FABRICATION OF A DEFINITIVE CAD/CAM TITANIUM ABUTMENT PRIOR TO GUIDED SURGERY: A PILOT STUDY

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ABSTRACT

William Patrick Scruggs: Fabrication of a Definitive CAD/CAD Titanium Abutment Prior to Guided Surgery: A Pilot Study
(Under the direction of Lyndon Cooper)

Purpose: The purpose of this prospective comparative study is to determine the possibility of designing a CAD/CAM patient specific abutment that reproducibly predicts the clinical relationship of the abutment/crown interface with the peri-implant mucosal margin.

Materials and Methods: Seventeen patients were allocated to 2 groups of subgingival abutment margin depths: 1.5mm and 0.5mm**.** A surgical guide, custom abutment and provisional crown were fabricated prior to surgery. Implants were placed in 16 participants using a guided surgery protocol.

Results: Five of the sixteen abutments had abutment margin exposure at abutment delivery. Four of the five abutment margin exposures occurred at molar sites. Ten out of sixteen provisional crowns fit with zero adjustment.

Conclusions: The results of this pilot study suggest that the digital workflow of producing a definitive titanium abutment and milled provisional crown prior to guided surgery is initially successful. Abutment Margin Exposure is more likely in molar sites.

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LIST OF ABBREVIATIONS

3D	Three-Dimensional
4V	4% Vanadium
6Al	6% Aluminum
ASA	American Society of Anesthesiologists
CAD/CAM	Computer Aided Design/Computer Aided Manufacture
CBCT	Cone Beam Computed Tomography
CNC	Computerized Numeric Control
DICOM	Digital Imaging and Communications in Medicine
Del	Delivery
EV	Evolution (Astra Tech EV)
IAI	Implant/Abutment Interface
IP	Implant Placement
ITI	International Team for Implantology
IV	Intravenous
MM	Millimeters
MPI	Modified Plaque Index
μM	Micrometer
Nc	Newton Centimeters
PES	Pink Esthetic Score
SBI	Sulcus Bleeding Index
SLA	Stereolithography (Manufacturing Technique)

ST	Single Tooth
STL	Stereolithography (Digital File Format)
Sub-G	Sub-Gingival
TiN	Titanium Nitride
UCLA	University of California, Los Angeles
UNC	University of North Carolina at Chapel Hill
VAD	Virtual Abutment Design
WES	White Esthetic Score

CHAPTER 1: Fabrication of a Definitive CAD/CAM Titanium Abutment Prior to Guided Surgery: A Pilot Study

INTRODUCTION

Osseointegration, the direct apposition of vital bone against the surface of a load bearing endosseous implant, provided dentists with a means of anchoring teeth to the residual alveolar ridge in a predictable and healthy manner[1]. With the high success of dental implant rehabilitation in fully edentulous patients, the use of dental implants in partially edentulous jaws became a primary focus. In 1986, the use of endosseous dental implants for single missing teeth was introduced[2]. The early use of cylindrical endosseous implants for single tooth applications required development of abutments to support single crowns. These abutments needed to provide both anti-rotation and adaptation to the peri-implant mucosa in a tooth like manner. This was in distinct contrast to implants used for edentulism where abutments intentionally displaced prostheses from the mucosa and multiple implants were splinted, thereby geometrically preventing rotation about the abutment.

The initial restorative challenges for single tooth implants were met with simple abutments that provide anti-rotation and retention for a cemented crown. Two examples

were the Cera-one(Nobel Biocare)[3] and ST abutments (AstraTech)[4]. Both provided for key single tooth abutment features of anti-rotation, crown retention and adaptation to peri-implant mucosa by custom crown form (Figure 1). These manufactured or "stock" components were limited in the extent to which clinicians could adapt them to patient-specific requirements.

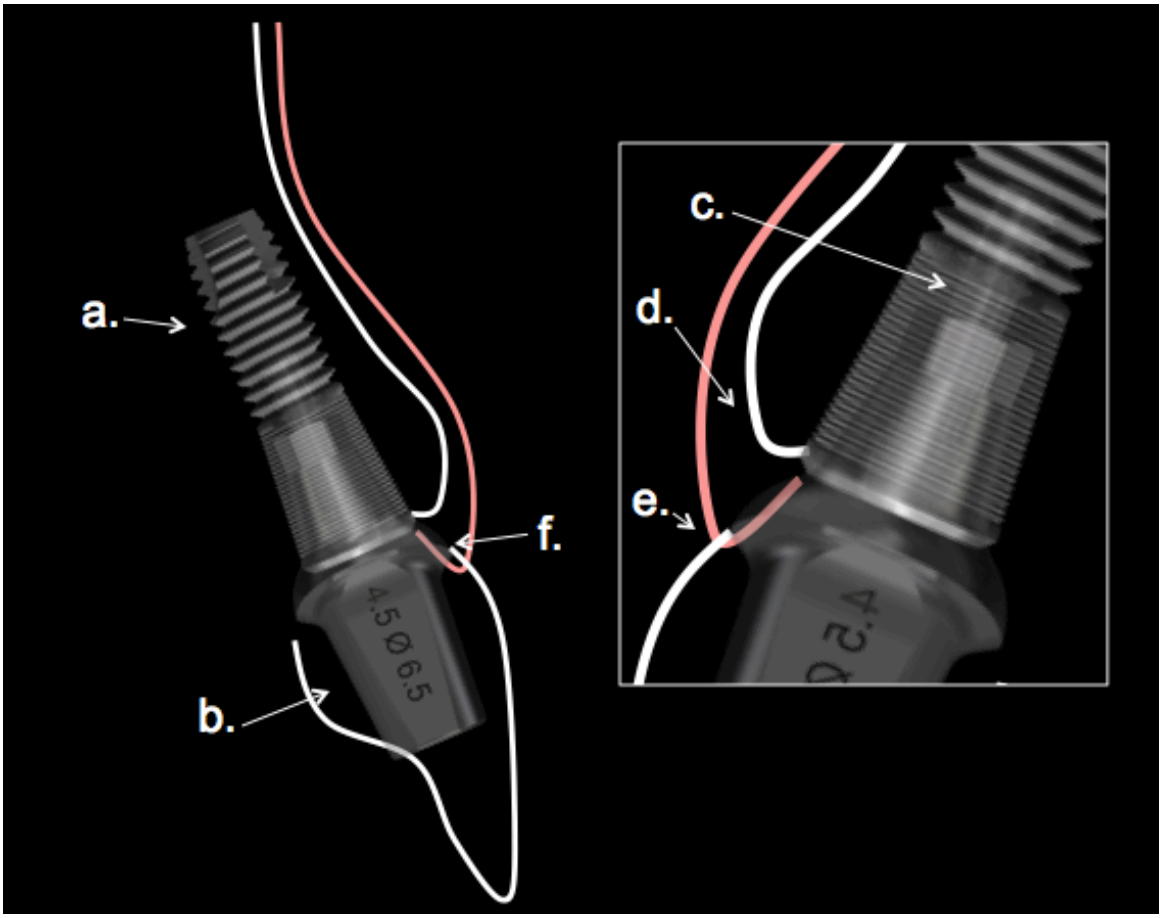

Figure 1. Parameters requiring consideration when designing patient specific implant components. (a) Implant, (b) Abutment, (c) Abutment Screw, (d) Alveolar Bone, (e) Gingival Margin, (f) Abutment/Crown Interface.

It quickly became evident that rehabilitating single teeth or the partially edentulous patient required careful examination of the emergence profile (transition contour) from the implant to create a crown with contours that supported excellent soft tissue esthetics and cleansability. The UCLA abutment, first introduced in 1988, allowed for customization

of an implant abutment permitting proper crown contour and soft tissue support[5]. The UCLA abutment consists of a plastic cylinder that connects directly to the implant and can be subsequently waxed for patient specific customization. The resulting abutment can then be cast in metals such as chrome cobalt or a variety of noble metal alloys. Abutments made of cast metal alloys to allow this customization of the emergency profile while keeping the crown margin slightly sub-gingival became standard in the treatment of highly esthetic single tooth restorations until the advent of Computer Aided Design/ Computer Aided Manufacturing (CAD/CAM) in the early 2000's[6,7]. Whether cast or manufactured through CAD/CAM techniques, the fabrication of custom abutments allows for patient specific design providing support to both the peri-implant soft tissues and the final restoration.

The family of early custom cast abutments to include the UCLA subtype has advantages mainly related to providing patient specific customization to support the restoration. Markedly, one could overcome inter-occlusal space issues and implant angulation problems. While castable abutments provided many advantages over stock abutments, they are not without problems. Depending on the type of metal used to cast the abutment, it can be an expensive and time-consuming endeavor. Also, because the abutment is fabricated through the lost wax process, castings can result in misfit at the implant-abutment interface. This misfit proved to result in screw loosening[8] and fracture or biological complications related to inflammation from leakage[9] at the level of the implant platform. Creation of patient-specific abutments by casting methods became a common means of addressing the esthetic needs of single implant care. The complex problem of coordinating implant location, soft tissue architecture and crown form were

solved at the implant abutment interface level on a patient by patient basis at the stage of abutment connection.

Another approach to coordinating the needs of single implant therapy involved the use of prefabricated abutments that offered alternatives in shape, dimension and materials. While there exists no data to define the scope of this therapeutic approach, the clinical enterprise of the mid 1990's to the present is filled with a remarkably large range of prefabricated abutment solutions.

Together, the prefabricated, modified and custom solutions to abutment design for single implant crowns provided solutions to restoring implants with either cement or screw-retained crowns. Over time, the limitations and complications associated with dental implant abutments were illuminated in emerging clinical reports.

Currently, data regarding single tooth implant and abutment outcomes highlights abutment limitations and complications as the predominant clinical problem facing clinicians and patients. The high dental implant survival and success reported by systematic reviews is supported by repeated analyses[10].

Systematic reviews comparing implant survival rates shows similar ten-year results between the two alternatives (89.9% survival for single tooth implants and 89.1% survival for tooth supported fixed partial dentures)[11,12]. In a recent systematic review, survival rates of implants supporting single crowns were 97% for implants and 96.3% for single crowns. The generally acknowledged high success of single tooth dental implants has promoted the use of implants as a primary clinical activity involving dental implants in the United States[13]. Single implant therapy is a widely used method of tooth replacement[13]. However, beyond dental implant survival, the complications with implant abutments and

crowns may challenge the initial interpretations of dental implant therapy as widely successful.

Single tooth dental implant therapy is not without biological and technical complications. Biological complications rates range from 7.1%-9.7% after 5 years and include signs of inflammation, mucositis, peri-implantitis, bleeding and soft tissue dehiscence. Technical complications are also frequently reported to include screw loosening (8.8%), abutment screw fracture, fracture of the veneering material (3.5%), loss of retention (4.1%) and implant fracture (.18%)[14].

Since first described by Jemt in 1986 and others by the late 1980's, the survival rates of single tooth implant restorations with dental implants has increased. Meanwhile, biological and technical complications associated with these restorations have decreased with improved techniques, materials and implant surfaces[14]. A systematic review in 2014 revealed that complications with implant restorations include abutment screw fracture, loose abutments or abutment screws, loss of retention, ceramic chipping, framework fracture and loss of access hole restoration. The most frequent of these complications are loose abutments or screws, loss of retention and ceramic chipping with cumulative complication rates per one hundred crown years of 8.8%, 4.1%, and 3.5% respectively[14]. As reported in the previously mentioned study, the most common complication reported in the literature is abutment screw loosening. This complication however has been reduced with improvements in the design of the implant-abutment interface as a high number of reported screw loosing was attributed to many of these abutments being connected to external hex designed implants[15, 16].

Seemingly, current emphasis in evaluating these restorations is esthetic complications, as these can be the most challenging issues clinically to reconcile[15,17,18]. It is estimated that an esthetic complication rate of 7.1% exists with single tooth implant restorations at 5 years. Most frequent esthetic complications reported were soft tissue recession, unfavorable color, and visible crown margins[14]. Esthetic complications also include mucosal discoloration, papilla deficiency and deficiency of the alveolar process.

In evaluating esthetic complications in implant dentistry, Pink Esthetic Score (PES)/ White Esthetic Score (WES) scores are often used to evaluate dentist and patient esthetic satisfaction[19]. In a study evaluating single implant treatment in healing vs. healed sites in the anterior maxilla; it was reported that regardless of the stage of implant therapy, an overall unfavorable esthetic outcome occurred in 26% of subjects with an additional 4% resulting in complete esthetic failures[20].

While there is certainly evidence of esthetic complications with single tooth implant restorations, improvements in abutment design have solved many biomechanical, technical and esthetic issues involved with these restorations. Computer aided design and manufacturing (CAD/CAM) has improved in these measures as well. The ability to recreate proper emergence for support of the soft tissues, place the crown margin at an appropriate level in relation to the peri-implant soft tissues and controlled cutback to support the restorative materials has reduced technical and esthetic complications compared to decades past.

Computer aided design and computer aided manufacturing (CAD/CAM) has several advantages in developing replacements of single missing teeth. Having total control of critical factors related to the restoration that can be incorporated by merging a myriad of

information on a computer screen increases the potential for success. Specific advantages of CAD/CAM are listed in the table (1.1).

Table 1. Advantages of CAD/CAM Abutments
Patient Specific
Numeric Control of Critical Dimensions
CNC Control of Manufacture Dimension Integrity
Diverse Material Selection
Integrations with Implant Planning Software
Cost (Relative to Cast Custom)
Esthetic Management

The past decade's experience with single tooth implant therapy reveals the central importance of treatment planning for esthetic success [20, 35, 37]. The management of implant complications by abutment design solutions is often a time intensive and self-limiting activity. Preventing these complications by comprehensive planning and careful execution to assure implant placement that supports an ideal restoration can eliminate the majority of single tooth implant complications, particularly those of esthetic nature[35]. Implied is an approach to therapy that begins with crown design, followed by related implant placement decisions and together these two parameters constrain and define esthetic abutment solutions. It is well established that sufficient bone volume and proper three-dimensional position of the implant are required to achieve esthetically pleasing results[31].

Treatment planning for single tooth implants involves consideration of several critical factors in achieving success. These factors include a three-dimensional view of the patient's volume of bone in the form of CBCT, a model of the final restoration in the form of a wax-up, and a representation of the soft tissues in the site. Emerging digital imaging methods that have enabled merging of DICOM images of host bone for implant location and

STL images of planned crown form within a single three-dimensional environment allow the clinician to identify or create an 'ideal' abutment solution for a given implant crown scenario. This is often described as a 'prosthetically driven' or 'crown-down' approach to implant treatment planning and therapy.

With continued improvements in virtual implant planning software, prosthetically driven treatment planning is easier utilized and communicated during implant surgery. Many different planning and surgical guidance methods have been advocated over the past decades. However, innovation with CBCT, DICOM file management, and STL manufacture of surgical guides has established a new standard for guided implant surgery. The use of volumetric imaging to create useful surgical guides was first introduced for the edentulous mandible and maxilla[21]. The manufacture of surgical guides by SLA provides relative accuracy and fidelity in implant placement[22]. Surgical implant positioning is improved by using guided surgery protocols[21]. These protocols use cone beam computed tomography (CBCT) and implant planning software to allow the clinician to plan a virtual surgery based on the prosthetic and anatomical parameters of the patient. Steriolithographic templates are then fabricated to assist the surgeon in transferring the planned virtual surgery to the patient through a flapless surgery protocol[22].

For the patient, these protocols result in significantly less intra-operative pain and discomfort as well as post-operative morbidity[33]. For the operator, surgical chair time is significantly reduced, as well as implant positioning and intraoperative decision making errors[32]. Prosthetically driven esthetic results may be predictably achieved using guided surgery because of related improvement in implant positioning and depth, as well as soft

tissue compromise and maintenance with a flapless technique in patients with enough attached mucosa[34].

Table 2. Advantages and Disadvantages of Guided Surgery

	Advantages	Disadvantages
Patient Related	Less Intra-operative Pain	Cost
	Less Post-operative Morbidity	Radiation Risk
	Decreased Chair Time	Absence of Keratinized Tissue
Surgeon Related	Three-dimensional Implant Location	Planning time/Guide Fabrication Time
	Enables Flapless Procedure	Cooling
	Increased Safety	Visibility
	Decreased Chair time/Efficiency	Inability to Alter Procedure

Implant position has emerged as an important variable influencing esthetic outcomes. In a systematic review regarding the influence of restorative procedures on esthetic outcomes of single tooth implants; no significance was found for co-variables such as the timing of provisionalization with regard to implant placement, restorative platform size and form, abutment material, final prosthetic material or mode of retention of the final prosthesis. It was consistently reported, however, that implant position had a significant effect on esthetic outcome and facial mal-positioning of implant increases the likelihood of facial mucosal recession. The authors identified several procedural options capable of influencing both the esthetic quality of the treatment and the predictability of the esthetic outcome from the perspective of the restorative dentist or prosthodontist. Most pertinent of these procedural options was communication of optimal implant position through the use of templates[18].

Implant position based on the final prosthesis is required to attain long-term esthetic success. This is most easily accomplished through the use of diagnostic waxing or

virtual representation of the final restoration in conjunction with the patient's CBCT data while simultaneously evaluating the patient's bone volume in assuring endosseous placement of the implant. Pertinent to success is the transfer and communication of the virtual implant position to the patient to the clinical environment, a process most easily done using guided surgery protocols[32,34].

Recent advances in three-dimensional planning for dental implants includes the merging of CBCT DICOM data with three-dimensional surface scans of the patient (or model) in the STL format (Figure 2). These composite images display the patient's underlying bone, soft tissues and clinical crowns in high fidelity in a single image. Given the current ability of the dental laboratory technician to produce dental prostheses from these STL formatted models, connecting of the virtual implant with the virtual crown seemed within grasp of technology and clinically valuable. It is possible to create within a single three-dimensional virtual environment a virtual model of the planned implant, the planned crown and the planned abutment connecting the implant and crown.

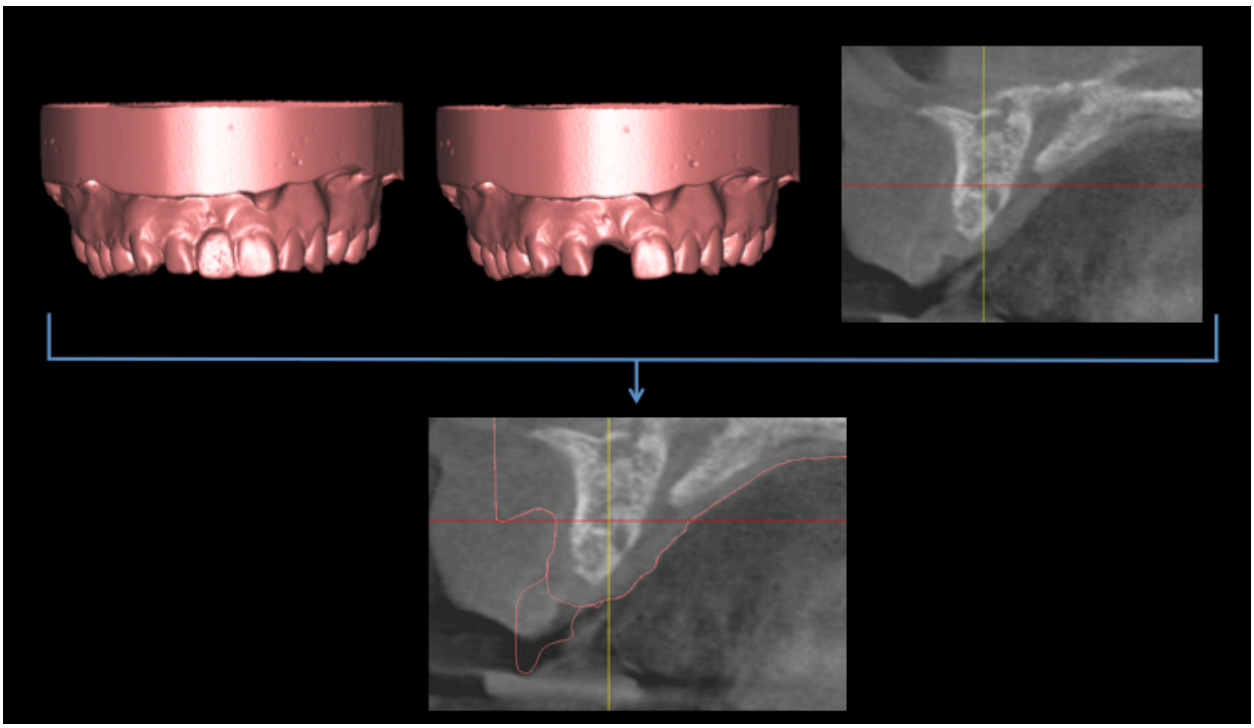

Figure 2. Merging of Surface Scanned Models with CBCT DICOM Data.

While it is simple to envision that this process can be made available to clinicians for delivery of single implant restorations, there are several important factors that must be empirically defined. The digital process is robust but not fully developed on the quality of information obtained and how it is used to create virtual models. A Primary concern in this process is the assurance that both the DICOM and STL images are of sufficient quality. This is essential so that a composite model of high fidelity can be produced. The registration of the DICOM with the STL images must be performed with high dimensional accuracy relative to the surface contours of the teeth present at both the bound edentulous space and the edentulous alveolar ridge. With an accurate composite three-dimensional model, the task of positioning a virtual implant in relationship to the planned crown (present in the STL image) is straightforward.

Design of the abutment is more challenging and requires several pieces of information to create an abutment that adequately supports the soft tissues and proposed crown contour. Information necessary for abutment design includes implant position, soft tissue position, mechanical factors, esthetic factors, planned crown contours and emergence, a practical path of draw and position of the screw access. Abutment design can be achieved using proprietary software for abutment design that accepts the composite three-dimensional models. However, it is important to recognize that little information is available regarding the fidelity of the use of these models.

What is not described and what has not been investigated is the fidelity of the planned relationship of the abutment/crown interface with the post-operative peri-implant mucosa. This is important for esthetic reasons and requires careful evaluation. One approach to abutment design might be to assume that it is not possible to assure the planned relationship of the abutment/crown interface to the soft tissue margin. Based on this, the design of the abutment within the three-dimensional models would require that the abutment/crown interface be placed apically far (1 -2 mm; figure 2a) from the soft tissue border. The placement of this margin far below the soft tissues would negate the benefits of a custom, patient specific abutment that include support of the soft tissues, natural emergence profile beginning at the implant/abutment interface, and relative ease of cement removal in cement retained restorations. If the ultimate relationship of the abutment/crown interface with the peri-implant mucosa could be assured from the planning, the abutment/crown interface could be located in approximation to the peri-implant mucosal margin (0-1mm; Figure 2b).

The aim of this prospective comparative study was to determine the possibility of designing a CAD/CAM patient-specific abutment within a three-dimensional composite model environment (Simplant 16) that reproducibly predicts the clinical relationship of the abutment/crown interface with the peri-implant mucosal margin.

MATERIALS AND METHODS

Patient Selection

Twenty patients were recruited through a convenience sample at the UNC School of Dentistry in Chapel Hill, NC. Patients recruited presented to the Graduate Prosthodontic clinic seeking implant restoration of a single edentulous space. Inclusion criteria include an edentulous space with tooth extraction at least two months prior to inclusion in no need of bone or soft tissue grafting prior to implant placement. Patients with a smoking history in the last 6 months, untreated periodontal disease or ASA Class III+ were excluded from the investigation (Table 2.1). Upon recruitment, patient were informed of basic study procedures and underwent an initial clinical examination to include health history, general exam, standardized radiographs (panoramic film), standardized photographs and alginate impressions of the both the maxillary and mandibular arches. Assuming inclusion criteria are met, patients were given a consent form to inclusion in the study to review prior to the next appointment (Figure 3). Following consent to participate in the investigation (IRB# 13-2376), a Cone Beam Computed Tomographic (CBCT) examination was completed and reviewed by investigators.

Table 3 Inclusion/Exclusion Criteria
Inclusion Criteria
Single Edentulous site with Adjacent teeth/Restoration Present Age 18-99 Extraction > 2 Months Prior ≥20 teeth Consent to Participate in Clinical Trial
Exclusion Criteria
ASA Class 3+ Smoking within the past 6 months Severe Bruxism Untreated Caries/Periodontal Disease History IV Bisphosphonate Therapy Site in need of grafting prior to implant placement Lateral Window Sinus Augmentation Necessary Present Drug Use

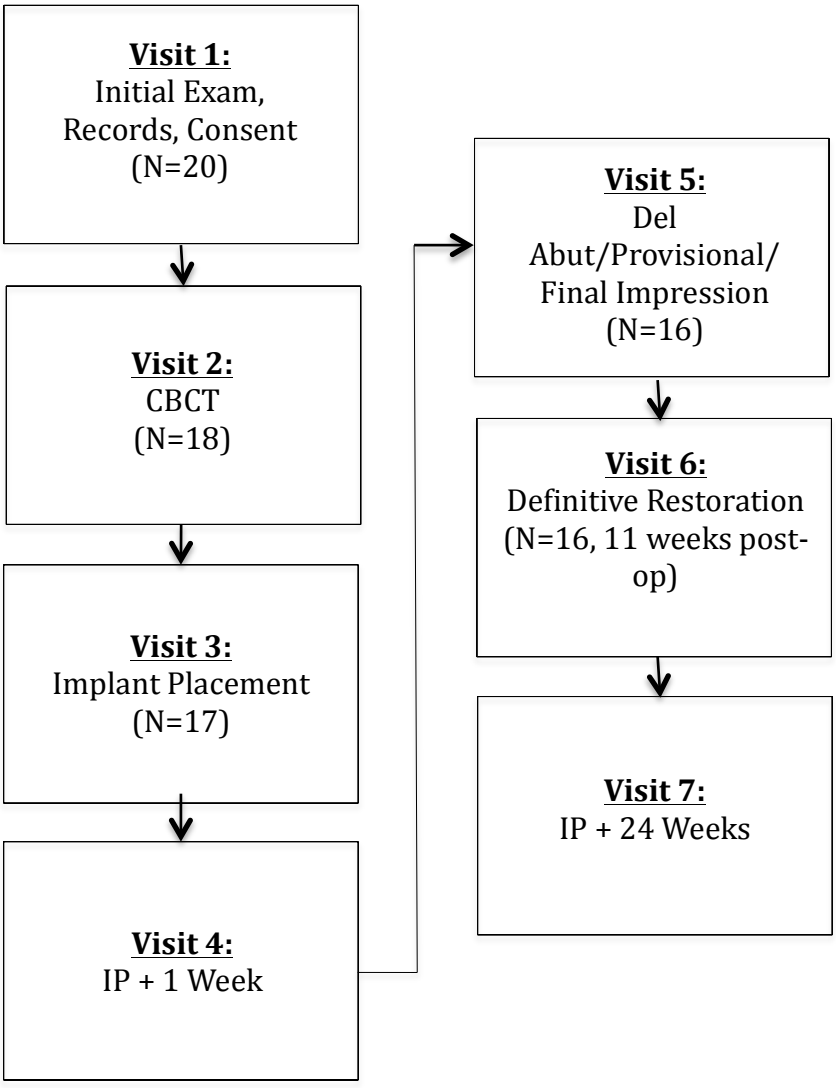

Figure 3. Materials and Methods Flowchart

Diagnostic Procedures

Following review and assurance of adequate anatomic three-dimensional bone volume for implant placement in the presenting edentulous site, CBCT DICOM data was uploaded to Simplant (Waltham, Ma) planning software for surgical planning. A full contour wax-up was completed on models made from the alginate impressions for each patient in the edentulous site in the laboratory.

Models, including the wax-up, were sent to Simplant (Waltham, MA) for merging with CBCT DICOM data uploaded to the software. Merging the preoperative model, the preoperative model with the wax-up, and the CBCT DICOM data allowed implant planning in the proprietary implant planning software (Simplant) based on the three-dimension anatomy of the patient, the soft tissues of the edentulous space and the proposed final restoration as represented by the diagnostic wax-up. Implants planned were Astra Tech EV (Dentsply Inc) of various lengths and widths based on the patients presenting anatomical constraints.

Following digital implant planning for each patient, Simplant safe guides were ordered. The Immediate Smiles protocol offered for use with Astra Tech and Atlantis (Dentsply, inc.) was followed, an Atlantis abutment was ordered along with the surgical guide for each patient. Once processing was completed for the surgical guide order, the plan was sent to Atlantis where an abutment was designed using a Virtual Abutment Design (VAD) technique. Prior to surgical guide fabrication, abutment modification and

approval was completed by the investigator through the Atlantis Web Order website to assure proper prosthetic placement of the planned implant. Abutments used were designed with full anatomic sub-gingival contour coated with Gold Hue titanium nitride. Once approved, the surgical guide was fabricated through stereolithography and sent, along with the Atlantis abutment, to the investigator for completion of surgical procedures.

Surgical Procedures

Astra Tech EV implants were placed using the manufacturer protocol in each subject using appropriate guided surgical drills for implant placement using a stereolithographic surgical guide (Simplant, Dentply Inc). Cover screws were placed at each site to allow two-stage healing of the implant. Post-operative peri-apical radiographs were exposed to assess appropriate implant placement in bone. Post treatment medications included antibiotics (Amoxicillin/Clindamycin), antimicrobial Chlorhexidine mouth rinse (Peridex), and analgesics (Ibuprofen). Follow-up was performed at 1 week for assessment of patient comfort and appropriate soft tissue healing at the site.

Restorative Procedures

Patients returned to the clinic eight weeks following implant placement for delivery of the Atlantis abutment and a provisional crown milled from the 3D core file provided by Atlantis. Soft tissue punches were made through the original surgical guide to return the tissue to the same architecture of the day of surgery. Atlantis abutments were delivered and torqued to 25Nc. Peri-apical radiographs were made to assure proper connection of

the abutment to the implant fixture. Abutments were assessed for proximity to the gingival margin and margin exposure. Final impression of the abutment was made at abutment level for final crown fabrication using Polyvinyl Siloxane impression material in a stock tray. Impression of the opposing arch and a centric bite record was also made in preparation for the final restoration.

Provisional crowns were inserted and assessed for fit with respect to the abutment, adjacent proximal teeth and opposing teeth in the opposite arch. Provisional crowns were cemented with temporary cement (Figure 4).

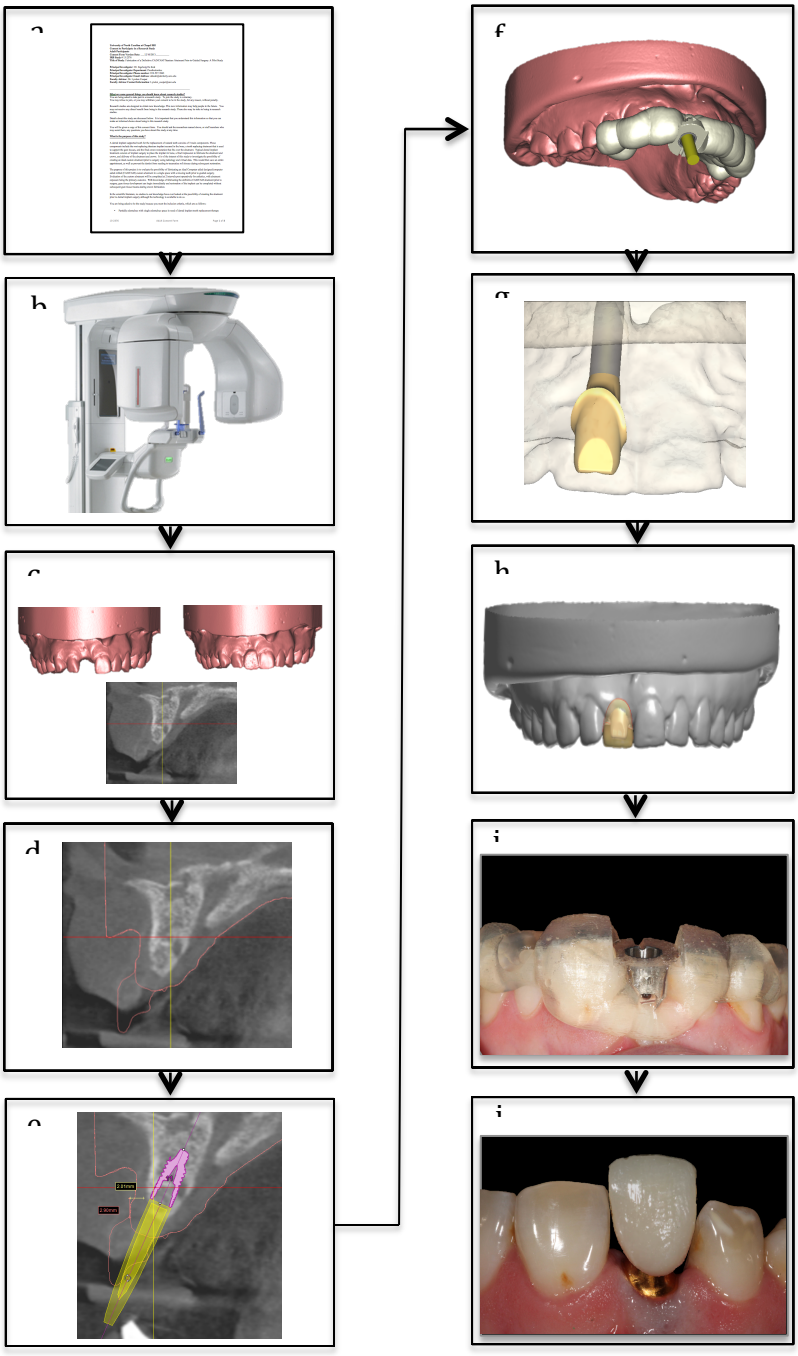

Figure 4. Steps in Protocol. (a) Consent, (b) CBCT, (c) Impression and Surface Scan, (d) Merging Process in Simplant, (e) Virtual Implant Placement, (f) Design Guide, (g) Design Abutment, (h) Design Crown, (i) Surgical Guide Placement, (j) Abutment and Crown Placement.

Three weeks later (11 weeks from implant placement), a definitive e-max crown was inserted and cemented with conventional resin modified glass ionomer cement (FujiCem, GC America). Probing pocket depth values, bleeding on probing and abutment margin exposure was also assessed at the crown delivery visit.

6-month follow-up

A twenty-four week post-operative visit was also completed to assess probing pocket depth values, bleeding on probing and abutment margin exposure. Abutment margins exposed were remade along with the definitive crown for adequate esthetic results for the patient.

Data Acquisition and Analysis

Abutment margin exposure (the primary outcome variable) was assessed as a nominal variable (yes or no) at crown delivery at 11 weeks and the post-operative visit at 24 weeks. Probing pocket depths and bleeding on probing (secondary outcome variables) were also assessed at these visits.

RESULTS

Seventeen participants were recruited. Seven men and 10 women were included and the average age was 52 years (Table 3.1). Among the 17 participants, implants were required for restoration of single missing teeth in diverse locations (Table 3.2).

Table 4 Description of Patient Demographics

	.5 mm (Sub-G)	1.5mm (Sub-G)	Total
Number of Subjects	8	9	17
Mean Age	50.85±19.52	54.22±15.67	52.75±16.92
Sex			
Male	4 (57%)	3 (43%)	7
Female	4 (40%)	6 (60%)	10
# Surgeries by site			
Central Incisor	2	1	3
Lateral Incisor	0	0	0
Canine	1	0	1
Premolar	4	2	6
Molar	2	5	7

Table 5 Implants by Length

	6 mm	8 mm	9 mm	11 mm	Total
1.5 mm (Sub-G)	1	1	4	3	9
.5 mm (Sub-G)	0	1	3	4	8
Total	1 (5.8%)	2(11.7%)	7(41.1%)	6(35.2%)	**17**

Implant placement and healing was uneventful with two exceptions. One participant experienced transient numbness associated with the inferior alveolar nerve; a shorter implant was placed immediately without further complication. A second participant experienced implant failure at 4 weeks following implant placement (Table 3.3).

Abutment placement occurred after two-stage implant surgery. For 16 participants, abutments were placed in accordance with the presurgical digital plan. There were two complications involving rotational discrepancy at abutment placement. (Table 3.3) One involved the implant replaced due to transient numbness (Table 3.4, Patient #1). The other (Table 3.4, Patient #3) occurred for an uncomplicated guided surgery.

Table 6. Implant Survival and Complications

Complication	Number of Implants
Failure to Integrate	1/17 (5.8%)
Temporary IAN Numbness	1/17 (5.8%)
Rotational Discrepancy	2/17 (11.6%)
Provisional Crown Infraocclusion	1/17 (5.8%

Table 7 Abutment Display

Patient	Position	Implant Size	IAI-Gingival Zenith (mm)	Sub-G Margin Location	Clinical Tissue Thickness (mm)*	Abutment Display
1	18	4.8s x 9	2.97	-1.5	3.2	No
2	8	3.6s x 9	3.01	-0.5	4.4	No
3	30	4.8s x 9	3.01	-1.5	3.0	No
4	3	4.8s x 8	2.98	-0.5	1.8	Yes
5	20	4.8s x 11	2.94	-1.5	2.1	No
6	14	4.8s x 9	3.01	-1.5	3.0	No
7	20	4.8s x 11	3.01	-0.5	3.1	No
8	14	4.2s x 6	2.99	-1.5	1.7	Yes
9	19	4.8s x 11	2.97	-0.5	2.0	Yes
10	4	4.2s x 9	2.98	-1.5	3.0	No
11	6	3.6s x 8	3.07	-0.5	3.0	Yes
12	29	4.2s x 11	3.02	-1.5	3.1	No
13	5	3.6s x 11	2.99	-0.5	3.0	No
14	30	4.8s x 11	3.06	-1.5	2.0	Yes
15	8	3.6s x 9	2.91	-0.5	5.4	No
16	9	4.2c x 11	2.97	-1.5	4.5	No

* - Clinically measured at 8 weeks = Abutment Placement

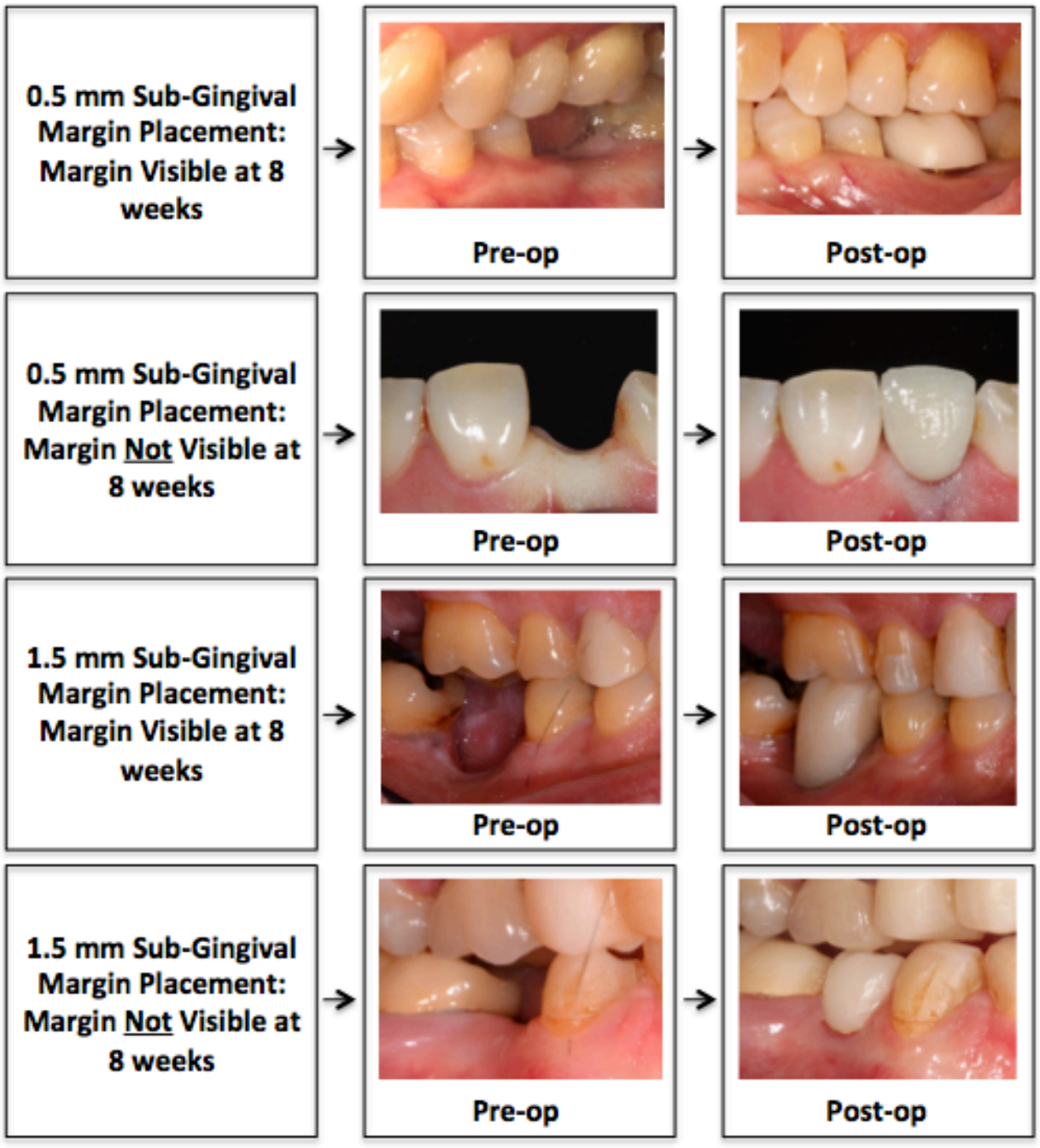

Figure 5. Representative Outcomes

The primary outcome measure of this study, abutment margin exposure, was dichotomously scored. For 11 of the 16 implants, the clinical crown margins of abutments was located in a submucosal position (Table 3.5, p=.210). No significant difference was found between the 2 different subgingival margin locations (Table 3.5, p=0.377). Among the 5 abutments in which the abutment/crown margin was displayed, 4 were molar locations (Table 3.6, p=.049). Significant differences were also found in mucosal thickness between the molars and non-molars (Table 3.6, p=.024)

Table 8. Margin Show	**Yes**	**No**	**Total**	**Sig.**
1.5 mm	2 (22%)	7	**9**	**p = 0.377**
0.5 mm	3 (43%)	4	**7**	
Total	**5**	**11**	**16**	**p = 0.210**

Table 9. Tooth Position	Tooth Type	Abutment Margin Show	Statistics	Tissue Thickness (mm)*	Statistics
19	Molar	No		3.2	
30	Molar	No		3.0	
3	Molar	Yes		1.8	
14	Molar	No		3.0	
14	Molar	Yes		1.7	
19	Molar	Yes		2.0	
30	Molar	Yes		2.0	
		4/7 : 57% (Yes)		**Mean: 2.38**	
8	Non-Molar	No		4.4	
20	Non-Molar	No		2.1	
20	Non-Molar	No		3.1	
4	Non-Molar	No		3.0	
6	Non-Molar	Yes		3.0	
29	Non-Molar	No		3.1	
5	Non-Molar	No		3.0	
8	Non-Molar	No		5.4	
9	Non-Molar	No		4.5	
		1/9 : 11% (Yes)	**p = .049**	**Mean: 3.51**	**p = .024**

*Clinically Measured at 8 weeks = Abutment Placement

A secondary outcome measure of this study was the clinical fit of the associated, digitally designed and milled provisional crowns. In the absence of a related model, 10 of the 16 crowns fit without any adjustment (Table 3.7). Three required interpoximal reduction measured to be less than 0.25 mm and was considered clinically acceptable (Table 3.8). The remaining 3 crowns required less than 0.5 mm of adjustment.

Table 10. Provisional Fit		
	Yes*	10 (63%)
	No	6 (37%)
Total		**16**

*No Adjustment Necessary

Table 11.Provisional Adjustment

Patient Number	Provisional Fit	Adjustment Necessary (mm)
1	No	0.25
2	No	0.5
3	No	0.5
4	No	0.25
5	Yes	N/A
6	Yes	N/A
7	Yes	N/A
8	Yes	N/A
9	Yes	N/A
10	No	0.25
11	Yes	N/A
12	Yes	N/A
13	Yes	N/A
14	No	0.5
15	Yes	N/A
16	Yes	N/A

DISCUSSION

This investigation examined in a preliminary manner the therapeutic outcome of integrating abutment design with existing volumetric implant surgical planning software and digital crown design tools. The clinical challenge of defining the peri-implant soft tissue architecture surrounding the planned abutment was evaluated by comparison of two alternative abutment designs. Abutment crown margins were designed at 0.5 and 1.5 mm below the anticipated or estimated soft tissue margin. Here we observed that it was possible to reproducibly designate the proper location of the crown margin along the abutment during a digital design process. Abutments with a 0.5 mm submucosal margin design were not more frequently present above the actual peri-implant mucosal margin upon delivery of the crown ($p=.377$).

This is the first clinical examination of a comprehensive digital planning and workflow for single tooth implant restoration. There are many factors that impact the process of implant placement and restoration that influenced the designated protocol and the reported outcomes.

The first of these factors is the role in data acquisition during the planning process. This study utilized cone beam computed tomography (CBCT) to obtain the patient's radiographic anatomy for use in an implant planning software. Cone beam computed tomography is commonly used for preoperative planning for dental surgery because as opposed to multi slice computed tomography or medical grade CT, CBCT offers relatively similar imaging at a lower dose and lower cost than the other alternatives. For the use of guided implant surgery, cone beam computed tomography and multi slice computed

tomography showed minute but statistically insignificant differences in deviations in both in vitro and in vivo studies[59,24].

Another factor impacting the current protocol and computer guided implant placement is the planning software and surgical guide accuracy. Simplant (Dentsply) was used as the planning software in this study. While there are no comparison studies between different commercially available software systems, the accuracy and usability of the software system plays a role in three-dimensional implant location. It is known that stereolithographically produced surgical guides show minimal inaccuracy (<.25 mm)[25], it is unknown to what extent this process plays in overall deviations from planned implant position during guided surgery.

Finally, the accuracy of digital crown manufacturing without the use of a traditional model is a factor in the success of this protocol. With that said, the dental literature shows success with digital workflows and CAD/CAM milling of restorations similar to traditional techniques[26,27,28].

Integrating these technologies, based upon the data supporting the accuracy of the individual components, suggests that it should be possible to provide an abutment and crown for a single, unsplinted crown in a defined, bound edentulous space. In fact, the current clinical experience demonstrated that it was possible to place an implant, place a pre-fabricated abutment and place a pre-fabricated crown in such situations with dimensional accuracy. However, because the clinical process involves the manipulation of bone and oral soft tissues, these static three-dimensional models do not account for potential changes that occur following the surgical intervention.

Changes in soft tissue architecture surrounding implant crowns have been a point of significant concern. It has been suggested that buccal peri-implant mucosal instability should be expected. In a 1 year longitudinal study, it was found that .8-1.0 mm of buccal recession occurred within the first 3 months following abutment connection. It was suggested in the same study that a period of provisionalization should be invoked following implant abutment connection prior to final abutment fabrication[29]. However, more recent evaluations suggest that soft tissue stability may be possible. Coysn et al, in a systematic review of single tooth implant outcome suggest that stability in approximately 90% of individuals is possible when certain conditions are met. These conditions include but are not limited to proper implant location (both mesio-distally and bucco-lingually) and minimally invasive soft tissue procedures (flapless protocols when feasible).

Given what is known regarding soft tissue architecture and esthetics surrounding dental implants, the present use of guided surgery to place the implant in a standard position relative to the soft tissue landmark is revealed the value of imparting clinical control to a process with many clinical variables.

Controlled Virtual Implant Placement

For the procedure under investigation to be functionally and esthetically successful, the first step of accurate implant placement must be assured. Precise implant placement was planned in the Simplant software with the relationship between the anatomic bone volume, soft tissues and the proposed gingival margin of the full contour wax-up. These three parameters represent the necessary data to be able to plan precise implant placement, design a patient specific abutment, and produce a highly accurate all ceramic crown through a digital workflow. This is made possible through a “merging” process (Simplant,

Waltham, Ma) that combines the CT DICOM data of the patient, an STL model made from scanning of a dental stone model of the pre operative condition, and an STL model of the same stone model of the full contour wax-up in the proposed implant site. Generally, accuracy of these scanned models are very high as most manufacturers of scanners state accuracy within 5-30 μm[30].

Three-dimensional implant placement was completed using the guided surgical protocols for all patients. Each implant was placed as designated in the virtual model and according to the guide (approximately 3 mm apical and 2 mm lingual to the proposed gingival zenith) of the proposed tooth form[35,37,31](Figure 6).

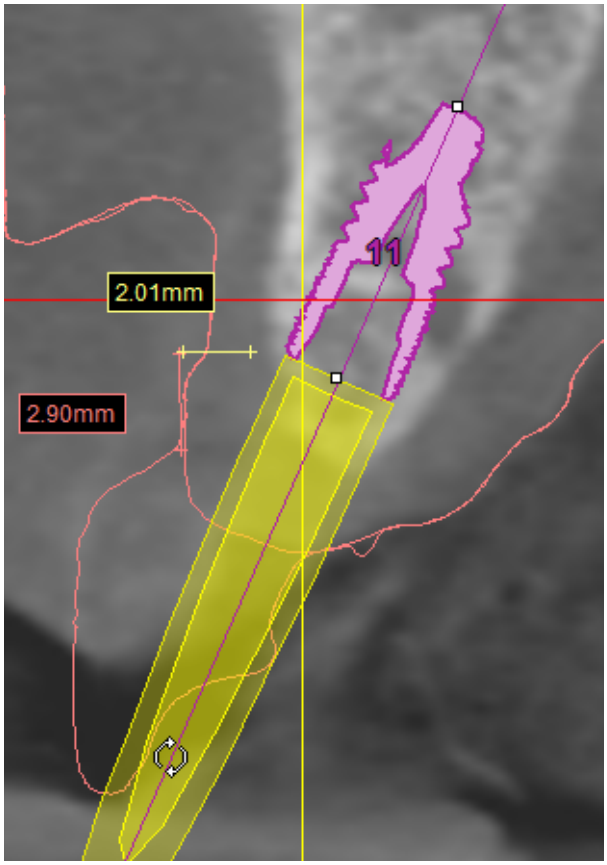

Figure 6. Virtual Implant Placement based on the implant abutment margin 3mm apical and 2 mm lingual to the proposed gingival zenith.

Proper implant position to obtain esthetics requires an understanding of the correct position of the supporting bone that supports the soft tissues and its relationship to the desired tooth position. The gingival zenith specifically of the planned restoration has a remarkable influence on the esthetic outcome of single tooth implant restorations. This landmark represents the most apical part of the clinical crown, in addition to the facio-lingual and mesio-distal relationship of the clinical crown to the edentulous ridge[36]. Because of these relationships, the gingival zenith of the planned restoration is the logical landmark in a crown down approach to treatment planning proper three-dimensional implant positions.

In an apico-coronal direction, proper implant depth was planned in the digital environment based on the understanding of a biologic width that forms around dental implants. Biologic width describes the combined width of connective tissue and junctional epithelium formed adjacent to a tooth and superior to the crestal bone. A similar constant soft tissue dimension can be described around implants and violation of this dimension through incorrect placement of the dental implant can lead to undesirable esthetic outcomes. Animal studies have demonstrated a constant thickness or peri-implant soft tissue width measuring 3 mm. This dimension is split into two main zones of connective tissue and epithelial structures. The supracrestal connective tissue attachment around dental implants comprises 1 mm of this biologic dimension. The epithelial structures that include the junctional and sulcular epithelium encompass the remaining 2 mm of supracrestal peri-implant tissue height[37]. Based on these anatomic dimensions it has been recommended that implant depth be 3-3.5 mm apical to the planned zenith of the

restoration[35,37], which is the dimension followed in the present study when planning virtual implant placement.

In a bucco-lingual direction, the implant shoulder was placed 2 mm palatal to the planned gingival zenith of the proposed restoration. This dimension is necessary to ensure satisfactory thickness of the buccal bone and soft tissue to support proper tissue form. It has been recommended in the Prosthodontic literature that the implant shoulder be placed 1-2 mm lingual to the emergence of the adjacent teeth to ensure adequate thickness of buccal bone and allow tissue stability in the buccal regions[37]. Implants placed at or buccal to the line drawn between the cervical margins of the adjacent teeth demonstrated three times more recession than implants placed lingual to this line[39]. Using these guidelines, implant shoulders in the present study were placed approximately 2 mm lingual to the planned gingival zenith to ensure proper buccal bone and soft tissue thickness to support the restoration. In a prospective study, when implant placement was achieved at an average of 1.5 mm palatal to the tissue reference, stability of the buccal soft tissue level was observed at the 5 year evaluation period[40].

The Effects of A Guided Surgery Protocol

Prior to the advent of Cone Beam Computed Tomography (CBCT), bone volume morphology was analyzed by 2-dimensional radiographs (peri-apical and panoramic films). Three-dimensional assessment occurred only in the surgical arena via a full thickness flap procedure. CBCT has revolutionized the ability to three-dimensionally evaluate the available volume of bone to house a dental implant prior to implant surgery. Planning the proper placement of an implant requires prerequisite understanding of the planned position of the dental restoration. CBCT images permit the coordination of implant

placement with the dental restoration position only if the restoration's location is visualized within the CBCT-derived three-dimensional model. The ability to merge the patient's CBCT DICOM data and the planned prosthetic restoration with commercially available implant planning software, it is possible to place a virtual dental implant into this three-dimensional view[41]. Although this technology enables assessment of the patients bone quantity and quality, transferring the exact position of the planned implants to the patient can be challenging and imprecise.

Building upon the fidelity of three-dimensional models that repeat bone and tooth position, it is possible to design and manufacture surgical guides. Guided surgery protocols use the preoperative plan in the software and transfer this plan to the clinical setting via a stereolithographic surgical guide. This CAD/CAM surgical template provides an accurate means of transferring the planned implant position in the planning software to the patient.

The main advantage of guided surgery is that it reduces implant-positioning errors frequently observed in freehand implant placement[42]. Precise implant position combined with the possibility of a flapless surgical technique can make implant placement safer, more predictable[43], and less traumatic for the patient causing less postoperative morbidity and discomfort[44].

While guided surgery protocols have provided the ability to transfer a preoperative plan based on the patient's three-dimension bone volume to the patient in the clinical setting, the accuracy is limited. Many investigations have compared post-operative patient implant positions with pre-operative implant positions in the planning software. One such investigation found tooth supported surgical guides to be more accurate than bone and mucosa supported guides. Mean coronal deviations of .87mm and apical deviations of .95

mm were found in an evaluation of 110 (50 with tooth supported guides) implants placed through a guided surgery protocol[45]. Confining this magnitude of error, a post-operative evaluation of 89 implants revealed a mean depth deviation of 1.1 mm between actual vs. planned implant position[46].

The previously mentioned deviations of approximately 1mm seen in systematic reviews on the topic may represent the accumulation of errors from the pre-operative digital workflow concluding with the intra-operative surgical procedure. Pre-operatively, the digital workflow may incorporate possible errors that include the radiographic technique (CBCT), patient movement during acquisition of the radiograph, and surgical guide production through stereolithography (STL)[47]. Intraoperatively, correct positioning and stabilization of the surgical template during drilling procedures is highly important and lends to deviation errors if not properly executed. Other parameters in the literature include mucosal thickness and tolerances of the drills in the drilling sleeves as possible sources of global deviation seen in systematic reviews of guided surgery[46]. Despite the possible sources of error, a global deviation of approximately 1 mm reported is a reduction from traditional techniques[34].

Comparison of analog versus digitally generated surgical guides demonstrates the advantages in accuracy. Entrance point deviations on average were 1.5 mm and coronal deviations were 2.1 mm for conventionally placed implant. When using the stereolithic surgical guide these deviations were significantly reduced to .9 mm at the entrance point and 1.0 mm at the apex[48]. There is an improvement in precision, yet errors of approximately .5-1mm remain and present challenges for improvement.

Within the planning software, the previously mentioned inaccuracies are accounted for at the level of implant placement by use of a visual "safe zone" creating a halo around the implant. If this "safe zone" is housed within the patient's available bone, even with deviations as seen in the literature, the implant will be placed in an anatomically safe position within the patient. A safety zone of at least 2mm is recommended in the literature to avoid impingement of anatomical structures or extra-osseous placement of the implant[48]. Placement of the implant accurately and safely within bone is but one challenge.

The inaccuracy related to guided surgery is biologically and anatomically innocuous when accounted for during planning. In the present study, the accuracy of the guided surgery protocol becomes important when prefabricating the patient specific abutment and provisional crown because inaccuracies in planned versus actual implant placement will result in inaccuracies of the abutment margin and provisional restoration. Abutment margin location as planned preoperatively could be adversely affected with depth deviations as indicated above.

Optical scanning and CAD/CAM software developments have provided a technical platform that enables clinicians to provide single crown restorations without conventional impressions or analog models. The digital three-dimensional model offers sufficient information to manufacture the crown. The integration of optical scanning and CBCT images provide the opportunity to design both the crown and the abutment. Provisional crowns in this investigation were milled off of a virtual three-dimensional model of the designed abutment in the form of a core file available through Atlantis. Inaccuracies related to coronal and apical deviation of the implant in vivo compared to preoperative planned implant position in the planning software will lead to inaccuracies when seating

the provisional restoration. These complications are similar to those found for inaccuracies of guided surgery in the literature. D'haese et al concluded in their review that complications of positional errors are most frequently reported when combining computer guided implant placement with immediate loading/provisionalization protocols. Furthermore, misfit between the installed implants and the prefabricated provisional prosthesis[49] specifically are the main reasons for complications during guided surgery. As found in the present investigation, inaccuracies in the guided surgery protocol exist and complications resulting from these inaccuracies are most often related to misfit of prefabricated restorations rather than biological sequella during surgery related to impingement of unwanted hard or soft tissue landmarks. Nevertheless, the usefulness of the surgical template in relating the implant position in the planning software to the patient to within 1 mm in any direction is a useful tool for the surgeon to ensure implants are in a position for positive restorative results once osseointegration is complete.

Surgical Protocol: Submerged in 2 stages

The present study utilized a two stage surgical protocol prior to restoration of the implant with subsequent patient specific abutments and all ceramic crowns. A two-stage submerged approach was chosen to present a worst-case scenario upon implant placement. This cautious approach accounts for implants that are not stable following placement and thus, would not be suited for an immediate provisionalization procedure. It is also a stringent test for the concept of designing and manufacturing a patient-specific abutment and provisional crown prior to implant placement using a guided procedure. Since the abutments were fabricated prior to implant placement, it would be ideal to have soft tissues closely related to the soft tissues during abutment margin planning. A 2-stage

approach following complete soft tissue healing provides gingival tissues similar to those found in the planning of the abutment margin with robust contours to support the restoration.

Although a two-stage approach was chosen for this protocol, it has been shown in previous studies following clinical and radiographic examination of both the hard and soft tissues that similar success can be achieved through either a submerged or non-submerged surgical protocol[50]. Further investigations revealed that peri-implant tissues react to the type of implant surface and the presence of the microgap (implant/abutment interface), but any changes in these tissues occur irrespective of the surgical protocol (submerged vs. Non-submerged) [51]. In a study that followed 324 implants in 84 patients utilizing the Astra Tech dental implant system peri-implant bone level change was found to be unrelated to whether initial soft and hard tissue healing following implant installation had occurred under submerged or non-submerged conditions[52].

In the present study, a delayed loading protocol was chosen for restoration utilizing a two stage technique to allow complete soft tissue and hard tissue healing with no possible pressure on the healing implant. When utilizing a guided surgery protocol, as in the present investigation, the second surgery is very simple and efficient for the provider and the patient. If the stereolithographic surgical guide is saved, the same guide can be used as a pilot for the second stage surgery to allow accurate and fast access to the cover screw as was done to access the healed alveolar ridge at the time of implant placement. Because the second surgery can be very simple with the guide, it is prudent to choose a 2-stage protocol to ensure soft tissue protection of the implant during the critical osseointegration phase.

Flapless Implant Surgical Technique

Traditionally, dental implant placement involves full thickness reflection of the soft tissues to allow visualization of the surgical site and availability of alveolar bone to house the implant. This practice of reflecting a soft tissue flap reduces the risk of osseous perforations or fenestrations following placement. Reflection of a soft tissue flap can lead to increased post operative discomfort and mucosal recession if optimal soft tissue management is not achieved. It has been shown that full and partial thickness flaps lead to bone resorption[53]. This is most likely due to trauma to the periosteum during flap elevation and alteration in blood supply to the bone and soft tissues. More recently, flapless surgical techniques have become popularized in which the implant is placed through the mucosal tissues without reflection of a flap[54]. A flapless technique overcomes the challenge of soft tissue management and may reduce the chance of postoperative peri-implant tissue loss[55]. Because flapless techniques do not alter periosteal attachment, blood supply to the bone and soft tissues remain intact [56,57]. Flapless techniques have shown in dogs to have lead to lower buccal soft tissue recession and lower mean values of biologic width longitudinal dimension[58]. Other obvious advantages include reduced trauma at the time of surgery, decreased operative time, rapid postoperative healing, and increased patient comfort[60].

A consideration when guided surgery is being planned utilizing a flapless surgical technique is if the patient presents with adequate keratinized peri-implant gingiva to sacrifice during flapless techniques using a soft tissue punch. Traditional full thickness flap elevation is conducted using a simple incision in which soft tissues are released for access during the surgery and replaced immediately following the surgery with suture techniques

in an attempt to retain the soft tissue architecture that was present preoperatively. While elevation of a flap can be accompanied by marginal bone loss and recession, it retains keratinized tissue present in the implant site that was available preoperatively[59]. Flapless protocols are very simple and efficient, however most often the tissue housed within the 4-5 mm soft tissue punch is sacrificed. If the patient presents with a keratinized tissue band that is thinner than the necessary soft tissue punch to allow installation of the dental implant, the flapless procedure may result in sacrificing what little keratinized tissue the patient has. It is suggested that in ideal situations, 2 mm of keratinized tissues remain around natural tooth crown margins to prevent recession[68]. Similar characteristics are desired around implant crowns. It has been shown that a lack of keratinized gingiva around dental implants in some patients may be increase the risk for plaque accumulation, tissue soreness while brushing, increased gingival inflammation, recession and bone loss[61]. Careful case selection and clinical judgment is needed at treatment planning to determine if the patient is a candidate for flapless surgical protocols.

Abutment Material

Conventional dental implant abutments for single implant crowns were fabricated using machined titanium that was veneered with acrylic resin in a 1-piece type restoration, or prefabricated titanium components to be used with metal-ceramic cement-retained single restorations[2]. In 1988, the UCLA abutment was introduced that used the lost wax process to fabricate a custom cast abutment that screwed directly into the implant[5]. The UCLA abutment was frequently cast gold, which was not only a proven dental material mechanically but introduced the possibility of affecting the peri-implant mucosal tissue hue creating a more esthetically pleasing restoration[60]. It became evident that materials with a

traditional metal hue lead to bluish-grey discoloration of the peri-implant soft tissues; a displeasing effect especially in areas of thin biotype that affected the ability to recreate natural gingival tissue coloration[60]. In 1993, alumina ceramic was introduced as an abutment material in an attempt to fix the soft tissue color problems of traditional metal abutments[63]. Subsequently, in 2004, yttrium-stabilized Zirconia was introduced as a stronger ceramic "tooth colored" abutment material[64]. Although many believe that Zirconia materials created a more esthetically pleasing restoration and resulted in less discoloration of the peri-implant soft tissues, these materials have shown to be mechanically more fragile than traditional metal titanium components. In a systematic review of abutments in the anterior region, 11 total fractures were reported. Eight of these fractures occurred with alumina based materials and 3 occurred with zirconia. No abutment fractures were reported on titanium or cast metal abutments[15]. An ideal combination of esthetics and strength in combination with clinical judgment and case selection are necessary to find a material for a restorative scenario.

Contemporary evaluation of dental implants has shifted from a purely mechanical evaluation to one that focuses on soft and hard tissue esthetics[14]. This is especially true when evaluating implant restorations for single crowns. Studies looking at peri-implant soft tissue color around metal and zirconia abutments have been conducted with spectrophotometry showing that both titanium and zirconia abutments induce a visible discoloration compared with soft tissue color around natural teeth[65]. When looking at specific subjective and objective criteria when evaluating esthetics by both clinicians and patients, it was shown that the effect of metal and ceramic abutment materials on peri-

implant soft tissues is indistinguishable and material choice alone does not ensure esthetically pleasing results[66].

Further investigations have compared not only titanium and zirconia, but also incorporated evaluations using cast gold as a material for abutment fabrication and its effects on the discoloration of peri-implant soft tissues. One such investigation compared CAD-CAM fabricated titanium, cast gold alloy and zirconia abutments on each of 20 patients. Spectrophotometry was used to evaluate peri-implant mucosal color changes for each abutment and compared these results with the mucosa of the contralateral tooth. It was found that all three abutments (titanium, cast gold, zirconia) induced a color change when compared to the natural tooth. Zirconia abutments induced the least color change but were not significantly different than cast gold. Titanium abutments were however associated with significantly higher change in color[67].

The present study used Atlantis CAD/CAM patient specific abutments (DENTSPLY) for restoration of single implant crowns to support an all-ceramic lithium-disilicate crown. The material chosen was Gold Hue, a titanium alloy (Grade 5- 6Al-4v) based abutment offered through Atlantis that has a gold hue titanium nitride (TiN) coating in an attempt to combine the strength of titanium and the esthetics of cast gold. Being that the present investigation was not site specific and included implant restorations in all sites within the dentition, it was prudent to use a titanium abutment that could withstand occlusal forces in both the anterior and posterior regions. It is the author's belief that if the margin of the abutment remains sub-gingival, the gold hue can yield similar esthetic results to zirconia. Also, within the present study, the gold hue color allows better evaluation of abutment margin exposure when such a phenomenon occurred.

The Atlantis system incorporates a CAD/CAM Virtual Abutment Design (VAD) procedure in which the abutment is designed from a virtual representation of the tooth in full contour. The crown contour is "cut back" based on specific material requirements for the overlying crown. This information, along with desired sub-gingival contours can be selected prior to fabrication of a virtual abutment. Upon design of the abutment from Atlantis, the design file of the abutment may be viewed and modified if desired by the provider where specific changes can be made using 3D editor related to margin location, depth and width. Bodily changes can be made to the overall abutment as well. Any changes made can be saved and approved for manufacture of the abutment.

It has been suggested that margins of both natural tooth crowns and implant crowns should be placed no more than .5mm sub-gingival so as to sufficiently hide the restorative margin but avoid impinging on the biologic width[68]. Conventionally, an implant level impression for fabrication of the final restorations is made at sites with completely healed soft tissues and the chances for gingival recession are low. In the case of the present study in which the final abutment is delivered at second stage surgery (or at the time of surgery), it must be considered if the margin of the abutment should be placed further sub-gingivally to avoid abutment margin exposure with the final restoration. This of course could compromise the health of the peri-implant soft tissues if the biologic width is impinged. In the present study, placement of the abutment/crown margin 0.5mm sub-gingivally was insufficiently deep to anticipate soft tissue architecture changes following healing nd abutment placement. Abutments with margins 1.5mm beneath the soft tissues showed fewer tendencies toward margin exposure at delivery of the abutment.

A very important consideration when contemplating proper single tooth implant abutment margin depth is the type of retention planned for the final restoration. Often times, especially in anterior regions, it is necessary to use cement as the form of retention because the screw access hole of the implant cannot be hidden lingual to the planned incisal edge position. If the position of the screw access hole deviates from ideal, an unaesthetic crown may result[69]. Also, if the screw access hole is located in a non-ideal location close to the cusp tips, the porcelain is weaker and is at higher risk of chipping and fracture[70]. The buccal architecture of the maxilla frequently prohibits implant positioning, with a trajectory that enables lingual screw access. Incisal or buccal trajectory of the screw requires a cement-retained restoration in which a traditional crown is placed over a custom abutment correcting for the necessary angulation of the implant. Even without anatomic constraints, many dentists prefer cement retained restorations because it is the most similar to traditional natural tooth crown techniques, easier to fabricate, and often times is cheaper than screw retained restorations[71].

If the planned restoration is cement-retained as opposed to screw-retained, abutment margin depth is an important consideration with regard to ease of cement removal. If the crown margin must be placed deep within the soft tissue margin for esthetic reasons, removal of excess cement by the dentist becomes very difficult. Excess sub-gingival cement can cause inflammation and lead to peri-implantitis[72]. Modified plaque index (MPI) and sulcus bleeding index (SBI) were found to be significantly higher for cement retained restorations versus screw retained restorations in a prospective clinical trial of 152 ITI implants. The study concluded that after 6 and 12 months post-

loading, cement-retained crowns revealed a consistently higher degree of sulcus bleeding and plaque accumulation than screw-retained crowns[73].

In regard to the influence of margin position on the ability to clean this excess cement and prevent peri-implant inflammation, many clinical and laboratory studies have been conducted showing that only visible abutment margins are capable of being completely cleaned of cement. One specific prospective clinical trial found that the deeper the abutment margin in relation to the gingival margin, the more undetected cement remains adhered to the abutment/restoration complex and in surrounding tissues. This finding is after thorough radiographic evaluation and sub-gingival cleaning[74]. In-vitro and clinical studies have also revealed the deeper the abutment margin, the more difficult removal of residual cement becomes. These studies also found that abutment margins at or close the gingival margin often still revealed residual cement at the abutment-crown interface[75,76].

In the current study, two sub-gingival abutment locations were tested in an effort to develop guidance in selecting margin location when an abutment is fabricated prior to surgery. Obviously, for ease of restoration and cement removal, a margin location .5 mm below the gingival margin would be preferred. If soft tissue healing and continued modification of soft tissues after surgery requires further sub-gingival placement of the abutment margin, restorative procedures and cement removal become more difficult, putting into question the current validity of the technique.

Certainty treatment time and patient satisfaction are improved if a reliable protocol is developed to deliver a patient specific custom abutment at the time of implant surgery or at second stage surgery facilitating immediate provisionalization or early

provisionalization protocols. Another advantage of delivering the final abutment at implant surgery or at second stage surgery is to reduce the abutment dis/reconnect rate in an attempt to retain health of peri-implant soft tissues next the implant-abutment interface. In animal studies, it has been shown that disruption of the mucosal barrier around the implants due to continuous disconnections and reconnections of the abutments during the restorative phase compromise the health of the peri-implant soft tissues resulting in a more apically placed connective tissue zone. This mechanical disruption causes a wound healing response and the resulting more apically placed mucosal tissues cause bone resorption around the implant in an attempt to reform proper biologic width dimension[77]. This continuous abutment dis/ reconnection during the prosthetic phase is attributed to the significantly higher "normal" bone loss during the first year of healing compared to subsequent years[78]. This concept, known in the literature as "One abutment-one time[79]," may be an advantage to the current protocol in which the patient specific final abutment can be manufactured and delivered at the time of surgery.

Fabricating the Atlantis abutment prior to surgery as done in this investigation allows the dentist to choose whether delivery of the abutment is conducted immediately after surgery or delayed if implant stability of location do not warrant immediate provisionalization. In either case, the amount of times the abutment is disconnected/reconnected is lower, thus giving a more reliable soft tissue healing around the abutment and gives the possibility of less mucosal recession, more robust tissue around the implant and potentially less peri-implant bone loss during the first year as often times expected.

This protocol involved placement of a provisional crown fabricated from a CAD file generated using the abutment design. The provisional crowns were milled by a CAM procedure without use of a model. The virtual design process resulted in delivery of 10 of the 16 crowns without any adjustments. Three of the 16 required only 0.25 mm interproximal adjustment prior to clinical cementation. Recent investigations, while not focused on the quality of provisional restorations made from abutment core files, have evaluated the ability to produce crowns using a 'modeless' procedure. Brenes et al recently demonstrated similar goodness of fit for an exclusively digital process of manufacture for single crowns. Batson et al also confirmed it is possible to produce clinically acceptable single crowns using a digital workflow[80]. The present use of an abutment core file to produce a majority of clinically acceptable crowns without a model for interproximal and occlusal contact determination is compelling. These initial results demonstrate that a) virtual implant placement with guided surgery is sufficiently accurate to enable abutment and crown placement (a surrogate assessment of surgical accuracy), b) abutment design prior to implant placement was sufficient to enable provisional crown placement following implant placement without an intervening abutment placement, and c) the core file provides information that enabled a third party laboratory to mill a provisional crown that fit the abutment and bound edentulous space with little or no adjustment a majority of times. Several possible factors may account for misfit of the provisional crown at the time of implant and / or abutment placement. The primary and most obvious factor is the already acknowledged relative fidelity of guided surgery. Existing data reveals angular and linear discrepancies between planned and placed implant positions; angular discrepancies of greater than 1 degree and crestal linear discrepancies of greater than 0.5 would demand

interproximal crown adjustment. The present results suggest that surgical guidance using the tooth-supported guides produced outcomes consistent with or better than anticipated from these earlier reports. It is possible to place an implant, abutment and crown with sufficient clinical dimensional accuracy.

Among the 16 crowns delivered, 6 of the 7 discrepancies observed at the tissue/abutment interface were located in molar positions (p=.049). Conversely, only one of the remaining single tooth implant crowns (anterior and premolar teeth) revealed the abutment following implant and abutment placement. While we may preliminarily conclude that the virtual implant placement and abutment design in accordance with a preferred '3/2' placement rule (Cooper 2008) results in a clinically acceptable crown margin/ tissue relationship for anterior teeth, there may be specific reasons that this was not achievable at molar sites. Fortunately, there is limited esthetic risk inferred by these results.

There may be several reasons why abutment margin exposure was observed with frequency at molars but not other teeth. First, the relative depth of tissue may differ at anterior versus posterior teeth. In fact, direct measurement at the time of abutment placement (buccal mucosal thickness) demonstrated that the average tissue thickness at molars was 3.51mm versus 2.38mm at other tooth positions. The variability in tissue dimensions at different tooth locations within the mouth may require further consideration in the further development of a comprehensive digital workflow for single tooth implant restorations.

A possible second and related factor that may have introduced abutment margin exposure in molars is the inherent geometry of the molar implant compared to other tooth

specific abutments. The relative diameter of the wider molar tooth relative to the smaller, fixed diameters of the implant results in a geometry that imposes acute angles to place the crown margin in a submucosal position. In addition, the length of the transmucosal wall of the abutment may exceed the transmucosal tissue dimension, resulting in display after tissue displacement.

Finally a third practical factor is inherent to the VAD software that limits the actual position and dimension of the transmucosal portion of the abutment. It is not possible to create extremely acute or markedly reduced dimension necessary to achieve submucosal marginal location.

CONCLUSIONS

The results of this study demonstrate that the possibility exists to fabricate a definitive CAD/CAM titanium abutment of appropriate margin depth prior to guided surgery. Although no statistical difference was found between two subgingival margin depths, the protocol in areas of abundant mucosal tissue thickness (nonmolar sites) lends itself to a more predictable final abutment/crown interface position than sites with less mucosal thickness (molar sites). Further investigation is necessary to determine the possibility of designing a CAD/CAM patient specific abutment that reproducibly predicts the clinical relationship of the abutment/crown interface with the peri-implant mucosal margin.

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