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Original article

Use of a 3D-printed splint for the treatment of distal radius fractures: A randomized controlled trial

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ABSTRACT

Background: Management of distal radius fractures typically includes a period of immobilization with either a cast or a splint. Traditional immobilization methods can have inconveniences such as poor resistance to water and poor ventilation, which can result in skin maceration, skin breakdown, and infection in case of wetting.
Hypothesis: 3D-printed splints could potentially overcome the inconveniences of traditional casts. In this report, we compare a 3D-printed splint (3DPS) with a conventional removable splint (CRS) and a traditional cast in a randomized clinical trial.
Patients and methods: Thirty-four patients with a recent distal radius fracture were randomized to receive either a 3DPS or a CRS. An additional subset of nine patients benefitted from both splints for a direct comparison. Primary outcomes were measured based on a subjective assessment questionnaire and a clinical outcome.
Results: There was no statistical difference in the subjective assessment between the 3DPS and the CRS groups. Based on the clinical assessment, patients with the 3DPS experienced more pressure-related pain. Among the sub-sample of nine patients that benefited from both splints, eight preferred the CRS and one chose the 3DPS. The 3DPS was judged better for perspiration, coolness, and water resistance.
Discussion: The 3DPS was successful in solving shortcomings of conventional splints and cast (better ventilation, less perspiration, less warmness, more durability and water resistance). However, the rigid structure and sharp edges made it less comfortable, overall favouring the CRS.
Level of evidence: II.

1. Introduction

Distal radius fractures (DRF) are among the most common orthopaedic injuries and affect all age groups [1,2]. Management of these injuries can be either surgical or conservative, both of which typically include a period of immobilization with either a cast or a splint [3,4]. Treatment of these injuries has seen many innovations [5], but immobilization methods have seen less improvement.

The main goal of upper extremity splinting is to provide immobilization and protection while allowing the patient to carry out his daily life activities. Traditional casts are made with plaster of Paris or synthetic material, while splints are made with either thermoplastics or fabric [6,7]. Traditional casts are not resistant to water, and wetting can result in skin irritation, skin breakdown, and infection [6]. Skin maceration can also occur due to friction or inadequate ventilation. Poorly fitting splints can lead to blisters and ulceration due to heterogeneous pressure distribution, particularly over bony prominences [7].

Several authors have described the conception and design of 3D-printed casts that could potentially overcome the inconveniences of traditional casts, with promising results [8–11]. However, clinical comparisons with traditional casts and splints remain scarce [12]. In this report, we compare patients' preference between a 3D-printed splint (3DPS), a conventional removable splint (CRS) and a traditional cast in a randomized clinical trial.

Abbreviations: 3DPS, 3D-printed splint; CRS, conventional removable splint.

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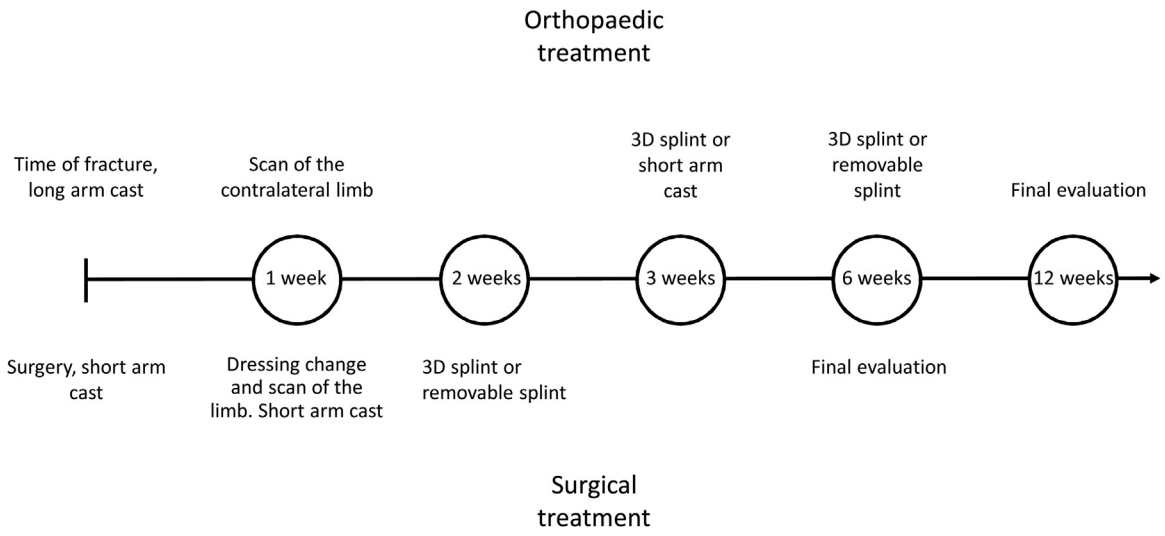

Fig. 1. Timeline detailing the patients' recruitment.

2. Methods

2.1. Patients

Patients with a recent distal radius fracture were recruited from the hand surgery consultation of Cliniques universitaires Saint-Luc in Brussels, between July 2019 and July 2020. The inclusion criteria were being more than 18 years old and being able to understand and fill in questionnaires. Patients provided written informed consent to participate. This study was approved by the ethical committee of Cliniques universitaires Saint-Luc-Université catholique de Louvain (No. 2019/12 MAR/115).

Patients were randomized into two parallel groups with equal allocation based on sealed and opaque envelopes, following a randomized sequence from www.randomization.com, using random blocks of four and six patients. One group benefited from a 3DPS while the other got a CRS (BraceID, Orthobroker, Ranst, Belgium). The recruited patients with a distal radius fracture were treated either operatively or non-operatively. For patients who underwent surgery, the splint was put on two weeks postoperatively according to standard protocol. For patients treated conservatively, the splint was put on instead of the short arm cast (after three weeks of long arm cast), and patients were told to keep it on the whole time for 3 weeks. They were allowed to wear it intermittently six weeks after the date of the fracture. The timeline for a typical patient is detailed in Fig. 1.

A preliminary analysis was done after enrolling 50 patients, and statistical tests were found to be underpowered due to a large variance. It was thus decided that a subsample of nine patients would benefit from both splints for a more direct comparison. Patients were instructed to alternate between the two splints every other day. At the end of the follow-up period, they filled in a questionnaire comparing the two splints and gave their choice for their preferred splint.

2.2. 3D-Printed splint

The 3DPS was provided by Spentys, a Belgian company focused on the customization of immobilization devices. The first step in creating the 3DPS was to scan the limb using a portable three-dimensional scanner connected to a tablet using infrared pattern emission technology (Fig. 2). This step was achieved by scanning while moving the tablet around the limb, which took between 30 seconds and one minute. The limb modelling was done on the contralateral limb in 80% of the cases, and the mirror image was generated for the splint production. When scanning the contralateral limb, the volume of the model was increased by 10% to accommodate for the swelling. This imaging technique is non-invasive, and the infrared radiation is a class one laser, which is considered safe under normal use. Once the numerical model was obtained (Multimedia 1), the treating surgeon could modify it by altering the wrist axis, the splint length, or the location of the alveoli (i.e. to allow access to certain areas of the skin or to protect the underlying surgical scar).

For the final step, a modelling software was used to create the custom splint (Multimedia 2). The 3D-printing technology used was the fused deposition model type, i.e. the 3DPS was built by melding plastics and depositing polyolefin materials (a mixture of additive and polypropylene) in layers of 0.2 mm at a rate of 30 mm per second to form the splint. This material has been biochemically tested and certified as biocompatible according to ISO10993, which makes it non-cytotoxic and hypoallergenic. The splint was produced in a time interval of five to 15 hours, weighing between 50 and 150 grams. Once the splint was 3D printed, it was shipped to the hospital. The whole process took around 24 hours.

The final 3DPS has a supple structure with an opening on the dorso-ulnar side and surrounding Velcro straps that can be tightened or released to accommodate the swelling of the forearm (Fig. 3).

2.3. Outcomes

For the outcome evaluation, the authors compiled a subjective assessment questionnaire based on previous publications [12,13]. The authors modified it by adding items that were judged pertinent and by modifying the response format to a 4-level Likert scale (Supplementary material 1). The questionnaire items cover different aspects of the splint such as comfort, breathability, durability and stabilization. The questionnaire total score was computed by adding up the individual responses and dividing by the number of answered items. The same items from this questionnaire were adapted for the group of patients that received both splints (Supplementary material 2). Patients completed the questionnaire in the presence of the first author who made sure that the instructions were clear and correctly followed.

A clinical assessment was filled in by the surgeon to assess parameters such as stability of the immobilization, blood circulation, pressure-related pain and pressure sores [12]. Patients also

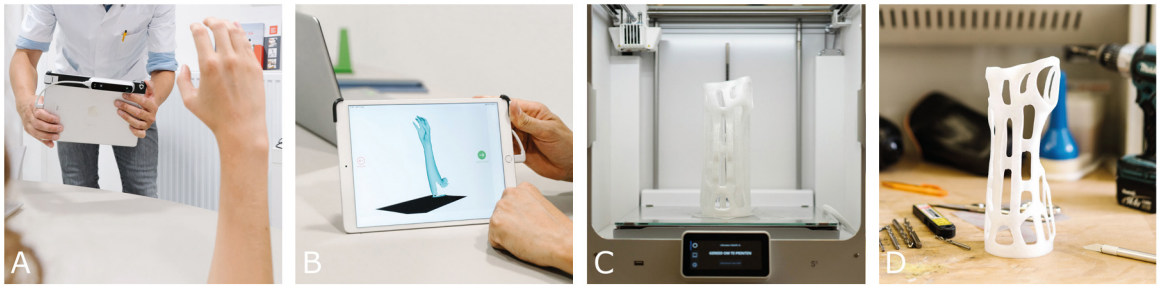

Fig. 2. Photos of the 3D-scanning process and the 3D-printed splint production. Panel A. Scanning of the limb. Panel B. 3D model of the limb. Panel C. Printing of the splint in a 3D-printer. Panel D. Final 3D-printed splint.

Fig. 3. Photos of the 3D-printed splint.

filled in the QuickDASH [14], the SF-12 [15] and a numerical pain scale. The Physical Component Summary (PCS) and Mental Component Summary (MCS) were derived from the SF-12. These scores are standardized based on the US population to have a mean of 50 and SD of 10.

2.4. Statistical analyses

Statistical analyses were completed in IBM SPSS Statistics for Windows, version 25 (IBM Corp., Armonk, N.Y., USA). Data normality was verified using Q-Q plots. Non-parametric tests were used as data was found to be non-normal and variables were ordinal. A Kruskal Wallis test was used for multiple-group comparisons. A Mann-Whitney *U*-test (two-tailed) was used for differences in questionnaire scores between the two groups. Pearson Chi-square test was used for proportions comparisons. *P*-values < 0.05 were considered significant.

3. Results

Patients recruitment is detailed in Fig. 4. Our final sample consisted of 34 patients for the group comparison. Sample characteristics are detailed in Table 1.

There was no difference in the subjective outcome questionnaire scores between casts made with either POP or synthetic material ($U = 18.5$, $Z = -0.797$, $p = 0.426$). Comparison between casts, 3DPS and CRS revealed a significant difference in the subjective scores: both splints were rated significantly better than the casts ($H = 15.019$, 2 df, $p = 0.001$).

There was no statistical difference in the subjective assessment between the 3DPS and the CRS groups ($U = 141$, $Z = -0.52$, $p = 0.958$). These two groups did not differ with regard to other outcome measures except for the MCS score. Results are detailed in Table 2.

Most patients achieved the highest total score on the clinical assessment. Patients with some level of impairment in each domain are detailed in Table 3. A Pearson Chi-square test between the 2 groups was non-significant, although a notable difference was found with the wear and pressure-related pain.

3.1. Direct splints comparison

Among the sub-sample of nine patients that benefited from both splints, eight preferred the CRS and one chose the 3DPS ($p = 0.02$). Results are detailed in Fig. 5. The CRS was favoured regarding soft edges, bulkiness, adaptation, activity limitations, facility for putting on and comfort. The 3DPS was better for perspiration, coolness and water resistance.

3.2. Complications

No serious complications (i.e. skin breakdown, ischemia and loss of reduction requiring re-intervention) were observed in our sample. We had one case of contact allergy with the 3DPS that resolved by adding a stockinet between the splint and the skin. In the group of patients who wore the 3DPS continuously for the conservative treatment of their DRF, the authors observed oedema that takes the shape of the splint alveoli (Fig. 6). Most patients in both groups reported some degree of skin irritation at the level of the first web space. The cast structure with Velcro straps allowed the accommodation of the swelling at the level of the forearm but was proven too rigid around the wrist and the hand. Minor adjustments had to be made in half of the patients by heating the material.

4. Discussion

In this report, we compared a new 3DPS with a CRS and a traditional cast in a sample of patients with a distal radius fracture. Both splints were rated better than casts. Even though the 3DPS offered several advantages in terms of weight, durability and breathability, most patients preferred the CRS as it was judged more comfortable.

The strengths of our study include a randomized trial, followed by a subsample that benefited from both splints. Our sample is representative of patients seen in our clinical practice, covering all age groups and socioeconomic classes. The study design is as close as possible to our normal practice with no additional follow-up visits. The group comparison did not show any difference regarding the patient-reported outcomes, mainly because of a high variance leading to an under-power of statistical tests. The only difference that emerged was the higher MCS score in the 3DPS group. This might be due to better emotional well-being and social functioning, which translates into fewer limitations. Other authors used radio-

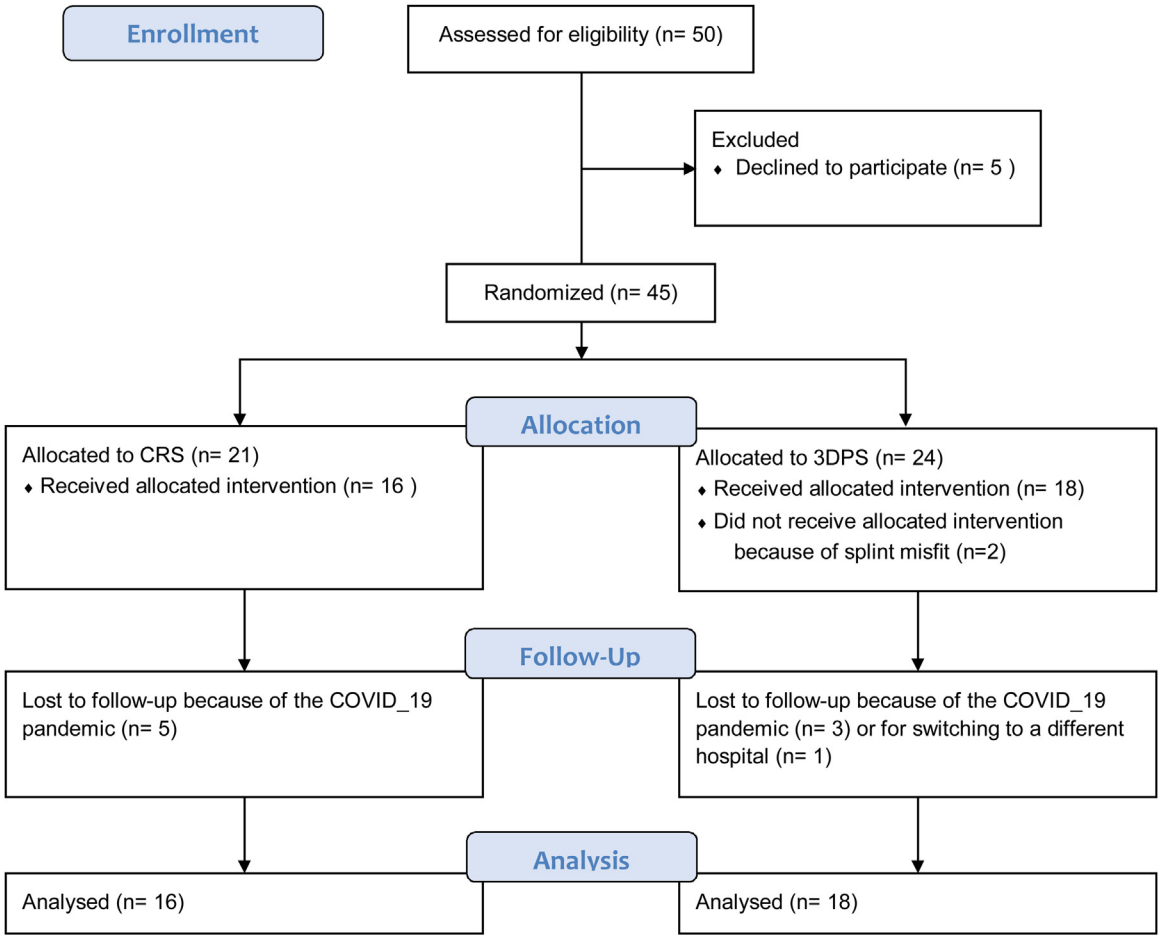

Fig. 4. Diagram of patients' recruitment.

Table 1
Sample characteristics.

Characteristic	Conventional removable splint ($n = 16$)	3D-printed splint ($n = 18$)	p-value
Mean age (SD), years	54.44 (20.8)	56.72 (17.7)	0.695
Gender, n (%)			
Women	11 (69)	10 (56)	0.429
Men	5 (31)	8 (44)	
Work status, n (%)			
Worker	8 (50)	10 (56)	0.746
Retired	8 (40)	8 (44)	
Hand dominance, n (%)			
Right	15 (94)	17 (94)	0.932
Left	1 (6)	1 (6)	
Affected side, n (%)			
Right	7 (44)	8 (44)	0.968
Left	9 (56)	10 (56)	
Treatment, n (%)			
Surgery	12 (75)	11 (61)	0.388
Conservative treatment	4 (25)	7 (39)	

Table 2
Statistical comparison of patient-reported outcome measures.

	Mann-Whitney U-test				
	Subjective questionnaire	QuickDASH	PCS	MCS	Pain scale
CRS, mean (SD)	85.18 (9.49)	37.50 (19.21)	43.61 (7.44)	45.57 (5.55)	2.20 (2.06)
3DPS, mean (SD)	86.25 (8.00)	45.17 (20.57)	40.83 (6.90)	51.86 (7.82)	1.91 (1.69)
p-value	0.932	0.336	0.367	0.041	0.897

Table 3
Statistical comparison of the clinical assessment.

	Pearson Chi-square test			
	Stability of immobilization	Blood circulation	Wear/pressure-related pain	Pressure sores
CRS	0/16 (0%)	1/16 (6.3%)	1/16 (6.3%)	1/16 (6.3%)
3DPS	2/18 (11.1%)	2/18 (11.1%)	6/18 (33.3%)	5/18 (27.8%)
p	0.169	0.618	0.051	0.100

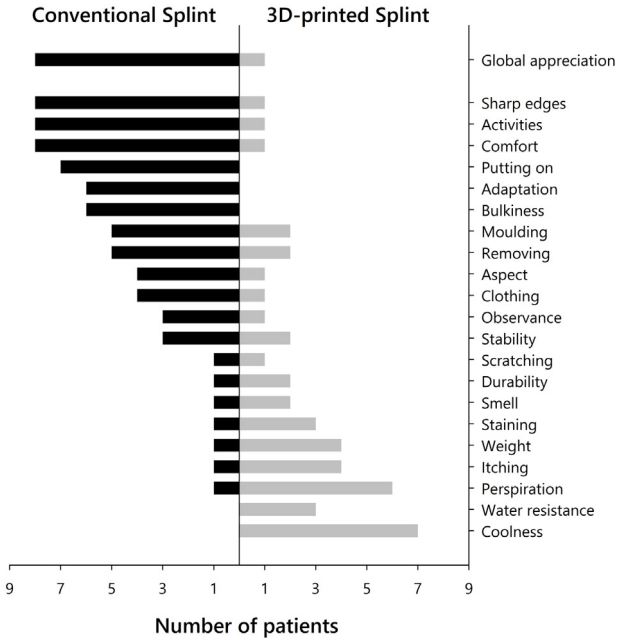

Fig. 5. Distribution of patients' preferences regarding the different aspects of the 3D-printed splint (3DPS) and the conventional removable splint (CRS). Black and grey bars represent the number of patients favouring the CRS and the 3DPS respectively. Items with a total number of patients that does not add up to nine, are due to patients answering that both splints were similar, or that they did not experiment the featured characteristic (water resistance). The keywords summarizing the items are detailed in Supplementary material 2.

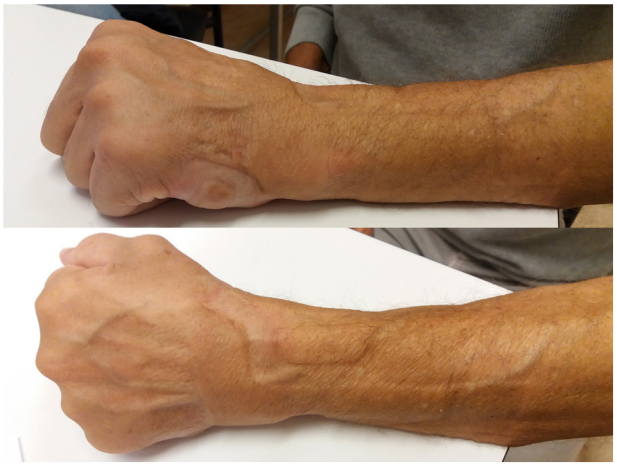

Fig. 6. Photos of the pitting oedema taking the shape of the alveoli after three weeks of wearing the splint continuously.

logical images such as CT scans to obtain surface information from the limb [12], but this is expensive, time-consuming and irradiating, compared to the use of infrared. Our scanning method requires very little equipment and is portable.

The casts described in this study are made of a single piece, while they were composed of two parts in other studies [12,16,17]. We seldom used padding to soften sharp edges, while it was systematically used by other authors [12,16]. By using padding more generously, we could have gotten better results as pressure pain and skin irritation were the main complaints of patients. The 3DPS had a design that allowed the splint to be flexible enough around the forearm to accommodate the post-operative swelling as well as oedema subsidence after the initial trauma. However, the rigid parts on the dorsum of the hand and wrist were the cause of discomfort, and the part around the first web space did not accommodate the thumb movements and caused various degrees of irritation. Although patients rated the 3DPS better than the traditional cast, we recommend caution when using the actual design during the first 6 weeks of a distal radius fracture. Its lightweight, water resistance and ventilated structure are attractive features, but the rigid structure and the pitting oedema that takes the shape of the alveoli (Fig. 5) merit attention. Modifications in design by reducing the size of the alveoli would allow for better pressure distribution.

In previous studies, the 3DPS was preferred over traditional casts. The results in our study are more mixed. While the CRS was judged more comfortable and was favoured by patients, many features of the 3DPS were judged better than the CRS, such as the light weight, durability and breathability. Comparison of different studies remains tricky because of the differences in splint design and material, as well as patient characteristics and pathologies. Graham et al. found that 3D-printed casts were superior to a short fiberglass cast regarding comfort, satisfaction and perceived function in normal subjects [16]. We had similar results in our study where patients preferred both types of splints over casts. In the study by Chen et al., patients expressed a strong preference for 3D-printed casts [12]. However, casts were worn for the first week after the fracture, while the 3D-printed casts were worn thereafter. The results could have been influenced by this difference in timing as traditional casts were always worn during the first week after the fracture. Patients' experience during this period such as increased pain and swelling might have altered the results.

Limitations include the use of a non-validated subjective outcome measure. Although this might have been an issue with the randomized samples, each patient in the sample that benefited from both splints had the opportunity to compare them and pick the one they preferred. We chose patients with distal radius fractures to test the 3DPS. This choice was made as distal radius fractures are the most common diagnosis requiring an immobilisation in our practice. However, this was probably not the best group to test the 3DPS as an immobilisation is not necessary after a volar locking plate fixation [18]. In most cases, the patient's contralateral limb was scanned to acquire the data for the 3DPS. Asking a patient to hold his fractured limb during the scanning time is not feasible in clinical practice mainly due to pain and the risk of losing reduction. Most 3DPS were fabricated using the mirror image from the unaffected side. This might have produced some printing errors due to the variation in normal anatomy. However, most pressure points and irritating edges were due to the rigidity of the material and the lack of padding, rather than data acquisition and printing errors. The 3DPS can be heated to change its shape to a limited extent, but the amount of deformity correction is far less than that of thermoformed splints. Since it takes 24 to 48 hours to

Table 4
Pros and cons of the 3D-printed splint.

Pros	Cons
Recyclable material	Rigid material
Light weight	Sharp edges
Breathable	Production time
Skin visibility	Printing errors
Reduced cost	
Novel aesthetics	
Water resistance	

produce a splint, which is longer than the time needed to produce other splints, we anticipated the delay by scanning the patient's limb during the previous appointment. This might have generated some inaccuracies regarding limb oedema and muscle atrophy. For future clinical application of the splint, the delivery time with the actual printing methods might be a drawback. With more developed equipment and different printing techniques and materials, such as digital light processing which is based on the photopolymerization of resins using ultraviolet light, we might be able to produce a 3DPS in two hours.

Compared with traditional manufacturing methods, the cost of 3D printing is more competitive for small production runs and when customization is required. 3D printing can also reduce manufacturing costs by decreasing human interactions through automation and digitalization and by limiting the number of unnecessary resources [19]. Indeed, the ability to produce parts on-demand without the need for equipment and setup is a standard for a new solution in supply chain management of orthosis manufacturing on the market. The manufacturing of a 3DPS has a positive environmental impact through improved logistics, raw material consumption and recycling [20,21]. A 3DPS is produced by using only the necessary material for the manufacturing of the orthosis, far less than the material needed to produce a traditional plaster or synthetic cast. Contrary to materials used for traditional casts, the 3DPS can be recycled and reused by mixing half of the waste with fresh material.

5. Authors' take-home message

Following our initial experience, the 3DPS was successful in solving shortcomings of conventional splints and cast (better ventilation, less perspiration, less warmness, more durability and water resistance). However, the rigid structure and sharp edges made it less comfortable, overall favouring the CRS. Advantages and disadvantages are detailed in Table 4. Improvements in material choice, design (e.g. smaller holes) and padding will probably solve the inadequacies of the current splint. Shape memory materials will allow us to ditch the Velcro straps for an easier fitting and a more aesthetic design. Future developments include reducing printing time to less than two hours so that the splint can be produced on-site. Modifications will be implemented to produce an improved splint that will be tested in a future clinical trial.

Disclosure of interest

The authors, G.E.K., X.L. and O.B., declare that they have no competing interest. Florian De Boeck is the cofounder of Spentys and reports personal fees and non-financial support from Spentys.

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Contribution of authors

G.E.K. designed the study, collected and analyzed the data, wrote the first draft of the manuscript. O.B. and X.L. designed the study, provided the patients and reviewed the manuscript. F.D.B. wrote the parts of the manuscript related to the 3D-printed splint.

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Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.otsr.2022.103326.

References

[1] Karl JW, Olson PR, Rosenwasser MP. The epidemiology of upper extremity fractures in the United States, 2009. J Orthop Trauma 2015;29:e242–4.
[2] MacIntyre NJ, Dewan N. Epidemiology of distal radius fractures and factors predicting risk and prognosis. J Hand Ther 2016;29:136–45.
[3] Mauck BM, Swigler CW. Evidence-based review of distal radius fractures. Orthop Clin North Am 2018;49:211–22.
[4] Tang JB. Distal radius fracture: diagnosis, treatment, and controversies. Clin Plast Surg 2014;41:481–99.
[5] Barbier O, Obert L. Distal radius fracture: the right treatment for each patient. Orthop Traumatol Surg Res 2019;105:403–5.
[6] Halanski M, Noonan KJ. Cast and splint immobilization: complications. JAAOS 2008;16:30–40.
[7] Taylor E, Hanna J, Belcher HJCR. Splinting of the hand and wrist. Curr Orthop 2003;17:465–74.
[8] Blaya F, Pedro PS, Silva JL, D'Amato R, Heras ES, Juanes JA. Design of an orthopedic product by using additive manufacturing technology: the arm splint. J Med Syst 2018;42:54.
[9] 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. J Eng Med 2017;231:881–97.
[10] Chen Y, Lin H, Yu Q, Zhang X, Wang D, Shi L, et al. Application of 3D-printed orthopedic cast for the treatment of forearm fractures: finite element analysis and comparative clinical assessment. BioMed Res Int 2020;2020:9569530.
[11] Zolfagharian A, Gregory TM, Bodaghi M, Gharaie S, Fay P. Patient-specific 3D-printed splint for mallet finger injury. Int J Bioprint 2020;6:259.
[12] Chen Y-J, Lin H, Zhang X, Huang W, Shi L, Wang D. Application of 3D-printed and patient-specific cast for the treatment of distal radius fractures: initial experience. 3D Print Med 2017;3:11.
[13] Inglis M, McClelland B, Sutherland LM, Cundy PJ. Synthetic versus plaster of Paris casts in the treatment of fractures of the forearm in children: a randomised trial of clinical outcomes and patient satisfaction. Bone Joint J 2013;95-B:1285–9.
[14] Beaton DE, Wright JG, Katz JN. Development of the QuickDASH: comparison of three item-reduction approaches. J Bone Joint Surg 2005;87A:9.
[15] Ware J, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care 1996;34:220–33.
[16] Graham J, Wang M, Frizzell K, Watkins C, Beredjiklian P, Rivlin M. Conventional vs 3-dimensional printed cast wear comfort. Hand (N Y) 2020;15:388–92.
[17] Li J, Tanaka H. Rapid customization system for 3D-printed splint using programmable modeling technique — A practical approach. 3D Print Med 2018;4:5.
[18] Duprat A, Diaz JJH, Vernet P, Gouzou S, Facca S, Igeta Y, et al. Volar locking plate fixation of distal radius fractures: splint versus immediate mobilization. J Wrist Surg 2018;7:237–42.
[19] Ventola CL. Medical applications for 3D printing: current and projected uses. P T 2014;39:704–11.
[20] Attaran M. Additive manufacturing: the most promising technology to alter the supply chain and logistics. J Serv Sci Manag 2017;10:189–206.
[21] Cruz Sanchez FA, Boudaoud H, Camargo M, Pearce JM. Plastic recycling in additive manufacturing: a systematic literature review and opportunities for the circular economy. J Clean Prod 2020;264:121602.