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A simple, no-cost method for 3D printed model identification

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Introduction :

The indication and use of 3D printing and 3D printers in maxillofacial surgery is on the rise as the availability of this technology increases and the cost of the hardware goes down. However, the 3D printed models are often very similar in shape and can be inadvertently switched if the related patient is not identified correctly. Their Identification can be done on a separate physical structure (box or container), but this comes with a risk of loss, which then compromises the entire process, including any patient benefit from this technology.

These 3D models are based on a digital file (STL file), and it seems safer to add an identification code directly within the digital 3D model, which could be saved in a virtual medical file. Moreover, as 3D printed models may be used as medical devices (for example as a customized printed metallic implant), the manufacturers of these 3D models are required to comply with the 93/42/CEE European Directive if these 3D models are to be used in Europe^{1,2,3}. This directive notes the necessity of biocompatibility of the 3D model and establishes a list of quality requirements, mainly related to the traceability of the 3D model.

Here, we present a free and simple method to imprint letters and numbers in a 3D model STL file to identify 3D printed models, linking them with a patient's medical file. This digital identification of 3D printed models is an efficient solution to answer the traceability requirements of the 92/42/CEE European Directive regarding their use as personalised medical devices.

Materials and Methods :

A 27 year-old patient was treated in Lille University Hospital Center for condylar hyperplasia. The diagnosis was made clinically and confirmed by a cranio-facial technetium 99* PET scanner (SIEMENS Symbia T2 HFS, CHRU de Lille, France).

The scouting scan, made before the positron emission recording, was used in Lille University Hospital Center's maxillofacial and stomatology department to create a 3D replica of the mandible at the request of the referring surgeon. This 3D model was used in the pre-operative simulation of hyperplasia removal and for peri-operative visualization of the surgical site. The parameters of this scout scan were 1.25 mm slice thickness, 58 mAs, 110 kV with a H08s filter. The pitch was at 1.4 and the increment at 3 millimetres. The region of interest included the head and neck from the upper part of the skull to the 6th cervical vertebrae.

The CT scan data (DICOM files) were used to create an STL file of the patient's mandible following this method:

1/ DICOM files were loaded into the 3D slicer software⁴ [(version 4.4.0 r23774, National Alliance for Medical Image Computing (NA-MIC)], which was funded by the National Institutes of Health through the NIH Roadmap for Medical Research Grant (U54 EB005149, under direction of Ron Kikinis, MD at Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts), which is a free and open source software. The DICOM files were then reconstructed from standard axial cuts to multiplanar cuts. This was all exported into an .nrrd file.

2/ The .nrrd file was imported into ITK-snap software⁵ (version 3.2.0, supported by the U.S. National Institute of Biomedical Imaging and BioEngineering through grant R01 EB014346 and developed by Paul A. Yushkevich (Associate Professor, University of Pennsylvania, Richards Medical Research Laboratories, Philadelphia), PI and Lead Developer).

There, a procedure for automatic contour segmentation was performed:

- 1) A region of interest (ROI) was selected. We chose the area of this ROI according to the patient's mandible size.
- 2) Thresholding of the bone density was performed, keeping only densities above 341 Hounsfield units, which allowed the inclusion of bones and teeth.
- 3) We chose a label, which is a signal that can be interpreted to create 3D models (seven different labels were available, including a no-colour label used as an "eraser"). We set a series of label spheres to differentiate the areas of the mandible we wanted to retain from the areas we wanted to erase. These spheres were placed on different slices of the ROI (Figure 1).
- 4) An automatic segmentation was performed based on the label 1 signal to obtain a 3D replica of the patient's mandible. The areas that needed modification because of artefacts or decreased accuracy were modified using the pencil tool of the software and the eraser label.

Finally, we obtained a 3D replica of the patient's mandible based on the label 1 signal. We saved the resulting file as a new .nrrd file. We then re-imported the .nrrd file into the 3D-Slicer software⁴. The options selected during this importation (show option box) were "centred", "labelmap" and "single file" (Figure 2).

There, the 3D model was created with the use of the model maker module. The input volume was the label .nrrd file, and we created a new model hierarchy. Model maker parameters were 1 as label (the corresponding label used in ITK-snap), with the start label at -1, and the end label at +1. We skipped un-named labels. Joint smoothing was set at 8%. We used the Laplacian filter type, decimate at 0.25, with split normals, point normals and pads.

The 3D model obtained through this procedure was saved as an .stl file. It was "closed" and did not need any further fixation, unlike "opened" STL files, which cannot be printed without repair. We anonymized the file name, and it was impossible to extract the initial identification of the patient from the 3D model file.

The second step consisted of adding identification letters and numbers to a 3D virtual model.

We chose to keep only a part of the angle of the mandible because its surface was flat enough to add letters and numbers in a readable size. The 3D virtual model was cut with Nettfab Basic (version 7.4.0 532, Autodesk, San Rafael, California, USA), which comes in a free version that was sufficient for this study. Only the lower posterior part of the mandible was kept intact.

We then used Blender software (version 2.78a, Blender Foundation, Amsterdam, Netherlands), which is a free open source software mainly used for 3D video games scene creation, to import this file and modify it with numbers and letters.

The command "add" (or Shift + A as a shortcut) was used to add a new object. We then added text. The standard font used in blender is bfont, but we chose to use Arial bold instead. The font could be changed in the display and edit panel, which is in the data section. A "standard" font data base is available on PCs in C:/Windows/Fonts[figure Blender]. Modification of the text could be achieved by switching from "object mode" (which is used to modify the global object position, size and orientation) to "edit mode" (edit mode in the lower tool bar or tabulation as a shortcut). We also extruded our text over 0.3 blender units. The goal of the first extrusion was to give the text its third dimension and not to be accurate in size. The depth of the letters could be modified later with the scaling tool.

For some models, we chose to add a horizontal support bar under the text (Add > Mesh > Cube) fitting the text size with a height of one to two millimetres. The aim of that support bar

was to avoid failures in the definition of the lower part of the cantilevered letters and numbers. The measurements were made with the rule/protractor tool (Tool Panel > Grease Pencil > rule/protractor). Once the text and the support bar were added, we exported the entire project into an .stl file (file > export > Stl).

Our models were all printed with an Up plus 2 – easy 120 3D printer (Beijing Tiertime Technology Co., Ltd., HuaiRou District Beijing, China), which is a low-cost 3D fusion deposition modelling printer already validated for maxillofacial use⁷. We chose to keep the settings normally used for daily clinical 3D printing, which are a 0.4 mm layer thickness, a filling with narrow mesh, a reinforced support under the structures making an angle below 50° with the horizontal plane, and three layers of thickness for the surface of the 3D model.

We used standard 1.75 mm white acrylonitrile butadiene styrene. The 3D printer plate was pre-heated to 70°C for better adhesion of the support before the start of the printing.

We wanted to obtain a sample of 3D printed letters and numbers involving every shape possible to check the readability of letters and numbers after 3D printing. We chose representative letters and numbers with shapes similar to most of the letters and numbers of the Latin alphabet. The lowest common denominator was based on horizontal and vertical bars, obliques and large and small loops⁶. We chose to imprint a series of four letters and numbers on each of our 3D models because this approach is close to the type of patient medical file identification systems used in Belgium and France.

The letters selected were: A B E G H K Q R S W (table 1). Our final choice consisted of 5 vertical bars, 6 horizontal bars, 10 obliques bars, 2 large loops and 4 small loops. We also added the numbers 0, 2, 3, 4, 6, 7, 8, and 9. Since there were already enough vertical bars, we did not select the number 1. The number 5 was also discarded because of its similarity with S and the number 6. All those characters were used to test the reliability of their components

(bars and loops) once printed, searching for flaws in the printed models which could lead to identification impairment.

We asked 10 potential users of these 3D models to read the characters we imprinted on 6 different 3D models. Those readers were chosen among the medical and paramedical team of Saint Luc University Clinic of Bruxelles and were blind to each other for to read the 3D models (table 2). We evaluated the number of mistakes made during the lecture of each imprinted model, and the easiness of the reading according to the readers. At last we recorded the flaws we could observe on the printed models.

Results :

Six 3D "identified" models, including the mandible, letters, and numbers, were printed without any major failures (complete failure of the printing).

Three models were printed with a support bar and different character sizes to evaluate the readability of the letters and numbers. The sizes of the overall inscriptions with support bar excluded were 50 (length) x 7 (height) x 4 (depth) millimetres for model SAGE0234, 40 x 6.5 x 2 millimetres for model GREW8407 and 53 x 7.5 x 4 millimetres for model BHKQ9647 (figure 3).

Model SAGE0234 was printed a second time without the support bar to evaluate the potential flaws of the lower part of the letters and numbers without the support bar. This model was also printed a third time with an adaptation of the overall "identification number" to the shape of the mandible, with a depth of 1 mm and without a support bar. This helped us to evaluate the necessity of the support bar in this case. Last, we printed a series of 4 S and 4 E, each one cantilevered 1 millimetre more than the last to reach at least a maximal depth of 4 mm (figure 4). This model was designed to evaluate a cut depth at which letters may start to be flawed during the 3D printing process.

There were flaws on the model SAGE0234 without the support bar, such as a defect at the lower part of the S, and a flat aspect on its upper part that could make it mistaken for an 8. The upper part of the G had a curved aspect, as did the horizontal bars of the E. For the numbers, only the 3 had a definition flaw on its upper part. These flaws were partially found in the model SAGE0234 with a support bar. The S could still be mistaken for an 8, and the upper part of the G was not clearly defined. The horizontal bars of the E, and the number 3 presented with better readability. The adapted model SAGE0234 was considered flawless.

The model GREW8407 presented with flaws on the upper horizontal bars (letter E and number 7). The model BHKQ9647 showed flaws on the middle part of the number 9, on the upper curve of the number 6 and on the horizontal bar of the number 7. The support bar was flawed in both cases, without any impact on the readability of the letters and numbers on the 3D printed models.

The SSSSEEEE model was printed with a removable support under the letters and had very few flaws, such as a minor definition problem for the lower part of the letter S and the upper bar of the letter E.

Regarding readability, mistakes were made on the SAGE0234 support bar 3D model, where the letter S was mistaken for a number 8 by one reader, and on the model GREW8407, where the number 0 was mistaken for a number 6 by another reader. There were no other reading mistakes in these 3D model identifications.

Seven out of ten readers preferred the model BHKQ9647 because of its larger size, which made it easier to read the letters and numbers (53 x 7.5 x 3 mm). Conversely, 5 readers out of ten said that the model GREW8407 was too small and thus more difficult to read. Three observers spotted the flaw on the model SAGE0234 with the support bar, and three other observers reported that the adapted model SAGE0234 was easy to read.

At last, the favourite extrusion depth was 3 mm for 7 observers, 2 to 3 mm for one observer and 4 mm for 2 observers on the model SSSSEEEE.

Discussion :

With the increase in the use of 3D printing in the medical field comes the issue of printing identification. Without this process, 3D models can be mistakenly switched between patients if 3D printing is used in routine clinical practice. Moreover, 3D model identification becomes a legal requirement when 3D printed models are used as medical devices^{1,2,3}. Our method allows easy, fast and free 3D text identification by adding lettering to these printed models.

Concerning the size of the letters and numbers, there is no limit except for the 3D printer precision and printing parameters. A majority of observers from our study preferred the largest possible size for 3D identification. Here, myopia, hyperopia and presbyopia are common reading limitations that should be taken into account. The favourite depth for the 3D lettering was 3mm (one of the thickest) as it was considered easier to read. The adapted 1 mm thick SAGE0234 model raised no major interest among the observers.

The use of a support bar directly under the identification lettering can improve the 3D printing quality in case of the failure of automatic support that the 3D printer is proposing by default for lettering. The use of the horizontal bar can help avoid confusion in letters such as E and F. It represents a simple and fast solution when there is enough space on the shape of the 3D anatomical model for a 3D straight text a few centimetres long. This support bar is not needed when we can adapt the 3D text to the shape of the mesh surface using a depth of 1 to 2 mm for letters and numbers.

The identification location should take into consideration the future indication of the 3D printed medical model. For reconstruction plates bending on the 3D mandible printed model, the 3D identification should not be in any conflicting position that can interfere with the shaping of the mandible plate. A safe positioning of the 3D identification may be the lingual cortical bone of the contralateral mandibular angle.

There is no objective evidence of superiority of any of these 3D printing text models, but we would recommend that 3D identification should be done using at least 7.5mm high letters and numbers, with a depth of 3mm, according to our observations. A support bar is strongly advised when the model is 3D printed without any support. The identification should also be placed in a location far from the region of interest and according with the predictable use of the 3D printed model. Different standard informatic fonts can be used. The most popular ones may be easier to read for every practitioner, nurse or any potential user of 3D printed models.

The identification of the models could also be done at different times and by different means during the workflow of the 3D model production process, for example by engraving or writing on it with a permanent marker. This post-production method lacks the possibility of identifying the root file if the file name is changed though. The post-production methods can also be altered by 3D model sterilization. Therefore, it seems that identifying the 3D model during its creation is safer.

Moreover, dematerialised 3D STL files, including patient identification (letters and numbers), could be transferred (encrypted) through the internet without risking any identification leaks or mistakes, which is an advantage compared to the sending of physical 3D models in terms of quickness of data sharing and environmental cost. Finally, these identified 3D models could be saved in the digital patient medical file to keep them safe and available for the future.

At last, the time needed to add identification to the model via our method is dependent on the learning curve for the Blender software specific functions. It takes less than five minutes to do this manipulation for straight lettering and adding a support bar and less than ten minutes to adapt letters to a curved anatomical shape.

Considering the printing method, we could have chosen thinner slices to print our 3D model such as 0.3 mm, 0.2 mm, and 0.15 mm. Instead, we used 0.4 mm slice thickness. We wanted to perform this study with the 3D printer parameters we already use in daily clinical practice. These parameters are a compromise between clinical accuracy and fast 3D printing, which allows us to obtain mandibular 3D models in under one hour.

We used only one type of 3D printer and 3D printing technology (fusion deposition modelling) with Latin alphabet and Arabic numbers. Cyrillic, Arabic, ideograms, hiragana, and other forms of lettering were not tested. Only one material (ABS) was tested.

The SAGE0234 3D model was also used three different times. We could have varied the lettering to limit reading repetition but we would have lost the comparability value of these different models.

Lastly, only one method of 3D identification was tested here, and there may be other free and commercial software that can perform this task 8 .

This 3D text identification printing method may be a first step towards the legal use of 3D printed models made within the hospital, which could lead to medical devices 3D printing in the future. There is still room for improvement, such as QR code identification, which could be printed with a double colour material during the 3D printing process and which could carry much more useful information for practitioner in a simpler code.

Declaration of interest :

The authors have no pecuniary or other personal interest, direct or indirect, in any matter that raises or may raise a conflict with the submission and publication of this scientific paper.

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Table 1 - choice of letters and numbers according their shape (green and yellow overlighted

lignes showing the chosen letters and numbers for this study)

Table 2

Table 2 - readers caracteristics, number of mistakes while reading the models and preferred

extrusion depth in millimetres.

figure 1 - ITK-snap software, A) before automatic segmentation, B) after automatic segmentation

figure 2 - 3D slicer software, model maker tool, with 3D model created from the ITK-snap selected label

figure 3 – models SAGE0234, BHKQ9647 and GREW8407 printed with a support bar

figure 4 – models SAGE0234 without support bar, SAGE0234 adapted to mandibular shape and SSSSEEEE

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