Digitization in the Orthopedic & Prosthetic Industry: From 3D-Scan to Orthopedic Aid

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Abstract

In the O&P Industry, digitization allows for a faster and more precise process to create customized orthopedic aids. From 3D Scanning to a printed orthopedic aid, it is however a challenge to integrate these technologies into a traditional industry.

Keywords: 3D body scanning, 3D printing, Orthotics, Prosthetics

1. Introduction

The digital healthcare market is becoming increasingly attractive due to the driver of digitization, which explains its integration into orthopedic care. However, the orthotic and prosthetic industry (O&P industry) is an old-fashioned industry that has not seen a lot of change during past years and still heavily relies on skilled craftsmanship [1].

2. Digital process to create an orthopedic aid

The first iteration in integrating digitalization into the O&P industry is to create a digital alternative of the steps being done in the traditional workflow.

In order to create customized orthopedic aids, the certified prosthetist / orthotist (CPO) casts in the first step during the manual process the patient's body part he wishes to treat. The digital step that replaces this process is to gather the patient's anatomical data with 3D scanning [2].

The orthopedic technicians can be reluctant to try out such technologies, for the reasons shown in figure 1.

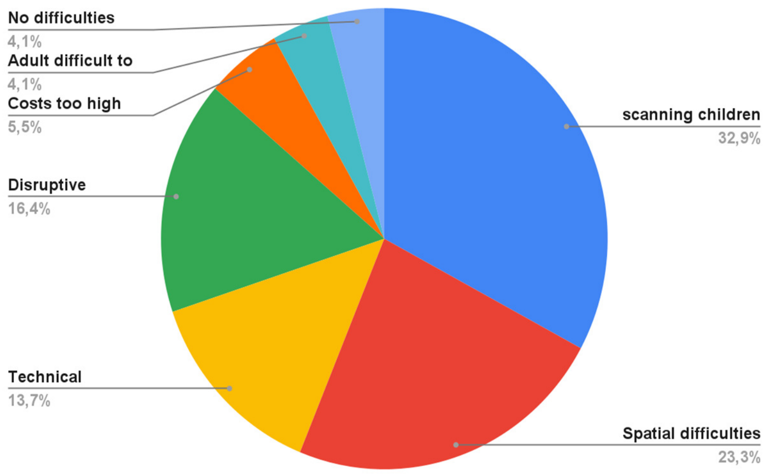

Figure 1 : Opinion poll made by Mecuris GmbH, concerning the difficulties in scanning for orthopedic technicians in Germany [3]

However, the advantages of scanning, in comparison with plaster casting, are considerable. Often mentioned are the comfort of the patient, the possibility to scan everywhere, the reduction of used material (plaster) and savings in production time. [4]

The main 3D scanning technologies we will cover in this paper are infrared laser triangulation and structured light. In order to choose the proper scanner, the following properties are considered: 3D Accuracy , 3D Resolution, technology, color capture, tracking capability, 3D frame rate and output formats. Some formats like .obj allow the orthopedic technician to scan with colors or texture. Therefore, annotations can be marked on the patient, and later be helpful in the digital creation of the orthopedic aid.

The next step in the traditional workflow would be to create the orthosis manually with various tools and machines on which the CPO's are trained during their education. The digital equivalent of this would be the digital processing step in the digital process chain (figure 2).

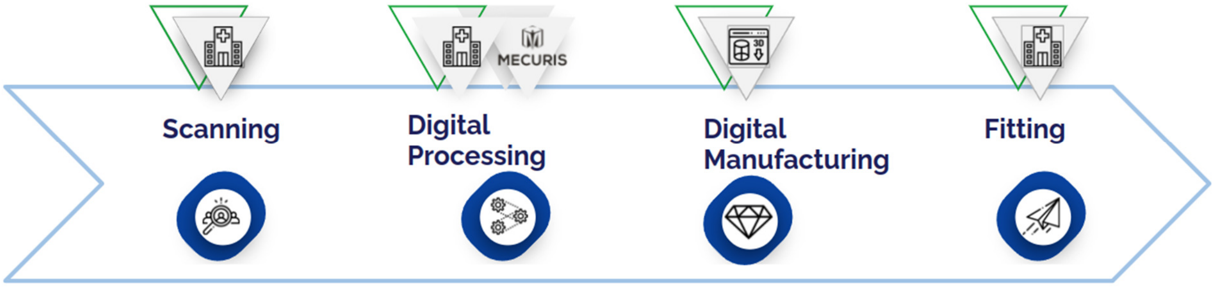

Figure 2 : The digital process chain to create a custom orthopedic aid, according to Mecuris GmbH

In this paper, we will show the digital process chain through the example of the creation of a transtibial socket for a transtibial amputee.

After the scanning, the patient's limb is uploaded into a modeling software (for example as provided by Mecuris GmbH). It allows the orthopedic technician to reproduce the modeling steps digitally. The important steps in the modeling of a transtibial residual limb are the reduction of the limb around the tibia area as well as on the calf and the control with measurements, as shown in figure 3.

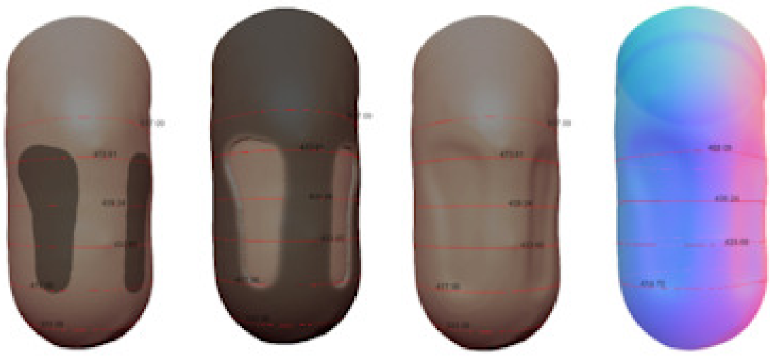

Figure 3: Digital modeling of a transtibial residual limb. Measurement check during volume reduction next to the tibia and below the art. tibiofibularis proximalis.

Once the modeling is complete, it is followed by the manufacturing process. The shape of the socket is again created via software. It can then be exported and sent to a 3D printer world-wide, reducing the need for shipping the final shape to the workshop, where the technician can finalize the socket and fit it to the patient.

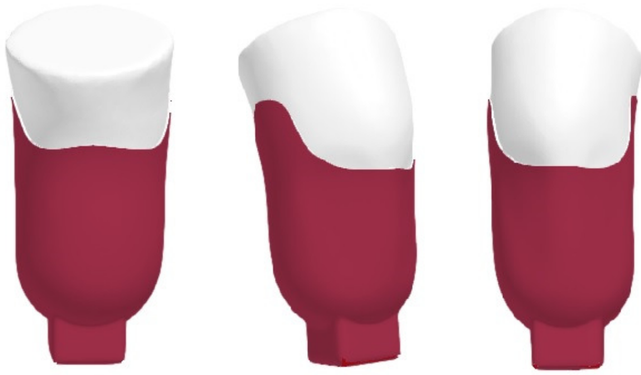

Figure 4 : Digital trans-tibial socket

Another possibility is to do a hybrid socket construction. In order to do that, the modeled limb (figure 3) can be CNC-milled from a block of foam and the orthopedic technician can continue the process in the traditional way, but with a precise residual limb that will fit his/her patient perfectly. In our case, carbon fibers can be applied to the model to build the final socket.

3. Opportunities and challenges of digital modeling

When it comes to the step of digitally modeling the 3D-scan to create a therapeutic shape to treat the patient's symptoms, there currently are aspects that simplify the work of the CPO and increase the quality of the treatment. For once, the process to create a digital positive model is faster than the equivalent traditional workflow [5, 6]. Therefore, it saves time and frees the CPO up to spend more time with the patient directly. Secondly, there are no tools other than a computer and a mouse required for digital modeling. Traditional workshops on the other hand are equipped with various specialized tools and heavy machinery, which is expensive and takes up large spaces of the workshop area. It can be cumbersome for the CPO to work with these heavy tools and sometimes requires protective gear due to the noise and debris. Having only a mouse as a tool also requires less training for CPO's. Additionally, using digital processes instead of heavy tools makes the job more attractive especially to young people and could be a solution to the ongoing shortage of apprentices. [7]

On the other hand, the digital process poses new challenges for trained CPO's. It disrupts the established process of manufacturing where a vast share of their experience and knowledge resides. This experience and knowledge is of course not lost, but it has to be brought in a new digital context and some routines have to be learned from scratch. Additionally, when capturing the patient's anatomy, 3D-scanning lacks one crucial feature: Since it renders the patient's anatomy as a simple surface model, it contains no information about the underlying tissue. Therefore, the technician cannot with certainty say to what degree the tissue below is made of muscles, fat, bones, tendons, ligaments etc. This in consequence means that when digitally modeling a 3D-scan, the technician has to guess or trust in their experience how much the surface can be altered to introduce the correct amount of pressure on certain points in the final orthosis design for example.

4. Solutions for digital modeling

Solutions to the problem of digital modeling in the O&P industry stated above have been introduced in various ways. In this paper we want to discuss two different approaches to overcome the issue of hard surface modeling.

4D deformable models use either statistical analysis or neural networks on 4D scans to extract the information for the shape and the pose of the scans. The result is a deformable model that can present the influence of a pose over the surface shape of the scan. [8, 9, 10, 11]

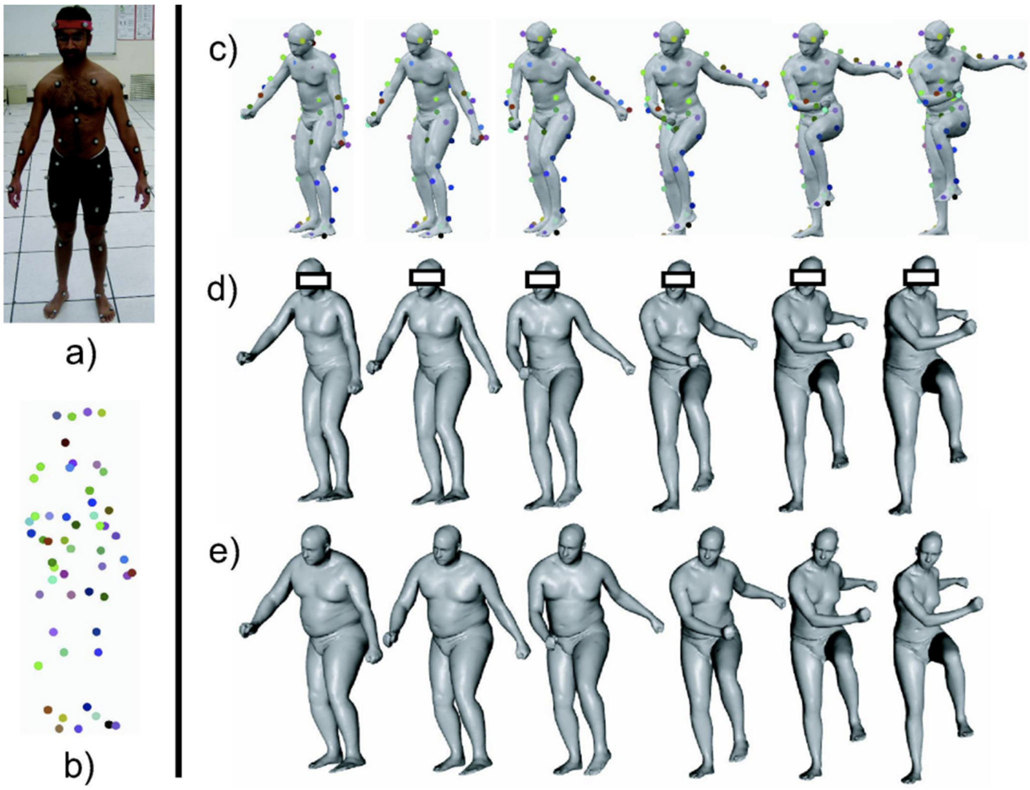

Figure 5 : SCAPE in action. a) Actor using motion capture b) Motion capture marker for single frame c) Animated actor with motion makers d) and e) Transferred motion capture data for different subjects and body shapes [8]

The first major breakthrough in creating a human body deformable model is the research "Shape Completion and Animation of People" (SCAPE) by Anguelov et al. [8]. SCAPE proposes factoring the total deformation into separate components of pose and shape. This factoring greatly simplified the learning and inference. SCAPE is based on triangle deformation under the influence of two transformation matrices: from shape and pose. The shape matrix is obtained from Principal Component Analysis (PCA) of the training data. The pose matrix is obtained by linear regression of the two nearest joints to each triangle. However the triangle based method used by SCAPE has some major problems such as: Over-parameterization of the model as well as no involvement of a skeleton/ rig model and therefore compromising the algorithm speed as well as the scalability.

The next major breakthrough came in the research "A Skinned Multi-Person Linear Model" (SMPL) by Loper et al. [9]. Inspired by the idea of factoring deformation into shape and pose of SCAPE, SMPL also separates into two components of pose and shape. The key innovation of SMPL is that it uses a Skinned Mesh, basically a rigged model as a template. The traditional workflow of standard skinning is to deform a mesh base on the rest pose vertices, joint location, and blend weight. The most common method is linear blend skinning (LBS), where rest pose vertices and joint locations are a static value. In SMPL-LBS, the rest pose vertices and joint locations are a function of shape and pose (Figure 6). The parameters for these functions are obtained by first obtaining the pose parameters via minimizing the difference between training model and registration model. The rest template and joint locations with respect to pose parameters are computed alternatively via the minimum squared euclidean distance between registration vertices and model vertices. Finally with the help of PCA, the rest template with respect to shape parameters is computed by applying PCA on the normalized subjects in the multi-pose data set. By taking the soft-tissue parameters of the body into account, SMPL can be enhanced to Dynamic-SMPL (DMPL), which is capable of creating very realistic deformations of the human body. In addition, using corrective blend shapes, presenting how local vertices deform under the influence of local joint movement, SMPL can achieve higher accuracy with fewer parameters. This improved model is known as "Sparse Trained Articulated Human Body Regressor" (STAR). [10]

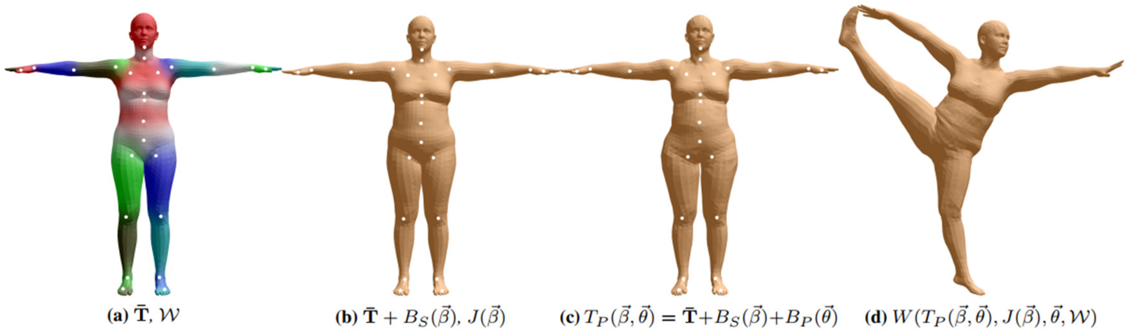

Figure 6 : SMPL model. a) Template mesh with blend weights, and joint location b) rest pose with shape parameter only c) rest pose under the influence of pose parameter d) final result by combining a), b), c) with pose [9]

Despite the robustness and performance of the SMPL based algorithm, it inherited one drawback: The preparation of the model is often tedious, as it requires heavy manual tweaking. To address this issue, Palafox et al. proposes the “Neural Parametric Models for 3D Deformable Shapes” (NPMs) [11], by using two separate Multilayer Perceptron (MLP) networks: one to learn the shape and one to learn the pose (Figure 7). The shape MLP is used to predict the implicit Sign Distance Field (SDF) for a shape in the canonical pose, known as the standard pose for every data point. The pose MLP learns the difference in each identity and their standard pose. The result is a continuous deformation field around the standard pose. As a result, NPMs can represent 4D sequence data accurately and dynamically. Compared to traditional 3D parametric models, NPMs can capture very well local details for both shape and pose. Furthermore, NPMs do not require special datasets (data with special annotations about the kinematic chain or skeleton). Therefore, they offer even more flexibility in developing new methods derived from NPMs.

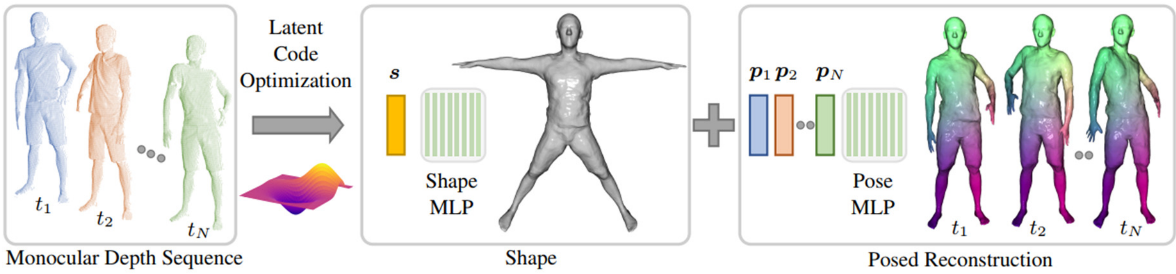

Figure 7 : Overview of NPMs. From monocular depth data, NPMs learn the shape and pose identity separately, by combining two models, NPMs can predict 4D sequences of dynamic objects correctly. [11]

Finally, the goal is to present the CPO with a dynamic deformable model that behaves anatomically correct. For instance, it is of interest what happens to the geometry (pose and shape) when a force is applied to the model, which poses an inverse problem of the current parametric deformable model. NPMs seem to be suitable candidates due to how general their applicability is to different datasets but further research and development has to be done to apply their concept for CPO specific workflows.

Finite-element simulations are used alongside radiology imaging to create a personalized model that behaves anatomically accurate while modeling. This patient model can be utilized to present important information such as the placement of bones, and how the bone deforms in case of external forces exerted to the outer geometry. This information is used by the technician to create an optimal design for medical aid devices. [12, 13]

During a study, Cobetto et al. created a 3D-reconstruction of the patient’s spine, ribcage and pelvis from X-ray images, with the purpose of creating an optimized brace design for the treatment of Adolescent Idiopathic Scoliosis - a spine deformity (figure 5A). This reconstruction was used to create a personalized Finite-Element-Model (FEM). These models are widely used to solve a large variety of structural problems numerically. Hereby, an object is divided into a large number of very small volume-bodies (finite elements). Then, forces and moments are applied to the model which can simulate pressure points or movement of the patient (figure 5B+C). Ultimately, the distance between the brace and the patient's skin, and therefore the fit of the orthosis design, can be simulated in different situations (figure 5D). This can be used to optimize the design of the orthosis and decrease the thickness in areas where it's not required. Cobetto et al. reported an average decrease of 61% in thickness and approximately 32% of the material could be removed to create large openings and 11 out of 15 patients found the new brace design to be more comfortable than the standard brace. [13, 14]

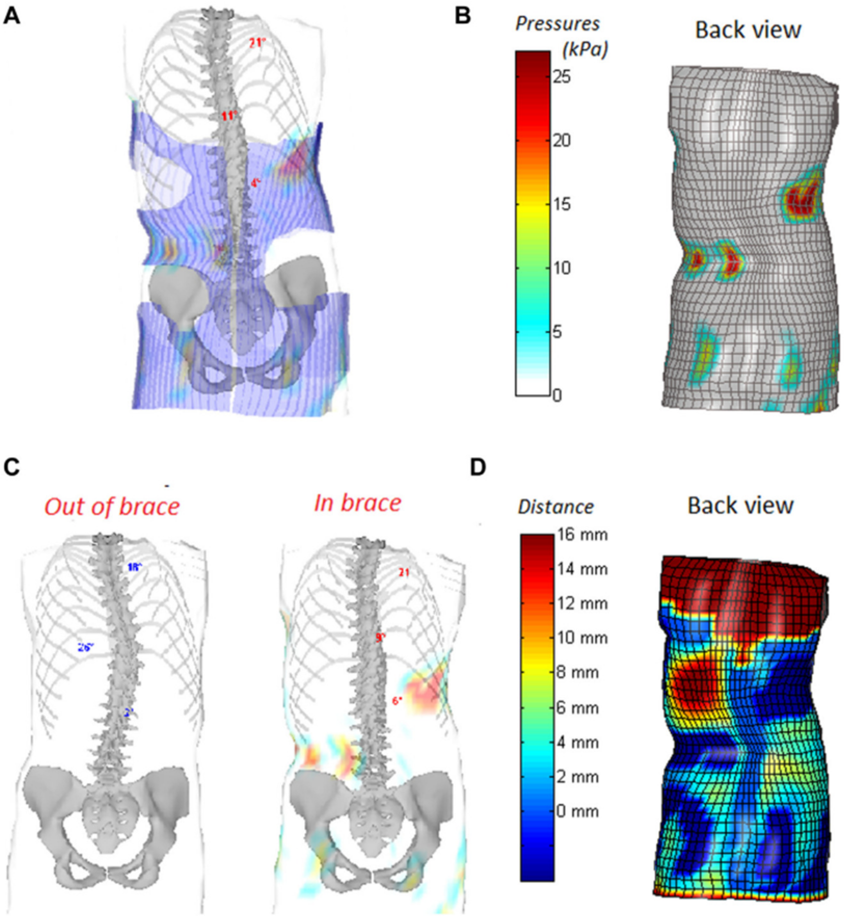

Figure 8: (A) Simulated image of the brace placement. (B) Externally applied pressure points. (C) Treatment (spine correction) simulation. (D) Distance between brace and patient's skin. [13]

The downside is that this method requires radiography data, which is not always available. Furthermore, creating a Finite-Element-Model for each body part is not automated, which severely limits its scalability.

4. Conclusion

The digitization of the construction of a custom orthopedic aid presents the following advantages :

- Faster and more flexible workflow than traditional production methods
- Increased reproducibility
- Fast and efficient: -75% production time on average
- Comfortable patient process since no plastering is involved
- Better availability of customized AFOs thanks to 3D scanning and 3D printing

With the implementation of a digital workflow, we enable the CPO workshops to transition toward digitization, removing the constraints imposed by traditional workflows. This could have the potential to change the expectations of all stakeholders about the way individual care is provided in orthopedics through the creation of future CPO workshops.

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