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Towards an Automated Process for Adaptive Modelling of Orthoses and Shoe Insoles in Additive Manufacturing

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Abstract

Although orthopedics is becoming increasingly important as a medical domain, especially in emerging countries, the level of automation is still marginal and hardly any Industry 4.0 paradigms have been implemented. In this scientific work, solution concepts for holistic process automation in orthopedics are introduced so that prosthetic covers and orthoses for different body regions can be automated by using AI and evaluated with sensor networks. In this process, body scan models are adapted to the conditions of the anatomy or prosthesis models, so that stability as well as fitting accuracy are given in comparison with the other half of the body. Automation in the field of orthopedics leads not only to a significant reduction in costs but can also help to close the research gap regarding objectifiability of results. The first partial aspects have already been successfully implemented for leg prostheses, arm prostheses and shoe insoles with the aid of machine learning processes and physical models for elastic form fitting. As soon as the overall process has been realized, the applicability will be validated in the following year of the project by means of clinical studies and evaluated by utilizing sensor networks for pressure and temperature measurements.

Keywords: orthoses modelling; ML in manufacturing; sensor grids; computer-aided therapy; 3D printing

1. Introduction

While many medical application domains have experienced increasing digitization in recent years, the field of orthopedic technology currently still relies on manual customization driven by expert knowledge. As a result, the production of orthoses in Austria is still a manual process, which is subject to the individual interpretations of the medical experts and the heterogeneous production processes.

In general, the field of computer-aided diagnostics and therapy is still underrepresented in Europe and especially in Austria compared to the US and other innovative nations. While in the U.S. a radiographer (technologist in radiology) also independently performs computer-assisted analysis on tomographic image data, in Austria this is still reserved for radiologists only, although the profile of radiology technicians is also constantly broadening (Rosenblattl, 2008). Orthopedic treatments are also becoming increasingly relevant in emerging countries. In these countries, too, orthopedic expertise and human resources are still quite limited, so the use of AI for process automation can provide valuable services here as well.

1.1. Motivation

As a result, WAKO Ltd. is aiming to digitize orthopedics in the sense of Industry 4.0 with this research project. Currently, it is up to the orthopedic technician with his domain-specific expert knowledge to design and manufacture the orthoses based on experience and manual fitting. In the near future, a self-learning suggestion system with automated patient-specific orthosis design should lead to significant process automation in the field of orthopedics.

Ultimately, the well-tuned interaction of the patient with his or her orthosis is decisive for increasing the quality of life, which is, after all, the ultimate goal of most orthopedic treatments. A particular challenge here is that the patient's body is constantly changing during treatment, which is often even a desired outcome. This makes constant adjustment of the fit of the orthosis unavoidable.

To our knowledge, this can be achieved for the first time by an intelligently digitized orthosis as defined in this research project.

There are many treatments in which the orthosis is intended to exert pressure on specific parts of the body in order to correct skeletal malpositions, for example in the growth phase of children, cf. *scoliosis*, pigeon chest (lat. *pectus carinatum*), helmet therapy in case of *plagiocephaly*, aso.. The digitized orthosis as the objective of this research project can precisely measure the pressure exerted during the entire therapy and thus objectify the course of treatment quantitatively.

1.2. State of the Art

With regard to the particular research questions, various algorithms exist for the registration and transformation of 3D models. Rigid transformation methods for surface (Blender™, 2023) or object deformation (Joshi et al., 2007) are well established in common 3D modeling programs like Blender[1]. Besides various Blender program extensions for registration based on Iterative Closes Points (ICP) or Distance Maps, the Visualization Toolkit (VTK) (Schroeder et al., 2006) focusing on the medical application domain can be utilized for these mesh transformation tasks, too. By applying CT reconstruction paradigms, partial surfaces of 3D volumes of different modality can be registered against each other utilizing the iterative registration process described by Backfrieder et al. (2017). The elastic registration process must meet the requirements of 3D printing and physical strength. Finite element analysis as well as solid state analysis are successfully used in 3D printing of elastically transformed 3D models (Schumacher et al., 2015).

In the area of the recommendation system for the selection/configuration of orthoses, the recent successes in the field of Deep Learning allow to significantly improve the classical and well-established expert systems in the medical environment in terms of extensibility (Ravuri et al., 2018). Furthermore, from the field of data science, suggestion systems for customer loyalty can be transferred to other domains by means of transfer learning (Zhang et al., 2020). So far, there is some scientific preliminary work on soft sensing with considerations for the use in orthotics, but still away from actual applications on commercially deployable systems (Tan et al., 2020) (Zhao et al., 2016) (Villa-Parra et al., 2017). In most cases, these are also concerned with assisting movement through sensor-controlled actuators rather than improving the fit of orthoses.

1.3. Related Work

In the context of digitization for the production of customized 3D-printed orthoses, there are various competitors who offer a process for creating such orthoses. However, none of these competitors offers an automated overall process from the scan to the individual fitting to the final creation and optimization. One such competitor is Ortho-Team AG [2], which manufactures individualized orthoses using an adaptive 3D printing process. Patients can have 3D scans made at selected locations in Switzerland, which are then used to manually create an orthosis model in further steps. Other competitors are Trinckle [3], Fior & Gentz [4], and Uniprox [5] offer orthosis configurators. These configurators allow the creation of orthoses in a semi-automated process, but are limited to certain body parts (hand: Uniprox ; legs: Trinckle and Fior & Gentz), or require a pre-created 3D model of the body part, which must be purchased independently of the process for creating the orthosis. The orthosis configurator "Paramete" offered by Trinckle only allows a purely manual adjustment of the 3D models (orthosis, body part) using drag & drop. The configurator of Uniprox allows the parameterization of the orthosis with regard to some fixed values such as material thickness or materials. The Fior & Gentz configurator, on the other hand, also allows parameters such as age, weight, height, athleticism or the clinical picture to be taken into account when creating the orthosis. In addition, none of the competitors use sensors built into the orthoses to determine pressure, temperature or humidity.

In contrast to the aforementioned competitors, a fully automated, parameterizable process is to be developed in this research project, which is not to be limited to specific body parts, but which can be continuously expanded to

1 https://www.blender.org/

2 https://www.ortho-team.ch/
3 https://trinckle.com/paramate.php
4 https://www.orthesen-konfigurator.de/
5 https://www.uniprox.de/de/handorthesen-konfigurator/

include supported orthoses by means of a modular structure. In addition, parameters such as clinical picture, age, weight, height or even the athleticism of the patient are to be automatically taken into account for the orthoses created and analyzed and further optimized with the help of sensors.

A central basis for the process automation for the production of the orthoses was already created in a preliminary project with a high-precision body scan taking into account the position-related deformation of skin and tissue during the scan process. Nevertheless, any 3D body scan of the patient's anatomy can be utilized as base for the proposed automated prothesis cover or orthesis modelling.

The stretchable and permeable sensor networks, which are provided by sendance GmbH, have been developed on the basis of the LIT Soft Materials Lab's research on soft electronics and robotics (Kettlgruber et al., 2020). There are also initial studies on the skin compatibility of the materials used in the manufacture of soft electronics (Baumgartner et al., 2020).

1.4. Research Questions and Project Foundation

Utilizing high-precision 3D surface models of the patient's anatomy, the automated selection of the ideal orthosis material and blank can be carried out using a self-learning ML recommendation system. Ideally, only a few patient parameters (weight, height, limb dimensions) are required for the recommendation system. Thereby, the preselected orthosis model is adopted to the target anatomy in a fully automated way applying elastics mesh registration. In this manufacturing process, the structure of the material (thickness, load limits, and structural integrity) must be preserved and rigid parts of the prosthesis covers, e.g. at closure points or sensor holders, must remain in their exact rigid position during the fitting process.

A key innovation of this research project is the ultrathin and freely formable sensor network, that can be utilized for both, namely the quantitative evaluation of the fit accuracy during the fitting of the orthosis but also later as a continuous monitoring of the pressure conditions during the daily wearing routine. In this way, it can also be determined whether the patient actually uses the medical aid in everyday life or not.

The sensor network allows the two-dimensional evaluation of the pressure on the 3D anatomy of the patient, which will serve as a necessary feedback loop for the self-learning suggestion system in the future. It is also envisaged that in future, in addition to pressure, temperature and moisture will also be measured by sensors and used for increased wearer comfort.

To enable an automated and self-adaptive system for elastic form fitting, hundreds of data sets of patients in the areas of shoe insoles and lower leg orthoses covers are required respectively, all of them with associated manual and validated planning annotations provided by medical experts.

The focus of this research paper is to provide an outlook on the necessary development steps and the current state of development towards an ML-supported automated manufacturing system for custom-fit orthoses. The paper is structures as follows: Chapter 2 addresses the input data sets that enable the machine learning of the suggestion system. The implementation methods are explained in Chapter 3, with the details of implementation in Chapter 4. The first results and their discussion can be found in Chapters 5 and 6. Finally, Chapter 7 shows the research and development steps that are still pending.

2. Process Overview and Material

For adjustment of orthoses covers, several datasets are required. In general, the subsequently described process assumes that only one side of the body is affected in the case of leg or arm orthoses. The basis for this is the scan of the healthy half of the body, e.g. lower leg, referred to as mesh $Model_{anatomy}$. This scan is mirrored onto the affected side of the body, referred to as $Model'_{anatomy}$. Furthermore, the 3D model of the prosthesis, denoted as $Model_{prothesis}$, must also be taken into account and the cover template, referred to as $Model_{cover}$, must be adapted. The final adaptation is called $Model'_{cover}$ and must have a perfect fit to the prosthesis on the inside and a similar shape to the mirrored body part on the outside, as well as elements to be statically positioned for assembly. The four key datasets involved are shown and delineated in Fig. 1.

2.1. Data Preparation for Deep Learning

Test data are allocated and processed in the two areas of shoe insoles and orthosis covers, respectively.

In the area of shoe insoles, either so-called blueprints, in which the patient leaves an imprint on a special foil with their body weight or RBG scan of the foot sole are used. The impressions for the left and right leg are digitized via scan and processed and archived together with the patient's metadata in the form of an image. For the training of the AI models, n = 117 blueprint data sets and n = 325 RGB scan data sets, which are available in the form of JPEG images with the resolution of 1084 $\times$ 451 pixels for blueprint images and 956 $\times$ 406 pixels for RGB scan images, when each foot is extracted, are divided into the data sets for training, validation and testing. Each foot are referred to as $Model_{bpLeft}$ and $Model_{bpRight}$, respectively for the extracted foot. For the training of a machine learning process, the 3D planning models manually prepared by human experts are also required. Here, different corrective shapes of different sizes are applicable, see Fig. 2. The manual planning variant with selection of the corrective in the most suitable size represents the ground truth for the supervised learning procedure.

In contrast to the shoe insole blueprints, several data sets per patient are required and prepared in the context of orthosis covers. Only if the required four models for a

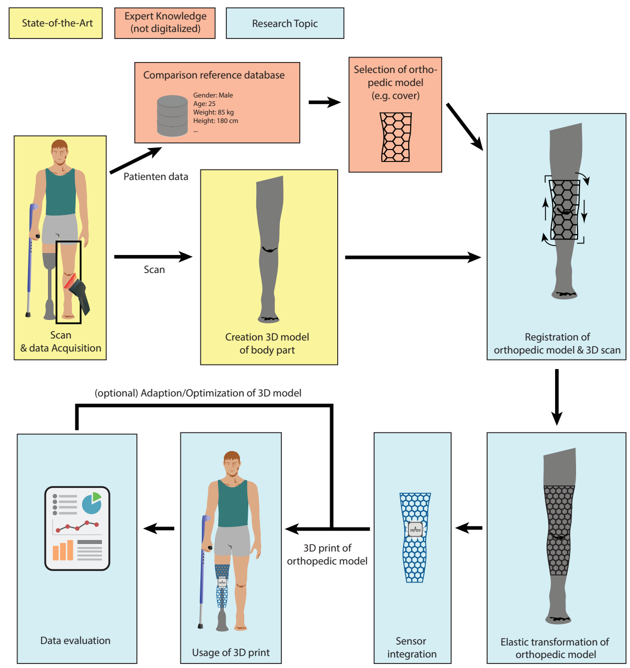

Figure 1. Process Overview illustrated for prothesis covers. For a patient with affected right leg, the healthy left leg gets 3D scanned, denoted as $Model_{anatomy}$. The patient's medical record is utilized to select an appropriate cover template, denoted as $Model_{cover}$. The cover then gets adjusted according to the body scan, the selected cover template as well as the model of the prothesis ($Model_{prothesis}$) leading to the fitting model $Model'_{cover}$. Besides, the sensor grid gets adjusted to the patient anatomy too, allowing for data evaluations on pressure, temperature and moisture during daily wearing.

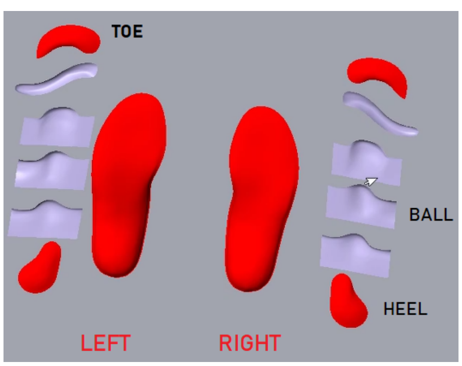

Figure 2. When planning the patient-specific remedy in the form of a foot orthosis adapted to the body shape, the orthopedist can select from a range of corrective devices in different sizes and position them on the 3D model of the shoe insole according to the blueprint and the specific situation prior to the production process. In total, $n = 6$ different corrective elements for toe, heel and ball respectively can get applied. It is further possible, that for one patient's leg two or even all three foot regions need to get corrected.

patient study are available, this data set can actually be used for training, validation and testing of the AI model. Thereby, the input data-sets are available as triangulated meshes available in *obj* data format. The cover model $Model_{cover_{man}}$, which has been adapted by medical experts in a semi-automated way, represents the reference in the sense of supervised learning, whereas the other 3 models represent the basis for the shape adaptation. While there are orthoses for different body parts (forearm, upper arm, lower leg, thigh, etc.), the first step focuses on lower leg covers and $n = 50$ data sets are prepared for training.

3. Methodology

In this chapter, the current manual process is first outlined before different AI algorithms for automatic adaptation are presented and explained. The chapter is concluded with the evaluation, on the one hand by applied sensor grids and on the other hand simulation-based by means of FEM analytics.

3.1. Present Manual Process

Right now, Wako Ltd. offers a semi-automated workflow process for orthopedists to adjust the orthoses in a patient-anatomy specific way. Therefore, the software *Geomagic Freeform* (3DSystems, 2023) is customized via automated process pipelines and features the use of a haptic 3D mouse for precise 3D navigation and interaction. While some elements such as the zipper or locking elements are placed in an automated way, the orthoses shape itself needs to be adjusted by the medical expert by dragging the 3D mesh model according to the reference patient anatomy. Thereby, the reference patient anatomy is provided either as 2D blueprint projected onto the 3D shoe inlay mesh or as 3D body scan meshes in case of lower leg orthoses covers. Nevertheless, the current process shows some notable drawbacks. It takes a lot of time to drag the template model to perfectly fit the patient anatomy in all three dimensions and the results are subjective and a matter of experience. Furthermore, tools such as freeforms offer a broad palette of functionality but lead to a steep learning curve, too. Thus, to allow for both, cost reduction and quantitative results, an automated process for adaptive modelling of orthoses and shoe insoles is necessitated.

3.2. Automated Adjustment

For automated adjustment, two different aspects need to be handled. At first, an AI model gets trained to predict the target transformation. Subsequently, an ARAP (as-rigid-as-possible) algorithm is utilized to deform the model according to the AI prediction.

While the final mesh deformation strategy can be applied in a generic way by utilizing the ARAP algorithm, different AI models and strategies are required for the various body parts to consider as delineated in the subsequent paragraphs.

3.2.1. AI Prediction on Shoe Inlays

For training the AI model on predicting the shoe inlay correctives, the blueprints and RGB foot images are used as visual input for training of the correctives, cf. Fig. 3

Figure 3. Exemplary input images for blueprint and RGB footprint. First, the artifacts are removed from the background form and the line drawings of the medical experts. Then the images are split into left/right foot, mirrored and normalized.

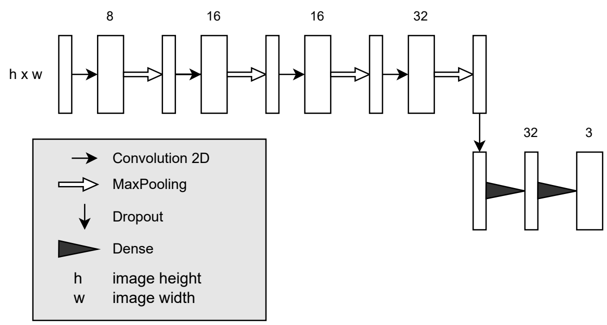

Figure 4. By applying four convolutional layers the input image is getting down-scaled to finally allow the categorical classification by using fully-connected layers

for one particular blueprint and RGB input image, respectively. Therefore, input images get mirrored to the same body side and the PhotoScissors version 0.9[6] algorithm is used to remove background artefacts from the visual input data. To enriched the amount of training data, several data augmentation strategies get applied. Thereby, blurring, gamma corrections, histogram adaptions and affine rigid body transformations are utilized. The chosen network architecture is shown in Fig. 4. Further details on the chosen Tensorflow network architecture, the various data augmentation strategies and a quantitative evaluation of the achieved results can be found in Bauernfeind et al. (2023).

3.2.2. AI Prediction on Covers for Legs and Arms

Handling input tensors of varying size, as it would be required for meshes of different size and resolution, is always hard to handle for deep learning architectures. Thus, the automated mesh adjustment problem as delineated in Fig. 6 is reduced from continuous 3D to discrete 2D domain. For tubular limbs such as upper arm, lower arm, upper

6 https://photoscissors.com/; accessed on 14.04.2023

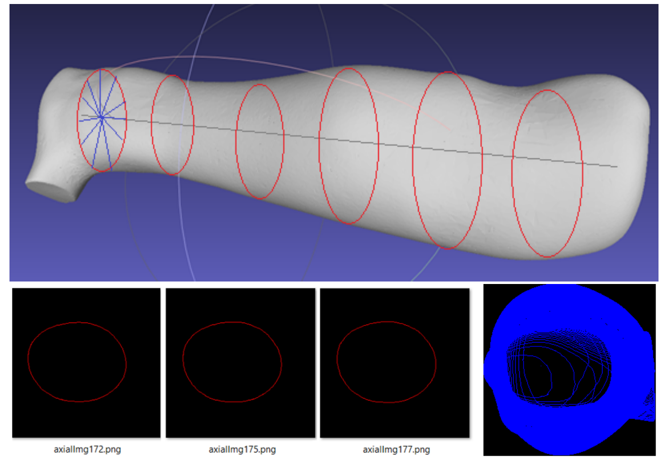

Figure 5. Illustration of the projection from the 3D mesh to 2D images for lower leg cover template, orthogonal to the skeleton axis (grey). At $n = 512$ equidistant axial slice positions (red ellipsis), the distances at 1° rotational granularity get evaluated (blue lines). The discrete and sampled circumference of some slices are charted in the lower row with all of them stacked in the lower right. Thus, the pre-processing allows to derive images of size 512×360 for input meshes of arbitrary resolution.

leg and lower leg, the inner limb skeleton is calculated by utilizing principal components analysis. Utilizing the derived skeletal representation, the axial circumferences at discrete positions get projected from 3D space to a 2D image space similar to cylinder projection in U,V texture coordinate mapping. The transformation from 3D to 2D together with exemplary results is presented in Fig. 5.

Thanks to this transformation strategy, all three required input models for training ($Model'_{anatomy}$, $Model_{prothesis}$, $Model_{cover}$) as well as the semi-automatically adjusted cover model ($Model'_{cover}$) as target result can get transformed from 3D to 2D representation, allowing for conventional multi-channel tensor representation in training encoder/decoder deep learning network architecture such as U-net Ronneberger et al. (2015). Therefore, the conventional 3-channel RGB layer is replaced by the three model layers as delineated before in contrast to Ronneberg's U-net.

3.3. Sensor-Based Evaluation

As stated previously, adjustment steps mostly rely on expert knowledge by a (medical) professional and subjective feedback by the patient. Utilizing a sensor grid that distributes sensing points across the orthopedic solution allows for quantitatively and objectively assessing its fit. Beyond key indicators for fit (applied pressure) and skin health (e.g. via surface temperature or humidity to indicate inflammations and abrasions), it further allows for extracting adherence and usage statistics (cf. Ngueleu et al. (2019)) as features for automated adjustments of future orthoses. To be able to utilize such a sensor grid for this purpose, it must comply with several requirements: (I) skin compatibility, (II) adaptability to various 3D forms

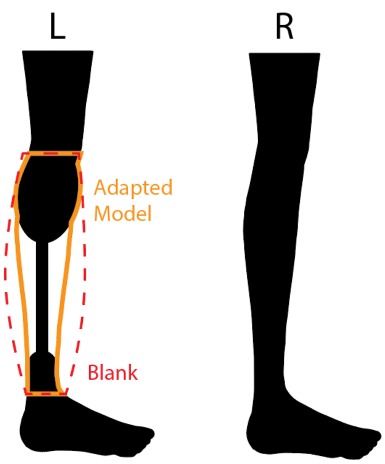

Figure 6. Illustration on the automated mesh adjustment for a lower-leg prothesis cover. An anatomical scan of the healthy right leg (denoted as mirrored $Model'_{anatomy}$) is acquired and used for adjustment along the orthosis area (orange color) to perfectly match the right leg in shape. In contrast, at the upper and lower parts of the prothesis (in red color), a tight fit according to the prothesis model $Model_{prothesis}$ is required for stability. The resulting cover model $Model'_{cover}$ finally can get post-processed in a semi-automated manner.

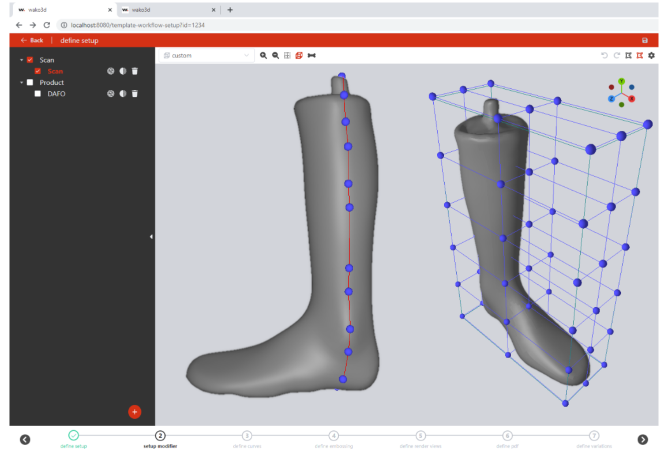

Figure 7. Illustration of the semi-automated adjustment in case of required post-processing. With a grid aligned according to the skeleton centerline, the user can move local grid elements to allow for elastic mesh deformation utilizing the ARAP algorithm.

of orthopedic solutions, and (III) cost-effectiveness. The latter could, for example, be realized by the self-learning ML system by optimizing type, positioning, and count of sensors employed. Factors such as confidence in the fit (full confidence → no sensors), previously seen pressure patterns (some areas receive no pressure → now validation sensors needed), or degree of non-fit (low pressure values → unlikely abrasions → no temperature/humidity sensors needed) will help the system in self-optimizing cost and complexity as long as the sensor grid itself is customizable in a sufficient manner.

3.4. Fine-Tuning in Manufacturing and Customization

Although it can be assumed that AI models can and will contribute to a very high degree of automation in the near future, manual inspection of the fitted models by medical experts is still indispensable. The orthopedists alone are responsible for the manufactured models, so it must be possible to make any corrections to the fit in a few simple steps in a post-processing step prior to 3D printing. For this purpose, a UI was implemented using *Three.js*. Using elastic grids, the selected diameters can be adjusted locally and transformed using ARAP algorithms, see Fig. 7.

4. Implementation

For the algorithmic aspects, we utilize *Python* in version 3.9 as well as *Tensorflow* in version 2.10 together with the *Keras* backend. For aspects of data pre-processing and data augmentation, we utilize *imgaug* version 0.4.

For visualization and 3D mesh manipulation, the *VTK* framework version 9.1 is accessed via available Python wrappers.

On the UI side for semi-automatic adjustment of the meshes or for customizing and post-adjusting the adjusted models, the web technology used is *three.js* in version r151.

To handle the hybrid stack of programming languages and platform that are required in this holistic project foundation, automated database wrappers and object mapping strategies are implemented to allow for smooth and novel technology interoperability and thus reduce the required programming effort, see Praschl et al. (2023) for details.

5. Results and Evaluation

In this chapter, the currently available prototypes for automatic shape adjustment and sensor integration are tested and evaluated.

5.1. Automated Shape Adjustment

With respect to the shoe inserts, which are determined based on the blueprints and RGB images respectively, the first AI model can be considered a successful proof of concept. Although only about 1000 training images could be used so far, the classification results for individual model correctives, such as Q1(transverse meta padding in size 1-5) and Q2(transverse meta padding in size 2-5) with a validation accuracy of 96% and 84%, respectively, are already remarkable.

For the tubular models for arms and legs, the 3D model can be successfully transformed into 2D projection images, which will be used for training U-Net deep learning architectures in the future. As can be seen in Fig. 8, the body shape stands out very well in the 2D representation. The left image covers a high resolution of 512×360, whereas the right image is quantized by a factor of 4, i.e. only 128

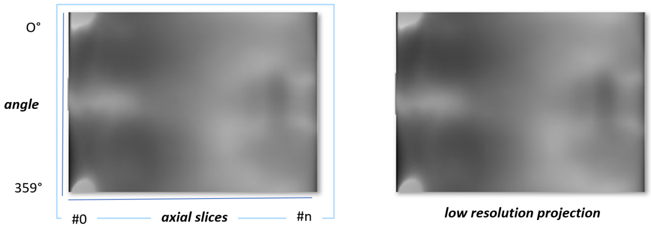

Figure 8. For each of the sampled axial slices along the skeleton of the body limb (x-axis), centerline projections at a granularity of 1° degree get evaluated (y-axis) and the distances are plotted a scalar pixel values . The right 2D projection is calculated at significantly lower resolution.

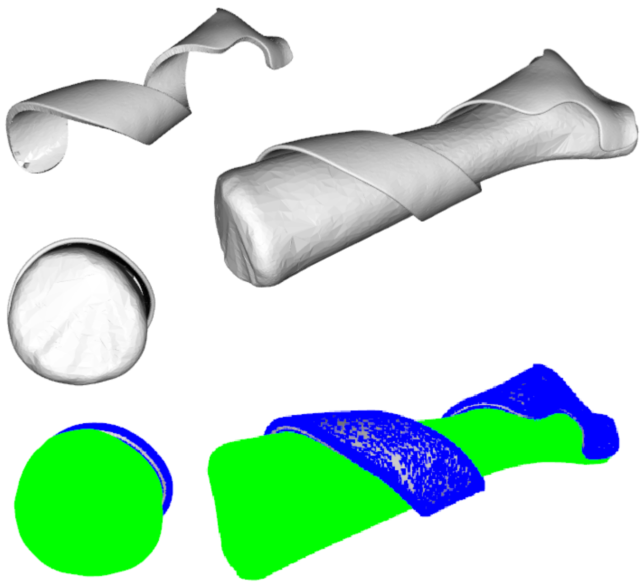

Figure 9. The generic forearm orthosis shown at the top initially has a poor fit with regard to the patient's anatomy (middle row) and is significantly better adapted to the respective body shape by adjusting the axial distances and with the aid of the ARAP algorithm (bottom row).

axial slices are sampled at 4° increments with respect to the angle. Nevertheless, even with the low-resolution display, the body anatomy is very well resolved. This is an important finding, as it allows the size of the input tensors to be kept relatively compact (small input images and thus a lower amount of model weights) for the Deep Learning methods to be applied.

Regarding the model shape adjustment to follow, these optimized local distances will allow to perfectly fit model templates and patient anatomy in future as first test runs with the ARAP elastic deformation applied in an axial way indicate, cf. Fig. 9.

5.2. Sensor-Integration

The sendance-grid provided by sendance GmbH satisfies the previously stated requirements (cf. section 3.3) by using a gelatin-based biogel or medical fabric as a medium (I), stretchable and deformable circuitry (II), and fully customizable sensor positions, types, etc. (III), see Koeppe et al. (2022). Additionally, to further allow seamless integration into the proposed process, sendance GmbH is currently implementing (1.) a fully digitized and automated production process with production machines that can produce the customized grids directly in the orthopedic manufacturer's facility, and (2.) an IoT-like cloud infrastructure to close the data feedback loop (i.e. gather sensor data and feed it back to the ML system).

6. Discussion and Conclusion

Automation in orthopedics can be in a variety of areas, from shoe insoles to prosthetic covers to orthotics for arms and legs. With the solution concept presented, AI can be used to automate the process one step further. While very promising results are already available for individual process steps, the overall system must be implemented as a seamless manufacturing process in the next few years of the project. A major benefit will come specifically from the novel sensor technology, which will be able to quantitatively assess wearing comfort and fit very well.

A current limiting factor is the lack of generalizability in orthopedics. Many different body parts require very different medical remedies. While in the course of this work exemplary areas are addressed and automated by means of AI, the holistic generalization is still the content of future research.

Currently, the amount of training data for the AI models has to be significantly increased and the bias in the class distribution, especially for shoe insoles, has to be compensated by applying data science methods. The way in which the input data is prepared will also require innovation in the area of data augmentation, since affine aspects such as the position and orientation of the models do not need to be varied in a meaningful way, cf. Procrustes Alignment, and yet a larger artificial stock of training data will be necessary.

7. Outlook

In this final chapter, an outlook is given on the upcoming developments both on the part of automated model fitting and on the part of sensor technology.

7.1. Automated Model Adjustment

In this area, the aim in the future is to gradually advance the level of automation and expand it to new body regions, such as the head with custom-fit helmet technology. Furthermore, the quantitative feedbacks of the sensor networks must also be taken into account in the future.

In the case of orthoses, the aesthetic aspect is of course of central importance in addition to functional expediency and accuracy of fit. Wako Ltd. will therefore enable the branding of its own orthosis through individual texture images used for a 3D embossing pattern. It is therefore conceivable to apply the logo of one's own soccer club to the orthosis cover. To ensure that the embossing does not invalidate the stability of the overall model, an FEM (finite element modeling) analysis is currently being developed for this purpose. FEM will then be used to validate and confirm the findings from the sensor technology.

In the field of medical applicability, a clinical study will be started in the course of the calendar year 2023 together with experts and patients of local orthopedic clinics or the Medical Faculty of Johannes Kepler University Linz (KUK).

7.2. Sensing

While we will further research on suitable sensor types, parameterizations, etc. to gather feedback data for our ML system, we also intend to investigate utilizing the grids for providing feedback to the patient directly. A supposed "bad fit", caused by a lack of adherence to, e.g., training routines or intended usage, could be prevented by clear (and undeniable) communication of observed usage (Bashir et al., 2022) or introducing gamification mechanics to facilitate adherence Dannehl et al. (2016), forming a promising opportunity when integrated on a broad scale with an automated system.

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