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Developing 3D-Printed Wrist Splints for Distal Radius and Scaphoid Fractures

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Abstract

Background The purpose of this study is to optimize conservative treatment of distal radius and scaphoid fracture, in terms of comfort, fracture stabilization, and prevention of cast complications.

Description of Technique Advances in additive manufacturing have allowed the development of patient-specific anatomical braces (PSABs) which have the potential to fulfill this purpose. Our specific aims were to develop a model of PSAB, adapted to fracture care, to evaluate if this brace would be well tolerated by healthy volunteers and to determine its mechanical properties as compared with conventional methods of wrist immobilization.

Materials and Methods Several three-dimensional-printed splint prototypes were designed by mechanical engineers based on surgeons' and hand therapists' clinical expertise. These experimental braces underwent testing in a preclinical study involving 10 healthy volunteers, assessing comfort, satisfaction, and activities. The final prototype was mechanically compared with a conventional cast and a prefabricated splint, testing different closing systems. A mathematical algorithm was created to automatically adapt the final PSAB model to the patient's anatomy.

Results The final prototype achieved an overall satisfaction score of 79%, weighing less than 90 g, made from polyamide, and fixed using hook and loop straps. The PSAB stiffness varied between 0.64 and 0.99 Nm/degree, surpassing the performance of both conventional plaster casts and prefabricated splints.

Conclusion The final wrist PSAB model, adapted for fracture treatment, is lightweight, comfortable, and provides anatomical contention. It is currently being tested for the treatment of stable distal radius and scaphoid fractures in comparison to conventional plaster cast.

Keywords
- 3D printing
- additive manufacturing
- patient-specific anatomical brace
- distal radius fracture
- scaphoid fracture

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Conservative treatment of relatively simple distal radius fractures may provide functional outcomes that are comparable to operative fixation.[1–4] However, plaster or synthetic casts molded onto a fractured wrist offer poor support.[5,6] A study using computed tomography scan has demonstrated major gap spaces between the inner surface of the cast and the surface of the wrist.[7] Other factors, such as the position and length of joint immobilization, and the type of fracture (involving or not involving the elbow or thumb), play a disputed role.

Although anatomical fracture reduction is generally believed to improve outcomes,[8] recent studies challenge this for distal radius[9–11] and scaphoid fractures.[12–14] Surgical interventions are associated with an increased risk of surgery-related complications, and there is a risk of fixation failure in osteoporotic bone.[15] Therefore, noninvasiveness, avoidance of complications, and patient comfort are important considerations in fracture management. Developing a more effective solution to maintain fracture reduction without the need for surgery would be a significant medical advancement.

To date, casting is still the gold standard treatment of stable distal radius and scaphoid fractures. However, despite advances in materials, casts continue to be cumbersome and poorly tolerated by the patients, limiting their ability to dress normally and perform daily activities.[16] This discomfort is particularly pronounced in young patients. In fact, many young adults with scaphoid fractures remove their plaster before the recommended period of immobilization has ended.[17] To overcome these limitations, three-dimensional (3D)-printed patient-specific anatomical braces (PSABs) have emerged as a potential solution. These PSABs are custom-made to perfectly match the patient's limb anatomy, providing better fracture contention and reducing the risk of fracture displacement and final malunion.[18] Recent advances in scanning and 3D printing have made it possible. Chen et al conducted two pioneering studies on the application of a 3D-printed cast for distal radius fractures.[19,20] They showed that their novel casting technology heals the fracture effectively, without casting complications. Their 3D-printed cast was patient specific, ventilated, and lightweight, increasing patient comfort and satisfaction. While the computer-aided design to obtain the STereoLithography (STL) format file for 3D printing can be time-consuming, recent studies have reported improved scanning and design times.[21] Keller et al presented an in-hospital production of patient-specific 3D-printed PSAB using a semiautomated modeling process and the use of photosensitive resin Digital Light Processing (DLP) printing, achieving faster production time.[22] However, uploading the scans to an online platform owned by an industrial company induces extra costs, and patient data protection must be top priority.

The purposes of the present study were to develop a model of wrist PSAB, adapted to fracture care, with an automatic design system, to evaluate if this brace would be well tolerated by healthy volunteers, and to determine its mechanical properties as compared with conventional methods of wrist immobilization.

Materials and Methods

A consortium group of engineers from Idiap Research Institute and HES-SO University of Applied Sciences, Fribourg, hand therapists and hand surgeons from the University Hospital Bern, and from the MedTech Swibrace Ltd was set up with the aim of creating a PSAB model that meets both technical and clinical requirements. By successive iterations, the engineers proposed various models adapted to distal radius and scaphoid fractures immobilization, sufficiently rigid to maintain fracture reduction, yet thin, lightweight, and esthetically pleasing. Thanks to the lateral opening on the ulnar side of the forearm and the semirigidity of the material, the PSAB model is able to adjust for changes in mild posttraumatic swelling. Hand therapists and hand surgeons first tested these prototypes for satisfaction, personal experience, and functionality during different activities of daily living. Based on their feedback, improvements were made until the final prototype was developed and tested in a preclinical study. Ethical approval was obtained from the ethical committee in Bern, Switzerland (No. 2021-00112).

Creation of the "Adult-Rated Splint Evaluation Questionnaire"

Due to lack of validated orthosis satisfaction questionnaires suitable for our study purposes,[23] we designed an original "Adult-Rated Splint Evaluation Questionnaire" (ARSEQ)[24] (►**Supplementary Appendix I**). The ARSEQ included orthosis-related questions, function-specific questions based on those used in the validated Patient-Rated Wrist Evaluation questionnaire,[25] and 3D technology-related questions. It was divided into five themes with several subquestions each: (1) satisfaction and (2) personal experiences with the splint; (3) specific (e.g., opening a door, using a mobile phone) and usual activities (e.g., doing household work, performing sports) in the splint; (4) personal attitude; and (5) scanning procedure. Volunteers could indicate pressure marks and skin irritations using pictures and photographs. The answers were rated on an 11-point Likert scale (0–10). Since the number of questions varied between themes, points were expressed as percentages. A mean satisfaction score of at least 70% was the threshold for considering a brace acceptable for clinical use. For the preclinical study, its psychometric properties were not yet validated.

Preclinical Study Procedures

For the preclinical study, a convenience sample of 10 healthy volunteers were recruited by e-mail. Inclusion criteria were $\geq$18 years old, German language proficiency, and no acute health problems affecting the hands.

Informed written consent was obtained before the procedure. The scanning was conducted using a HandySCAN 300 (Creaform), capturing the entire forearm (►**Fig. 1**). Volunteers chose which hand to scan and whether to test the brace model for radius or scaphoid fractures, with the latter also including the metacarpal and the proximal phalanx of the thumb. Subsequently, 3D printing of the splint was done using polyamide PA12 material and Selective Laser Sintering

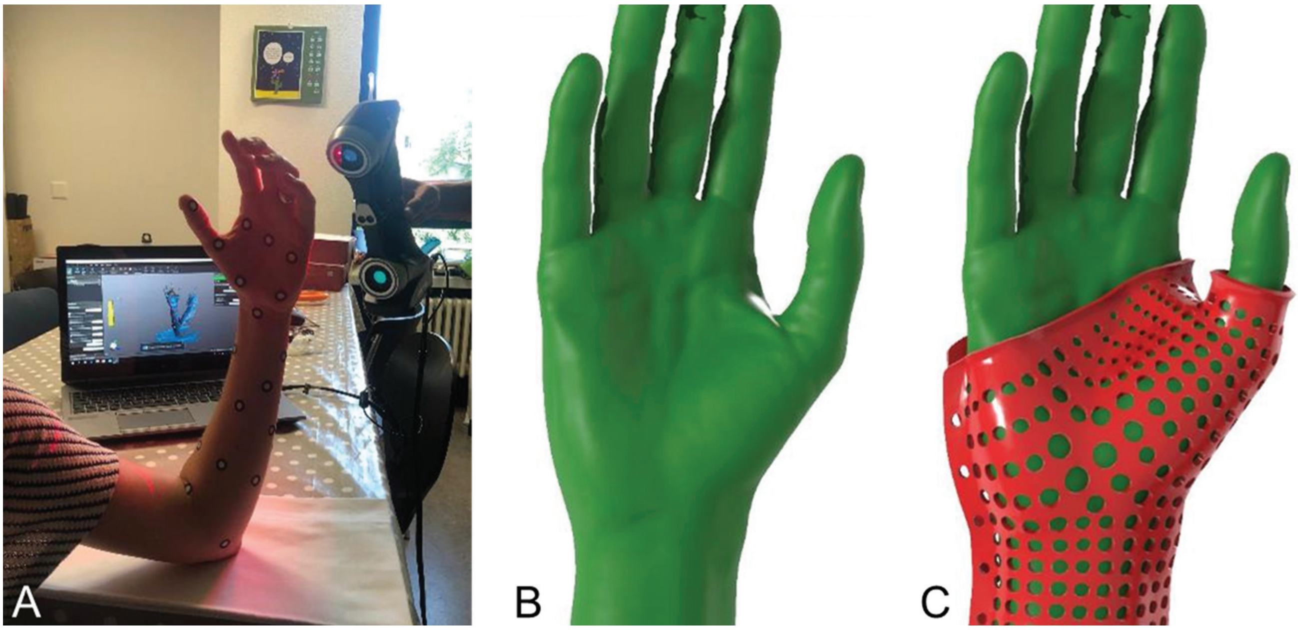


Fig. 1 Scanning procedure for a scaphoid splint. (**A**) Scanning the forearm with HandySCAN 300, reflecting self-adhesive dots are positioned on the arm to increase scanning quality. (**B**) Virtual forearm model. (**C**) Patient-specific anatomical brace model ready to be printed.

Table 1 3D splint properties

Surface scanner	HandySCAN 300 from the company Creaform
3D design software	VXelements from the company Creaform
Printing material	Polyamide PA12, biocompatible
Printing technique	Selective laser sintering
Layer thickness	2.0 mm
Postprocessing	Automatic
Favorable mechanical properties of printed splints	Lightweight, smooth, semirigid, long-term stability

Abbreviation: 3D, three-dimensional.

(SLS) printing technology (►**Table 1**). With this printing technology, no further postprocessing is necessary.

The splint was worn directly on the skin for a planned duration of 72 hours without interposing cotton. Volunteers were instructed to pursue their normal life including work, activities of daily living, sports, and sleep. To document their activities, they received a diary where they also noted whether they took off the splint occasionally and why (e.g., while driving a car). Upon completing the splint wearing period, volunteers filled out the ARSEQ.

The outcome measurements (ARSEQ and the activity diary) in the preclinical study were analyzed, with results reported as percentages for each theme and frequencies for each activity noted in the diary.

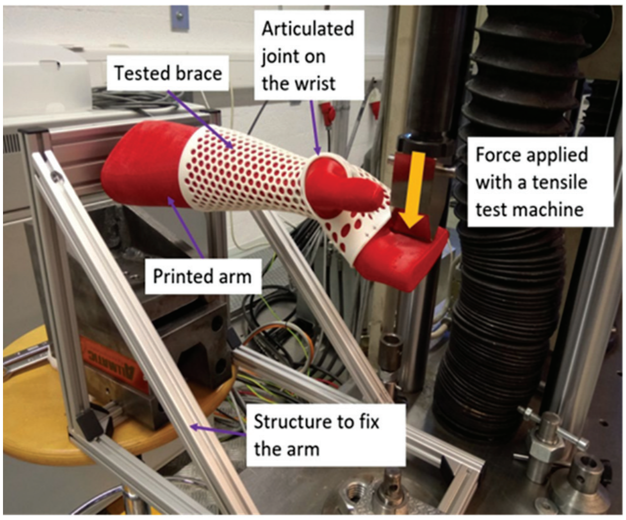
Mechanical Testing of the PSAB

A testing bench was constructed, allowing mechanical testing of the PSAB on an articulated, 3D-printed wrist and forearm mannequin (►**Fig. 2A**). Measurements were performed using a hydraulic Instron tensile testing machine with a 1 kN force cell, measuring both wrist flexion and extension. Brace stiffness, expressed in Nm/degree, was determined as resulting bending moment for a given rotation angle relative to the wrist joint. ►**Fig. 2B** shows typical stiffness curves for different brace fastening systems. Since the stiffness curve behavior is nonlinear, a reference bending moment of 3.4 Nm was used for stiffness determination, corresponding approximately to a 4 kg mass that the patient would hold in the hand.

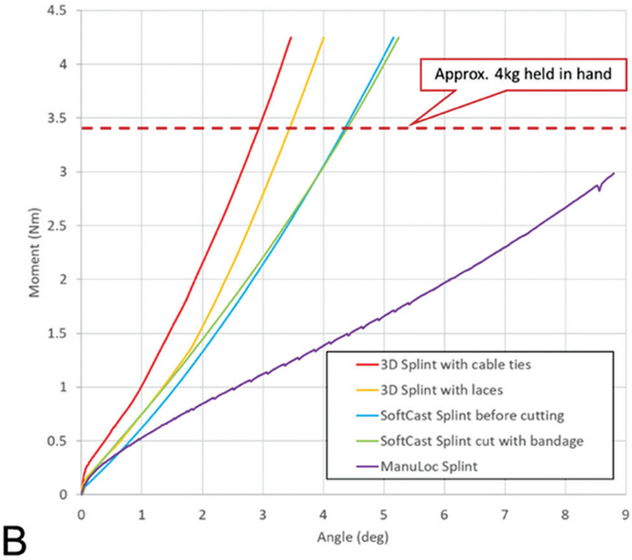
Three novel tests for mechanical stiffness were performed. The first compared the stiffness of braces fabricated with different materials and different 3D printing technologies: brace 1, fabricated using SLS technology from polyamide PA12 (Materialise, Belgium) and aged 2 years at testing time; brace 2, fabricated using SLS technology from PA12 (Chromos group, Switzerland) and aged 1 month at testing time; and brace 3, fabricated using DLP from resin reactive urethane photopolymers Ultracur3D ST45 (Production ToGo GmbH, Germany) and aged 1 month at testing time. The second test, employing a PA12 brace printed by Chromos, examined the influence of different attachment methods on brace stiffness: three cable ties, three hook and loop strips, and one lace. The third test compared the stiffness of the latter brace to other types of immobilizations: plaster cast, with or without cutting, and a commercial over-the-counter wrist brace (ManuLoc, Bauerfeind, Lena, Germany—►**Fig. 2B**).

Automatic Design of the PSAB

In parallel, a mathematical algorithm was developed, facilitating the adaptation of a standard model of the brace to the patient's anatomy. The approach used nonrigid registration to deform a template limb mesh.[26] The template carried



A



B

Fig. 2 (**A**) Test bench used to measure the brace stiffness in flexion and extension (forced wrist extension illustrated). (**B**) Stiffness curves for forced extension, representing the bending moment as function of the angular rotation: 3D splint with cable ties (red), lace (yellow), circular SoftCAST, split SoftCAST with bandage, and prefabricated ManuLoc splint. Reference bending moment for stiffness value determination (dashed red horizontal line).

landmarks and information used in an automated workflow, allowing for automatic design of the PSAB in a few minutes, based on the scanned morphology of the patient's anatomy and on the selected existing standard brace model (radius or scaphoid fracture model).

Results

Various models of PSAB were tested (►**Figs. 3** and **4**). Prototype 1, with large open areas, was poorly tolerated, with an average satisfaction rate reaching 56%, due to pressure marks that caused pain and numbness (►**Fig. 3A–D**). Prototype 2 was too tight, also causing skin irritations and pressure marks, with an average satisfaction rate of 62% (►**Fig. 3E–H**). Prototype 3 fared better, receiving an overall satisfaction score of 68% (►**Fig. 4A, B**).

The mean age of the 10 healthy volunteers (6 men, 4 women, all right-handed) was 46 ± 18 years. The group included four blue-collar workers, three white-collar workers, two retirees, and a student. Half of them wanted to test the PSAB on their dominant hand. Five volunteers tested the radius fracture model, and the other five tested the scaphoid fracture model.

The scaphoid fracture model scored worse than the radius, due to longer scanning time, and because having the thumb immobilized negatively affected function (►**Fig. 4C**). The main drawback was the closing system of the PSAB, which was too cumbersome. Prototype 4, featuring a more user-friendly hook-and-loop strap closing system (►**Fig. 4D, E**), achieved an overall satisfaction score of 79% (70% in the scaphoid and 87% in the radius groups), exceeding the previously set cutoff of at least 70% for clinical testing (►**Fig. 4F**).

Volunteers reported of being able to wear the PSAB for all self-care activities including taking a shower, eating, and sleeping. It was worn during work and housekeeping tasks, such as typing on a computer, driving a forklift, or cooking (►**Fig. 5**).

Mechanical Testing (Prototype 4)

The first test demonstrated that the brace's mechanical behavior (torque vs. angular displacement relation) was more linear and smoother for extension movement across all materials and printing techniques. The aging effect of PA12 on the material's mechanical properties was not significant, with the 2-year-old PA12 material being stiffer in flexion but more flexible in extension. The DLP brace had the highest stiffness in both flexion and extension (►**Table 2**).

The second test demonstrated that, with each fixation system, the brace had larger stiffness and more linear torque–angular displacement for the extension movement. In flexion, initial stiffness was smaller and increased with increasing angular deformations. Cable ties were the fixation method offering the highest stiffness to the brace (1.7 times stiffer than hook-and-loop straps, ►**Table 3**), both for flexion and extension. The curve presented a quasi-isotropic stiffness.

The third test demonstrated that the stiffness of the PSAB was slightly higher than the plaster cast and significantly better than the over-the-counter wrist brace (►**Table 3**).

Characteristics (Prototype 4)

The final PSAB model weighed 60 to 90 g, made of PA12, had a 2-mm thickness, was fixed by hook-and-loop straps (Velcro), and covered two-thirds of the forearm length. There was a 1-mm clearance between the brace's inner and the skin. Stiffness ranged from 0.64 to 0.99 Nm/degree. The production cost per PSAB model was 430 CHF including the printing and shipping of the orthosis. The average time between the scanning appointment and the delivery date of the PSAB was

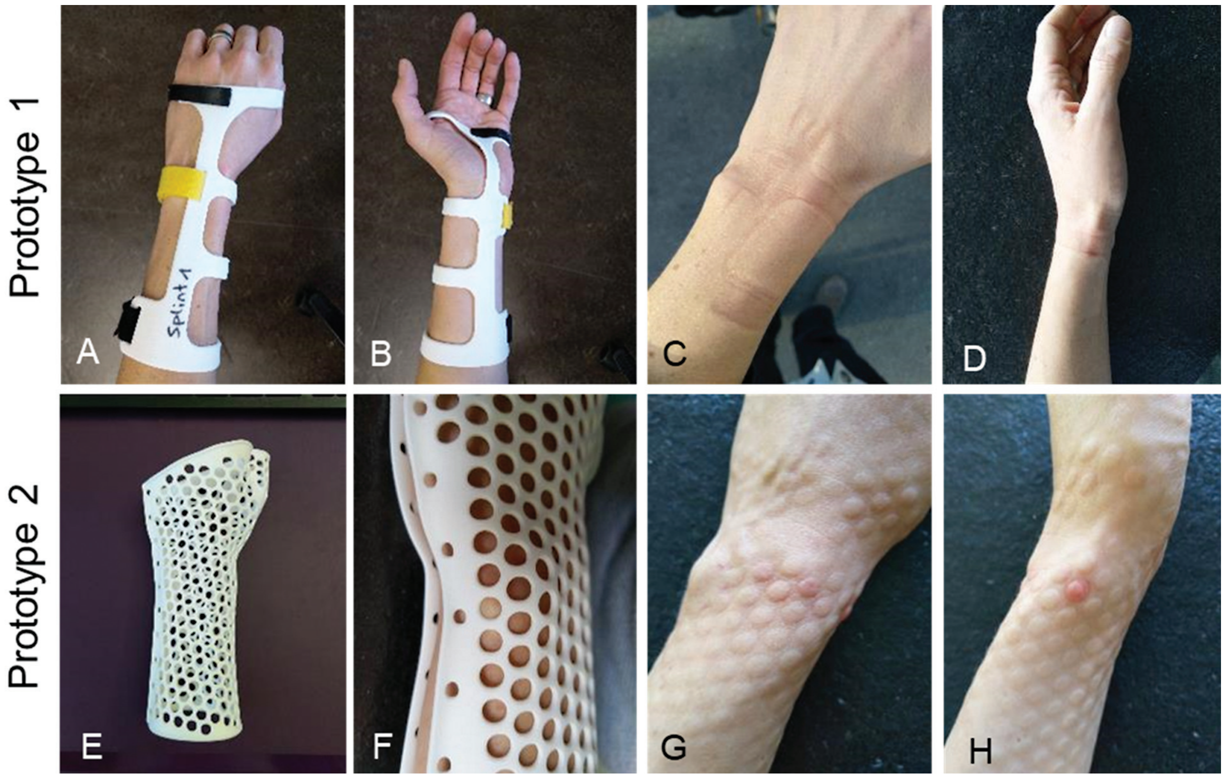


Fig. 3 First two prototypes tested by hand therapists from the University Hospital in Bern before testing on healthy volunteers. (**A**) Dorsal and (**B**) palmar views of the first prototype. (**C**) Pressure marks and (**D**) numbness of the thumb after a few hours of splint wearing time. (**E**) Dorsal and (**F**) ulnodorsal view of the second prototype. (**G, H**) Pressure marks after 5 hours of splint wearing time.

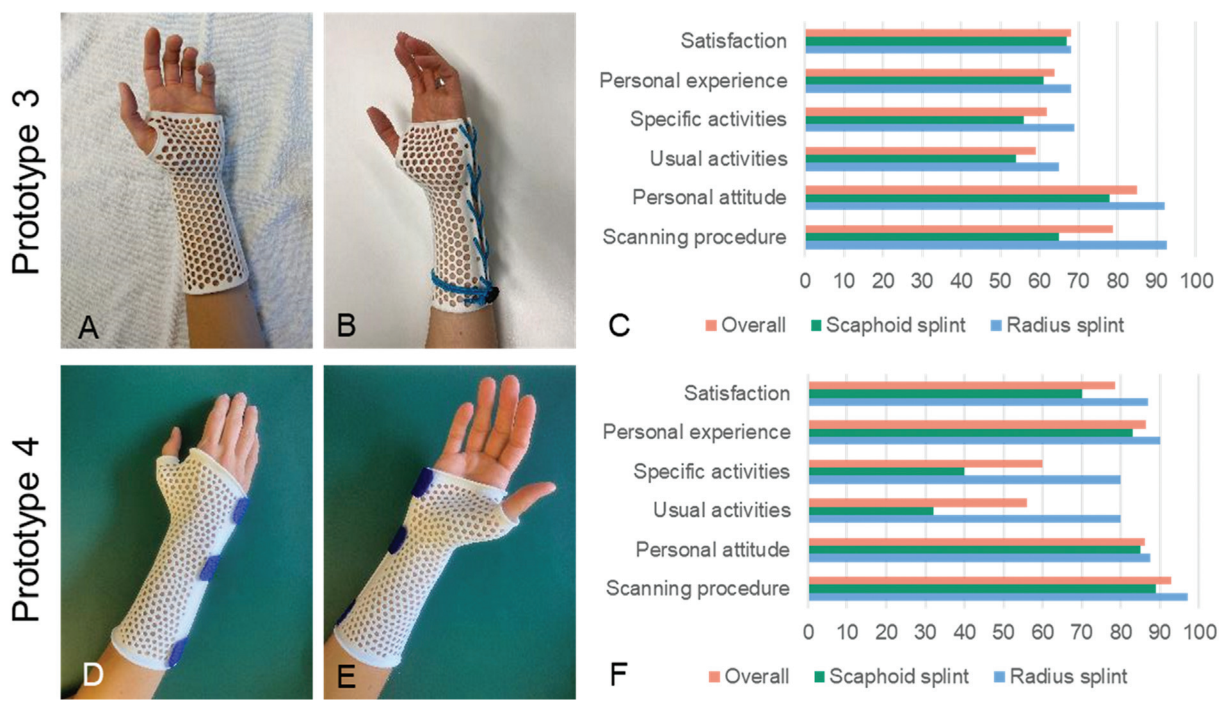


Fig. 4 Prototypes tested by healthy volunteers. (**A**) PSAB for radius fractures. (**B**) Closing system with an elastic lace. (**C**) Volunteers' feedback of the ARSEQ. Final PSAB model from (**D**) dorsal and (**E**) palmar views with hook-and-loop straps. (**F**) Volunteers' final ARSEQ scores. ARSEQ, Adult-Rated Splint Evaluation Questionnaire; PSAB, patient-specific anatomical brace.

8 ± 2 days. The rather long production time was due to the fact that the PSABs are printed by a company that operates SLS technology printers 24 hours a day, resulting in waiting times during production. Another reason was due to the postal shipping between Belgium and Switzerland and the therewith related delivery delay.

Fig. 5 Example of a cooking activity of a volunteer wearing the prototype 3 for radius fracture on the nondominant hand.

Table 2 Comparison of the stiffness of PSAB with different materials

Stiffness measured with the secant between 0 and 3.4 Nm	Stiffness (Nm/deg)	
	Extension	Flexion
PA12, aging 2 y	0.79 ± 0.02	0.69 ± 0.008
PA12, aging 1 mo	0.80 ± 0.01	0.64 ± 0.009
Ultracur3D ST45, aging 1 mo	0.85 ± 0.01	0.77 ± 0.01

Abbreviation: PSAB, patient-specific anatomical braces.

Table 3 Comparison of the stiffness of PSAB with plaster cast used in orthopaedic practice

Stiffness measured with the secant between 0 and 3.4 Nm	Stiffness (Nm/deg)	
	Extension	Flexion
PSAB with three cable ties	1.16	1.01
PSAB with lace	0.99	0.74
Circular plaster cast	0.78	0.84
Cut plaster cast, closed with bandage	0.77	0.76
ManuLoc	n/a	0.42

Abbreviations: n/a, not available; PSAB, patient-specific anatomical brace.

Discussion

Cast immobilization in fracture treatment offers poor stabilization and may be complicated by vascular, cutaneous, and neurological problems.[27] These complications are frequently attributed to high cast stiffness, unbalanced pressure caused by the cast, and impecunious ventilation. In contrast, 3D-printed casts are customized to the patient's anatomy, entirely well ventilated, lightweight, allow for radiological control, and have adjustable mechanical properties by changing their material, shape, thickness, structure, and type of fixation.[18,28]

PSABs seem to be particularly suitable for treating undisplaced or minimally displaced fractures. In such fractures, it is important to avoid secondary displacement which occurs in a significant proportion of the cases. For the acute stabilization of displaced distal radius fractures, where major swelling is present or anticipated, thermoplastic splints, allowing good molding and individual adjustments, may still be superior.

PSAB technology relies on scanning the limbs of patients. We used a highly accurate scanner, as the accuracy of cheaper scanning systems such as tablets with optical sensors was not sufficient. During scanning, patients need to be immobile for a few minutes in the specific position of immobilization. In the case of a displaced fracture, it is theoretically possible to scan the healthy contralateral limb and to mirror the morphological data (reversed symmetry). By doing so, one assumes that there is symmetrical morphology, which is not totally accurate. Janzing et al,[29] for example, found an average left–right wrist circumferential difference of 3 mm (range 0–20 mm) in 100 healthy volunteers. Another option, to be considered in the future, is to obtain selected anatomical data of the traumatized wrist and to base the brace design on a database of wrist scans.

For fracture treatment, a further limitation of PSAB treatment is the delay of obtaining the brace after the fracture due to design and additive manufacturing time. The newly created mathematical algorithm in this study will allow the development of a web-based software with immediate semiautomatic design, but the production unit cannot be installed in a hospital, at least for PSABs of acceptable quality obtained by laser sintering techniques. Fused deposition modeling printers can be installed in hospitals, but the braces obtained by filament fuse are of poor quality and not adapted to fracture care. DLP printing could be a possible compromise.[22]

In this study, the original questionnaire ARSEQ was developed to evaluate wrist cast immobilization, as validated quality assessment tools are lacking.[21] The authors are aware of the potential risk of measurement error introduced by using a self-designed questionnaire that is not validated yet. Further investigations are necessary to test the psychometric properties of the ARSEQ.

Volunteers wore the brace during unrestricted activities including sports, which does not correspond to the initial activity limitations a patient would have with a fractured distal radius or scaphoid. Two other studies provide clinical results from healthy volunteers wearing wrist braces (not including the thumb). In the study by Graham et al,[30] 12 healthy individuals tested a 3D splint for 2 hours. With 50.8/100 points, their satisfaction with the splint was lower than in this sample (79/100 points) (►Fig. 4F). In the study by Janzing et al,[29] 10 healthy persons tested a 3D splint for 7 days. Their comfort in the splint was good (80/100 points), which is comparable to the personal experiences (68–90/100) made by our volunteers wearing the PSAB designed for radius fractures (►Fig. 4). Our volunteers reported being more restricted in activities of daily living than those by Janzing et al,[29] who indicated no activity restrictions. The difference might result from the variation in age, our sample being on average younger (mean age 46 years) than in Janzing et al (mean age 58 years).

The original wrist PSAB models were developed for distal radius and scaphoid fractures, with the latter immobilizing the metacarpal and proximal phalanxes of the thumb as well. Both models are comfortable, elegant, and lightweight. The brace can be worn without any padding, as only minor skin irritations were reported by the volunteers on anatomical crucial points during specific movements (e.g., on the ulnar head when pronating the forearm; in the first commissure when grasping a small object in the scaphoid splint). The absence of padding enhances ventilation of the skin, prevents unpleasant smell from the splint, and allows for water contact, which is an advantage over conventional casts. Furthermore, the smooth surface and thinness of the 3D-printed material provide high wearing comfort, not only for the skin but also for the clothes. Despite its thinness, the brace offers better rigidity for fracture immobilization than conventional splints. It is hoped that this brace will enable better fracture stabilization and allow patients to continue with most of their daily activities despite their injury. The final PSAB model is currently being tested on a series of patients presenting stable distal radius or scaphoid fractures.

Conclusion

This collaborative research led to the development of a lightweight yet elegant PSAB, adapted to fracture care. The brace provides more rigid wrist immobilization than over-the-shelf splints or conventional casts. It is hoped that as the brace is more anatomical, without gap space under the brace, there will be less fracture secondary displacements, but this remains to be clinically demonstrated. PSABs represent the future of orthopaedic immobilization, not only for fractures but also in other conditions, such as degenerative or inflammatory osteoarticular affections, tendon diseases, and neurological conditions, among others.

Statement of the Location Where the Work Was Performed
The idea to design a patient-specific anatomic brace (PSAB) originates from Swibrace Ltd, 2 route de la Fonderie, CH-1700 Fribourg, Switzerland, as well as the organization of the project and foundation of the research consortium who collaborated in this project.
The mechanical testing of the PSAB was performed at the Department of Mechanical Engineering, HES-SO University of Applied Sciences, Fribourg, Switzerland.
The mathematical algorithm for the automatic adaptation of the final PSAB model to the patients' anatomy from the scanned limb geometry was developed at the R&D Department, Idiap Research Institute, Switzerland.
The development of the ARSEQ, the preclinical testing of the different 3D prototypes, and recruitment of volunteers were conducted at the Hand Therapy Research Unit, Inselspital Bern, University of Bern, Switzerland.

Conflict of Interest
None declared.

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