


## EVALUATION OF THE ACCURACY OF TWO IMPLANT-GUIDED POSITIONING SYSTEMS AT BONE MARROW AND CORTICAL DENSITIES: AN IN VITRO STUDY

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### ABSTRACT

**Objective:** The aim of the present study is to evaluate the accuracy of implant positioning with two different guided systems (milling and installation kits - with and without drill guides) in bone medullary and cortical densities.

**Materials and Methods:** 40 conical prosthetic junction implants and 20 blocks of 40PFC and 10PFC dual-density polyurethane were used, simulating medullary and cortical bone, respectively, divided into four groups (Group 1 - System 1 with drill/medullary guide; Group 2 - System 1 with drill guide/Cortical; Group 3 - System 2 without drill/medullary guide; Group 4 - System 2 without drill guide/Cortical). The blocks were scanned and tomographed for digital planning. The implants were positioned through digital planning in each center of density, that is, two implants per block and each of the implants was positioned with 17° of inclination. Two different surgical guides were made for each instrumentation kit. After milling and implant installation, the scanbody was installed on the implants and the blocks were scanned again. The 3D image and the STL file generated from each block were superimposed on the initial virtual planning and the coronal, axial and angular deviation was calculated in the software for each implant.

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Results: Comparing the 4 groups, there was a statistical difference between the groups for the angular deviation ( $p=0.002$ ) and axial deviation ( $p=0.001$ ) variables. When evaluating the multiple comparisons between the groups in the significant variants, the comparisons that presented  $p<0.05$  were Group 1 x Group 4; and Group 3 x Group 4. Comparing the two instrument kits – WITH and WITHOUT Drill guide (medullary and cortical), we noticed that there was no statistically significant difference in any of the variables ( $p >0.05$ ). In the descriptive analysis of the variables separated by the groups: Cortical (kit WITH Broca guide and WITHOUT drill guide), and Medullary (kit WITH Broca guide and WITHOUT drill guide), the deviation in the cortical bone was significantly greater than in the medullary bone.

Conclusion: The accuracy of installation of implants with Morse prosthetic junction was not affected by the two different types of guided instrumentation system used in both bone densities. Guided implants installed in cortical bone showed a greater deviation compared to those installed in medullary bone.

**Keywords:** Guided surgery, Dental implant, Digital.

## INTRODUCTION

With the advances and diffusion of the digital flow in dentistry added to the concept of reverse planning, which is already well established for the success of dental implants, the dental market begins to look for implant systems that present digital solutions for their installation with a high degree of precision, the guided surgery systems.

In 2009, Hämerled defined guided surgery as the use of a static surgical guide, which reproduces the virtual position of the implant directly from the CT scan and does not allow changes in this position during the operation. Today it is already possible to perform a guided surgery without the need for a static guide, through dynamic navigation. This navigable or navigating surgery has improved the process as it provides the surgeon with the real-time navigation tool to improve the accuracy of implant installation. However, the implementation of this type of technology requires a significant investment for the dental surgeon. In addition, the learning curve and the need for a period of training are necessary before the technique can be used in patients. Wu in his study, concluded that the accuracy of navigation surgery is similar to static surgery. (1) (2) (3) (4)

This positioning accuracy enables an optimized design of the final prosthesis, allowing adequate hygiene and consequently these factors contribute to the success of dental implants. Studies have shown that positioning errors occur more frequently in freehand techniques and can be minimized with the use of surgical guides. Guided surgery has become popular among dentists and patients as surgical intervention becomes faster, minimally invasive and more predictable. Additionally, the use of surgical guides can be useful as a means of preventing damage to vital structures. (5) (6) (7) (8)

Tamaseb in its review, showed to be an established treatment, which reduces the probability of damage to adjacent critical structures such as bone, nerves, adjacent dental roots and sinus cavities. Furhauser et al, showed greater aesthetics and predictability in implants installed through the guided flapless technique in the anterior region of the maxilla, due to the faithful transfer of the planned 3D positioning to the moment of surgery. (9)

All these benefits of guided surgery depend on the accuracy of transferring the digital planning to the patient's mouth. Recent systematic reviews indicate that coronal deviations and apical deviations are of great importance and should be minimized. These deviations are the result of errors from image acquisition, during the preparation of the guide, in the manipulation of the guide during surgery and mechanical errors caused by the tolerance of the surgical instruments. And all these errors are cumulative. (10)

One possibility of error may be related to the tolerance of the cutter in the washer. Recently studies on this specific issue, Koop in 2012, presented an in vitro study, tested 2 types of insertion in the washer, insertion of the washer in the hand (drill guide) compared to the insertion of the washer in the cutter (cutter with washer), which showed the largest deviations. (7) Commercially, these two types of systems are given the nomenclature "one hand" x "two hands".

Still aiming at the search for the ideal system, to transfer from digital to real, companies present a variety of surgical instruments to be able to carry out the milling and installation of implants in a guided way. Through this in vitro study, we analyzed the possibility of a significant difference in accuracy between two different guided surgical instrumentation systems, from the same company, for the same implant model, Helix Grand Morse (Neodent, Curitiba, Brazil) 4.0X13mm, in two untinted bone densities, simulating cortical and medullary bone in polyurethane blocks (Nacional Ossos- Jaú, Brazil).

## **MATERIALS AND METHODS**

A total of 40 Helix GM 4.0mmx13mm implants and 20 polyurethane blocks (Nacional Ossos - Jaú, Brazil) with double densities, medullary (40PFC – Pound Cubic Foot) and cortical (10PFC – Pound Cubic Foot) were used. The blocks were validated by means of tests applied at INMETRO (National Institute of Metrology, Quality and Technology, Duque de Caxias, Brazil) (11). Each block has a rectangular shape, measuring 2.5 cm x 3.0 cm x 6.0 cm, containing both densities in the same block, half of the cortical block (10PFC) and the other half of the block, medullary (40PFC) (Figure 1).

Figure 1 – Views of the dual-density polyurethane block.



The implants were divided into 4 groups, according to the two proposed instrumentation and installation kits:

Group 1 – NSG GM- WITH drill guide - Helix GM implants 4.0mmX13mm – bone marrow  
Group 2 – NSG GM- WITH drill guide - Helix GM implants 4.0mmX13mm – cortical bone  
Group 3 – Easy Guide GM- WITHOUT drill guide - Helix GM implants 4.0mmX13mm – bone marrow  
Group 4 - Easy Guide GM- WITHOUT drill guide- Helix GM implants 4.0mmX13mm – cortical bone

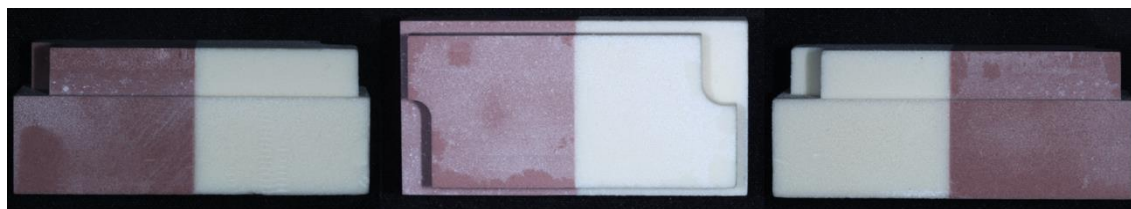
### SAMPLE CALCULATION

Considering previous data published by Kholy, the mean and standard deviation of the TL group were used using the GSM insertion system referring to the measurement of deviation 3 of the alveolar crest (mm) to calculate the sample size, which was carried out on the website [www.sealedenvelope.com](http://www.sealedenvelope.com) considering differences greater than 30% (d) as non-equivalent. The calculated sample size was 8 for  $\alpha=5\%$  and 95% power. Considering the low risk of sample loss in the experimental procedure, the sample size was increased by 25%, totaling  $n=10$ . (12)

### STANDARDIZATION, REGULARIZATION AND CUTTING OF BLOCKS

All blocks were obtained from the same batch and were cut at the Nacional Ossos factory (Nacional Ossos- Jaú, Brazil). They went through a dimension conference and planing was carried out to make it even more standardized. In addition, rounding cutouts were made in the blocks by the prosthetic laboratory D-LAB (Curitiba, Brazil) using the DMG Sauer Ultrasonic 20 machine (Deckel Maho, Germany), so that the surgical guide would have a better male-female fit and greater stability (Figure 2).

Figure 2 – Views of the dual-density polyurethane block after regularization and cutouts for fitting the surgical guide.

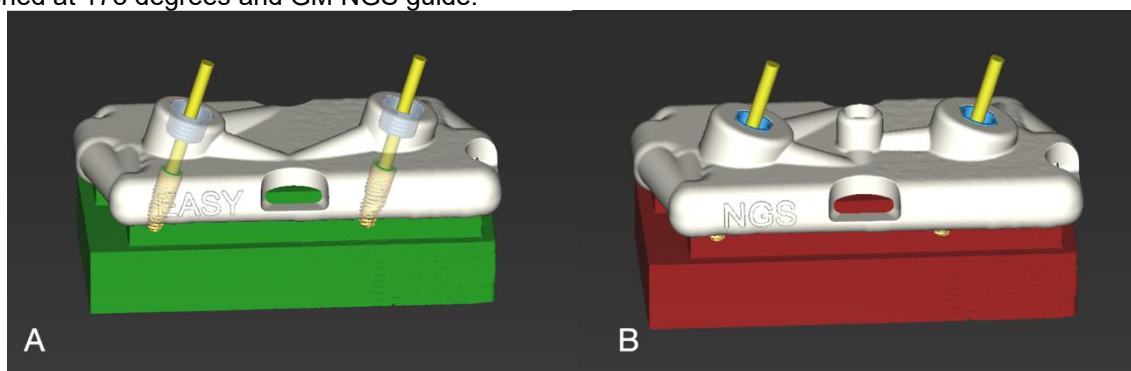


Blocks were numbered from 1 to 20 and it was established that blocks 1 to 10 would be instrumented by the Easy Guide surgical kit and blocks 11 to 20 would be instrumented by the NGS GM surgical kit.

## DIGITAL PLANNING

First, a block was scanned by a benchtop scanner (Virtuo Vivo, Dental Wings, Montreal – Canada) which generated an STL file. This same block was also tomographed at Ortophos (Sirona, Bensheim, Germany), with a FOV (Field of View) of 8.0x5.0 cm. With the CAI (computer aided image) process performed, the two three-dimensional files were imported into a digital implant planning software, co-DiagnostiX (Dental Wings, Montreal - Canada). In this software, the positioning of the implants was planned, and one implant was positioned in each center of the density of each block, that is, two implants per block, both at an angle of 17° degrees. In addition to the implants, a screw was planned to fix the surgical guide in the center of the block. Once the positioning was established in the software, two surgical guides were designed, one guide for the Neodent Easy Guide kit (Neodent, Curitiba - Brazil) with fixed positioning of the plate at 10 mm distance from the implants and another guide for the use of the NSG GM kit (Neodent, Curitiba - Brazil) with the plates positioned at 9 mm distance from the implants. Once the surgical guides were drawn, they were exported as an STL file (Figure 3).

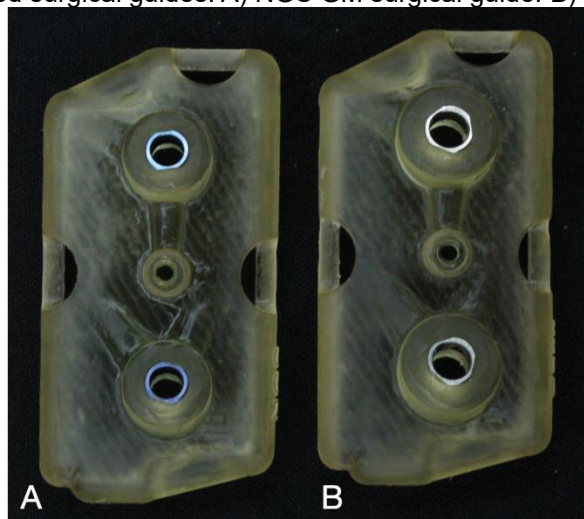
Figure 3 – Digital planning. A) GM implants positioned at 17o degrees and Easy Guide. B) GM implants positioned at 17o degrees and GM NGS guide.



## Making of Surgical Guides

The STL files of the guides were printed in Shera print-sg resin (Shera Werkstoff-Technologie GmbH&Co, Germany) on the P30 3D printer (Rapidshape - Heimsheim, Germany). The guides went through a polymerization finalization process, through washing, immersion in isopropyl alcohol in P-wash (Rapidshape - Heimsheim, Germany) and in a P-cure light flash chamber (Rapidshape - Heimsheim, Germany). At the end, the finishing was done, removing the excesses and the metal washers of each guide were introduced (Figure 4).

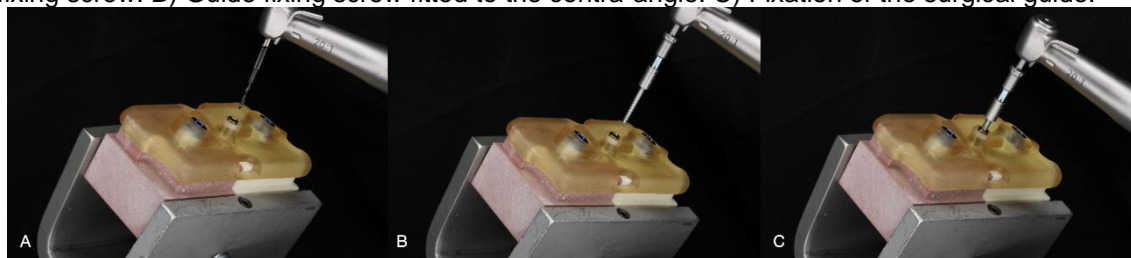
Figure 4 – Completed surgical guides. A) NGS GM surgical guide. B) Easy Surgical Guide.



### Fixing the surgical blocks and guides to the block

The blocks were locked in a single position with the aid of a vise on a workbench, so all the blocks were instrumented in the same position by the operator. The surgical guides were fitted and fixed by the Neodent guide fixation screw (Neodent, Curitiba, Brazil) (Figure 5).

Figure 5 – Block positioned in the vise on a workbench, NGS GM surgical guide. A) Drilling cutter for surgical guide fixing screw. B) Guide fixing screw fitted to the contra-angle. C) Fixation of the surgical guide.

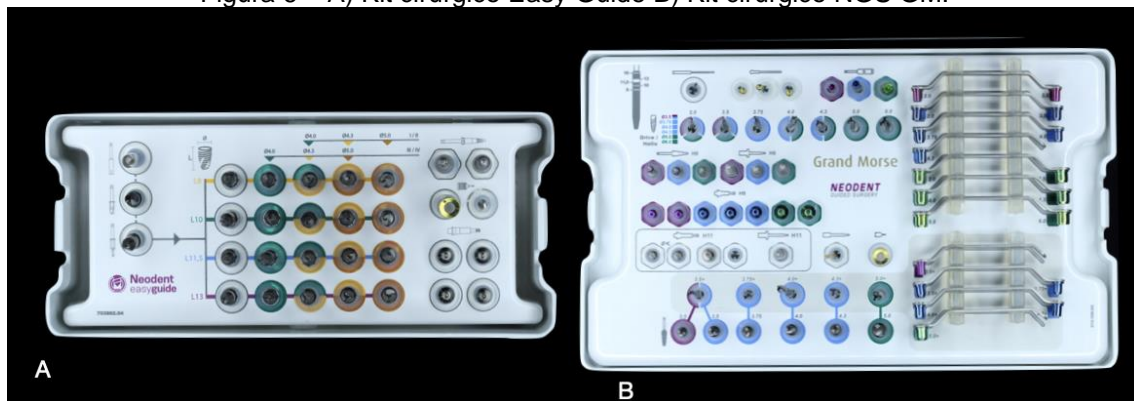


### Drilling and implant installation

In accordance with the recommendations of the implant manufacturer Helix GM (Neodent, Curitiba, Brazil), we standardized the perforations with an 800rpm rotation, 30rpm implant insertion rotation, with a maximum insertion torque 60N.cm.

The perforations were performed with the specific surgical kits of each group, Easy Guide and NGS GM (Figure 6). The milling protocol was according to the company's indications for each bone density. The Easy Guide surgical instrumentation kit has the guidance guides on the cutters themselves and the NGS GM features cutter guides separate from the cutters, thus being an additional surgical instrument. The speed and torque of the engine were the same for the instrumentation with the two kits.

Figura 6 – A) Kit cirúrgico Easy Guide B) Kit cirúrgico NGS GM.



The instrumentation of the Easy Guide kit for cortical bone was started with the planing cutter, followed by the spear cutter, 2.7mm diameter cutter, 4.0mm cutter and to finish the drilling with the 4.0/4.3mm cutter. For the medullary bone, the same sequence was repeated, but excluding the last 4.0/4.3mm cutter. The implants were installed using the guide, with a 20:01 contraangle (NSK - NAKANISH, kanuma, Japan) and in some cases finished at the turnstile (Figures 7, 8, 9, 10 and 11).

Figure 7 – Block positioned in the vise on a workbench, milling on the Easy guide surgical guide on cortical bone. A) Introduction of the planing drill. B) End of drilling of the planing bit. C) Introduction of the boom drill. D) End of the drilling of the jib bit.

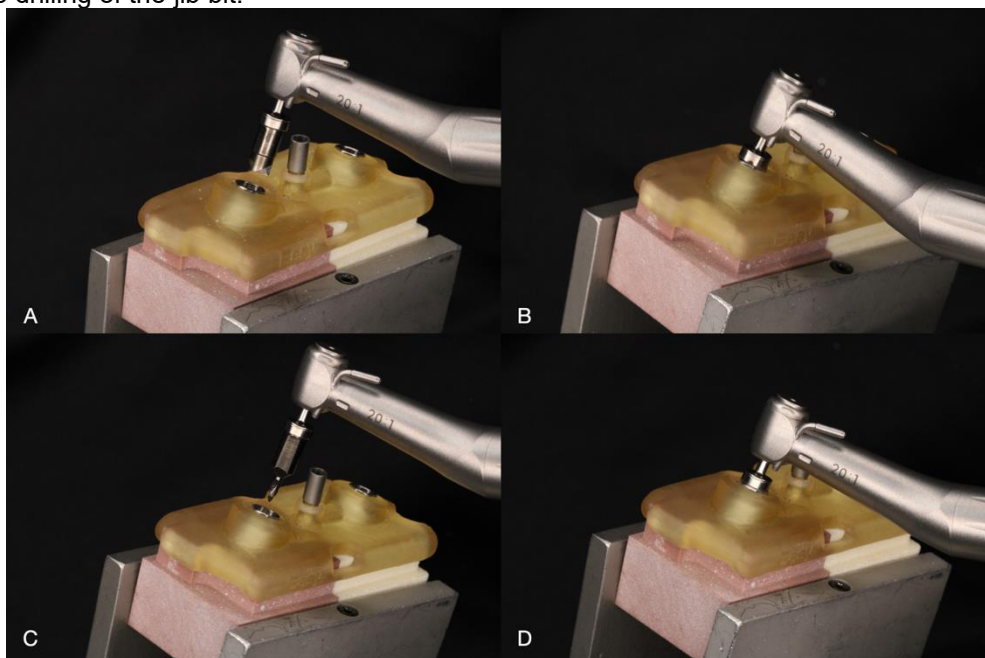




Figure 8 – Block positioned in the vise on a workbench, milling on the Easy guide surgical guide in cortical bone. A) Introduction of 2.7mm drill. B) Drill drilling end of 2.7mm. C) Introduction of 4.0mm drill. D) Drill bit 4.0mm drilling end. E) Introduction of the 4.0/4.3mm drill in the surgical guide. F) Drill End Drilling 4.0/4.3mm.

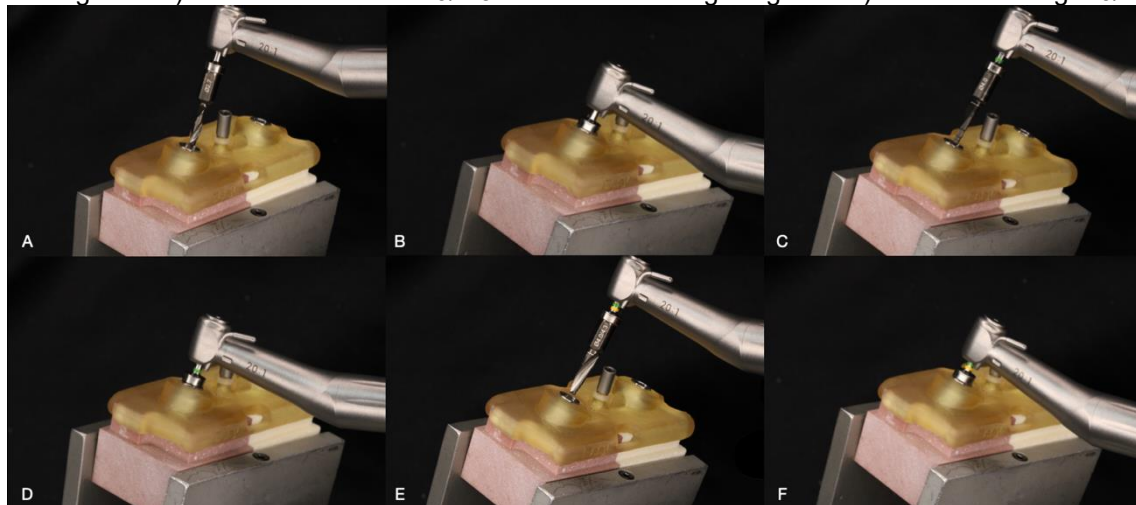


Figure 9 – Block positioned in the vise on a workbench, installation of a GM implant in the Easy guide surgical guide in cortical bone. A) Implant introduction. b) Installation limit with counter angle. D) Completion of the implant insertion with the aid of the manual ratchet.

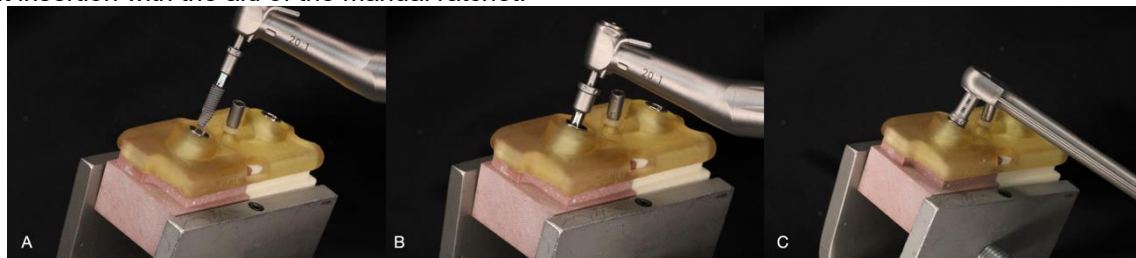


Figure 10 – Block positioned in the vise on a workbench, milling on the Easy guide surgical guide on medullary bone. A) Introduction of 2.7mm drill. B) Drill drilling end of 2.7mm. C) Introduction of 4.0mm drill. D) Drill bit 4.0mm drilling end.

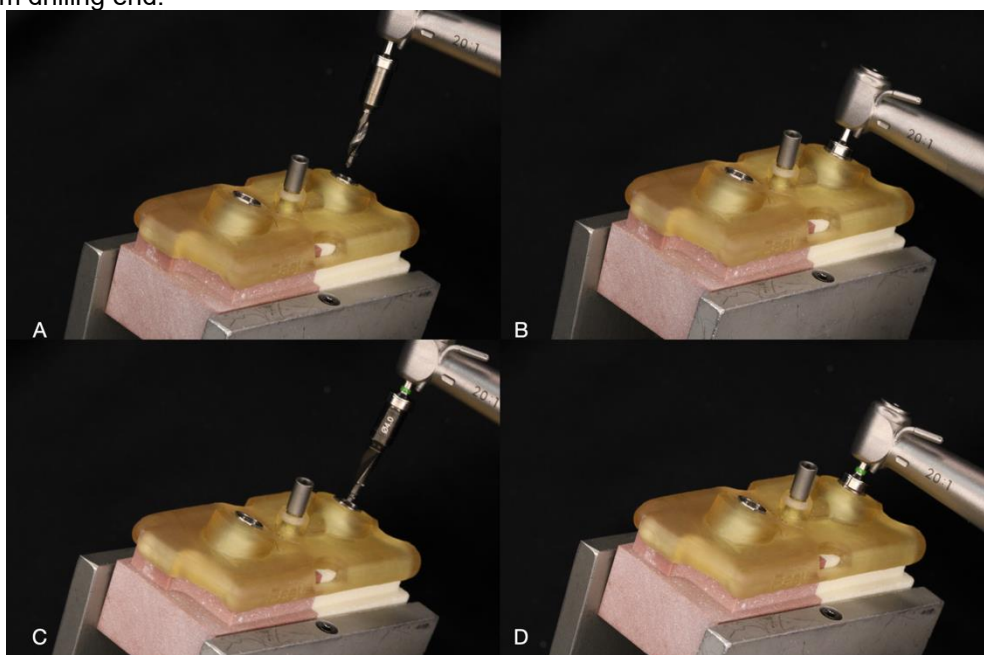
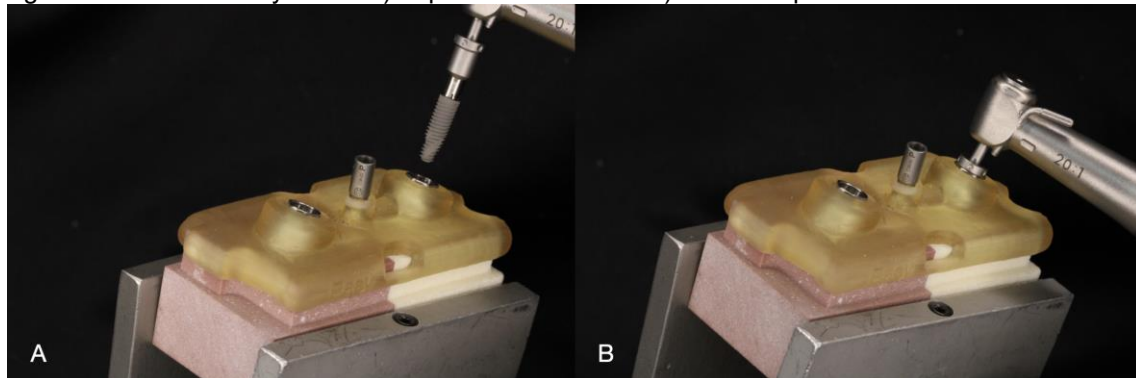


Figure 11 – Block positioned in the vise on a workbench, installation of a GM implant in the Easy guide surgical guide in the medullary bone. A) Implant introduction. B) End of implant installation with contra-angle.



Instrumentation with the NGS GM kit in cortical bone was performed with the blue drill guide sequence, which is compatible with the internal diameter of the washer used in the guide, of 4.5 mm. The sequence of milling cutter and drill guide was 2.0mm, 3.5mm, 3.75mm, 4.0mm and 4.0mm+. To finish the instrumentation, a 4.0mm pilot drill was used. The instrumentation of the medullary bone followed the same sequence, excluding only the milling with the 4.0 mm, 4.0 mm+ cutter and the pilot drill, which are not indicated for the medullary bone. The implants were installed using the guide, with a 20:01 contraangle (NSK - NAKANISH, Kanuma, Japan) and in some cases completed at the turnstile (Figures 12 and 13)

Figure 12 – Block positioned in the vise on a workbench, milling on the NGS GM surgical guide in cortical bone A) Introduction of the 2.0mm drill with the 2.0mm drill guide. B) Milling finish 2.0mm. C) Introduction of 3.5mm drill bit with 3.5mm drill guide. D) Finishing of the milling 3.5mm. E) Introduction of 3.75mm drill with 3.75mm drill guide. F) Milling finish 3.75mm. G) Introduction of 4.0mm drill bit with 4.0mm drill guide. H) Milling finish 4.0mm. I) Introduction of 4.0mm+ drill bit with 4.0mm+ drill guide. J) Milling finish 4.0mm+. K) Introduction of the pilot drill. L) Completion of pilot drill milling.

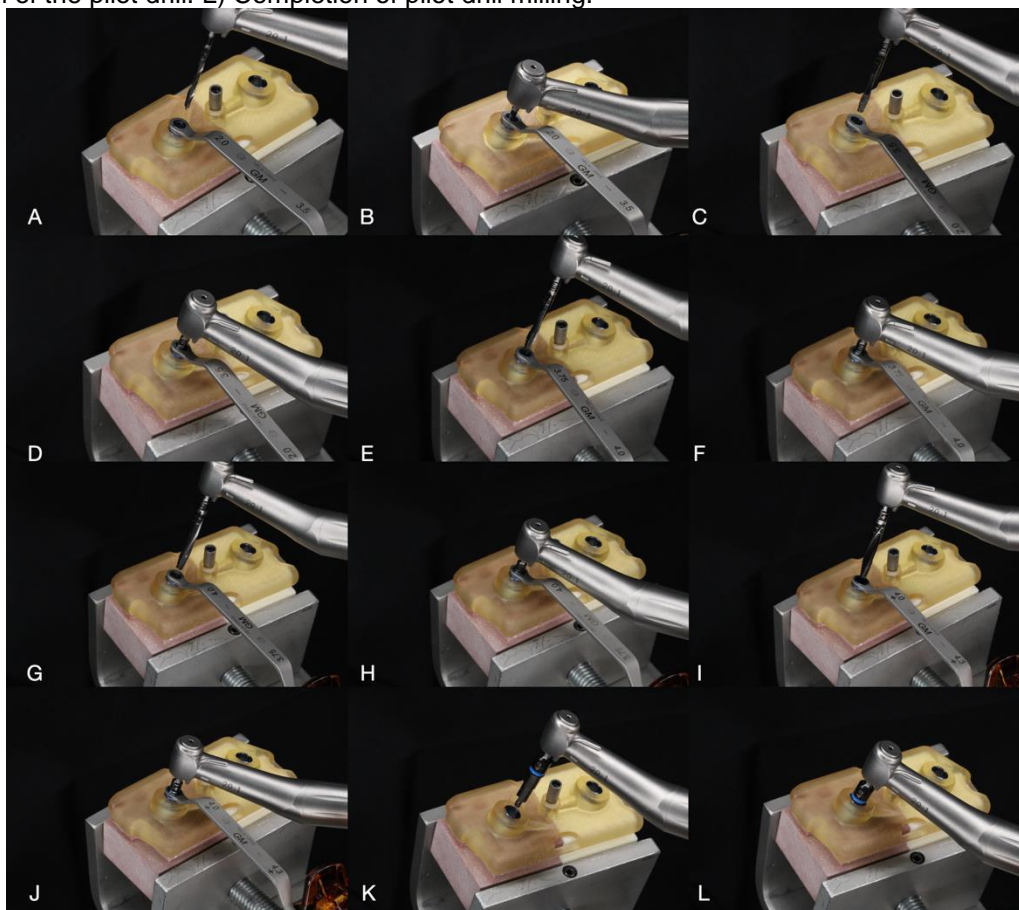
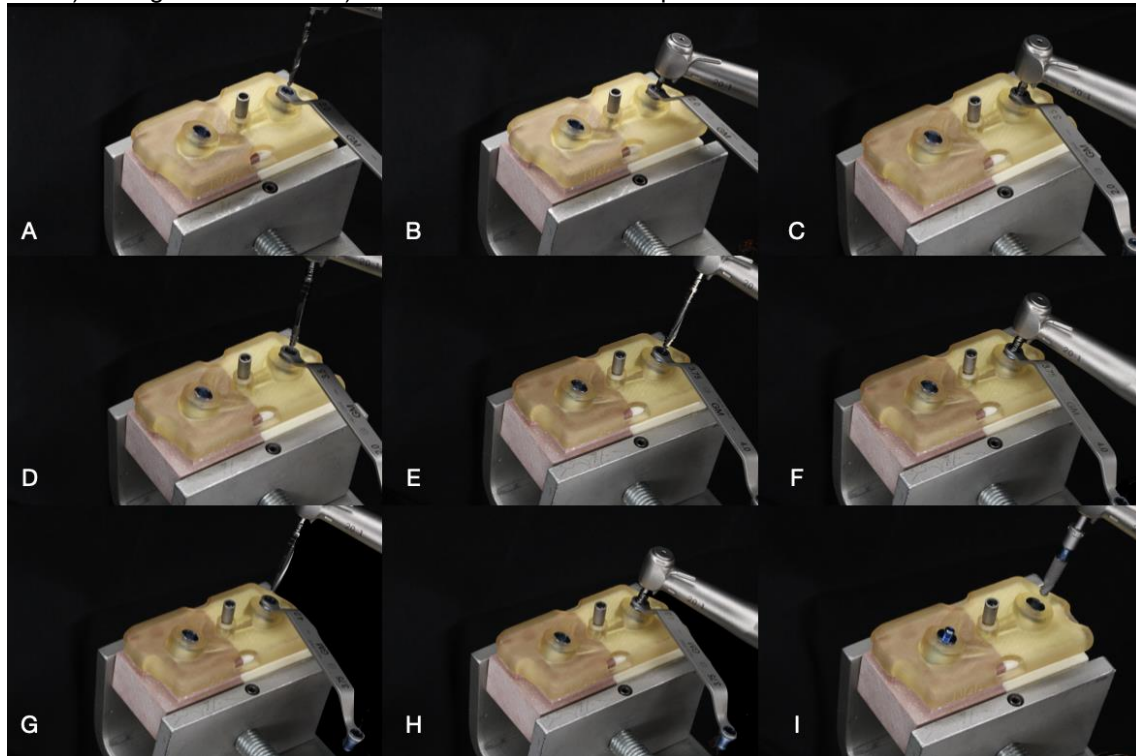


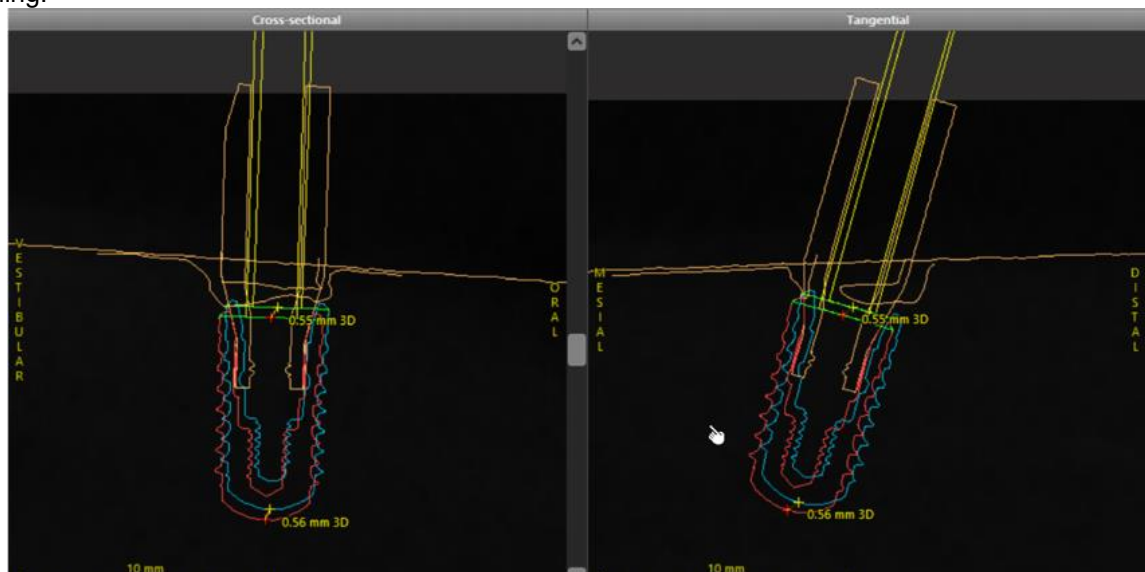
Figure 13 – Block positioned in the vise on a workbench, milling on the NGS GM surgical guide in medullary bone. A) Introduction of 2.0mm milling cutter with 2.0mm drill guide. B) Milling finish 2.0mm. C) Inserting the 3.5mm milling cutter with the 3.5mm drill guide. D) Finishing of the milling 3.5mm. E) Inserting the 3.75mm milling cutter with the 3.75mm drill guide. F) Milling finish 3.75mm. G) Introduction of 4.0mm cutter with 4.0mm drill guide. H) Milling finish 4.0mm. I) Introduction of the GM implant.



### Scanning the blocks with scanbody

Once the implants were installed, their respective GM scanbody was positioned in each implant (Neodent, Curitiba, Brazil) and these 20 blocks were scanned again by a benchtop scanner (Virtuo Vivo, Dental Wings, Montreal – Canada). These new 3D files were inserted into the Treatment evaluation module of the co-DiagnostiX software (Dental Wings, Montreal - Canada), which allows the positioning of the scanbody to simulate the position of the implant digitally (Figure 14). This image is superimposed on the initial planning and thus enabled the software to perform the measurements of angular and linear deviations between the executed and the planned in the axial and coronal portions of the implants. These measurements are made automatically by the software for each implant and can be exported in a spreadsheet format in Excel software (Microsoft, Redmond, United States).

Figure 14 – Screenshot of the software at the time of 3D image overlay, initial planning and scanbody scanning.



## STATISTICAL ANALYSIS

For the statistical analysis, initially, a descriptive analysis of the data was carried out with an estimate of mean, median, standard deviation, 25% percentile and 75% of the variables angular, coronal and axial deviation. To assess the differences between the groups, first the quantitative variables were tested for normal distribution with the Shapiro-Wilk normality test to determine the parametric and nonparametric approach. For variables with normal distribution, the difference between two groups was verified with the Student's t-test and 4 groups with ANOVA. For variables without normal distribution, the difference between two groups was verified with the Mann-Witney U test and 3 or more groups with the Kruskal-Wallis test. For a better visualization of these analyses, boxplots were produced. All tests were considered significant when  $p < 0.05$  and the analyses were performed in the R 4.0.4 environment (R Core Team, 2021).

## RESULTS

### MULTIPLE ANALYSIS BETWEEN THE 4 GROUPS

Comparing the 4 groups, Easy Guide medullary, Easy Guide cortical, NGS medullary and NGS cortical, there was no statistically significant difference for the variant coronal deviation ( $p = 0.154$ ). However, there was a statistical difference between the groups for the angular deviation ( $p=0.002$ ) and axial deviation ( $p=0.001$ ) variables (Table 1). When evaluating the multiple comparisons between the groups in the significant variants, the

comparisons that presented  $p < 0.05$  were Easy Guide medullary X cortical NGS and cortical NGS X medullary NGS (Table 1.1)

Table 1 – Descriptive analysis according to the four groups.

Variable	Group																p-value*
	EASY Cortical				EASY Marrow				NGS Cortical				NGS Medullary				
	M	MD	DP	IIQ	M	MD	DP	IIQ	M	MD	DP	IIQ	M	MD	DP	IIQ	
Detour <b>Angular</b>	3.23	1.4	1.7	2	1.7	1.2	1.8	4.2	4.3	1.5	1.5	1.8	1.6	0.7	0.5	<b>0.002</b>	
Detour <b>Coronal</b>	0.4	0.3	0.2	0.2	0.5	0.5	0.1	0.2	0.5	0.5	0.1	0.1	0.4	0.4	0.1	0.1	0.154
Detour <b>Axial</b>	0.8	0.7	0.3	0.4	0.6	0.6	0.2	0.2	<b>1</b>	<b>1</b>	0.3	0.3	0.5	0.6	0.2	0.2	<b>0.001</b>

M= Mean; MD= Median; SD= Standard deviation; IIQ= Interquartile range;  
\* ANOVA for parametric approach and Kruskal-Wallis test for nonparametric approach

Table 1.1 – P-values of the multiple comparisons between groups in the significant variables of the Table.

	Detour <b>Angular</b>	Detour <b>Axial</b>
EASY Cortical X EASY medular	0.627	0.474
EASY Cortical X NGS cortical	0.801	0.192
EASY Cortical X NGS medular	0.351	0.158
EASY Medular X NGS Cortical	<b>0.011</b>	<b>0.007</b>
EASY Medullary X NGS Medullary	<b>1</b>	0.9
Cortical NGS vs. Medullary NGS	<b>0.004</b>	<b>0.001</b>

#### ANALYSIS EASY GUIDE (MEDULAR E CORTICAL) X NGS (MEDULAR E CORTICAL)

Comparing the two kits of instruments Easy Guide (spinal cord and cortical) x NGS (spinal cord and cortical), we noticed that there was no statistically significant difference in any of the variables ( $p > 0.05$ ) (Table 2).

Table 2 – Descriptive analysis according to the EASY and NGS groups.

Variable	Group								p-value*
	EASY				NGS				
	M	MD	DP	IIQ	M	MD	DP	IIQ	
Angular Deviation	2.57	2.55	1.39	1.93	3.03	2.75	1.66	2.47	0.393
Coronal Deviation				0.43 0.45	0.16 0.27	0.43 0.45	0.12	0.18	0.926
Axial Deviation	0.69	0.68	0.27	0.24	0.77	0.7	0.35	0.48	0.442

\*Student's t-test for parametric approach and Mann-Whitney U-test for non-parametric approach parametric

## CORTICAL ANALYSIS VS. SPINAL CORD ANALYSIS

A descriptive analysis of the variables separated by the Cortical (Easy Guide + NGS) and Medullary (Easy Guide + NGS) groups was performed and the comparison between them was performed. There was a statistically significant difference between Cortical and Medullary for angular deviation ( $p=0.0004$ ) and axial deviation ( $p=0.0006$ ). In both variables, the cortical bone was significantly higher than the medullary bone (Table 3).

Table 3 – Descriptive analyses according to the Cortical and Medullary groups.

Variable	Group								p-value*
	Cortical				Medullary				
	M	MD	DP	IIQ	M	MD	DP	IIQ	
Detour	3.7	3.6	1.49	1.53	1.9	1.65	0.94	0.65	0.0004
Angular									
Detour	0.41	0.46	0.15	0.25	0.45	0.44	0.14	0.19	0.483
Coronal									
Detour	0.89	0.88	0.32	0.37	0.56	0.57	0.19	0.26	0.0006
Axial									

\*Student's t-test for parametric approach and Mann-Whitney U-test for non-parametric approach parametric

## DISCUSSION

The present study showed that the two models of "one hand" x "two hands" surgical instrumentation for guided surgery did not present a statistically significant difference in the installation accuracy of the Helix GM implants (Grand Morse®, Neodent, Curitiba - Brazil).

In the descriptive statistical analysis table, we observed maximum deviations of the angular, coronal and axial variables, being 7.4o/0.68mm/1.58mm respectively, which are within the values presented according to a systematic review carried out by Thamaseb (5), who obtained the maximum values angular, coronal and axial variables, being

21.16o/4.5mm/7.1mm, respectively. However, in the systematic review there are clinical studies, in cadavers and in models. Considering only the model studies of this review, the maximum mean values were 2.16°/1.38mm/1.39mm for the angular, coronal and axial variables, respectively. In our study, the means were 2.8o/0.43mm/0.73mm for the angular, coronal, and axial variables, respectively. Thus, we can conclude that the maximum coronal and axial deviations were lower than the maximum deviations of the review, only differing from the mean angular deviation that was higher than that of the systematic review to the maximum mean of the systematic review.

A possible explanation for this difference in angular deviation may be related to the type of support of the surgical guide. In his in vitro study, Dreiseidler used partially edentulous mandibles, with the surgical guide supported on teeth. Another explanation may be related to the type of material used. Another in vitro study used edentulous mandible models, without soft tissue simulation, in epoxy resin. (13) (14)

Considering a detailed analysis of the results, in the multiple comparison between the 4 groups, considering the significant variables (angular deviation and axial deviation), the groups that presented a  $p < 0.05$  were Easy Guide medullary X cortical NGS and cortical NGS X medullary NGS. However, in both situations, a statistically remarkable result is expected, since they are different bone densities, regardless of the type of surgical instrumentation. Chen, in a recent study showed greater angular and axial deviations in bone of higher densities. (15)

In the present study, in the comparison of the Easy Guide (medullary and cortical) x NGS (medullary and cortical) groups, there was no statistically significant difference. An in vitro study in 2012 compared the tolerance of these two types of surgical instrumentation, "One hand x Two hands" (SEM and COM drill guide), which showed greater angular, coronal and axial deviations for the washer system in the cutter itself. The possible explanation for this would be that the drill guide would give more stability from the beginning of milling. However, when analyzing the design of the "One Hand" milling system in the study and comparing it with the present study, there are differences in the design of the washer on the drill, in which the Easy Guide seems to have evolved to provide greater stability as soon as it comes into contact with the surgical guide. Another issue of important relevance, still considering the Koop study, is the material that was used for bone simulation, acrylic blocks, which have characteristics well separated from human bone, a higher density and greater homogeneity. (16)



Regarding the planning position of the implants, an inclination of 17° degrees was considered, since these are clinical situations that require greater skill from the operator and are increasingly frequent in total arch rehabilitation techniques. (17) (18)

## **CONCLUSION**

The accuracy of Helix GM implant placement was not affected by the two different types of guided instrumentation system used in both bone densities. Regardless of the surgical kit used for milling, guided implants installed in cortical bone showed a greater deviation compared to those installed in medullary bone.

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