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Accuracy of Implant Placement Comparing a Tissue Level Static Guide vs. Dynamic Navigation Using the X-Mark Protocol on Edentulous Mandibles: A Laboratory Study

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Accuracy of Implant Placement Comparing a Tissue Level Static Guide vs. Dynamic Navigation Using the X-Mark Protocol on Edentulous Mandibles: A Laboratory Study

by

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Each person whose signature appears below certifies that this thesis in his/her opinion is adequate, in scope and quality, as a thesis for the degree Master of Science.

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To my family and friends, thank you for the support through all of my school endeavors. Without your support, I would not have been able to persevere through this journey.

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ABSTRACT

Introduction: With the use of computer-aided design/computer-aided manufacturing (CAD/CAM), along with cone beam computed tomography (CBCT), clinicians can have a static surgical guide fabricated to aid in the placement of implants. Dynamic navigation forgoes the step of fabricating a static surgical guide. A new software and protocol have been created for dynamic navigation surgery. Data for the accuracy of this protocol on fully edentulous arches is limited and therefore leads us to this study.

Purpose: The aim of this study is to compare the accuracy of implant placement in an edentulous ridge using static tissue level surgical guides vs. dynamic navigation using the edentulous surgical protocol.

Materials and Methods: Virtually planned implants were placed in edentulous mandibular models with either a 3D printed static tissue level surgical guide (n = 24) or by using dynamic navigation (n = 24) (X-Guide, X-Nav Technologies, LLC, Lansdale, PA). Post-operative CBCT scans were taken of models and the position of the implants were compared for accuracy against the original virtual plan to determine deviations.

Results: The results showed mean deviations of 4.25° ± 2.01° angular, 2.47 ± 0.82 mm global platform and 2.88 ± 0.69 mm global apical with the use of tissue level surgical guides. The dynamic navigation group had deviations of 0.80° ± 0.38° angular, 1.84 ± 0.60 mm global platform and 1.84 ± 0.57 mm global apical. Statistically significant differences in deviations were found for the parameters of angular (p = <.001), global platform (p = 0.004) and global apical (p = <.001).

Conclusion: The accuracy of implant placement was shown to be more accurate when using dynamic navigation when compared to a tissue level surgical guide. The clinical

relevance of this study is that treatment planning time could be decreased. Also, changes can be made to the surgical plan at the time of surgery, this could be done chairside and then the clinician would still be able to continue with a completely guided surgery.

CHAPTER ONE

INTRODUCTION AND REVIEW OF THE LITERATURE

Over the last few decades, the clinical use of dental implants in the restoration of missing dentition has been ever increasing and evolving. Years of research has shown that it is a viable treatment option that allows adjacent dentition to remain untouched as well as have a very predictable outcome. With the use of dental implants, there are also challenges inherently encountered, such as anatomy of the ridge, location of nearby vital structures as well as the ability to place a prosthetically driven implant so that it can be adequately restored. Success of implant prostheses is dependent on the clinician's surgical skill and ability to precisely place implants at the prosthetically desirable pre-planned depth, angulation and crestal position while not violating the aforementioned challenges.[1] The use of static stereolithographic guides has been introduced to help aid in overcoming the challenges faced with implant placement positioning.[2]

The use of cone beam computed tomography (CBCT) has been increased in order to aid in the placement of dental implants. In combination with 3-dimensional (3D) planning software, it has allowed for precise planning to optimize implant positioning in bone with avoiding critical anatomical structures while still maintaining a prosthetically driven position.[3] Further advancements have built on this technology and have allowed the development of computer-assisted surgical (CAS) implant placement systems. These CAS systems can be both in static and dynamic forms. Static CAS systems are those that are pre-planned and fabricated with computer-aided design/computer-aided manufacturing (CAD/CAM) based on the patient's CBCT and 3D rendering which are then used on the day of surgery with no manipulations once the guide has been fabricated.[4,5] These static CAS systems have shown to be more accurate in implant placement compared to the traditional freehand drilling technique.[6] When evaluating implant placement on edentulous patients, implants were shown to be placed with higher accuracy in bone level surgical guides vs. mucosa supported surgical guides.[7] Research showed that, though mucosa supported static surgical guides resulted in acceptable implant placement, the resilience of the mucosa negatively affected the guide stability and thus resulted in increases in implant deviation.[8] Furthermore, technology has advanced to the point where we have the ability to place implants via dynamic navigation with no printed surgical guides at all. In this method, the patient and the dental instruments are mapped in real time, dynamically, which is displayed on a computer monitor for real-time feedback.[9] This has been mostly used on dentate patients as it makes for an easier case to set up and merge a CBCT scan with a surface scan for an accurate implant placement. But this is more difficult when we prepare fully edentulous cases. With a dynamic navigation system, it is possible to place an implant via a global positioning system (GPS) into a site on an edentulous ridge by placing five 1.5x4 mm self-drilling, self-tapping fiduciary screws into the arch to be restored prior to taking a CBCT. These fiducials can then be used by the software to orient itself.[10,11] With the navigation's software (X-Guide, X-Nav Technologies, LLC, Lansdale, PA), we may be able to bypass the fiducial placement step. This is achieved with their latest X-Mark software. If this method can be shown to be accurate, it would help to save the clinician surgical time and invasiveness to the patient compared to both the original navigation edentulous protocol. Previous studies have shown that, in dentate patients, both static surgical guides as well as dynamic navigation result in acceptable accuracy for implant placement.[12] Therefore, the aim of this study is to compare the accuracy of implant placement relative to the digital plan on an edentulous mandible between a tissue level 3D printed surgical guide vs. dynamic navigation system using the edentulous X-Mark surgical protocol. It is hypothesized that the accuracy of implant placement using a static tissue level surgical guide vs. dynamic navigation using the protocol on an edentulous mandibular model is comparable. Therefore, the null hypothesis is that there is no difference between the two groups. An additional aim was to compare the relative accuracy of implant placement of anterior, vertical implants vs. posterior, angled implants within each group.

CHAPTER TWO

MATERIALS AND METHODS

This study compared the accuracy of implant placement with both static tissue level surgical guides and dynamic navigation using a surgical navigation system with the software (X-Guide, X-Mark, X-Nav Technologies, LLC, Lansdale, PA) on edentulous mandible models. All of the sawbone models were identical. One of the models was scanned with an optical scanner(A/S TRIOS 3 scanner, 3Shape, Copenhagen K Denmark) and then a simulated denture, without a tooth setup, was created and 3D printed. This was to serve as the interim denture that is typically used for implant planning with fully edentulous cases. Twelve sawbone mandible models with simulated soft tissue (Sawbone USA, Vashon, WA) were then scanned using a CBCT scanner (NewTom VGi EVO, QR, Verona, Italy) at 12x8 field of view, 110 kvp and 3.72 mA. The six models which were randomly selected to be used in the tissue level surgical guide group had the sawbone mandible scanned with the simulated denture with fiducial markers placed. The simulated denture was then scanned separately. Surgical planning of a 4.3x13 mm implant (NobelParallel Conical Connection, Nobel Biocare, Yorba Linda, CA) was then carried out utilizing an implant planning software. DTX studio for the surgical guide group and X-Guide for the surgical navigation group. For the static guide group, the aforementioned plan was taken one step further to design a static tissue level surgical guide by importing the simulated denture dicom file and merging it with the CBCT dicom file. The static guide design was then executed using the same implant planning software and then exported as an .stl file and 3D printed (SprintRay Pro 95) with surgical grade resin (Surgical Guide 3 resin, SprintRayInc., Los Angeles, CA, USA).

Implant Placement

Six models had 4 implants placed via the static guide on each model, and the other 6 models had 4 implants placed on each model via dynamic navigation. Therefore, both groups had 24 implants placed in 6 models each. Posterior implants were placed at an angulation of 30 degrees and the anterior implants were placed vertically in order to simulate an All-On-Four® concept. The implants, 4.3x13 mm non-sterile implants were placed per the manufacturer's protocol. In order to minimize bias, a coin flip was done to determine whether the static guide or the navigation would be used first upon which each set of implants were placed in an every other fashion, i.e., 4 static, then 4 navigation, then 4 static, so on and so forth. At each set of implant placements, a coin flip was used to decide whether the left or right side would be placed first. All implants were placed via a single operator.

For the static tissue level surgical guides, the guide was seated on top of the ridge. The placement of the implants was then completed following the manufacturer's guided implant protocol. For the dynamic navigation, a clip was affixed to the midline of the mandible via the associated E-clip screws (2) provided, upon which the navigation tracker was attached. Implant drills were then calibrated prior to each use utilizing the guide's drill calibration plate in conjunction with the dual camera tracking system. Implants were then placed following the navigation protocol.

Accuracy Analysis

Following implant placement, all twelve sawbone mandible models had a post-operative CBCT scan taken. All models were analyzed using the navigation system software protocol.[10] This was done by superimposing the pre-operative virtual surgical plan with the post-operative CBCT scan and quantifying the deviations of the placed implant relative to the planned position and orientation. A trained engineer, who was blinded to the study groups, identified the exact location of the placed implant in the post-operative CBCT with the surgical planning software. The pre-operative and post-operative CBCT scans were then registered by aligning the sawbone models in each scan via a rigid transformation. In order to generate the registration, polygonal meshes representing the outer surface of the sawbone models were extracted from the pre-operative and post-operative CBCT scans with iso-surface thresholding techniques. The meshes were then cleaned and aligned in the open-source MeshLab software suite. The virtual pre-operative implant plan was then projected onto the post-operative CBCT scan where the position and orientation could be compared to the placed implant. Deviations analyzed are depth at both the platform and apex, 2D lateral deviation in both the buccal/lingual and mesial/distal directions at both the apex and the platform (non-depth deviation), global deviation (overall 3D deviation) at both the platform and apex and angular deviation in the 3D space (Figure 5).

Statistical Analysis

The statistical analysis was completed using a linear mixed model with an independent sample t-test to analyze the difference between the two methods of implant placement (tissue level guide vs. dynamic navigation). A generalized linear model was then used in order to adjust for the location of the implant placed (anterior vs. posterior) as well as the method of placement (tissue level guide vs. dynamic navigation) which was then analyzed using ANOVA. It was determined that a sample size of 6 samples per group is needed to show comparability, though this study used a sample size of 24 per group. Statistical significance was set at $p < .05$.

CHAPTER THREE

RESULTS

A total of 48 implants were placed into 12 edentulous sawbone mandibles. 24 implants were placed using a tissue level surgical guide and 24 implants were placed using dynamic navigation. For each group, 4 implants were placed into each mandible, 2 in the anterior in a vertical fashion, and 2 in the posterior tilted at 30 degrees (Table 1). All implants were placed by a single operator. The deviations between the planned implant position and actual implant placement were measured by a separate trained technician.

Table 2 shows the deviations of the planned implant positions compared to the final implant positions. Implants placed with a tissue level surgical guide had deviations of 4.25° ± 2.01° angular, 2.47 ± 0.82 mm global platform, 2.16 ± 0.93 mm platform depth, 1.00 ± 0.48 mm platform non-depth, 2.88 ± 0.69 mm global apical, 2.20 ± 0.92 mm apical depth and 1.62 ± 0.70 mm apical non-depth. Implants placed with dynamic navigation had deviations of 0.80° ± 0.38° angular, 1.84 ± 0.60 mm global platform, 1.37 ± 0.47 mm platform depth, 1.03 ± 0.79 mm platform non-depth, 1.84 ± 0.57 mm global apical, 1.37 ±0.46 mm apical depth and 1.03 ± 0.75 mm apical non-depth. Independent t-test showed statistically significant differences in deviations for the parameters of angular (p = <.001), global platform (p = 0.004), platform depth (p = <.001), global apical (p = <.001), apical depth (p = <.001) and apical non-depth (p = 0.007). There was no statistically significant difference in deviation for platform non-depth (p = 0.861).

A general linear model was used to assess differences when adjusting for anterior or posterior implant placement, which was tested for using an ANOVA test (Table 3). For angular deviation, there was a statistically significant difference depending on implant location (anterior vs. posterior) (p = 0.001), a statistically significant difference based on the method of placement (tissue vs. dynamic navigation) (p = <.005) and a statistically significant interaction between location and method (p = 0.006). For global platform deviation, there was no statistically significant difference depending on location (p = 0.308) or location and method interaction (p = 0.820), but there was a statistically significant difference depending on method (p = 0.004). For platform depth deviation, there was no statistically significant difference based on location (p = 0.193) or interaction of location and method (p = 0.632), but there was a statistically significant difference based on method (p = <.001). For platform non-depth deviation, there was no statistically significant difference based on the location (p = 0.740), method (p = 0.864) or the interaction of the location and the method (p = 0.760). For global apical deviation, there was no statistically significant difference depending on location (p = 0.642) or location and method interaction (p = 0.228), but there was a statistically significant difference depending on method (p = <.001). For apical depth deviation, there was no statistically significant difference depending on location (p = 0.223) or location and method interaction (p = 0.691), but there was a statistically significant difference depending on method (p = <.001). For the apical non-depth deviation, there was no statistically significant difference based on location (p = 0.138), but there was a statistically significant difference based on method (p = 0.005) as well as the interaction of location and method (p = 0.043).

CHAPTER FOUR

DISCUSSION

The results of this study reject the hypothesis that the accuracy of implant placement into an edentulous mandibular model utilizing dynamic navigation with the X-Mark protocol is comparable to implant placement utilizing a static tissue level surgical guide.

Various research articles have been released evaluating the accuracy and efficacy of dynamic navigation for the use of implant placement. A model-based study published in 2016 by Emery, et al. evaluated the accuracy of both dentate and edentulous maxillary and mandibular sawbone models.[10] Their edentulous protocol differed from this study as they used fiduciary screws pre-surgically placed in order to aid in the merging of the digital implant plan and the live patient model. This is different from the current study as the current study utilizes the new X-Mark protocol to help achieve this merging and alignment without the use of pre-surgical fiduciary screws. The edentulous mandible results of this study showed an angular deviation of 1.25 ± 0.65°. The results of the entry deviations were 0.49 ± 0.16 mm for global, 0.26 ± 0.18 mm for depth and 0.37 ± 0.17 mm for lateral deviation. The results for apex deviations were 0.48 ± 0.13 mm for global, 0.26 ± 0.18 mm for depth and 0.38 ± 0.10 mm for lateral deviation. Compared with the current study, these angular results are very similar, however, there is a noticeable difference in the distance measurements of approximately 1 mm for each parameter. This may be due to the difficulty in merging the model in the software or it could also be due to an inherent error in the operator placement.

A systematic review and meta-analysis by Wei, et al. assessed the accuracy of implant placement using dynamic navigation in both clinical and model-based studies. A total of ten studies were selected, five clinical and five model-based including both partially dentate and fully edentulous cases. The results were an average global platform deviation of 1.02 mm, an average global apex deviation of 1.33 mm and an average angular deviation of 3.59°. These results were for all five dynamic navigation systems used and the authors reported no statistically significant differences in any of the parameters including, dynamic navigation system, dentate vs. edentulous, maxilla vs. mandible, or human vs. model. These statistics reported are similar to the results of this current study apart from a greater difference in the angular deviation.

A study by Feng, et al. recently reported results on an in vitro study of evaluating the accuracy of implant placement with dynamic navigation on an edentulous mandibular model.[14] The results showed a deviation of 1.14 ± 0.5 mm at the entry point, 1.29 ± 0.48 mm at the apex and 3.02 ± 1.32° of angular deviation. There was no statistically significant difference in the four different implant positions used. This is in line with the current study as except for the variation in angular deviation, which was narrower in the current study.

A systematic review by Pellegrino, et al. reported an overall conclusion that implant placement with dynamic navigation had small placement errors, which were comparable to the use of static guides but more accurate than freehand surgery.[15] This study included in vitro, cadaver and clinical studies. The current study did not measure freehand implant placement and was only in vitro, however, it differs in that this study found the use of dynamic navigation to be more accurate in implant placement.

For comparison of the tissue level static surgical guide group, Seo, et al. had a systematic review which measured the accuracy of implant placement using stereolithographic mucosa-supported surgical guides in edentulous patients. All of the included studies were clinically based. Their findings showed angular deviations ranging from 2.6° (SD 1.61) – 4.67° (SD 2.68), global coronal deviations ranging from 0.6 (SD 2.5) mm – 1.68 (SD 0.25) mm and global apical deviations ranging from 0.67 (SD 0.34) mm – 2.19 (SD 0.83) mm. The results of the current study appear fairly consistent with these findings, though they would be in the upper limits of these findings. Once reason there could have been additional deviations in the static surgical guide group is that the surgical technique included a full thickness flap, both buccal and lingual, which extended to just distal of the most posterior implants. Thus, only the distal aspect of the static surgical guide was residing on mucosa when it was secured into place. This, invariably, could add additional error to this group, even though the thickness of the mucosa was approximately 1 mm in thickness.

When comparing the accuracy of implant placement for vertical anterior vs. tilted posterior implants, the factor that had the most impact on accuracy of each of the observed categories was the method of implant placement except for the platform non-depth deviation parameter, which had no statistically significant difference regardless of method, location or interaction between the two. Angular deviation, in addition to the method of placement, was also affected by the location of implant placement as well as an interaction between the method and location used. Apical non-depth deviation, in addition to the method of placement, also had an interaction between the method and location used.

This study has limitations as it was an in vitro study with prefabricated mandibular sawbone models. An additional limitation is that the sawbone models were prefabricated and were uniform in shape. This adds to the difficulty in aligning the scans as there are limited anatomical landmarks that can be used as a reference. In this sense, cadaver or clinical studies may reveal different results due to the possibility of having more accurately aligned scans when planning and executing implant placement.

Clinically, we must decide how much variation between an implant plan compared to the actual placement we can withstand before it interferes with the final prosthesis to be delivered to the patient as well as what our safety zones are relative to vital structures, such as the inferior alveolar nerve and the maxillary sinus. In a single crown restoration, or a fixed dental prosthesis, the room for error may be smaller as the implant emergence must be centered in a specific tooth position. This may differ in the treatment of a fixed complete denture, where the implant placement and emergence has much more flexibility as it just needs to be lingualized on the prosthesis. In the previous situation, angulation becomes one of the most important factors in order to fabricate a prosthesis which has a passive fit. As far as vital structures, depending on the amount of deviation one can expect, we may need to incorporate the range of error into our planning so we can be sure we will avoid encroaching on any nearby vital structures. So, moving forward, it is up to the clinician to decide which method of implant placement to use and how precise and accurate they must be given their clinical presentation of the patient.

CHAPTER FIVE

CONCLUSION

Within the limits of this study, it can be concluded that there was a statistically significant difference in the accuracy of implant placement relative to the digital plan when comparing static tissue level surgical guides vs. dynamic navigation in favor of dynamic navigation. When analyzing the placement of anterior vertical vs. posterior tilted implants, the method of implant placement has the most effect on the outcome of accuracy, in favor of dynamic navigation. The reader should be cautioned in all of the limitations that were stated in the discussion regarding the final conclusion of this study. It should also be cautioned that accuracy of implant placement when using dynamic navigation is highly dependent on an accurate merge of the digital information and the clinical presentation of the patient at the time of surgery. More studies must be done on in vivo research models.


Figure 1. Sawbone mandible

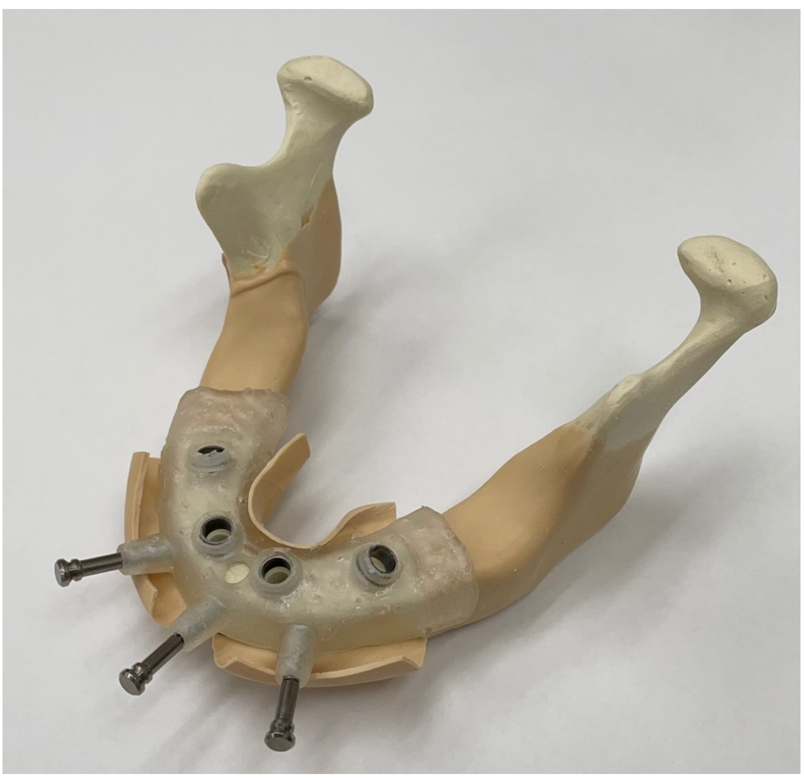
Figure 2. Tissue level surgical guide set-up

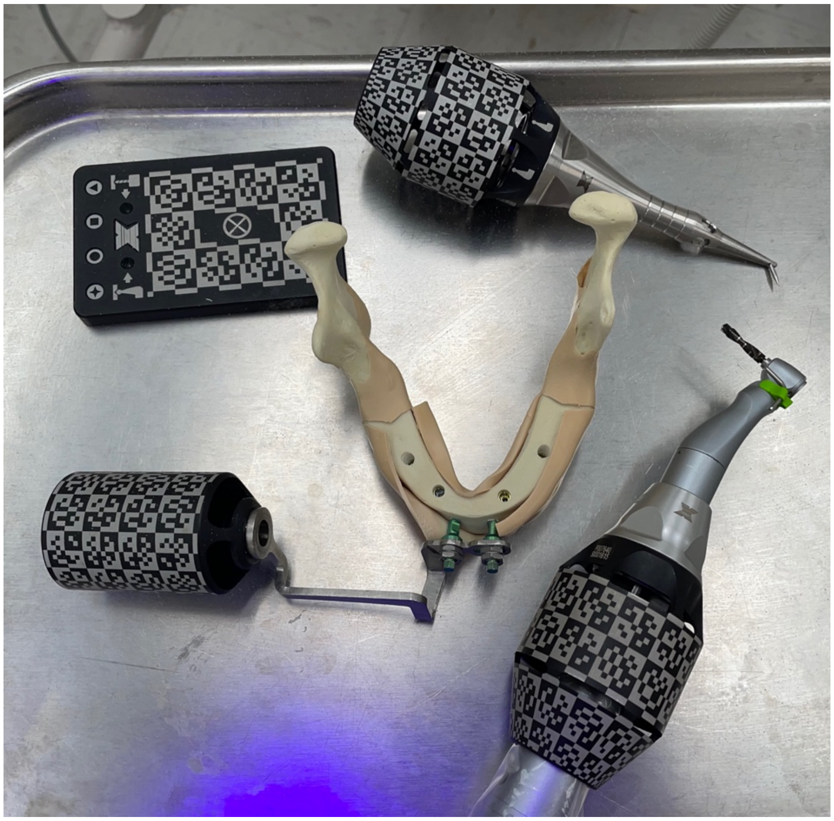

Figure 3. Dynamic navigation setup and instruments

Figure 4. X-Guide unit

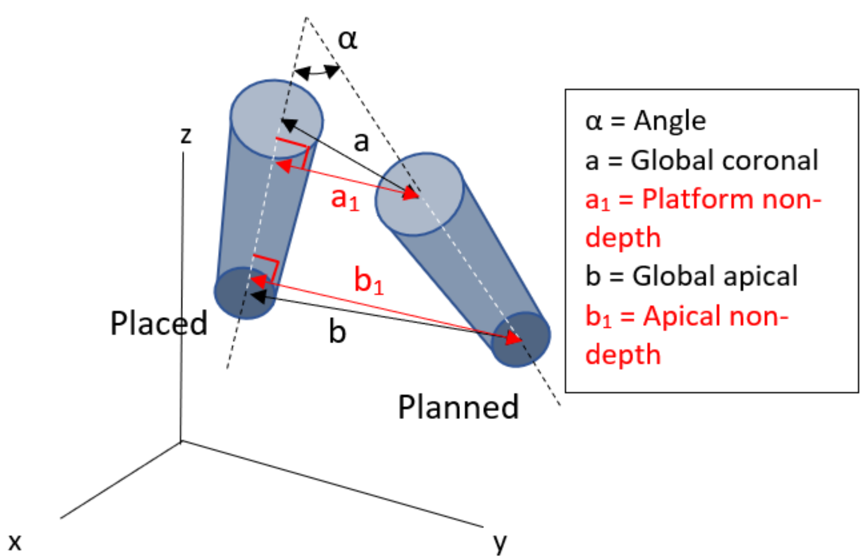

Figure 5. Illustration of the parameters of accuracy

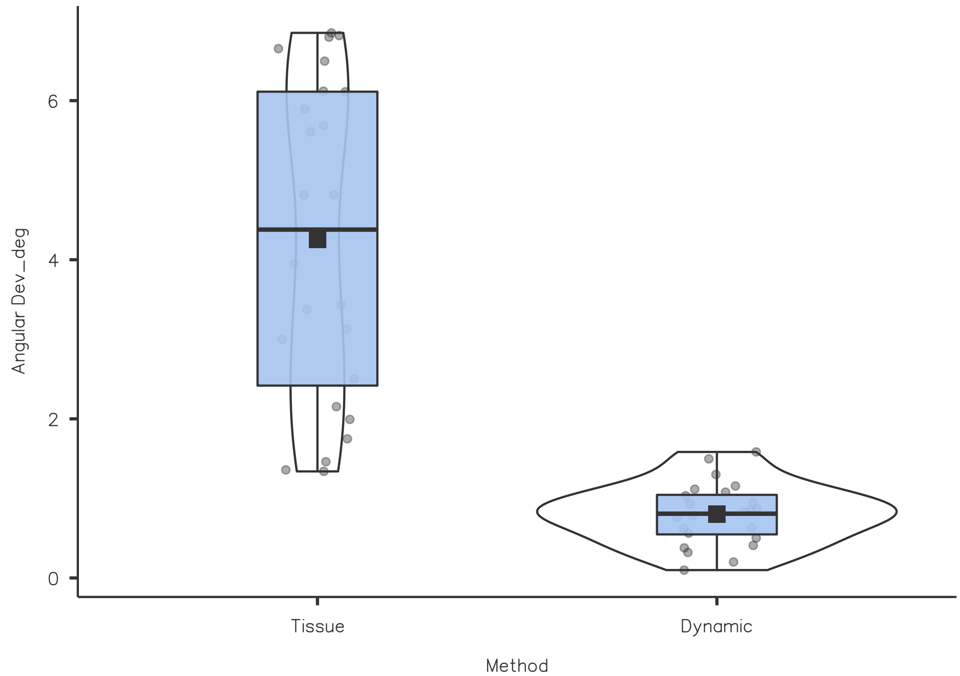

Figure 6. Box plot comparing angular deviation between the two groups

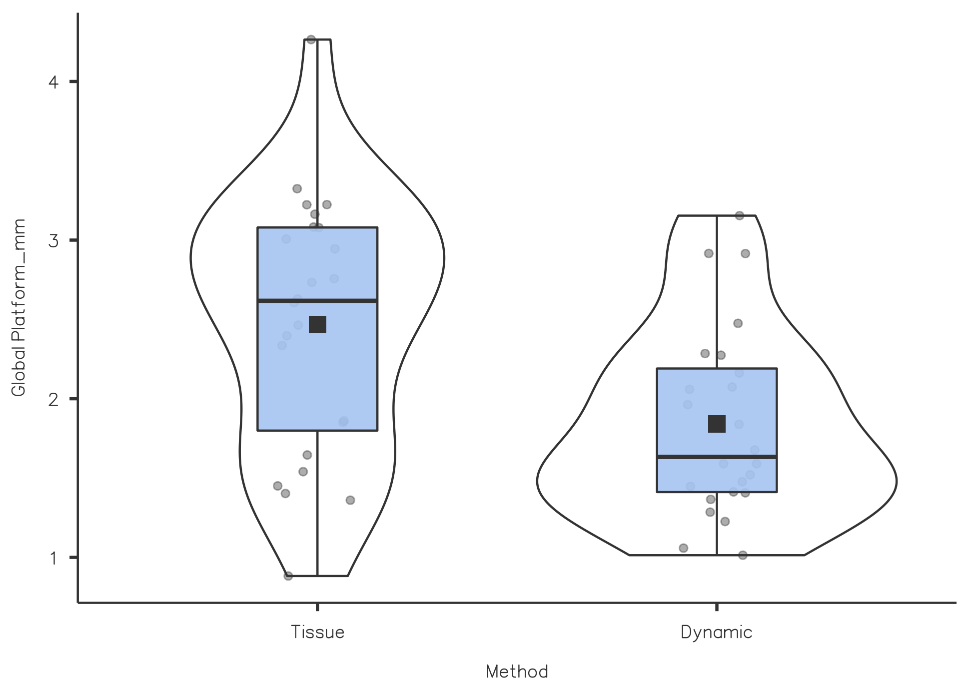

Figure 7. Box plot comparing global platform deviation between the two groups

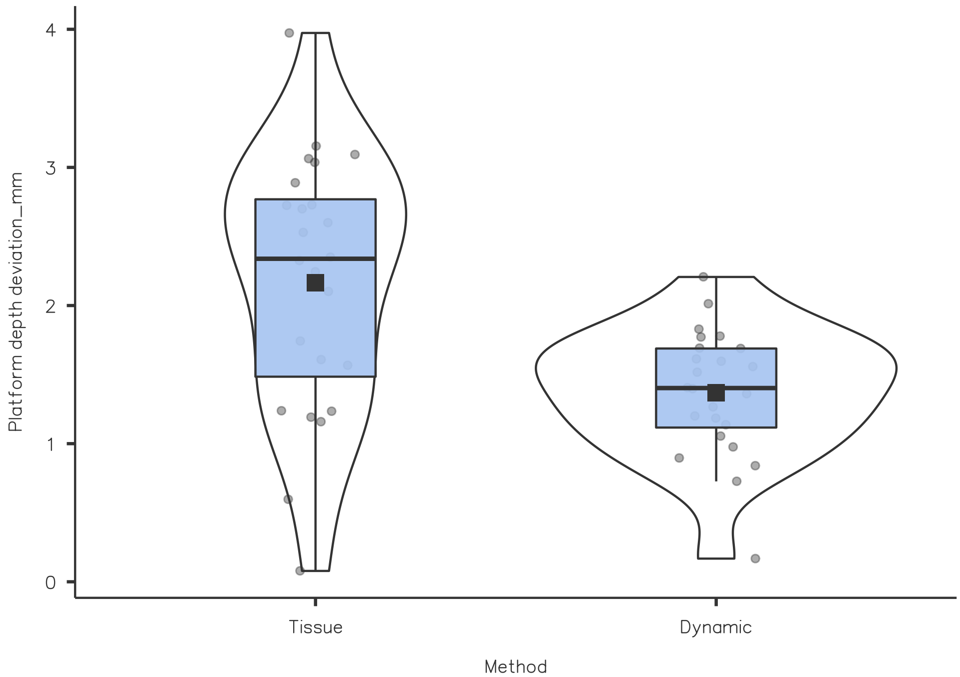

Figure 8. Box plot comparing platform depth deviation between the two groups

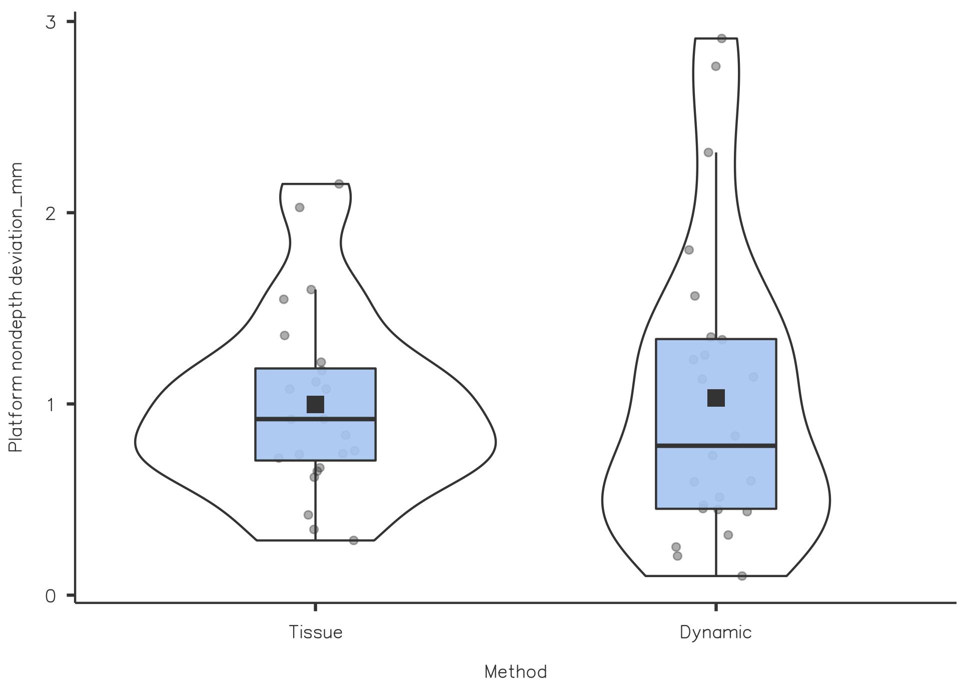

Figure 9. Box plot comparing platform non-depth deviation between the two groups

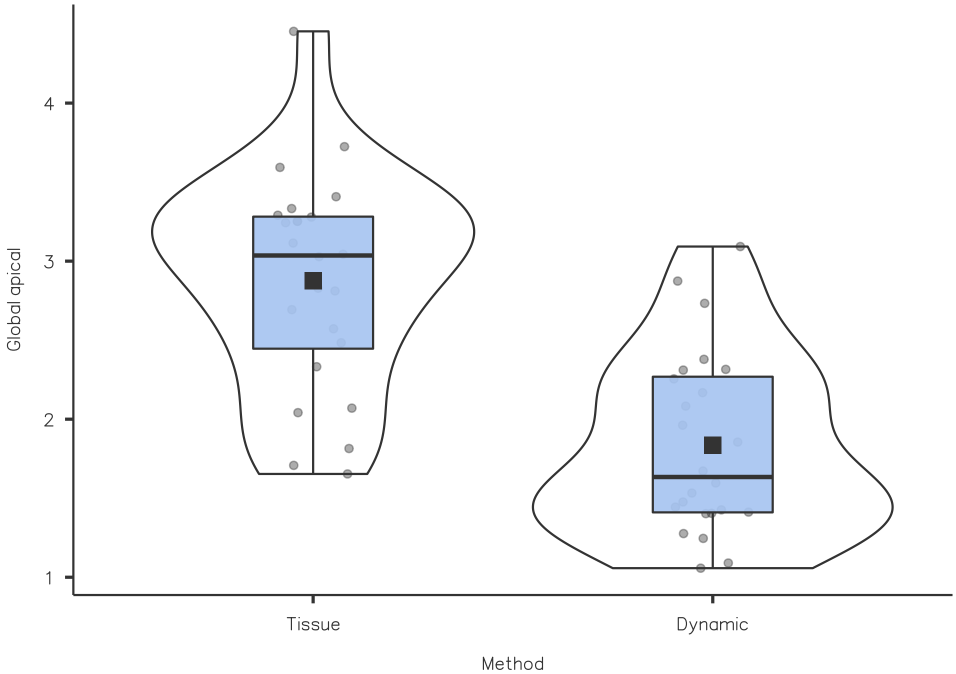

Figure 10. Box plot comparing global apical deviation between the two groups

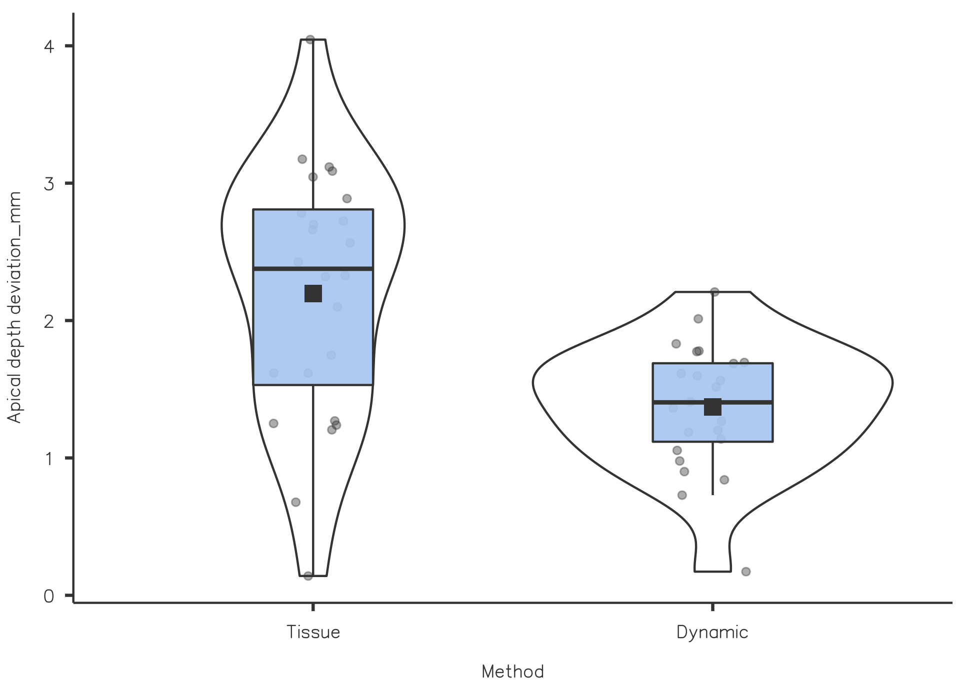

Figure 11. Box plot comparing apical depth deviation between the two groups

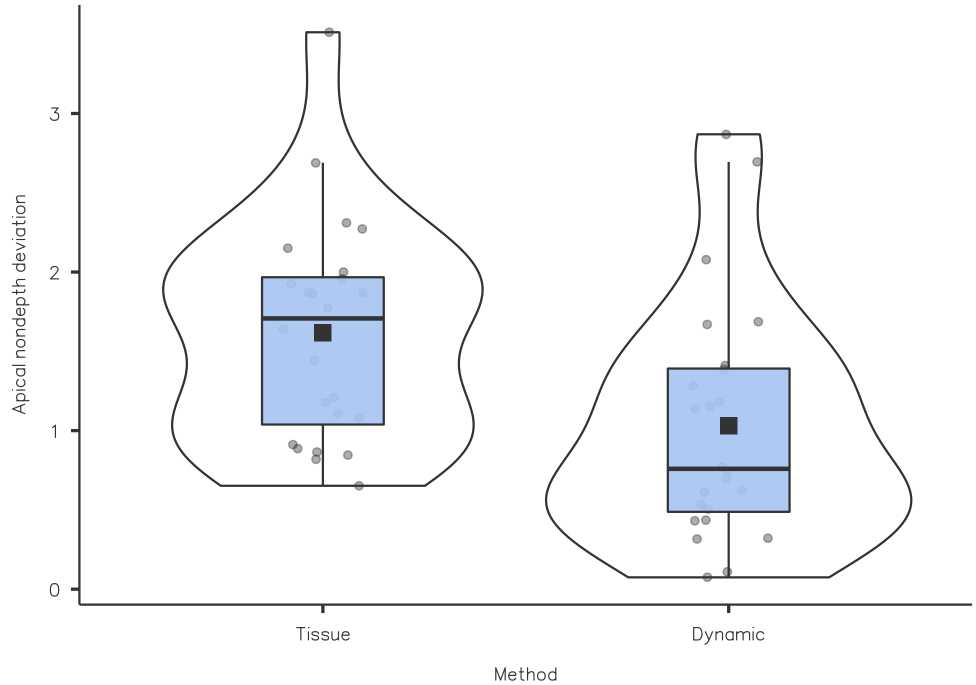

Figure 12. Box plot comparing apical non-depth deviation between the two groups

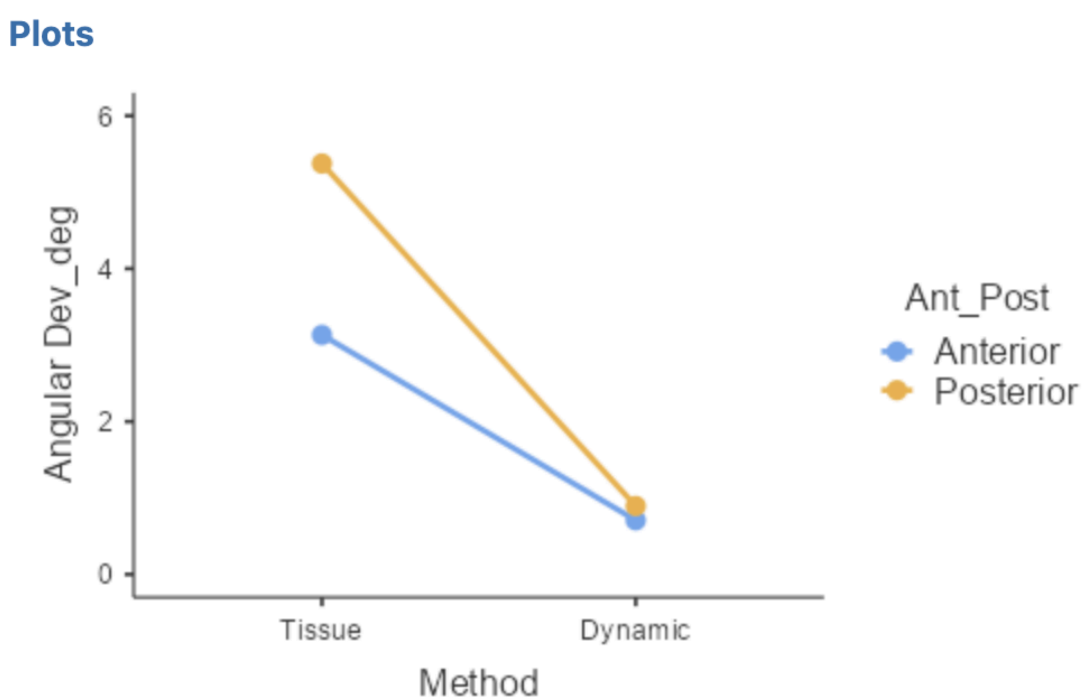

Figure 13. Plot of method vs. angular deviation for anterior vs. posterior implants

Plots

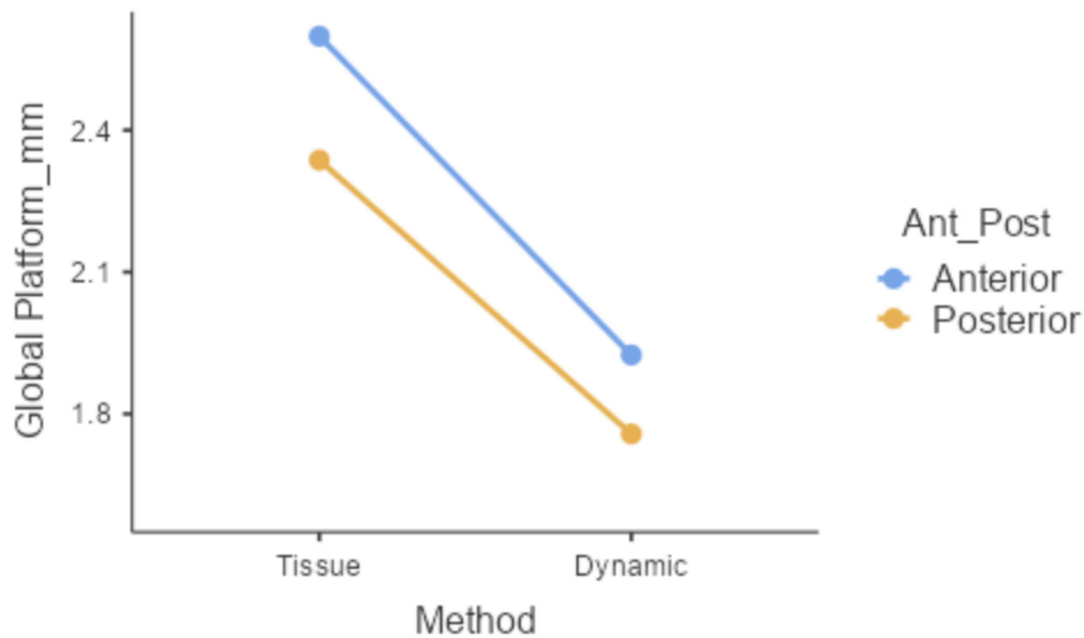

Figure 14. Plot of method vs. global platform deviation for anterior vs. posterior implants

Plots

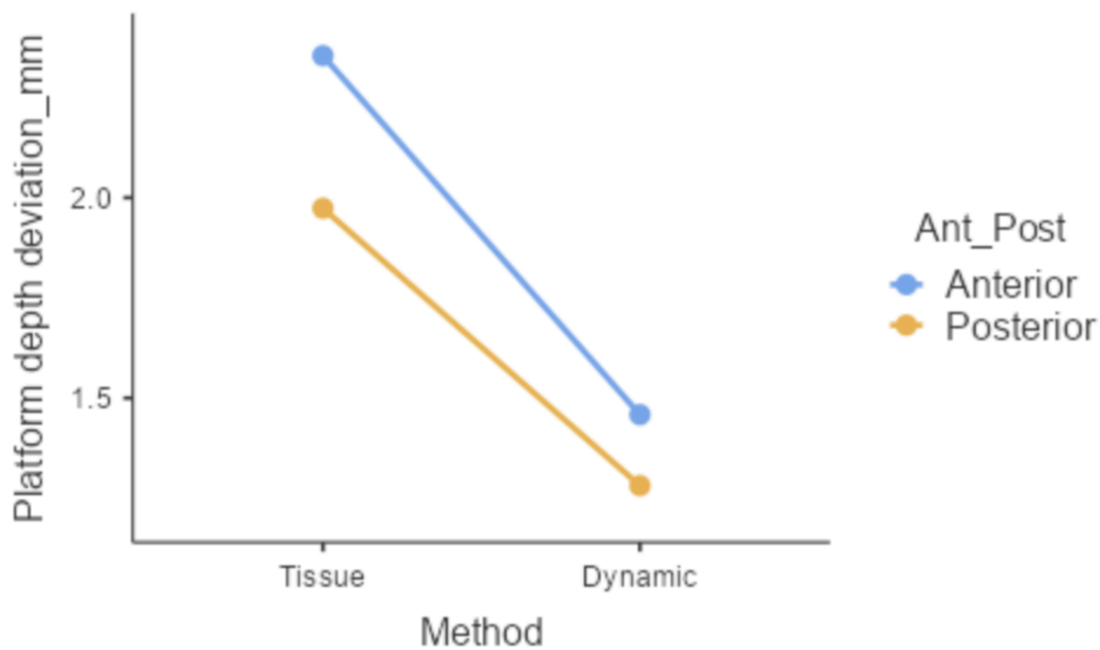

Figure 15. Plot of method vs. platform depth deviation for anterior vs. posterior implants

Plots

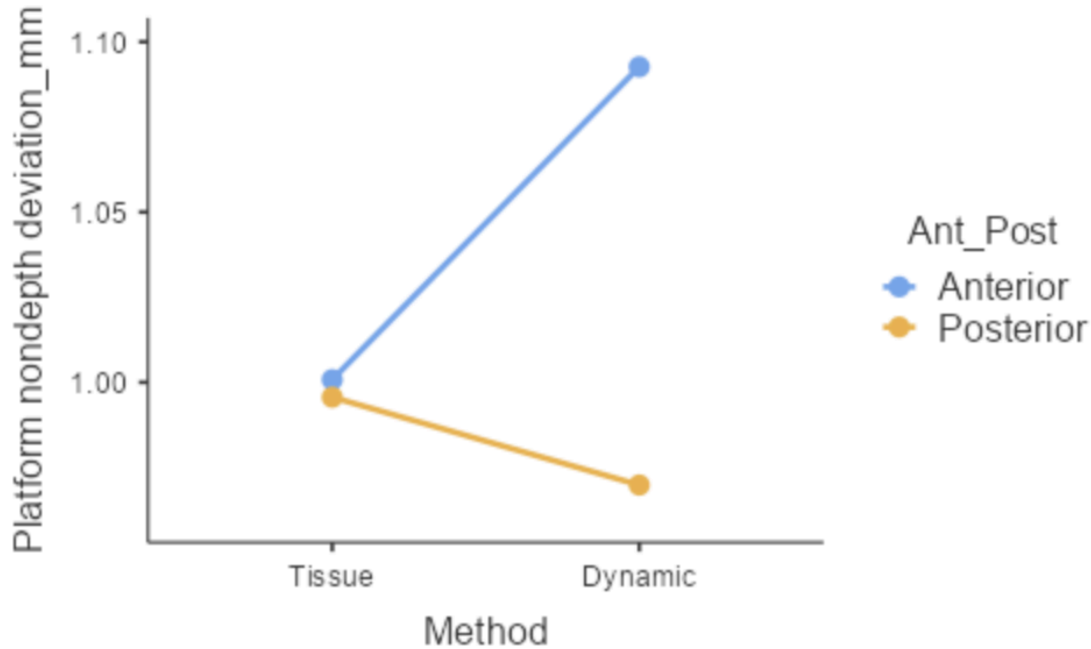

Figure 16. Plot of method vs. platform non-depth deviation for anterior vs. posterior implants

Plots

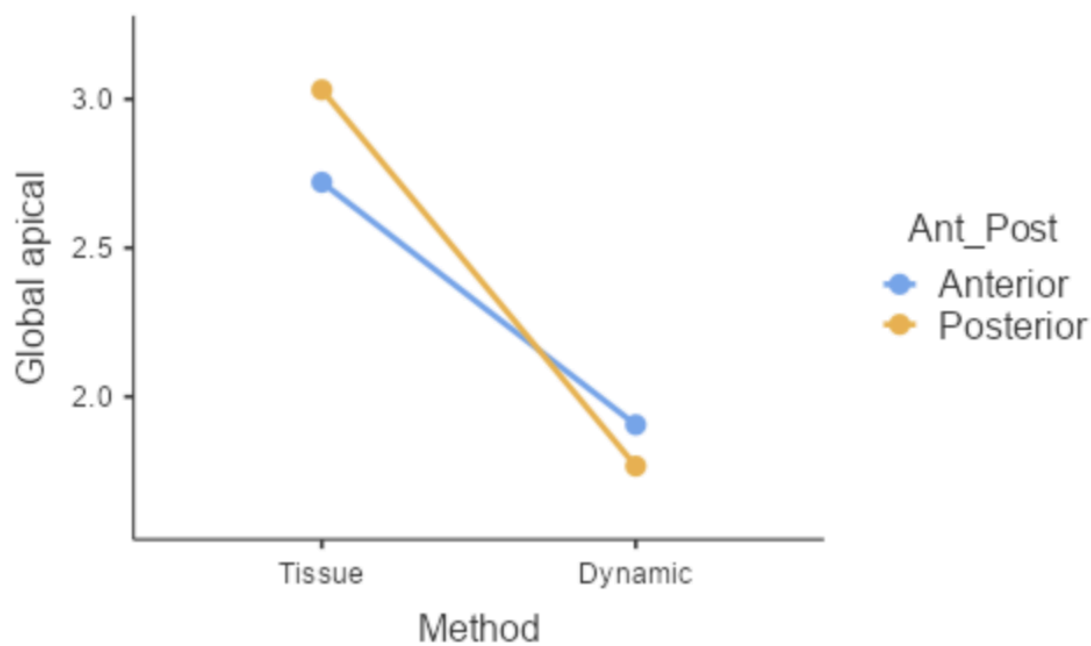

Figure 17. Plot of method vs. global apical deviation for anterior vs. posterior implants

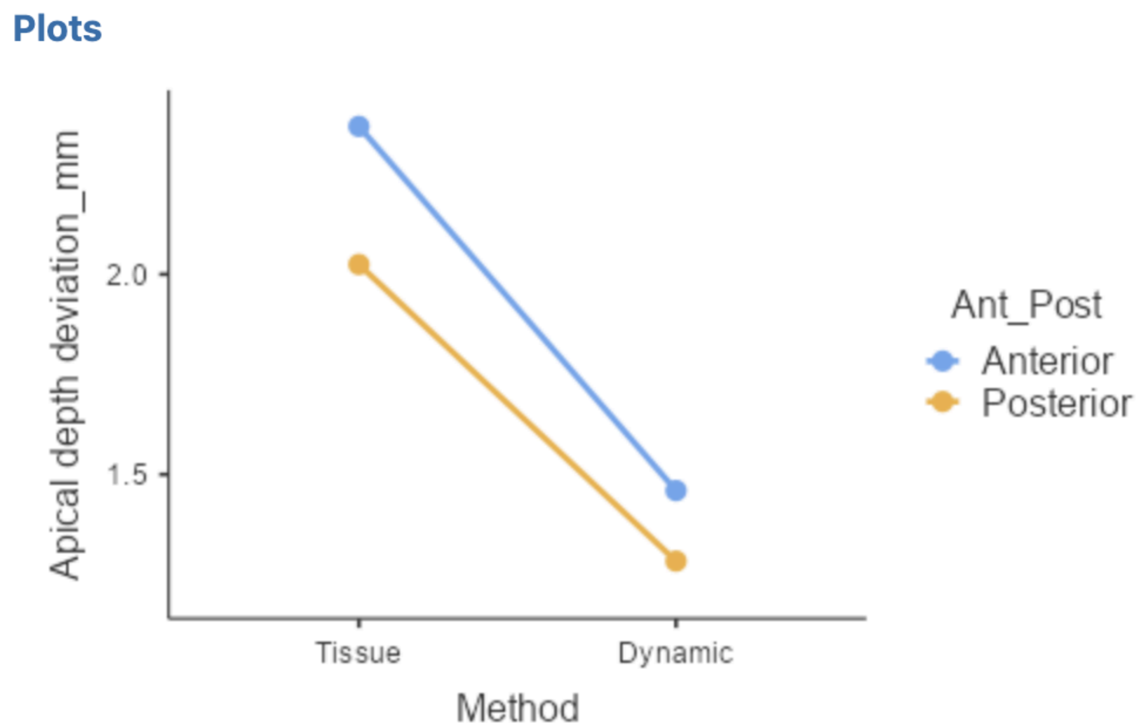

Figure 18. Plot of method vs. apical depth deviation for anterior vs. posterior implants

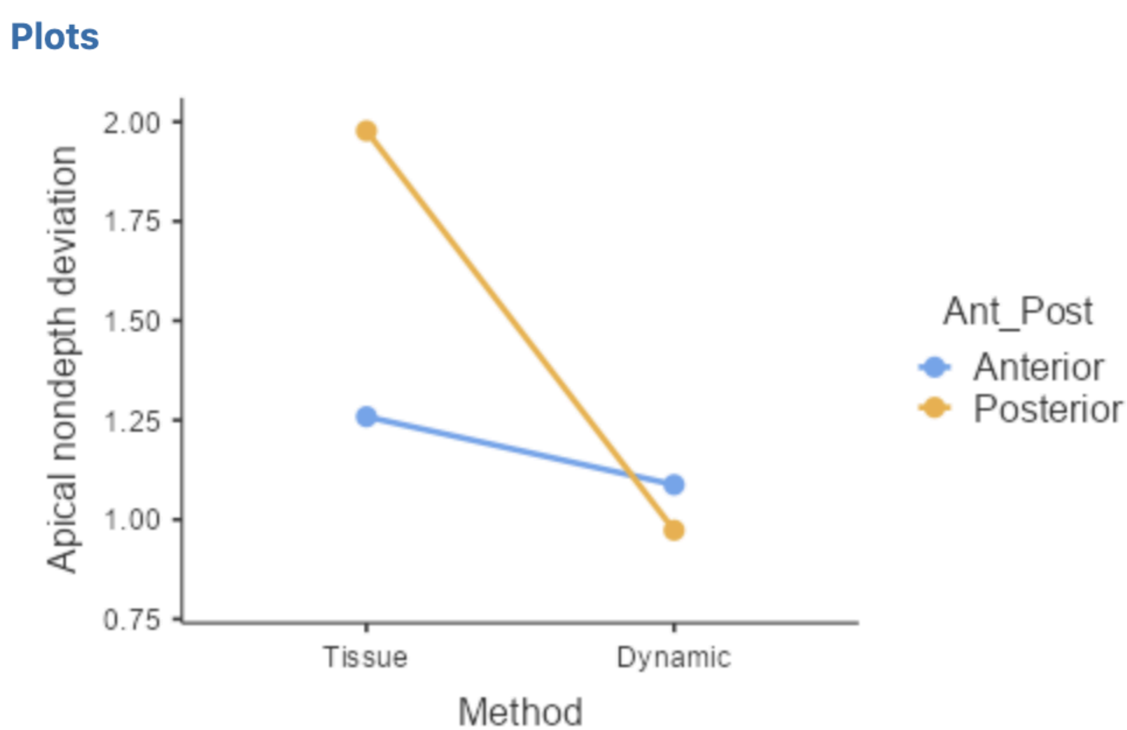

Figure 19. Plot of method vs. apical non-depth deviation for anterior vs. posterior implants

Table 1. Mean, standard deviation, maximums, minimums and p-values for measured deviations for each study group.

		Study Group			
		TL	DN	Mean Dif.	p
Angular deviation, °	Mean	4.25	0.80	3.45	<.001*
	SD	2.01	0.38		
	Max Ant	6.12	1.12		
	Min Ant	1.34	0.41		
	Max Post	6.85	1.58		
	Min Post	1.46	0.01		
Global Platform deviation, mm	Mean	2.47	1.84	0.63	0.004*
	SD	0.82	0.60		
	Max Ant	4.26	3.15		
	Min Ant	1.4	1.06		
	Max Post	3.32	2.92		
	Min Post	0.88	1.01		
Platform Depth deviation, mm	Mean	2.16	1.37	0.79	<.001*
	SD	0.93	0.47		
	Max Ant	3.97	2.21		
	Min Ant	1.19	0.84		
	Max Post	3.09	1.78		
	Min Post	0.08	0.17		
Platform Non-depth deviation, mm	Mean	1.00	1.03	-0.03	0.861
	SD	0.48	0.79		
	Max Ant	2.15	2.77		
	Min Ant	0.34	0.1		
	Max Post	2.03	2.91		
	Min Post	0.29	0.21		
Global Apical deviation, mm	Mean	2.88	1.84	1.04	<.001*
	SD	0.69	0.57		
	Max Ant	4.45	3.09		
	Min Ant	1.65	1.06		
	Max Post	3.72	2.87		
	Min Post	2.04	1.09		
Apical Depth deviation, mm	Mean	2.20	1.37	0.83	<.001*
	SD	0.92	0.46		
	Max Ant	4.05	2.21		
	Min Ant	1.21	0.84		

	Max Post	3.12	1.78		
	Min Post	0.14	0.17		
Apical Non-depth deviation, mm	Mean	1.62	1.03	0.59	0.007*
	SD	0.70	0.75		
	Max Ant	1.87	2.7		
	Min Ant	0.82	0.08		
	Max Post	3.51	2.87		
	Min Post	0.65	0.11		

* = denotes statistical significance (*p* <.05)

Table 2. ANOVA of General Linear Models				
	SS	df	F	p
Angular deviation				
Ant_Post	17.7	1	11.88	0.001*
Method	143.1	1	95.98	<.001*
Ant_Post*Method	12.7	1	8.51	0.006*
Global Platform deviation				
Ant_Post	0.5523	1	1.0632	0.308
Method	4.7104	1	9.0677	0.004*
Ant_Post*Method	0.0272	1	0.0523	0.820
Platform Depth deviation				
Ant_Post	0.935	1	1.745	0.193
Method	7.567	1	14.128	<.001*
Ant_Post*Method	0.125	1	0.233	0.632
Platform Non-depth deviation				
Ant_Post	0.0491	1	0.1119	0.740
Method	0.0131	1	0.0298	0.864
Ant_Post*Method	0.0415	1	0.0946	0.760
Global Apical deviation				
Ant_Post	0.0889	1	0.219	0.642
Method	12.9781	1	31.952	<.001*
Ant_Post*Method	0.6066	1	1.494	0.228
Apical Depth deviation				
Ant_Post	0.8149	1	1.529	0.223
Method	8.1781	1	15.340	<.001*

Ant_Post✻Method	0.0853	1	0.160	0.691
Apical Non-depth deviation				
Ant_Post	1.10	1	2.28	0.138
Method	4.14	1	8.64	0.005*
Ant_Post✻Method	2.08	1	4.34	0.043*

*denotes statistical significance (p <.05)

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