Methods of diagnosis, planning, and treatment have evolved over the years. Technologic advances have provided a more accurate diagnosis and construction of better-quality 3D images, allowing the evaluation of bone tissue and anatomical structures. Cone beam computed tomography (CBCT) facilitated planning and prognosis when placing dental implants. Association between virtual planning and the conventional surgical technique to perform implant placement aided in the preservation or regeneration of the alveolar bone and visualization of the implant position prior to flap elevation. Preoperative planning played a major role in improving patient esthetics and masticatory and phonetic function in the long term. Although the reported benefits are well established in the literature, it is important to understand that these results were obtained mostly from research where an experienced surgeon placed the implants.

When the whole population of dentists are considered, few dentists have the appropriate training to place implants in the ideal position. With technology improvements, implant virtual planning could be reproduced in the patient with the aid of 3D printed surgical guides (3D-PSG). The 3D-PSG is a tool that helps in the positioning and angulation of the implant with great accuracy. The software used to fabricate the 3D-PSG allows a wide visualization of the scanned area, which facilitates the treatment plan formulation and implant position. Proper implant positioning that is aided by the 3D-PSG can reduce the risk of the occurrence of a gingival...

Keywords: 3D, computer-guided surgery, dental implant, flapless procedure, surgical guide
recession due to incorrect positioning of the implant, especially in patients with a thin gingival phenotype.\textsuperscript{12} If there is a proper amount\textsuperscript{13} of remaining bone, flapless guided surgery (FGS) can even be performed. This type of procedure is less invasive than conventional surgery (CS), reducing the risk of infection in the postoperative period and allowing the preservation of blood supply to both bone and soft tissue.\textsuperscript{14} However, CS may be indicated if there is a need to maintain or apically reposition the soft tissue to avoid the need for future mucogingival procedures.

It is expected that FGS will deliver better patient-related outcomes, especially if the operator is not experienced and has to place multiple implants.\textsuperscript{15–17} A randomized controlled split-mouth clinical trial performed by experienced surgeons compared CS with FGS and did not report these advantages whenever a single implant was placed in the posterior region.\textsuperscript{18} Since most dentists do not have extensive clinical experience in implant dentistry and training is very important to achieve such status, FGS can help both dentists and patients in different ways. Implant continuing education courses must be taken, and even undergraduate students must be trained both in the conventional and computer-assisted methods of implant dentistry. The aim of this study was to evaluate the patient-reported outcomes of FGS, comparing it with CS performed by undergraduate students who had never placed implants in patients.

**MATERIALS AND METHODS**

A controlled and randomized split-mouth clinical trial was carried out to analyze the results of conventional surgery (group CS—control) and flapless guided surgery (group FGS—test). A total of 143 medical records were analyzed to find patients who had bilateral mandibular posterior tooth loss and sufficient bone thickness and height to place an implant; 43 were screened between February and May 2019 at FAESA University Center, and 10 were selected for the study. The study was approved by the institution’s ethics committee under the protocol CAAE 14224619.0.0000.5059, followed the CONSORT guidelines, and was registered at the Brazilian Registry of Clinical Trials, which is associated with the World Health Organization (U1111-1250-5594 —http://www.ensaiosclinicos.gov.br/rg/RBR-7j49sm/). Patients were included according to the inclusion and exclusion criteria and signed an informed consent form to participate in the research.

**Patient Selection**

The study included patients with good general health conditions. To participate in this study, patients had to present the following inclusion criteria: good oral hygiene with visible Plaque Index < 20%; age ≥ 18 years; sufficient bone availability for implant placement, with minimum height and thickness equal to 10 and 5 mm, respectively; loss on both sides of the mandible of posterior teeth; and sufficient interocclusal height to adapt the prototyped surgical guide and perform the osteotomies. Additionally, patients did not meet the following exclusion criteria: history of periodontal surgical procedures in the operated region; diseases and conditions that could compromise the surgical procedures or healing; presence of inflammation or infection involving the region to be operated; bone pathology in the implant site; and smokers, people with bruxism, alcoholics, drug addicts, diabetics, pregnant women or those who wish to become pregnant in the next year, people who have a history of radiotherapy treatment in the head and neck region, and people who take medications that may interfere with bone remodeling or who have pathologies that affect bone metabolism.

**Surgical Guides**

**3D Printed Surgical Guide.**

The DICOM file of a CBCT (OP300, Cone Beam 3D System, KaVo do Brasil) was imported to the software Blue Sky Plan (Blue Sky Bio), which allowed implant planning and construction of the surgical guide. An impression (Addition silicone, Zhermack) was performed of the maxilla and mandible. Gypsum casts were then scanned (Ceramill Map 400) to produce the standard tessellation language (STL) file. The virtual guide was fabricated with the aid of software that automatically aligned both DICOM and STL files; if it was observed that the overlap of the files was not ideal, a manual alignment was performed by choosing corresponding points from both files. Then, a Morse taper implant and the tooth crown that replaced the edentulous space were selected and ideally positioned. A tooth-supported 3D-PSG file was created by the Blue Sky Plan software. The guide was imported into software (Autodesk Meshmixer) to create lateral windows to improve visualization of the 3D-PSG adaptation. Then, the guide was printed in autoclavable biocompatible colorless resin (Smart Print Bio, Prizma) in a 3D printer (Anycubic Photon).

**Analogic Surgical Guide for Conventional Surgery**

On the control side, the guide was created in the gypsum cast. A diagnostic wax-up was performed by adding the missing teeth. The waxed model was duplicated with addition silicone putty (Futura). Then, the mold was removed and petroleum jelly was applied to the cast, and the new impression was filled with colorless self-curing acrylic resin (DuraLay, Reliance Dental).
After resin curing, the impression was removed, and the fabricated guide was finished and polished. Finally, the analogic surgical guide received a 2-mm-diameter perforation that demonstrated the planned position for implant placement.

Surgical Protocol
The surgical procedure started with local anesthesia with 2% lidocaine 1:100,000 UI, avoiding the direct blockage of the inferior alveolar nerve. Immediately after anesthesia sensation occurred, the time of the surgical procedure was recorded. All the osteotomies were performed under constant irrigation, and the implant (Singular, Dérig Implantes do Brasil) diameters were either 3.5 or 4.3 mm; the size depended on bone availability in height, and a distance of 2 mm was respected from the implant apex to the inferior alveolar nerve. At the end of the implant placement, torque was recorded with a manual torque wrench in Ncm (Dérig Implantes do Brasil), and in both study groups, all implants received an implant cover screw and sutures. In order to maintain the quantity of keratinized gingiva, it was decided to submerge all the implants. At the end of the surgical procedure, the timer was stopped and represented the surgical time.

Randomization regarding the side that received guided or conventional surgery and which was performed first was done with software (Randomizer for Clinical Trial). The operator was blinded to the type of surgery until after patient anesthesia. The patient was not informed of which type of procedure was received in each side. After 1 week, the postoperative evaluation of the surgery was performed, and in the same session, the patient received the placement of another implant on the opposite side with a different technique by the same student. Each patient was operated on by a different student.

All students who participated in the research underwent training prior to surgery. They had theoretical and laboratory practice on a dental manikin for two semesters, where the basic principles of implant dentistry were taught up to the clinical part. The virtual planning (Fig 1) was carried out by the same operator (N.C.N.) and was confirmed with the advisor (F.F.); then, the students were instructed in the implant planning and positioning of the patient to be operated on; information of the type of the surgery was not provided until after the anesthesia was performed.

On the side randomized to be the FGS group (test), the 3D-PSG was placed in position and a dichotomous evaluation (yes or no) was carried out to evaluate guide fit. With the 3D-PSG in position, the osteotomies were performed according to the manufacturer guidelines. All drills were used, and the implant was placed with the 3D-PSG in position, representing a fully guided flapless implant placement. An implant cover screw was placed, and two single interrupted sutures were performed to aid in keeping the blood clot in position since a submerged healing was desired (Fig 2).

In the CS group (control), the guide was placed in position after minor adjustments to improve fit. With the 3D-PSG in position, the osteotomies were performed according to the manufacturer guidelines. All drills were used, and the implant was placed with the 3D-PSG in position, representing a fully guided flapless implant placement. An implant cover screw was placed, and two single interrupted sutures were performed to aid in keeping the blood clot in position since a submerged healing was desired (Fig 2).

In the CS group (control), the guide was placed in position after minor adjustments to improve fit. Then, an incision was made over the ridge crest and in the teeth adjacent to the edentulous region, in a distance equivalent to a tooth for distal and one for mesial. After the incision, a full-thickness flap was raised both at the buccal and lingual aspect. The guide was placed in position, and the same drilling protocol performed in the FGS was performed. The implant cover screw was
placed, and two to four single interrupted sutures were performed depending on the mesial-distal length of the flap (Fig 3).

**Postoperative Medications**

After the surgical procedures, all patients received the appropriate medications: antibiotic (amoxicillin taken by mouth, 500 mg t.i.d. for 7 days), analgesic (ibuprofen taken orally, 300 mg every 6 hours in case of pain), and a mouthwash (rinse of 0.12% chlorhexidine digluconate 12/12 hours for 7 days). Immediately after the procedure, patients received a spreadsheet to complete an assessment regarding intraoperative discomfort, and after 7 days, another spreadsheet was filled out with new assessments, such as postoperative discomfort, general satisfaction, chance to recommend the procedure, and quantity of analgesic medications used. The operator and the assistant also received a spreadsheet where the operator’s intraoperative and postoperative stress was analyzed, as well as the difficulty of the procedure and the perception of the time of surgery of both. Another worksheet was handed over to the advisor, assessing his anxiety and stress during the operation. Questionnaires can be accessed in Appendix 1 (see Appendix in online version of this article at quintpub.com). Surgery time and placement torque are expressed in Fig 4.

**Statistical Analysis**

The primary outcome of the study was postoperative pain. The sample size calculation was performed using the data of the study by Magrin et al (2020). The normality of the data was tested using the Shapiro-Wilk test. Abnormal data were found and distributed in a nonparametric way, and the Wilcoxon test with combined pairs was used. The statistical significance level was set at .05 (GraphPad Prism 8.2).

**RESULTS**

A total of 10 patients were operated on by 10 different students; the same student operated on both sides with a 1-week interval. Twenty implants were placed, and no significant complications occurred. The implant diameter was 4.3 mm in 18 implants and 3.5 mm in two implants (both placed in the same patient). Implants were placed between teeth (intercalated edentulous areas) in 16 sites, while there were 4 terminal edentulous sites. Each patient received two implants on one side using the conventional flap technique (CS group) and on the other side guided without raising a flap (FGS group). The 3D printed guides presented a great fit in the supporting teeth. No patients presented paresthesia or sensitive alterations of the inferior alveolar nerve after the surgical procedures were performed.

The surgery of patients in the FGS lasted 30 minutes, 1 second ± 6 minutes, 2 seconds, while in the control group, it lasted 56 minutes, 36 seconds ± 8 minutes, 38 seconds; these data and placement torque are expressed in Fig 4. It was also observed in the control group that a greater amount of total medication was used in the postoperative period; in the CS group, a total of 49 (4.8 ± 3.1) pills were taken, whereas in the FGS group, only 15 (2.4 ± 3) pills were used by the patients.

Statistical analysis showed that in the FGS group, there was a statistically significant decrease in both intraoperative and postoperative pain, time of surgery, amount of medication used in the postoperative period (Fig 5), operator anxiety during surgery (Fig 6), and the duration of the procedure perceived by the assistant (Fig 7). Patients were satisfied with both techniques used.

**DISCUSSION**

Patients were benefited by receiving FGS in comparison to CS in several clinical aspects. The reduction in the time of the procedure and in the assessment of intraoperative and postoperative pain was large, which justifies the reduced amount of medications used after the procedures. The reduction in surgical morbidity generates benefits for patients, especially those who have medical conditions or who are afraid of performing invasive procedures. The present results support the concept that FGS provides better outcomes that are related to the patient, especially for professionals who do not have much experience. However, the benefits of FGS to replace a tooth should be interpreted with caution, since it is not possible to see if the region is being
properly irrigated and what is happening below the soft tissue, such as a bone fenestration, and, in addition, small angular deviations are usually found but tolerated for prosthetic restorations.\textsuperscript{20,21} Have minimal effects on the surrounding tissues,\textsuperscript{22} and require knowledge of the technique that will be used.

The significant differences in the postoperative assessment of patients who received FGS was not reported in a systematic review of the literature.\textsuperscript{23} This study analyzed three different flapless surgeries: freehand without a surgical guide, use of surgical guide based on prosthetic position and reverse planning, and prototyped surgical guide based on virtual planning. In terms of postoperative pain, no differences were reported between the three surgical approaches. A split-mouth study also showed no significant difference between surgeries with and without a flap.\textsuperscript{18} However, it is important to clarify that the surgeries were performed by experienced professionals, who were specialists for more than 5 years.

Not all implants placed in the world are performed by specialists with a high degree of training; one of the objectives of guided surgery is to increase the procedure precision and facilitate both the planning and performance of the surgical procedure.\textsuperscript{24} Digital planning helps in the teaching and learning process of undergraduate and graduate students, in addition to facilitating the perception of important details even for experienced professionals.\textsuperscript{25} It is also important to note that the soft tissue around the future implant plays an
important role in the long term. Conventional flapless guided surgeries should be performed in sites with a sufficient amount of keratinized tissue. If there is limited quantity, a soft tissue graft can be performed to improve the site condition. In the present study, it was decided to place a cover screw and submerge all the implants in order to maintain the quantity of soft tissue in the implant site regardless of the procedure. In that way, it could be possible to achieve similar soft tissue outcomes in the long term by performing the implant reopening (stage-two surgery).

The guided technique requires a surgical kit designed specifically to perform guided surgeries, which can be performed with or without a flap. The great advantage of this type of surgery is the placement of the implant in the ideal 3D position, previously planned in the software, that takes into account the position of the teeth, roots, patient occlusion, bone anatomy, and noble structures of the jaws. Regardless of the type of surgery, with or without a flap, it is important that the professionals have knowledge of both techniques to know how to deal with complications arising from these procedures.

A correct 3D position of the implant was identified as an essential factor in the rehabilitation for an ideal esthetic result. In addition, a recent study on peri-implant risk assessment showed that almost half of peri-implantitis cases were related to the poor positioning of the implant. These findings demonstrate that the long-term esthetics and success of dental implants depend a lot on the correct positioning of the implant. Guided surgery provides the clinician with the necessary tools to safely place the implants in the ideal 3D position, both anatomically and prosthetically, minimizing the risks of possible complications. The postoperative comfort provided by the flapless approach can have a positive influence on reducing pain and other symptoms inherent to the surgical procedure. The results reported by patients are subjective parameters, and further clinical studies with professionals with different degrees of experience are needed to determine the real effect of FGS in the postoperative period.

The limitations of this study include the sample size, which despite being sufficient according to the sample size calculation, is still doubtful since the main parameters assessed such as intraoperative and postoperative pain, level of anxiety, and stress are latent variables, making this assessment more difficult and subjective according to each patient.

CONCLUSIONS

Considering the limitations of the study, FGS performed by nonexperienced individuals showed reduction in the surgical time, while patients reported better intraoperative and postoperative outcomes.

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REFERENCES


Appendix

Patient: [Flapless Guided] [Conventional]  

Date: __/__/____

Right side

1- Intraoperative Pain

2- Postoperative Pain

3- General Satisfaction

4- What is the chance to recommend the procedure? (0= none, 10= highest chance)

5- Torque obtained when installing the implant:

6- Total procedure time:

7- How many painkillers and anti-inflammatory drugs were used?

Interventions:

Comments:

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Patient: ___________________________ Date: ___/___/___

Flapless Guided  □  Conventional  □

Left side

1- Intraoperative Pain

2- Postoperative Pain

3- General Satisfaction

4- What is the chance to recommend the procedure? (0= none, 10= highest chance)

5- Torque obtained when installing the implant: __________________________

6- Total procedure time: __________________________

7- How many painkillers and anti-inflammatory drugs were used? __________________________

Interventions: __________________________

__________________________

Comments: __________________________

__________________________
Operator - Assistant - Advisor: Date: ____/____/____

Right side

1- Ease of procedure

2- Time of procedure (0= too long, 10= too fast)

3- What is the chance to recommend the procedure? (0= none, 10= highest chance)

4- Intraoperative anxiety (operator only)

5- Intraoperative stress (operator only)

6- Advisor anxiety

7- Advisor stress
Operator - Assistant - Advisor: Date: __/__/____

Left side

1- Ease of procedure

2- Time of procedure (0= too long, 10= too fast)

3- What is the chance to recommend the procedure? (0= none, 10= highest chance)

4- Intraoperative anxiety (operator only)

5- Intraoperative stress (operator only)

6- Advisor anxiety

7- Advisor stress