ThermoFit: Thermoforming Smart Orthoses via Metamaterial Structures for Body-Fitting and Component-Adjusting

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Smart orthoses hold great potential for intelligent rehabilitation monitoring and training. However, most of these electronic assistive devices are typically too difficult for daily use and challenging to modify to accommodate variations in body shape and medical needs. For existing clinicians, the customization pipeline of these smart devices imposes significant learning costs. This paper introduces ThermoFit, an end-to-end design and fabrication pipeline for thermoforming smart orthoses that adheres to the clinically accepted procedure. ThermoFit enables the shapes and electronics positions of smart orthoses to conform to bodies and allows rapid iteration by integrating low-cost Low-Temperature Thermoplastics (LTTPs) with custom metamaterial structures and electronic components. Specifically, three types of metamaterial structures are used in LTTPs to reduce the wrinkles caused by the thermoforming process and to permit component position adjustment and joint movement. A design tool prototype aids in generating metamaterial patterns and optimizing component placement and circuit routing. Three applications show that ThermoFit can be shaped on bodies to different wearables. Finally, a hands-on study with a clinician verifies the user-friendliness of thermoforming smart orthosis, and technical evaluations demonstrate fabrication efficiency and electronic continuity.

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CCS Concepts • **Human-centered computing** → **Ubiquitous and mobile computing** → *Ubiquitous and mobile computing systems and tools.*

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1 INTRODUCTION

Smart orthosis holds great potential for sports performance, rehabilitation, and clinical treatment. Compared to traditional orthosis, smart orthosis incorporates additional features such as vital signs monitoring, wearing timing [69], and conformity sensing [56]. Patients wearing smart orthoses can better monitor their health condition and use smart home assistance seamlessly [57] with improved wearing compliance [70]. Meanwhile, clinicians can use objective biometric health monitoring data from smart orthoses to eliminate bias in subjective self-reported data [2,26] and facilitate diagnosis, thus effectively adjusting the treatment to minimize side effects [56].

However, the design and fabrication of personalized intelligent orthoses at the intersection of sensing and healthcare remain difficult. First, it is difficult for orthosis with electronics to conform to complicated body forms and joint movements because of cumbersome equipment, obtrusive wires, and various rehabilitation needs across patients. Second, while the body shapes and medical requirements of patients change gradually [31], it is difficult to adapt the shapes and electronic positions of smart orthoses once they have been manufactured. Ill-fitted orthoses may induce adverse effects (e.g., skin abrasion and pressure sores [52]) and diminish the effectiveness of monitoring when the electronics (e.g., pressure sensors and electrodes) are not in the correct location. Third, customizing smart orthosis with electronics requires significant effort from healthcare professionals with clinical experience, which is not supported by existing fabrication and design tools [18,51]. Few of them are involved in the production of smart healthcare wearables due to a lack of electronic knowledge and a heavy workload [18].

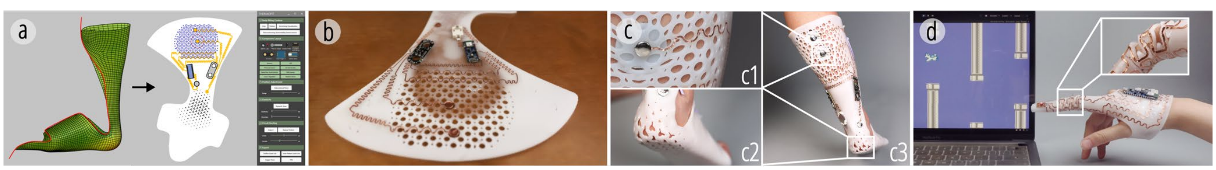

Fig. 1. ThermoFit embeds metamaterial structures and circuits within thermoplastic materials to fabricate smart orthoses with customized shapes and functions. (a) A design tool to generate contour with metamaterial structures and to assist circuit routing. (b) The prefabricated thermoplastic boards embedded with electronics can be heated and shaped on the body directly by clinicians. The smart orthosis (c) conforms to a complex body surface and allows electronic components adjustment. (d) The dynamic smart orthosis with a 3D spring conforms to joint movement with a driving force.

In our vision, the next-generation smart orthoses conform to body contours, assist body movements, and adapt to alterations in rehabilitation progress to facilitate rehabilitation progress. Therefore, we offer a process for customizing body-fitting and component-adjustable intelligent orthoses. We combined circuits with Low-Temperature Thermoplastics, which are widely utilized in clinical practice for the quick customization of orthoses. Clinicians can thermoform the prefabricated thermoplastic sheet containing circuits (Fig. 1b) into a smart orthosis. We utilize designed metamaterial structures on thermoplastics with customized thermoforming ductility, inner relocation ability, and enhanced elasticity, allowing the shape of orthosis and the circuits to conform to the organic shape of patient bodies (Fig. 1c) and the gradual change of bodies during recovery, and to support joint movements (Fig. 1d).

The motivation for the development of ThermoFit is derived from a formative user study with clinicians and electrical engineers. We then present design ideas for enhancing the adaptability of smart orthoses using metamaterial structures. We also characterize the metamaterial structures on thermoplastic material that can be created by our design tool and manufactured with accessible devices. We demonstrate the capability of body-fitting and component adjustment through three application examples of smart orthoses, validate the ease-of-use of prefabricated circuit sheets for clinicians to thermoform a smart orthosis via a hands-on expert study, and evaluate the fabrication and iteration efficiency, mechanical stability, and circuit stability.

We believe that the future application of this technology in clinical settings could significantly improve how orthoses are customized and used, as well as how physicians and patients assess and perceive orthoses in real-time. The main contributions of this paper are as follows:

- We propose an accessible fabrication pipeline for customized and adaptive smart orthoses, utilizing low-temperature thermoplastics embedded with circuitry and metamaterial structures to allow physicians to shape and adjust smart orthoses with sensing functionality.
- We design and characterize a series of parametric metamaterial structures on thermoplastic to facilitate adaptability, with a computational design tool aiding in the design of the shape, metamaterial structures, and circuits.
- A demonstration of ThermoFit's applicability across different sensing and body-fitting uses as well as the efficiency of fabrication and iteration using three smart orthoses. A hands-on expert study validating the ease-of-use of prefabricated circuit boards for clinicians to thermoform, and a technical evaluation of the mechanical stability and electronic continuity.

2 BACKGROUND

2.1 Orthosis

Orthosis, an external device designed to protect and support bones, tendons, ligaments, and nerves by restricting the range of motion, is widely utilized in orthopedics and rehabilitation. Orthoses are frequently prescribed to individuals with fractures, scoliosis, arthritis, nerve damage, and cerebral palsy. There are two types of orthoses: static orthosis and dynamic orthosis [49]. Static orthoses are used to immobilize or limit motion at a joint by providing stabilization, support, and protection. Dynamic orthoses commonly incorporate extra elastic materials such as coils or springs that provide the driving or traction forces during joint movement.

Orthoses should be routinely checked, adjusted, or modified to accommodate patients' changing medical demands and to ensure fitness and functionality. These changes include the range of motion of joints as training progresses, the decreased swelling of the injured body parts [31], the angle of the spine with scoliosis treatment, and the physical development of adolescents. All patients are required to promptly report discomfort and follow-up appointments, with intervals ranging from 3-5 days (e.g., tendon rehabilitation training period [47]), two weeks (e.g., fracture [11]) to half a year (e.g., Scoliosis [63]).

2.2 Low-Temperature Thermoplastics Orthoses

Low-Temperature Thermoplastics (LTTPs) are frequently utilized in orthoses due to their high efficiency and reshaping flexibility [49]. Compared to 3D-printed orthoses, LTTP-made orthoses are more flexible and easily reformable. LTTPs will rapidly soften when heated (60-74 °C) and can be molded directly on the human body. It will harden and regain its previous rigidity upon cooling. The shape memory ability of LTTPs enables the orthotic device to be reheated and reshaped, allowing it to be relocated at a new angle or redesigned. There is a vast selection of LTTPs on the market, each with unique features such as stiffness, memory, and stretch resistance. Clinicians can select LTTPs with appropriate qualities to meet the requirements of different orthoses.

Based on the literature research [49], expert interviews, and field observations (Fig. 2), we conclude the typical fabrication steps for thermoplastic orthoses are as follows, and that experienced therapists may omit certain steps:

- Cut the contour of the thermoplastic sheet, including (1) drawing an orthotic contour around the patient's body part or plaster mold modified according to human body shape on a paper towel, (2) cutting out the contour, checking the fitting by placing the paper on the patient's body or other molds, and adjusting the contour as necessary, (3) tracing contour on the thermoplastic sheet, heating the material, and cutting out the sheet.
- After checking the temperature, the sheet is placed on the body and shaped into the desired position until it cools.
- Mark and trim excess areas and attach extra components.
- For thermoplastic orthosis adjustment, the clinician reheats local sections using a heat gun or reheats the entire orthosis, reshapes the orthosis, and trims the excess area.

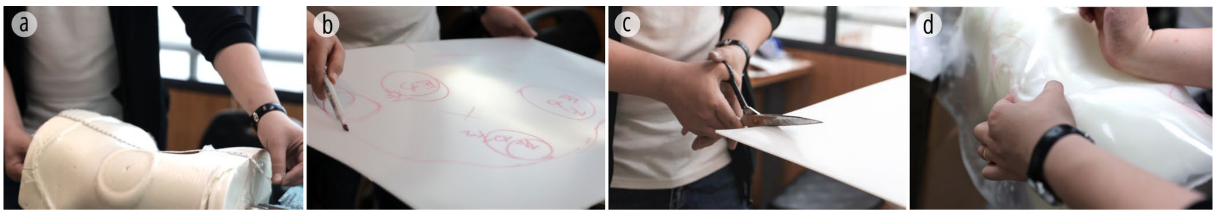

Fig. 2. Conventional orthosis fabrication workflow demonstrated with scoliosis orthosis: (a) rough measurement; (b) approximate contour tracing on the thermoplastic sheet; (c) cutting out the shape; (d) on-body shaping and trimming.

Orthotic fabrication is a skill that develops through practice and repetition [49]. Shaping an even thermoplastic sheet to a complicated, highly curved, organic, and undeveloped body surface. For instance, the ankle or the elbow is susceptible to wrinkle and crease formation. Clinicians may overstretch, cut, or fold excess materials based solely on their practice experiences to address the issue of garments that do not conform to body shape. In addition, the customization of dynamic orthosis frequently necessitates the use of milting accessories, such as a spring, screw, and nut, as well as several procedures.

3 RELATED WORK

3.1 Smart Orthoses

The development of smart orthoses and related medical devices has been a significant and promising subject at the intersection of sensor work and healthcare. Smart orthoses have been vastly investigated for clinical applications within health assessment [56,70], assistive technology [8,27,34,59], and rehabilitation [37,41]. These applications are usually achieved by attaching sensors that make personalized healthcare available with objective data [9,16,45,58].

However, most of them are unsuitable for in-home health monitoring due to their cumbersome equipment. While some research has attempted to enhance wearability by reducing the number of sensors [22] or by embedding printed electrodes on the inner surface of the orthosis [9], their electronics still require bulky equipment with exposed wires that is difficult for patients to operate in their daily life.

In addition, adaptive smart orthoses that adapt to user needs for long-term healthcare difficulties are lacking. Few existing research has addressed the issue of variance in body form and medical requirements. Knibbe et al. [29] employed elastic stretchable bands to alter the body contour fitting for electrode insertion. Tan et al. [56] adhered a separate stretchy circuit layer to the patient's skin inside a brace when they encountered altered body geometries. While both procedures are customizable, they may induce skin allergies and tissue damage.

ThermoFit produces tailored smart orthoses that are ready for use by merging electronics with thermoplastic sheets. It is transportable and durable for long-term usage outside the laboratory and in everyday life. In addition, it conforms to body shape variations and is skin-friendly for long-term care.

3.2 Fabrication by Healthcare Professionals

In recent years, personal fabrication technologies have been developed and applied to healthcare products [3,10,13,38,64,66,69]. Meanwhile, healthcare professionals such as clinicians have been increasingly involved in the maker movement, alternatively referred to as the technology-oriented do-it-yourself (DIY) movement. These healthcare professionals benefit from the efficiency of customization by digital fabrication [33] and are encouraged to innovate with open-source hardware and collaborate with other field experts [4,14,35].

Researchers in the HCI community have worked with healthcare professionals to incorporate digital fabrication into the medical-making process through class training [39], workshops [1], and co-design [23]. Healthcare professionals were encouraged to learn 3D scanning [68], computer-aided design [10], and additive manufacturing [17] to apply their clinical expertise to healthcare customization, such as producing orthosis [64], prostheses [48], and assistive device [25].

Nevertheless, several issues were exposed throughout the practice. Firstly, considering the learning cost and limited access to training resources [7], it has always been difficult for healthcare professionals to create and modify digital prototypes [39]. Secondly, existing rapid prototyping and digital fabrication processes, especially iterations on low-fidelity versions, conflict with the ethos of "do-no-harm" in clinical practice [57]. Instead of digital iterations, clinicians prefer to use customized designs with physically adaptable material [20].

Moreover, few studies have examined how to involve clinicians in the development and fabrication of smart healthcare and mobile health products. During the customization of smart orthoses, medical professionals serve only as design consultants and evaluators, deciding the type of data to record following the medical protocol [36] and testing the intelligent clinical decision support system [57]. Customizing smart orthoses and related medical devices at the intersection of sensor work and healthcare requires significant effort from clinicians that is unsupported by current fabrication and design tools.

ThermoFit engages healthcare professionals without 3D modeling or electronic expertise in the customization and adjustment of smart healthcare wearable devices, which has the potential to fill a gap to support clinician needs for efficient and flexible smart orthoses. The combination of adaptive material, metamaterial structures, and electronics enables physically adaptive iteration, which conforms to the "do-no-harm" philosophy of clinical practice and reduces patient costs.

3.3 Adaptive Material and Structure

The HCI community has developed shape-changing interfaces using pliable materials (e.g., thermoplastic materials) [55,61]. For instance, Ko et al. modified the shape of 3D printed models by heating the thermoplastic materials [30]. Yamaoka et al. proposed ProtoMold to change the morphology of 2.5D objects through vacuum-forming thermoplastic materials [65]. While versatile, their output has limited interaction function without electronics, since trimming and stretching during the shaping process of thermoplastic materials might be difficult to perform if there are electronic components and wires embedded in the thermoplastic materials. The circuits tend to fracture or delamination under the flexural strain [21,60] and limit conformability [44].

Enhancing the overall shape-changing properties of materials with inner area unit stability via mechanical structures [18,54] is a potential method for constructing shape-changing circuit interfaces. Material science and the HCI community have investigated how metamaterial structures [43] can give single-material objects novel material properties defined by the structure rather than the material composition. For example, LASEC introduced Y-shaped slits to enhance the stretchability of an otherwise non-stretchable material to create 2D stretchable circuits [18]. Shyu et al. utilized the high strain and high conductivity of 3D Kirigami nanocomposites for tunable electrodes [50]. We are the first to present patterns for smart thermoplastic rigid wearable healthcare devices with both rigidity for protection and adaptability for body-fitting and electronic adjustment in response to the gradual change in body and medical requirements.

As shown in Table 1, pioneering works in material science and HCI characterize and employ the properties of metamaterial structures at room temperature [18] and in a flat sheet state [24]. In contrast, ThermoFit utilizes the ductility in a heated and softened state as well as the elasticity after thermoforming to create a three-dimensional spring. In addition, ThermoFit expands the properties of biholar patterns, a regular array of large and small holes, from compression to inner displacement adjustment after heating.

Table 1. Comparison of material properties of metamaterial structure research objects similar to our study.

Metamaterial structures	Metamaterial Properties in Previous Work	Metamaterial Properties in ThermoFit
Y-slits	Tensile properties at room temperature [18]	Stretchability in the heated and softened state Stability at room temperature (non-ductile)
Parallel slits (Kirigami)	Elasticity of flat sheet [24]	Elasticity of a thermoplastic three-dimensional spring
Biholar patterns	Squeezing [15]	Internal displacement adjustment after heating

4 FORMATIVE STUDY: EXPERT INTERVIEW

We conducted a formative study to further explore the challenges and possibilities in customizing smart orthoses.

4.1 Method

We conducted individual interviews with six experts from diverse fields. Two of them were orthopedics (E1) and rehabilitation (E2) specialists who have been using orthoses in their medical practices for more than eight years; two were clinicians (E3 and E4) with extensive experience in making orthoses (for four and sixteen years, respectively); and two non-healthcare professionals were a designer (E5) and an electronics engineer (E6) who had previously designed sensor-embedded wearable devices.

We conducted 50-minute semi-structured interviews with each participant. First, we inquired about their experiences and difficulties in designing and fabricating orthoses or rigid electronic wearable devices. Next, we showed them images of existing smart orthoses and collected their feedback [9,37,70]. We also described the initial idea of ThermoFit: to design and manufacture a body-fitting smart orthosis from thermoplastic sheets. In addition, a video of a low-temperature thermoplastic orthosis in operation was shown to the electronic engineer to give him an idea of the current fabrication method. We gathered their initial feedback and fleshed out a number of the design specifications, which are detailed below.

After completing the interviews, we analyzed the interview transcripts using thematic analysis [6] and iterative open coding [53]. Two researchers coded and evaluated the recordings for emerging themes, and the co-authors iteratively discussed the findings until they achieved a consensus.

4.2 Key Insights

4.2.1 The Value of Clinical Expertise. Clinical expertise is essential for the design, fabrication, and adjustment of orthoses, which directly affect the rehabilitation results [20,52]. For instance, experience is necessary for making clinical decisions on the customization and adjustment of orthoses. As the clinician (E4) explained: "when delivering an orthosis, although we have the x-ray examination result, we still have to check the fitness on-site and decide whether to modify." In addition, all clinicians (E1, E2, E2, E4) agreed that the accumulation of fabrication expertise through practice-based learning enhances orthosis quality and wearability. As E3 expressed, "To avoid wrinkles and folds when fabricating orthosis is vital for comfort and wearability. But these [defects] are inevitable without months of practice by the clinician."

4.2.2 Desires and Constraints for the Implementation of Electronics.

Concerning the prospective involvement in smart orthosis with electronic functions, there is a tension between (1) the clinicians' desire to enjoy the clinical application of smart orthosis and (2) their lack of electronic engineering skills and available time to work. All of the professionals reacted favorably to the application of smart orthoses based on their personal experiences or their anticipation of the near future. However, each clinician (E1, E2, E3, and E4) reported having no prior expertise with electronics. and E2 added that "I don't think we have time to learn it." In addition, they feared that customization of smart orthoses could necessitate back-and-forth collaboration with additional electronics technicians, which may reduce the efficiency of orthosis customization, a highly valued aspect. E1 stated: "I am too busy to take on new tasks for making smart orthosis."

4.2.3 Focus on Body Adaption and Accurate Electronic Placement.

The initial concept of using thermoplastic sheets for customized smart orthoses was well received by experts, who then focused on the adaptation of shape and circuitry to bodies. Adaptation is the primary concern for a custom orthosis, E1, E3, and E4 emphasized that the fit of the orthosis influences the patient's willingness to use it, as well as the wearing time and rehabilitation efficacy. "The pre-made orthosis can't fit the patient well since everyone has different conditions and these conditions change" (E1). In addition, when an orthosis no longer fits, it must be "reshaped by reheating and trimming, or even replaced" (E4). When asked about thermoplastic orthoses with electronics, four participants (E1, E2, E4, E6) expressed their concern regarding circuit stability and electronics placement accuracy, as E4 elaborated, "Since we [clinicians] fold or trim extra thermoplastic materials to avoid wrinkle or loss of contact, the placement and continuity of electronics may be hard to ensure." E2 mentioned that "accurate alignment of the local area is hard for hand shaping orthoses." Four experts (E2, E4, E5, E6) also questioned the placement accuracy once the thermoplastic orthosis is reshaped and trimmed. Accurate placement of electronics (e.g., electrodes) on muscles or pressure points with reliable electrical contacts is crucial for data quality and bioelectrical stimulation efficacy. E5 recommended allowing fine-tuning of the component position during shaping according to the actual situation thus clinician can "justify electrode position through touching the muscle by hand".

4.2.4 Challenges and Opportunities in Fabricating Dynamic Smart Orthosis.

Dynamic orthoses are commonly used to facilitate rehabilitation, and there is a significant demand for dynamic orthosis with a smart interaction function. E2 stated that the hospital where he works has recently implemented gamified dynamic rehabilitation training machines. However, experts reflected that the customization of dynamic orthoses would be a difficult task. E3 stated, "The production of dynamic braces is a challenge for me because the parts to be assembled, the corresponding hand tool and the operations are cumbersome. It takes half a day to customize and adjust a dynamic orthosis. I guess it will be more troublesome to make dynamic smart orthosis with embedded circuits. " When it comes to thermoplastic dynamic smart orthoses, three (E2, E4, E6) are concerned about the conformability to body movement. E6 exemplified: "Electronics for monitoring joint movements is large and inconvenient for daily wear." Even though some devices were small, E2 doubted their usability by saying, "they look fragile and unattractive, connected to many obtrusive wires." E4 proposed that "it may be helpful to simplify the customization of dynamic orthosis and embed electronics conforming to the movement of body joint."

4.3 Design Goals

Based on prior work and our findings in the previous section, we derived three design goals for the fabrication workflow for smart orthosis taking into account clinical expertise.

- **Goal 1 Easy Operation for Clinicians**. The fabrication should require minimal tools and no or little additional knowledge for clinicians to manipulate. During the fabrication process, we should avoid the need for electronics-related expertise.
- **Goal 2 Adaptive Materials and Shapes**. The shape of the orthosis and the circuits should be adaptive to the body shape of patients and accommodate the gradual change during recovery.

- **Goal 3 Dynamic Conforming to Joint Movement**. The fabricated smart orthosis should conform to body movement, especially on body joints with aggressive bending.

5 OVERVIEW OF THERMOFIT

5.1 Pipeline of Customizing Smart Orthosis

Based on these design goals, we developed ThermoFit, a design and fabrication pipeline employing a thermoforming plastic sheet with precise placement of on-body electronics for healthcare monitoring.

To ensure ease of operation for clinicians (Goal 1), ThermoFit provides a custom-made thermoplastic sheet with prefabricated circuits. It enables clinicians to fabricate smart orthosis using their existing tools with minimal learning and time requirements. It prevents the removal or reinstallation of electronic components during orthosis adjustment. We replace protruding wires with body-fitting copper wires to ensure circuit stability, conformity, and wearability. Fig. 3 depicts the process of configuring and modifying a smart orthosis.

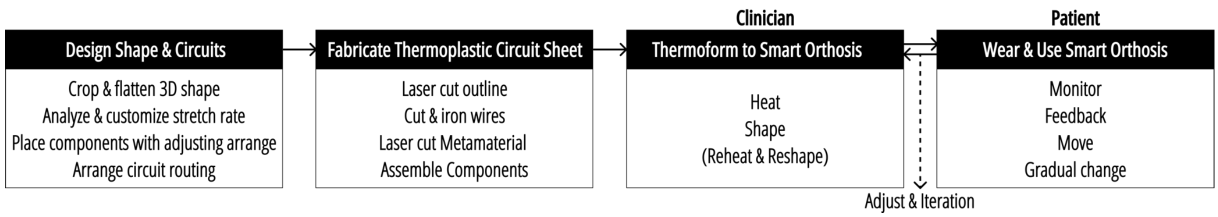

Fig. 3. Workflow of ThermoFit. ThermoFit provides a custom-made thermoplastic sheet with prefabricated circuits. It enables clinicians to use their existing tools with little training time and work time to complete the shaping of a smart orthosis. It allows adjustment after long-term use, preventing removing or re-installing electronic components.

5.2 Design Strategies for Enhancing Adaptability

The existing workflow of thermoforming orthoses has limited abilities in customizing smart orthoses. Existing hand shaping of orthoses has not taken precise alignment of the local inner area into account and usually fold or trim extra materials to address body unfitting, such as wrinkles or contact looseness. Thus, the placement and continuity of electronics are hard to ensure. Regarding this, we propose to laser-cut metamaterial structures on LTTP sheets to improve the adaptability of structures and electronic placement to body shape (Goal 2) and joint movement (Goal 3). Fig. 4 depicts the design goals and corresponding design strategies.

- **Customize thermoforming stretchability**. First, to improve conformability to highly curved organic surfaces, particularly undevelopable surfaces (Goal 2), we tailor thermoforming stretchability (ductility) to reduce overstretch and corresponding wrinkles or creases. Local thermoforming stretchability enhancement improves sheet conforming to a complex surface (such as the nose and mouth) with minimal wrinkling at the outer edge (Fig. 4a). Second, ductility improvement aids in accommodating the gradual change in body shape (Goal 2). As depicted in Fig. 4b, once the swelling is reduced (simulated with varying layers of bandages), the orthosis can be reshaped without trimming while maintaining circuit stability and proper placement.
- **Enable thermoforming inner replaceable range**. We distribute thermoforming inner replaceable metamaterial structure to enable the fine-tuning of crucial electronic components placement to adaptive placement (Goal 2). As shown in Fig. 4c, the local adjustable range is tolerant of errors caused by manual shaping and adapts to the gradual change in body shape, thereby maintaining the correct placement/positions of electronic components with adequate electrical contact.

- **Enhance elasticity.** To dynamically conform to joint movements (Goal 3), we enhance the elasticity of thermoplastic sheets through optimized Kirigami slits and enable the conversion of the thermoplastic sheet to a 3D spring conforming to body shape and body movement (Fig. 4d). This elastic system facilitates the fabrication and assembly of dynamic orthoses without the need for additional accessories like coil springs, bolts, or nuts. It is simpler and quicker than 3D printing without the need to remove support material. Integrated into the 3D elastic structure, circuits remain stable during body movement without the risk of disconnection due to becoming entangled or stuck.

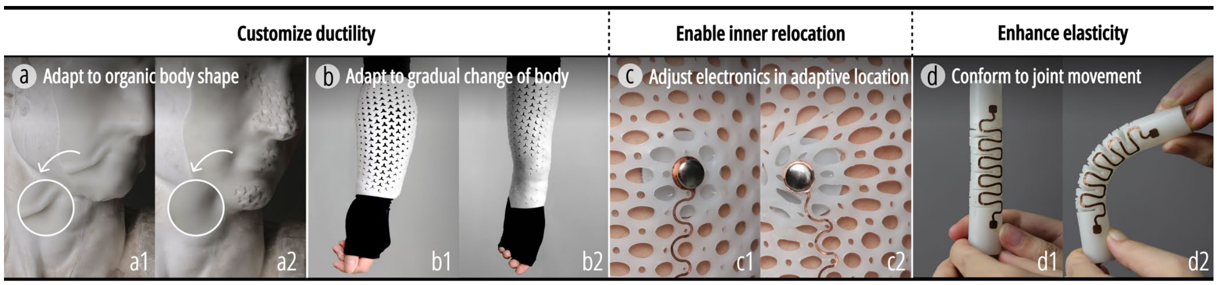

Fig. 4. Body-fitting and component-adjusting improvement of ThermoFit: customized metamaterial pattern: (a) improves the conformity to the body shape with more details (such as nose, mouth) and fewer wrinkles or creases; (b) allows body deformation during the process of rehabilitation (such as the decreased swelling) through reshaping without trimming; (c) allows adjustment of electronic components placements through inner relocation; (d) conforms to dynamic joint movements through 3D spring

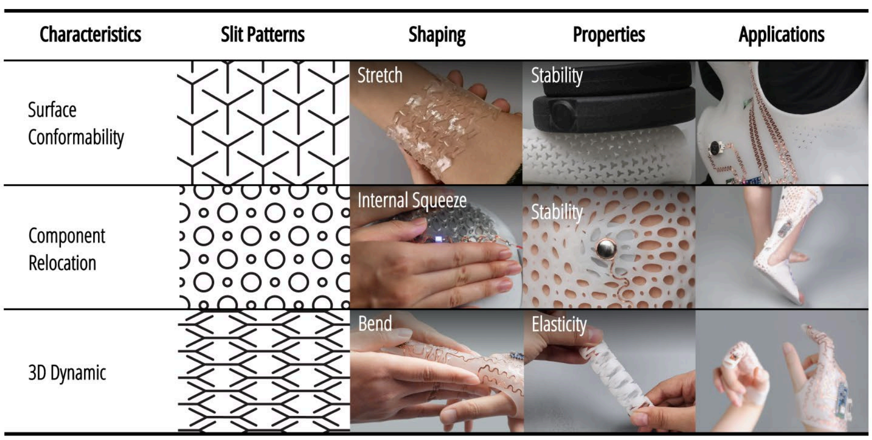

Fig. 5. Overview of three metamaterial slit patterns.

6 MECHANICAL PROPERTY CHARACTERIZATION

Based on the design strategies, this section presents a parametric cut pattern design through a series of experiments that (1) customizes thermoforming stretchability to conform to the body surface, (2) enables thermoforming inner replaceable range for electronic adjustment, and (3) enhances elasticity for dynamically conforming to joint movement (Fig. 5). All the patterns should be compatible with circuit routing to ensure a consistent circuit connection during shaping.

6.1 Enhancement of Ductility / Thermoforming Stretchability

When a 2D sheet is deformed to a 3D undeveloped (double-curved) surface, the local areas of the sheet will stretch to varying degrees. LTTP materials are ductile in their soft state above the glass-transition temperature and can be stretched by hand. However, without advanced skills, the manual shaping process is difficult because the stretch is difficult to control. Additionally, our orthosis is equipped with smart sensors and circuits that require precise placement and stability.

We characterized the Y-slit pattern, which increases the conformability of the surface by introducing structural stretchability. Two parameters, L and S (Fig. 6a), affect the stretchability simultaneously. We adopt the following design considerations for the form factors and associated parameters of the pattern:

- Plastic deformation: According to the interviewed clinicians, the common fabrication process of orthosis usually involves 0%-30% of stretching. We confirm that this rate of ductile deformation could be easily achieved by hand shaping.
- Mechanical strength: the minimum mechanical strength for orthosis function should be attained after shaping.
- Compatibility with circuit routing: The adjacent slits should maintain enough distance to allow the circuit traces to pass through and maintain connectivity after shaping and stretching.

Considering the points above, we conducted mechanical and electrical experiments below.

6.1.1 Experiment 1: Stretchability in Different Material States. For LTTP materials, heating above their glass-transition temperature, which is approximately 65°C for the material we chose, softens the material and transforms the material into a rubbery state. At room temperature, the material is said to be in a glassy state and exhibit glass-like material properties - stiff, hard, and brittle. To evaluate the change in stretchability of the LTTP, we selected different cut pattern densities in different material states and conducted tensile loading experiments on an uncut bulk LTTP sheet and eight different pattern densities as shown in Fig. 6b. The LTTP sheets (50 × 100 mm) Y-slit patterns (50 × 50 mm) centered on the sheets were steadily stretched at a slow tensile speed of 50 mm/min by the test machine (ZwickRoell Z005).

We selected two sets of parameters that are suitable for our application according to the result (Fig. 6b). In the rubbery state (65°C), a loading of 0.15N, approximating hand shaping force, induces a strain of 30% on the sample with S = 10 mm and L = 5 mm, and a strain of 12% on the sample with S = 10 mm and L = 4 mm. In comparison, the bulk sheet has a 2.7% strain. Additionally, at room temperature and glassy state, these two groups can withstand 50N with a strain of less than 1%. Their mechanical strength is adequate for orthotic use.

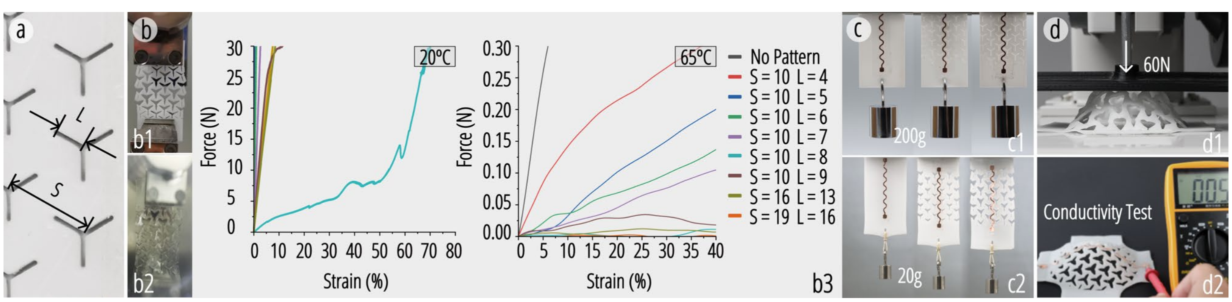

Fig. 6. Parametric cut pattern characterization for custom thermoforming stretchability. (a) Y-slit pattern characterized by slit length L and unit center distance S; (b) Experiment 1: tensile tests of different parametric structures at (b1) room temperature and (b2) heated state (65°C); (c) Experiment 2: tensile tests of two groups of parameters (S = 10 mm L = 4 mm, S = 10 mm L = 5 mm) with circuits under (c1) rigid state and (c2) heated state; (d) Experiment 3: (d1) rigidity and (d2) circuit stability after shaping.

6.1.2 Experiment 2: Tensile Tests with Circuits. Considering the effect of the embedded circuit on stretchability and to test the circuit continuity during stretching, we applied weight to the test samples and observed the deformation of the conductive traces. The test results (Fig. 6c) indicate that samples with embedded circuit traces of S = 10 mm, L = 4 or 5 mm maintained circuit continuity under a 200 g load. When heated to a rubbery state and subjected to a load of 20 g (equivalent to the force used to thermoform an orthosis), they stretch by 6% and 12%, respectively. Stretching did not affect the continuity of the circuit traces.

6.1.3 Experiment 3: Rigidity and Circuit Stability after Shaping. We evaluated the circuit's rigidity and stability after stretching and shaping it. As suggested by Fig. 6b3, increasing L increases stretchability in the rubbery state. Thus, we speculate that a cutting pattern with S = 10 mm and L below 5 mm would be ideal. We laser-cut a Y-slit pattern with parameters S = 10 mm and L = 5 mm and Y-slits arranged in a 60 mm-diameter circle on an 80 × 80 mm sample. The sample was molded on a hemispherical mold at 65°C and cooled down to room temperature. Fig. 6d shows that the sample remains physically intact under a load of 60 N and electrically functional after loading.

In conclusion, Y-slit patterned LTTPs with parameters S = 10 mm and L < 5 mm have appropriate material properties with sufficient mechanical strength and improved stretchability without compromising circuit stability. These parameters are adopted to tool for body-conforming.

6.2 Enhancement of Shear Displacement

The sensors and electrodes are encircled by a mesh pattern to aid in on-body fitting and fine-tuning of sensor and electrode placement. This design allows for localized deformation without affecting the perimeter. This pattern's mechanical strength and electrical stability are described below.

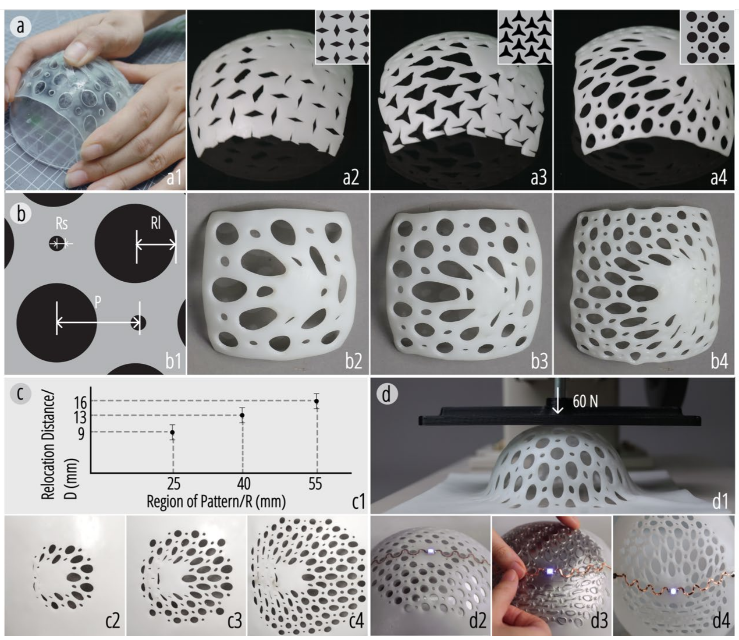

Fig. 7. Parametric cut pattern characterization for inner relocation of electronic components. (a) (a1) Setup of shear displacement test and (a2) Experiment 1: three patterns selection for shear displacement; (b) A biholar pattern characterized by hole radius Rl, Rs, and pitch P; Experiment 2: hear displacement test to the biholar pattern with different hole sizes and densities; (c) Experiment 3: center displacement related to patterned area; (d) Experiment 4: (d1) rigidity and (d2-d4) circuit stability test.

As shown in Fig. 7, we used 80 × 80 mm LTTP sheets and laser-cut various patterns with varying sizes and densities. The center area (15 × 15 mm) of the test sheets was left uncut for attaching electronics (e.g., electrodes, here an LED as a proof of concept). After being heated, the sample was molded on a hemispherical mold. The center was sheared toward the edge until the sample cooled. Each sample's maximum center displacement was measured and compared in Fig. 7.

6.2.1 Experiment 1: Patterns Selection for Shear Displacement. We first measured the displacement of the center on three different cutting patterns - diamond (resembling the rotating square model), star (resembling the rotating triangle model [46]), and biholar (alternating large and small circles) [15] (Fig. 7a). In each pattern, we regulated the distance between adjacent center cuts to 3 mm, leaving sufficient space for routing the circuit. The results indicated that the center of the biholar pattern with alternating large and small circles could be displaced by 19 mm, whereas the centers of the diamond and star patterns can only be displaced by 8 mm and 12 mm, respectively. We chose the biholar pattern for sensor placement and tested its properties further.

6.2.2 Experiment 2: Hole Size and Density. To determine the appropriate pattern parameters for internal mobility, we conduct the shear displacement test on a hollow pattern with varying parameters. Three parameters can affect the internal displacement of a hollow pattern with large and small holes: the radius of the large circle (Rl), the radius of the small circle (Rs), and the pitch (P). The difference in hole diameter produces a difference in the polarization of the hole pattern, thereby influencing the compression direction. When an area of the pattern is compressed, the large voids will flatten along the direction of compression, whereas the small voids will flatten perpendicular to the direction of compression.

The optimal maximum distance of relocation is achieved when the shape of the circles in the direction of movement is compressed to a slit. We experimented with various parameter combinations at a ratio of 1:2:4, ensuring that the sum of the diameters of large circles in the direction of compression remained constant. Fig. 7b demonstrates that small size combinations (Rl = 3 mm, Rs = 1 mm, P = 7 mm) allow for a greater inner mobile distance (19 mm) than proportionally enlarged hollow patterns (13 mm and 7 mm) in the same distribution space. Consequently, we selected this combination of parameters for the ThermoFit intelligent orthosis.

6.2.3 Experiment 3: Sensor Displacement vs. Patterned Area. To reduce fabrication time and maintain material integrity, we developed three samples with identical pattern parameters R2, R2, and P, each covering a different section of a sheet. As illustrated in Fig. 7c, the diameters of the patterned areas are 25 mm, 40 mm, and 55 mm, respectively. Each sheet measured 80 × 80 mm and was formed on a hemispherical mold (R = 30 cm) by shearing the sheet's center. Each sample had a center displacement of 9 mm, 13 mm, and 16 mm, respectively. The ratios between center displacement and diameter of pattern dispersion were 0.36, 0.33, and 0.29 respectively. Although the trend is somewhat decreasing, it is nearly linear, indicating that the range of displacement may be roughly adjusted by adjusting the pattern distribution area when constructing the entire pattern.

6.2.4 Experiment 4: Rigidity and Circuit Stability after Sensor Displacement. To validate the circuit stability after sensor displacement, we fabricated a functional circuit that illuminates an LED on a biholar-patterned LTTP sheet and thermoformed it into a dome. Throughout the entire procedure, the linked multimeter displayed a steady reading and the LED remains lit. We then placed a 3.75 kg load on top of the dome to determine its rigidity. The sample did not change while loading.

6.3 Enhancement of Elasticity

Elasticity plays a vital role in orthotic applications that need cyclic bending and rebounding, such as physical therapy. Compared to ductility, elasticity is the capacity to recover to the constructed shape when the orthosis is in use. We examine the critical Kirigami design factors that enhance the elasticity of the metamaterial structure.

6.3.1 Pattern Design for Elasticity. As shown in Fig. 8a, we began by evaluating a Kirigami pattern consisting of an array of thin beams that has been widely employed [18]. However, the LTTP sheet is thicker than materials often used in other publications, such as PET film, paper, and cloth. Furthermore, we must also consider circuit route spacing.

Inspired by [24], we added two notches to the ends of the beams (Fig. 8b) and created non-prismatic kirigami beams, which resulted in a significant enhancement in deformability and stiffness control. This pattern is referred to below as the fork pattern.

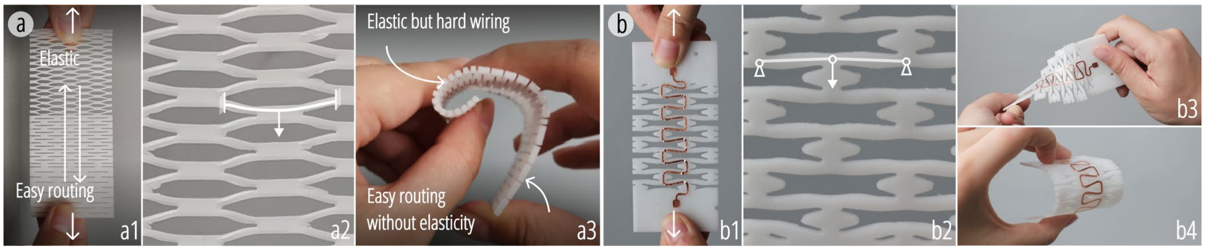

Fig. 8. Pattern iteration for elasticity. (a) Kirigami (Parallel lines) cannot balance elasticity and sufficient spacing for easy routing; (b) Kirigami with minor cuts at the end (Fork pattern) enhance the elasticity with sufficient spacing for circuit routing.

6.3.2 Experiment 1: Parametric Design of the Fork Pattern. The elasticity is quantified by measuring the spring constant, which is the ratio of the applied force to the displacement when the material shows fully elastic behavior. We evaluated the elasticity of fork patterns using three distinct parameter combinations. Similar to the tensile test described in Section 6.1, the sheets with fork designs were stretched at room temperature. The result demonstrates that spring constants K = 5.38 N/mm, 1.69 N/mm, and 0.57 N/mm have varying degrees of elasticity (Fig. 9a).

In addition, we conducted bending tests on precut samples comprised of varying fork densities enclosed within a thin cylinder (Fig. 9b). The diameter of the cylinder was 14 mm, and its length was 50 mm. Under a load of 200 g, the cylinder whose fork density is greater has a greater bending displacement.

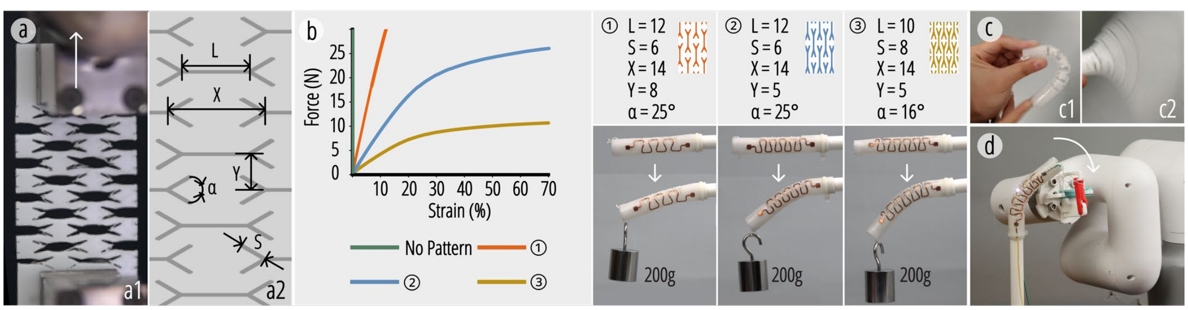

Fig. 9. Parametric cut pattern characterization for enhancing customized elasticity. (a) Tensile test for sheets of fork patterns with different parameters in Experiment 1; (b) Bending test of a cylinder of fork patterns with different parameters with circuits in Experiment 1; (c) Elastic deformation demonstration of a cylinder with fork patterns; (d) Experiment 2: circuit stability and structure durability test of 1200 times bending.

6.3.3 Experiment 2: Circuit Stability under Cyclic Bending. We evaluated circuit stability when the samples were subjected to cyclic bending (Fig. 9d). Using an Avometer-charged LED on a cylindrical sample, we bent it to 60° and 1200 times in 40 minutes. The LED remained intact and the circuits remained steady after being bent 1200 times. Eventually, the cylinder was bent by 5 degrees.

Overall, we select appropriate metamaterial structures and corresponding parameters for customized smart orthoses. The findings of these experiments (shown in Table 2) are adopted to the prototype design tool in the next Section.

Table 2. Summary of parametric patterns characterization for physical properties customization.

Enhance Goals	Considerations/Requirements of Balance	Results
Thermoforming stretchability	Sufficient mechanical strength, circuit stability	Selected parameter arranges (S = 10 mm, L < 5 mm); L ∝ Stretchability
Relocation arrange	Sufficient mechanical strength, circuit stability	Selected patterns (Biholar); Selected parameters (Rl = 3 mm, Rs = 1 mm, P = 7 mm); Distribution area ∝ Relocation arrange
Elasticity (tensile & bend)	Easy routing, circuit stability, durability	Optimized patterns (Fork); Slit density ∝ Elasticity

7 THERMOFIT DESIGN TOOL

We design and implement an interactive design tool to assist the design process of creating body-fitting and adjustable smart orthosis. The structure's parameters are based on the thermoforming metamaterial structure's test results. The application is created using Python and Rhino plugins (e.g., Grasshopper [71]). In this section, we describe the workflow and function of our tool's usage.

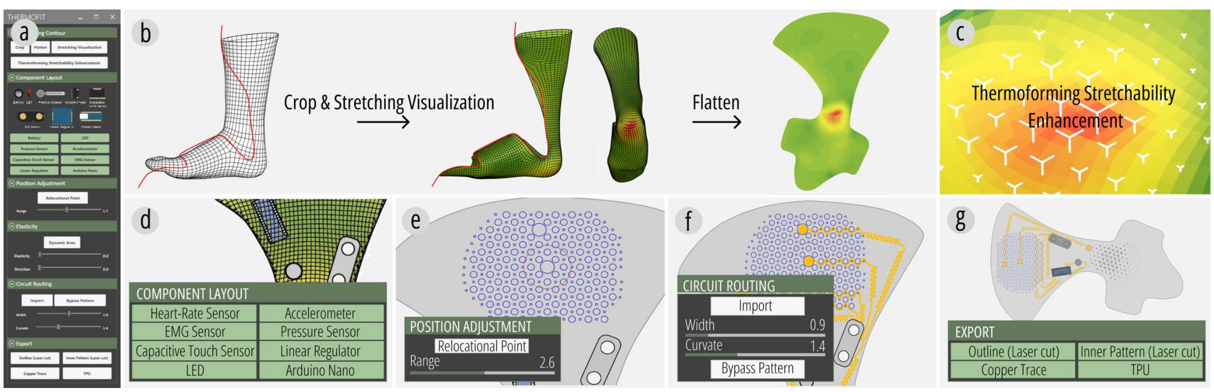

Fig. 10. (a) Interface of the design tool; (b-g) Example of software workflow: (b) flattening the target 3D shape based on the input model; (c) auto-generating Y-pattern to enhance the conformity to surface based on stretch analysis; (d) designing component layout through avoiding overstretch areas (red region of stretching visualization); (e) customizing adjustable arrangement; (f) arranging circuit routing; (g) exporting files.

Flattening the targeted 3D shape. The first step is to achieve a flattened shape for the orthoses that correspond to the human body and orthopedics (Fig. 10b). The procedure consists of three steps: (1) import a pre-modified 3D model of a target body part, providing a shape reference for the following design. Users can obtain this 3D shape by modifying the 3D model scanned by a 3D scanner (e.g. a mobile application (e.g., Trnio 3D scanner or hand-held 3D scanner) according to the orthopedic needs from the medical perspective; (2) drawing the desired outline of the smart orthosis on 2D or 3D perspective view to extract and trim the target shape of orthosis; and (3) flattening the non-developable curved surface (curved in two directions). This command flattens each mesh into a uniform 2D surface by minimizing changes in facet and edge length.

Visualizing and enhancing the degree of thermoforming stretchability. To assist with body-fitting shaping and component layout, the design tool can calculate the stretch rate of each mesh based on the ratio of its area before and after flattening (Fig. 10b). Our tool will mark the entire surface with a color gradient from green to red, corresponding to the stretch rate from low to high. In other words, the expanding regions will appear in red, while the unchanging regions will appear in green. In addition, the local distribution of the thermoforming stretch enhancement metamaterial structure (Y-slit pattern in section 6.1 and Fig. 10c) will be automatically generalized, allowing for improved body-fitting with fewer folds. We compute the stretch rate (R) at the location of the array of dots with a pitch of 10 mm and set the parameter L of the "Y-slit" pattern so that it is centered on the corresponding points. Based on the results of the experiment described in section 6.1, areas with a 30% stretch rate will be filled with the Y pattern with 5mm L, whereas areas with a stretch rate below 5% will not be filled with Y patterns (L = 0). Additional Y-slit patterns can be added for specific purposes, such as reducing the trim during long-term body-fitting adjustments.

Customizing the dynamic area and elasticity. If a dynamic orthosis is required, which means some parts of the orthosis should be able to move with the body, users can select the target parts (such as joints) and convert them to dynamic and elastic parts with customized elasticity. We allow users to set the elastic direction and elastic stiffness (High elasticity (0.57 N/m) to low elasticity (5.38 N/m), incorporating the experimental results of elastic metamaterial structure (Section 6.3).

Designing Component Layout and Adjustable Area. To facilitate the design of orthoses with digital sensors, our software enables users to select electronic components from a database and position them on a 2D surface (Fig. 10d). To improve the stability of components during thermoforming, users are advised to position the components on a relatively flat area with slight tensile force, as depicted by the green area in the thermoforming tensile visualization. Then, users are required to set the radius of the adjustable area for the metamaterial structure (hollow pattern) that surrounds the critical electronic components. Our tool is capable of calculating the position and size of each pattern and displaying them per the experiment settings and results in section 6.2 (Fig. 10e).

Arranging Circuit Routing. Our design tool allows users the freedom to draw circuit lines on the surface as they see fit. If the circuit is inaccessible in practice, such as when passing through the metamaterial structure's cutting areas, it will be rerouted automatically to ensure usability. In addition, instead of straight lines, we use wavy, serpentine wires to connect interpolated points for greater stretchability and stability (Fig. 10f). In summary, users can export the custom-designed outline and inner pattern of the thermoplastic sheet to the laser cutter and the shape of circuits to the cutter plotter (Fig. 10g).

8 FABRICATION PROCESS

We present a novel smart orthosis fabrication workflow. It enables designers, makers, engineers, and HCI researchers to rapidly fabricate electronic boards/sheets with common laboratory tools and enables clinicians to thermoform smart orthoses with their current skills and tools. The fabrication procedure for the intelligent orthosis consists of five stages: (i) laser-cutting outline of a thermoplastic substrate, (ii) cutting and heat-stamping copper trace, (iii) laser-cutting metamaterial patterns, (iv) assembling electronic components, and (v) thermoforming and shaping until cooling down (Fig. 11).

8.1 Laser-cutting Outline of Thermoplastic Substrate

Using a standard CO_2 laser cutter (57-9060, Vollerun), we begin the fabrication process by laser-cutting low-temperature thermoplastic sheets (LTTPs) to the desired shape (Fig. 11a). To facilitate subsequent operations, the layout of the corresponding circuit and electronic components is lightly marked on the surface (at a speed of 100 m/s and a power of 10%). For components with protrusions on the bottom or which must be arranged on the back of the thermoplastic substrate (such as pressure sensors and EMG electrodes), the corresponding holes for embedding or penetrating are drilled.

8.2 Cutting and Heat-stamping Copper Trace

ThermoFit uses a commercial cutter plotter (CA16, YiTu) to fabricate copper circuit traces. During the thermoforming process, we introduce a thermal bonding film (TPU) as a phase-changing adhesion interlayer to reduce cracks caused by delamination between layers. Thin, conformable, and heat-resistant TPU film with a thickness of 0.15 mm adheres to a sticky cutting sheet, and flexible copper-clad tape (FR7031, DuPont) is applied over the TPU film. Copper (the upper layer) is cut into circuit traces (at a speed of 100 m/s and a knife pressure of 15) and the bottom TPU film interlayer is cut into an offset shape of copper trace distribution area (at a speed of 100 m/s and a knife pressure of 100) (Fig. 11b1). After removing the excessive copper sheet, users can laminate the copper trace with the TPU film substrate onto the corresponding position of the thermoplastic sheet, using a hand iron at 120°C for 30 seconds (Fig. 11b2-4). The TPU film adheres the copper trace and the thermoplastic sheet together.

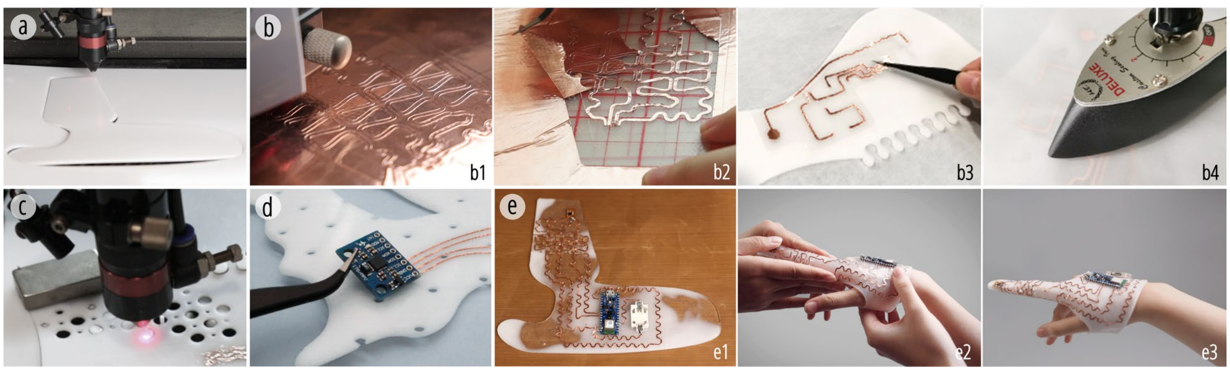

Fig. 11. Fabrication process: Prefabricating circuit board, including (a) Laser-cutting outline of a thermoplastic substrate; (b) Cutting, transferring, and heat-stamping copper traces; (c) Laser-cutting metamaterial patterns; (d) Assembling electronic components. (e) Thermoforming smart orthosis by clinicians, including (e1) heating and (e2) shaping on the body till it (e3) cools down.

8.3 Re-Laser-cutting Metamaterial Structure Pattern

For the area where copper traces needed to pass through the metamaterial structure pattern, we reinsert the substrate with copper traces into the laser cutter, align it with the original position, and cut the metamaterial structure patterns to both layers (TPU film and thermoplastic sheet) (Fig. 11c).

8.4 Assembling Electronic Components

After integrating circuits and the target substrate with the metamaterial structure, we connect the copper traces with other electronic components (Fig. 11d). It is verified that ThermoFit supports three standard connection methods: (a) conductive silver paste (Kemo-electronic) [12]; (b) conductive double-sided tapping (3M 9703); (c) soldering.

8.5 Thermoforming and Shaping

After integrating LTTPs and electronics, the customized thermoplastic sheet can be sent to a seasoned clinician for thermoforming in the clinic or studio. Similar to the common fabrication procedure of traditional thermoplastic orthosis (session 2.2), the thermoplastic sheet with electronics can be heated in the clinic or studio with common tools, such as a heat plate or heat gun (Fig. 11e1). During thermoforming, the clinician places the heated thermoplastic sheet on the patient's body or a mold modified from the patient's body shape, controls the overall external shape and the placement of critical electronic components (e.g. electrodes), and maintains the shape as the material cools back to rigidity (Fig. 11e2).

After thermoforming a smart orthosis, the clinician can install the battery and test the patient's structural and electronic function while the device is powered up. If adjustments are necessary for optimizing or adapting to physiological changes in the body and pathological conditions, the clinician can reshape the orthosis by reheating the local area or the entire device and applying electronics to the new position.

9 EXAMPLE APPLICATIONS AND USE CASES

Several examples of customized smart orthoses were implemented to validate the strengths of ThermoFits in terms of conforming to complex body shapes, body shape change, and accurate placement.

9.1 Long-term Ergonomic Fitting Iteration: Scoliosis Brace

ThermoFit enables the body to adapt to different stages of development. During long-term rehabilitation, we provide a pressure-sensor-based scoliosis orthosis that monitors the wearing time and level of fitness (Fig. 12). As the user ages and the angle of the scoliosis curve changes, the existing orthosis pressure point may cause excessive or inadequate force. This will be detected by the pressure sensor of the smart orthosis and serve as a reminder for re-examination and adjustment to the physician, clinician, patient, and family members. In addition, the Y-slits pattern improves the thermoforming extensibility of orthoses; consequently, the orthosis can be reshaped to accommodate growth and varying rehabilitation demands.

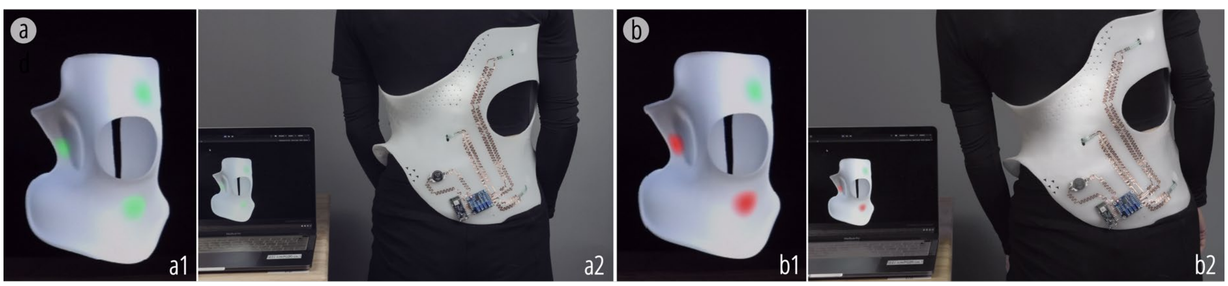

Fig. 12. Smart scoliosis orthosis conforming to the growth or body-shape change of users. The pressure monitoring and visualization of key pressure points.

9.2 Adjusting Electronics Placement and Complex Surface Fitting: Ankle-Foot Orthoses

ThermoFit enables the customization of electronic component placement for body fitting. We present intelligent ankle-foot orthoses (AFO) with electromyographic (EMG) technology for patients with cerebral palsy or foot drop. By placing the electrode on the gastrocnemius muscle, the intelligent AFO can monitor the signal generated by muscle activity. As depicted in Fig. 13, the EMG value increases abruptly when the user is on their toes and the corresponding muscle is contracting. During rehabilitation, the EMG signal can be used to detect gait performance and muscle activation. The placement of electrodes is crucial for the quality of the EMG signal. If the electrodes of EMG sensors are not properly positioned, they will pick up noises. As depicted in Fig. 13g, the hollow pattern surrounding the electrodes enables the operators to relocate the placement of electrodes by reheating and dragging them directly on the human body. In addition, Y-slits on heels facilitate the smooth conforming to a highly curved shape.

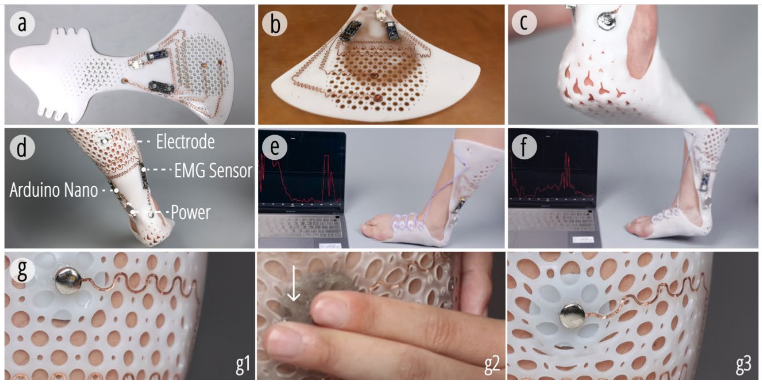

Fig. 13. EMG monitoring Ankle-Foot Orthoses that fits complex surface and allows electrode placement adjustment: (a) A flat ThermoFit AFO as fabricated. (b) Heating to soften state. (c) The AFO fits perfectly onto the foot through the enhancement of local thermoformability at the heel. (d) Electronics on AFO. (e-f) EMG monitoring muscle movement. The value of EMG goes up when the muscle is in contraction. (g) Adjusting the position of the electrode in the area with biholar patterns.

9.3 Conforming Dynamic Body Movement: Finger Extension Splint

ThermoFit conforms to body movement with elasticity. We customized a smart dynamic finger extension splint for rehabilitation of the index finger's extensor tendon injuries or spasms (Fig. 14). The elastic structure keeps the finger straight when the user does not exert any force and provides a reaction force when the user actively bends the fingers, thus avoiding joint stiffness and muscle atrophy. The smart dynamic splint monitors the bending of the finger through an acceleration sensor on the fingertip. In addition, we developed a functioning game that enables users to control the aircraft through bending motion, to enhance users' willingness and compliance with self-rehabilitation and exercise. The 3D spring is made of a thermoplastic sheet without extra accessories or long printing time. It fits the shape of the fingers, adapts to the movement of the joints, and maintains the stability of circuits on it.

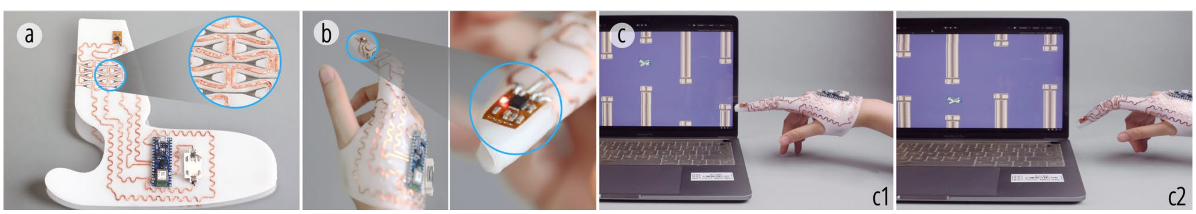

Fig. 14. A finger extension splint with a 3D high-density spring for finger treatment. (a) A flat circuit board as fabricated. (b) After shaping the body, it turns to the smart finger extension splint which monitors the bending of the finger with an acceleration sensor at the fingertip. (c) The fork pattern at the joint keeps the finger straight when the user does not exert any force and provides a reaction force when the user actively bends the fingers. The functioning game enables users to control the aircraft through bending motion.

10 HANDS-ON EXPERT STUDY & EVALUATION

10.1 Hands-on Expert Study

To determine the usability of ThermoFit prefabricated circuits sheet for clinicians without electronics and design skills to thermoform a smart orthosis with minimal effort, we asked a clinician with 16 years of experience in customizing orthoses to thermoform a smart orthosis in his clinic.

10.1.1 Procedure. Before the study, we designed and prepared a layer of LTTP substrate with circuits, using a 3D model with three clinician-marked support points. This study focuses on scoliosis; the custom orthosis conforms to a body mold and applies corrective force to the spine.

We went to the clinic of the clinician and conducted a study in three sessions: (1) a 15-minute introduction session, (2) an operating session, and (3) a semi-structured interview session. We began the study by introducing ThermoFit, along with the scope of the study, the function of metamaterial structures, and the application examples described in the previous section. Then, we demonstrated the prefabricated thermoplastic sheet and instructed the clinician to thermoform the scoliosis orthosis (Fig. 15) on a mold while ensuring that the pressure sensors were correctly positioned on the three major support points along the scoliotic curve. Using the think-aloud method, we encouraged the clinician to freely communicate his thoughts and questions throughout the entire surgical procedure. Finally, we conducted a semi-structured interview to comprehend the thermoforming smart orthosis experience.

Fig. 15. Scenarios of hands-on expert study: Clinician completed the fabrication steps of heating and shaping orthosis, correcting electrode placement, and turning on the electronic function with battery installment.

After the study, the observed user behaviors, the think-aloud records, and the interview transcripts were refined using thematic analysis [6] and open coding [53].

10.1.2 Results. The clinician was able to complete the task. We observed that he encountered no difficulty throughout the heating and shaping processes. We described the themes of findings induced from the observations, think-aloud records, and transcribed interviews.

Ease-to-learn and ease-to-operate of thermoforming. The participant completed the heating, shaping, and cooling processes in a single 30-minute session. In post-study questionnaires, participants reported that the ThermoFit workflow for thermoforming a smart orthosis is simple to learn (score of 6 on a 7-point Likert scale, where 1 represents strongly disagreeing and 7 represents strongly agreeing). Prefabricated thermoplastic with slit structures and circuits were shaped without difficulty. While the pre-cut sheet in flattened orthosis shape with embedded electronics required a brief check to identify the outer and inner sides and avoid upside down, which is additional and slightly different from fabricating traditional orthoses with entire sheets, the participant finished these quickly and independently. In addition, the participant's familiarity with LTTP's material allowed him to confidently use his prior experiences and routines with making traditional thermoplastic orthoses, such as setting the temperature of the heat bed, giving priority to the fixation during shaping, and installing nylon snap clasps after thermoforming.

Shape conformity and sensor position accuracy with adjustability. The final shape of the smart orthosis closely matches the original mold, and the sensors are positioned as desired. The clinician noted that the slit patterns of metamaterial structures "*do help me to judge and control the degree of stretch; thus, I can align the sensors to desired positions.*"

Electronic stability during thermoforming. The circuits on the orthosis remained intact and firmly attached to the surface of the substrate throughout the heating and shaping process, and the electronics functioned normally after thermoforming and battery installation. While the clinicians were concerned about the adhesion of the circuits and the heat resistance of the electronics, checking the status of the circuits and PCB boards multiple times during the heating of the substrate, he later admitted that the circuits were surprisingly firmly adhered.

Acceptance for clinicians. The participant considered working with ThermoFit to be a "unique" opportunity to explore electronic/sensing aspects of orthosis customization and its application. He prided himself on their ability to fabricate and adjust smart orthosis. He noted that "It is my first time to accomplish a smart orthosis, and it deserves a record." Surprisingly, this novel operation and novel prototype attracted the interest and attention of the colleagues of the participant - other clinicians - who were passing by. After observation and inquiry, they praised the ingenuity of this approach and described it as a rich opportunity of integrating electronics in the form of orthoses for healthcare improvement, initiatively inviting further cooperation in the development of specific smart orthoses.

Recommendation for further clinical practice. When asked about difficulties and suggestions, the participant expressed concern that water may damage the thermoplastics' circuits. He added that the water-proofing property would permit softening the smart orthosis substrate or the shaped smart orthosis in a water tank or other containers such as a pot or washbasin, thereby providing more flexible and efficient heating options for clinical practice and adapting to a wider range of operating conditions. In addition, he anticipated the applicability of this method to other types of thermoplastic materials with varying thicknesses and strengths for a variety of medical applications. Moreover, He proposed cross-client reusability to further improve the fabrication efficiency and costs, adding that "*If we can recycle the electronics afterward and reuse them for the next patient. Maybe the cost of smart orthosis for patients can be reduced.*" These are clinical practice concerns we aim to address in future work (see Section 11).

10.2 Performance Evaluation

This section evaluates ThermoFit through three aspects: (1) the time efficiency of fabrication and iteration, (2) the stiffness of the orthosis with metamaterial structure, and (3) the electronic continuity during the wearing out of the lab.

10.2.1 Efficiency of Fabrication and Iteration. As shown in Fig. 16, the orthosis sheets of example applications can be softened in 17 minutes and cooled and hardened in 4-8 minutes. The incorporation of metamaterial structures into thermoplastic sheets accelerates thermoforming by enhancing heat conductivity.

Application	Volume (L x W x H mm)	Laser Cutting Time (min)	Circuit Cutting and Assembly Time (min)	Thermoforming (min)		Total Time (min)	Iteration Time (min)
				Heating	Shaping & Cooling		
Scoliosis Brace	210 x 340 x 310	20	17	17	8	62	25
Ankle-Foot Orthosis	200 x 130 x 310	12	15	13	5	45	12
Finger Splint	185 x 80 x 50	6	12	9	4	31	/

Fig. 16. Time efficiency of fabrication and iteration of ThermoFit smart orthoses in Section 9.

Since ThermoFit converts 2D electronic boards to 3D smart orthosis, the fabrication time is much shorter than other fabrication techniques such as 3D printing. 3D printed scoliosis orthosis without a circuit requires 34 hours and 13 min (calculated by 3D slicing software on an FDM 3D printer), while ThermoFit only requires 20 minutes and an extra 17 minutes to fabricate and assemble the circuit. The shape of smart orthosis can be easily adjusted when reheated. Therefore, it shortens the iteration time.

10.2.2 Mechanical stability. To characterize the protection and support provided by ThermoFit orthoses, the mechanical stability was evaluated by applying a load to simulate a cantilever bending test. The test sample was a wrist brace with Y-split structures distributed all over to accommodate edema (localized swelling). The arm end of the brace was secured with a clamp. 15 hours were spent applying a load to the wrist area of the brace 43 mm away from the clamping point. A camera captured the orthosis's fatigue process, helping us measure the difference between the initial state and the state after 15 hours of load application. After 15 hours, we removed the weights and compared the shape of the brace to its original state.

The result is shown in Fig. 17. After bearing a load of 1.25 kg for 15 hours, the brace had a slight deformation. Specifically, the thumb end of the brace dropped 2 degrees relative to the clamping point (Fig. 17b). After the weights were removed, the brace deformed by 0.80 degrees relative to its initial state (Fig. 17c). As a comparison, we also tested an existing wrist orthosis from a hospital, and the angle of shape-changing is only 0.1 degrees different from ThermoFit. Overall, the ThermoFit sample met the orthotic brace's strength requirements.

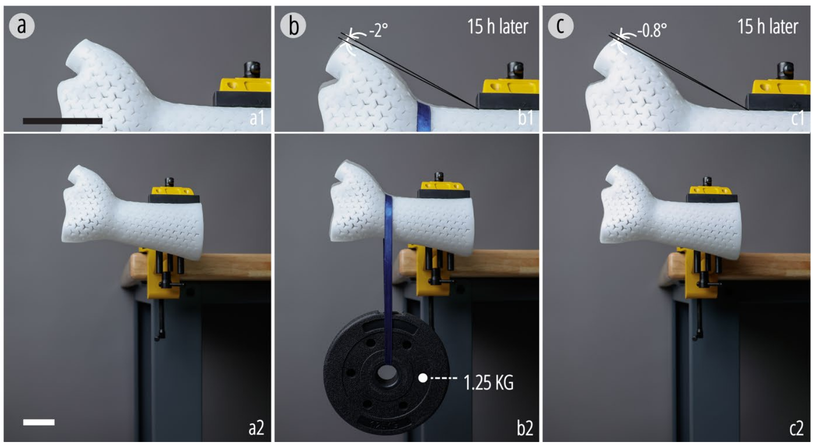

Fig. 17. Stiffness test: (a) The initial state of the ThermoFit wrist orthosis with Y-slits; (b) Deformation of the orthosis under 1.25 kg loading for 15 hours; (c) Deformations of the orthosis after bearing the load of 1.25 kg for 15 hours and removing the load. (Scale bar: 5cm)

10.2.3 Electronic continuity. This section evaluates the electronic stability of ThermoFit smart orthoses. Participants were asked to wear smart orthoses for two hours while engaging in typical daily activities (such as group discussion) outside of the lab.

Three participants took part in the experiment and wore the custom orthoses described in Section 9. The ankle-foot orthosis wearer and the scoliosis orthosis wearer were instructed to wear their ThermoFit orthoses for a total of two hours with the battery plugged in while engaging in normal daily activities. For the dynamic finger-extension splint wearer, we request that she wear the splint for two hours and play the rehabilitation game through finger-bending control for 20 minutes.

During the two-hour study, all three ThermoFit orthoses remained electrically functional and collected all data via BLE. All electrical connections remained solid.

11 DISCUSSION, LIMITATIONS, AND FUTURE WORK

In this section, we discuss the limits of ThermoFit as well as its potential in future clinical practice.

Water-proofing and heat condition compatibility. The clinician hands-on study revealed that the water-proof performance of the electronic components must be enhanced to make the smart orthosis washable for daily use and able to be heated in a variety of containers with hot water, thereby adapting to a wider range of clinical practice situations. This issue can be resolved in future iterations by insulating the PCB and all electrical connectors with a waterproof covering.

Extension of using material structures on different thermoplastic materials. For orthoses with varying structural strength needs, numerous types of thermoplastic materials with varying thicknesses and mechanical qualities are available in clinical practice. Although we have not quantified the effect of metamaterial structures on the performance of other LTTPs, the fundamental idea and design techniques of metamaterial structures can be applied to other thermoplastic materials for the production of smart orthoses.

User experience of the design tool for healthcare professionals. This version of the design tool is a prototype that has not yet been evaluated by clinicians. There is an exciting and valuable opportunity to improve the user experience of the design tool for clinicians customizing smart orthoses, thus further involving healthcare practitioners in the session of designing and customizing smart orthoses. For instance, choosing the placement of vital sign sensors on the 3D models of patients' bodies would be easier than laying them out on the flattened state of the orthosis. Ideally, this clinical CAD tool would feature smart orthosis libraries for a variety of diagnoses and smart healthcare tasks, allowing clinicians to search and customize them for individual clients.

Mass-Manufacturing of thermoplastic circuit boards for in-the-wild deployment. The current method for fabricating thermoplastic circuit boards requires a cutter plotter for fabricating circuit wires and a laser cutter for processing thermoplastic substrates, neither of which are easily available in current clinical settings. If ThermoFit is integrated into clinical practice, we view thermoplastic circuit sheet manufacturing as a valuable possibility. ThermoFit is also compatible with various methods of circuit creation, like conductive inject printing. Electronic components and cables can also be connected using low-temperature soldering, conductive double-sided tape, and other cost-effective, resilient, and readily available construction techniques.

User acceptance for patients. We realized the importance of patient acceptance of orthoses to rehabilitation effect through expert study, but have not evaluated the patient acceptance of ThermoFit customized smart orthoses in this work. Currently, volunteers without health conditions or limitations requiring orthoses wear our application samples. They were not the best candidates to objectively evaluate user acceptability since orthoses are typically uncomfortable when first worn and social acceptance may vary greatly depending on the user's need to weigh tradeoffs. In the future, we will customize smart orthoses for patients who frequently wear orthoses to evaluate ThermoFit's effectiveness in terms of patient comfort [19], acceptance of appearance [5], and satisfaction with other aspects [42,67].

Cross-client Reusability. As the clinicians' hands-on study suggested, reusing electronic components for the next patient can minimize the cost of smart orthosis for patients. It is an opportunity to combine easily attachable and detachable electrical components, which further reduces labor costs and assembly time while enhancing flexibility and reusability.

Sensing techniques and power management. The electronic components used for smart orthoses could be optimized and expanded. Firstly, the smart orthosis can incorporate smaller [62] or more flexible sensors [32] and PCBs, such as sponge pressure sensors. ThermoFit enables them to conform to the human body and permits position modification. ThermoFit can insert additional healthcare functions, such as Functional Electrical Stimulation (FES), within orthoses to aid rehabilitation. Thirdly, actuation control could be utilized to optimize power management. Other energy supply techniques, such as the piezoelectric method for collecting energy from vibration [28], or the thermoelectric effect for collecting energy through heat transfer [40] can be implemented at a cost.

Healthcare Service. The prospective application of this technology in clinical settings could significantly alter how orthoses are utilized and how physicians and patients judge the orthoses' real-time effect. For doctors, patients, and their families, orthoses-related healthcare services such as rehabilitation training games, rehabilitation status visualization, and adjustment reminder can be developed as applications, small programs, or webs.

Beyond Smart Orthosis. Although inspired by smart orthoses, ThermoFit's simple and robust customization of body-fitting and component-adjusting wearables is applicable in other domains, such as electric fashion, sports protection, and rapid prototype for the HCI community.

12 CONCLUSION

We introduce ThermoFit for customizing smart orthoses, whose structure and electronics fit complicated body forms, changes in pathological states, and body mobility while enabling on-the-go adjustments. ThermoFit uses three metamaterial structures on thermoformable materials. They improve the material's local extensibility and internal component displacement in its soft state, and its elasticity in its hard state. Additionally, technical tests validate the stability of the circuit. We offer a design tool to assist in the personalization of orthoses, including body-fitting guidance, local elasticity prediction, and layout display of electronics with the adjustment range of important components. The practical viability and adaptability of ThermoFit are demonstrated by three application examples and evaluations of mechanical stability and circuit continuity. The expert assessment confirms that ThermoFit enables individual therapists to shape and alter smart orthosis.

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