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Towards a digital process chain for the automated manufacturing of pediatric orthoses

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Abstract: Playing and raving are important for child development. Injuries, diseases or congenital deformities can limit them in doing so. Orthoses that support these children, are usually custom made which requires manual labor. In research, 3D-printing of those devices is often proposed. To have a fully digital process chain, additional techniques are required, which are fundamental for the orthosis fit and efficacy. In this contribution we describe all necessary steps from recording a patient's individual anthropometric data to the automated design of structural parts. We show existing approaches and new concepts and highlight difficulties and challenges.

I. Introduction

Diseases and injuries can limit a child's ability to move and play. Causes for orthopaedic treatment are for example fractures, cerebral palsy, or deformities of the limbs [1, 2]**.** Orthoses are used to alleviate the problems that arise as a consequence. Orthoses can be defined as body-enclosing or body-adjacent structures that mobilize or immobilize, limit the range of motion, stabilize, relieve pressure or correct the posture [3]. Orthoses are offered as ready-to-wear products or manufactured individually by an orthotist. Because of the fast growth and large range of needed sizes, orthoses for children are mostly custom-made, which is a labor-intensive and time consuming process. With the increasing availability of additive manufacturing techniques, in combination with improving 3D scanning methods, orthopedic technicians can be supported in the production of patient-specific orthoses. The small size and the smaller forces of children compared to adults increase the applicability of additive manufacturing technologies, as the mechanical properties of the produced parts and the build volume constraints are frequently criticized.

II. Recording anthropometric data

The development and application of an appropriate measuring system is crucial for the fit and effectiveness of the orthosis. Currently, shells and dynamic orthoses are produced by first creating a negative cast. For this purpose, the patient's body is molded with plaster bandages in the desired position. Then the negative cast is filled with plaster in order to make the positive cast which has to harden completely [4]. The method for data acquisition within a digital process chain is usually 3D surface scanning, both in the field of research, and occasionally in the case of commercially available orthoses. The patient's body is scanned directly or a scan of a negative mold of the patient is made. Using movable truss pads, pressure can be applied in specified areas, with position and intensity depending on the diagnosis to treat malposition and take scans in corrected pose [5]. The traditional way of producing custom fit orthoses is a time consuming manual production process. The plaster hardening on the patient's body takes time and restricts the patient, which can be especially problematic for children with an urge to move or when the patient has spinal muscle atrophy. For the digital construction process additional information such as position of bones and joints is crucial information for the design [6]. Furthermore, it is usually necessary to record the patient's shape in a corrected posture, which results in incomplete surface scans as hands or truss pads are recorded instead of the patient's skin.

III. Design process of orthoses

During the design process the orthosis is customized to the anthropometry of the patient. The orthotist shapes the plaster model in order to ensure an optimal fit. On top of bones or correction zones material gets added. To improve the fit some material gets taken off and the edges of the orthosis get designed, etc. Finally, he produces the orthosis by positioning the joints and shaping the shell elements, e.g., by laminating the positive cast or deep drawing of thermoplastics. There are some approaches to use additive manufacturing in the orthopedic field. The design however, often relies on the digital, but manual design of the printed geometry. In some cases, an automated design process is implemented [7]. Shaping a plaster model to the desired shape is time consuming and causes dirt. In many cases additive manufacturing does not save time either, since the orthosis is commonly modeled by hand on the computer.

IV. Approaches for the automated design process

To automate the manufacturing process of custom orthoses, the design of structural parts is calculated and transferred to the additive manufacturing machine. MATLAB (MathWorks, Natick, USA) allows both geometric and structural calculations. STL files can be created directly in this software [8]. Examples for automated design according to this approach are individualized joints for orthoses and exoskeletons [9] or flexible hinge structures for soft robot applications [10].

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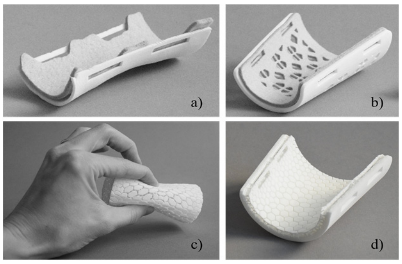

Figure 1: Arm shells for an orthosis manufactured by Selective Laser Sintering with a laser cut felt padding on basis of a 3D scan (a) and measurements (b). Additively manufactured flexible structures (c) that can be used for padding of arm shells (d).

In order to show the feasibility of the automated design process for orthoses, first prototypes of arm shells have been realized. Based on simple surface data or body measurements, a shell was generated (see Fig. 1 a,b). For the incorporation of paddings there are two proposed options. The first one is to automatically generate the cut lines for the desired padding material including the cut outs for better ventilation, which can be directly fed into a laser cutter (see Fig. 1 a,b). The second method is the direct manufacturing of elastic padding zones in the SLS process (see Fig 1 d). These are created by separating a surface into hexagonal tiles. These tiles are interconnected with very thin structures which allow a certain elastic deformation with adjustable stiffness. The benefits of this method are the integration of the padding in the printing process, the variable stiffness in different areas and the air flow between the core body of the orthosis and the padding tiles.

Comfort is an important factor influencing the duration of orthosis wearing time. Frequently occurring problems are unfavorable pressure distributions and heat accumulating under the orthosis. Therefore, these factors were examined in first experiments. For the evaluation of the pressure distribution between the wearers skin and the orthosis pressure sensitive film (Prescale, Fujifilm, Tokio, Japan) with a pressure sensing range from 0.05 to 0.2 MPa was used. The printed cushioning seems to distribute the pressure more evenly than the standard orthosis (Fig. 2). In addition to the printed padding, the fact that the shell was individually adapted probably also plays a certain role.

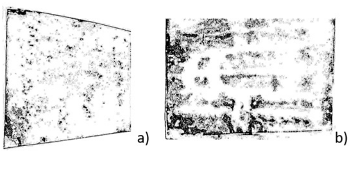

Figure 2: Pressure distribution for the (a) printed padding and (b) a standard orthosis (Epico ROMs, medi, Germany, Bayreuth) applying a weight of 5 kg. Darker shades indicate higher pressures

For the evaluation of the accumulation of heat an individually made arm shell (Fig. 1 b but without holes) and an individually made arm shell with printed padding (Fig. 1 d) were compared. The results suggest that the shell with printed padding (max. temp. 34.6 °C) heats up less than the shell with felt padding (max. temp. 36.5 °C) (Fig. 3). The printed cushion possibly allows improved ventilation between the arm and the shell, reducing the accumulation of heat.

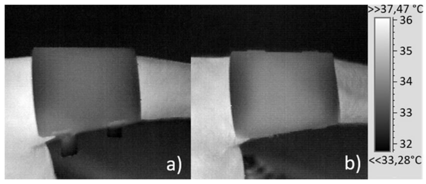

Figure 3: Infrared image of the shell with the printed padding (a) and the shell with the felt padding (b) worn in a climate chamber at 30 °C after wearing them for one hour.

V. Conclusions

In order to ensure a responsive medical treatment, a reduced manufacturing time of orthoses is beneficial. Especially for growing children, a fast and uncomplicated production of a new adapted orthosis is desirable. The automated design saves time and manual labor, since no positive cast has to be created and shaped. First design examples using this approach are presented and first experiments indicate benefits in comfort. Nevertheless, the recording of useful digital body measurement data is still one of the key challenges for a fully digital process chain.

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References

[1] M. Stavsky et al., Cerebral Palsy-Trends in Epidemiology and Recent Development in Prenatal Mechanisms of Disease, Treatment, and Prevention, Frontiers in pediatrics, vol. 5, p. 21, 2017.
[2] E. M. Hedström, O. Svensson, U. Bergström, and P. Michno, Epidemiology of fractures in children and adolescents, Acta orthopaedica, vol. 81, no. 1, pp. 148–153, 2010.
[3] C. Disselhorst-Klug et al., Orthesen, Schienen und Bandagen, in Rehabilitationstechnik, M. Kraft and C. Disselhorst-Klug, Eds., Berlin: De-Gruyter, 2015, pp. 279–338.
[4] D. Hohmann and R. Uhlig, Orthopädische Technik, 9th ed., Stuttgart: Thieme, 2005.
[5] C. Kienzle and M. Schäfer, Integration additiver Fertigungsverfahren (3D-Druck) in den orthopädietechnischen Versorgungsalltag, Othopädie Technik, no. 5, pp. 48–57, 2018.
[6] H. Herr, Exoskeletons and orthoses: classification, design challenges and future directions, (eng), Journal of neuroengineering and rehabilitation, vol. 6, p. 21, 2009.
[7] H. Lin, L. Shi, and D. Wang, A rapid and intelligent designing technique for patient-specific and 3D-printed orthopedic cast, 3D printing in medicine, vol. 2, no. 1, p. 4, 2015.
[8] T. C. Lüth and F. Irlinger, Berechnete Erzeugung von dreidimensionalen Oberflächenmodellen im STL-Format aus der Beschreibung planarer Mechanismen für die generative Fertigung durch selektives Lasersintern, in 10. Kolloquium Getriebetechnik, 2013, pp 267–284.
[9] C. M. Hein, P. A. Maroldt, S. V. Brecht, H. Oezgoecen, and T. C. Lueth, Towards an Ergonomic Exoskeleton Structure: Automated Design of Individual Elbow Joint., in 7th IEEE International Conference, Twente, Netherlands, Aug. 2018, pp. 646–652, 2018.
[10] Y. S. Krieger et al., Fatigue strength of laser sintered flexure hinge structures for soft robotic applications, in 2017 IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS), Vancouver, BC, Sep. 2017, pp. 1230–1235, 2018.