups could be explained by the differences in time between implant surgery and definitive crown placement for the two groups, even differences in flap adaptation and suturing may have played a role as well. Moreover, the DL group may present a higher score due to the reshaping of the emergence profile until patient satisfaction was reached. Others have suggested that such soft tissue conditioning by customizing the shape and contour of a provisional restorations in the aesthetic zone helps the achievement of a better aesthetic outcome. ${ }^{26}$ It is expected that a longer follow-up period than the one observed in the present study could result in additional papilla formation. ${ }^{12}$ Concerning softtissue changes, there were no statistically significant differences between the two groups. There was an overall tendency of the papilla to gradually increase in height, correlating to the changes found in the papilla index score. The gradual increase in aesthetics and also changes in soft tissue shape may be explained by the gradual papillae formation and the healing process of the mucosa over time. ${ }^{27}$ It is expected after placement of implant crowns in edentulous sites that the PES will automatically improve in correlation with wound healing and papillae formation, as many of the evaluation parameters are related. Also, an increase in the WES can be related to the soft tissue healing and adaptation, as the perception of the crown shape and contour may change in the areas in close proximity with the soft tissue. The final PES and WES found in this study for both groups are comparable with the findings reported by others. ${ }^{6,28}$

The statistically significant improvement of OHIP-14 between pretreatment and after receiving a temporary crown for both groups could

TABLE 5 Patient-centered outcomes

| Variable | Immediate loading | Delayed loading | P-value |
| :--- | :--- | :--- | :--- |
| OHIP-14 additive | mean $\pm \mathrm{SD}(\min -\mathrm{max})$ | mean $\pm \mathrm{SD}(\min , \max )$ |  |
| Initial appointment | $26.68 \pm 9.30(15-46)$ | $23.40 \pm 8.64(14-52)$ |  |
| Temporary crown placement | $18.64 \pm 5.32(14-34)$ | $18.67 \pm 9.06(14-57)$ |  |
| 6 months of definitive crown | $16.92 \pm 4.68(14-30)$ | $16.48 \pm 7.09(14-48)$ |  |
| 12 months of definitive crown | $16.48 \pm 3.87(14-29)$ | $15.38 \pm 2.58(14-25)$ | $.162^{* *}$ |
| VAS |  |  | $.383^{* *}$ |
| 12 months of definitive crown | $89.6 \pm 9.5(70-100)$ | $876^{* *}$ |  |

SD, standard deviation.
Student's $t$-test. **Mann-Whitney test.
probably be a result of increased comfort while eating, and the feeling of less insecurity and embarrassment. This improvement occurred earlier in the IL than in the DL group, due to the immediate placement of a temporary restoration. The low OHIP-14 score may be explained by generally healthy patients with good oral status and overall wellfunctioning prosthetic restorations. Others have reported high scores when patients are asked to judge the aesthetic outcome of the given restoration, in contrast to a more critical judgment by the dentists. ${ }^{29}$ Factors of paramount importance for the patient's satisfaction may differ from the attitudes of the professionals. ${ }^{30}$ Furthermore, there was a moderate correlation between VAS and OHIP-14, suggesting that low OHRQoL scores affect the patient's judgment of aesthetics in a negative sense.

An important limitation of this study is the short follow-up time (1 year). Further follow-up appointments would provide long-term data on the immediate loading protocol and the evaluated implant system. Moreover, only implants placed in the maxilla were evaluated. For further research, a volumetric evaluation of soft tissue alterations during the healing phase would possibly present more precise information

The authors believe that new research efforts should be concentrated in a comparison between immediate loading with a flapless procedure and delayed loading with no intermediate restoration.

## 5 | CONCLUSION

This prospective randomized study showed that single implants in the maxilla can present satisfactory results with regard to either immediate loading or delayed loading after 12 months. With comparable MBL, soft-tissue, aesthetic, and patient-centered outcomes.

## ACKNOWLEDGMENT

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## CONFLICT OF INTEREST

We certify that we have no affiliation with or financial involvement in any organization or entity with direct financial interest in the subject matter or materials discussed in the manuscript, and that the material is original and has not been published elsewhere. The authors have no conflict of interest relevant to the content of the submission.

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## III

RESEARCH AND EDUCATION

# Accuracy of surgical guides from 2 different desktop 3D printers for computed tomography-guided surgery 

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The use of computed tomography (CT)-guided surgery for the installation of dental implants involves cone beam computed tomography (CBCT), intraoral digital scan, planning design, and fabrication of the surgical guide. In each step of the workflow and in the surgical procedure, errors may in fluence the overall accuracy. ${ }^{1-8}$ Such errors can be the alignment of CBCT and the acquired digital scan, errors during CBCT image acquisition, inexact tolerance, or imprecise mounting of the guide sleeve. ${ }^{1,9,10}$ Furthermore, the level of accuracy is affected by the intraoral support of the surgical guide with respect to bone, mucosa, or teeth. The surgical workflow (fully guided pilot guide, freehand dental implant placement) and single or multiple dental implant surgical guides will affect accuracy. ${ }^{2,11-15}$ As the accuracy of the treatment protocol is essential to prevent damage to surrounding structures, each step in the process needs to be carefully executed. ${ }^{12}$ Regarding the fabrication of the surgical guide, one can distinguish between 2 fabrication methods: additive manufacturing and the use of mechanical positioning devices. ${ }^{16}$

ABSTRACT
Statement of problem. Different factors influence the degree of deviation in dental implant position after computed tomography-guided surgery. The surgical guide-manufacturing process with desktop 3D printers is such a factor, but its accuracy has not been fully evaluated.

Purpose. The purpose of this in vitro study was to evaluate the deviation in final dental implant position after the use of surgical guides fabricated from 2 different desktop 3D printers using a digital workflow.

Material and methods. Twenty 3D-printed resin models were prepared with missing maxillary premolar. After preoperative planning, 10 surgical guides were produced with a stereolithography printer and 10 with a digital light-processing (DLP) printer. A guided surgery was performed; 20 dental implants ( $3.8 \times 12 \mathrm{~mm}$ ) were installed, and a digital scan of the dental implants was made Deviations between the planned and final position of the dental implants were evaluated for both the groups.

Results. A statistically significant difference between stereolithography and DLP were found for deviation at entry point ( $P=.023$ ) and the vertical implant position ( $P=.009$ ). Overall lower deviations were found for the guides from the DLP printer, with the exception of deviation in horizontal implant position.
Conclusions. The tested desktop 3D printers were able to produce surgical guides with similar deviations with regard to the final dental implant position, but the DLP printer proved more accurate concerning deviations at entry point and vertical implant position. (J Prosthet Dent 2019;121:498-503

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## Clinical Implications

Digital techniques can be used for postoperative verification of computed tomography-guided surgeries. With careful control of the manufacturing process, desktop 3D printers are a suitable option for fabricating surgical guides.
defined as the deviation between the dental implant position in the planning and postoperative position. ${ }^{10}$

Along with the increased methods of surgical guide manufacturing, evaluating the accuracy of the procedures is important. A recent study evaluating the accuracy of 3Dprinted surgical guides produced with a desktop 3D printer concluded that producing surgical guides of high quality was possible. ${ }^{19}$ However, different desktop 3D printers and surgical guide materials may affect the overall accuracy of the procedure and may need to be further investigated. Both stereolithography (SLA) and digital light processing (DLP) are used in dentistry. SLA printers create shapes layer by layer using ultraviolet laser light to solidify a liquid photopolymerizing resin, an additive manufacturing process. The DLP printer operates in a similar way, except that it uses projector technology for photopolymerization and has significantly faster print times. However, the resolution may be reduced, depending on the quality of the projector and the material used.

The accuracy of guided surgery is frequently defined as the deviation between the position of the dental implant postoperatively and the planned position. A common procedure for this involves a postoperative CBCT examination of the patient. ${ }^{4}$ The use of digital scans and dental implant scan bodies has been evaluated and demonstrated to be a valid alternative to conventional impressions and in registering the dental implant position..$^{20-28} \mathrm{~A}$ mean trueness of $50.2 \pm 2.5 \mu \mathrm{~m}$ and a mean precision of $24.5 \pm 3.7 \mu \mathrm{~m}$ for the TRIOS 3 (3Shape) scanner for digital scans of a partially edentulous maxilla have been reported. ${ }^{21}$ Using digital scans to acquire the final implant position may eliminate the need for a postoperative CBCT examination. ${ }^{29}$ This method has been recommended for the evaluation of guided surgery. ${ }^{30}$

The purpose of this in vitro study was to evaluate the degree of deviation in the final dental implant position after the use of surgical guides fabricated from 2 different desktop 3D printers using a digital workflow. The null hypothesis was that no difference would be found in the 2 groups with different surgical guides.

## MATERIAL AND METHODS

A digital scan (TRIOS 3; 3Shape) of a maxillary typodont was used to create a 3D model. The model was then digitally manipulated in a 3D sculpting-based computer-


Figure 1. Guided surgery planning.
assisted design (CAD) software program (Meshmixer 3.2; Autodesk) as follows: the first premolar on the left side was removed, and the space was flattened and cropped to a half dental arch. Using an SLA printer (Form 2; Formlabs) 20 surgical models were fabricated (Tough Resin V4; Formlabs). The models were numbered 1 through 20 and divided into 2 groups, namely SLA and DLP. Each model was digitally scanned (TRIOS 3; 3Shape) and radiographed with a CBCT machine (ProMax 3D; Planmeca). All CBCTs were performed with the same characteristics: voxel size of 0.2 mm , exposure factors were 60 kV and 8.0 mA ; and exposure time was 4.065 seconds. A series of axially sliced image data were obtained and exported to digital imaging and communications in medicine (DICOM) format and numbered according to corresponding model. Digital scans and DICOM files were imported into a CT-guided surgery software program (Implant Studio; 3Shape) for planning and surgery guide design.

For each situation, a dental implant (Tapered Internal; BioHorizons), 12 mm in length and 3.8 mm in diameter, was selected, resulting in the same drilling protocol. In the guided surgery software, the dental implants were virtually positioned 1 mm above the model surface as seen in Figure 1. In the DLP group, 10 surgical guides were fabricated from a photopolymer resin (E-Guide; EnvisionTEC) using a DLP printer (Vida; EnvisionTEC) as seen in Figure 2A. Guide thickness was 1.4 mm , offset from teeth to guide was 0.02 mm , and offset from sleeve to guide was 0.01 mm , according to manufacturing recommendations. In the SLA group, 10 surgical guides were fabricated from a different photopolymer resin (Dental SG Resin; Formlabs) using an SLA printer (Form 2; Formlabs) as seen in Figure 2B. Guide thickness was 2 mm , offset from teeth to guide was 0.06 mm , and offset from sleeve to guide was 0.05 mm , according to manufacturing recommendations. The surgical guides were positioned, printed, and then processed according


Figure 2. A, Surgical guide DLP (Vida 3D printer and E-guide material). B, Surgery guide SLA (Form two 3D printer and Dental SG Resin material). DLP, digital light processing; SLA, stereolithography.
to the manufacturers' guidelines. Master cylinder sleeves (Master Sleeve; BioHorizons) were then incorporated into the surgical guides. The two 3D printers were calibrated before guide fabrication.

A visual inspection was performed to evaluate the correct seating of the surgical guides on their respective surgical model. All 20 dental implants were installed using a guided surgery kit (BioHorizons) by 1 operator (B.G.), following the drill protocol and the implant manufacturer's instruction for fully guided surgery. The implant driver and a torque wrench (BioHorizons) were used to reach the indicated stop position and adjust the implant hexagon to correspond with the indication marking on the surgical guide.

After implant placement, scan bodies (PEEK Scan Abutments; BioHorizons) were attached onto each dental implant, and the models were digitally scanned (TRIOS 3; 3Shape). The digital scans and the guided surgery planning were separately imported into a dental design software program (Dental Designer; 3Shape), from which standard tessellation language data sets were exported with incorporated geometric dental implant structures. Corresponding data sets of the planned and final dental implant position were then imported into a 3D data measurement analysis software program (GOM Inspect 2017, build 2017-09-14; GOM Metrology). To make the superimposition more precise, irrelevant areas beyond the field of interest were not selected for alignment after the primary alignment between the data sets.

Alignments were performed using a best-fit algorithm based on the selected surfaces of the neighboring teeth. ${ }^{23}$ Color-coded deviation maps were generated to show the difference between 2 aligned data sets as seen in Figure 3, in addition to the mean deviation. To identify the central entry point and apex of the dental implant, fitting elements were applied to key geometric surfaces of the dental implant using the Gaussian best-fit approach. The following parameters were calculated: deviation at


Figure 3. Alignment of data sets, color-coded deviations maps, and mean deviation.
entry point, measured at the center of the implant (in mm ); deviation at apex, measured at the center of the implant apex (in mm); angular deviation (in degrees); deviation in vertical implant position, measured at the center of the implant (in mm ); deviation in horizontal implant position, measured at the center of the implant (in mm ); and rotational deviation of the implant hexagon (in degrees). ${ }^{2}$ The parameters are illustrated in Figure 4. The software calculated the distance between the measuring points on the $x, y$, and $z$ axes and the Euclidian distance (dxyz) (Fig. 5) using the following equation:
$d x y z=\sqrt{\left(x_{\text {ref }}-x_{\text {test }}\right)^{2}+\left(y_{\text {ref }}-y_{\text {test }}\right)^{2}+\left(z_{\text {ref }}-z_{\text {test }}\right)^{2}}$.
Statistical analysis was performed using a statistical software program (IBM SPSS Statistics, v22; IBM Corp). The data were tabulated, and from these measurements, median, mean, minimum, maximum, and standard deviations (SDs) were calculated. The


Figure 4. Deviation measurements: Deviation at entry point (a); deviation at apex (b); angular deviation (c); deviation in vertical implant position (d); deviation in horizontal implant position (e); rotational deviation of implant hexagon (f).

Mann-Whitney $U$ test was used to analyze the 2 independent groups ( $\alpha=.05$ ).

## RESULTS

A total of 20 dental implants were placed with no unexpected occurrences during surgical guide fabrication or fixture installation. The mean $\pm$ SDs for the deviation between the points used for the best-fit alignment of the 2 data sets were $18.8 \pm 4.0 \mu \mathrm{~m}$ for DLP and $18.9 \pm 4.3 \mu \mathrm{~m}$ for SLA $(P=.739)$. In the DLP group, the lowest mean deviation was found for vertical implant position (0.16 $\pm 0.11 \mathrm{~mm})$ and for the SLA group in horizontal implant position ( $0.16 \pm 0.11 \mathrm{~mm}$ ). The SLA group had the highest mean deviation at the apex $(0.49 \pm 0.17 \mathrm{~mm})$. For the DLP group, the deviation at the apex was $0.34 \pm 0.14$ mm . Statistically significant differences were found for deviation at the entry point ( $P=.023$ ) and for vertical implant position ( $P=.009$ ). A summary of the statistical analysis for deviations in dental implant position between the DLP and SLA groups is presented in Table 1.

## DISCUSSION

The null hypothesis was partially rejected because significant differences were found in the final dental implant position between the guides fabricated from the 2 tested desktop 3D printers.

A digital scan of a dental implant with an intraoral scan body is commonly used in the fabrication of


Figure 5. Inspection variables software output.
implant-supported crowns and has been investigated. ${ }^{22,24,25}$ This procedure, in conjunction with data from the guided surgery software, can be used to extract data sets with the intended and postoperative dental implant positions. Cristache and Gurbanescu ${ }^{29}$ used a similar method to compare the data sets from the surgical planning with post insertion digital scan data sets. In the past, a second CBCT examination of the patient was necessary to identify the postoperative implant position, exposing the patient to additional radiation. Use of intraoral scan bodies reduces radiographic exposure and is in accordance with recommendations of a recent systematic review. ${ }^{30}$

No significant difference in deviation was found between the 2 groups for the alignment of planned and final data sets. Best-fit alignment has been commonly used to align data sets and can be used in studies to evaluate the accuracy of digital scans. Ender et $\mathrm{al}^{26}$ reported on the precision of repeated quadrant dental arch silicone impressions ( $18.8 \pm 7.1 \mu \mathrm{~m}$ ) and the TRIOS 3 (3Shape) scanner ( $26.1 \pm 3.8 \mu \mathrm{~m}$ ). Full-arch best-fit alignment might, however, generate systematic errors because of the deviation between 2 large data distances. ${ }^{20,27}$ The precision and trueness of the intraoral scanner used in the present study have been evaluated. ${ }^{21,27,28}$

In the present study, the DLP and SLA groups presented a low degree of deviation between the planned and postoperative dental implant positions. The findings fall within the mean system error of 1.2 mm for the horizontal and 0.5 mm for the vertical direction established by the European Association for Osseointegration consensus in 2012. ${ }^{15}$ For in vitro studies, lower deviations are to be expected, as reported in a recent systematic review with a mean horizontal coronal deviation of 1.10 $\pm 0.09 \mathrm{~mm}$ for clinical studies and $0.77 \pm 0.15 \mathrm{~mm}$ for in vitro studies. ${ }^{3}$ These results do not consider the number of dental implants or type of guide support.

Table 1. Deviation difference (Mann-Whitney $U$ test)

| Variable | DLP |  | SLA |  | U Value | P |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Median | Mean $\pm$ SD ( min-max) | Median | Mean $\pm$ SD (min-max) |  |  |
| Deviation at entry point (mm) | 0.28 | $0.27 \pm 0.08$ (0.15-0.36) | 0.38 | $0.39 \pm 0.01$ (0.21-0.63) | 20 | .023* |
| Deviation at apex (mm) | 0.36 | $0.34 \pm 0.14$ (0.10-0.53) | 0.53 | $0.49 \pm 0.17$ (0.23-0.77) | 25 | . 063 |
| Angular deviation (degrees) | 0.86 | $0.99 \pm 0.57$ (0.27-1.90) | 1.29 | $1.25 \pm 0.49$ (0.52-1.98) | 35 | . 280 |
| Deviation in vertical implant position (mm) | 0.12 | $0.16 \pm 0.11$ (0.02-0.33) | 0.34 | $0.34 \pm 0.18$ (0.09-0.58) | 16 | .009* |
| Deviation in horizontal implant position (mm) | 0.16 | $0.17 \pm 0.09$ (0.07-0.36) | 0.16 | $0.16 \pm 0.11$ (0.02-0.33) | 48 | . 912 |
| Rotational deviation (degrees) | 3.06 | $3.66 \pm 1.89$ (0.98-7.64) | 3.66 | $4.68 \pm 4.14$ (0.53-14.59) | 50 | 1.000 |

DLP, digital light processing; SD, standard deviation; SLA, stereolithography. For vertical deviation, positive values represent more coronal position of implant. *Statistically significant, $P<.05$.

Lower deviations are to be expected for single dental implants tooth-supported guides, ${ }^{13}$ but a variation in deviation does occur. ${ }^{4-8}$ In the present study, the deviations could in part be explained by the tolerance between the guide tools, length of dental implant, and distance between guide sleeve and implant site. ${ }^{10}$ The high SD for rotational deviation, indicating data with a wide spread, was to be expected as the hexagon position was visually aligned during installation. Further improvement of guided surgery tools may help reduce such deviations.

A statistically significant difference was found between the DLP and SLA for deviation at the entry point $(P=.023)$ and in vertical implant position ( $P=.009$ ), with a lower mean deviation in the DLP group. However, for all deviations values, with the exception of horizontal deviation, the mean results favored the DLP group. An explanation for the statistically significant differences could be that the larger offset values needed for the master cylinder sleeve and between guide and teeth for the SLA printer used could have influenced the mounting of the sleeve and the seating of the surgery guide on the model. Also, the surgery guides from the SLA printer needed to undergo a longer postpolymerization process than the DLP guides because of a lower degree of photopolymerization during 3D printing. Handling during the postpolymerization process may have caused minor distortions leading to improper seating of the guide. Factors related to the manufacturing of surgical guides including incorporation of the master sleeve, 3D printer resolution, surface finish of the material, machine reproducibility, offset values, postprocessing, and calibration of a 3D printer can affect the definitive implant position. Further research is recommended before any conclusions can be drawn. With the increased accessibility of desktop 3D printers and the possibility for more in-office production of surgical guides, validation of the workflow is important. The use of a digital scan to confirm the postoperative dental implant position as described in the present and another study ${ }^{29}$ could easily be incorporated into guided surgery software and would greatly help in the quality control of the procedure. The authors are unaware of any CT-guided surgery software that has implemented this feature.

Clinical accuracy may be affected by different variables. This study did not account for saliva, soft tissue, patient movement, or humidity in the oral environment. Also, the material used for the surgical models does not have the same physical properties as bone, enamel, and soft tissue, meaning that seating of the guide and implant insertion may be different in a clinical setting. An additional limitation was that no reference objects were incorporated into the model design. Such objects would have helped in the alignment of the 2 data sets and the following measurements. ${ }^{19,20,27}$ The use of a high-accuracy industrial scanner would also further minimize errors from the scanning procedure. These types of objects and scanners are not present in a clinical setting where the procedure would be more consistent with the present one.

## CONCLUSIONS

Within the limitation of this in vitro study, the following conclusions were drawn:

1. The tested desktop 3D printers proved capable of producing surgical guides with similar deviations to definitive implant position.
2. The DLP printer proved more accurate concerning deviations at the entry point and vertical implant position.

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## Immediate loading of single implants, guided surgery and intraoral scanning: a nonrandomized study

Running title: Immediate loading and fully guided surgery: single implants

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## Abstract

## Purpose

To compare clinical and aesthetic outcomes between immediately loaded single implants placed with and without a fully guided-surgery procedure.

## Materials and Methods

Patients with a missing maxillary tooth (15-25) were considered for inclusion this 1-year prospective non-randomized study. Exclusion criteria were general health contraindications for oral surgery, besides need for bone grafting or ridge augmentation One group received digital implant planning, fully guided-surgery and immediate loading (DIL). The other freehand surgery and immediate loading (IL). Outcome measures were implant survival, marginal bone loss, soft tissue changes, papilla index, pink and white esthetic score (PES and WES) and patient reported outcome measures (PROMs).

## Results

Two implants of 21 failed in DIL-group soon after installation, contrary to none in the IL-group. Resulting in a 1-year implant survival rate of 90.5 \% for DIL. Statistically significant higher papilla index scores and less soft tissue change were found for DIL compared to IL. No difference was found after 1-year regarding marginal bone loss, PES, WES, and PROMs.

## Conclusion

Within the limitations of this study, immediate loading in combination with fully guided surgery might negatively affect the implant survival. Immediate loading, fully guided surgery and a digital workflow appear to have a positive effect on early soft tissue adaption.

## Introduction

Clinicians need to take many factors into consideration before proposing a restorative treatment for the loss of a single anterior tooth. Demands from the patient can be high concerning treatment procedure and the expected outcome. Many clinical factors affect the treatment outcome and several techniques for improving the success of dental implant treatment have been proposed. ${ }^{1-5}$ To evaluate dental implant treatment the traditional criteria for success proposed by Albrektsson et al. ${ }^{6,7}$ are still commonly used, in addition to several other criteria for assessing the aesthetic outcome of single implant restorations. ${ }^{8-12}$ High aesthetic outcome and stable marginal bone levels alone do not always guarantee a successful treatment outcome for which implant treatment is further evaluated with patient reported outcome measures (PROMs) and oral health related quality of life (OHRQoL). A systematic review has revealed a lack of references with respect to the patient satisfaction of single tooth implants in the aesthetic zone ${ }^{13}$.

Treatment time, pain, prognosis, function, economy and aesthetic outcomes are some concerns that can be raised by the patient when implant treatment is considered. Immediate installation and immediate loading may have an effect on these and several other. Several studies have shown that good results with immediate treatment protocols can be achieved. ${ }^{14-19}$ However, immediately loaded dental implants may result in high failure rates under unfavourable conditions. ${ }^{20,21}$ The clinical success of the technique is dependent on several factors such as: patient selection, bone quality and quantity, primary stability and surgical skills. ${ }^{22}$ Of these factors, primary stability of the dental implant and optimal condition for a biological stabilisation during the initial healing period are considered to be most important. ${ }^{22-24}$

Important factors to ensure treatment success includes proper planning of the implant position. Guided surgery helps the clinician to pre-plan and install dental implants in such an optimal position. ${ }^{25}$ The computer software does not only help the clinician to plan the designated site for the dental implant, but in addition visualizes the planned prosthetic reconstruction for the patient and serves as a way of communication between the dentist and the technician to further optimize the treatment plan. Fully guided-surgery protocol gives the clinician the possibility to prepare a custom healing abutment and/or interim restoration based on the planned position from the guided surgery software, ${ }^{26,27}$ which may eliminate the need for post-operative intervention and simultaneously reducing the patient chair time. Studies on immediate loading and guided surgery report possible positive effects on papilla formation,
less post-operative pain and swelling compared to absence of guided surgery. ${ }^{28,29}$ The accuracy of the guided surgical procedure is essential for the clinical outcome. Tooth supported fully-guided implant surgery is reported to achieve greater accuracy concerning final implant position compared to implants placed without the splint after osteotomy, mucosa-supported and bone-supported guides ${ }^{30}$, however the accuracy is dependent on various factors, as the operator experience, accuracy in surgical guide fabrication, fit of the surgical guide, limitation in surface acquisition and radiographic imaging data. ${ }^{31}$ The development of intraoral scanner (IOS) technology and three-dimensional (3D) printing technology has made guided surgery more accessible to the dental practice. The technique is considered as a valid alternative to conventional impressions, ${ }^{32}$ and for guided surgery in combination with 3D printing technology proven capable of manufacturing surgical guides of high accuracy. ${ }^{33,34}$ However, there is a further need for clinical data to support clinical decisions with regard to digital planning and fully guided-surgery.

The aim of this prospective non-randomized study was to compare clinical and aesthetic outcomes between immediately loaded single implants placed with and without a fully guided-surgery procedure, during a 1-year follow-up period.

## Materials and Methods

This prospective non-randomized clinical trial was conducted in accordance with the Helsinki declaration of 1975 as revised in $2000 .{ }^{35}$ The study protocol was approved by the Regional Ethical Review Board in Lund, Sweden (Dnr 2015/671). ClinicalTrials.gov ID: NCT04061694. Patients referred to the Centre of Dental Specialist Care, Malmö between November 2011 and February 2018 were consecutively considered for inclusion in the present study.

Inclusion criteria were as follows:

1. At least 18 years old.
2. In need of a single-tooth replacement of an incisor, canine or pre-molar in the maxilla.
3. Signed informed consent.

Exclusion criteria were as follows:

1. General health contraindications for oral surgery.
2. Inadequate oral hygiene, defined as a full-mouth plaque score of above $25 \%$.
3. In need of bone grafting or ridge augmentation

## Immediate loading group (IL)

The control group (IL) was a cohort of 25 immediately loaded (IL) dental implants, treated and rehabilitated by the exact same group of clinicians. ${ }^{14}$ Treatment included conventional surgery, dental implants (Tapered Internal, BioHorizons, Birmingham, AL), immediate loading with temporary restorations that were fabricated manually immediately after surgery and final restorations in situ 2 months after surgery, see Gjelvold et al. ${ }^{13}$ for detailed description of surgical and prosthetic procedures.

## Digital planned, fully guided-surgery and immediate loading group (DIL)

Following the clinical examination, an intraoral scanning of the maxilla and antagonist arch was performed with an IOS (Trios 3, 3Shape A/S, Copenhagen, Denmark). Cone beam computed tomography (CBCT) (ProMax 3D, Planmeca Oy, Helsinki, Finland) of the implant site was acquired. Digital imaging and communications in medicine (DICOM) files obtained from CBCT examination and the intraoral scanning were imported into a guided surgery software (Implant Studio, 3Shape, Copenhagen, Denmark). The dental implants (Tapered Internal, BioHorizons, Birmingham, AL) were positioned optimal in relation to a predesign of the prosthetic restoration and thereafter the appropriate implant diameter and length were selected for each individual case.

Surgical guides were designed and fabricated for each case. The surgical guides (E-Shell 600 Clear, Deltamed GmbH, Friedberg, Germany) were made with additive technology, using a digital light processing (DLP) 3D printer (Vida, EnvisonTEC GmbH, Gladbeck, Germany). A master cylinder sleeve (BioHorizons, Birmingham, AL) was incorporated into each surgical guide. The surgical guides were then submitted to cold sterilization according to the material suppliers' guidelines.

The temporary restorations were finalised (Dental Designer, 3Shape, Copenhagen, Denmark) according to the intended prosthetic design and 3D printed (E-Dent 400, EnvisonTEC GmbH, Gladbeck, Germany). The 3D printed restorations were cemented on a titanium base abutment (BioHorizons, Birmingham, AL)

## Surgery protocol DIL

All implants were placed into healed bone (at least 4 months after tooth loss) in sites that were free from clinical signs of inflammation/infection. Prior to surgery a single-preoperative dosage of 2 g amoxicillin was administered. Surgery was performed under local anesthesia (Xylocaine with 2\%
adrenaline, Dentsply, Mölndal, Sweden). The dental implants were installed using a guided surgery kit (BioHorizons, Birmingham, AL) by one operator, following the drilling protocol supplied by the manufacturer. Mucosal tissue at the implant site was removed with a soft tissue punch from the guided surgery kit, no mucoperiosteal flaps were raised. The installation torque was registered for each implant and resonance frequency analysis (RFA), measured as the implant stability quotient (ISQ). The implant driver and a torque wrench were used for final adjustments of the dental implant hexagon position. To ensure the seating of the temporary restoration additional soft tissue was removed besides that already removed with the soft tissue punch. The temporary restorations were immediately mounted onto the dental implants. The restorations were adjusted to a light centric contact and free from eccentric contacts, necessary adjustments to approximal contacts points were performed. The restorations were then tightened to 15 Ncm . Postoperatively, the patients were instructed to rinse twice daily with a solution of $0.2 \%$ chlorhexidine for 14 days and to take analgesics in case of need (paracetamol 500 mg 6/6h, Alvedon, GlaxoSmithKline AB, Solna, Sweden). All patients returned after 14 days for a postoperative check-up.

## Definitive prosthesis procedure DIL

Two months after surgery, an intraoral scanning (Trios 3, 3Shape A/S, Copenhagen, Denmark) was performed using a scan body (Snap scan body, BioHorizons, Birmingham, AL). The final screwretained single implant crown consisted of a titanium base abutment (BioHorizons, Birmingham, AL) and a zirconia crown (BruxZir, Glidewell Labratories, Newport Beach, CA), see Figure 1. The zirconia crowns were designed with a buccal cutback for veneering (GC Initial, GC EUROPE N.V., Leuven, Belgium). All laboratory procedures were performed by the same team of dental technicians and all prosthetic procedures by the first author (B.G.).

## Assessments

DIL and IL baseline and follow-up examinations were conducted by the same examiner responsible for the prosthetic treatment, however subsequent assessments of radiographs and aesthetics were performed by an examiner not involved in patient treatment and blinded to patient group allocation.

## Radiographic and soft tissue

Marginal bone loss (MBL) for each dental implant was measured by comparing marginal bone level at baseline and 1 year after installation of the permanent prosthetic crown. Digital intra-oral periapical
radiographs (Schick Digital X-ray Sensor, Sirona, Salzburg, Austria) were taken using the long-cone parallel technique. The marginal bone level measurements were calibrated using the inter-thread distance of the dental implants $(1.00 \mathrm{~mm})$ and using the implant-abutment junction as measurement reference point. All radiographs were individually calibrated. For each dental implant both the mesial and distal sides were considered and the mean value calculated. The Image J software (National Institute of Health, Bethesda, MD) was used for all measurements. Implant success and survival were evaluated according to Albrektsson et al. after 12 months. ${ }^{6,7}$ Success, a defined criteria for marginal bone loss over time, stated as a maximum 1 mm of bone loss during the first year and $<0.2 \mathrm{~mm}$ annually thereafter. In addition absence of implant mobility, peri-implant radiolucency, pain and infection. The gingival index (GI) by Löe and Silness ${ }^{36}$ was registered for the distal tooth on the initial appointment and at the dental implant site on each subsequent follow-up examination. The papilla index by Jemt ${ }^{37}$ was scored for each site as follows: after temporary crown delivery, definitive crown placement and on the 12 months follow-up examination. Change in gingival zenith position and papilla levels were measured from intraoral scanning's acquired following delivery of the temporary restoration, completion of the final restoration, and at the 3 and 12 months follow-up visits for DIL. The datasets were imported into a 3D data measurement analysis software (GOM Inspect 2017, build 2017-09-14, GOM Metrology, Braunschweig, Germany) for a best fit alignment and subsequent measurements, see Figure 2. The photographic measuring technique used for the IL group has been described by Gjelvold et al. ${ }^{14}$

## Aesthetics

Photographs (Nikon D7000, Nikon Corporation, Tokyo, Japan) taken after definitive crown placement and at the 3 and 12 months follow-up appointments were used to register the pink esthetic score (PES) $)^{10}$ and the white esthetic score (WES). ${ }^{8}$ Perfect outcome and aesthetic failure were considered according to Cosyn et al. ${ }^{38}$ as follows: (almost) perfect outcome for PES and WES as PES $\geq 12$ and WES $\geq 9$, respectively, and aesthetic failure as PES $\leq 7$ and WES $\leq 5$, respectively.

## Patient-centred considerations

The validated Swedish version of the Oral Health Impact Profile (OHIP-14) ${ }^{39}$ questionnaire was filled out by the patients at the following appointments: pre-surgery visit; after two months with the temporary crown; on the 12 months follow-up. The additive score was obtained by summation of the response codes for the 14 items, with a possible score range of 14-70. A high score indication a poor
oral health related quality of life (OHRQoL). Visual analog scales (VAS) were used to assess patient perceived aesthetic satisfaction, pain and discomfort. The aesthetic outcome was scored by the patients at the same appointments as OHIP-14. Pain and discomfort were scored after the surgery and impression appointments. The patients marked their decision on a non-numerical 100 mm line ranging from "not at all satisfied, severe pain and severe discomfort = 0" (left) to "very satisfied, no pain and no discomfort = 100" (right). Each response were given a numerical value by measuring in millimeters the distance from the left end of the line. For OHIP-14 and VAS the patient were given the same oral and written information before left alone to complete the questioners in private.

## Implant deviation from the planned implant position

For the DIL group datasets from guides surgery software and intraoral scans after fixture installation were used to identify key geometric surfaces of the dental implant. ${ }^{34}$ The following parameters were calculated: deviation at entry point, measured at the center of the implant (in mm); deviation at apex, measured at the center of the implant apex (in mm); angular deviation (in degrees); deviation in vertical implant position (in mm, + deviation in coronal direction); and deviation in horizontal implant position (in mm). The parameters are illustrated in Figure 3. A 3D data measurement analysis software (GOM Inspect 2017, build 2017-09-14, GOM Metrology, Braunschweig, Germany) was used for all calculations of Euclidian distance (dxyz).

## Statistics

All data were statistically analyzed by one examiner, who did not take part in any of the clinical procedures. The software used was the Statistical Package for the Social Sciences (SPSS) version 25 (SPSS Inc., Chicago, IL). The data were tabulated, and from these measurements mean, standard deviation (SD), minimum and maximum were calculated. Kolmogorov-Smirnov test was performed to evaluate the normal distribution of the variables, and Levene's test evaluated homoscedasticity. The performed tests for two independent groups and two dependent groups were Student's $t$-test or MannWhitney test and Wilcoxon signed-rank test, depending on the normality. Pearson's chi-squared or Fisher's exact test was performed for categorical variables, depending on the expected count of events in a $2 \times 2$ contingency table. For DIL, correlation and linear regression were performed to check the relationship between PES, survival and implants position deviations. The degree of statistical significance was considered $p<0.05$.

## Results

A total number of 25 patients were included in the IL group. The number of included and excluded patients for this has previously been reported. ${ }^{14}$ A total of 25 patients were initially allocated to group DIL, of which four patients were not included in the study for the following reasons: one patient did not want treatment for economic reasons, two patients presented extensive osseous defects prior to the planned treatment and one patient decided to leave the study before surgery. The remaining 21 patients were included in the DIL group and for both IL and DIL there were no drop-outs during the treatment for the 3 and 12 months follow-up examinations. Two implants were lost 2-4 weeks after surgery, resulting in an implant survival of $90.5 \%$ for DIL, as opposed to $100 \%$ for IL after 1 year ( $p=$ 0.203 , Fisher's exact test). The lost implants were installed in regions 21 and 24 . Both patients with failed implants displayed signs of parafunction at the initial examination and one was a smoker. Implant success after 1 -year for the DIL and IL was $85.7 \%$ and $96.0 \%$, respectively ( $p=0.318$, Fisher's exact test). For the DIL group, besides the lost implants, one further implant displayed marginal bone loss of more than 1 mm after the first year. For the IL-group the implant success was $96.0 \%$. No complications to the implants or implant supported screw-retained crowns occurred during the follow-up period. Clinical trial outline is shown in Figure 4. Patient data, treatment specifications and ISQ values at the time of the implant surgery are reported in Table 1. For implant survival no statistically significant correlation were found for bone quantity, implant length, implant diameter, implant site and ISQ value.

## Radiographic and soft tissue

Outcomes for MBL, gingiva index and papilla index for DIL and IL are shown in Table 2. The mean $\pm$ SD marginal bone level for DIL and IL at fixture installation was $0.28 \pm 0.29 \mathrm{~mm}$ and $0.40 \pm 0.45 \mathrm{~mm}$, respectively ( $p=0.550$, Mann-Whitney test). A statistically significant higher papilla index score was found for mesial and distal site at temporary crown placement ( $p=0.002$ and $p<0.001$ ) and for the distal site at definitive crown placement $(p=0.002)$ for DIL. A complete papilla fill according to papilla index on both mesial and distal sides for DIL and IL after 12 months was 36.8 \% and 28.0 \%, respectively ( $p=0.382$, Fisher's exact test).

Soft tissue changes for gingival zenith and papilla levels for DIL and IL are shown in Table 3. Statistically significant less soft tissue change was found for mesial and distal papilla from final
restoration to 12 months ( $p=0.047$ and $p=0.008$ ), mesial papilla from temporary to final restoration ( $p=0.042$ ) and distal papilla from final restoration to 3 months follow-up ( $p=0.033$ ).

## Aesthetic Evaluation

PES and WES results for DIL and IL groups are described in Table 4. No statistically significant difference was found between the two groups concerning aesthetics.

For the PES there was a statistically significant improvement between initial evaluation and 12-month follow-up both for the DIL and the IL ( $p<0.001$ and $p<0.001$, Wilcoxon signed-rank test).

Overall aesthetic outcome after 12 months was assessed by combining PES and WES. Three implants ( $15.8 \%$ ) for DIL and 5 implants ( $20.0 \%$ ) for IL showed an almost perfect outcome (PES $\geq 12$ and WES $\geq 9$ ). Acceptable results were found for $68.4 \%(n=13)$ and $64.0 \%(n=16)$ of the DIL and IL cases, respectively. Aesthetic failure (PES $\leq 7$ or WES $\leq 5$ ) was found for $15.8 \%(n=3)$ and $16.0 \%$ ( $n$ $=4)$ of the DIL and IL cases, respectively.

## Patient-centered outcomes

OHiP-14 and VAS outcomes for DIL and IL are summarized in Table 4. Statistically significant differences between the two groups were found for the OHIP-14 score pre-surgery and after two months with a temporary crown $(p=0.009)$. For the OHIP-14 there was a statistically significant improvement between pre-surgery evaluation and 12 months follow-up both for DIL and IL ( $p=0.027$ and $p<0.001$, Wilcoxon signed-rank test). For the VAS aesthetic score there was a statistically significant improvement between initial evaluation and 12 months follow-up for DIL ( $p<0.001$, Wilcoxon signed-rank test).

## Deviation from the planned implant position

The mean $\pm$ SD (min, max) deviation at entry point, implant apex, angular deviation, vertical position and horizontal position for DIL were $0.72 \pm 0.36 \mathrm{~mm}(0.18,1.55), 1.09 \pm 0.56 \mathrm{~mm}(0.19,2.27), 2.60 \pm$ $1.53^{\circ}(0.31 .5 .84), 0.48 \pm 0.31 \mathrm{~mm}(0.13,1.17)$ and $0.49 \pm 0.30 \mathrm{~mm}(0.10,1.47)$, respectively. The relationship between final PES (12 months) and deviation entry point was moderate ( $R=.554, R 2$ $=.307, P=.014$; Pearson correlation). The relationship between final PES (12 months) and deviation vertical position was moderate $(\mathrm{R}=.515, \mathrm{R} 2=.265, P=.024$; Pearson correlation $)$. The relationship between survival and vertical position was moderate ( $\mathrm{R}=.567, \mathrm{R} 2=.321, P=.007$; Pearson correlation). Linear regression analysis showed increased implant deviation negatively affected both PES and survival.

## Discussion

In the DIL-group two implants were lost shortly after fixture installation, resulting in a survival of $90.5 \%$, contrary to none in the IL-group. Compared to a mean survival rate of $98.2 \%$, reported in a recent systematic review ${ }^{20}$, this raises some concerns. Immediate loading does result in a statistically significant higher risk of implant failure, especially in single implant cases. ${ }^{20,21}$ A limitation in the present non-randomized study is the possibility of selection bias, particularly related to the inferior survival for the DIL group. Selection bias could imply potential systematic differences between characteristics of participants in the two groups, however patient characteristics were similar between the groups. To limit this possibility inclusion were first completed for the IL group before the DIL group were subsequently included in the study. No patient were especially selected for inclusion in one group contrary to the other. The two patients who lost implants presented particularly signs of parafunction on adjacent teeth, and one of these patients was a smoker. This is considered a possible risk factor and could be a contribution to implant loss in the present study. ${ }^{22}$ However, excluding these patients would limit the identification of possible risk factors. The IL group in this case was immediately loaded and the same inclusion and exclusion criteria applied. There were no statistically significant difference in ISQ values between the two groups, nor did implant survival correlate to bone quantity, implant length, implant diameter and site. Something else may certainly have contributed to implant loss in the DIL group. Another possible contributing factor, not evaluated in the present study, is the possible effect of inadequate irrigation during flapless fully guided-surgery, as drilling osteotomies may induce thermal trauma and prejudice the treatment outcome from the early stages of healing. ${ }^{40}$ Further, for DIL implants there was a moderate correlation between survival and vertical deviation in implant position, suggesting that deviation in implant position can have effect on implant survival when subjected to immediate loading. The results for deviation in implants position reported for DIL implants were in agreement with previous reported results. ${ }^{30,34}$

Marginal bone loss was similar for the two groups after 12 months and corresponds to previous studies evaluating immediate loading and the same implant system. ${ }^{15}$ A digital workflow with guided surgery does not seems to have any negative effect on the marginal bone within this short evaluation period.

The statistically significant higher papilla index scores and papilla fill found for the DIL-group could be explained by the less invasive flapless surgery procedure. Similar findings for guided surgery have
been reported by others. ${ }^{29}$ The papilla index scores correlates very well with the statistically significant lesser change in soft tissue papilla levels for the DIL group and could further be connected to the reported less postoperative swelling following guided surgery. ${ }^{28}$ The present results suggest a positive effect using a custom interim restoration from the day of fixture installation. Combining this with posthealing soft tissue conditioning as suggested by others could further help to improve the aesthetics outcome. ${ }^{3}$ With the present results it is not possible to conclude if pre-designed temporary restorations have any superior effects on papilla formation compared with temporary restoration fabricated directly after installation. The punch procedure for flapless surgery in the DIL group amount for some loss of keratinized soft tissue and could possibly compromise the aesthetic outcome. However, change in gingival zenith and PES did not significantly differ between the two groups.

As for the aesthetic outcome, no statistical significant difference was found between the groups, except for an improved PES over time as previously reported. ${ }^{14}$ One could in addition to the present procedure, consider additional interventions to further improve the aesthetic outcome, as for instance bone augmentation to improve the shape of the alveolar process. ${ }^{4}$ Further, the aesthetic results compares to the finding of others concerning aesthetic failures and perfect outcome. ${ }^{38}$ There was a moderate correlation between the degree of deviation and PES, suggesting that increased deviation effects the PES negatively, supporting the finding of others. ${ }^{41}$

Concerning OHIP-14 a statistically significant difference was found prior to surgery. No explanation could be found for this finding. It could be assumed that the baseline significant difference had an effect on the statistically significant difference found after two months with the temporally restoration. The OHIP-14 score improved over time for both evaluated groups. The patients scored high when asked to judge the aesthetic of the final reconstruction, in agreement with previous findings ${ }^{14,38}$. Reported pain and discomfort were generally low for both the surgical and impression appointment, but equivalent data lacked for the IL-group. As previously reported, patient-judged aesthetic outcome after 12 months for the conventional delayed loading procedure is equally as high. ${ }^{14}$ One should be careful with the risk for bias concerning subjective evaluations.

Despite the short follow-up period, it is very important to evaluate patients submitted to these protocols in the early post-treatment period, when the soft tissues are more prone to most of the expected anatomical changes. Moreover, it is also important from the implant perspective, as a great deal of implants fail within one year after installation, regardless of whether a very long follow-up is planned or
not. ${ }^{42}$ Further, the very limited positive effects gained for early soft tissue adaption and reported additional positive effects like less chair time and reduced post-operative swelling ${ }^{28,29}$, should be put in perspective to the increased risk of early failure in the present study. Concerning the measurements of the gingival zenith position and papilla levels, two different measuring techniques were used.

Calibrated measurements on photographic images were used in the IL-group, instead of the use of 3D models as in DIL, the results should therefore be interpreted with cation.

## Conclusion

Within the limitations of this study, immediate loading in combination with fully guided surgery might negatively affect the implant survival. Further evaluation of the procedure is therefore warranted. Immediate loading, fully guided surgery and a digital workflow appears to have a positive effect on early soft tissue adaption.

## Conflict of Interest

The authors have no conflict of interest relevant to the content of the submission.

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## Figure Legends

Figure 1 Final restoration in situ.
Figure 2 GOM Inspect intraoral scan soft tissue measurement.

Figure 3 Deviation measurements: a) deviation at entry point, b) deviation at apex, c) angular deviation, d) deviation in vertical implant position and e) deviation in horizontal implant position.

Figure 4 Clinical trial outline.

Figures
Figure 1


Figure 2


Figure 3


Figure 4


## Tables

Table 1. Characteristics and treatment specification of study group and control.

| Variable | DIL | IL | P value |
| :---: | :---: | :---: | :---: |
| Implant surgery day |  |  |  |
| Mean age $\pm$ SD (years) | $40.2 \pm 21.0$ | $40.8 \pm 13.3$ | 0.544† |
| Men/women | 11/10 | 14/11 | $0.806 \dagger \dagger$ |
| Smokers/Non-smokers | 1/20 | 2/23 | 0.567 $\ddagger$ |
| Bruxers/Non-bruxers | 3/18 | 2/23 | $0.415 \ddagger$ |
| Diabetic/Non-diabetic | 2/19 | 0/25 | 0.203 $\ddagger$ |
| Reason for missing tooth |  |  |  |
| Trauma | 4 | 15 |  |
| Agenesia | 6 | 3 |  |
| Advanced caries | 6 | 5 |  |
| Root resorption | 0 | 2 |  |
| Apical destruction | 4 | 0 |  |
| Advanced periodontitis | 1 | 0 |  |
| Implant diameter: 3.8/4.6 mm | 19/2 | 18/7 |  |
| Implant length: 9/10.5/12/15 mm | 1/5/15/0 | 0/0/16/9 |  |
| Bone quantity: A/B/C/D/E | 4/17/0/0/0 | 5/20/0/0/0 |  |
| ISQ values | $72.19 \pm 8.36$ | $73.64 \pm 7.88$ | 0.303† |
| SD - standard deviation |  |  |  |
| $\dagger$ Mann-Whitney test |  |  |  |
| $\dagger \dagger$ Pearson Chi-squared test |  |  |  |
| $\ddagger$ Fisher's exact test |  |  |  |

Table 2. MBL, gingiva index and papilla index outcomes.

| Variable | DIL | IL | P value |
| :--- | :---: | :---: | :---: |
| MBL (mm) | mean $\pm$ SD | mean $\pm$ SD |  |
| MBL after 12 months | $-0.40 \pm 0.41$ | $-0.57 \pm 0.52$ | $0.230 \dagger \dagger$ |
| Gingival index |  |  |  |
| Initial appointment | $1.10 \pm 0.30$ | $1.24 \pm 0.52$ | $0.313 \dagger$ |
| 3 months of definitive crown | $1.05 \pm 0.23$ | $1.08 \pm 0.28$ | $0.724 \dagger$ |
| 12 months of definitive crown | $1.63 \pm 0.90$ | $0.12 \pm 0.33$ | $0.720 \dagger$ |
| Papilla index, mesial | $2.21 \pm 0.53$ | $1.88 \pm 0.97$ | $0.283 \dagger$ |
| Temporary crown placement | $2.68 \pm 0.51$ | $2.56 \pm 0.51$ | $0.407 \dagger$ |
| Definitive crown placement |  |  | $0.002 \dagger$ |
| 12 months of definitive crown | $1.63 \pm 0.60$ | $0.72 \pm 0.54$ | $<0.001 \dagger$ |
| Papilla index, distal | $2.00 \pm 0.58$ | $1.24 \pm 0.88$ | $0.002 \dagger$ |
| Temporary crown placement | $2.42 \pm 0.51$ | $2.12 \pm 0.67$ | $0.136 \dagger$ |
| Definitive crown placement |  |  |  |
| 12 months of definitive crown |  |  |  |

SD - standard deviation, MBL - marginal bone loss (negative values represent bone loss),
$\dagger$ Mann-Whitney test
$\dagger \dagger$ Student's t-test

Table 3. Soft tissue changes.

| Variable | DIL | IL | P value † |
| :---: | :---: | :---: | :---: |
| Soft tissue changes: mesial papilla (mm) | mean $\pm$ SD | mean $\pm$ SD |  |
| Temporary to final restoration | $0.10 \pm 0.56$ | $0.33 \pm 0.47$ | 0.042 |
| Final restoration to 3 months | $0.18 \pm 0.43$ | $0.24 \pm 0.39$ | 0.227 |
| Final restoration to 12 months | $0.37 \pm 0.55$ | $0.74 \pm 0.70$ | 0.047 |
| Soft tissue changes: distal papilla (mm) |  |  |  |
| Temporary to final restoration | $-0.18 \pm 0.57$ | $-0.01 \pm 0.54$ | 0.148 |
| Final restoration to 3 months | $0.06 \pm 0.34$ | $0.30 \pm 0.44$ | 0.033 |
| Final restoration to 12 months | $0.24 \pm 0.39$ | $0.63 \pm 0.47$ | 0.008 |
| Soft tissue changes: gingival zenith (mm) |  |  |  |
| Temporary to final restoration | $-0.10 \pm 0.25$ | $-0.17 \pm 0.45$ | 0.906 |
| Final restoration to 3 months | -0.04 $\pm 0.26$ | $0.09 \pm 0.31$ | 0.197 |
| Final restoration to 12 months | $-0.02 \pm 0.36$ | $0.10 \pm 0.38$ | 0.538 |

SD - standard deviation, positive values represent a gain in soft tissue,
$\dagger$ Mann-Whitney test

Table 4. Aesthetic outcomes and patient-centered outcomes

| Variable | DIL | IL | $\mathbf{P}$ value † |
| :---: | :---: | :---: | :---: |
| PES | mean $\pm$ SD | mean $\pm$ SD |  |
| Definitive crown placement | $8.79 \pm 2.42$ | $8.56 \pm 2.27$ | 0.598 |
| 3 months follow-up | $9.68 \pm 2.06$ | $9.32 \pm 2.14$ | 0.453 |
| 12 months follow-up | $10.53 \pm 2.04$ | $10.36 \pm 2.46$ | 0.781 |
| WES |  |  |  |
| Definitive crown placement | $7.11 \pm 1.76$ | $7.00 \pm 1.41$ | 0.824 |
| 3 months follow-up | $7.26 \pm 1.56$ | $7.24 \pm 1.36$ | 0.788 |
| 12 months follow-up | $7.79 \pm 1.36$ | $7.76 \pm 1.30$ | 0.961 |
| OHIP-14 additive |  |  |  |
| Pre-surgery | $21.57 \pm 7.17$ | $26.68 \pm 9.30$ | 0.037 |
| Temporary crown | $15.42 \pm 2.47$ | $18.64 \pm 5.32$ | 0.009 |
| 12 months follow-up | $17.10 \pm 3.23$ | $16.48 \pm 3.87$ | 0.356 |
| VAS |  |  |  |
| Pain surgery | $25.9 \pm 29.8$ |  |  |
| Discomfort surgery | $21.4 \pm 24.8$ |  |  |
| Pain impression | $9.9 \pm 10.7$ |  |  |
| Discomfort impression | $6.3 \pm 17.5$ |  |  |
| Aesthetic pre-surgery | $34.6 \pm 25.8$ |  |  |
| Aesthetic temporary | $67.4 \pm 20.1$ |  |  |
| Aesthetic 12 months follow-up | $88.9 \pm 14.8$ | $89.6 \pm 9.5$ | 0.644 |
| SD - standard deviation |  |  |  |
| $\dagger$ Mann-Whitney test |  |  |  |

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[^0]:    *Fédération Dentaire Internationale (FDI) notation system, ISO 3950

[^1]:    SD - standard deviation

    * Mann-Whitney test, * * Student's t-test

[^2]:    SD - standard deviation

    * Kruskal-Wallis test

[^3]:    Bilateral agenesia
    $\begin{array}{lc}\text { WES } & 7.18 \pm 2.37(1,10) \\ \text { PES-final } & 12.71 \pm 1.56(7,14) \\ \text { VAS-1 } & 78.4 \pm 18.5(33.8,100) \\ \text { VAS-2 } & 84.7 \pm 13.1(50.3,100) \\ \text { Add-OHIP-14 } & 16.3 \pm 3.2(14,24)\end{array}$

