- Official Title: Periimplant Mucosa Dynamics Around Divergent and Concave Atlantis Abutment Transition Profiles

- NCT Number: NCT01871220

- Document Date: October 1, 2019

Protocol Synopsis Template

- Investigator Initiated Study -

Date *(YYYY-MM-DD)* 2012-08-03

Submitted by

Title and name of Principal Investigator	Christopher A. Barwacz, DDS, Assistant Professor (PI) Gustavo Avila-Ortiz, DDS, MS, PhD, Assistant Professor
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Study title

Periimplant Mucosa Dynamics Around Divergent and Concave Atlantis™ Abutment Transition Profiles.

Study design *(A one-sentence summary of study design features)*

A two-arm, parallel group, randomized controlled clinical trial on adult human subjects receiving divergent or concave Atlantis™ abutments to assess peri-implant mucosa changes from prosthesis delivery to 1 year.

Study centre(s) and number of subjects planned *(The address where the study will be conducted, number of patients planned and if applicable distribution of patients per site)*

Craniofacial Clinical Research Center (CCRC) at The University of Iowa College of Dentistry
n= 60 subjects (30 subjects – concave abutment profile, 30 subjects – divergent abutment profile)

Study period *(month & year)*

- **Estimated Start date** *(first patient enrolled)* Summer 2013 to Fall 2013
- **Estimated End date** *(last patient completed follow up)* Fall 2014 to Winter 2015
- **First data available for presentation** Winter 2015

Study objectives

• (Primary) Compare the influence of experimental concavities in the subgingival transition zone of Atlantis™ abutments on peri-implant mucosal dynamics from final restoration delivery to one year, as compared to current Atlantis™ abutments with linear divergent transition profiles.
• (Secondary) Quantify the horizontal soft tissue thickness changes around concave and divergent abutment transition profiles from final restoration delivery to one year.
• (Secondary) Evaluate changes in peri-implant health indicators, such as Gingival Index (GI), Probing Pocket Depth (PPD), and Bleeding on Probing (BOP).

Study population *(Short description of target population and indication studied, including relevant criteria for exclusion/inclusion)*

We propose to invite 60 patients participating in a RCT at The University of Iowa College of Dentistry, beginning early/mid 2013 on the efficacy of alveolar ridge preservation (Dr. Avila-Ortiz – Principle Investigator). If necessary, additional patients requiring a single-tooth implant (with the same inclusion/exclusion criteria proposed below) will be recruited.

Inclusion Criteria:
- 18 years of age or greater
- Subjects requiring replacement of a single-rooted tooth in the maxillary arch from first premolar to first premolar with an implant-supported restoration
- Teeth adjacent (mesial and distal) to study site must consist of two stable, natural teeth without signs of periodontal bone loss (<2.0mm) and/or significant soft tissue loss
- An opposing dentition with teeth, implants, or fixed prosthesis
- Subjects must be willing to follow instructions related to the study procedures
- Subjects must have read, understood, and signed the informed consent document

Exclusion Criteria:
- Insufficient interocclusal space for implant placement and/or restoration at study site
- More than 2.0mm vertical bone loss at study site as measured from the mid-buccal crest of the bone on the adjacent teeth
- Untreated rampant caries
- Tobacco use free for ≤ 6 months
- Liver or kidney disfunction/failure
- Active severe infectious diseases that may affect normal healing and/or bone metabolism (e.g. AIDS)
- Uncontrolled diabetes
- Current alcohol or drug abuse
- Need for systemic corticosteroids or any other medication that would influence post-operative healing and/or osseointegration
- History of relevant head/neck cancer and/or radiation of the head/neck
- Subjects who currently use bisphosphonates or have a history of bisphosphonate use
- Subjects with metabolic bone diseases such as osteoporosis or Paget's disease of bone
- Known pregnancy or nursing mothers
- Unable or unwilling to return for follow-up visits for a period of 1 year
- Unlikely to be able to comply with study procedures according to investigators judgement

Investigational product/comparator *(State the devices / products that will be investigated / used and for comparative studies also the comparator/s)*
Atlantis™ Crown abutments fabricated with either divergent or concave subgingival transitional profiles supported by Dentsply Osseospeed™ PLUS implants.

Outcome variables

- Apico-coronal changes of the peri-implant mucosal zenith from prosthesis delivery to one year (Primary).
- Submarginal bucco-lingual soft tissue thickness in the peri-implant transition zone relative to a fixed reference point.
- Quantification of the topographical and volumetric features of the interface between the peri-implant mucosa and the transition zone.
- Keratinized mucosa width in an apicocoronal direction at the midfacial aspect of the implant site.
- Gingival Index (GI), Plaque Index (PI), Bleeding on probing (BOP) and probing pocket depths (PPD) at six sites (disto-lingual, mesio-lingual, mid-lingual, mesio-buccal, disto-buccal, mid-buccal).

Materials and method

The perception of an implant restoration as esthetic is often attributable to the soft-tissue architecture that frames the clinical crown. (1) In order for an implant-supported restoration to accurately mimic its adjacent natural counterpart, the restorative complex must traverse the soft tissues, transitioning from a cylindrical implant interface to an anatomic configuration determined by the clinical crown. (2) Thus, it has been recognized that the transitional contour design, and any subtle changes to this transmucosal parameter, can have significant effects on the profile of the peri-implant gingival architecture. (3)

Atlantis™ CAD/CAM custom abutments currently offer four design parameters for the degree of lateral angulation of the transition zone from the head of the implant to the restorative margin. Various displacement options of the soft tissues on a primary plane (degree of divergence) can be chosen. However, less flexibility is offered to the clinician regarding modification of secondary planes along the primary plane (i.e., concavities or convexities). Such limitations are currently being addressed utilizing the Atlantis™ “Option 5” or “EPS” (Emergence Profile System) design parameter, which is still in beta mode and not disclosed publicly.

The concept of whether secondary planes along the existing primary plane can aid in enhancement of the peri-implant soft-tissue response remains ill-defined in the current literature and therefore has yet to be adequately addressed. In a recent pilot study (4), a total of 54 implants with an internal connection and an experimental abutment containing a concave, inwardly narrowed profile at the transmucosal level were delivered to 40 consecutive patients. The implant sites were in esthetically demanding areas, the majority (n=43) were placed in the anterior maxillary region. Patients were monitored clinically and via digital photography at abutment placement, and 1, 3, 6, and 12 months post-abutment delivery to assess soft-tissue zenith levels on the mid-facial aspect of the implant restorations. Rompen and colleagues found that in contrast to previous cited reports of 0.6 to 1.5mm of mid-facial soft tissue recession at 1 year (5-7), the experimental concave abutments yielded soft tissue stability, and for the majority of cases observed, soft tissue gain at the mid facial aspect of the implant site. The

study reported seven implant fixtures (13.0%) displaying mid facial recession of <0.5mm at 12 months, and 29 patients (53.7%) exhibiting a vertical gain of keratinized soft-tissue from baseline to 12 months. No implant sites demonstrated recession of >0.5mm at 12 months. Thus, a statistically significant gain in keratinized soft tissue on the mid-facial aspect of the experimental abutments with inwardly narrowed profiles at the transmucosal level was observed. The authors attributed the gain in keratinized soft tissue height to three principle factors afforded by the abutment's concave secondary plane:

1. The circumferential concavity created a profile that enabled a localized thickening of the soft-tissues to occur, relative to a divergent abutment.

2. The curved concave profile allowed for an increase in length of the soft tissue-to-abutment interface, meaning that a greater biological seal could be obtained for the same vertical height of the implant platform relative to the gingival margin.

3. The circumferential concavity enabled a greater amount of connective tissue attachment to form, enabling a more robust seal to be established.

In a 2009 study, Redemagni et. al (8) examined 28 patients treated with 33 XiVE implant fixtures restored with concave facial emergence profile abutments in the anterior maxillary region for a mean of 20.4 months. For this study population, a mean of 0.0mm (range of -0.5mm to +1.0mm) of labial mucosal recession was observed. The authors' observations agreed with Rompen's findings that concave facial emergence designs were consistent with facial soft tissue stability, most likely due to increased connective tissue volume in the apical transition zone.

Kim and colleagues (9) investigated the influence of the configuration of the surface topography of the transmucosal portion of three commercially available one-piece implant systems in a beagle dog model. The three systems were represented by 1) a flared, machined transmucosal profile (FM group), 2) a concave, machined transmucosal profile (CMG group), and 3) a straight, anodic oxidized surface (SA group). Mandibular premolars (P1-P4) were extracted, and 1 month after extraction, three implants (one of each type) were placed in alternating orders in each beagle's hemimandible, with 4.0mm between each implant type. After 6 months of function, the dogs were sacrificed, and histologic analysis was performed (Fig. 1). The study demonstrated that despite all three implant designs displaying the same biologic widths histologically, the concave (CMG) transmucosal profile displayed the greatest amount of connective tissue contact (0.92mm ± 0.36mm) as compared to the flared (FM) transmucosal profile (0.39mm ± 0.25mm) and straight (SA) transmucosal profile (0.63mm ± 0.34mm)

The above three studies, each unique in their design, have inherent limitations that prevent widespread acceptance and adoption of these concepts. For both the Rompen (4) and Redemagni (8) studies, there was no control cohort group by which to compare the effects of the concave facial abutment profile. As well, the Rompen study did not use standardized photography to obtain precise measurements of the mid-facial gingiva, which induces potential error over multiple follow-up time points. The Redemagni study was retrospective in analysis, and connective tissue grafts were placed on the facial aspect of the implant fixtures at the same time as implant provisionalization. This treatment factor introduces an additional variable that complicates the analysis due to multiple co-variables being present simultaneously. The beagle dog evaluation by Kim (9) is the first histological evidence in support of the concept of concave abutment profiles, but further clinical evaluation in human subjects is needed.

Therefore, we hypothesize that a well designed, randomized clinical trial comparing divergent to concave abutments in controlled clinical conditions should be pursued to investigate whether this proof-of-principle is demonstrable.

The investigators thus proposes to conduct a randomized, prospective, controlled clinical trial comparing the facial gingival profiles around Atlantis™ abutments that have either a linear "divergent" or "concave" transitional profile on the facial and proximal aspect of the abutments (Fig. 2).

Sixty study subjects requiring replacement of a single-rooted tooth with an implant-supported restoration will be recruited. To facilitate recruitment, subjects participating in a funded, randomized, controlled clinical trial at The University of Iowa College of Dentistry on the efficacy of alveolar ridge preservation (Dr. Avila-Ortiz – Principal Investigator) will be invited to participate in the proposed study (Fig. 5). Neither implant placement nor restorative therapy will be provided for the 60 subjects participating in the ridge-preservation study.

The authors propose the placement of Osseospeed™ Plus implant fixtures for all 60 subjects, and Uni healing abutments to minimize lateral tissue displacement during healing. After implant placement, but before final impressions are obtained (8 weeks post-placement), subjects will be randomized to either a "divergent" or a "concave" transmucosal abutment design. For fabrication of the experimental abutment, Atlantis™ engineers will initially design a control "divergent" prototype that will be modified with a concavity on the facial and proximal transition zones to obtain an abutment that will otherwise retain all the features of the control abutment. Engineers will measure the linear topographical changes ($\Delta L = Lc - Ld$) of the transition zone, as well as the volumetric change (x) on the mid-facial aspect of the abutment induced by the formation of a submucosal concavity (Fig. 2). The primary outcome of the study will be the apico-coronal change of the peri-implant mucosal zenith from prosthesis delivery to one year.

The investigators propose to utilize a standardized digital stereotactic photography setup (Canfield Dental Camera, Canfield Imaging Systems, Fairfield, NJ) (Fig. 3) from the date of abutment/restoration delivery, and subsequently at 1, 3, 6, and 12 months to accurately document the dynamics of the facial soft tissue. Use of standardized stereotactic digital photography will enable greater accuracy and precision with regard to soft-tissue zenith measurements over time (Fig. 4). This technique is currently being employed as part of a Dentsply Implants-sponsored prospective, randomized, multicenter study called "PROOF" (YA-OSS-0003). After photographic documentation is completed for all time points, a digital software analysis program such as NIH Image J (National Institutes of Health, Bethesda, MD) can be utilized to measure length changes at the mid-facial gingival crest to any desired scale (i.e., tenths of a millimeter or pixels). At recall visits, bucco-lingual peri-implant mucosal thickness will be measured from a fixed reference point, as well as other clinical parameters that include: Plaque Index (PI), Gingival Index (GI) (10), probing pocket depth (PPD), bleeding on probing (BOP) and keratinized mucosa width (KMW) using a UNC-style probe (Fig. 6). These data will be used along with the photographic data to extrapolate the potential role that concavities in the abutment transition zone may play in preserving or enhancing facial soft tissue dynamics.

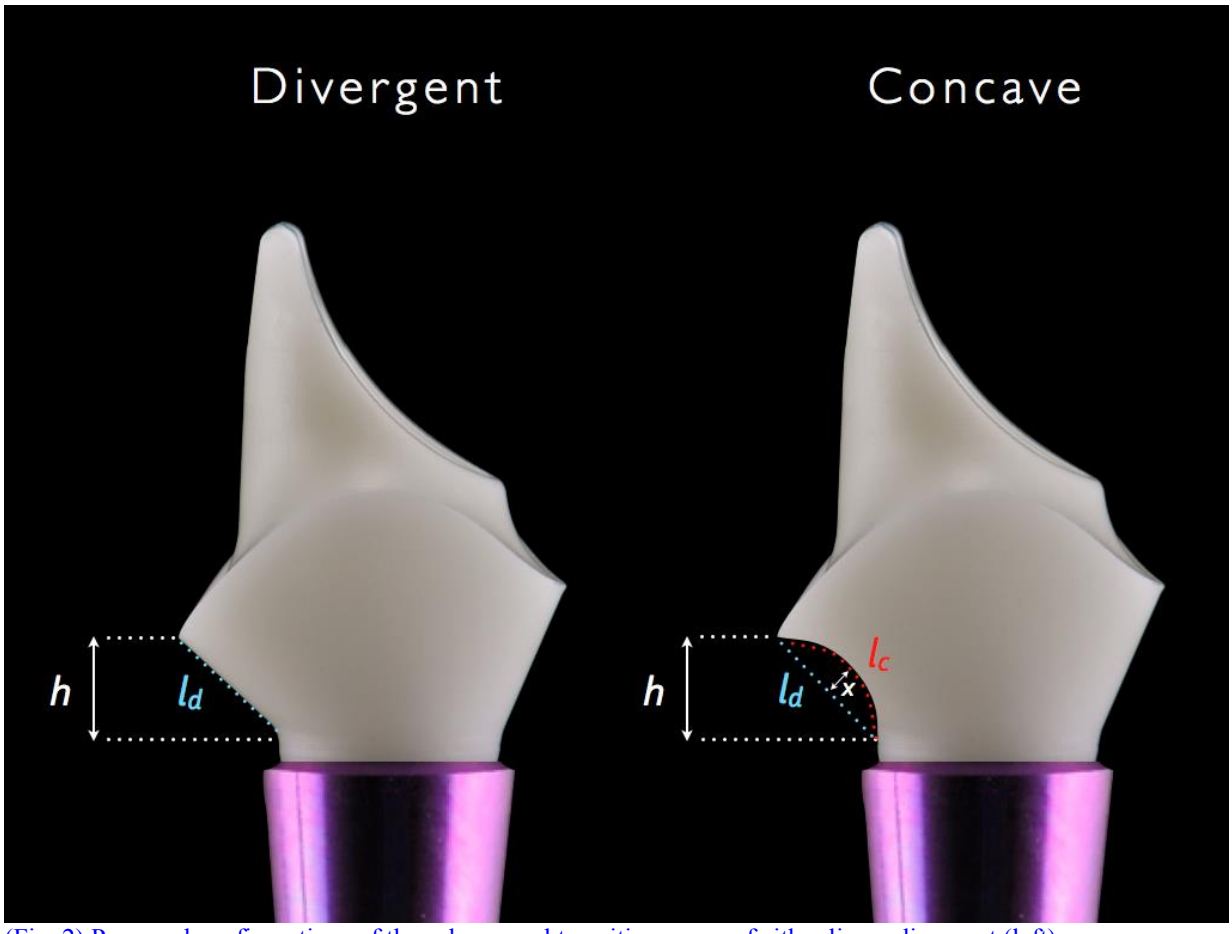
FIGURES:

Fig 6a Mesiodistal section of FM group implant.

Fig 6b Mesiodistal section of CMG group implant.

Fig 6c Mesiodistal section of SA group implant.

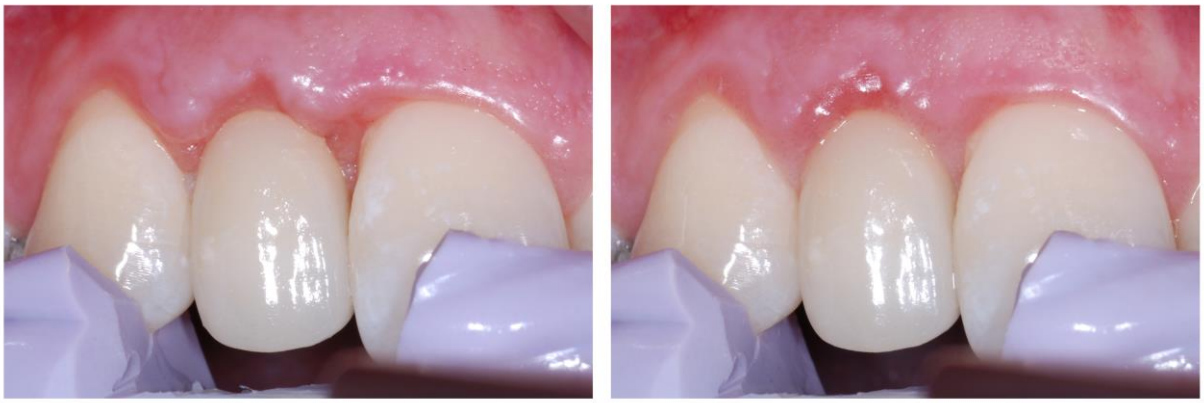
(Fig. 1) Histological sections of FM (Fig. 6a), CMG (Fig. 6b), and SA (Fig. 6c) transmucosal profiles, demonstrating superior quantity of connective tissue for CMG configurations.9



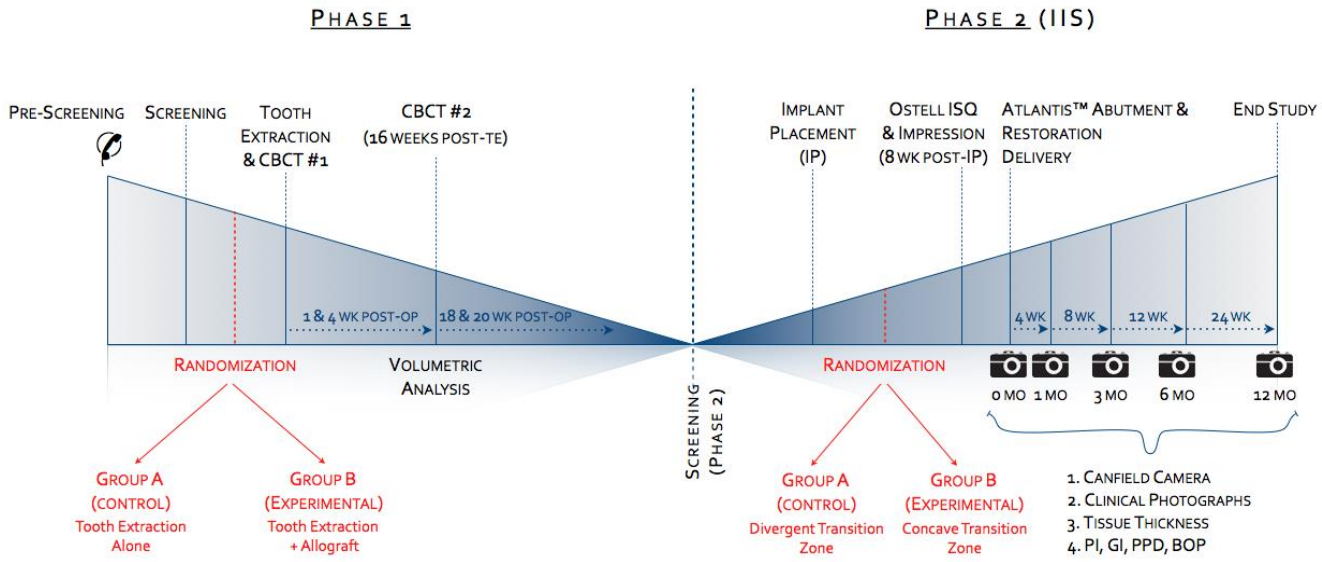
(Fig. 2) Proposed configurations of the submucosal transition zones of either linear divergent (left) or concave (right) Atlantis™ abutments. Relative lengths of either the divergent (Ld) or concave (Lc) can be calculated

during the design/manufacturing process. The volumetric space (x) provided for by the experimental concavity can also be extrapolated from the Atlantis™ software.

(Fig. 3) Canfield Dental Camera (Canfield Imaging Systems, Fairfield, NJ) setup. The patient is oriented in a repeatable position via a bite registration jig and a semicircular camera dial that enables recording of the gingival zenith position at a specific angle between 0-180 degrees.



(Fig. 4) Example of stereotactic digital photographic documentation of a single tooth implant restoration at site #7 using the Canfield Dental Camera (Canfield Imaging Systems, Fairfield, NJ). Such standardized photographs enable precise measurements in the change of the mid-facial soft tissue.



(Fig. 5) Grahical representation of clinical trial Phases 1 and 2. Phase 2 represents the protocol synopsis for the proposed Investigator Initiated Study (IIS). The intent is for 60 patients to be recruited via invitation from Phase 1 (Ridge Preservation RCT) to the Phase 2 portion to optimize completion of the study.

	Visit		1	2	3	5	6	7
	Visit Description		Screening	Implant Placement (IP)	Follow-up	Final Impression & Ostell ISQ	Permanent Crown	Recall Visit
	Visit Window			IP	IP + 2w	IP + 8w	IP + 12w (±5 days)	IP + 1, 3, 6, 12m
Selection process	Informed Consent		X					
	Medical/Dental history		X					
	Oral examination		X					
	Inclusion/exclusion criteria		X					
	Radiographic examination		X (From previous records, if available)		X (optional)			
Study outcomes	Implant Stability			X		X	X	X
	Canfield Photographs						X	X
	Clinical Photographs						X	X
	Bucco-lingual soft-tissue thickness						X	X
	Condition of peri-implant mucosa	PI, GI, PPD, BOP						X
	Adverse Events/Adverse Device Effects			X	X	X	X	X

(Fig. 6) Proposed study plan

Statistical methods *(Describe where relevant the statistical methods to be used, the populations to be analysed (e.g. determination of sample size, intention to treat, per-protocol), and any interim analyses)*

A unified repeated measures analysis (11,12) will be used to describe the time course and to assess the effects of divergent vs. concave abutment design. This approach will make it possible to take into account the correlation of repeated measures on a given subject over time, and to consider the impact of abutment type, as well as other potential covariates. Subject will be treated as a random effect and other factors as fixed effects. Candidate covariate effects that will be explored include sex, age, history of periodontal disease, tooth position, clinical crown anatomy and the condition of adjacent teeth. So as not to exceed the limitations of sample size, we will first consider the relationship of each candidate with the outcome separately, and incorporate those with promising relationships into subsequent modeling. Parameters will be estimated using restricted maximum likelihood

(REML) methods, and a variety of different variance-covariance structures will be entertained, as appropriate. These approaches can accommodate missing data and possible time-dependency of the covariate, both of which may be relevant to this situation. Appropriateness of assumptions associated with the modeling, such as normality, will be fully assessed, and normalizing transformations considered as appropriate. Should these approaches not appear feasible, nonparametric methods for longitudinal data (13, 14) will be considered.

Comparisons of tissue alterations between the two abutments types at each follow-up time are also of interest: Changes relative to baseline will be compared at each of the four recall time points, initially using either the two-sample Student's t-test to compare abutment types, or its nonparametric analog, the Wilcoxon rank sum test, as appropriate. In addition, standard linear modeling will be used to incorporate the possible impact of other covariates. Adjustment for multiple comparisons will be made using the modified Bonferroni method due to Holm (15) in conjunction with an overall Type I error of 0.05.

Analysis of the quantitative secondary outcomes (e.g., keratinized mucosal widths) will be analogous to that for the primary outcome. In addition, we will also characterize the longitudinal course with respect to the categorical outcomes constituting the clinical periodontal evaluations , with initial emphasis being placed upon transition approaches.(12) These will be considered descriptively in terms of the complete three- or four-point ordinal scales, but specific attention will also be given to shifts from clinically acceptable to clinically inacceptable designations. (16,17)

POWER CONSIDERATIONS:

Evaluations of power and detectable effect size are calculated for change in peri-implant mucosal zenith position at 12-month follow-up relative to baseline over the course of follow-up. Since this research is to be based on a patient population from another study, sample sizes are fixed at 30 subjects for each of the two abutment groups. Assuming dropout of 10-15% over the year of follow-up, calculations were based on completed sample sizes of 27 and 25 per treatment group. Values of 0.4 – 0.7 mm were found in the literature (18, 19) for the standard deviation (s.d.) of this change measure. Taking a conservative approach, estimates of power and detectable effect size were considered for s.d. values of 0.5, 0.7, 0.9 and 1.0 mm; calculations were made based on a Type I error level (α) of 0.05 for the key 12-month comparison, as well as α = 0.05/4 = 0.125, representing Bonferroni adjustment for four multiple comparisons corresponding to follow-up evaluations at four time points. Due to the scarcity of information in the literature, standard deviation values were assumed to be uniform across time points. Power was set at 80% and 90% for calculations of detectable effect sizes.

A minimum difference of 1 mm between the two abutment groups was felt to be clinically relevant. Based on these sample sizes, at least 99% power is anticipated to detect this effect size, even with adjustment for multiple comparisons and 15% attrition, if the true standard deviation is within the range found in the literature, i.e., 0.7 mm or less. For a larger standard deviation of 1.0 mm, we anticipate 93% power to detect this difference for a single test, and 82% power with multiple comparisons adjustment, again assuming 15% attrition. We therefore anticipate having more than adequate power to detect a clinically important difference in tissue changes between the two abutment designs. The minimum detectable differences are considerably smaller, as indicated in the table below. These results also show that we will be able to detect, with at least 80% power, differences on the order of that considered clinically relevant even if the standard deviation is somewhat greater than that described in the literature cited.

80% POWER								
Sample Size Per Abutment Group+	**Detectable Effect Size Between Abutment Groups (mm)**							
	Type I Error Level: α = 0.05				Type I Error Level: α = 0.05/4 = 0.0125*			
	SD (mm)				SD (mm)			
	0.5	0.7	0.9	1.0	0.5	0.7	0.9	1.0
25	0.40	0.57	0.73	0.81	0.49	0.68	0.88	0.98
27	0.39	0.54	0.70	0.78	0.47	0.66	0.84	0.94
90% POWER								
Sample Size Per Abutment Group+	**Detectable Effect Size Between Abutment Groups (mm)**							
	Type I Error Level: α = 0.05				Type I Error Level: α = 0.05/4 = 0.0125*			
	SD (mm)				SD (mm)			
	0.5	0.7	0.9	1.0	0.5	0.7	0.9	1.0
25	0.47	0.66	0.84	0.94	0.55	0.77	1.00	1.11
27	0.45	0.63	0.81	0.90	0.53	0.74	0.96	1.06

*Based upon Bonferroni adjustment for multiple comparisons corresponding to four follow-up times.

+ Based upon recruitment of 30 per group and attrition of 15% (25 per group) or 10% (27 per group)

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Publications & Presentations *(Describe your plans with regard to publications or public presentations i.e. what journals or conferences/meetings)*
Initial study data would be available for presentation during the first quarter/half of 2015 at both local (e.g., Midwest Society of Periodontology) and national conferences (e.g., Academy of Osseointegration (AO) and American Association of Dental Research (AADR) Annual Meetings). Final study data would be prepared for manuscript publication in journals such as Journal of Clinical Periodontology (JCP) or Journal of Dental Research (JDR).

Total study cost *(Provide an estimate for the total study cost divided on main activities)*

Title: Periimplant Mucosa Dynamics Around Divergent and Concave Atlantis Abutment Transition Profiles								
Personnel	**Role**	**Effort**	Salary Base	Request Salary	22.60% Finge	Total	Project Total	Patient Costs
Barwacz, Christopher	PI		Provided by Astra PDPA				$0	
Stanford, Clark	Investigator		Provided by Astra PDPA				$0	
Avila-Ortiz, Gustavo	Investigator	10%	$106,080	$10,608	$2,397	$13,005	$13,005	
Thomann, Lauren	Coordinator		Provided by Astra PDPA				$0	
TOTAL SALARY REQUESTED							$13,005	
Crown Abutments and Facilitate Guides: Provided by Sponsor								
WIRB processing							$2,300	
UI cost for WIRB							$800	
IRB Modifications ($400/ea X 2)							$800	
IRB one yr review							$1,000	
Implant Placement Surgical Fee ($875/ea X 60)								$52,500
Cone Beam Clean-up ($100/ea X 60)							$6,000	
Recall visits ($30/visit x 4 visits/patient x 60 patients)							$7,200	
Patient Participation Fee: $25 X 60 (1 mo)							$1,500	
Patient Participation Fee: $50 X 60 (6 mo)							$3,000	
Patient Participation Fee: $75 X 60 (1 yr)							$4,500	
Biostats Consulting ($100/hrx20hrs)=		$2,000					$2,000	
TOTAL -SUBTOTAL							$29,100	
TOTAL DIRECT COSTS							$42,105	
Finance & Administration Costs (25%)							$10,526	
TOTAL PROJECT COSTS							$52,631	
In kind donation								
60	Denal implants							
60	Atlantis ZrO abutments							
60	Facilitate Guides							
	Associate prosthetic parts as described.							
Patient Costs								
	Implant Placement (surgical fee)		$875					
	Abutment		$0					
	Implant Crown		$1,250					
			$2,125					

Requested support *(Describe extent of requested support – financial or other support e.g. products)*
Product Donation: (60 Atlantis™ Crown Abutments, 60 Facilitate™ Guides)

Details of products requested

Product	Ref. No.	Quantity
Osseospeed Plus 3.6 S (H 9.0mm)	25069	12
Osseospeed Plus 3.6 S (H 11.0mm)	25070	12
Osseospeed Plus 3.6 S (H 13.0mm)	25071	6
Osseospeed Plus 4.2 S (H 9.0mm)	25072	12
Osseospeed Plus 4.2 S (H 11.0mm)	25073	12
Osseospeed Plus 4.2 S (H 13.0mm)	25074	6
Osseospeed Plus 4.8 S (H 9.0mm)	25075	5
Osseospeed Plus 4.8 S (H 11.0mm)	25076	5
Osseospeed Plus 4.8 S (H 13.0mm)	25077	5
Healing Abutment 3.6 (4.2mm low)	25128	20
Healing Abutment 3.6 (4.2mm high)	25127	10
Healing Abutment 4.2 (5.0mm low)	25102	20
Healing Abutment 4.2 (5.0mm high)	25103	10

Product	Ref. No.	Quantity
Healing Abutment 4.8 (5.0mm low)	25105	15
Implant Pick-Up 3.6	25130	30
Implant Pick-Up 4.2	25131	30
Implant Pick-Up 4.8	25132	15
Implant Replica 3.6	25133	30
Implant Replica 4.2	25134	30
Implant Replica 4.8	25135	15

Products will be distributed to the below contact person and address:

Ms. Lauren Thomann
801 Newton Rd.
Craniofacial Clinical Research Center
University of Iowa College of Dentistry
W423 Dental Science Building
Iowa City, IA 52242-1010
(lauren-thomann@uiowa.edu)

Periimplant Mucosa Dynamics Around Dynamic and Concave Atlantis^{TM} Abutment Transition Profiles

October 1, 2019

We removed all patients without a randomized treatment and/or without any data collection. We did keep subjects with partial data in at least one of the variables. All analyses were performed using R version 3.6.0.

Table 1: Canfield

Treatment	Mean	SD	Min	Max	Median	N
Delivery						
Concave	9.770	1.146	7.46	11.67	9.86	29
Divergent	9.860	1.148	7.42	11.90	10.06	25
1 Month						
Concave	9.618	1.160	7.05	11.52	9.79	29
Divergent	9.684	1.203	7.25	11.92	9.84	25
3 Month						
Concave	9.610	1.174	6.96	11.52	9.75	29
Divergent	9.674	1.231	7.10	11.78	9.81	25
6 Month						
Concave	9.599	1.160	7.10	11.52	9.73	29
Divergent	9.652	1.166	7.27	11.56	9.80	25
12 Month						
Concave	9.596	1.167	6.91	11.45	9.70	29
Divergent	9.622	1.258	6.89	11.54	9.80	25

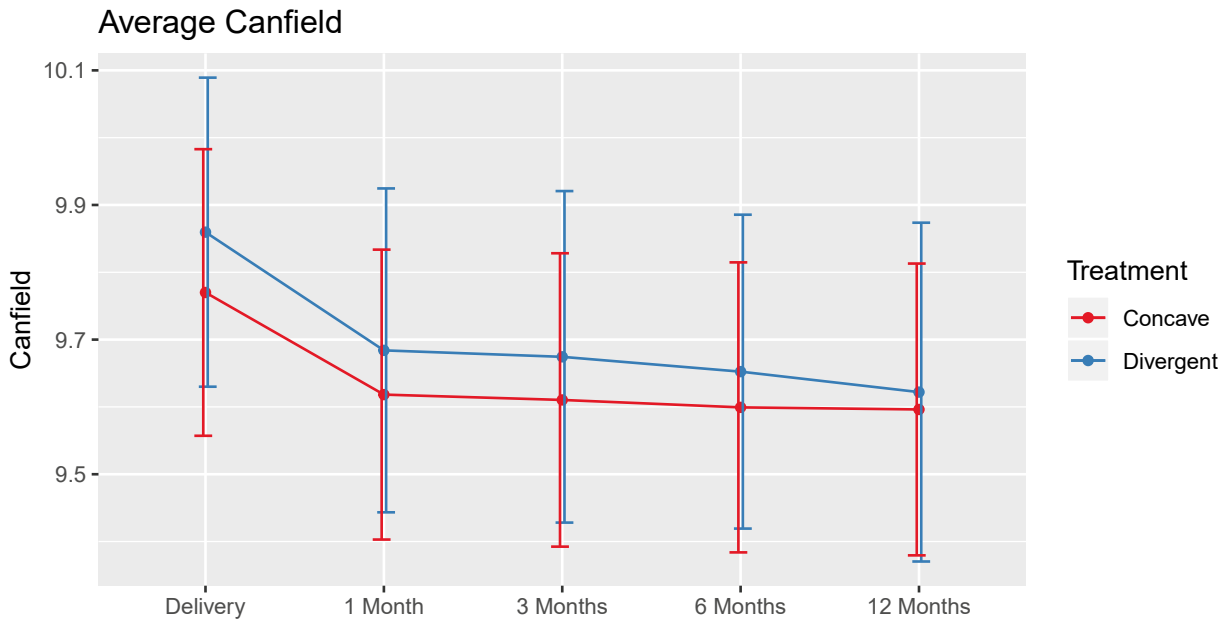


Table 2: Geomagic

	Mean	SD	Min	Max	Median	N
L_d (Divergent)	2.5039	0.6349	1.4212	4.1078	2.457	29
L_c (Concave)	2.6484	0.6608	1.5736	4.3982	2.539	29
Δ Linear (L_c - L_d)	0.1445	0.1361	0.0122	0.6119	0.117	29
V_d (Divergent)	165.8893	41.7412	91.9577	242.6630	165.796	29
V_c (Concave)	157.9359	41.1081	88.1219	226.8050	161.692	29
Δ Volume (V_c - V_d)	-7.9534	6.1022	-21.7929	-0.2594	-6.537	29

Table 3: Probing Depth

Surface	Treatment	Mean	SD	Min	Max	Median	N
1 Month							
MB	Concave	2.68	0.65	2	4	3	31
	Divergent	2.63	0.56	2	4	3	27
MIDB	Concave	1.5	0.5	1	2	1.5	27
	Divergent	1.82	0.66	1	3	2	22
DB	Concave	2.58	0.72	2	4	2	31
	Divergent	2.85	0.77	2	4	3	27
ML	Concave	2.81	0.7	2	4	3	31
	Divergent	2.85	0.77	1	4	3	27
MIDL	Concave	1.89	0.51	1	3	2	27
	Divergent	1.86	0.77	1	3	2	22
DL	Concave	2.84	0.78	2	5	3	31
	Divergent	2.85	0.82	1	4	3	27
Average	**Concave**	**2.42**	**0.4**	**1.67**	**3.17**	**2.5**	**31**
	Divergent	**2.53**	**0.45**	**1.67**	**3.25**	**2.5**	**27**
3 Months							
MB	Concave	2.68	0.6	2	4	3	31
	Divergent	2.56	0.58	2	4	3	25
MIDB	Concave	1.63	0.49	1	2	2	27
	Divergent	1.75	0.61	1	3	2	22
DB	Concave	2.58	0.67	2	4	2	31
	Divergent	2.92	0.57	2	4	3	25
ML	Concave	2.84	0.86	1	5	3	31
	Divergent	3.06	0.68	2	4	3	25
MIDL	Concave	1.85	0.77	1	3	2	27
	Divergent	2.18	0.73	1	4	2	22
DL	Concave	2.94	0.73	2	4	3	31
	Divergent	3.12	0.73	2	5	3	25
Average	**Concave**	**2.47**	**0.47**	**1.67**	**3.5**	**2.5**	**31**
	Divergent	**2.61**	**0.56**	**1**	**3.67**	**2.67**	**25**

Table 4: Probing Depth, continued

Surface	Treatment	Mean	SD	Min	Max	Median	N
6 Months							
MB	Concave	2.82	0.84	2	6	3	30
	Divergent	2.56	0.65	1	4	3	25
MIDB	Concave	1.57	0.57	1	3	2	30
	Divergent	1.78	0.65	1	3	2	25
DB	Concave	2.83	0.65	2	4	3	30
	Divergent	2.68	0.75	1	4	3	25
ML	Concave	2.87	0.78	1	5	3	30
	Divergent	2.92	0.49	2	4	3	25
MIDL	Concave	2.03	0.67	1	3	2	30
	Divergent	2.08	0.57	1	3	2	25
DL	Concave	3	0.83	1	5	3	30
	Divergent	3.08	0.7	2	4	3	25
Average	**Concave**	**2.52**	**0.46**	**1.67**	**3.5**	**2.5**	**30**
	Divergent	**2.52**	**0.38**	**1.83**	**3.17**	**2.5**	**25**
12 Months							
MB	Concave	2.8	0.72	2	5	3	28
	Divergent	2.76	0.97	2	6	3	25
MIDB	Concave	1.54	0.58	1	3	1.5	28
	Divergent	1.84	0.69	1	4	2	25
DB	Concave	2.89	0.82	2	6	3	28
	Divergent	2.96	0.61	2	4	3	25
ML	Concave	2.96	0.79	2	5	3	28
	Divergent	3.2	0.87	2	5	3	25
MIDL	Concave	2	0.61	1	3	2	28
	Divergent	2.12	0.88	1	5	2	25
DL	Concave	3.11	0.88	2	6	3	28
	Divergent	3.16	0.69	2	5	3	25
Average	**Concave**	**2.55**	**0.5**	**1.67**	**4**	**2.54**	**28**
	Divergent	**2.67**	**0.54**	**1.67**	**4**	**2.83**	**25**

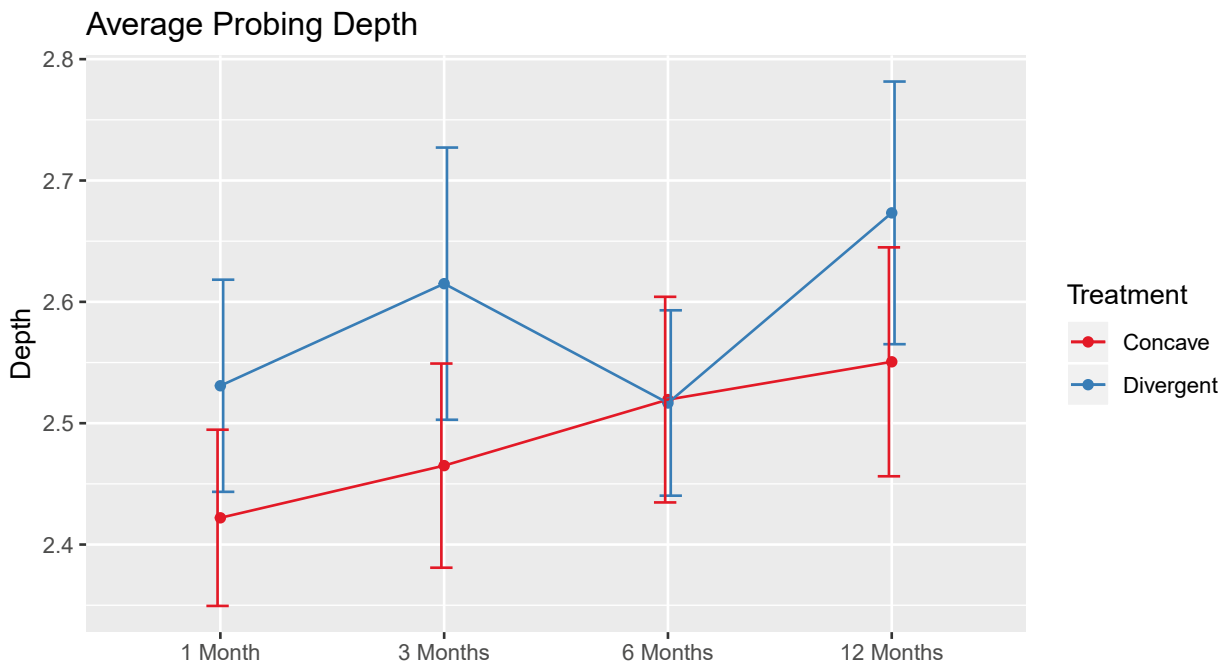


Table 5: Bleeding on Probing

Surface	Time	Concave	Divergent
MB	1 Month	25.81%	29.63%
	3 Months	22.58%	11.11%
	6 Months	19.35%	11.11%
	12 Months	22.58%	18.52%
MIDB	1 Month	25.81%	29.63%
	3 Months	6.452%	25.93%
	6 Months	22.58%	18.52%
	12 Months	29.03%	22.22%
DB	1 Month	9.677%	14.81%
	3 Months	6.452%	22.22%
	6 Months	12.9%	14.81%
	12 Months	25.81%	22.22%
ML	1 Month	25.81%	29.63%
	3 Months	35.48%	22.22%
	6 Months	12.9%	14.81%
	12 Months	19.35%	33.33%
MIDL	1 Month	9.677%	14.81%
	3 Months	12.9%	7.407%
	6 Months	22.58%	14.81%
	12 Months	29.03%	14.81%
DL	1 Month	12.9%	29.63%
	3 Months	19.35%	22.22%
	6 Months	19.35%	25.93%
	12 Months	35.48%	37.04%

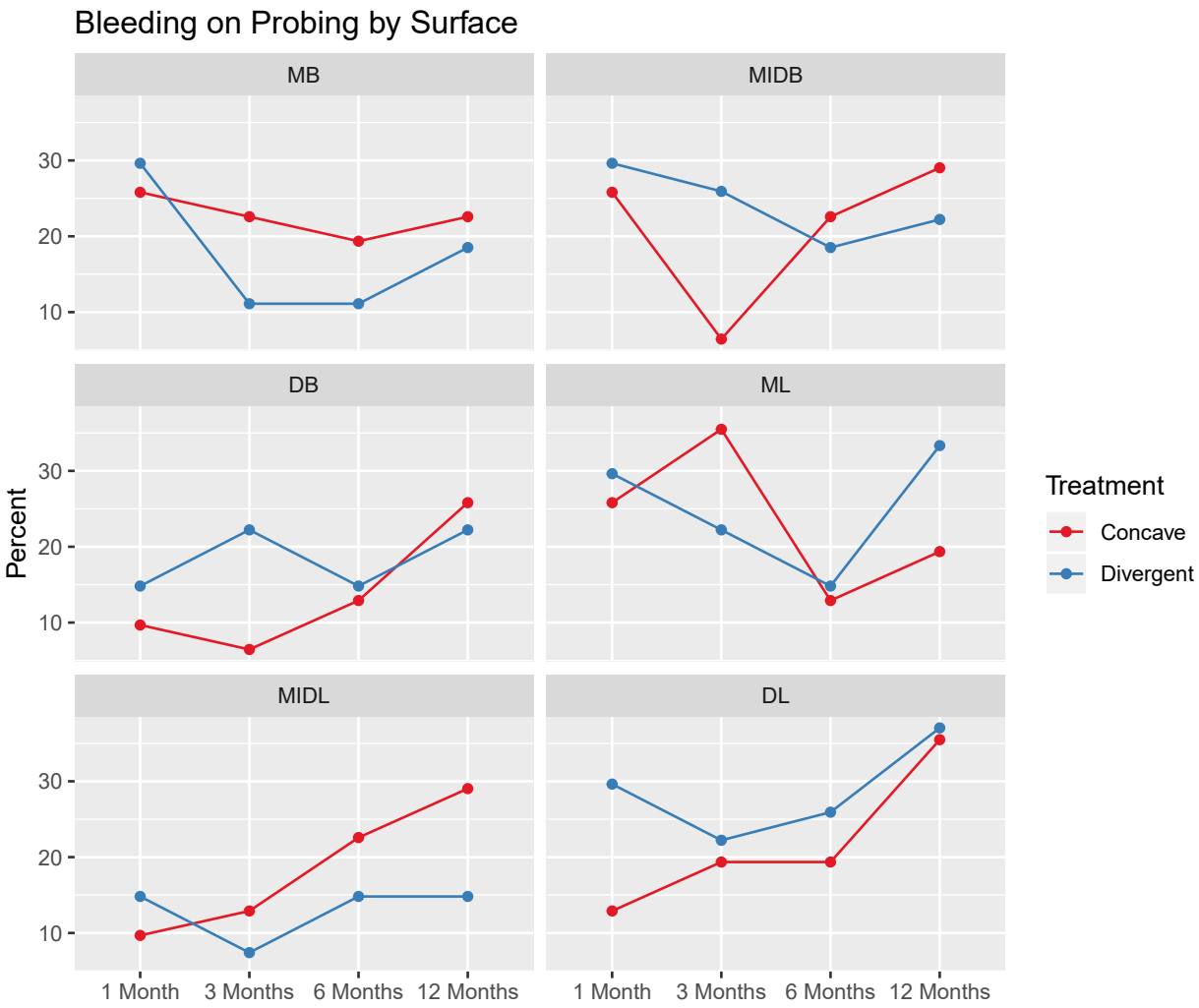

Bleeding on Probing by Surface
MB
MIDB
DB
ML
MIDL
DL
Percent
30
20
10
1 Month
3 Months
6 Months
12 Months
Treatment
Concave
Divergent

Table 6: Number of Surfaces with Bleeding on Probing

Treatment	Mean	SD	Min	Max	Median	N
1 Month						
Concave	1.097	1.2478	0	6	1	31
Divergent	1.482	1.5285	0	5	1	27
3 Months						
Concave	1.032	1.0160	0	4	1	31
Divergent	1.111	1.3960	0	5	1	27
6 Months						
Concave	1.097	1.1932	0	5	1	31
Divergent	1.000	0.9608	0	3	1	27
12 Months						
Concave	1.613	1.4532	0	6	1	31
Divergent	1.482	1.3118	0	5	1	27

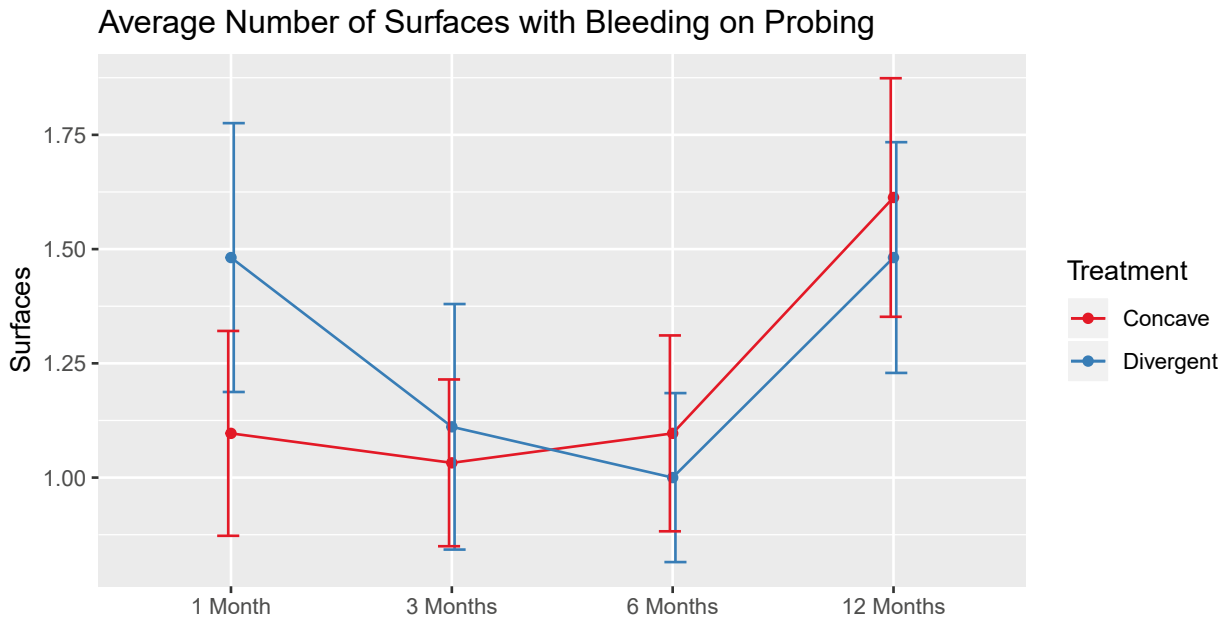


Table 7: Plaque Index

Surface	Treatment	Mean	SD	Min	Max	Median	N
1 Month							
MB	Concave	0.26	0.63	0	3	0	31
	Divergent	0.41	0.75	0	3	0	27
MIDB	Concave	0.15	0.46	0	2	0	27
	Divergent	0.14	0.47	0	2	0	22
DB	Concave	0.33	0.66	0	3	0	30
	Divergent	0.44	0.75	0	2	0	27
ML	Concave	0.39	0.72	0	3	0	31
	Divergent	0.44	0.89	0	4	0	27
MIDL	Concave	0.11	0.32	0	1	0	27
	Divergent	0.32	0.78	0	3	0	22
DL	Concave	0.52	0.72	0	3	0	31
	Divergent	0.48	0.8	0	3	0	27
Average	**Concave**	**0.29**	**0.51**	**0**	**2.5**	**0**	**31**
	Divergent	**0.36**	**0.67**	**0**	**2.67**	**0**	**27**
3 Months							
MB	Concave	0.26	0.58	0	2	0	31
	Divergent	0.36	0.76	0	3	0	25
MIDB	Concave	0.11	0.32	0	1	0	27
	Divergent	0.14	0.35	0	1	0	22
DB	Concave	0.23	0.56	0	2	0	31
	Divergent	0.44	0.87	0	3	0	25
ML	Concave	0.23	0.56	0	2	0	31
	Divergent	0.4	0.76	0	3	0	25
MIDL	Concave	0.07	0.27	0	1	0	27
	Divergent	0.18	0.39	0	1	0	22
DL	Concave	0.32	0.6	0	2	0	31
	Divergent	0.48	0.82	0	3	0	25
Average	**Concave**	**0.22**	**0.46**	**0**	**2**	**0**	**31**
	Divergent	**0.33**	**0.6**	**0**	**2.33**	**0**	**25**

Table 8: Plaque Index, continued

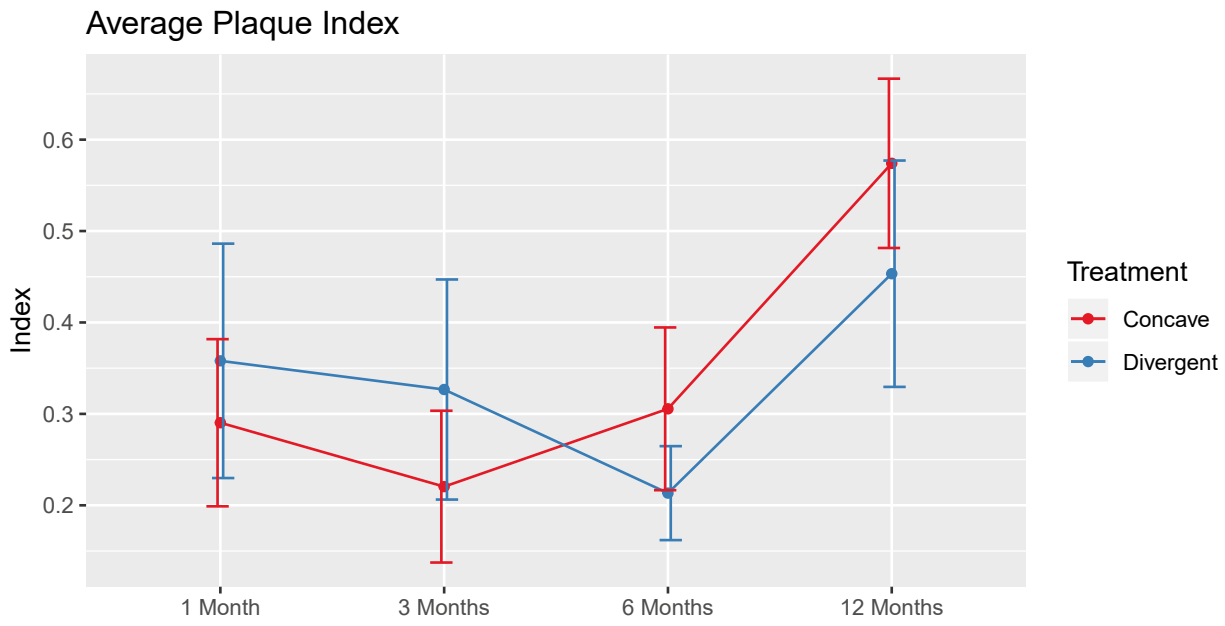
Surface	Treatment	Mean	SD	Min	Max	Median	N
6 Months							
MB	Concave	0.4	0.67	0	3	0	30
	Divergent	0.2	0.41	0	1	0	25
MIDB	Concave	0.1	0.31	0	1	0	30
	Divergent	0	0	0	0	0	25
DB	Concave	0.33	0.66	0	3	0	30
	Divergent	0.36	0.49	0	1	0	25
ML	Concave	0.4	0.72	0	3	0	30
	Divergent	0.24	0.44	0	1	0	25
MIDL	Concave	0.2	0.41	0	1	0	30
	Divergent	0.04	0.2	0	1	0	25
DL	Concave	0.4	0.56	0	2	0	30
	Divergent	0.44	0.51	0	1	0	25
Average	**Concave**	**0.31**	**0.49**	**0**	**2**	**0**	**30**
	Divergent	**0.21**	**0.26**	**0**	**0.67**	**0**	**25**
12 Months							
MB	Concave	0.56	0.58	0	2	1	27
	Divergent	0.48	0.92	0	4	0	25
MIDB	Concave	0.19	0.4	0	1	0	27
	Divergent	0.28	0.54	0	2	0	25
DB	Concave	0.74	0.71	0	3	1	27
	Divergent	0.56	0.77	0	3	0	25
ML	Concave	0.85	0.72	0	2	1	27
	Divergent	0.52	0.77	0	3	0	25
MIDL	Concave	0.26	0.45	0	1	0	27
	Divergent	0.2	0.41	0	1	0	25
DL	Concave	0.85	0.72	0	2	1	27
	Divergent	0.68	0.8	0	3	1	25
Average	**Concave**	**0.57**	**0.48**	**0**	**1.67**	**0.67**	**27**
	Divergent	**0.45**	**0.62**	**0**	**2.67**	**0.33**	**25**

Table 9: Gingival Index

Surface	Treatment	Mean	SD	Min	Max	Median	N
1 Month							
MB	Concave	0.52	0.57	0	2	0	31
	Divergent	0.74	0.76	0	2	1	27
MIDB	Concave	0.7	0.67	0	3	1	27
	Divergent	0.77	0.81	0	2	1	22
DB	Concave	0.55	0.62	0	2	0	31
	Divergent	0.7	0.72	0	2	1	27
ML	Concave	0.55	0.62	0	2	0	31
	Divergent	0.81	0.79	0	2	1	27
MIDL	Concave	0.56	0.58	0	2	1	27
	Divergent	0.73	0.55	0	2	1	22
DL	Concave	0.61	0.62	0	2	1	31
	Divergent	0.78	0.75	0	2	1	27
Average	**Concave**	**0.59**	**0.47**	**0**	**2**	**0.5**	**31**
	Divergent	**0.74**	**0.63**	**0**	**2**	**0.67**	**27**
3 Months							
MB	Concave	0.68	0.75	0	3	1	31
	Divergent	0.58	0.78	0	2	0	24
MIDB	Concave	0.59	0.57	0	2	1	27
	Divergent	0.64	0.79	0	2	0	22
DB	Concave	0.48	0.63	0	2	0	31
	Divergent	0.6	0.71	0	2	0	25
ML	Concave	0.74	0.63	0	2	1	31
	Divergent	1	0.76	0	2	1	25
MIDL	Concave	0.59	0.57	0	2	1	27
	Divergent	0.68	0.78	0	2	0.5	22
DL	Concave	0.87	0.63	0	2	1	30
	Divergent	0.96	0.79	0	2	1	25
Average	**Concave**	**0.65**	**0.47**	**0**	**2**	**0.67**	**31**
	Divergent	**0.74**	**0.66**	**0**	**2**	**0.5**	**25**

Table 10: Gingival Index, continued

Surface	Treatment	Mean	SD	Min	Max	Median	N
6 Months							
MB	Concave	0.67	0.61	0	2	1	30
	Divergent	0.52	0.71	0	2	0	25
MIDB	Concave	0.53	0.63	0	2	0	30
	Divergent	0.68	0.69	0	2	1	25
DB	Concave	0.7	0.6	0	2	1	30
	Divergent	0.68	0.63	0	2	1	25
ML	Concave	0.83	0.75	0	2	1	30
	Divergent	0.96	0.61	0	2	1	25
MIDL	Concave	0.6	0.62	0	2	1	30
	Divergent	0.68	0.56	0	2	1	25
DL	Concave	0.83	0.59	0	2	1	30
	Divergent	0.92	0.57	0	2	1	25
Average	**Concave**	**0.69**	**0.47**	**0**	**1.83**	**0.67**	**30**
	Divergent	**0.74**	**0.43**	**0**	**1.67**	**0.67**	**25**
12 Months							
MB	Concave	0.71	0.76	0	2	1	28
	Divergent	0.74	0.69	0	2	1	23
MIDB	Concave	0.71	0.6	0	2	1	28
	Divergent	0.65	0.71	0	2	1	23
DB	Concave	1.04	0.79	0	3	1	28
	Divergent	0.87	0.63	0	2	1	23
ML	Concave	1.04	0.79	0	3	1	28
	Divergent	1.04	0.77	0	2	1	23
MIDL	Concave	0.82	0.61	0	2	1	28
	Divergent	0.74	0.62	0	2	1	23
DL	Concave	1.11	0.74	0	2	1	28
	Divergent	1.39	0.66	0	2	1	23
Average	**Concave**	**0.9**	**0.54**	**0**	**2.17**	**0.67**	**28**
	Divergent	**0.91**	**0.51**	**0.33**	**2**	**0.67**	**23**


Average Plaque Index
Index
0.6
0.5
0.4
0.3
0.2
1 Month
3 Months
6 Months
12 Months
Treatment
Concave
Divergent

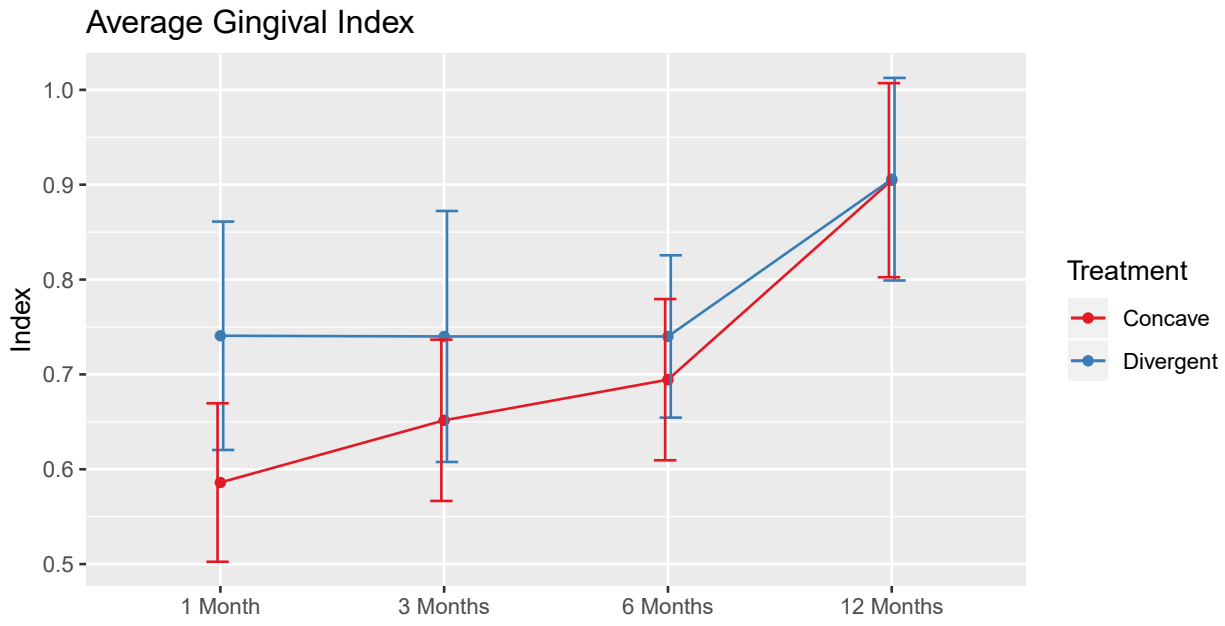

Average Gingival Index
Index
1.0
0.9
0.8
0.7
0.6
0.5
1 Month
3 Months
6 Months
12 Months
Treatment
Concave
Divergent

Table 11: Bucco-Lingual Thickness

Treatment	Mean	SD	Min	Max	Median	N
Baseline						
Concave	2.814	1.1291	1.0	6.0	2.50	31
Divergent	2.722	1.1294	1.0	6.0	2.50	27
1 Month						
Concave	2.597	0.6248	1.0	4.0	2.50	31
Divergent	2.667	0.6202	1.5	4.0	2.50	27
3 Months						
Concave	2.468	0.5764	1.5	3.5	2.50	31
Divergent	2.840	0.7176	1.5	4.0	3.00	25
6 Months						
Concave	2.517	0.5796	1.5	3.5	2.50	30
Divergent	2.920	0.6403	1.5	4.5	3.00	25
12 Months						
Concave	2.500	0.5000	2.0	4.0	2.50	29
Divergent	2.740	0.7654	1.5	4.0	3.00	25
Average						
Concave	2.594	0.4731	1.9	3.7	2.55	31
Divergent	2.785	0.5159	1.8	3.7	2.80	27

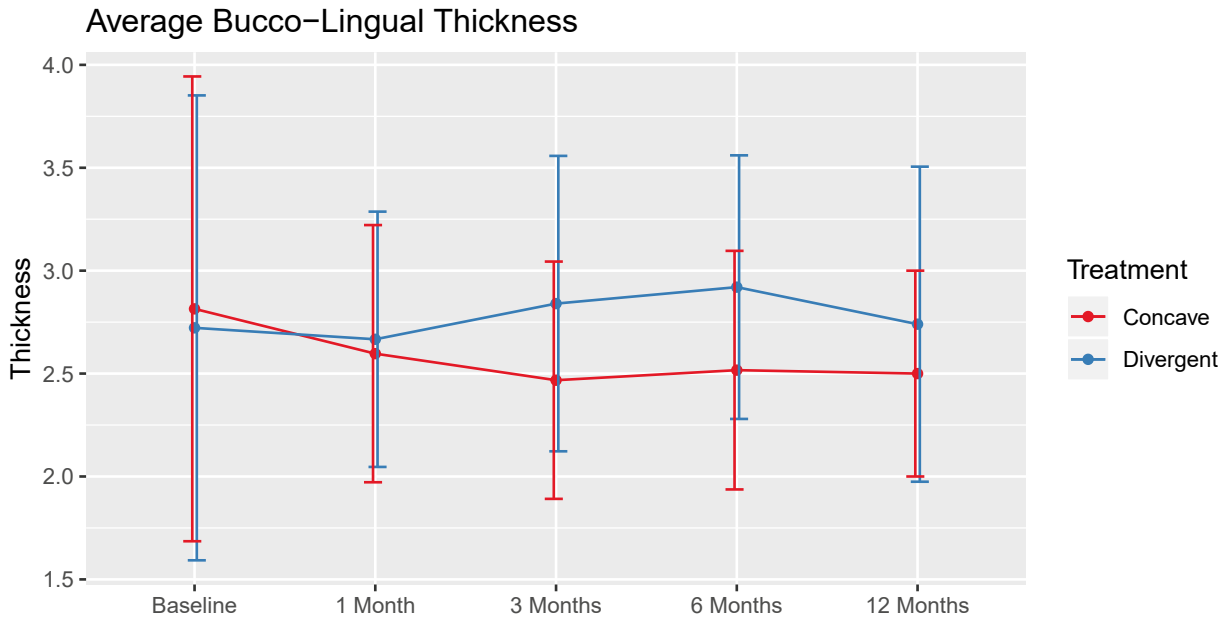
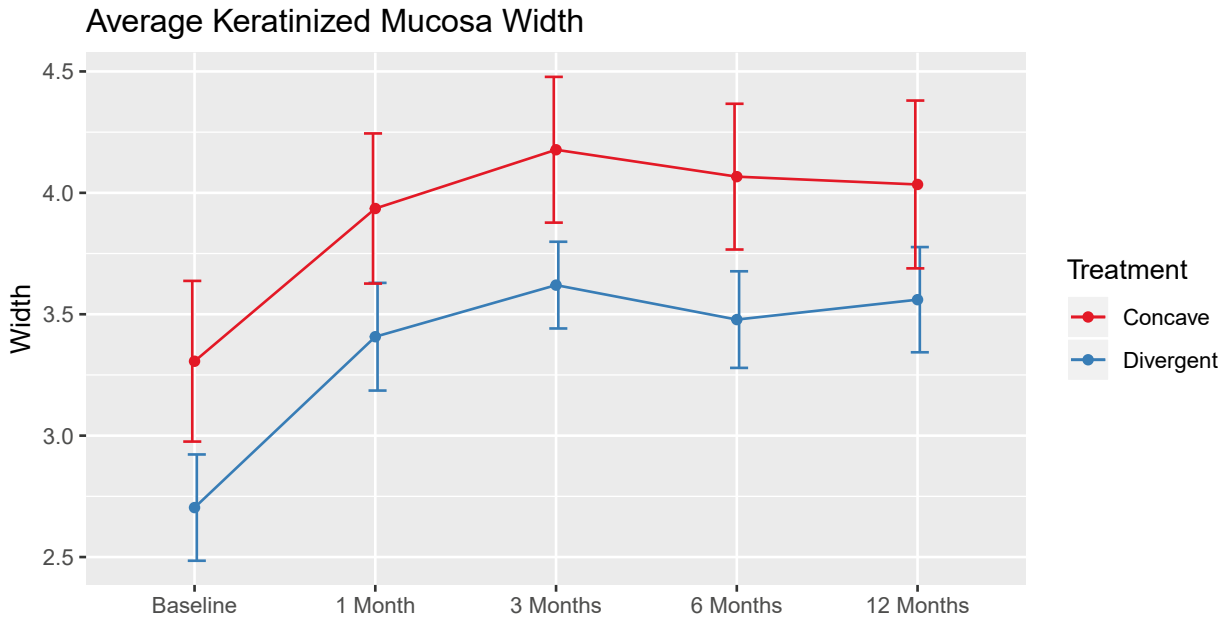


Table 12: Keratinized Mucosa Width

Treatment	Mean	SD	Min	Max	Median	N
Baseline						
Concave	3.307	1.8425	0.0	9.0	3.0	31
Divergent	2.704	1.1373	0.0	5.0	3.0	27
1 Month						
Concave	3.936	1.7212	2.0	9.0	3.5	31
Divergent	3.407	1.1522	0.0	5.0	3.5	27
3 Months						
Concave	4.177	1.6711	2.0	9.0	4.0	31
Divergent	3.620	0.8930	2.0	5.0	4.0	25
6 Months						
Concave	4.067	1.6439	2.0	8.0	3.5	30
Divergent	3.478	0.9946	1.5	5.5	3.5	25
12 Months						
Concave	4.035	1.8609	1.0	9.0	3.5	29
Divergent	3.560	1.0832	1.0	5.5	4.0	25
Average						
Concave	3.878	1.6421	1.4	8.4	3.4	31
Divergent	3.257	1.0644	0.0	4.7	3.3	27



Statistical Analyses

We used mixed models to analyze the effect of time and treatment on each of the variables of interest. The results are summarized in tables below.

Canfield values, bleeding on probing, plaque index, gingival index, and keratinized mucosa width changed significantly over time. Canfield values, bleeding on probing, plaque index, and keratinized mucosa width have a curved relationship with time. Treatment alone is not significant in any model, but is significant in

an interaction with time in bucco-lingual thickness; the effect of treatment on this measure is significantly different across time points.

Table 13: Canfield Model

	P-Value
Time	$< .001$
Time^2	$< .001$
Treatment	0.853

Table 14: Probing Depth Model

	P-Value
Time	0.096
Treatment	0.307

Table 15: Bleeding on Probing Model

	P-Value
Time	0.0791
Time^2	0.0282
Treatment	0.9170

Table 16: Plaque Index Model

	P-Value
Time	0.1640
Time^2	0.0436
Treatment	0.9880

Table 17: Gingival Index Model

	P-Value
Time	0.00146
Treatment	0.40900

Table 18: Bucco-Lingual Thickness Model

	P-Value
Time	0.0744
Time^2	0.1440
Treatment	0.6740
Treatment:Time	0.0169
Treatment:Time^2	0.0359

Table 19: Keratinized Mucosa Width Model

	P-Value
Time	$< .001$
Time^2	$< .001$
Treatment	0.106

Over time, there was not a significant relationship between bucco-lingual thickness and any of Canfield values, probing depth, bleeding on probing, or keratinized mucosa.

Table 20: Canfield and Bucco-Lingual Thickness

	P-Value
Time	$< .001$
Time^2	$< .001$
Thickness	0.178

Table 21: Probing Depth and Bucco-Lingual Thickness

	P-Value
Time	0.0928
Thickness	0.6720

Table 22: Bleeding on Probing and Bucco-Lingual Thickness

	P-Value
Time	0.1190
Time^2	0.0381
Thickness	0.7340

Table 23: Keratinized Mucosa Width and Bucco-Lingual Thickness

	P-Value
Time	$< .001$
Time^2	$< .001$
Thickness	0.705

Baseline-adjusted Analysis

We adjusted for baseline values of Canfield, bucco-lingual thickness, and keratinizaed mucosa width by subtracting the baseline from each subsequent measure, since any differences at delivery for these variables should be due to chance and not implant type.

Table 24: Canfield (Adjusted for Baseline)

Treatment	Mean	SD	Min	Max	Median	N
1 Month						
Concave	-0.152	0.180	-0.74	0.09	-0.15	29
Divergent	-0.176	0.302	-0.73	0.73	-0.14	25
3 Month						
Concave	-0.160	0.242	-0.89	0.54	-0.15	29
Divergent	-0.185	0.329	-0.91	0.71	-0.17	25
6 Month						
Concave	-0.171	0.280	-0.99	0.54	-0.15	29
Divergent	-0.207	0.323	-0.74	0.72	-0.23	25
12 Month						
Concave	-0.174	0.278	-0.84	0.54	-0.20	29
Divergent	-0.238	0.362	-0.85	0.75	-0.31	25

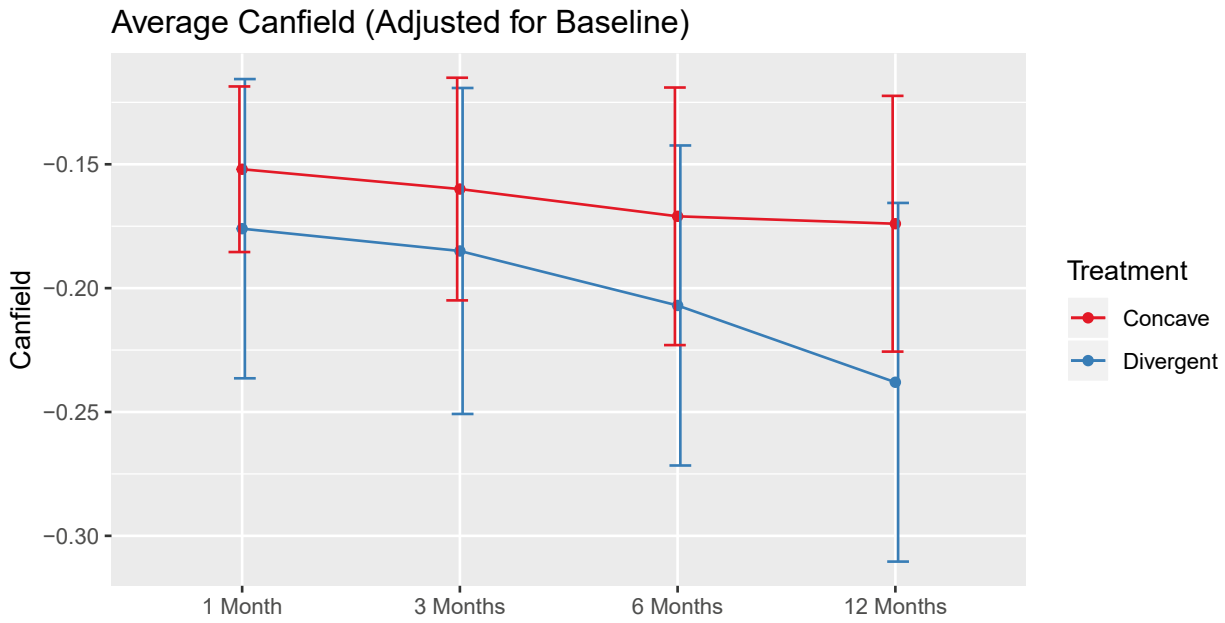


Table 25: Bucco-Lingual Thickness (Adjusted for Baseline)

Treatment	Mean	SD	Min	Max	Median	N
1 Month						
Concave	-0.218	1.138	-3.5	2.0	0.0	31
Divergent	-0.056	1.204	-3.5	2.0	0.0	27
3 Months						
Concave	-0.347	1.030	-3.0	1.5	0.0	31
Divergent	0.120	1.244	-2.5	3.0	0.0	25
6 Months						
Concave	-0.258	1.175	-4.0	2.0	0.0	30
Divergent	0.200	1.199	-3.5	2.0	0.5	25
12 Months						
Concave	-0.267	1.250	-3.5	2.0	0.0	29
Divergent	0.020	1.036	-2.0	2.5	0.0	25

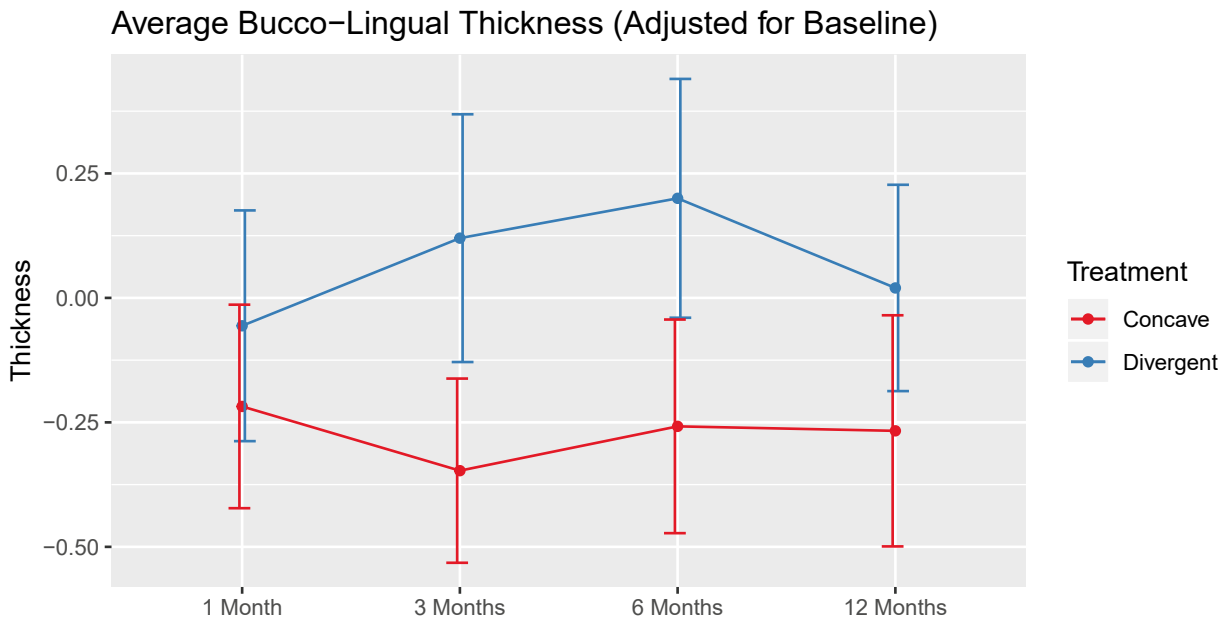
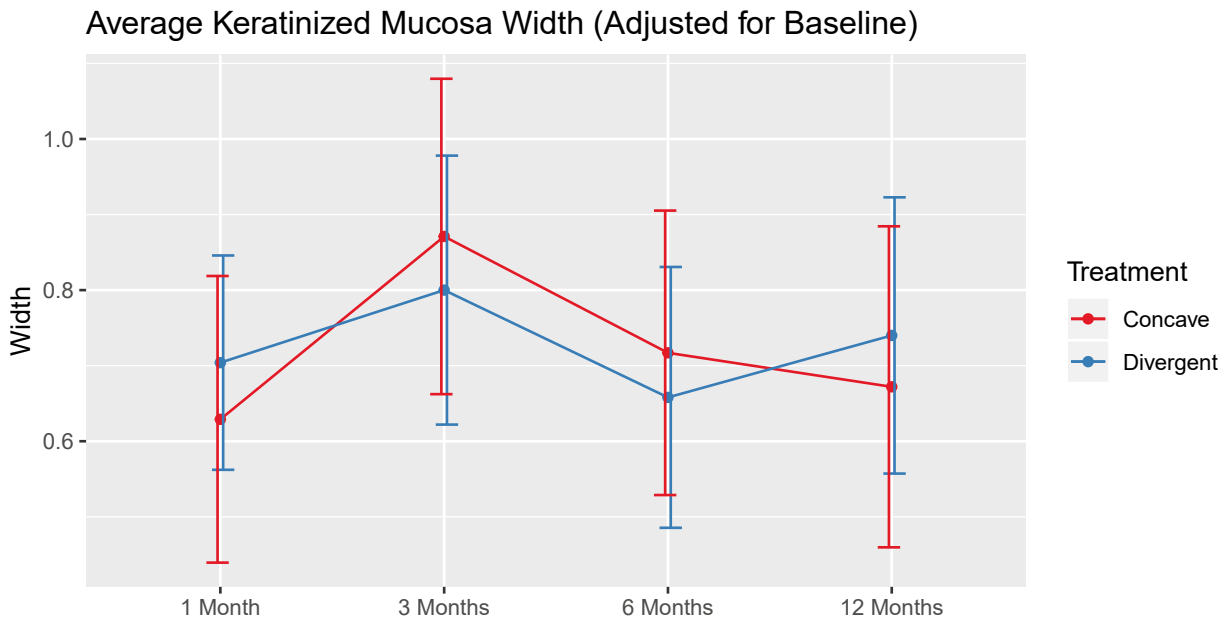


Table 26: Keratinized Mucosa Width (Adjusted for Baseline)

Treatment	Mean	SD	Min	Max	Median	N
1 Month						
Concave	0.629	1.056	-1	4.0	0.5	31
Divergent	0.704	0.737	0	2.0	0.5	27
3 Months						
Concave	0.871	1.162	-2	4.0	1.0	31
Divergent	0.800	0.890	-1	2.5	1.0	25
6 Months						
Concave	0.717	1.031	-1	4.0	0.5	30
Divergent	0.658	0.863	-1	2.0	0.5	25
12 Months						
Concave	0.672	1.144	-3	4.0	1.0	29
Divergent	0.740	0.914	-1	2.0	1.0	25



Statistical Analyses

We used mixed models to analyze the effect of time and treatment on each of the variables of interest. The results are summarized in tables below.

For Canfield, time was marginally significant but treatment was not. For bucco-lingual thickness, there were significant interactions between treatment and both time and time^2: the effect of treatment changed over time. In the keratinized mucosa model, neither time nor treatment were significant.

Table 27: Canfield Model (Adjusted for Baseline)

	P-Value
Time	0.0571
Treatment	0.6130

Table 28: Bucco-Lingual Thickness Model (Adjusted for Baseline)

	P-Value
Time	0.5680
Time^2	0.5760
Treatment	0.8330
Treatment:Time	0.0465
Treatment:Time^2	0.0510

Table 29: Keratinized Mucosa Width Model (Adjusted for Baseline)

	P-Value
Time	0.694
Treatment	0.952