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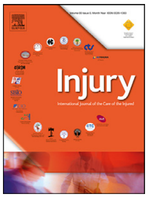

Personalized 3D-printed forearm braces as an alternative for a traditional plaster cast or splint; A systematic review[☆]

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ABSTRACT

Forearm fractures such as distal radius fractures are traditionally treated with a plaster or synthetic cast. Patients commonly report inconvenience of the cast, skin problems, and occasionally radial sensory nerve numbness. A known issue with casting is that the rate of secondary dislocation is high. As an alternative to casts, personalized 3D-printed braces are increasingly used. This review provides an inventory of current developments and experience with 3D-printed forearm braces. Main focus was on the design requirements, materials used, technical requirements, and preclinical and clinical results.

Review of 12 studies showed that all printed braces used an open design. Fused Deposition Modelling is most commonly used 3D-printing technique (seven studies) and polylactic acid is the most commonly used material (five studies). Clinical evaluation was done in six studies, mainly involving distal radius fractures, and generally showed a low complication rate and high patient satisfaction with the printed brace. Whether or not the results obtained with 3D-printed braces are superior to results after casting requires further studies.

Introduction

Distal radius fractures are among the most common types of fractures [1]. Despite development of surgical alternatives, the majority of fractures is treated nonoperatively using a plaster or synthetic cast. Patients often report that they find such casts bulky, heavy, and uncomfortable, and it interferes with personal hygiene. This may cause skin irritation, skin complications, or when applied wrongly even temporary dysfunction of the radial sensory nerve. In addition to being inconvenient, the major disadvantage of a cast is the risk of secondary fracture dislocation, which may occur even in up to 75% of patients [2]. Other complications that may require secondary surgical intervention are malunion and compartment syndrome [3,4].

Surgical treatment is no guarantee for uneventful fracture healing, so improvement of surgical implants and techniques is not the holy grail. The development of computer aided design (CAD) software and 3D-printing of customized braces introduced an option to improve the nonoperative treatment. While this introduced options that allow for individualized modeling and production of braces, it also faced researcher with challenges regarding design choices, material options, and additive manufacturing options. The available materials have their own properties that may affect the quality of the printed product, and the different printing techniques affect the printing time [5,6]. Ideally, a 3D-printed brace is tailored to fit the individual patient, providing optimal fracture stabilization and immobilization, and at the same time be more convenient to patients than the traditional plaster cast.

Treatment with 3D-printed foot and ankle orthoses resulted in better results than traditional nonoperative treatment [7]. For application in the upper extremity, on the other hand, developments are still emerging. A recent systematic review concluded that currently used 3D-printed orthoses for hand therapy use lightweight and well-ventilated materials, and appear to be effective at limb immobilization [8]. The authors also concluded that the printing technology in hand therapy settings remains challenging in part due to the resources required. Another recent systematic review reported that current literature addressing the effectiveness of 3D-printed orthoses for traumatic and chronic hand conditions con-

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Table 1
Overview of included studies

Study	Country	Targeted brace application	Evaluation
Chen *et al.* (2017) (10)	China	DRF	Patients
Blaya *et al.* (2018) (12)	Spain	General forearm splint	Design
Guida *et al.* (2019) (13)	Italy	Pediatric DRF	Patients
Yan *et al.* (2019) (14)	China	DRF	Design
Chen *et al.* (2020) (11)	China	Forearm fractures	Biomechanical and patients
Gorski *et al.* (2020) (15)	Poland	General wrist-hand orthosis	Design
Graham *et al.* (2020) (16)	USA	General forearm splint	Healthy persons
Hoogervorst *et al.* (2020) (17)	USA	DRF	Biomechanical
Janzing *et al.* (2020) (18)	Netherlands	DRF	Biomechanical, healthy persons, and patients
Lukaszewski *et al.* (2020) (19)	Poland	General wrist-hand orthosis	Biomechanical
Skibicki *et al.* (2021) (20)	USA	Pediatric wrist fractures	Patients
Wang *et al.* (2021) (21)	Canada	General wrist splint	Design

DRF, Distal Radius Fracture; RCT, Randomized Control Trial.

sists primarily of small and poor methodological quality studies [9]. Both reviews appreciate there is a need for well-designed controlled trials including patient-reported outcomes, production time and cost analyses. Limitations of the two reviews is the minimal amount of detail given on the design and production processes.

The aim of the current review was therefore to provide an inventory of current developments and experience with 3D-printed braces for patients with a forearm fracture or other forearm indications. Main focus was on the design requirements, materials used, technical requirements, and preclinical and clinical results.

Literature search

The PubMed database was searched for literature on 3D-printed brace designs for forearm applications. Distal radius, fracture, brace, orthosis, splint, cast, 3-dimensional, and printing were used as words in the search string, including all synonyms. Studies that reported on the development of 3D printed braces or their using in preclinical or clinical setting (both in healthy volunteers or fracture patients) were considered eligible. Studies that did not provide original data (*e.g*, reviews or meta-analysis) were excluded. No language restrictions were used. The search identified 12 publications (Table 1) [10-21]. Five studies were performed in Europe, four in Northern America, and three in China. Most of the designs were targeted for the treatment of distal radius fractures (n=5; 1 pediatric), while others were developed for the treatment of forearm fractures in general (n=1), pediatric wrist fractures (n=1), or no specific indication beyond forearm or hand-wrist immobilization was specified (n=5).

Design process

Although each of the designs differed, the development processes all followed a common five-step approach. In step 1, image data with 3D spatial information of the limb is captured by a 3D scanner or medical imaging device. If case of a fracture, the contralateral side is commonly scanned and used as a mirror image. The image is exported to a computer aided design (CAD) software program. In step 2, the brace is further developed using reverse engineering software and computer-aided design. In step 3, additive manufacturing techniques for printing are used. The mesh and openings in the mesh are designed. As desired, design additives can also be designed as part of this step. This may be restricted to pressure padding, but also sensors (for real-time monitoring or pressure, temperature, or humidity below the brace), nerve, muscle, or bone stimulators, or infrared spectral photodiodes (for monitoring bruising and skin color over time) can be added to the brace design. The final design is stored as a Stereolithography (STL) format file for 3D printing. Step 4 is the actual printing process. Step 5 is the post-printing processing. Edges may require smoothening or grinding. In addition, the pressure padding and other elements listed for step 3 are added. Finally, the closure mechanism is applied as applicable.

Material and device characteristics

All of the design processes started with scanning of the affected and (as applicable) the contralateral, unaffected limb. In 10 cases, that was done using a 3D scanner (Table 2) [12-21]. The other two studies, that involved the same brace, used a Computed Tomography (CT)-scan with or without additional Magnetic Resonance Imaging (MRI) [10,11].

With respect to the 3D-printing technique, four different options were used. With use in seven studies, fused deposition modeling (FDM) was the commonest technique used [12-15,18-20]. The other techniques used were selective laser sintering (SLS) alone or in combination with stereolithography (SLA; n=2) [10,11] or multi jet fusion (MJF; n=1) [17].

The material used for the design also differed across the designs. Most of the 3D-printed braces were composed of polylactic acid (PLA; n=5; Table 2) [12,14,18,21]. Others used polyamide/Nylon alone (n=3) [11,15,17] or combined with polypropylene (n=1) [10], or used acrylonitrile butadiene styrene alone (ABS; n=2) [15,19] or combined with polycarbonate (n=1) [13]. The remaining device was composed of high impact polystyrene (HIPS) [15]. It is worth noting that Gorski *et al.* used four different braces, each with a unique but different material [15]. Two studies did not report the printing technique or the material used [16,21].

The third noteworthy difference across the available designs is the openness of the structure. This varied from a more closed design that only had a few rows of 10-15 small holes to fully open design where large holes are separated by (small) printed deposits. The shape of the holes were round/oval (n=4) [10,11,13,18], organic (n=4) [12,17,20], diamond (n=2) [15,19], triangular (n=1) [21], or organic combined with tetrahedral (n=1) [14]. For the final design, the hole pattern was not specified [16].

The current printed designs are produced in two halves. Upon application, the braces are closed with either a rubber button (n=3) [12,13,17], Velcro straps (n=2) [10,11], or polystyrene screws (n=1; Table 2) [18]. The closure mechanism of the other designs is not specified and cannot be concluded based on the images provided [14-16, 19-21].

Five studies reported a weight of the brace between 49 and 136 grams [13-15, 19,21].

Results from preclinical tests

Four studies presented biomechanical testing results for the 3D-printed brace [11,17-19].

Table 2
Material and device characteristics of the 3D-printed braces

Study	Scanning		3D printing Technique*				Material*						Hole pattern					Closure mechanism			Weight (g)
	3D scanner	CT/ MRI	FDM	SLS	MJF	SLA	PLA	ABS	PA/ NylonNylon	HIPS	Polycarbonate	Polypropylene	Round/ oval	Diamond	Triangular	Tetrahedral	Organic	Rubber button	Polyethylene screws	(Velcro) straps	
Chen *et al.* (2017) (10)		X		X		X			X			X	X							X	N.S.
Blaya *et al.* (2018) (12)	X		X				X										X	X			N.S.
Guida *et al.* (2019) (13)	X		X					X			X		X					X			120
Yan *et al.* (2019) (14)	X		X				X									X	X				136
Chen *et al.* (2020) (11)		X		X					X				X							X	N.S.
Gorski *et al.* (2020) (15)	X		X				X	X	X	X				X							53-100
Graham *et al.* (2020) (16)	X																				N.S.
Hoogervorst *et al.* (2020) (17)	X				X				X								X	X			N.S.
Janzing *et al.* (2020) (18)	X		X				X						X						X		N.S.
Lukaszewski *et al.* (2020) (19)	X		X					X						X							49
Skibicki *et al.* (2021) (20)	X																X				N.S.
Wang *et al.* (2021) (21)	X		X				X								X						126
Total	**10**	**2**	**7**	**2**	**1**	**1**	**5**	**3**	**4**	**1**	**1**	**1**	**4**	**2**	**1**	**1**	**4**	**3**	**1**	**1**	**5**

ABS, Acrylonitrile Butadiene Styrene; CT, Computed Tomography; FDM, Fused Deposition Modeling; HIPS, High Impact Polystyrene; MJF, Multi Jet Fusion; MRI, Magnetic Resonance Imaging; N.S., Not Specified; PA, Polyamide; PLA, Polylactic Acid; SLA, Stereolithography; SLS, Selective Laser Sintering.

* If none of the options for 3D-printing technique or material are ticked, these items were not specified by the authors.

Based on an integrated finite element (FE) model, Chet *et al.* showed that their 3D-printed cast was capable of exerting the appropriate mechanical correction loads on specific areas to maintain optimal alignment of a fractured forearm [11].

Hoogervorst *et al.* created a cadaveric subacute fracture model in eight pairs of forearms [17]. The specimens were equally allocated to a fiberglass cast or the 3D-printed cast. Measurement of flexion and extension of digits, pronation and supination of the hand, 3-point bending, and inter-fragmentary motion showed no meaningful difference between the groups.

Janzing *et al.* used a cadaveric model for a dislocated distal radius fracture to test if their 3D-printed brace retained fracture reduction upon applying fracture reducing forces [18]. In all six embalmed human anatomical specimens, maintenance of fracture reduction by the printed brace was confirmed radiologically.

Lukaszeweski *et al.* performed bending tests on separate elements of their 3D-printed brace as well as on the total brace [19]. The obtained values of Young's modulus were characterized by a large discrepancy between the standard samples and the entire orthosis. The samples with the shape of the middle part of the orthosis were similar in the value of Young's modulus to the results obtained during the examination of the complete brace.

Results from healthy persons

Clinical test results from healthy persons are provided in two studies (Table 3) [16,18].

Graham *et al.* determined the functionality of a 3D-printed short arm cast versus a fiberglass cast in 12 healthy volunteers [16]. All persons received both interventions. Results showed no significant differences in the Jebsen Hand Function Test (JHFT), although one-third of the participants in the 3D cast could perform the tasks in a normal time, which they could not in the fiberglass cast. The average Patient-Rated Wrist Evaluation (PRWE) function score was lower in the 3D cast group than in the fiberglass group (45.5 versus 80.8). Minor skin irritation was noted in 5 (42%) persons in the fiberglass cast group versus only one (8%) in the 3D cast group. One patient in the fiberglass group required a cast change due to inappropriate fit. These results show that whereas both casting techniques demonstrate similar objective function based on the JHFT, patient satisfaction, comfort, and perceived function are superior in the 3D printed casts.

Janzing *et al.* first investigated left-right differences in wrist circumference of 100 healthy volunteers (age 50 years or older); results showed the difference ranged between 0 and 20 mm (mean 3 mm) [18]. Next, they tested the brace for comfort in 10 healthy volunteers (50 years or older; mean 58) for seven days. The participants reported a mean comfort score of 80/100 (SD 99) and a mean pain score of 6/100 (SD 11). None of the participants reported restriction in activities of daily living while the brace was in place (ADL, Katz index). One participant showed a small blister of 1 cm in diameter on the volar wrist, and another one had a small superficial scrape on the dorsum of the ulnar head.

Results from patients

Clinical test results from patients with a fracture are provided in five studies (Table 3) [10,11,13,18,20].

Chen *et al.* evaluated the performance of their personalized 3D-printed brace in 10 patients (aged 5-78 years old) with a distal radius fracture [10]. Fracture reduction was maintained in all patients. One patient developed a blister of 5 mm diameter on the bony prominence near the head of the ulna. No pressure sores or other skin problems were seen. At final follow-up, patients scored a mean clinical efficacy score of 9.8/12 (range 8-11) and a mean

Table 3
Clinical results of the 3D-printed braces

Study	Population	Age (year)	Male/ female	Application (days)*	Loss of reduction	Complications	Pain	Comfort	PRWE	Patient satisfaction	Clinical Effectiveness
Chen *et al.* (2017) (10)	6 DRF + ulnar styloid; 3 DRF; 1 DRF + ulna	Range 5-78	4/6	49	0	1 blister	N.S.	N.S.	N.S.	11.5/15	9.8/12
Guida *et al.* (2019) (13)	18 DRF	Mean 11.9	16/2	40	N.S.	0/18	0.22/10 ± 0.65	N.S.	8.8 ± 9.0	4/5	N.S.
Chen *et al.* (2020) (11)	19 Colles; 3 Smith; 1 ulnoradial diaphyseal	Range 5-78	24/36	42	0	N.S.	N.S.	N.S.	N.S.	8.65/15 ± 1.04	10.20/12 ± 0.95
Graham *et al.* (2020) (16)	12 Healthy people	Mean 31 (SD 3.7)	5/7	2 hours	N.S.	1 skin irritation	N.S.	9/10	45.5	50.8/100	N.S.
Janzing *et al.* (2020) (18)	10 Healthy persons	≥50	4/6	7	N.A.	1 blister 1 scrape	6/100 ± 11	8/100 ± 19	N.S.	N.S.	N.S.
	5 Unstable DRF	≥50	N.S.	35	2	1 pressure point	0-70/100	0-90/100	N.S.	N.S.	N.S.
Skibicki *et al.* (2021) (20)	10 DRF; 1 ulnar fracture	Mean 11.3 (SD 3.7)	8/2	28	0	2 skin irritation	N.S.	9.1/10	N.S.	9.4/10	N.S.

ABS, Acrylonitrile Butadiene Styrene; FDM, Fused Deposition Modelling; HIPS, High Impact Polystyrene; MJF, Multi Jet Fusion; N.S., Not specified; PLA, Polylactic Acid; PRWE, Patient Rated Wrist Evaluation; SLA, Stereolithography; SLS, Selective Laser Sintering; VAS, Visual Analog Scale.

For the patient-reported outcomes, the maximum score is given (*e.g.*, 4/5 means 4 out of a maximum of 5 points).

* Follow-up measurement took place at the last day the 3D-printed brace was in place.

patient satisfaction of 11.5/15 (range 9-14). Finally, patients stated to strongly prefer the printed brace over a traditional plaster cast.

Janzing *et al.* showed in five patients with a dorsally displaced distal radius fracture (age 50 years or older), that the mean difference in wrist circumference between the injured and uninjured was 13.2 (SD 6.9) mm [18]. This swelling resolved during the first week, and all braced had to be tightened again to prevent a loose fit. The comfort scores were lower and pain scores higher than in the healthy volunteers. After about 3 weeks all patients were independent in ADL according to the Katz index. No sensory abnormalities of the median, ulnar, or radial nerve were noted, however, one patient suffered from a pressure point on the ulnar styloid (without skin necrosis). Two patients showed secondary fracture displacement after 1 week and underwent open reduction and internal fixation. Based on this, the study was terminated early. The other three participants showed good fracture reductions on radiologic examination at five weeks when the brace was removed.

Guida *et al.* tested their customized 3D-printed brace in 18 pediatric patients with a non-displaced metaphyseal distal radius fracture [13]. The brace was applied $<$48 hours after trauma and remained in place for four weeks. All fractures healed both radiologically and clinically after the treatment, with no complications reported. Based on their data (pain and PRWE), the authors concluded that children's activities of everyday life improved during the immobilization thanks to the brace treatment.

Chen *et al.* conducted a comparative clinical study in 60 patients (age 5-78 years) with a forearm fracture [11]. Patients were treated for six weeks with a 3D-printed cast, traditional plaster cast, or splint. Wrist function and patient comfort in the printed brace group were superior to those in the other two groups ($p<0.05$). No breakage of braces was seen, and patients in the brace group reported higher satisfaction overall and for comfort.

Skibicki *et al.* compared their customized 3D-printed brace in a group of 11 pediatric patients with a distal radius or ulnar fracture (mean age 11.3 (SD 3.7) years) versus 11 patients treated with a conventional fiberglass cast [20]. In both groups $>$90% fractures healed fully and in an excellent position. Patients reported significant differences in skin irritation, comfort, satisfaction, and cast care favoring 3D casts ($p<0.05$).

Discussion

The traditional manufacturing process of custom-made orthopedic splints as well as the application of a plaster cast depends on the operator skills. The main complications of traditional casts are skin irritation and nerve dysfunction due to compression injuries. In general, cast immobilization can lead to joint stiffness (if applied over a joint), muscle wasting, and impaired circulation. More specifically, lower extremity casts put the limb at risk of systemic complications like thromboembolism or compartment syndrome. Especially plaster casts have often been critiqued by patients for their issues with patient-friendliness. For example, the weight of a traditional arm cast can lead to pain in the neck or back and loss of muscle mass in the arm. The difficulty of showering or bathing and the lack of ventilation can cause induced sweating with consequent dermatitis and itching due to the poor hygiene of the device and the arm [12]. Another reported negative aspect of a traditional cast is the difficulty of handling it in some daily activities by patients [22,23]. Finally, the closed surface of the cast does not allow to start rehabilitation or visual control of the damaged limb during the immobilization period.

The medical applications that use 3D-printing are increasing, and include both invasive and noninvasive applications. CAD software allows the design of patient-specific alternatives to the traditional cast, and the resulting 3D-printed brace can be further tailored using additive manufacturing. The materials used in printed brace designs included in this study are lighter than plaster, are water-resistant, and have (high) mechanical resistance. To what extent the materials are able to resist normally imposed loads and/or accidental impact loads remains to be studied. Some of the materials used in the included studies like polycarbonate are also impermeable, elastic, resistant to UV-rays and do not interfere with X-rays for diagnosis [12]. FDM is the most commonly used manufacturing strategy. It is cheap and allows for the creation of complex geometries with high resistance and precision [12]. The open structure of the 3D-printed braces favors ventilation and inspection of the skin, allows better personal hygiene of the skin, and improves the esthetics of the brace. The fact that, at least some, printed braces show reduced ADL limitations supports that they may improve the quality of life of the patient.

Disadvantages or limitations to the use of 3D-printed braces include, but not be limited to, the necessity of some sort of imaging, the need for image post-processing, manual preparation and assembly of the printed brace, cost considerations, and quality assurance of the printed product. Although the use of personalized 3D-printed braces are currently compliant to regulations such as the medical device regulation, the regulatory requirements for these devices are expected to increase in the future.

Whether these developments can truly compete with traditional casts remains an open question due to lack of comparative studies. While a reduction in frequently occurring but minor complications such as skin irritation would certainly increase patient comfort, superiority in maintenance of fracture reduction and additional costs associated with 3D-printed casts when compared with traditional casts should definitively be taken into account in future studies.

Conclusions

The data provided in this review show a large heterogeneity in materials and design characteristics of 3D-printed forearm braces. Fused Deposition Modelling is most commonly used 3D-printing technique and polylactic acid is the most commonly used material. Current clinical evidence on the applicability and effectiveness is gathered both in healthy persons and in pediatric and adult patients with difference fracture types. The studies were heterogeneous in design and included relatively small sample sizes. Despite variability in the complication rates across studies, patient satisfaction with the printed brace was generally good. More studies in larger populations are needed in order to confirm if a 3D-printed brace is superior to a traditional plaster cast in terms of fracture healing and healing time, risk of fracture healing complications and (pressure-related) skin complications, and patient-reported outcomes on ADL limitations, limb function, and patient comfort and quality of life.

Declaration of Competing Interest

There are no conflicts of interest to declare for any of the authors involved in this study.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.injury.2022.07.020.

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