

# **Comprehensive Alveolar and Tooth Esthetic Replacement**

BY

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## TABLE OF CONTENTS

### SUMMARY

<b>1. INTRODUCTION.....</b>	<b>Page 1</b>
1.1 Background and Significance .....	Page 1
1.2 Specific Aims.....	Page 3
1.3 Hypothesis.....	Page 3
<b>2. REVIEW OF LITERATURE.....</b>	<b>Page 4</b>
2.1 Considerations for implant treatment .....	Page 4
2.2 Soft tissues and hard tissues considerations.....	Page 5
2.3 Bone changes after extraction and implant placement .....	Page 6
2.4 Importance of keratinized tissue .....	Page 7
2.5 Soft tissue augmentation .....	Page 8
2.6 Soft tissue grafting technique around implant .....	Page 9
2.7 Free Gingiva connective tissue graft vs. Synthetic .....	Page 12
2.8 Immediate smile: One-time abutment concept .....	Page 13
2.9 Intraoral scanning value in doing longitudinal measurements .....	Page 14
<b>3. METHODOLOGY.....</b>	<b>Page 15</b>
3.1 Study Design.....	page 15
3.2 Materials and Methods .....	Page 23

3.3 Statistical Analysis.....	Page 29
3.4 IRB Approval.....	Page 29
<b>4. RESULTS .....</b>	<b>Page 30</b>
4.1 Demographic Results.....	Page 30
4.2 Collected Data .....	Page 31
4.3 Results .....	Page 34
<b>5. DISCUSSION.....</b>	<b>Page 45</b>
<b>6. CONCLUSION .....</b>	<b>Page 48</b>
<b>CITED LITERATURE .....</b>	<b>Page 49</b>
<b>VITA PAGE.....</b>	<b>Page 51</b>

## LIST OF TABLES

I. OHIP-14 survey questions and the score of each response .....	Page 28
II. Demographics .....	Page 30
III. Pre-treatment and post-treatment longitudinal comparison .....	Page 31
IV. Post-treatment and 1-year follow-up after treatment longitudinal analysis.....	Page 33
V. Independent T-test comparison between pre-post means grafted vs. non-grafted..	Page 38
VI. Independent T-test comparison between Post-1y Post-treatment means grafted vs. non-grafted .....	Page 39
VII. OHIP-14 Test group scores .....	Page 39
VIII. Independent T-test comparison between Post-1y Post-treatment means grafted vs. non-grafted .....	Page 41
IX. Vertical measurements from incisal edge-cusp to the gingival margin for the test group .....	Page 42
X. Vertical measurements from incisal edge-cusp to the gingival margin for the control group .....	Page 43
XI. Independent t-test for Vertical measurements from incisal edge-cusp to the gingival margin .....	Page 44

## LIST OF FIGURES

1. Concept map of the study protocol .....	Page 16
2. First visit: Clinical evaluation and intraoral scan are taken and a CBCT scan....	Page 17
3. Components of Simplant Immediate smile Dentsply Sirona for implant placement and same-day restoration. ....	Page 18
4. Fully guided Surgical guide was used for implant placement .....	Page 18
5. Implant stability measured with Osstell ISQ stability meter.....	Page 19
6. On the day of the implant placement, a Perioderm Allograft soft tissue graft membrane was randomized.....	Page 19
7. If the implant has adequate primary stability, custom abutment and provisional were delivered on the same day of implant placement. ....	Page 20
8. After approximately four months of implant placement, the definitive crown was delivered, and a new intraoral scan was taken. ....	Page 21
9. Merging of STL before and after implant placement .....	Page 26
10. 3D comparison of merged STL in a sagittal plane with longitudinal measurements at the gingival margin, 1mm, 2mm, and 3 mm from the gingival margin. ....	Page 27
11. Mean longitudinal measurements of all groups between STL before implant placement and STL after delivery of definitive crown.....	Page 35
12. Mean longitudinal measurement of Grafted vs. non-grafted groups between STL before implant placement and STL after delivery of definitive crown.....	Page 36

<b>13.</b> Mean longitudinal measurements of all groups between STL after delivery of definitive implant crown and STL one year after implant placement.....	Page 37
<b>14.</b> mean the longitudinal difference between STL after delivery of definitive implant crown and STL one year after implant placement.....	Page 38
<b>15.</b> OHIP-14 Mean responses in control and test subjects pre-treatment and one year follow-up after treatment. ....	Page 41
<b>16.</b> Vertical Longitudinal analysis.....	Page 44

## **LIST OF ABBREVIATIONS**

CAD-CAM	Computer-assisted design, computer-assisted manufacture
IRB	Institutional review board
G.M	Gingival margin
OHQOL	Oral health-related quality of life
OHIP	The Oral Health Impact Profile
HIV	Human immunodeficiency virus
FGG	Free Gingival Graft
PRP	Platelet-rich plasma
PRF	Platelet-rich fibrin
ADM	Acellular dermal matrix
3D	Three-Dimensional
ISQ	Implant stability quotient
UIC	University of Illinois at Chicago
PI	Principal Investigator
Co-Is	Coinvestigators
COD-CRC	College of Dentistry Clinical Research Center
STL	Stereolithography

## Summary

Recent studies suggest a positive association between the volume of the peri-implant mucosa surrounding a dental implant. A soft allograft (e.g., PerioDerm®) has been advocated to increase mucosa volume avoiding autogenous soft tissue grafting morbidity. However, the evidence supporting this is limited and inadequately controlled, and prospective trials are lacking. This study evaluates whether including an allograft during implant therapy improves the implant's health and appearance.

Thirty-nine patients needing a single implant placement were recruited and enrolled in the study. Patients were randomized into test and control groups to receive or not a PerioDerm when the implant was placed. This was done following a fully digital and completely guided protocol by Immediate smile by Dentsply Sirona implants. In the test group, patients (19) received the PerioDerm at the implant placement appointment, while the control group (20) was left free of graft at implant placement. OHIP-14 questionnaire was asked to be answered before implant placement and then re-done one year after treatment. Intraoral scans of the complete arch were taken with a Trios 3 intraoral scanner before implant placement, at definitive crown delivery, and a year after implant placement. Then, STL files were used and merged to compare horizontal and vertical longitudinal changes in buccal tissue contours at the implant site at the gingival margin, and 1 mm, 2 mm, and 3 mm away from the G.M. Comparisons were made using Geomagic Control X 2020, 3D systems software. Graft dimensional measurements were taken by comparing the pre-treatment STL with implant crown delivery STL, as well as the comparison between delivery date STL and one-year post-surgery STL. Horizontal longitudinal measurements between groups when comparing STL before implant placement and STL after delivery of definitive crown were calculated, and independent t-test



resulted in a  $P=0.34$  at G.M, 0.20 at 1 mm from G.M, 0.13 at 2 mm from G.M. and 0.56 at 3 mm from G.M . Horizontal longitudinal measurements between post-treatment and one-year follow-up post-treatment, Independent t-test resulted in p values: 0.23 at the Gingival margin, 0.79 at 1 mm from the G.M, 0.32 at 2 mm from the G.M, and 0.56 at 3 mm from the G.M. Results describe nonsignificant differences between groups. Vertical measurements assessed the vertical changes within STL at the time of delivery and one-year follow-up. The mean result for the test group was 0.18 mm, and for the control group was 0.16 gain in vertical height of the G.M. An Independent t-test was performed, and the p-value was 0.77. The results are not statistically significant. However, both groups seem to have vertical gain over a one-year follow-up. OHIP-14 Results in patients demonstrate a positive impact on their OHQoL regardless of the use of graft, with an average total score of the test group of 2.47 after the 1-year follow-up after treatment. However, these low scores indicate that all patients have an excellent OHQo, and the differences were not statistically significant (  $p = 0.11$ ).

The findings suggest that there is a similar longitudinal dimensional change when performing allograft at the time of implant placement. However, allograft uses at implant placement are still a promising option to ensure favorable gingival contours around dental implant.

## **1. Introduction**

### **1.1 Background and Significance**

Edentulism includes psychological and physiological outcomes like loss of support and function, the continuation of residual ridge bone reabsorption, and loss of confidence. (Felton 2016) One of the treatments for partial and complete edentulism is dental implants; this procedure, with a 97% success rate for ten years, improves the maintenance of bone in the edentulous site while restoring missing teeth (Gupta, Gupta, and Weber 2022).

However, following implant placement, the remaining ridge tends to resorb from 0.5 to 1.0 mm approximately during the first year. (Pagni et al. 2012; Sanz et al. 2012). Keratinized mucosa is crucial to ensure peripheral sealing and resistance to mechanical forces and facilitate hygiene, which is critical for implant survival and bone support. A deficiency of Keratinized tissue, less than two millimeters around the implant, results in poor plaque control, marginal bone loss, gingival recession, and bleeding on probing (Tavelli et al. 2021).

Soft tissue augmentation promotes the health of peri-implant tissues by preventing crestal bone loss and maintaining peri-implant architecture for at least 48 months (Oh, Ji, and Azad 2020). Both autogenous grafts and allogeneic grafts are used for these purposes. Still, there is controversy regarding the effectiveness of this supplemental graft during implant treatment.

Recent studies suggest a positive association between the volume of the peri-implant mucosa surrounding a dental implant and the ultimate health and appearance of a dental implant-supported crown. Therefore, using a gum allograft (e.g., PerioDerm®) at implant placement has

been advocated to increase mucosa volume to avoid the morbidity of autogenous soft tissue grafting from the patient's palate (Herford et al. 2010).

Xenografts have successfully increased soft tissue thickness and volume stability with less morbidity and less duration of surgical procedures. The evidence supporting this is limited and inadequately controlled, and prospective trials still need to be improved. Despite this, many clinicians already use gum allografts during implant therapy. However, the most recent systematic review concerning the advantages of soft tissue augmentation, with only four randomized controlled trials, did not include any studies using allogeneic materials. Thus, the present literature identifies a significant gap in knowledge regarding using allogenic materials and relatively few longitudinal measurements of any soft tissue augmentation procedure. Nevertheless, the existing literature indicates that a submucosal connective tissue allograft placement is not associated with increased risks of implant failure or complications.

As the quality of dental treatments improves, patient feedback in evaluating different treatment modalities is more important. (Brennan et al. 2010) This can be obtained through oral health-related quality of life (OHQOL) assessments, such as the Oral Health Impact Profile (OHIP), which is a standardized tool to determine the impact of different dental treatments (Strassburger, Kerschbaum, and Heydecke 2006). OHIP has been a reliable tool for providing qualitative information about their experiences (Slade and Spencer 1994).

This study evaluates whether including an allograft during implant therapy improves the implant's health and appearance. A comparison of the clinical outcomes of placing a submucosal graft material in front of the dental implant immediately after the placement of the implant. In addition, this soft tissue augmentation was evaluated compared to implants placed without augmentation. An example of the significance of such a study is a healthy implant with sufficient

soft tissue and an anesthetic and an inflamed implant with mild tissue recession. Clinicians can prevent this by increasing the thickness of the peri-implant mucosa using allogenic graft materials.

## **1.2 Specific Aims**

This research aims to investigate:

- 1) Changes in the health and appearance of oral tissues in patients receiving an artificial gingiva soft tissue graft when the implant was placed. Specifically, we want to know if adding a PerioDerm® allograft with the dental implant will improve the health and appearance of a dental implant with a crown.
- 2) Comparing patient satisfaction and the effect on the OHQOL with implant placement when adding PerioDerm® allograft and the dental implant will improve patient satisfaction.

The study duration was approximately 18 months, involving six months of recruitment and 12 months of treatment and evaluation, and one year of follow-up from the day of implant placement.

## **1.3 Hypothesis**

- 1) Longitudinal Linear measurements comparison:
  - a. Null Hypothesis: Including soft tissue allograft (e.g., PerioDerm®) at implant placement does not affect implant health and appearance
  - b. Alternative Hypothesis: Including soft tissue allograft (e.g., PerioDerm®) at implant placement enhances implant health and appearance

- 2) OHIP-14 patient satisfaction Questionnaire
- a. Null Hypothesis: Including soft tissue allograft (e.g., PerioDerm®) at implant placement does not affect patient satisfaction.
  - b. Alternative Hypothesis: Patients will be more satisfied with soft tissue allograft (e.g., PerioDerm®) at implant placement.

## **2. Literature Review**

### **2.1 Considerations for implant treatment**

Before Implant therapy: consultation and exam are necessary for an adequate anamnesis of the patient regarding his medical and social history. Especially to patients immunocompromised with Diabetes, HIV, osteoporosis, and behavioral, neurogenic, psychosocial, and psychiatric disorders. Also, parafunctional habits present that could compromise the healing process after implant placement. (Daubert et al. 2015)

Special considerations are needed for patients taking hypertensive medication; antidepressant SSRI (Wu et al. 2014), proton pump inhibitors (Chrcanovic et al. 2017), and opioid anticoagulants could negatively influence the healing process. Contraindications include lack of bone, soft tissue pathology, infections, or related contraindications such as parafunctional habits.

Some risk factors for implant placements are severe bone disease causing impaired bone healing, medication with steroids, uncontrolled diabetes mellitus, irradiated bone, active periodontal infection, refractory periodontitis, smoking habits, non-compliant oral hygiene, and bruxism. (Buser, Martin, and Belser 2004)

## 2.2 Soft tissues and hard tissues considerations

Implant success requires sufficient alveolar bone volume and mucosal tissue to protect against biofilm-mediated inflammation, assure functional comfort, and contribute to dental implant esthetics. (Borges et al. 2020)

Extraoral, it is necessary to evaluate: the height of the smile line, lip support, midline, occlusal plane, incisal edge position at rest, and smile symmetry. (Sadowsky and Hansen 2014)

Intraorally, adequate evaluation of the bone and soft tissue volume to achieve successful treatment outcomes of a single implant. Implant success requires sufficient bone alveolar volume and good mucosal tissue to protect against biofilm-mediated inflammation, assure functional comfort, and contribute to dental implant esthetics. (Borges et al. 2020)

Soft tissue Evaluation: gingival esthetics accompany healthy free buccal keratinized soft tissue and appropriate attached mucosa levels to create papillae and proper gingival contours.

Keratinized mucosa ensures peripheral sealing and resistance to mechanical forces and facilitates hygiene.

Ways to measure gingival esthetics:

- Several factors are evaluated with the Pink esthetic score: mesial and distal papilla height, soft tissue level, contour, texture, and alveolar process deficiency. (Furhauser et al. 2005)
- Papilla index: evaluates the level of interproximal mucosa, medial and distal papilla adjacent to the implant. Scores 0 (no papilla) to 4 (hyperplasia papilla).
- Other factors to be considered are biotype, probing depth, gingival health, the balance of gingival levels (zeniths), gingival morphotype, presence and width of keratinized

mucosa, presence of keratinized gingiva, position and quantity of gingival tissue, tissue biotype, oral hygiene.

#### Hard tissue Evaluation:

- Condition of adjacent teeth: arrangement, tooth shape, contour, and shade of adjacent teeth.  
Supra eruption of antagonist. Tilt and drift teeth
- The white esthetic score evaluates factors such as tooth form, outline, volume, color, surface, texture, translucency, and characterization. (Belser et al. 2009)
- Interocclusal relationship
- Dimension of the edentulous gap: Mesiodistal space
- Evaluation of edentulous ridge: osseous crest buccolingual width dimensions and architecture. Compromised esthetic outcomes due to the crest collapse that occurs following extraction. Especially during the first three months after the extraction, it is a significant risk.
- Buccal Bone Changes after implant considerations

### **2.3 Bone changes after extraction and implant placement**

Research has demonstrated that following dental implant placement in healed ridges or extraction sockets, the alveolar ridge continues to resorb approximately 0.5 to 1.0 mm during the first year of healing. (Chappuis et al. 2013)

Healed ridges are also often volumetrically deficient, losing up to 30% of their horizontal volume following tooth extraction. Following dental implant placement, the alveolar ridge resorbs approximately 0.5 to 1.0 mm during the first year. (Pagni et al. 2012; Sanz et al. 2012)

The volume of an alveolar ridge can be measured by taking a 3D intraoral scanning and clinically as a metric of oral health. (Fernandes et al. 2021; Avila-Ortiz et al. 2020; Tavelli, Barootchi, Majzoub, et al. 2021; Borges et al. 2020)

## **2.4 Importance of having keratinized tissue band**

Implants, compared to teeth, lack periodontal fibers and collagenous supra-crestal connective tissue fibers. Therefore, keratinized tissues are needed around implants to preserve the bone surrounding. In addition, the soft tissue seal around implants is important for long-term success because it simplifies hygiene and provides a friendly environment for peri-implant tissues(Luo et al. 2020)

Plaque control is improved with 2 mm or more keratinized tissue around implants. However, when lack of keratinized tissue, an increase is needed. Then, an autogenous connective tissue graft or allograft procedure is a possible alternative to stabilize the interproximal marginal bone levels. (Thoma et al. 2018)

The insufficient width of attached and keratinized mucosa around implants may induce a higher degree of mucosal tissue recession. The presence of an adequate width of keratinized attached mucosa around the implant favors peri-implant health. There is a strong correlation between the long-term stability of pink esthetics and a thick peri-implant phenotype. (Chackartchi, Romanos, and Sculean 2019)

Deficient keratinized mucosa width of less than 2 mm increases the likelihood that the patient will have discomfort—suboptimal plaque control, marginal bone loss, and bleeding on probing. (Tavelli, Barootchi, Avila-Ortiz, et al. 2021)



Lack of Keratinized mucosa negatively affects crestal bone levels around dental implants. Augmentation of keratinized mucosa for dental implants prevents crestal bone loss for at least 48 months. (Oh, Ji, and Azad 2020)

To account for this loss in peri-implant architecture, peri-implant mucosal grafting has been proposed and is currently part of dental implant therapy. Both autogenous grafts (mucosal connective tissue from the roof of the patient's mouth or "palate") and allogeneic grafts (collagen-rich grafts derived from a genetically non-identical human donor) are used for these purposes. Still, there is controversy regarding the effectiveness of this supplemental graft during implant treatment. (Schneider et al. 2011; Zuiderveld, Meijer, den Hartog, et al. 2018; Froum et al. 2015; Zuiderveld, Meijer, Vissink, et al. 2018).

## **2.5 Soft tissue augmentation**

Mucosal grafting for peri-implant tissues has been proposed and is currently part of dental implant therapy. (Fernandes et al. 2021; Schneider et al. 2011)

Principles of Soft tissue grafting (Luo et al. 2020):

Recipient site:

- Must be vascularized
- Must facilitate rigid immobilization and intimate adaptation of the donor tissue.
- Excess movement of the graft precludes starving the site of adequate nutrition.

Therefore, large areas should include a pedicle rather than a free graft.

Donor site:

- The harvested graft should have a uniform thickness to facilitate intimate adaptation and immobilization to the recipient site
- Secondary contracture is often a concern when considering the thickness of a harvested graft.

Soft tissue augmentation promotes the health of peri-implant tissues. An Osteology foundation consensus systematic review observed that plaque indexes are reduced on implants treated with soft tissue augmentation. (Giannobile, Jung, and Schwarz 2018)

## **2.6 Soft tissue grafting techniques used around implants:**

### **1-Autogenous graft**

- Free Gingival graft: a graft harvested from the palate with an overlying epithelium—indications of increased keratinized tissue width, adequate gingival thickness, and increased vestibular depth. (Zucchelli et al. 2020) Free gingival Grafts can be a practical treatment option to maintain crestal bone loss around implants with limited keratinized mucosa. (Oh, Ji, and Azad 2020) However, FGG, the harvested graft, retains the tissue characteristics from the donor site, eliminating FGG as a treatment option for anterior esthetic areas. Additionally, the donor site is left with a soft tissue defect that must heal by secondary intention. (Luo et al. 2020).
- Connective tissue graft could be harvested by several sites such as the palate or the maxillary tuberosity, de-epithelialized FGG., aiming to lower donor site morbidity and pt discomfort. It provides a harmonious gingival margin resulting in better esthetics when compared to FGG, which retains its original appearance of the palatal tissue.

Autologous soft tissue grafting is highly predictable and effective in achieving soft tissue augmentation around natural teeth and dental implants. (Zucchelli et al. 2020).

Marginal bone levels around implants had better outcomes for those implants treated with apically positioned flaps in conjunction with autogenous grafts than all other treatments. Therefore, they concluded that connective tissue graft is the most appropriate, especially considering it helps maintain marginal bone levels.

Free gingival grafts remain the gold standard for soft tissue grafts. However, there exists a change of complications with this graft, such as

- The most common complications are associated with the donor site: excessive bleeding, postoperative bone exposure, a painful open palatal wound, and discomfort when chewing.
- The duration of the procedure is related to postoperative complications and pain.

There are also contraindications for this type of graft, such as

- Collagen disorders such as erosive lichen planus and pemphigoid.
- Smoking
- Local factors: adequate tissue thickness at the palatal donor site or restricted surgical access to intraoral donor sites.

Knowledge of soft tissue healing and management techniques and proper treatment planning enables the clinician to avoid short and long-term complications and meet the increasing esthetic demands of the patient. (Chackartchi, Romanos, and Sculean 2019)

## 2- Allograft

Is a freeze-dried dermal matrix that has removed cellular components. - shrinkage is noticeably higher - The disadvantage is lack of ability in epithelial differentiation. The amount of time required to incorporate the graft is higher because vasculature or cells are absent. (Luo et al. 2020)

## 3- Xenografts

Xenogeneic collagen matrix has lower patient morbidity and is equivalent to Connective tissue graft for peri-implant soft tissue augmentation. (Gargallo-Albiol et al. 2019)

Xenograft mucosal materials are grafts from non-human donors. Popular in Europe, where allograft materials are not widely used and used for soft tissue augmentation at implants, xenografts have successfully increased soft tissue thickness and volume in a stable manner. (Zeltner et al. 2017)

- Platelet-rich plasma (PRP) - harvested from the patient's plasma mixed with an anticoagulant, then centrifuged to isolate the platelets from the plasma. This isolate contains multiple biologically active components and growth factors conducive to wound healing, including fibrin, fibronectin, and vitronectin. (Luo et al. 2020)
- Platelet-rich fibrin (PRF) - is a second-generation modification of PRP, designed for increased operator convenience by eliminating the need for thrombin application for clot formation - PRF has been shown to sustain the release of growth factors for between 7 and 28 days. (Luo et al. 2020)

## **2.7 Free gingival connective tissue graft vs. synthetic**

A detailed systematic literature review by Tavelli et al. compared mucosa thickness among different tissue augmentation techniques; Connective tissue graft and acellular dermal matrix (ADM) had the most significant mucosa thickness gain. (Tavelli, Barootchi, Avila-Ortiz, et al. 2021)

Soft tissue stability after a connective tissue graft around implants depends on multiple factors and cannot be determined clearly by existing studies that differ. A review discovered that connective tissue grafts enhanced keratinized mucosa width and soft tissue thickness for an observation period of up to 48 months. However, some shrinkage may occur and decrease soft tissue by more than 40 %, mainly in the first three months. (Poskevicius et al. 2017)

Both autogenous grafts (mucosal connective tissue from the roof of the patient's mouth or "palate")(van Nimwegen et al. 2018) and allogeneic grafts (collagen-rich grafts derived from a genetically non-identical human donor) are used for these purposes. Still, there is controversy regarding the effectiveness of supplemental graft use during implant treatment. (Tavelli, Barootchi, Majzoub, et al. 2021)

The studies cited above attest to the safety and efficacy of soft tissue grafting at implants. In addition, these studies have not indicated that soft tissue grafting at implants increases the risk of implant failure. Further, there is evidence that increased soft tissue thickness enhances the patients' comfort when performing oral hygiene and reduces associated signs of inflammation, such as bleeding on probing. These cited studies further revealed no incidence of untoward morbidity or related complications.

The general conclusion of a recent systematic review concerning the effects of soft tissue augmentation procedures on peri-implant health or disease were: 1) good peri-implant health, 2)

increased keratinized mucosa, 3) reduced bleeding on probing, 4) less marginal bone loss with increased mucosal thickness. These advantages were reported in 10 articles. However, only four studies were randomized controlled trials. (Thoma et al. 2018)

Unfortunately, this review did not include any studies that have used allogeneic materials like those proposed here. Thus, the present literature identifies a significant gap in knowledge regarding using allogeneic materials for soft tissue augmentation at dental implants and relatively little volumetric assessment of any soft tissue augmentation procedure. Nevertheless, the existing literature indicates that a submucosal connective tissue allograft placement is not associated with increased risks of implant failure or complications.

Recent studies suggest a positive association between the volume of the peri-implant mucosa surrounding a dental implant and the ultimate health and appearance of a dental implant-supported crown. Therefore, the use of a gum allograft (e.g., PerioDerm®) at the time of implant placement has been advocated to increase mucosa volume to avoid the morbidity of autogenous soft tissue grafting from the patient's palate (Herford et al. 2010)

However, the evidence supporting this is limited and not adequately controlled, and prospective trials still need to be improved. Despite this, many clinicians already use gum allografts during implant therapy.

## **2.8 Immediate smile: one-time abutment concept and its effect on marginal bone loss**

Digital technology can be used as a tool for planification and ensuring that all procedures go according to plan. Possible errors from the conventional analog methods are eliminated with the use of a digital workflow. As well as minimizing the number and time of appointments. This

is crucial for the success of oral rehabilitation, especially in the esthetic zones (Kongkiatkamon and Rokaya 2022)

“One abutment, One time” means that the final abutment at the bone level is placed over the implant from implant placement and not removed. Compared with a repeated disconnection of the healing abutment, placing the definitive abutments in the same implants could influence the maintenance of the peri-implant crestal bone. As well as, the higher the abutment, the better influence on the maintenance of the Crestal bone level around the implant (Ríos-Santos et al. 2020)

The constant removal and placing back of abutments have been associated with the contribution of bone loss between implant placement and six months post-loading and 3 -year follow-up compared to one-time abutment placement. (Molina et al. 2017).

## **2.9 Intraoral scanning value in doing the longitudinal measurements.**

It is known that IOS can improve the patient experience and comfort and can provide reliable prosthodontic outcomes while still reducing procedure working procedure time. (Siqueira et al. 2021) However, IOS technology can be valuable for analyzing changes between scans over time. In research, this tool has been applied to measure the amount of dental wear (O'Toole et al. 2019) and tissue changes by merging scans and employing linear (3D) measures to study outcomes. (Bienz et al. 2017) Using 3D measurement to assess outcomes of soft tissue changes at implant placement is essential to evaluating this clinical intervention. (Marzadori et al. 2018)

### **3. METHODOLOGY**

#### **3.1 Study Design**

This study is a prospective randomized interventional clinical study that compares the use of PerioDerm® soft tissue allograft (“+Graft”) at the time of implant placement and restoration with crown therapy; with the standard dental implant placement with crown therapy alone (“-Graft”).

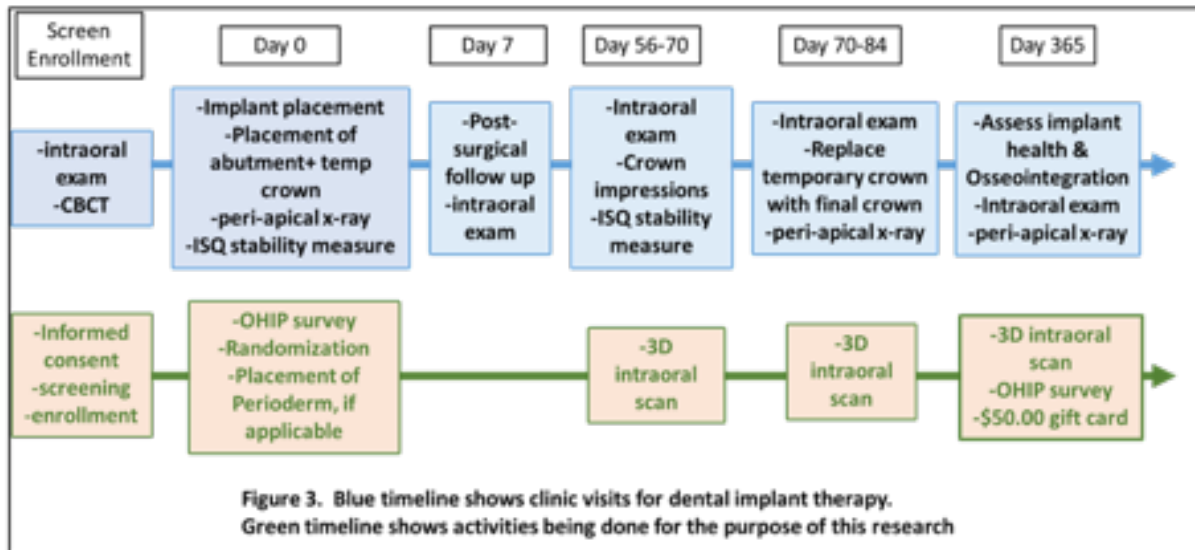
Study Outcomes:

- Primary outcomes are the alveolar ridge longitudinal measurements. In addition, implant survival, probing depths, and complications were recorded.
- Secondary outcomes are implant survival, bleeding upon probing, and patient satisfaction measured by the OHIP patient survey.

The study was performed at the UIC Dental School Clinical Research Center and involved multiple clinic visits. These clinic visits usually occurred at the same time as the subject's clinic visits for implant therapy to avoid any research-only visits. The timeline for obtaining a dental implant is shown in Figure 1 in blue, with research visits shown in green, and is described below:



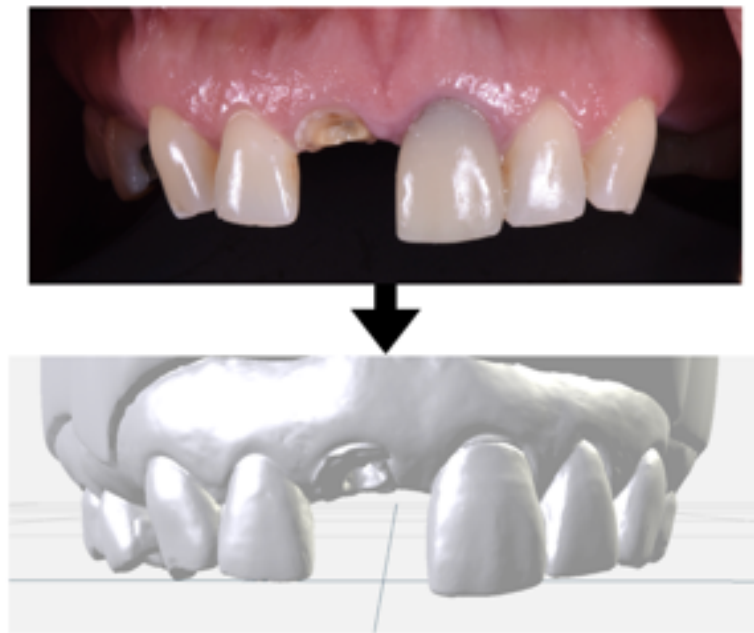
Figure 1: Concept Map of Study Protocol



# 1. First visit: (“Screening/Enrollment”)

Subject screening, enrollment, and the informed consent discussion occurred at this visit. The subject’s medical and dental history was obtained upon obtaining consent. In addition, a scanned image of the subject's jaw bones called a “cone beam CT” (CBCT) and a 3D intraoral scan is obtained for a standard of care. This visit required 30 - 60 minutes.

Figure 2: First visit, clinical evaluation and intraoral scan and CBCT scan are taken.



## 2. Second visit: (“Implant surgery”)

The second visit was coordinated as the usual treatment for dental implant therapy. The subjects were asked to complete the OHIP patient satisfaction questionnaire before implant surgery. Patients were instructed to answer the questions only as they pertained to their experiences with the OHIP-14 questionnaire.

Additionally, at the second visit, subjects were randomized (+Graft vs. -Graft) by authorized study personnel, and his/her implant, with abutment and temporary crown, was placed (+/- Graft). The abutment and temporary crown were placed onto the implant if primary stability was achieved. If this implant was not stable enough, a healing abutment was placed instead, and a removable temporary was provided within 24 hours. The experimental variable in this study is the placement of a submucosal allograft in randomized patients. PerioDerm® is not an experimental material and is available in the USA.

Figure 3: Components from Simplant Immediate-Smile Dentsply Sirona for implant placement and same-day provisional restoration

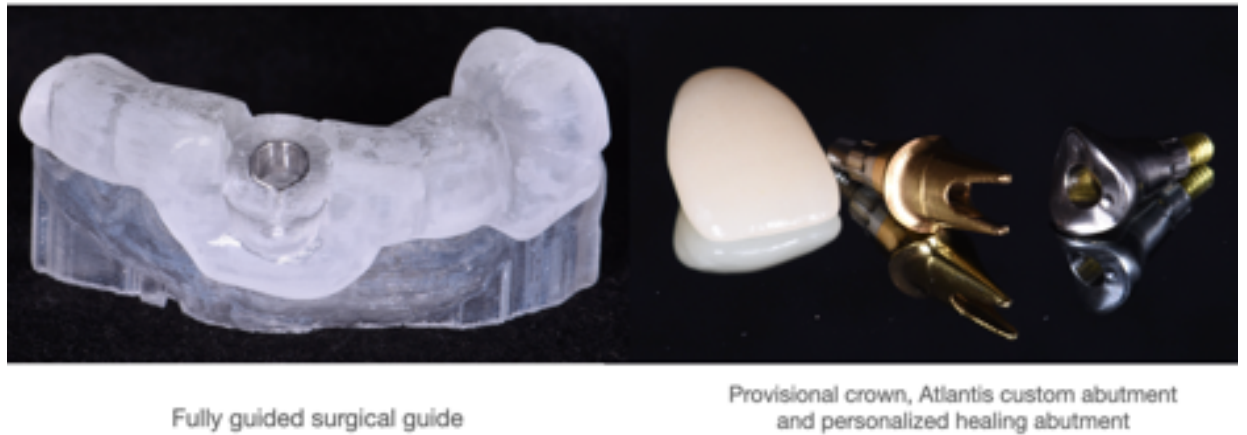


Figure 4: Fully guided surgical guide was used for implant placement



Figure 5: Implant primary stability measured with Osstell ISQ stability meter



Figure 6: The day of the implant placement, it was randomized to use a Periderm allograft soft tissue graft membrane.



Figure 7: If the implant has adequate primary stability, custom abutment and provisionals were delivered on the same day of implant placement.



### 3. Third visit: (“1-week follow up”)

The third visit was an approximately 1-week post-surgical follow-up and is standard of care. This visit required approximately 15 – 30 minutes. Again, if any complication was observed, appropriate standard-of-care interventions were done.

### 4. Fourth visit: (“8 weeks: crown impression”),

This visit was an optional, approximately 8-week post-surgical follow-up and is standard of care. At this visit, the implant health and osseointegration were assessed by tactile evaluation, and impressions were taken for a Final crown. At this visit, a 3D intraoral scan was performed for research purposes. This visit required approximately 1.5 hours. When any complication was observed, appropriate standard-of-care interventions were done. When the implant failed to osseointegrate, the implant was explanted in an atraumatic technique. Then, the implant was replaced.

### 5. Fifth visit (10-12 weeks; crown delivery)

This visit was approximately 10-12 weeks post-surgery and is standard of care. At this visit, implant health and osseointegration were assessed by tactile evaluation, and the final crown was delivered. This visit required approximately 1.5 hours. The appropriate standard of care interventions was made when any complication was observed. If the implant failed to osseointegrate, the implant was explanted in an atraumatic technique. Then, the implant was replaced.

Figure 8: after four months of implant placement, the definitive crown was delivered, and a new intraoral scan was performed.



#### 6. Sixth visit: (“1-year follow-up”)

This final visit was an approximately 1-year post-surgical follow-up performed following the standard of care. Additionally, a 3D intraoral scan was performed. The subject was asked to complete the OHIP patient satisfaction questionnaire. This visit required approximately 30 – 60 minutes.

## Expected Risks/Benefits

The risks of dental implant therapy are minimal. Still, they include complications such as bleeding and bruising after surgery, post-surgical pain, infection, delayed healing, temporary speech problems, bone fracture, temporary or permanent damage to the nerves of the jaw, loss of bone on the upper or lower jaw (including the altered appearance of the gum line), infection in the bone, damage to the adjacent teeth, chronic pain, abscess, and infection of the gums.

Risks of a PerioDerm® allograft include local or systemic infection, dehiscence (wound rupture along the line of incision), and necrosis (death of tissue) due to poor revascularization or allergic response to some component(s) of the graft material. Following the graft manufacturer's instructions, tissue recipient records for subjects receiving PerioDerm® will be maintained for post-transplant tracing, which could increase the risk to the privacy of subjects randomized to +Graft.

CBCT and other 3D intraoral scanners capture light-generated images, compiled by the appropriate software into a 3-dimensional geometric image. Since these scanners do not utilize x-ray technology, the medical risks of use are minimal and include mild fatigue of the facial muscles.

Subjects were encouraged to contact the PI in the event of medical emergencies related to their dental care answer provided with a 24-hour emergency contact number. Subjects experiencing complications required additional (>5) clinic visits during this study. This was indicated within the consent document. If implant integration fails or the implant site was infected, the implant is explanted in an atraumatic technique. Then, the implant was replaced. Restoration of the oral cavity benefits all subjects, irrespective of the study group. The potential for an

enhanced restoration in the +Graft study group, as compared to the –Graft group, is the focus of this study.

### 3.2 Materials and Methods

Eligibility,

The subject population was:

- a. Patients at the UIC Dental School who desired placement of a dental implant for an already missing tooth or
- b. Patients at the UIC Dental School who desired placement of a dental implant for a tooth that was soon to be extracted or
- c. Patients in the community who desired placement of a dental implant: for an already missing tooth or a tooth that was soon extracted.

The UIC PI assessed and determined subject eligibility at UIC with assistance from authorized UIC study co-investigators (Co-Is) and coordinators.

Inclusion Criteria

Patients within the UIC Dental School and the community are:

- at least 18 years of age and
- willing and able to provide informed consent.
- in need of one implant to replace a missing tooth
- at least 20 teeth in good repair and occlusion



- Sufficient bone volume for dental implant placement without required bone augmentation
- Site development (soft or bone tissue) performed at least five months before implant placement when required.

### **Exclusion Criteria**

- The implant cannot be placed without a bone graft
- Unable to pay for the crown
- Current smoker
- Untreated rampant caries and uncontrolled periodontitis
- Current alcohol or drug abuse
- Absence of adjacent (mesial and distal) natural tooth
- Uncontrolled diabetes
- Systemic or local disease or condition that would compromise post-operative healing and osseointegration
- Use of bisphosphonates
- History of radiation in the head and neck region
- Unable or unwilling to return for follow-up visits
- Unrealistic esthetic or functional demands
- Unlikely to be able to comply with study procedures
- Unwilling or unable to provide informed consent

This study did not include Vulnerable Populations (minors, pregnant women, and prisoners).

### **Subject Enrollment**

Subjects screened by the UIC PI, UIC Co-I, and authorized UIC study personnel at the UIC College of Dentistry Clinical Research Center. Dental Axium records were reviewed for recruitment purposes. Patients attending the UIC Dental Clinic who desired implant therapy were examined per standard of care; those found eligible for dental implant therapy were also screened for possible study inclusion.

Recruitment flyers were posted on campus and on the websites of both UIC and the Chicago Dental Society. In addition, a recruitment email was periodically released on the UIC campus listserve. Interested patients were instructed to contact the College of Dentistry Clinical Research Center (COD-CRC) to schedule a screening appointment where informed consent discussion and study eligibility will be confirmed.

The total subjects enrolled and treated were 39 participants between the ages of twenty-seven (27) and seventy-four (74) years old, twenty-four (24) females and fifteen (15) males.(Table #1) Using a fully digital surgical and restorative protocol Simplant® Immediate Smile® sponsored by Dentsply Sirona Implants. Nineteen (19) participants received an allograft dermal graft, called commercially PerioDerm®, at implant placement and provisionalization, and twenty (20) did not.

### **Methods:**

- 1) Volumetric longitudinal changes in millimeters differ between scans before implant placement (pre) and after the implant is restored (post). As well as Volumetric longitudinal changes in millimeters differences between a scan after the implant are restored (post) and a scan one year after follow-up (1-year post):

For this part of the study, 3D intraoral scanners capture light-generated images, compiled by the appropriate software into a 3-dimensional geometric image. Intraoral scans of the complete arch were taken with a Trios 3 intraoral scanner before implant placement, at definitive crown delivery (4 – 6 months), and a year after implant placement. Then, STL files were used and merged to compare longitudinal changes in buccal tissue contours at the implant site at the gingival margin and also 1 mm, 2 mm, and 3 mm away from the gingival margin. Comparisons were made using a 3D analysis software program, Geomagic Control X 2020, 3D systems software. STL merged and compared with longitudinal measurements was: (a) STL before implant placement with the STL of the delivery date and (b) STL delivery date with the STL 1 year after implant placement.

Figure 9: Merging of STL before implant placements with STL after implant placement

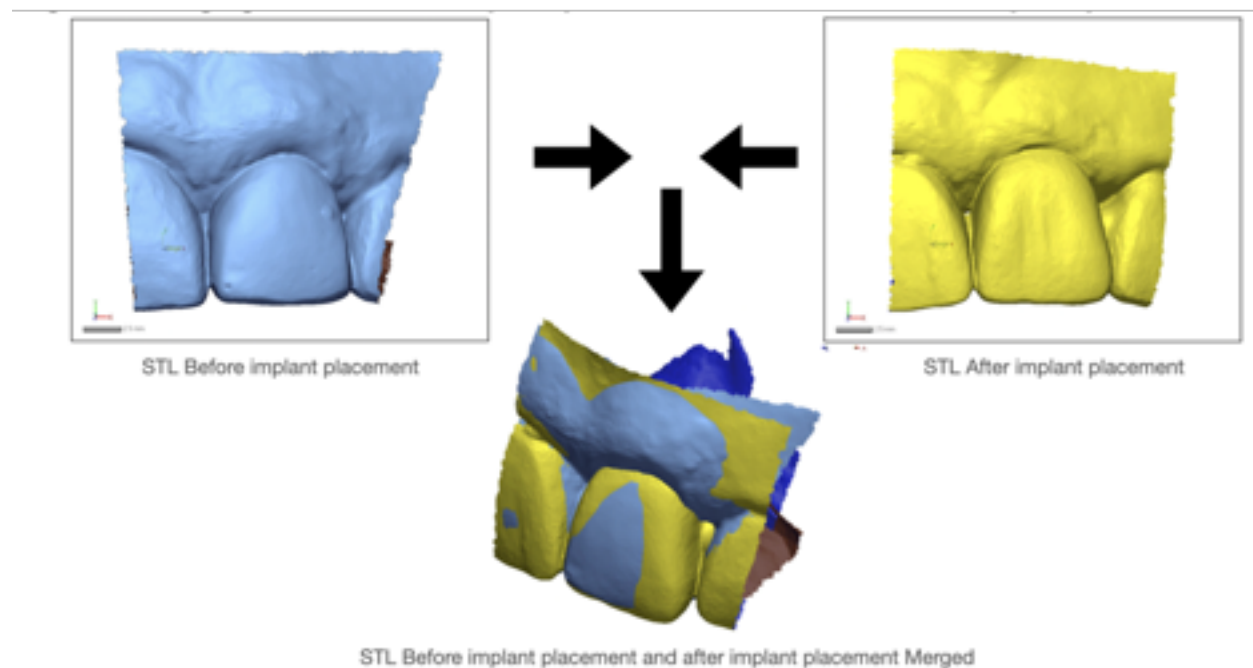
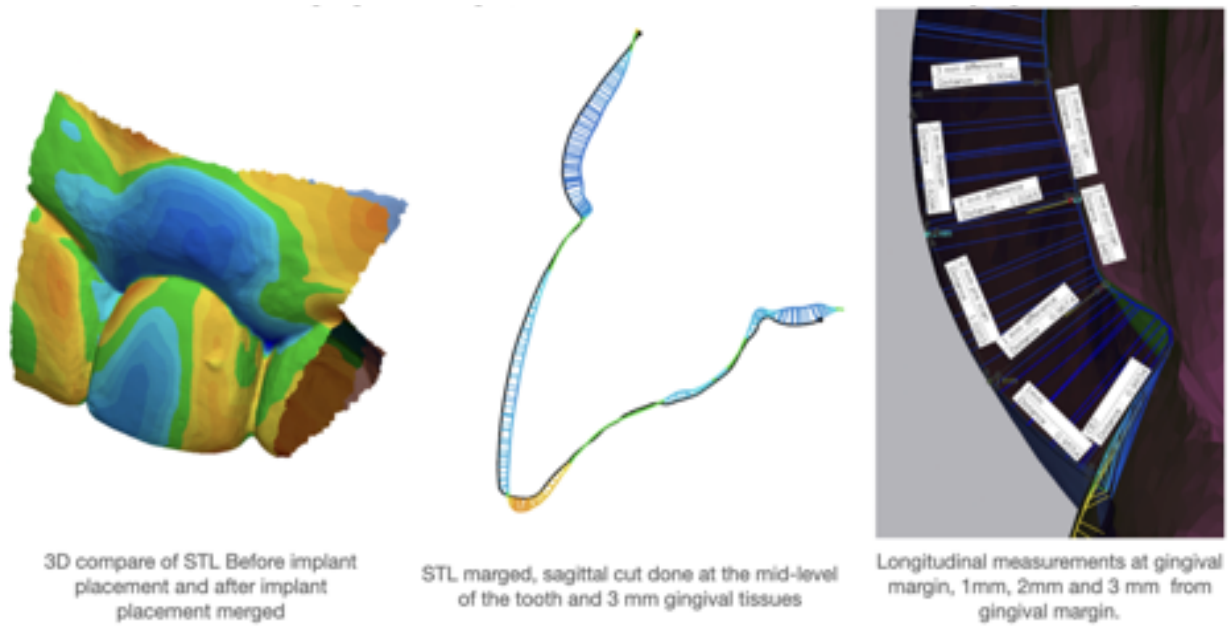


Figure 10: 3D comparison of merged STL in a sagittal plane with longitudinal measurements at the gingival margin, 1mm, 2mm, and 3mm from the gingival margin.



### **Oral Health-Related Quality of Life**

Severity scores were averaged for the OHIP-14 survey. Patients responded to each of the 14 survey questions regarding the incidence of a given complication with an answer from “never”=0 to “very often”=4. Therefore, the total score range from 0 to 56; the closer a score is to 0, the better the patient’s OHQoL. (Table #1)

Table #1: OHIP-14 survey questions and the score of each response.

**OHIP-14**

Study subject ID \_\_\_\_\_

Study subject ID \_\_\_\_\_

**OHIP-14**

	Never (0)	Hardly Ever (1)	Occasionally (2)	Fairly Often (3)	Very Often (4)
1. Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Have you had painful aching in your mouth?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Have you ever been self-conscious because of your teeth, mouth or dentures?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Have you ever felt tense because of problems with your teeth, mouth or dentures?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Have you ever had to interrupt meals because of your teeth, mouth or dentures?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Have you found it difficult to relax because of problems with your teeth, mouth or dentures?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Have you been totally unable to function because of problems with your teeth, mouth or dentures?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

### 3.3 Statistical Analysis

Excel software microsoft 365 app software was used for descriptive and statistical analyses.

An independent t-test was used, mean average of the longitudinal comparisons was determined separately for the overall sample for each group.

Average OHIP-14 scores were calculated. For statistical analyses, significance levels were set at  $p < 0.05$ . An independent t-test was used, mean average as determined separately for the overall sample for each group.

### 3.4 IRB Approval

Informed consent was obtained under a protocol (# 2019-0255.) reviewed and approved by the University of Illinois at Chicago Institutional Review Board for human participation in this study.

## 4. Results

### 4.1 Demographic Results

Thirty-nine patients presented to the clinic for dental examination and met the inclusion criteria. The study sample includes men and women with an age range of twenty-seven (27) and seventy-four (74) years old, twenty-four (24) females, and fifteen (15) males. (Table #1) Using a fully digital surgical and restorative protocol Simplant® Immediate Smile® sponsored by Dentsply Sirona Implants. Nineteen (19) participants received an allograft dermal graft, called commercially PerioDerm®, at implant placement and provisionalization, and twenty (20) did not. (Table #2)

Table #2. Demographics

	Group	Age	Gender
1	Test	68	Female
2	Test	42	Male
3	Test	49	Male
4	Control	27	Male
5	Control	47	Female
6	Test	48	Female
7	Test	74	Female
8	Control	52	Male
9	Control	45	Female
10	Test	44	Male
11	Control	43	Male
12	Test	52	Male
13	Test	67	Female
14	Control	42	Male
15	Control	44	Male
16	Test	44	Male
17	Control	38	Female
18	Control	68	Female
19	Control	69	Female
20	Control	58	Female

21	Control	65	Female
22	Test	37	Male
23	Control	50	Female
24	Test	62	Male
25	Control	56	Female
26	Test	53	Female
27	Control	50	Female
28	Control	60	Female
29	Control	35	Female
30	Test	47	Male
31	Test	25	Female
32	Test	38	Female
33	Test	71	Female
34	Control	53	Male
35	Test	50	Female
36	Test	40	Female
37	Control	84	Male
38	Control	74	Female
39	Control	55	Male

## 4.2 Collected Data

Comparison of grafted and non-grafted with longitudinal measurements in millimeters difference between STL before implant placement and STL after delivery of definitive crown displayed in Table 3.

Table #3. Pre-treatment and post-treatment longitudinal comparison at the gingival margin (G.M), 1mm from G.M, 2mm from G. M, 3mm from G.M.

	Implant Site	Group	At G.M	1mm from G.M	2mm from G.M	3mm from G.M
1	9	Test	-0.99	-0.96	-1.02	-0.9
2	19	Test	2.1	2.78	2.91	2.76
3	30	Test	1.4	1.44	1.15	1.08
4	30	Control	1.26	0.94	0.63	0.46
5	5	Control	0.83	0.79	0.57	0.36



6	29	Control	1.74	1.56	1.18	0.67
7	21	Test	0.62	0.23	0.1	0.19
8	31	Test	1.05	0.97	1.08	0.94
9	13	Control	1.14	1.54	1.32	1.11
10	13	Test	1.8	1.64	1.4	0.93
11	9	Control	0.34	0.28	0.33	0.25
12	4	Test	1.06	0.72	0.56	0.31
13	8	Control	0.68	0.3	0.22	0.09
14	12	Control	0.03	0.14	0.07	0.3
15	9	Test	0.08	0.012	0.025	0.024
16	19	Test	0.72	0.87	1.15	1.28
17	20	Control	1.34	1.65	1.52	1.34
18	30	Test	0.82	0.41	0.21	0.33
19	10	Control	1.43	2.02	1.78	1.38
20	30	Control	2.93	1.85	1.71	1.79
21	13	Control	0.56	0.43	0.55	0.41
22	9	Control	2.44	2.87	2.64	2.35
23	5	Control	0.97	0.92	0.74	0.65
24	5	Test	0.86	0.888	1.06	1.15
25	31	Control	0.11	-0.18	-0.19	-0.2
26	8	Test	0	-0.1	0.14	0.3
27	18	Control	-3.2	-2.8	-2.5	-2.5
28	14	Control	0.64	0.23	-0.03	-0.1
29	9	Test	0.64	1.04	0.95	0.29
30	9	Test	0.2	0.2	0.6	0.3
31	30	Test	1.03	1.06	1.24	1.23
32	19	Test	1.48	1.26	1.07	0.93
33	19	Test	1.61	1.57	1.02	1
34	8	Control	0.47	0.38	0.37	0.39
35	6	Test	1.39	1.71	1.72	1.39
36	12	Test	1.24	1.18	0.9	0.61
37	29	Control	-1.34	-1.22	-1.13	-0.41
38	10	Control	-1.1	-0.75	-0.65	-0.73
39	29	Control	1.47	1.89	1.72	1.47

Mean and standard deviation of nongrafted (Control) subjects of longitudinal comparison between Pre-treatment and post-treatment delivery day.

	At G.M	1 mm from G.M	2mm from G.M	3mm from G.M
Mean	0.99	1.05	1.01	0.75
Standard Deviation	0.67	0.77	0.73	0.87

Comparison of grafted and non-grafted with longitudinal measurements in millimeters difference between STL after delivery of definitive crown and STL one year after implant placement.

Displayed in Table 2 values displayed in yellow are the values for grafted subjects and blue for the values of the non-grafted subject. Patients lost for follow up displayed in red.

Table #4 Post-treatment and 1-year follow-up after treatment longitudinal analysis.

	Implant Site	Group	At G.M	1mm from G.M	2mm from G.M	3mm from G.M
1	9	Test	0.32	0.36	0.28	0.27
2	19	Test	-0.87	-0.77	-0.82	-0.79
3	30	Test	0.99	0.93	0.24	-0.15
4	30	Control				
5	5	Control	-0.05	0.07	0.19	0.18
6	29	Control	0.13	-0.17	-0.18	-0.19
7	21	Test	-0.11	-0.21	-0.24	-0.15
8	31	Test	1.00	1.25	0.78	0.36
9	13	Control	-1.02	-0.86	-0.74	-0.71
10	13	Test	-0.18	-0.14	-0.13	-0.14
11	9	Control	0.26	0.1	0.11	0.04
12	4	Test	0.23	0.19	0.19	0.28
13	8	Control	0.39	0.32	0.2	0.15
14	12	Control	-0.22	-0.31	-0.28	-0.26
15	9	Test	-0.09	-0.08	-0.01	-0.02
16	19	Test	1	0.58	0.24	0.25
17	20	Control	0.11	-0.18	-0.16	-0.13
18	30	Test	0.56	0.27	-0.2	-0.18
19	10	Control				
20	30	Control	0.02	-0.4	-0.16	-0.17
21	13	Control	-0.17	-0.13	-0.23	-0.29
22	9	Control	0.18	-0.12	-0.14	-0.16
23	5	Control	-0.11	-0.16	-0.17	-0.17
24	5	Test	-0.07	0.39	0.36	0.55
25	31	Control	1.1	0.14	0.25	1.19
26	8	Test	0.19	0.06	0.05	0.06
27	18	Control	-0.25	-0.21	-0.22	-0.20
28	14	Control	0.9	0.74	0.48	0.36
29	9	Test	0.5	0.46	0.53	0.47
30	9	Test	0.06	0.04	-0.10	-0.17

31	30	Test	1.4	1.2	0.53	0.36
32	19	Test	0.2	0.2	-0.15	-0.25
33	19	Test	0.17	0.06	-0.28	-0.63
34	8	Control	0.1	0.21	0.2	0.15
35	6	Test	0.7	0.19	0.03	0.09
36	12	Test	0	-0.15	-0.22	-0.20
37	29	Control	0.73	0.5	0.37	0.28
38	10	Control	0.29	0.31	0.34	0.36
39	29	Control	-0.03	-0.19	-0.26	-0.27

Mean and standard deviation of nongrafted (Control) subjects of longitudinal comparison between post-treatment 1 year follow up

	At G.M	1 mm from G.M	2mm from G.M	3mm from G.M
Mean	0.33	0.12	0.065	0.09
Standard Deviation	0.39	0.29	0.23	0.34

Mean and standard deviation of grafted (Control) subjects of longitudinal comparison between post-treatment 1 year follow up

	At G.M	1mm from G.M	2mm from G.M	3mm from G.M
Mean	0.14	0.094	-0.007	-0.04
Standard deviation	0.46	0.34	0.28	0.32

### 4.3 **Results**

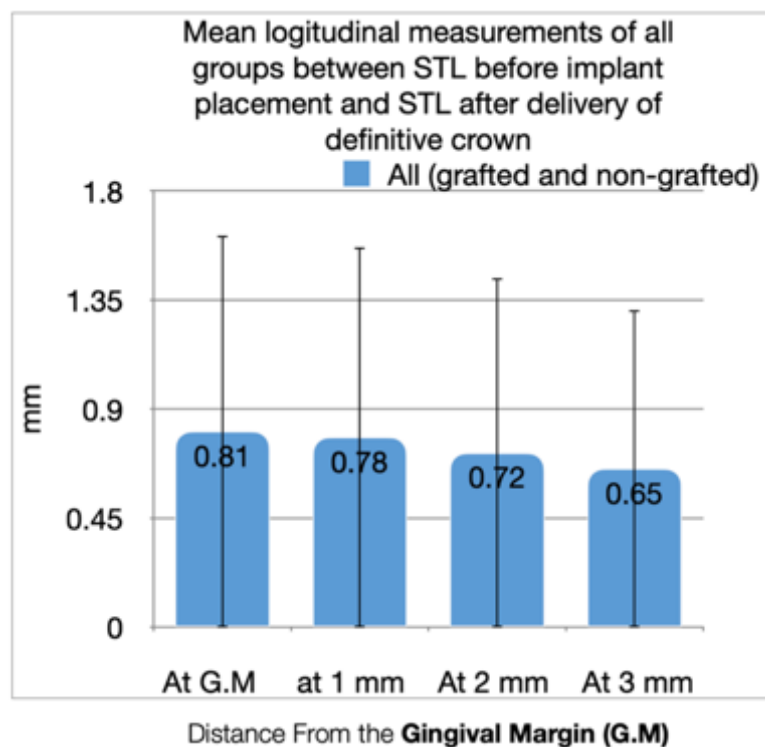
#### 1) Longitudinal analysis

Results were analyzed using the mean value of all groups, the mean value of the grafted and mean value of non-grafted of longitudinal measurements comparing the millimeters difference between STL before implant placement and STL after delivery of definitive crown and when doing

longitudinal measurements comparing the millimeters difference between STL after delivery of definitive crown and STL one year after implant placement.

All groups (grafted and non-grafted) had favorable results in gingival gaining when doing longitudinal measurements between STL before implant placement and STL after delivery of definitive crown. (Figure 11) Corresponding means at the gingival margin, 1 mm, 2mm, and 3mm from the gingival margin are 0.81 mm, 0,78 mm, 0.72mm, and 0.65. (Figure 11)

Figure 11: Mean longitudinal measurements of all groups between STL before implant placement and STL after delivery of definitive crown.

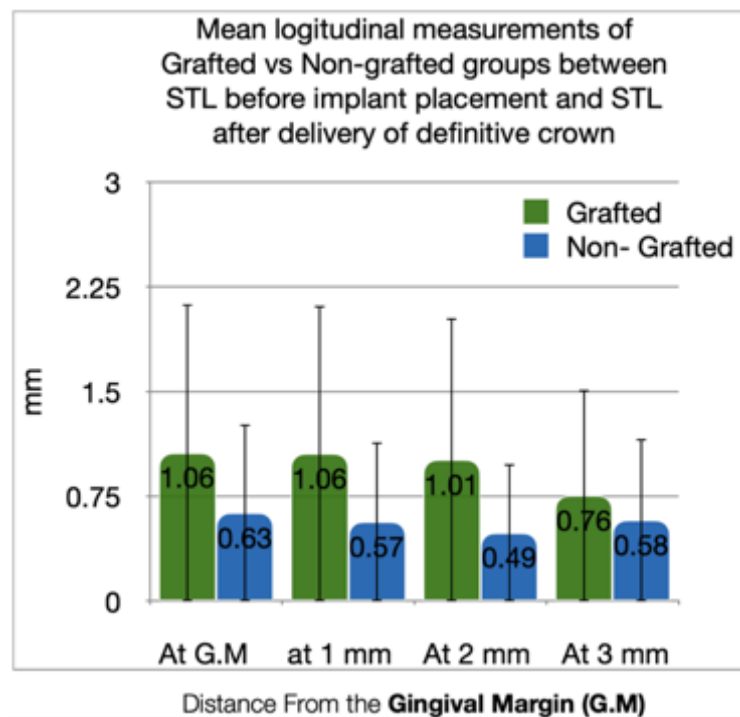


The grafted group had better results in gingival gaining than the non-grafted group when doing longitudinal measurements comparing STL before implant placement and STL after delivery of definitive crown. Corresponding means for the grafted group at the gingival margin, 1mm,

2mm, and 3mm from the gingival margin are 1.06 mm, 1.06 mm, 1.01 mm, and 0.76.

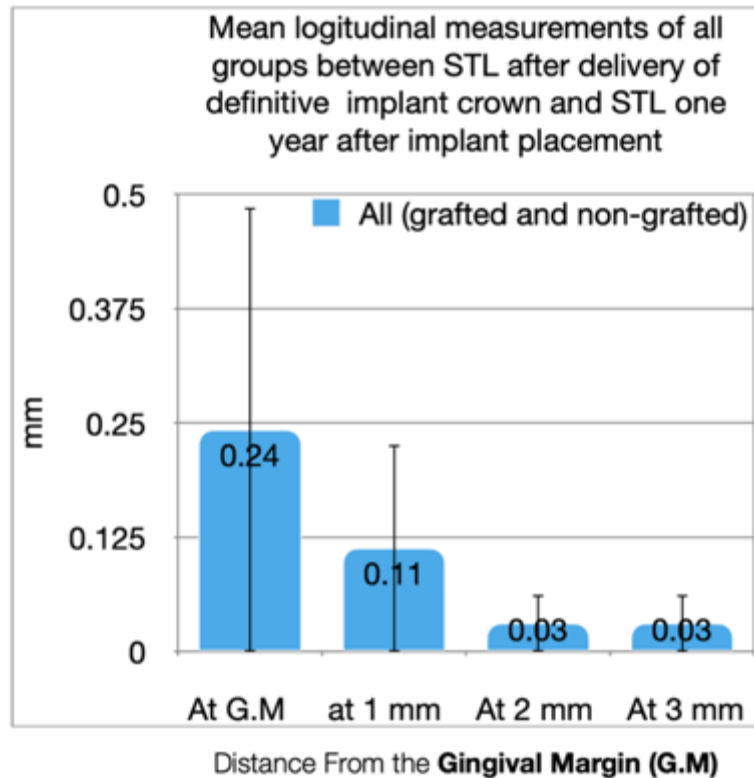
Corresponding means for the grafted group at the gingival margin, 1 mm, 2mm, and 3mm from the gingival margin are 0.63 mm, 0.57 mm, 0.49 mm, and 0.58. (Figure 12)

Figure 12: Mean longitudinal measurement of Grafted vs. non-grafted groups between STL before implant placement and STL after delivery of definitive crown.



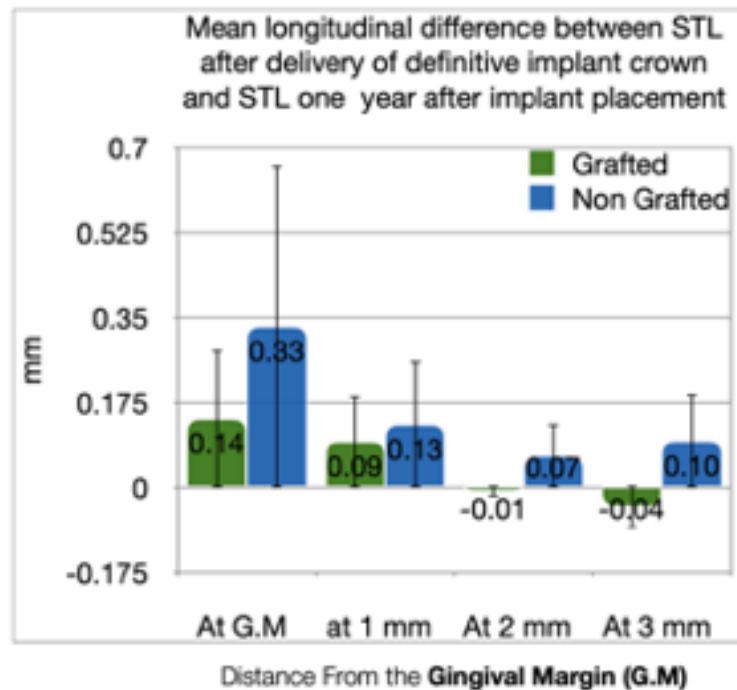
All groups (grafted and non-grafted) had favorable gingival gains when doing longitudinal measurements between STL after delivery of the definitive crown and STL one year after implant placement. (Figure 13) Corresponding means at the gingival margin, 1 mm, 2mm, and 3mm from the gingival margin are 0.24mm, 0.11mm, 0.03mm, and 0.03mm. (Figure 13)

Figure 13: Mean longitudinal measurements of all groups between STL after delivery of definitive implant crown and STL one year after implant placement.



The non-Grafted group had better results in gingival gaining than Grafted group when doing longitudinal measurements between STL after delivery of definitive crown and STL one year after implant placement. Corresponding means for the Non-grafted group at the gingival margin, 1mm, 2mm, and 3mm from the gingival margin are 0.33 mm, 0.13 mm, 0.07 mm, and 0.10. Corresponding means for the grafted group at the gingival margin, 1 mm, 2mm, and 3mm from the gingival margin are 0.14 mm, 0.09 mm, -0.01 mm, and -0.04.(Figure 14)

Figure 14: mean the longitudinal difference between STL after delivery of definitive implant crown and STL one year after implant placement.



An independent T-test was done between grafted and non-grafted at comparison measurements at 1 mm, 2mm, and 3mm from CEJ between pretreatment and post-treatment. Independent t-test resulted in p values: 0.34 at the Gingival margin, 0.20 at 1 mm from the gingival margin, 0.13 at 2 mm from gingival margin, and 0.56 at 3 mm from the gingival margin. Results describe nonsignificant differences between groups.

Table #5: Independent T-test comparison between pre-post means grafted vs. non-grafted.

	At G.M	1 mm from G.M	2mm from G.M	3mm from G.M
Independent T-test	0.34	0.20	0.13	0.56

An independent T-test was done between grafted and non-grafted at comparison measurements at 1 mm, 2mm, and 3mm from CEJ between post-treatment and one-year follow-up post-treatment.

Independent t-test resulted in p values: 0.23 at the Gingival margin, 0.79 at 1 mm from the gingival margin, 0.32 at 2 mm from the gingival margin, and 0.56 at 3 mm from the gingival margin. Results describe nonsignificant differences between groups.

Table #6: Independent T-test comparison between Post-1y Post-treatment means grafted vs. non-grafted.

	At G.M	1mm from G.M	2 mm from G.M	3mm from G.M
Independent T-test	0.23	0.79	0.32	0.56

2) OHIP-14 Results in allograft patients had a positive impact on their OHQoL, with an average total score of 2.47 after the 1-year follow-up after treatment. However, the overall low scores from both groups indicate that all patients have an excellent OHQoL, and the differences were not statistically significant ( $p=0.11$ ).

Table #7. OHIP-14 subjects scores.

	Group	Pretreatment	Follow up
1	Test	0	0
2	Test	4	0
3	Test	0	1
4	Control	5	2
5	Control	4	3



6	Test	7	4
7	Test	39	14
8	Control	2	4
9	Control	14	4
10	Test	4	0
11	Control	27	4
12	Test	1	0
13	Test	12	7
14	Control	0	0
15	Control	15	5
16	Test	3	0
17	Control	5	0
18	Control	16	4
19	Control	10	0
20	Control	0	0
21	Control	0	0
22	Test	2	2
23	Control	31	0
24	Test	6	8
25	Control	4	0
26	Test	6	0
27	Control	5	0
28	Control	1	0
29	Test	3	0
30	Test	7	3
31	Test	2	0
32	Test	0	0
33	Test	6	0
34	Control	1	0
35	Test	51	8
36	Test	3	0
37	Control	25	0
38	Control	6	0
39	Control	4	0

Figure 15: OHIP-14 Mean responses in control and test subjects pre-treatment and one year follow up after treatment.

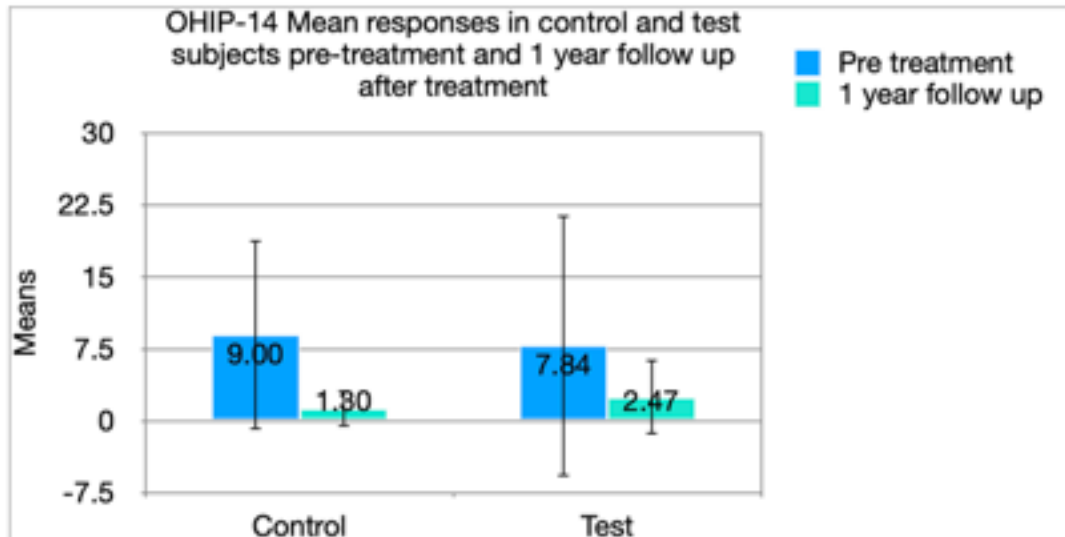


Table #8 Independent T-test comparison between Post-1y Post-treatment means grafted vs. non-grafted.

T-test between pretreatment and follow up	P value
Test Group	0.11
Control Group	0.001

### Vertical longitudinal analysis:

Vertical measurements were done to assess the vertical changes within STL at the time of delivery and one-year follow-up. The goal was to evaluate the possible gain recession or gain vertically after using or not using a Perioderm graft at implant placement. The mean result for the test group was 0.18 mm gain in vertical height of the gingival margin, and the mean value for the control group was 0.16 gain in vertical height of the gingival margin. An Independent t-test

was performed, and the p-value is 0.77. The results are not statistically significant. However, both groups seem to have vertical gain over a one-year follow-up.

Table #9 Vertical measurements from incisal edge-cusp to gingival margin for test group:

	Group	Post-treatment	1 yr follow up	Gingival margin recession(-) or gain(+)
1	Test	10.91	10.67	0.24
2	Test	11.60	11.80	-0.2
3	Test	7.47	6.72	0.75
7	Test	6.27	6.04	0.23
8	Test	5.98	5.46	0.52
10	Test	6.31	6.41	-0.1
12	Test	6.89	6.48	0.41
14	Test	8.43	8.52	-0.09
15	Test	10.11	10.10	0.1
17	Test	8.66	8.66	0
24	Test	5.58	5.58	0
26	Test	9.86	9.84	-0.02
29	Test	4.07	3.71	0.36
30	Test	10.03	9.86	0.17
31	Test	8.51	7.91	0.6

32	Test	9.14	9.19	-0.05
33	Test	8.28	7.79	0.49
35	Test	9.85	9.76	0.09
36	Test	7.03	7.03	0
Mean Test				0.18

Table #10 Vertical measurements from incisal edge-cusp to gingival margin for the control group:

	Group	Post-treatment	1 yr follow up	Gingival margin recession(-) or gain(+)
5	Control	8.07	7.85	0.22
6	Control	6.66	6.29	0.37
9	Control	7.59	7.94	-0.35
11	Control	10.29	10.29	0
13	Control	10.88	10.93	-0.05
16	Control	7.29	6.95	0.34
18	Control	7.34	6.54	0.08
20	Control	7.22	7.22	0
21	Control	6.87	6.81	0.06

22	Control	10.64	10.56	0.08
23	Control	6.01	5.98	0.03
25	Control	6.31	5.37	0.94
27	Control	5.90	5.97	-0.07
28	Control	9.82	9.54	0.28
34	Control	11.10	10.75	0.35
37	Control	6.89	6.21	0.68
38	Control	10.87	10.82	0.05
39	Control	6.19	6.40	-0.21
Mean control				0.16

Figure 16: Vertical Longitudinal analysis

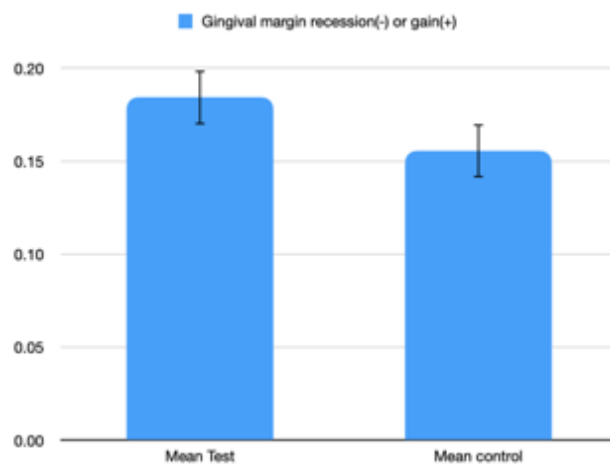


Table #11 Independent t-test for Vertical measurements from incisal edge-cusp to gingival margin:

	P value
<b>Independent T-test</b>	0.77

**Table 2. List of Complications Assessed**

***Biologic Complications:*** one implant had a biological failure. The implant was explanted, a bone graft was placed, and after four months, a new implant was placed following the same protocol to be included in the study.

***Prosthetic Complications:*** Thirteen implants had to be rescanned after four months because the final crown did not fit correctly. This could result in some vertical discrepancy at the implant placement, where the implant was placed in a deeper position than the one established initially in the treatment plan.

***Functional Complications:*** one implant failed because of trauma. The implant was explanted, a bone graft was placed, and after four months, a new implant was placed following the same protocol to be included in the study.

## 5. Discussion

### **Longitudinal Analysis:**

A sample size of 39 subjects is based on previous studies. Previous investigations of peri-implant mucosal levels have demonstrated that it is possible to distinguish differences of 0.5 mm among

groups of 25 subjects. In addition, a recent prospective clinical study comparing no graft to an autogenous connective tissue graft demonstrated a significant difference with 20 subjects/group.(Zuiderveld et al. 2018) Other studies utilized similar inclusion/exclusion criteria and performed a similar intervention. Even a smaller study compared eight subjects with grafts to 10 without demonstrating significant 3D volume changes using a similar scanner-based analytic method (Bienz et al. 2017). In this study, it was anticipated augmentation of approximately 1.0 mm – 1.5 mm with allograft and saw significant differences between 20 subjects/groups. However, although all groups (grafted and non-grafted) had favorable results in gingival gaining when doing longitudinal measurements between STL before implant placement and STL after delivery of definitive crown, means were not statistically significant between the groups.

- Pre-Post treatment Longitudinal analysis:

Independent t-test resulted in p values: 0.34 at the Gingival margin, 0.20 at 1 mm from the gingival margin, 0.13 at 2 mm from the gingival margin, and 0.56 at 3 mm from the gingival margin. Results describe nonsignificant differences between groups. Still, results are promising with the grafted group, which had better results in gingival gaining than the non-grafted group when doing longitudinal measurements comparing STL before implant placement and STL after delivery of definitive crown. (Figure 12)

- Post-treatment - One-year Longitudinal follow-up analysis:

All groups (grafted and non-grafted) had good gingival gains when doing longitudinal measurements between STL after delivery of the definitive crown and STL one year after implant placement. (Figure 13) Surprisingly, the non-Grafted/control group had better results in gingival gaining than Grafted group when doing longitudinal measurements between STL after delivery of definitive crown and STL one year after implant placement. (Figure 14)

This variation in results could be attributed to the additional bone loss expected after one year of implant placement, the morbidity of the Allograft, or the possibility that the mucogingival line changed at the 3 mm from the gingival margin at those subjects that did not receive a graft.

Doing longitudinal measurements represented a challenge in some of the cases, especially in the post-treatment- one-year follow-up comparison, because of the reliability of the software to merge STL adequately and the minor difference in mm between some of the STL files. Doing longitudinal measurements in a sagittal plane of a 3D object that does not have a straight line but more of a curve or several curves can be challenging when accurately doing the measurements.

- One-time abutment protocol from Dentsply Sirona (Immediate Smile):

This fully-digital protocol was very convenient for the patient and the clinicians. Thanks to the impressionless approach resulted in fewer appointments and procedures that could compromise the tissues around the implants. In most cases, it was successful except for thirteen implants which had to be rescanned after four months because the final crown did not fit correctly. This result could be attributed to some vertical discrepancy at the implant placement, where the implant was placed in a deeper position than the one established initially in the treatment plan.

- OHIP-14

Overall Results in patients in both groups were low, which means that regardless of the graft, all patients had an excellent OHQoL after implant treatment. However, mean values in grafted pre-one year after treatment were not statistically significant ( $p=0.11$ ). Conversely, the Control group resulted in statistically significant change related to the initial score values before treatment.

These results could be attributed to the small study size for this part of the study and variations in patient opinions and experiences before treatment. It is expectable that a patient that is losing a



front tooth might have higher score values in the OHIP-14 questionnaire than a patient missing a posterior tooth because of esthetics. Alternatively, a patient missing many teeth distributed in different quadrants might have a higher score value than another patient who only misses a tooth because of different masticatory comfort and function.

The OHIP-14 questionnaire results showed overall satisfaction after treatment, regardless of whether grafting was included in implant placement. Even when the results seemed promising, the results were not statistically significant ( $p=0.11$ ). Furthermore, there could be selection bias involved. Average OHIP-14 scores among patient satisfaction after one year of follow-up ranged from 0 to 4, consistent with the literature.

- Vertical longitudinal Analysis,

The mean result for the test group was 0.18 mm gain in vertical height of the gingival margin, and the mean value for the control group was 0.16 gain in vertical height of the gingival margin. An Independent t-test was performed, and the p-value is 0.77. The results are not statistically significant. However, both groups seem to have vertical gain over a one-year follow-up.

## **6. Conclusions**

A complete digital workflow has been validated to permit crown delivery on Cad-Cam abutments without implant impressions. The augmentation of alveolar mucosa on the buccal aspect of single tooth implants is associated with clinically favorable outcomes, especially at the 1 to 2 mm from the gingival margin. However, results are not statistically significant, so it cannot be determined whether the use of allograft during implant placement is strictly necessary. More research using volumetric measurements is needed to determine if the use of allograft during implant placement could be a determining factor in achieving better esthetic results.

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