Acta Orthop. Belg., 2020, **86**, 378-382

ORIGINAL STUDY

Orthopaedic support with 3D printing in children : marketing effect or solution of the future?

David Mazy, Robert Elbaum, Gautier Beckers, Chloé Matriche, Olivier Vannieuwenhove

From the Orthopaedic Department, CHIREC Orthopaedic Group, Brussels, Belgium

In pediatric orthopaedics, the immobilization of a limb is traditionally done by a cast. The emergence of 3D technologies allows us to produce restraints specific to the anatomical characteristics of the patient. This paper aims to determine the feasibility of the process of developing these restraints.

Descriptive study of the creation process involving 19 patients aged 2 to 14 years for whom a restraint was placed between April 2018 and November 2018. This was mainly post-traumatic pathology (12) and children having a clubfoot (7).

This type of restraint has the following characteristics : use of recyclable material ; lightness ; ventilation ; visibility of the underlying skin tissue and its hydro-compatibility. The major limitations remaining are production time and printing errors.

The emergence of 3D printing, allows us to extend its application to the medical world. When the therapeutic effectiveness of a restraint is achieved, quality of life becomes the main selection criterion. Based on observations already made in the past, we were able to develop a model that combines the advantages of the different approaches.

New 3D printing technologies allow the creation of restraint devices with many advantages and customized adaptation possibilities.

Keywords : 3D printing ; orthopaedic support ; paediatrics.

INTRODUCTION

In pediatric orthopaedics, the immobilization of a limb is traditionally done by a cast. This can be used for initial treatment of traumatic pathology, post-operative immobilization or for the progressive correction of certain deformities such as club feet *(11,12,15)*. They are generally made of plaster, resin or thermoformable material. They regularly cause discomfort, have poor ventilation and are constraining to the patient *(7)*. Their production is essentially dependent on the clinician's skills and experience. Very few major advances have been made in this area. However, the emergence of new technologies allows us to consider restraints produced by 3D technology, specific to the anatomical characteristics of the patient. Indeed, three-dimensional printing has played an increasingly important role in our

■ David Mazy[1], M.D.
■ Robert Elbaum[2], M.D. PhD
■ Gautier Beckers[1], M.D.
■ Chloé Matriche[1], M.D.
■ Olivier Vannieuwenhove *, M.D.

[1]*Orthopaedic Department, CHIREC Orthopaedic Group, Brussels, Belgium*

[2]*Paediatric Orthopaedic Department, CHIREC Orthopaedic Group, Brussels, Belgium*

Correspondence : D. Mazy, Hôpital de Braine l'Alleud-Waterloo, CHIREC, 35 rue Wayez, 1420 Braine L'Alleud, Belgique, 024349913.

E-mail : david.mazy@ulb.be

No benefits or funds were received in support of this study.
The authors report no conflict of interests.

society, particularly in the health sector, since the early 2000s *(16)*. In this context, and for several years now, numerous attempts have been made to produce restraints by 3D printing without obtaining a really convincing model *(3,5,10)*. Subsequently, a start-up company has developed a process for modelling and producing these restraints. This paper aims to determine the feasibility of the process of developing these restraints.

MATERIALS AND METHODS

This is a descriptive study of the process of creating and manufacturing these restraints involving 19 patients aged 2 to 14 years for whom a restraint was placed between April 2018 and November 2018. These were twelve post-traumatic conditions and seven patients with clubfoot requiring nocturnal restraints after the age of 2 years (Tab 1). The follow-up was performed by a surgeon within the same institution. Concerning the methodology for the creation of these orthopaedic restraints, several steps are necessary (Fig 1). The first step consists in modelling the injured limb using a portable three-dimensional scanner connected to a tablet (Fig 2) using infrared pattern emission technology. The Occipital Structure Sensor application is used to obtain this modeling. The tablet simply has to be

Fig 1. — Production path.

Tablel I. — Description of patients.

Patients	Gender	Age	Region	Pathology	Side	Weight (g)	Duration (weeks)
1	M	14	Forearm	Fracture	R	85	5
2	M	7	Forearm	Fracture	R	79	12
3	M	7	Forearm	Fracture	R	74	4
4	F	13	Forearm	Fracture	R	85	4
5	F	9	Forearm	Fracture	R	74	4
6	M	14	Forearm	Fracture	R	94	6
7	F	12	Forearm	Fracture	L	97	3
8	F	8	Forearm	Fracture	L	84	8
9	M	6	Leg	Clubfoot	L	102	32
10	M	5	Leg	Clubfoot	L	114	32
11	M	8	Leg	Clubfoot	R	124	32
12	F	7	Leg	Clubfoot	L	101	32
13	M	7	Leg	Clubfoot	R	95	24
14	F	5	Leg	Clubfoot	Bilateral	89	12
15	M	6	Leg	Clubfoot	R	87	12
16	M	3	Elbow	Fracture	R	104	4
17	M	6	Elbow	Fracture	R	85	6
18	F	2	Elbow	Fracture	L	67	8
19	F	11	Knee	Sinding -Larsen	R	147	4

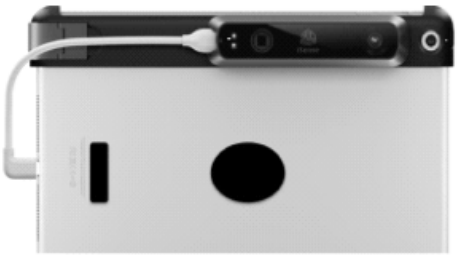

Fig 2. — Infrared scanner.

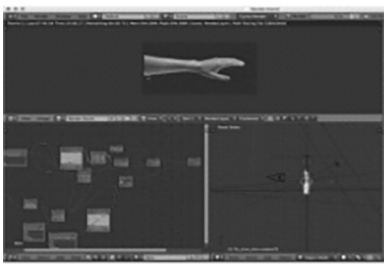

Fig 3. — Three-dimensional modeling.

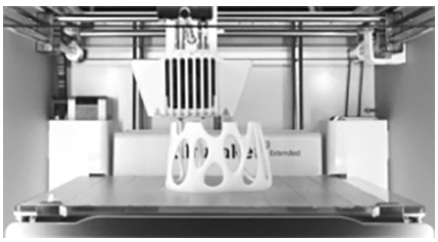

Fig 4. — Three-dimensional printing.

rotated around the limb in question, while it scans. This imaging technique is non-invasive and the infrared emission is a class 1 laser, considered safe under normal use. Then, the 3D scanner file is encrypted and sent via a secure platform. The latter is then processed to correct any errors. Finally, it is transferred to a 3D modeling software, to allow the creation of the custom orthopaedic restraint (Fig 3).

To control the dimensions of the device, the orthopaedic restraint will be built on the 3D scan of the patient's limb, using an algorithm developed by a start-up (Spentys). Once the 3D model of the orthopaedic support has been created, printing is then possible. The 3D printers used are the fused deposition modelling (FDM) type, (Fig 4) i.e. they will build the medical device by depositing, in layers of 0.2 mm at a speed of 30 mm per second, material at defined locations. The material used for the production of orthopaedic restraints is polyolefin, a mixture of additive and polypropylene. This material has been biochemically tested and certified biocompatible according to ISO10993 ensuring that the material is non-cytotoxic, hypoallergenic and does not cause irritation. Concerning the evaluation of the restraint, two questionnaires allowing to establish a score were developed by the report authors, which could also be used for a future comparative study. One is to be completed by the doctor, the other by the patient. Other parameters were also measured, such as weight. A medical consent form was signed by each patient's legal representative. In addition, the study project was presented to the institution's ethics committee, which agreed to its implementation.

RESULTS

This production method is applicable to the manufacturing of orthopaedic restraints (Fig 5, 6, 7), for antebrachial, brachio-antebrachial as well as for nocturnal leg restraints. A restraint can be produced in a time interval of 5 to 15 hours, for a weight of between 67 and 147 grams. The time required to scan the member takes between 15 and 30 seconds. The size of the restraints is limited to 60 cm of the largest axis due to the size of the printers. The materials used do not show any degradation due to exposure to water.

Fig. 5. — Antebrachial.

Fig. 6. — Brachio-antebrachial.

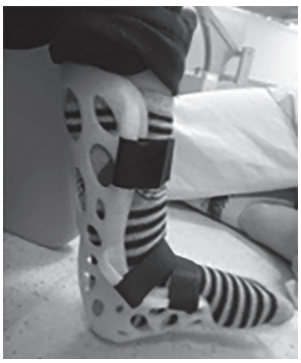

Fig. 7. — Leg restraint.

DISCUSSION

An orthopaedic restraint by 3D printing appears to be a tool totally adapted to the immobilization of a limb *(1,5,6)*. Indeed, in orthopaedics, the ideal restraint has often been thought about but has not been achieved *(14)*. The emergence of new technologies, in particular 3D printing, allows us to extend its application to the medical world and to offer new opportunities to get closer to this ideal *(16)*. When the therapeutic effectiveness of a restraint is achieved, quality of life becomes the main selection criterion. Based on observations already made in the past, as well as collaboration between engineers, orthopaedists, orthotists and patients, we were able to develop a model that combines the advantages of the different approaches. Indeed, this type of restraint has interesting characteristics : use of recyclable material, lightness, ventilation, underlying skin visibility and its hydro-compatibility. The major limitation remains production time, printing errors delaying the delivery date and the size of the largest axis of the part to be printed (**table** 2). After use, the product can be returned to the start for reuse of about forty percent of the polypropylene. The production line therefore requires no special storage space. The immobilization positions of the limbs are determined in collaboration with the surgeon. The restraint can also be adjusted to avoid contact with any underlying wound. Restraints are never put in at first, but later in the development of the trauma. Graham et al. (2018) compared conventional restraints with 3D printing restraints in healthy patients and were able to demonstrate increased satisfaction among wearers of 3D printing restraints.

Table II. —. Advantages and disadvantages of 3D restraint

Advantages	**Disadvantages**
Hydro-compatible	Production time
Weight	> 60 cm
Skin visibility	Printing errors
Ventilation	
Recyclability	
Radio-transparence	

However, no comparative clinical studies have been carried out on subjects with real pathologies. In an emergency, this type of restraint does not currently seem to have its place given the rapid changes due to post-traumatic swelling *(3)*. However, its usefulness seems major in periods of transition between a classic restraint and the complete absence of maintenance or in the maintenance of joints in the context of chronic pathologies such as rheumatoid arthritis or spastic limbs *(3,13)*. Our restraints are made in 1 piece, while other studies have tried to make them in several pieces in order to reduce the printing time *(10)*. The assembly is fixed with Velcro strips but can also be fixed with non-removable devices. In the context of clubfoot, its indication is proposed as an alternative to conventional night splints (AFO) prescribed beyond the age of 2, while retaining the undeniable advantages, mentioned above, of 3D compression *(4,8,9)*. Some studies use radiological images such as CT scans or magnetic resonances to obtain surface information from the limb, but this seems extremely expensive and time-consuming compared to the use of infrared, which also avoids any irradiation *(3)*. It should also be noted that the scanning method requires very little equipment and is portable. The major disadvantage of this method currently remains the printing time, but this will be reduced in the future. Indeed, this requires an additional visit to the patient to place the 3D printed restraint. It should be noted that before obtaining the current model, several attempts were unsuccessful. First of all, due to printing defects, allergic reaction, excessive flexibility or material weakness. Then, the experience of previous studies made it possible to adapt the current model as well as possible, thus aiming at optimal patient comfort while maintaining the therapeutic effectiveness initially sought. A randomized study on a larger

number of patients comparing conventional restraints with the model produced by 3D printing is necessary to formally affirm the effectiveness of this new device and reverse a possible effect of trend.

CONCLUSION

New 3D printing technologies allow the creation of restraint devices with many advantages in terms of quality of life as well as customized adaptation possibilities for each patient. The purpose of this study is to describe the production method and the advantages and disadvantages that result from it. However, further studies are needed to compare these devices with the restraints traditionally used in terms of therapeutic efficacy on the one hand and quality of life on the other, as well as its extension to other anatomical regions.

Acknowledgement

Thanks to Broze L-P. and De Boeck F. from the start-up Spentys.

REFERENCES

1. **Blaya F, San Pedro P, Silva JL *et al.*** Design of an orthopedic product by using additive manufacturing technology *: The arm splint. J Med Syst.* 2018 ; 42 : 54.
2. **Cazon A, Kelly S, Paterson AM, Bibb RJ, Campbell RI.** Analysis and comparison of wrist splint designs using the finite element method : Multi-material three-dimensional printing compared to typical existing practice with thermoplastics*. Proc Inst Mech Eng [H].* 2017 ; 231 : 881-897.
3. **Chen Y-J, Lin H, Zhang X. *et al.*** Application of 3D-printed and patient-specific cast for the treatment of distal radius fractures : initial experience. *3D Print Med.* 2017 ; 3 : 11.
4. **El Batti S, Solla F, Rampal V, Oborocianu I**. Clément J-L. Méthode fonctionnelle versus Ponseti dans le traitement du pied bot varus équin. *Rev Chir Orthopédique Traumatol.* 2014 ; 100 : S270-S271.
5. **Fitzpatrick AP, Mohanned MI, Collins PK, Gibson I.** Design of a patient specific, 3D printed arm cast. *KnE Eng.* 2017 ; 2 : 135-142.
6. **Graham J, Wang M, Frizzell K. *et al.*** Conventional vs 3-Dimensional Printed Cast Wear Comfort. *Hand N Y N.* 2018 ; 1558944718795291.
7. **Guyton GP.** An analysis of iatrogenic complications from the total contact cast*. Foot Ankle Int.* 2005 ; 26 : 903-907.
8. **Herzenberg JE, Radler C, Bor N.** Ponseti versus traditional methods of casting for idiopathic clubfoot*. J Pediatr Orthop.* 2002 ; 22 : 517-521.
9. **Laaveg SJ, Ponseti IV.** Long-term results of treatment of congenital club foot*. J Bone Joint Surg Am.* 1980 ; 62 : 23-31.
10. **Li J, Tanaka H.** Rapid customization system for 3D-printed splint using programmable modeling technique – a practical approach*. 3D Print Med.* 2018 ; 4 : 5.
11. **Musgrave DS, Mendelson SA**. Pediatric orthopedic trauma : principles in management. *Crit Care Med.* 2002 ; 30 : S431-S443.
12. **Rang M, Pring ME, Wenger DR.** Rang's Children's Fractures. Lippincott Williams & Wilkins. 2005 ; 336.
13. **Rosenmann GC, Weigert MC, Poier PH. *et al.*** Additive Manufacturing applied to development of low cost custom splint for spastic hand. *Addit Manuf.* 588 : 701-711.
14. **Schuind F, Moulart F, Liegeois J. *et al.*** Mise au point review article*. Acta Orthopa Edica Belg.* 68 : 5-2002.
15. Tachdjian's Pediatric Orthopaedics : From the Texas Scottish Rite Hospital for Children - 5th Edition.
16. **Ventola CL.** Medical Applications for 3D Printing : Current and Projected Uses. *Pharm Ther.* 2014 ; 39 : 704-11.