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WEB-BASED APPLICATION FOR CUSTOMIZATION OF THERMOFORMABLE 3D-PRINTED WRIST-HAND BRACES

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Abstract: *Thermoformable 3D-printed wrist-hand orthoses, or braces, offer an alternative to traditional manufacturing methods for these medical devices. Using additive manufacturing via the material extrusion process, these customized braces can be produced flat, eliminating the need for support structures typically required in the forearm-scanned-based approach, thus reducing printing time. To make these orthoses accessible to therapists without 3D scanning or advanced modeling skills, this paper presents a web-based application that simplifies customization of the braces' type, dimensions, and pocket shapes. The integration of FreeCAD and Python in the application provides a combination of 3D modeling and automation leveraging open-source software advantages, and automatically generates the STL file of the custom orthosis. The application's open architecture supports the implementation of new designs, making it suitable for use in 3D printing point-of-care settings. Usability tests with eight participants indicate that the application is easy to use and effective. The mean time to generate the orthosis file for 3D printing was 2 minutes and 12 seconds, while the average time required to gather patient hand and forearm dimensions and input them into the app was 11 minutes and 32 seconds. Notably, this time was reduced by about half during the second use of the app by two of participants.*

Key words: *FreeCAD; Python; 3D printing; thermoforming; wrist-hand orthosis; brace; web-based app.*

1. INTRODUCTION

The use of Artificial Intelligence (AI) in healthcare 3D-printed wrist-hand static orthoses, including casts and braces, have proved their clinical suitability for specific medical conditions, both chronic and traumatic [1–3]. These devices are well-received by patients due to their comfort and visually appealing designs [1], attributes that stem from the design freedom offered by Additive Manufacturing (AM), also known as 3D Printing. The typical 3D-printed orthoses' design includes open pockets of various shapes that serve to reduce mass, improve thermal comfort and hygiene, and allow for the assessment of patients' skin conditions [4], these features being easier to obtain by AM than by traditional manufacturing methods [2]. In the production of upper limb orthoses, various processes such as material extrusion (MEX), vat photopolymerization (VP), laser sintering, or binder jetting, are used [5–6].

Both in literature and practical applications limitations that revolve around two main aspects are mentioned. Firstly, the production of 3D-printed orthoses relies on engineering expertise in 3D scanning and 3D modeling. Additionally, the process can be time-consuming; for instance, printing a cast may take as long as 19 hours [5]. These aspects complicate the feasibility of integrating customized orthosis production directly within hospitals or medical centers, a concept known as 3D Printing Point-of-Care. Thus, efforts were made to decrease the development time by mainly targeting two production steps: the 3D printing process and the orthoses design process.

The printing time can be reduced by selecting a build orientation that optimizes this factor or by reducing the volume of support structures. However, less support can produce orthoses detachment from the printing bed, while orientation is influencing also their mechanical resistance and surface quality. Another approach is to produce the orthosis as flat and then thermoforming on patient's forearm and hand. A comparative analysis of orthoses built in a vertical position (in a ready-for-use shape) versus one built in a flat position showed a significant reduction in printing time [7]. The limitation of the flat configuration approach is that the material used in the 3D printing process must be thermoformable at a relatively low temperature to ensure patient comfort during molding and to prevent the risk of burns. Polylactic acid (PLA) is one of example of a thermoformable material [8], but also PLA-$CaCO_3$ composites being studied [9].

Efforts to optimize the development process of customized orthoses' focused also on simplifying and automating of the design process [10–11]. Two main strategies have emerged: 1. orthoses 3D printed in their functional position, with tailored shapes generated based on 3D scans or discrete measurements [10, 12]; 2. orthoses 3D printed in flat configuration and then thermoformed to fit the limb, with their shapes determined from measurements taken by a hand therapist and input into a dedicated application [13]. The first

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approach is more common and involves the reconstruction of the patient's limb customized model based on 3D scans, followed by CAD-based orthosis design, which may include semi-automated features for creating pockets or lattice structures, or using specialized CAD software. In a related study, Portnoy et al. conducted a pilot study in which 36 occupational therapy students tested in-house design software for creating finger mallet orthoses. This was followed by semi-structured interviews to gather feedback [12]. Additionally, usability tests for wrist-hand 3D-printed orthoses design software were conducted [14]. There are also commercial applications based on forearm and hand 3D scanning [15–16], which transform the design process into an interactive one, the user establishing the type of orthosis, its height, the position of the trimming zone around the thumb, silhouette curves, ventilation pockets, etc.

On the other hand, the orthoses with flat configurations approach has been less researched, few existing studies focusing on design [8, 13, and 17], as well as on the mechanical performance and time efficiency of thermoformable orthoses [18]. To address the automated customization aspect in this approach, the current research presents the development and usability testing of web-based application based on open-source software that facilitates the generation of STL files of flat orthoses by occupational therapists. This application was tested by eight participants, and the results are discussed.

2. MATERIAL AND METHOD

2.1. Customizing flat 3D-printed wrist-hand orthoses using ForTE V2 app

The developed application, ForTE V2, is an improved version of that presented in [20]. It offers an online interface that eliminates the need for downloading or installing modeling software; users need only an internet connection to access it. This app calls 3D modeling software, platform-independent, FreeCAD, which currently supports the automatic generation of STL files for two types of orthoses: a volar brace and a radial bar wrist cockup brace. The application generates these models based on parameters measured by therapists according to traditional thermoplastic casting guidelines [21], which typically involve drawing the forearm and hand contour on paper, adding the brace shape, and including an offset distance to ensure the material partially encircles the forearm. The resulting shape is measured, and the data are inputted through an online webpage. A Python script links this data to FreeCAD's modeling parameters, thus enabling the production of customized braces tailored to individual patients.

As detailed in [20], the backend of this open-source application was developed using Python, enhancing resource efficiency and speed in FreeCAD operations, while the frontend utilizes ReactJs to create a rapid and scalable web interface. Nginx handles the web server duties, managing static pages and SSL implementations, while Gunicorn serves as the WSGI server for running the Python components. More information on the application modules and functions for a volar design of wrist-hand orthosis were presented in a previous paper [20]. The next section details how therapists should proceed when using the app. This information was provided to usability test participants in the instruction phase of the test.

Figure 1 presents the layout of the bar wrist brace from the app including the parameters that should be acquired by the occupational therapist (Fig. 1,*a*) after drawing the patient hand/forearm contour and measuring the required dimensions (Fig. 1,*b*).

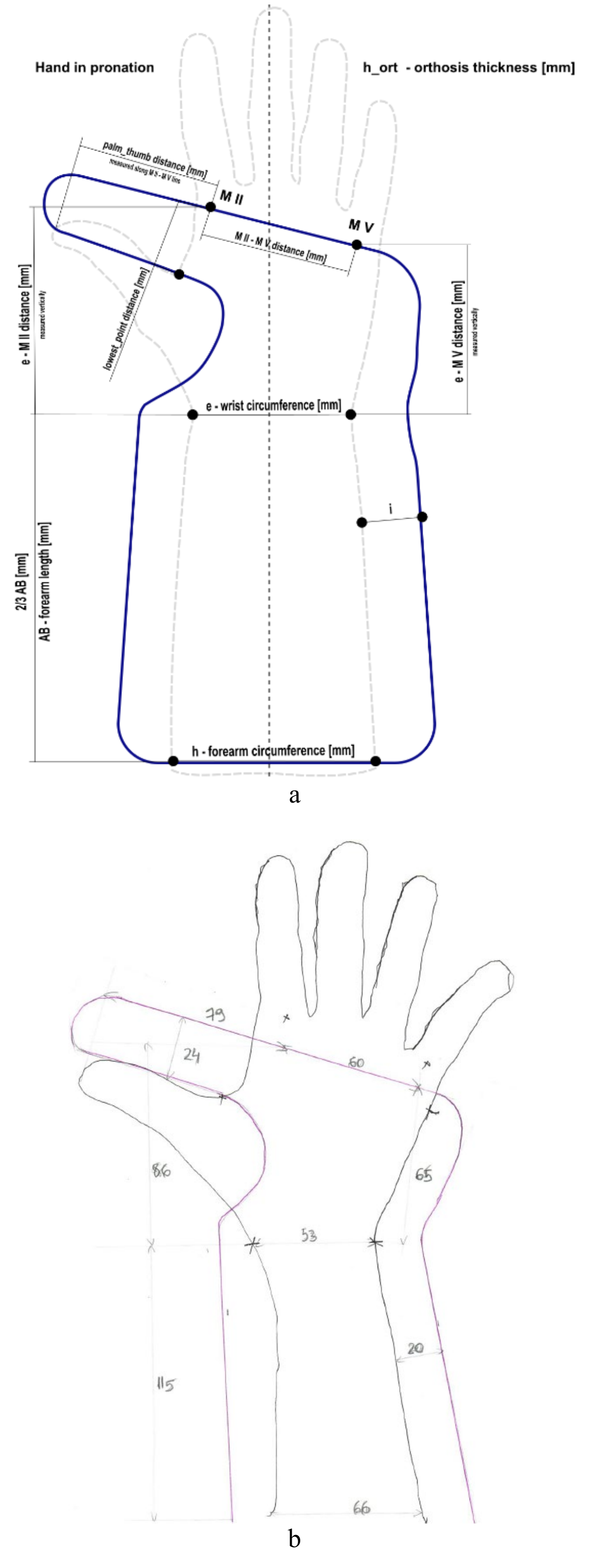

Fig. 1. Layout of the bar wrist brace: *a* – example from the app with parameters for bar wrist brace generation; *b* – layout of hand-forearm contour acquired by the therapist.

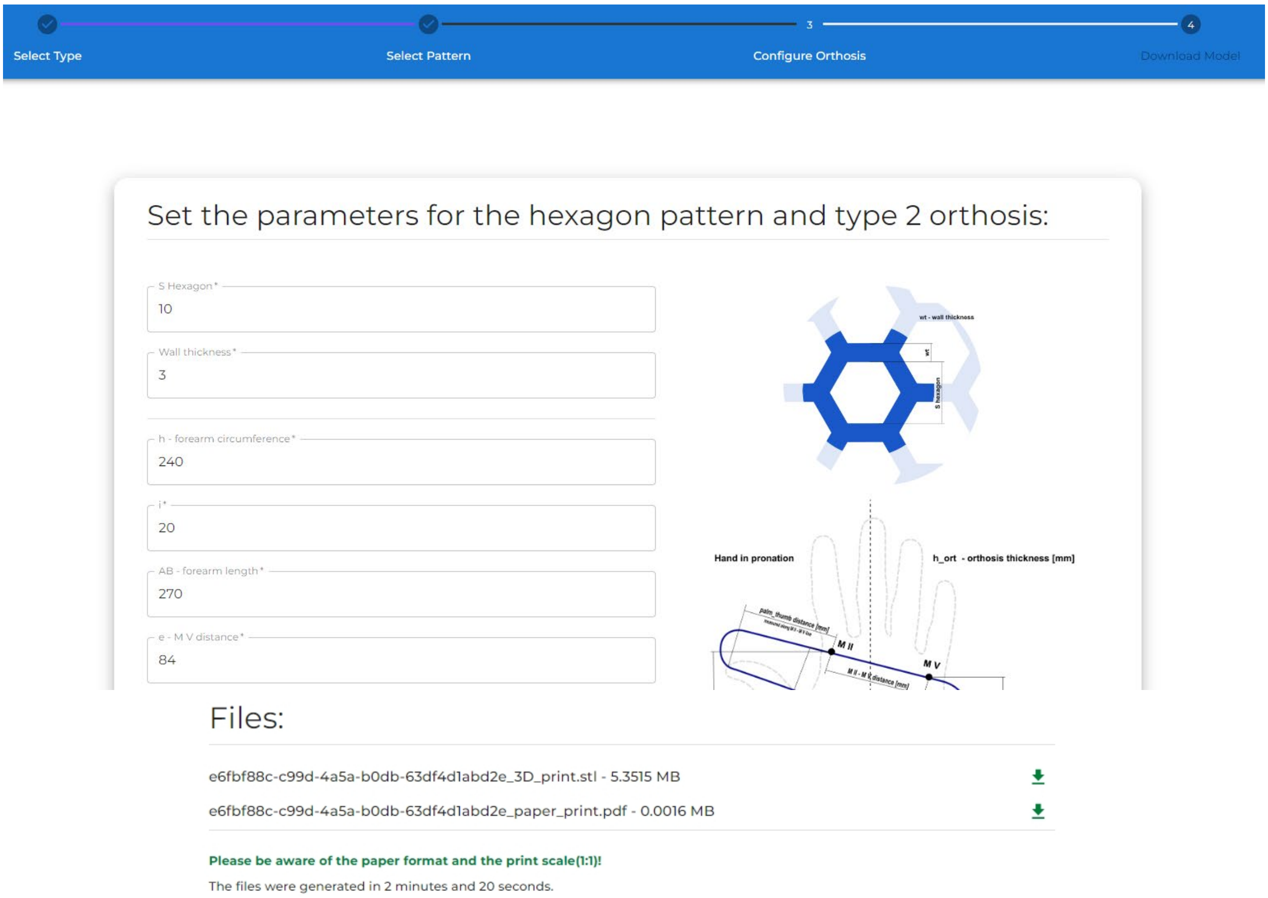

Fig. 2. FoRTe V2 online application prototype interface.

A bar cock-up brace is designed specifically to support and immobilize the wrist, ensuring it remains in a slightly extended position at an angle of 20 to 30 degrees, balancing support with hand functionality. This position balances support with hand functionality, and helps reducing swelling, aligning the wrist properly, and ensuring a comfortable recovery process. The brace is useful during activities that pose a risk of straining the wrist, offering essential support and helping to avert further injury.

The brace design includes a rigid or semi-rigid bar that extends from the underside of the forearm to the palm. This structure is mandatory for supporting the wrist in the aforementioned position, adjustable fabric or Velcro straps being used to that securely fix the orthosis on wrist and forearm.

This type of brace is used for the treatment of different wrist-related conditions that required immobilization for facilitating healing and alleviate pain. It is effective in managing carpal tunnel syndrome by keeping the wrist in an extended position to relieve pressure on the median nerve. Additionally, it is suitable for recovering from wrist sprains, strains, or undergoing post-surgical rehabilitation.

Dimension ranges were established to ensure that the models generated automatically in FreeCAD conform to the shapes of the braces currently included in the app. These models are created based on dimension inputs from therapists and orthosis templates. An example of such a model, generated using an extruded sketch, pattern features, and Boolean operations for a bar cockup wrist brace, is presented in Fig. 3.

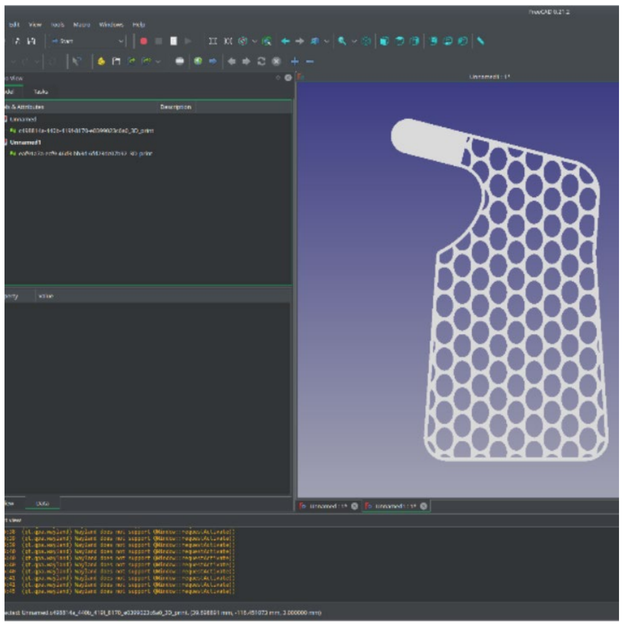

Fig. 3. 3D model of flat orthosis in FreeCAD based on template and input dimensions.

It is important to note that individuals without a medical or occupational background should not use this application for generating, 3D printing and then using the orthosis. This is a medical device and its use should be prescribed and designed by specialists.

The following six steps are applied in the app (Fig. 2):

1. User enters the home page of the application.
2. The user decides which type or orthosis choose to generate: volar splint/brace, bar wrist splint/brace.
3. Once the user decides on the type of the orthosis, a CAD file is prepared for editing.
4. The user decides which open pockets pattern should be applied to the orthosis (for the current version of the application, hexagon and ellipse are available).
5. The user should define pockets dimensions by providing the required parameters used by the script to create the shape of it. In the same page the user is required to enter the measurements taken before entering the application as parameters of the 3D model. The application provides default values for the parameters so the user can modify these parameters. The parameters are different according to the type and the pattern selected and the dimensions are entered in mm.
6. The application uses the parameters entered by the user and runs the script which will modify and update the 3D solid of the orthosis. When the update is finished the script exports the solid as STL file, and the outer contours of the 3D model as PDF file. The user is provided with the download links of these two files, and with two important notes regarding the time of generating the files and an awareness warning on the scale used to print the pdf file.

The application gives the user the opportunity to restart the process or go back one or more steps at any time.

A timer is also included to measure how long it takes to generate the STL model of the orthosis/brace.

2.2. Testing protocol

During the instruction phase of the usability test, the participants were given a demonstration of the testing and app workflows, as well as the correspondence between the dimensions in Fig. 1,*a* and those recorded on paper by each therapists (as Fig. 1,*b*). This latter aspect was needed for participants who do not understand English and are not proficient in using online apps. Then, demographics data were collected including age, professional status, years of experience as therapist, digital literacy (own evaluation), previous knowledge on 3D printing or 3D CAD.

In the second step of the test, participants were asked to select one of the two types of orthoses, draw the contour of their own hand and of the orthosis, measure the dimensions with a ruler, and write the values on paper. The type of orthoses was assigned randomly so that half of participants to generate volar braces and the other half bar wrist braces. Subsequently, in the third phase of the test, the participants input the dimensions into the app and recorded the time for file generation. All participants conducted the test at the same time using the same Wi-Fi internet connection.

In the last phase of the application testing, the therapists answered questions based on Likert scale (1 – very dissatisfied/difficult to 5 – very satisfied/easy), as well as two open questions:

1. How would you rate the ease of accessing the application?
2. Was the information provided within the application clear and easy to understand?
3. How intuitive was to navigate the application?
4. Did the application allow for easy input of the measured dimensions?
5. How satisfied were you with the time taken to generate the STL model of the orthosis?
6. Overall, how satisfied are you with the web-based application?
7. Are there any improvements you would recommend for the application?
8. Did you face any issues or difficulties while using the application? If yes, please describe.

2.3. 3D-printed customized orthosis

One of the STL models generated by the platform was 3D printed from PLA, thermoformed and its fit on therapist hand was tested. The main process parameters are presented in Table 1, while the remaining parameters are set to the default values in Cura Ultimaker, the slicing software used in this study. An estimation of the total time from the hand-forearm contour drawing up to the moment of fixating the orthosis on the hand was computed. The manufacturing process was made using

Figure 4 shows an image from the 3D printing (3DP) process of the flat orthosis using a Bamboo 3D printer. A brim support was employed to secure the brace on the printing bed. This was required as the dimensions of the brace increased the risk of detachment from the platform.

3. RESULTS AND DISCUSSIONS

Table 2 presents the demographics of the participant group. Participants reported a mean of 6 years of experience in the field of occupational therapy.

Table 1

Main 3DP parameters for the customized wrist-hand brace

Process parameter	Value
Layer height	0.2 mm
Infill density	55%
Infill pattern	grid
Top/bottom layers	2
Printing temperature	210 °C
Bed temperature	60 °C
Printing speed	60 mm/s
Wall line count	2
Infill overlap	30%

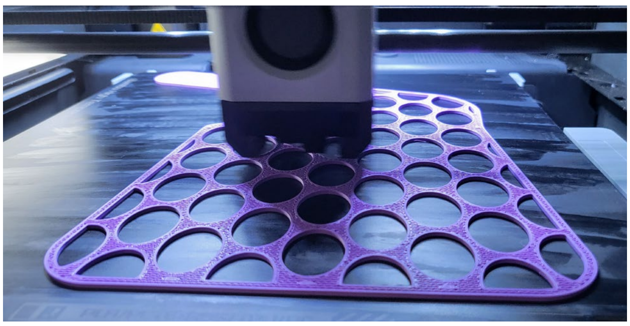

Fig. 4. 3D printing a flat shaped orthosis.

Table 2

Demographics of the participants group

Mean age	6
Years of experience < 3 (3–8) > 8	 1 participants 4 participants 3 participants
Computer literacy Beginner Intermediate Advanced	 1 participants 3 participants 4 participants
Previous 3D printing experience	No
Previous 3D CAD experience	No
Professional status	2 Occupational therapists 5 Kinesiotherapists 1 Physical therapists

Anova: Two-Factor Without Replication

SUMMARY	*Count*	*Sum*	*Average*	*Variance*
Row 1	6	20	3.33333	1.06667
Row 2	6	25	4.16667	0.56667
Row 3	6	29	4.83333	0.16667
Row 4	6	29	4.83333	0.16667
Row 5	6	30	5	0
Row 6	6	27	4.5	0.3
Row 7	6	28	4.66667	0.26667
Row 8	6	28	4.66667	0.26667
Column 1	8	37	4.625	0.26786
Column 2	8	33	4.125	0.69643
Column 3	8	34	4.25	0.5
Column 4	8	38	4.75	0.5
Column 5	8	38	4.75	0.21429
Column 6	8	36	4.5	1.14286

ANOVA

Source of Varic	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Rows	12	7	1.71429	5.33333	0.00032	2.28524
Columns	2.75	5	0.55	1.71111	0.15784	2.48514
Error	11.25	35	0.32143			
Total	26	47				

Cronbach's Alpha 0.8125

Fig. 5. Cronbach's Alpha test results.

Before interpreting the Likert scale-based questionnaire results, reliability and validity tests should be applied.

Using Excel, a Cronbach's Alpha test was conducted (Fig. 5) for evaluating the internal consistency. For the collected data, two-way ANOVA without replication was applied, and correlation coefficient was calculated as:

$$r = 1 - MS\_Error / MS\_rows. \quad (1)$$

The value of 0.813 means a good reliability of results.

Figure 6 presents the scores calculated based on questionnaire responses, as the mean of the Likert scores provided by participants.

The access to the application from laptops was rated 5 out of 5. However, when two participants attempted to use the application on their mobile phones, they reported that the window for inputting dimensions was too small. It is important to note that the V2 app was not initially intended for optimization on smartphones. This functionality is planned for the final version of the application. Therefore, the participants were ask to rate

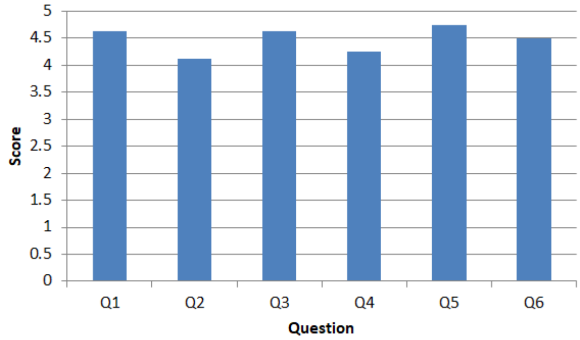

Fig. 6. Scores on the questions aimed at evaluating the online application.

the application only based on their experience using laptops.

No significant differences in scores were recorded between the two types of braces currently implemented in the app.

The overall satisfaction with the application was rated at 4.5 out of 5. A slightly lower score was attributed to the use of English within the app, which created difficulties for two participants who were not proficient in the language. In this sense, the inclusion of illustrative images for each selection task was positively received and proved beneficial in helping the user comprehension throughout the online usage process. This was proved by the scores of 4.125/5 and 4.625/5 to the second and third questions. Participants also mentioned one might consider improving the app by adding explanatory text to each step. Additionally, the participants mentioned the benefit of the demo session conducted at the start of the experiment, which significantly aided in understanding the whole procedure. Consequently, a decision was made to enhance the platform by integrating a video tutorial to exemplify the use.

A lower of 4.25/5 was recorded for the forth question, two reasons explaining this score. The respondents were not familiar with the notations used for the parameters and need time to understand how to correlate the input field name and the image, while the second motive relates to the language barrier already mentioned.

Figure 7 presents the 3D-printed orthosis fit on the hand after its thermoforming at a temperature of 75 °C, exceeding PLA glass transition temperature which is around 55–60 °C according to producer's data [22]. The brace fixed on hand and forearm with three Velcro straps in the palm, wrist and forearm zones.

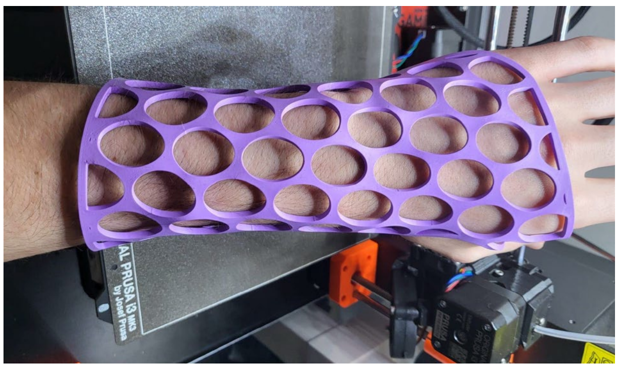

Fig. 7. Customized orthosis fit on forearm and hand after thermoforming and secured with Velcro straps.

The total time for generating the orthosis in Fig. 4 was divided as follows:

- Paper drawing and measurements: 5 min 13 s;
- Online app usage (menu selections and data input): 2 min 45 s;
- Files generation: 3 min 03 s;
- 3D printing: 3 h 52 min.

The most time-consuming process was the 3D printing, followed by sketching the hand-forearm and orthosis on paper. However, with increased familiarity and practice, the time required for drawing can be significantly reduced. For example, one participant was able to decrease the drawing time by nearly half during a second attempt. Also, the time she spent using the online application was reduced by approximately 30% during subsequent uses, as the participant became more accustomed to the brace parameters presented in Fig. 1,*a*.

4. CONCLUSIONS

This study demonstrated the effectiveness of the ForTE V2 web-based application in customizing the design of thermoformable 3D-printed wrist-hand braces. The application based on the integration of FreeCAD and Python, allowed the participants at the test, all therapists with a mean of 6 years of experience, to generate custom orthosis designs without needing 3D modeling or to 3D scanning skills. This represents a significant advancement in making custom orthotic solutions more accessible and feasible at the 3DP-POCs.

Participants in the usability test rated their overall satisfaction with the application highly, with an average score of 4.8 out of 5. This is a high level of satisfaction, which underscores the application's ease of use and the effectiveness of its design tools. However, the usability test also evidenced several areas for improvement, especially in mobile accessibility and multilingual support. These issues are important as they can limit user engagement and accessibility, especially for non-English speaking users or those relying on mobile devices.

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