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Polyamide based wrist orthosis generated by selective laser sintering

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Abstract: This study deals with the design and the additive manufacturing of a patient-specific wrist orthosis including integrated functional parts. The orthosis should meet the requirements for a defined clinical picture and at the same time represent the advantages of additively manufactured medical devices. The focus is on constructing the wrist orthosis to a corresponding 3D body scan model as a reference, so that it is exactly adapted to the anatomical body geometry. The subsequent additive manufacturing process of the wrist orthosis is carried out using the selective laser sintering process with the laser sintering system Lisa 1.5 from Sinterit sp. z o.o., Krakow, Poland.

I. Introduction

The possible applications of additively manufactured (AM) medical devices range from medical aids, implants and prostheses to orthoses [1]. Additively manufactured medical devices also have the great advantage to have a very short post-processing time in comparison to conventionally (manually) manufactured medical devices. Instead of this fact, they are more cost-effective (calculating manually work load) and faster available. The reason is the fact that patient-specific medical devices can be tested as a digital model during the design phase. This is even possible with certain mechanical load scenarios and under consideration of the biomechanical requirements of the human musculoskeletal system. [1, 2]. In orthopedics selective laser sintering (SLS) is gaining more and more attention [3, 4]. SLS allows a variety of design possibilities and at the same time the prints are mechanically in a very high quality and also extremely precise [2]. In 2008 M. C. Faustini presented prosthetic socket constructions manufactured using the SLS process [5]. Today, a wide variety of orthopedic products as prosthetics [1, 2] and orthotics [6, 7] are successfully manufactured using the SLS process. The aim of this study is to demonstrate the feasibility of manufacturing an orthosis using the selective laser sintering process without special machine or process knowledge in AM (similar to a user in an orthopedics company). Therefore, only the standard parameters of the machine used are used. The orthosis is nevertheless adapted precisely to the anatomical body geometry of the individual patient. The focus here is on the integration and additive production of movable functional parts that is a direct printed component inside the orthosis.

I.I. Benefit of individual orthoses

Individual orthoses have the great advantage that they can be precisely adapted to the body geometry of the body part to be supported. In addition, the therapeutic requirements can be addressed in a more targeted way, allowing the corresponding clinical picture to be optimally treated. In contrast to the prefabricated orthosis the patient experiences a significantly improved wearing comfort and thus a significant improvement in the quality of life over the wearing time with individual adjustment. Prerequisite for manufacturing of an individual orthosis is the precise acquisition of the dimensions of the corresponding body part. The main advantage over the traditional gypsum modelling technique is that it is possible to reproduce every working step right up to the digital basic model and, if necessary, make changes to the CAD model. Simulations are also available for e.g. weight optimization in the design of the construction.

II. Material and methods

The LISA 1.5 model from Sinterit sp. z o.o., Krakow, Poland, a desktop printer is used as the laser sintering system. The chamber is limited, therefore the device is particularly suitable for the production of smaller high-precision series and individual components. The principle of the system differs somewhat from conventional SLS systems in terms of beam guidance. Instead of solid-state lasers and deflecting mirrors a diode laser is used. It is driven by stepper motors via a belt drive and guided onto an x-y slide rail system. The individual manufacture of additively manufactured orthoses is initially carried out by digitally capturing the shape of the human body or the part of the body to be treated. For the digital acquisition structural light 3D scanning systems are used according to the state of the art. These systems deliver high-quality scans of the human body with a point accuracy of up to 0.1 mm. The body scan model is then usually as a STL data format on which the orthosis is designed after that using a CAD program (SolidWorks, Dassault Systèmes, France). In this study a 3D-Scan of a human arm of the company Artec 3D from Luxembourg was used. Magics V.22.03 software from Materialise NV, Belgium followed by Sinterit Studio 2019 V.1.3 was used to prepare the print for production.

III. Results and discussion

The shape of the orthosis is created from the scan of a human arm. To do this, the affected area is isolated and an offset over the surface contour was created (see Figure 1). This guarantees an individual fit. One of the requirements placed on the orthosis is the saving of material and thus also the saving of weight. The basic design shows that by

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integrating an air-permeable honeycomb structure it is also possible to integrate an attractive design. Figure 2 shows the integration of a hinge to realize a degree of freedom for moving the wrist in one rotational axis (immobilization in left and right but 30deg freedom of movement in up and down). The angle allows some hand function ability to perform his or her daily occupations or return to work e.g. for patients with rheumatoid arthritis [8]. Nevertheless, the wrist is aligned and stabilized. The overall printed orthosis shown in figure 3 is made by using the material polyamide (PA12 - smooth) from Sinterit at a layer thickness of 0.125 mm and the standard settings of the device for laser power and installation chamber temperature. After AM process, no effects such as curling, cracking or imperfections were found on the samples.

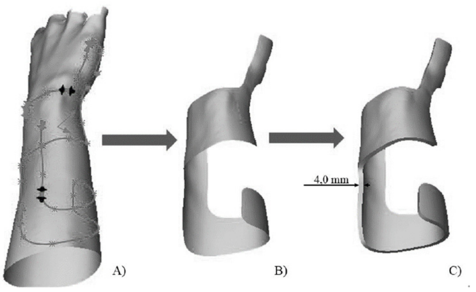

Figure 1: Isolation of the technically relevant contours (Process follows steps A to C)

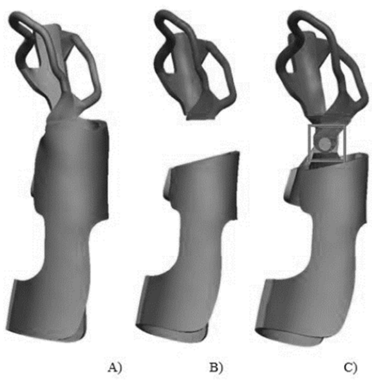

Figure 2: Integration of a joint for the control of mobility (Process follows steps A to C)

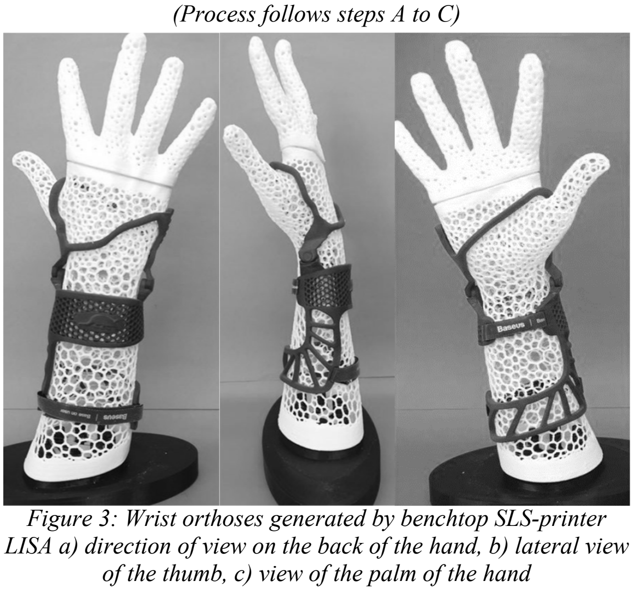

Figure 3: Wrist orthoses generated by benchtop SLS-printer LISA a) direction of view on the back of the hand, b) lateral view of the thumb, c) view of the palm of the hand

A comparison with an arm printed by using Fused Deposition Model-ling (also originally scan from Artec 3D, printed by Replicator Z18, Makerbot Inc., U.S.A.) shows excellent fitting accuracy without exposing the orthosis to mechanical stresses. Wear and fitting studies with a test person (see fig. 4) also showed that the orthosis fits as planned and that the desired movement restrictions, but also the planned degrees of freedom of movement are well implemented.

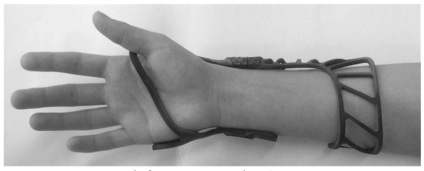

Figure 4: Wear and fitting study (woman, age 15 years)

IV. Conclusions

The sample can be used to show that an orthosis can be produced without special requirements for the 3D printer and with basic CAD knowledge. Selective Laser Sintering allows a setup without any supporting structures. Compared to Fused Deposition Modelling (FDM), these do not have to be removed and thus do not leave any contact points on the surfaces. However, it is indisputable that the material costs are higher by a factor of 2 compared to FDM (60€/kg vs. 30 €/kg) in our case. But simple commercially available powder materials are suitable for such applications.

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Author's statement

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