Customized Surgical Protocols for Guided Bone Regeneration Using 3D Printing Technology: A Retrospective Clinical Trial

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Abstract: 3D printing is one of the most significant technological advancements of the modern era. Among the various surgical disciplines, this new technology has shown significant improvements in the diagnosis and treatment of many diseases. The application of 3D printing has many benefits in training, preoperative planning and education.

A retrospective study was conducted at the European University of Madrid (UEM). Patients were selected in this study using the following inclusion criteria: age over 18 years old, a preoperative cone beam computed tomography (CBCT), patients with moderate or severe vertical or horizontal defects, presence or absence of the tooth in the area to regenerate, no bone regeneration surgery before. Bone defects were measured: in the CBCT using White Fox Imaging, on the 3D printed model and then intraoperatively from the area to be regenerated. The average of the bone defects on the 3D measurements was statistically compared with the average of the bone defect measurements in the patient's mouth to evaluate the model reliability.

The mean age of the patients was 53,07 years old, with a range from 45 to 63. Females were more affected than males, with a ratio of 12/13 (92%). The most frequent side affected was maxilla 10/13 (77%) and the most type of defect reported was horizontal 10/13 (77%). The means in width ($x = 8{,}2923$) and height ($x = 6{,}9615$) of the 3D model, were close and clinically acceptable if compared with the means obtained from the measurements in width ($x = 7{,}9230$) and height ($x = 6{,}8076$) of the patients' bone defects. None of the patients underwent further surgeries or needed intraoperative surgical corrections obtaining reliable results in terms of presurgical planning.

It is possible to affirm that the use of 3D printed models can be a crucial complement when planning guided bone regeneration procedures, due to high reliability, and representing a turning point in many aspects of oral surgery.

Key Words: 3D printing, additive manufacturing, anatomical models, stereolithography, guided bone regeneration

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Three-dimensional printing, also known as "additive manufacturing" or "rapid prototyping," is generally used to describe a technology for building three-dimensional physical structures, layer by layer, based on their respective virtual models. This technology reproduces replicas through automated construction processes using solid, liquid or powder materials. 3D printing is promoted as one of the most significant technological advances of our modern era and the successful use of Rapid Prototyping technology for clinical applications is well documented in the Literature.[1]

The Rapid Prototyping technology has shown significant improvements in the diagnosis and treatment of a variety of diseases due to a better appreciation of the pathological structure and a better understanding of the complex underlying conditions. This technology allows for a more meticulous preoperative planning.[2]

It is expected that through this technology a complete understanding of human anatomy will be achieved, making it a crucial prerequisite for performing a surgical procedure. It has been proved that 3D printing can improve the learning experience for the surgeon and the students as well as being a very valuable tool to improve patient's education, providing a better understanding of the procedures and expected results.[1–3]

All 3D systems work similarly to each other. They are made of three functional components: a machine transforming geometry into digital data processed by a computer; a software that processes the scanner data and produces a data set readable by a manufacturing machine; a manufacturing technology that takes the data set and transforms it into the desired product.[4]

Three-dimensional printers do not accept Digital Imaging and Communications in Medicine (DICOM) files. Instead, 3D printers include individual objects defined by surfaces that enclose a region of space. A standard file format to define these surfaces is the standard tessellation language (STL). The STL format defines surfaces as a collection of triangles (called facets) that come together like a puzzle[5] (Fig. 1).

Fused Deposition Modeling (FDM) printers are considered as the first step to learn how to use 3D printing since good quality models are obtained and are sufficient at the dental level to plan, simulate and communicate with the patient. Besides, FDM printers have the advantage that the model does not have to be cleaned, and with a minimal cost of the material used for printing.[6]

The objective of this retrospective clinical study was to evaluate the use of 3D printed models as a complement for planning Guided Bone Regeneration (GBR) procedures in alveolar bone defects.

MATERIALS AND METHODS

A retrospective study was carried out in the Master of Advanced Periodontics of the European University of Madrid (UEM). The collection period started in October 2018 and finished in November 2019. Patients with moderate or severe bone defects in the maxilla and/or mandible were selected (Fig. 2).

Data were collected from the database of the UEM Dental Clinic.

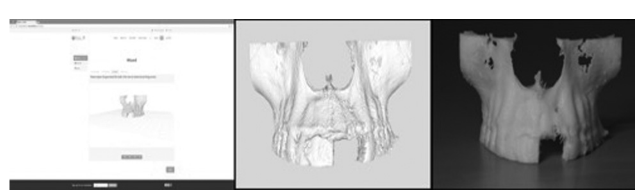

FIGURE 1. Obtaining a 3D model from the STL file. First the CBCT data of each patient is acquired, then the Dicom files are transformed to STL files through the website www.oral3d.eu obtaining the virtual 3D model (STL files processed). At the end of the process the 3D model is printed. STL, standard tessellation language.

FIGURE 2. Oral examination and diagnosis of element 2.1. A 50-year-old man presented for pain 2.1 region. Upon visual examination, a small protuberance was found in the vestibular gum of this piece. A periodontogram and CBCT were performed and an 8 mm vestibular mesial probing depth was observed.

Fifteen patients were selected with the following inclusion criteria: age over 18 years old, a preoperative CBCT, patients with moderate or severe vertical or horizontal defects, presence or absence of the tooth in the area to regenerate, no bone regeneration surgery before. 13 patients were included, 2 patients were excluded because they did not match the inclusion criteria.

The CBCT DICOM files were analyzed using the measurement tool present into the White Fox Imaging (3D and panoramic imaging program viewer) to measure height, width of each bone defect.

Then, the 3D models were printed to have a tactile analysis of the defect. The 3D model was obtained creating a file of STL images from the DICOM files of the CBCT of each case. To perform this conversion, it has been used the application presented on the website www.oral3d.eu. The created file is sent to the Sindoh DP201 3D printer (FDM): the printer has a size of ($421 \times 433 \times 439$ mm) and a print area of ($210 \times 200 \times 189$ mm). The filament used for printing is polylactic acid (PLA), a 100% biodegradable material made from renewable resources like corn starch or sugar cane, which presents good print quality to carry out the bio models necessary for surgery planning, without using complementary programs to retouch the models. PLA compared to other materials like acrylonitrile butadiene styrene is less strong but easier to print and less toxic a cause of the reduced production of styrene, a possible carcinogen.[7]

The surgical procedure was simulated case by case on models, selecting the appropriate approach to treat the defect and individuating the most appropriate materials.

Subsequently, the guided bone regeneration procedure was carried out on the 3D model: a resorbable membrane tacked with 2 pins was positioned on the model to measure its correct size, the defect was filled with xenograft material, and finally, the membrane was secured under the palatal flap, with subsequent suture of the flap providing a tension-free closure (Fig. 3). In the postoperatory phase, patients' bone regeneration was evaluated with a new CBCT, to verify the amount of new ossification.

Surgery

All patients were treated by the Author (GC) and fellow students of the Advanced Periodontics Master at the UEM. On the day of the surgery, the same surgical procedure mentioned above was performed.

The surgical procedure was similar for all cases. First, with a 15C scalpel blade, the incision started in the required area, and then

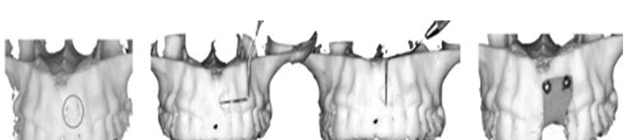

FIGURE 3. Surgery simulation on the 3D model. To see better the bone defect, a high-speed turbine and a small round diamond burr were used. Then it was measured in width and height with a periodontal probe. Subsequently, a surgical simulation of the guided bone regeneration surgery was performed.

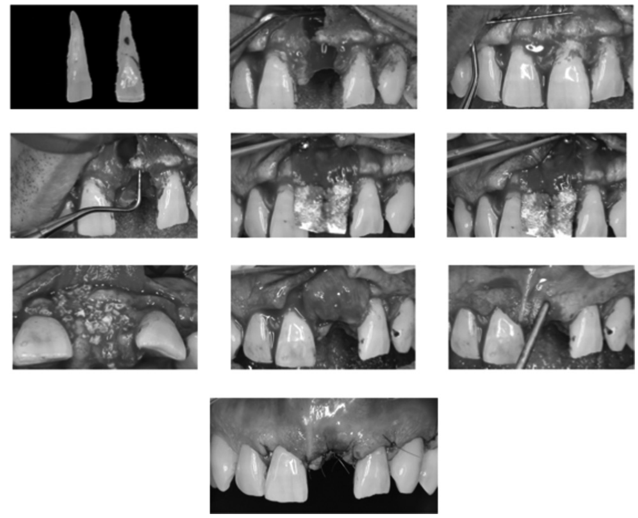

FIGURE 4. Surgical procedure on the patient's mouth: defect exposure, measurements, filling, and then flap arising with final stitches suture. The measurements obtained in the 3D model were checked and verified during surgery.

a full-thickness flap was raised. Then, the bone defect was exposed. With a periodontal probe, width and height of bone defects were measured. Collected data was subsequently added to the database. The regeneration was carried out with the necessary materials: all cases of horizontal regeneration were performed with xenograft material of Bio-oss type, and with an absorbable collagen membrane, Biogide or Copios; the cases needed of vertical regenerations, were treated with a Nonabsorbable polytetrafluoroethylene (PTFE) membrane. The customized membrane prepared was verified if was fitting accordingly with the clinical defect without any intraoperative modifications (Fig. 4).

After filling the bone defect, the flap was closed and sutured with 5/0 monofilament suture. The first revision was made after 1 week, the sutures were removed after 2 weeks, and controls continued monthly.

Finally, the data collected obtained from the CBCT, 3D model and patients' mouth inspection were compared and analyzed.

Statistical Analysis

The defect measurements were performed on the 3D model and then compared to the measurements in real surgery to evaluate the matching.

The average of both measurements in width and height were compared. To conduct a proper correlation analysis, normality testing using Shapiro-Wilk test was first used.

F-test was used to assess whether the variances of data sets were equal.

To conclude the analysis, the difference in means was analyzed. For this comparison, a *t*-Student test and a *P*-value were obtained. Statistical significance was set <0.05

RESULTS

The mean age of the patients was 53,07 years old, with a range from 45 to 63. Females were more affected than males, with a ratio of 12/13 (92%). The most frequent side affected was maxilla 10/13 (77%) and the most type of defect reported was horizontal 10/13 (77%). All the patients selected had a moderate (4–6 mm) or severe (>7 mm) bone defect, vertical or horizontal, according to Wang's classification described in 2002, which required a guided bone regeneration procedure (GBR).[8]

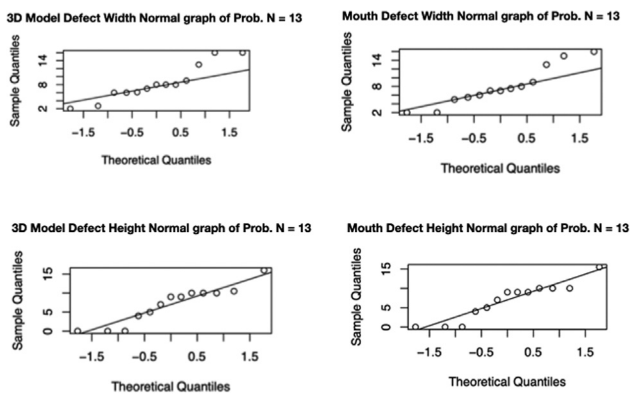

FIGURE 5. Graphical comparison between clinical and 3D model measurement in height and width, distributed in a normal.

Statistical Analysis

The mean of widths was 8.29 in 3D models, and 7.93 in patients. The graphical comparison with a Shapiro-Wilk test obtained a $W = 0.9016$ and a P-value $= 0.1407$ in 3D models, while a $W = 0.91686$ and a P-value $= 0.2274$ in patients. Both following a normal distribution. As the P-value was greater than 0.05, it was stated that the 3D models' defects in width matched the patients' defects. The F-test was 0.98781, with a P-value $= 0.9834$. The P-value was greater than 0.05, it was stated that the width of the 3D models' defects had the same variance of the patients' ones. t-Student analysis showed a result of 0.21455 and a P-value $= 0.8319$. With a P-value higher than 0.05, it was stated that the 3D models and the patients' widths of defects were superimposable (Fig. 5).

Heights' mean was 6.96 in 3D models, and 6.8 in patients. The means were quite identical. The Shapiro-Wilk test graphical comparison showed 0.90582 as W-value and a 0.1607 P-value in 3D models. In the patients' mouth, the results were $W = 0.90037$ and a 0.1353 P-value. Both were following a normal distribution. As the P-value was greater than 0.05, it was stated that the height of the 3D models' defects matched with patients' defects. The F-test result was 1.0645, with a P-value $= 0.9156$. The same variance was observed in both 3D models and patients. t-Student analysis showed a result of 0.081272 and a P-value $= 0.9359$. With a P-value higher than 0.05, it was stated that the 3D model and the patients' heights of defects were superimposable.

DISCUSSION

In today's market, there is a wide range of materials that can be used with the purpose to simulate surgery on a model. Many literature reviews help and guide to perform oral surgery procedures.[9] The technological advances presented by CBCTs allow a digital archive to be reproduced in an immediate physical product. In this way, it allows the possibility to have a replica in the hands of the clinician in a short time, to analyze, to plan and to make decisions about the surgery that must be carried out. In the same way, it allows to have a clearer and more precise communication with the patient, allowing a better understanding of the treatment

Besides, the FDM technology makes it easy to produce 1: 1 scale models at a low cost, and therefore cost-effective, customized, that any clinic can have for daily use, such as other devices that are used routinely. The PLA used in this study has a price of 50 euros per kg: with half kilo, with the possibility to print around 20/22 pieces (maxillas or mandibles) for a single unit cost of around 1 euro.

In the surgical preoperative simulation on the 3D model, the residents were able to select the type of membrane to be used, filling material for the regeneration, membrane anchoring tacks, and suture material. This approach improves the learning curve in this procedure and represents a valid opportunity to start surgeries in complete autonomy. The 3D printed model of the patient's skeletal structure offers advantages over the surgery to be performed, such as: evaluation of the patient's anatomy, treatment planning and simulation of the surgery. Likewise, real tactile and visual information of the bone condition of the surgical site, at a disadvantage to the 2D images presented by the CBCT. It is really rare to face unexpected events during surgeries if 3D model is used. For example, surprises like the running of the inferior alveolar nerve are evident even just the simulation of the model, besides the opportunity to study it during the imaging analysis. During the preoperative analysis of the 3D model, the necessary measurements of the membrane that will serve as a guide in the surgery were determined, ideally reducing the surgical procedure time, avoiding mistakes that could be made during the surgical procedure.

Several authors agree on the use of 3D printing for teaching purposes in the field of dentistry, but also in other medical specialties, such as in traumatology and or maxillofacial surgery. It is an increasingly common practice in clinical case analysis. Its use in the oral surgery field is advancing and is projected as a fundamental tool for preoperative surgical planning since the limiting factors for its use are decreasing, making it a technique that is easily available and accessible.[10,11]

Cohen et al in 2009, described that thanks to rapid prototyping technology, physical models can be built from a computer-aided design and subsequent 3D printing. On multiple occasions, maxillary or mandibular bone reconstruction are considered as a challenge for the surgeon who wishes to restore anatomical harmony, through bone grafts or titanium plates, since it requires a thorough intraoperative time. But, with the use of 3D models before the surgical act, it is possible to plan and perform said surgery previously, in a unique way and tailored to each case, providing less time and future complications in performed surgery.[12] Mean treatment time can take between 45 minutes and 1 hour. With the 3D model surgical simulation era, it is now possible to reduce the operation time for a better comfort of the patient.

Oh et al in 2018 relies on the modeling of 3D prototypes for the planning of auto-transplants intending to perform surgery more precisely. This confirms the benefits cited by Maryam Shahbazian et al in 2013, of using dental replicas in the planning, reducing time and errors of placement, that if they had been done conventionally.[13,14]

It is important to keep in mind that, in the middle of the surgical process, any predefined planning, reduces the time in which the area of oral action is open, reducing postoperative complications. It will also facilitate decision making. Thus, Esses et al in 2010 they anticipated that 3D modeling can be used to visualize complex anatomical structures, which allow the surgeon to plan the area to treat. Not less important, being able to "touch with the hands" the defect, the doctor-patient relationship will be favored by achieving better communication.[15]

In this clinical study, having statistically analyzed the measurements in the patient's mouth and the measurement in the 3D model (Fig. 6), after checking the variances of the means of the 2 measurement fields, and after having obtained sufficient precision to be able to use it in surgery planning, authors support the treatments planned by Shepherd et al in 2017.

In 2018, Werz et al used 3D printed models for the simulation of maxillofacial surgeries using accessible printing filaments; reiterating that this approach is a very promising tool for surgical planning.[9,16]

However, Park et al in 2017 explained that to perform a complete surgical simulation, more than the hard tissue

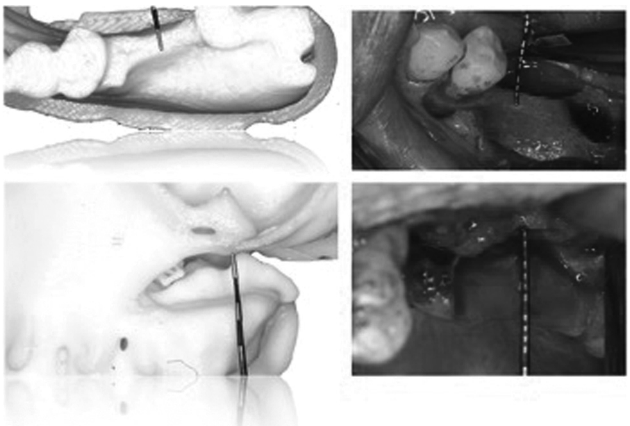

FIGURE 6. Author checking residual bone ridge width in 3D models and surgery. With the periodontal probe the measurements obtained were compared in width and height of the 3D models.

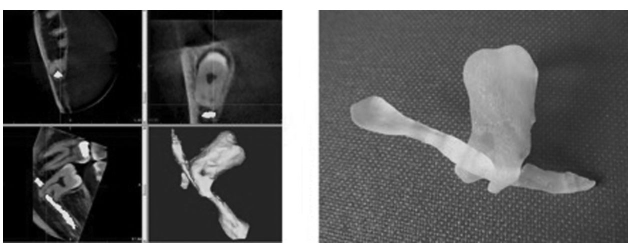

FIGURE 7. Simulation of a third molar included surgery with the 3D model showing the possibility to enhance and print also the running of the inferior alveolar nerve.

management itself is required, and soft tissue management is considered equally important since according to one of the principles of GBR is that a tension-free closure of the flap must be achieved.[17] The lack of soft tissue in the 3D models is since, in the CBCTs, these structures do not appear with the same definition and radio-opacity as dense structures, such as teeth and bone, which are well defined. In the same way, it happens with the vessels, nerves, and periosteum. But currently, there are computer programs that manage to solve certain situations, such as, for example, the signaling of the dental nerve as seen in the following image, being able to print structures that in the CBCT are not appreciated with such precision (Fig. 7).[17,18]

The limitations of this study reside, above all, in the small sample size, 13 patients. A greater number of results would have been obtained that would corroborate the validity of the oral surgery planning method using 3D models. Besides, the sample is made up of patients treated by different students of the Master's Degree in advanced Periodontics at the European University of Madrid, which may introduce bias in the sample, such as interpretation in the measurement reading with the periodontal probe.

CONCLUSIONS

The aid of a 3D printed model is a good complement to plan guided bone regeneration procedures. The precision obtained is within the acceptable margins of error to be used in the planning of real surgeries. The use of bio models allows performing customized surgeries as well as implementing preoperative training for surgeons and students, allowing the doctor to visualize, practice on the area to be operated before surgery. This new approach improved communication with the patient: describing the surgical procedure on a model made the surgery more understandable to patients. The necessary equipment for the reproduction of 3D models is no longer a problem because they have sizes and prices affordable for clinics. The reproduction of models can be obtained in few hours and at a low price.

The results of this clinical study serve as reference for further clinical studies and applications that may be carried out in the future.

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