Innovation and Technology Transfer

Custom-Made Orthoses with 3D Printing for Orthopedic Pediatric Application.

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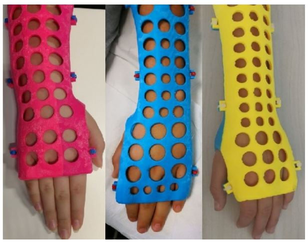

Distal forearm fractures represent about 70Using classic plaster cast can cause discomfort and skin damage as well as infections and irritations that can aggravate during the immobilization treatment. Nowadays, there are several works about 3D printed cast, focused on different aspect of process, but few have undertaken a clinical trial. The aim of this paper is to show a reverse engineering and 3D printing-based process to produce patient specific casts, ventilated and waterproof. Production process described in this work has been used in the clinical trial activity performed at Paediatric Orthopaedic Department of Santobono Hospital in Naples according to the project approved by ethical committee to test this new kind of immobilizer on 30 patients.
The process follows the technical consideration issued by FDA about 3D printed medical devices and it consists of three phases forearm scan, processing and printing.
Keywords: Patient-specific medical device, Reverse engineering, 3D printing, Pediatric Orthopedics.

1 Introduction

Distal radius and distal both bone fractures are very common in the paediatric population.[1]

This usually includes a plaster cast, splint, or a moulded synthetic material cast to immobilise the injured upper extremity.[2–4] Using casts, a normal course of the treatment includes its application up to six weeks and sometimes clinical follow up are required.[3,5,6] As a matter of fact, casts are described as having both poor ventilation and poor visibility of the skin.

This may bring to complications up to 31% of cast applications.[7–9] Particularly in orthopaedic 3d printing technologies allows to create patient specific devices, with an appropriate fit and a ventilated structure.

The 3D printing technology is rapidly advancing in medical applications.[10] 3D printing technology is applied to orthopaedic cast in order to create patient-specific features with an appropriate fit and a ventilated structure.[11] The first information, also if not clinic, started from two designers, Jake Evill and Deniz Karasahin.[12,13] They proposed a novel design of casts with a net-like structure and fabricated it by using additive manufacturing technique. The cast models were built from 3D–scanned images of subjects's limbs and created by using reverse engineering technique and Computer-Aided Design (CAD) software, which can generate a Stereolithography (STL) file, a standard file format widely used for 3D printing.

Although advance has made in development of cast using reverse engineering and 3D printing has made advances at a rapid pace in the development of casting techniques, all published papers are still in the concept stage without clinical application.[11] To date, there are few clinical studies investigating the application of 3D–printed casts.[14]

The aim of this paper is to show a reverse engineering and 3D printing-based process to produce patient specific casts. These devices (Fig. 1) are used in the clinical trial activity performed at paediatric orthopaedic department of Santobono Hospital in Naples according to the project approved by ethical committee to test this new kind of immobilizer.[15]

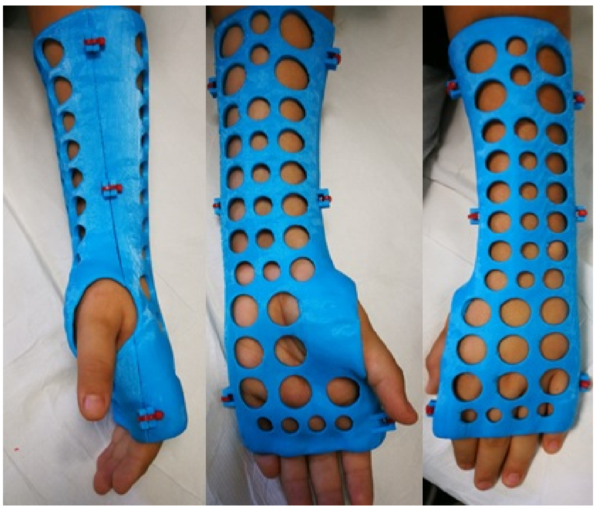

Fig. 1 3D model of casts designed.

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2 Definition of the process

As is shown in figure 2, the process considers three main steps:

1. Scan: acquisition of the 3D model of the forearm and validation;
2. Orthosis design: CAD design of cast;
3. Printing and post-processing (removal of supports and final smoothing);

These three phases have been identified and developed according to technical considerations for additive manufactured medical devices from American Food and Drug Administration, 2017.[16]

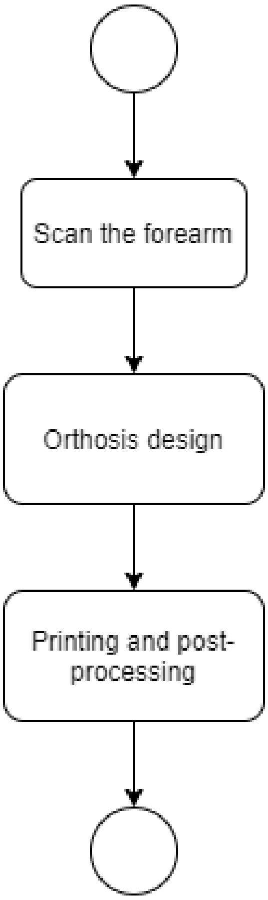

Fig. 2 Main Workflow

2.1 Scan

The acquisition of the patient's anatomical features is performed by a laser scanner (Sense 3D®; 3D Systems Inc., Rock Hill, South Carolina, USA), managed by a trainer operator.

The scan is performed in an ambulatory, placing the patient seated on a bed with the fingers set to a finger trap hooked to a drip bar, this allows the patient to hold position and discharges the fracture. Each scan is rapidly analysed with the 3D System Sense scan program to check the mesh regularity and the presence of holes. During this phase, there were some difficulties to acquire a valuable 3D image of the arm due to external light, and reflective objects from the environment. These has been overcome with some tricks such as covering of metalling parts and pc monitors. In the second phase of the project a structured light scanner avoids the main of these problems.

The final time required for these phase results to be about 1 minute reducing the patient stress.

2.2 Orthosis design

The surface model is processed using Rhinoceros® version 5.0 (Robert McNeel & Associates, Seattle, Washington, USA), a commercial 3D computer graphics and CAD application software.

The orthosis design takes up of several phases implemented according to predefined requirements from material characterization, stress studies and proof of concept evaluations.

The final dimensional specifications (thickness, length, holes dimensions and position, etc.) were defined from the above-mentioned technical studies and from practical clinical requirements pinpointed in special meetings between engineer and medical practitioners.

The CAD design procedure results as follows:

1. Import the model in Rhinoceros.
2. Remove the unnecessary portions of the model. (Helping with a plane, making a "Boolean subdivision").
3. Check the circumferences (using the command "Cross-section" and "Analyse/Length") of the wrist and of the proximal part of the arm (Fig. 3). Choose among the scans performed the one that has a better match with the measurements.

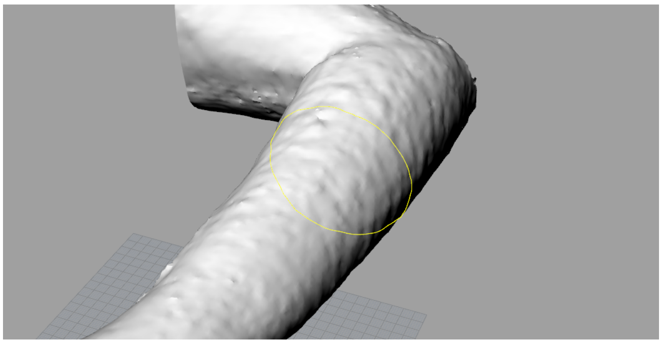

Fig. 3 Proximal Cross-section

4. Remove from the model the portion of the fingers after the first knuckle, then the proximal part of the arm and eventually the thumb, leaving a space suitable for the mobility of the same. (Helping with a plane and making a Boolean subdivision).
5. Remove the surfaces created after the phase 2. (Using the "Explode" command first, deleting the affected areas, then selecting all the polygons and using the "Merge" command).
6. Correct any defects (holes). (Using the "Fill Mesh Holes" command).
7. Expand the mesh by setting an offset of 0.5mm. (Using the "Whole model offset / offset" command).
8. Create the brace volume with a thickness of 4mm. (Using the "Shell / Shell" command).
9. Draw a reference plane for creating holes. (Fig. 4) (Using the "Surface Tools / Rectangular Plan" command).

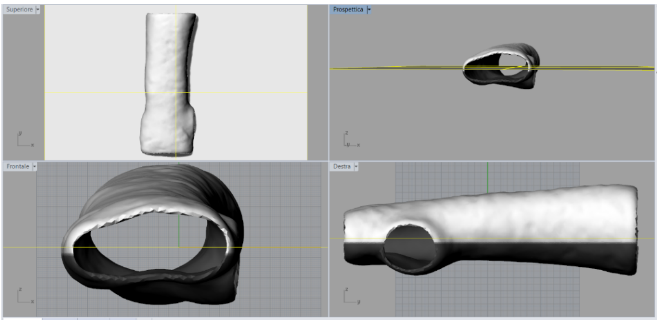

Fig. 4 Reference plane detail

10. Orient the model in such a way that the plane drawn divides the model into two parts and leaves enough space for the thumb hole.
11. Drill the model placing at least 15mm from the proximal edge and at 10mm from the distal edge, taking care not to remove the volume from the internal lateral surfaces. (Fig. 5 (Using the "Boolean Mesh Subtraction" command).

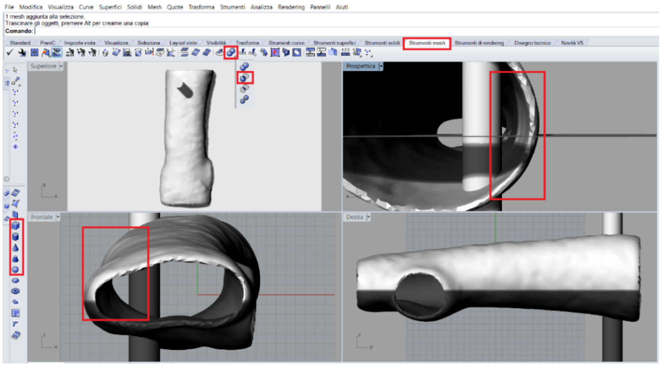

Fig. 5 Drilling model detail.

12. Split the model into two shells using the plane created in step 9. (Using the "Boolean Mesh Splitting" command).
13. Add the external closing stops by placing themselves at 0.2mm from the inner edges of the shells. (Using the "Mesh Boolean Merging" command, remove the excesses of the volumes used to create the closing stops with the Boolean splitting procedure with plane).
14. Add the internal latches making sure not to pierce the shell with the female volume. (Using the "Mesh Boolean Merging" command for adding male volumes and "Boolean Mesh Subtraction" for creating female volumes).
15. Place the shells for printing. (Fig. 6) (Using the "Rotate" command, rotate both shells approximately 35-40 degrees to the plane, making sure to place the shell volumes below the male volumes of the internal locking latches).

2.3 Printing and post-processing

Nowadays there are many kinds of 3D printing technology available, more or less expensive for different medical applications.[17] Fused deposition modelling is the most common and the less expensive 3D printing technology. We choose a cartesian, single extruder with 30x30x30 volume closed chamber, printer (Genius 3D HIKO). This allows a simple use in the clinical environment.

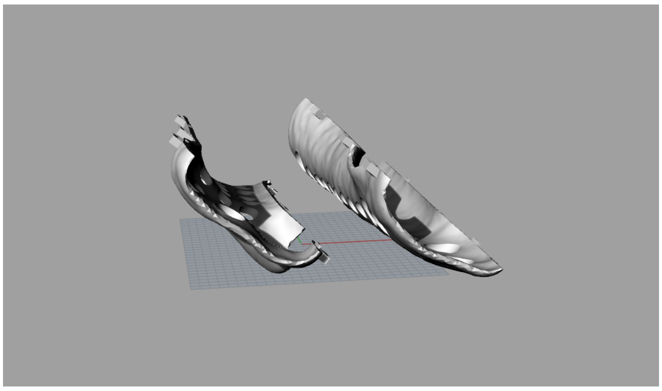

Fig. 6 Printing orientation.

The chosen material was Z-Ultrat (Zortarx) which is ABS based.

All the printing settings and model orientation have been defined in order to optimize printing time. Layer thickness, number of loops, amount, height and degree limit of the supports has been identified as primary settings for time consuming and mechanical features.

Skin thickness and layer height are relevant settings. Regarding the first, if too low, it could cause loss of parts of the external surface forming holes in the shell, during the removal of supports. Regarding the latter, it larger influence printing time. In this case, layer and skin thickness have been chosen respectively of 0.25 and 0.9 millimetres.

The right placement of the shells, with an angle of about 35 degrees (Fig. 6) has been demonstrated to be optimal in terms of time required to print the entire cast and for the amount of supports.

Right print orientation together with a degree limit of 60 degree and z-height of 25 millimetres, for the support settings, allow the production of a cast in about 18 hours.

Post processing requires removal of supports and sanding. Polishing with acetone makes the surface smooth and removes all little tips.

3 Results

The process described allows to produce an orthosis in less than 36 hours, from CAD design, in line with the mean clinical time. It ensures a fast immobilization of the patient's forearm. The lightweight, the ventilation and the aesthetics of the cast make it more acceptable to little patients.

4 Conclusion

The procedure allows to produce and install 30 orthoses, during the clinical trial protocol[15] As reported in[18] there were not medical problems or skin injuries for all patients. There was only one case of partial breakage of the orthosis because of an accidental fall from a swing.

In the figure 7 there is an example of installed cast.

Thanks to 3D printed cast, the little patients returned to school, moving easly during treatment and were less limited in their daily living activities.

Compared with the plaster cast, the 3D printed orthosis gives greater convenience, compliance, and satisfaction for both patients and their families. Patient satisfaction was mesured

Fig. 7 One of installed cast and relative radiological image.

by a visual analogue scale and the global patient rated wrist evaluation.

This experience highlighted usefulness information for the introduction of 3D technologies in a clinical environment. This process requires a great interaction technical staffs and clinicians starting from the early phases of this kind of innovative device.

Riferimenti

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