AUTOMATIC PRODUCTION OF PATIENT ADAPTED ORTHOPAEDIC BRACES USING 3D -MODELLING TECHNOLOGY

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ABSTRACT

The research group in biomechanics at NTNU Aalesund works in close cooperation with the orthopaedic surgeons at Aalesund Hospital. One of the research activities has been to develop an automatic procedure for producing individual patient adapted orthopaedic braces for hand fractures. This paper is a result of this cooperation. The work has so far resulted in the design and 3D printing of individually adapted orthopaedic braces for simple fractures in the hand and arm. However, much of the production of these has been manual and time consuming. Now, a practical procedure for producing such braces in the clinic is about to be realized. This paper presents the development of the production procedure and testing of the resulting braces. The results of this research are then discussed regarding the challenges involved and benefits of introducing this procedure into the orthopaedic clinic.

INTRODUCTION

For many years NTNU Aalesund has worked in close cooperation with the local Department of Health in Møre og Romsdal. In the field of biomechanics there are several interesting ongoing research projects between technology staff at NTNU and medical doctors. These projects represent a broader research context than most internal projects at NTNU and are very inspiring and stimulating for the researchers both at NTNU and Aalesund Hospital (Mork, Hansen, Strand, Giske, Kleppe, 2016). This ongoing activity has already resulted in several research articles, in the combined field of technology and medicine. Related to the work discussed here, a first paper on orthopaedic braces was presented in 2018 at the first International Industrial Conference on Cyber-physical Systems (IICPS2018) in St. Petersburg (Kleppe et. al, 2018).

In this research, we have combined the competence of the senior surgeons at the hospital with NTNU's considerable competence in the fields of mechatronics and 3D modelling. The combination of these two disciplines provides a strong basis for research in the field of biomechanics and we have managed to produce patient adapted orthopaedic braces. However, the process in the beginning was quite time-consuming involving many manual operations. This paper presents the work done to improve this process, looking closely at the different activities in order to find areas for improvements. The basis for such a project is a thorough competence in the field of 3D technology, including 3D scanning, data formatting, concept solution, surface processing, and 3D printing. Last, it is the orthopaedic surgeon's detailed knowledge of the anatomy and treatment of fractures that guides us towards a functional procedure for producing patient adapted orthopaedic braces in the clinic.

At the current stage of development, there are some shortcomings regarding the quality of the braces, but more seriously is the production time. The process is too slow within reasonable product costs. This problem involves both the scanning and the printing stages of the process. There are solutions, but these are still too expensive. However, there are many advantages of introducing such an automated process in the clinic, primarily for the patient, but also for the hospital. Both working time and material costs will decrease substantially once the equipment is installed in the clinic. This research has concentrated on the improvement and optimization of the methods and technology that are already included in the process. The general development in today's world of 3D technology is enormous, and our group has spent much time finding the correct technology and most suitable software for the implementation of a functional production procedure, (Gya and Thorsen, 2017). We regard it as only a matter of time until the obstacles to the realization of this procedure are removed. This novel way of producing orthopaedic braces is tailored to each patient, and will be both faster and cheaper than previous methods.

ORTHOPAEDIC BASIS

The motivation and benefits for the orthopaedic clinic are well described by Kleppe et al. (2018). The traditional way of making plasters is both time consuming and labour intensive, and represents a past technology. See Figure 1 for a traditional plaster cast. It is high time for this to be replaced by modern technology and an efficient new procedure. Wrist fractures (distal radius) are the most common types of fractures in Norway; it is estimated that there are more than 15,000 fractures annually among adults. After the introduction and spreading of electric scooters in Norway and most other countries, the notion of "The last mile" has become

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synonymous with a substantial increase in hand fractures. For a long time, the orthopaedic doctors At Aalesund Hospital been looking for a more efficient and accurate way to make casts. A customized cast fitted to each patient and produced by 3D scanning and 3D printing is now a realistic option that could |meet their needs. The production process will be highly automated and therefore save valuable time for the medical staff, and the quality of the product will be independent of the staff member's experience. The implementation of this 3D scanning and printing technology in the conservative treatment of fractures will make the process faster, more reliable and more cost effective compared to traditional manual work.

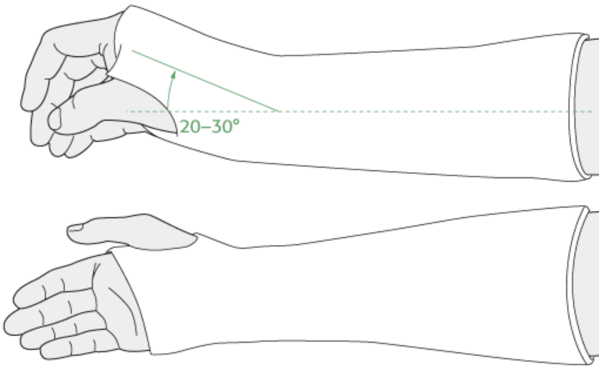

Figure 1: Illustration of a Traditional Plaster Cast

TECHNOLOGICAL BASIS

When it comes to technology, the necessary equipment already exists in the market. However, 3D technology is still an immature field regarding commercial applications and there are many challenges in cost, processing speed, software development and software interfacing. However, the current speed of development of this technology means that these obstacles will soon be overcome. The main focus will therefore be on system integration: choosing the correct equipment, finding the correct software and adapting it to the particular functioning product. In the process of making patient adapted braces there are four steps. First, the hand is scanned with the appropriate equipment to obtain a point cloud of the object. Second, the point cloud is imported in a suitable 3D modelling program, and a 3D surface model of the hand is made based on the data in the point cloud. Third, the orthopaedic brace is modelled based on the anatomy of the hand using special techniques for surface modelling. The last step is the 3D printing of the brace with a printer that fulfils the requirements of product quality and processing time at an affordable price. See as example Summitid (2014).

OBJECT SCANNING

The scanning units in this project are ordinary photographic cameras. The reason for this is that very good cameras are available at reasonable prices, and the 3D scanning technology and associated software using cameras are developing very fast. There are products in the market well suited for this kind of research and an increasing number of sources for free public domain software.

Photogrammetry

The basic platform for the reconstruction of 3D surfaces is the field of photogrammetry. With the introduction of 3D surface scanners, this technology is used in an increasing number of applications in many fields. Today there are many software programs available on the market that can generate dense point clouds and 3D surfaces from still images. There is also an increasing number of software tools available in the public domain for free use.

Photogrammetric methods

We use photogrammetric techniques in the process of scanning and reconstructing the surface of the patient's hand. This is based on the recording of synchronized images taken with several cameras at different angles surrounding the patient's hand. The reconstruction is based on the methods called Scale-Invariant Feature transform (SIFT) and Bundle Adjustment. The position and orientation of each camera must be determined exactly, and the necessary overlap of images decided upon.

SIFT-algorithm

Scale-Invariant Feature transform is a patented algorithm that seeks to find hallmarks of images, although there are several other algorithms that give similar results. The algorithm starts by searching for a set of reference images, so-called key points. These points have a unique identification and are found by searching for local maximums and minimums by the Difference of Gaussian (DoG) method. DoG uses a Gaussian blur filter to calculate new values of the image pixels. The filter consists of a Gaussian function to obtain these new values. New images are created by subtracting a blurred image from the original image. This process is repeated several times. In this way, DoG enhances the details of the image. The Gaussian function in two dimensions is given as follows:

$$\mathrm{G}(x,y) = \frac{1}{2\pi\sigma^2} e^{-\frac{x^2+y^2}{2\sigma^2}} \tag{1}$$

where σ is the standard deviation of the Gaussian distribution. When the key points are derived, they are compared to distinctive marks and details on the images that are manually defined in advance. The key points are used to recognize specific points in many images, and thus connect the images. The SIFT algorithm is very robust regarding rotation, stretching, distortion and light changes of the images. However, the algorithm may be sensitive to repetitive patterns by defining one key point at more places. The SIFT algorithm needs as much information as possible to derive the key points. The pictures must imitate the reality as closely as possible. Since the DoG principle creates key points in areas with much variation, images with high contrast and sharpness are valuable in photogrammetry. High spatial resolution images are necessary to obtain the required details of the object, while accurate time resolution and synchronization between images is important to achieve sharp images. All details in an image are important, also in the background of the object. The best result is obtained when the object is close and covers most of the image size. Objects with big shiny surface areas are also a problem because they have too few details to create good key points. In such cases, it may be necessary to change the texture of the surface by placing suitable patterns on it.

Bundle Adjustment

Bundle Adjustment is a method used to estimate structure in 3D from 2D images. By recognizing two-dimensional bundles of key points in different images, the method will calculate the position and direction from which each image is taken. The calculations are based on the distances and directions between the points of the bundle in each image. Changes in the orientation of points from image to image are due to either rotation or scaling, in addition to image distortion. Combined with knowledge about the characteristics of the cameras and their positions, this method can be used to find the orientation of points on the object.

Dense point cloud and surface reconstruction

A dense point cloud is the basis for the reconstruction of the 3D model of the scanned object. The point cloud consists of the key points found by SIFT, correctly oriented relative to each other in space by use of the Bundle Adjustment algorithm. From the information from the dense point cloud, the surface of the 3D model can be reconstructed. This reconstruction is based on algorithms using nearby points in the cloud to build small patches of the surface. These patches constitute a mesh of triangles representing the surface. Triangulation is a method much used in these algorithms. The size of the triangles determines the smoothness of the surface.

Smartphone as a photogrammetric device

In this research, we have tested the use of an iPhone for scanning. There has been great improvements in such software for the latest of these models. Scanning with a smart phone is very easy, and the software gives a point cloud in a format that is suitable for further processing in 3D modelling programs, such as Siemens NX.

SCANNER CONFIGURATIONS

One important issue is the design of the scanner. Depending on the scanning technique chosen, the scanner may have different configurations, and it is a question of choosing the optimum solution. The following presents the designs that have been tested.

Tube configuration with fixed cameras.

To ensure sufficient image overlap in radial and axial directions around the object, a concept for a photogrammetric device with eight cameras mounted on a ring was developed. The rings were stackable with four rings needed to cover one forearm. The outer diameter of the machine was carefully selected to be able to print parts on a standard 3D printer. The rings were divided into one segment per camera to modularise and simplify assembly. The camera stack, segments and rings, were kept together by truss rods that were slightly pretensioned. See Figures 2 and 3 for camera configuration and ring design. In this cylinder, each of the segments was equipped with a Raspberry PI camera, and the operation of all the cameras were synchronized through an Arduino controller. In this way, all cameras were remotely triggered from one master computer. Figure 4 shows the final design of this scanning device including a support for the patient’s hand (Aarsæther, Dale, 2019 and Alvestad, Nedrelid, Sjåstad, 2019).

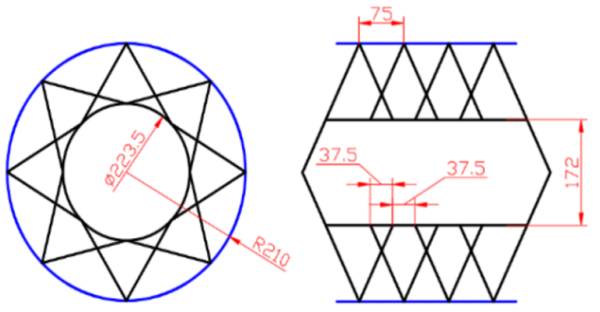

Figure 2: 32 (8x4) camera configuration

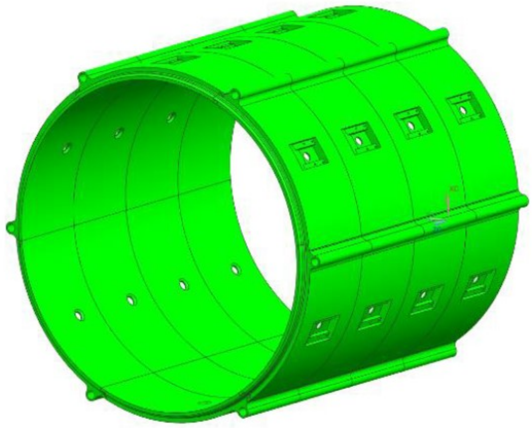

Figure 3: Scanning cylinder with camera segments

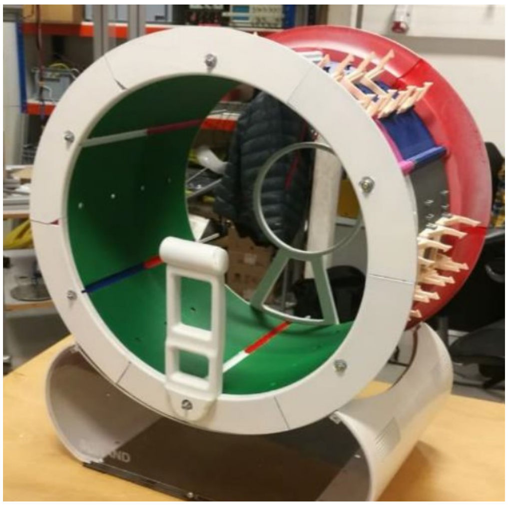

Figure 4: Scanner with fixed cameras

Rotating scanner.
Though some flexibility was built into the design of the fixed scanner by installing additional rings, the design became too rigid In addition, the availability of new types of scanners, such as lidars, and the fast development of photogrammetry software on smart phones, led our thinking towards a more flexible solution. We decided to build a simple device that could be used in testing different kinds of scanners. The result became a rotating arm controlled by a motor moving at the desired speed. The arm was supplied with moveable brackets to hold the scanning element (either a lidar or a mobile phone) in the desired position. The distance to the object could also easily be changed. With this device, we were able to test different scanner configurations to obtain the best result. See Figure 5.

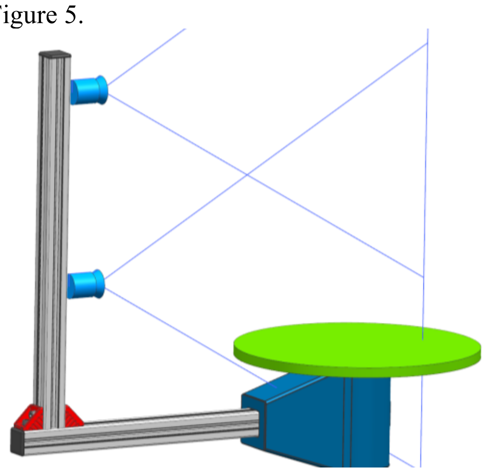

Figure 5: Design of the rotating scanner

GENERATING 3D-GEOMETRY

3D models and modelling tools

As described in Kleppe et al. (2018), several specialised 3D-applications were needed to efficiently create a 3D-supporting brace model of an adequate quality. Scan-data were imported into Geomagic X for clean-up, post-processing and to create anatomic surfaces. These surfaces were imported into Siemens to create the geometry of the brace. New and improved features in Siemens NX enables the CAD-operator (designer) to efficiently work with point clouds, facet data, b-rep surfaces, product configurators and manufacturing preparations in one single application.

Polygon modelling and polygon mesh is an approximate method to describe surfaces, while a vertex is a point in three-dimensional space. Two vertices connected by a straight line become an edge, and three edges connected to each other becomes a triangle (Hahnmann, Brunett, Farin, Goldman, 2002). Polygon modelling is also referred to as facet topology in Siemens NX. When capturing and post-processing 3D-scan data, the polygon approach is a common way of visualising the object. Scan resolution and number of points affect the accuracy of the model and the computer power needed to process the data.

NURBS or B-splines is a mathematical description of curves and surfaces. NURBS are quite common in computer aided design and engineering (CAD, CEA) software. Because of the mathematical nature of NURBS, they are quite efficiently handled by computer software. NURBS and B-spline are also referred to as B-rep topology in Siemens NX.

Both polygons and NURBS have their benefits in computer science and visualisation, but until recently combining both data formats is still a cumbersome process. However, some advances have been made, and with Siemens NX 11 convergent modelling has been introduced as a new feature combining polygon and NURBS as a modelling tool.

Convergent modelling in NX enables the designer to process scan-data, combining polygon and NURBS into one robust and efficient data processing CAD-model. Furthermore, this enables the use of product configurators to automate the design process and connect to manufacturing applications and software. These are the 3D modelling methods that were used to manage the reconstruction of the hand surface. See the following references.

Post-processing and model surface optimization

Based on the scanner setup and scan quality, several steps must be taken during the post-processing to achieve anatomic surfaces of the desired quality. A similar procedure was described in Kleppe (2018) and Scarano, Chiara and Erra (2008), but now it is possible to post-process scan data and design the brace in one single application. Based on the scanner setup and scan quality several of the steps may be skipped or automated by scripting during import from the scanner to Siemens NX. This procedure is described below:

First, remove background noise. Usually the scanner captures more than just the hand, but by using a bounding box, only the geometry required is selected for further processing. Second, heal the mesh. This procedure fills small holes and gaps in the mesh and aligns small surfaces with each other. Third, perform a global re-mesh. Based on modifications in the second step, further optimizations are carried out automatically by moving and aligning points to improve quality and reduce the number of triangles while keeping the initial shape of the geometry. Fifth, fill holes or replace rough surface areas by manual patching the mesh. Shown in Figure 6 and Figure 7. Sixth, optimize and smooth the mesh.

Defining cut boundaries

A concept for plaster design was developed by Dale, Thorsen et al. (2017). The procedure and 3D-modelling technique was further developed and integrated into one application (Siemens NX) by Alvestad, Nedrelid and Sjåstad (2019).

To create the cast geometry, the required surfaces are extracted from the scanned model by defining cut-boundaries. Three main cut planes are defined, on the fingers (1), thumb (2) and forearm near the elbow (3) as shown in Figure 8. Figure 9 shows anatomic surfaces of the arm to be used as a template for designing the customized cast. In addition, a fourth cut plane is added later in the design stage along the arm-axis to open up the plaster and enable it to be slid onto the arm. Slots for Velcro straps are added next. See Figure 10.

The end-result after all this processing is a brace geometry ready for 3D production, as shown in Figure 11.

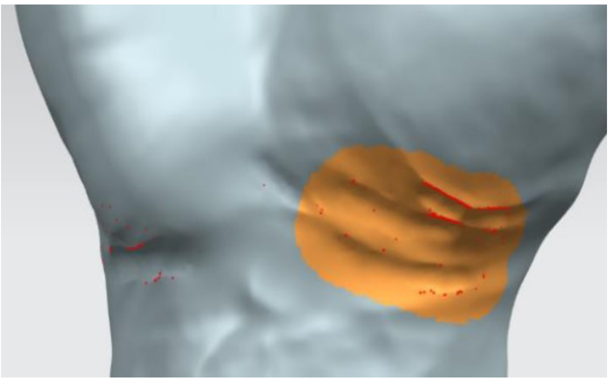

Figure 6: Before manual patching

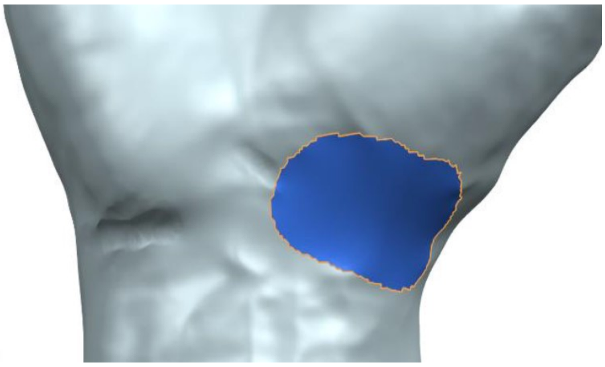

Figure 7: After manual patching

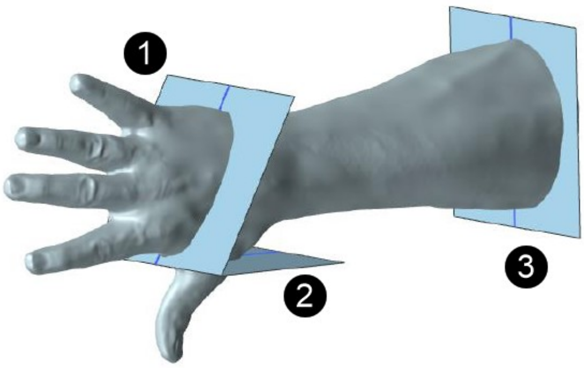

Figure 8: Cut boundaries

Figure 9: Anatomic surfaces and template for cast geometry

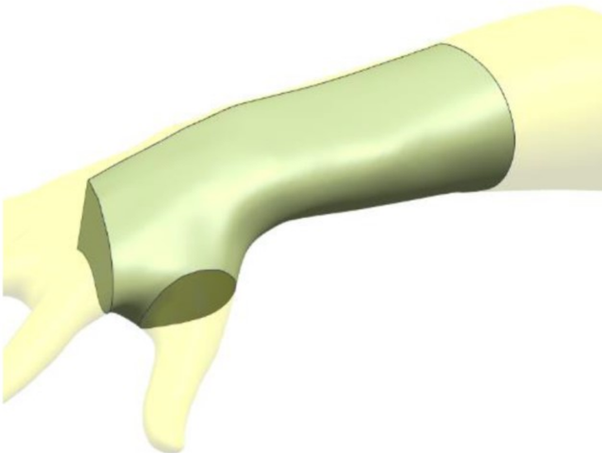

Figure 10: Plaster with all cut-boundaries defined

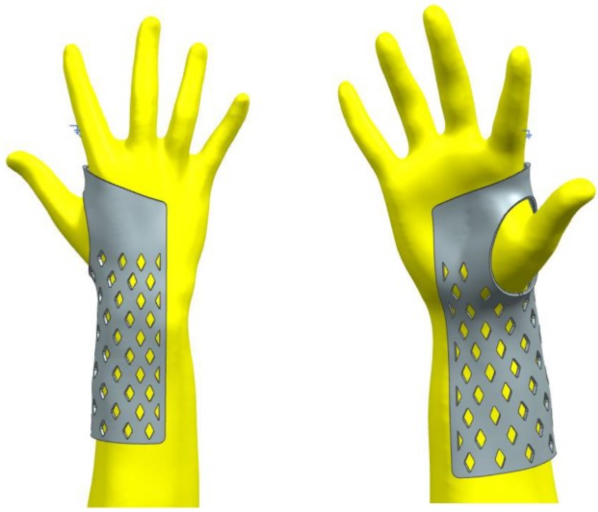

Figure 11: Complete plaster ready for manufacturing

MANUFACTURING AND 3D-PRINTING

Automatization of the design process

Creating 3D-Cast geometry with traditional 3D modelling software (CAD) as described in the procedure above usually requires highly trained CAD operators. However, the procedure is, except for some anatomical deviation between patients, the same for each new plaster. By using a product configurator (Product Template Studio) it is possible to simplify interaction with scanned data and the 3D CAD-model and thus reduce the need for training. A menu-driven interface is built on top of a 3D-model template. Scanned data for each new patient are imported, and the doctors or a trained operator can do geometric adjustments on the fly in an intuitive interface. Figures 12 to 14 show the menu driven interface processing and the generated 3D-geometry. A total of four tabs have been created to interact with the model.

1) **Placement:** Geometry adjustments can be done by moving and adjusting the angle of the cut planes.
2) **Cast geometry:** Thickness of the cast can be defined here: usually 2mm. In addition, clearance from the skin can be modified. Usually between 0.2mm and 0.5mm.
3) **Hole pattern:** In this menu it is possible to turn the hole pattern on and off and adjust the hole size. To enable 3D-printing of a cast with holes and avoid support during printing, a diamond shaped hole pattern is available, with width adjustments only. The height is automatically adjusted in a 2:1 ratio.
4) **Advanced tab:** Contains detailed adjustments for geometry in the thumb area. This is usually not necessary, but enables the user to adjust the angle between thumb hole and the centerline of the cast.

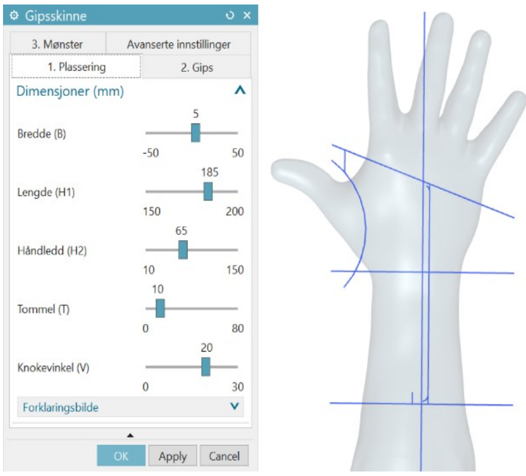

Figure 12: Geometry adjustments for plaster

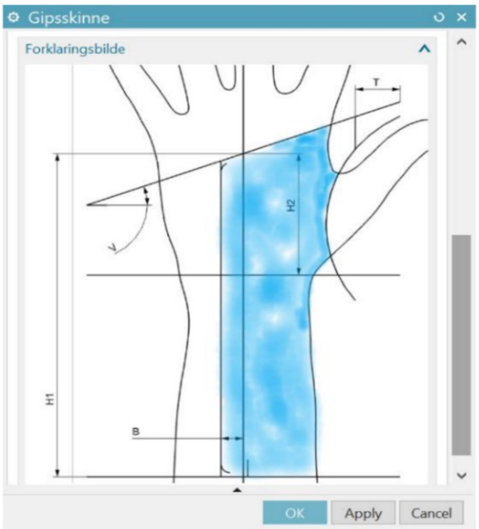

Figure 13: Outline of the brace

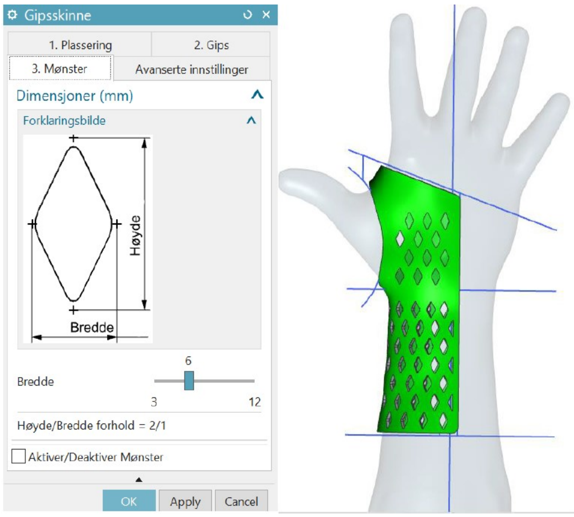

Figure 14: Hole pattern

Further optimization

- Connect the menu interface directly to the scanner to invoke scanning process and import the scan data directly.
- Automate the geometry cleanup post-processing of scanned data.
- Further automate the digital value chain and manufacturing pipeline and develop the interface to the 3D-Printer pool.
- Enable color selection from the menu interface.
- Vision, augmented reality and machine learning to speed up the process and further minimize the need for human interaction.

In an ideal world, the doctor/operator interacts with the machine in several simple steps:

1) The patient places their hand in the machine and the operator clicks on a button to start scanning. The scanning process takes less than a second.
2) The machine generates a digital model of the hand and iterates to create plaster geometry and suggest a design. This might take some minutes depending on the computing power. The operator approves the generated design and makes modifications if needed.
3) The patient selects a color from the library while the machine is generating design suggestions.
4) The operator sends the cast to production. Manufacturing data are instantly sent to a pool of 3D printers.

ADAPTATION IN THE CLINIC

The production process and the hardware and software selected are tailored to this special application. However, the production equipment is quite complex, so the main challenge has been the integration of the different parts into a complete system. Many solutions have been examined at each stage of the process with the focus on selecting the best options, regarding both hardware and software, and not least, the interfacing between the different stages. In this way, we have designed a production system for a product tailored to a particular customer. The implementation of this process in the clinic will have to be done in close co-operation between the engineer and the medical staff. This stage will also involve changing of the traditional routines in the clinic.

Software and interfacing

The software needed in such a complex production unit will consist of many parts. In this case, there are independent software components for the scanning, the preparation of the point cloud of data, the modelling process and the 3D printing. Most of the software covering our needs is available as open source products that may be modified and tailored to our use. The OEM manufacturers of the parts used in the product also deliver the necessary software used with this part. The main challenge is the interface between the different software components regarding parameter settings and the exchange of data. These components must connect into a single unit. Much effort has gone into making this a seamless software product. In addition, an easy and suitable user interface has been developed.

RESULTS

The purpose of this research project is the realization of a radical new way of producing orthopaedic braces, made possible by today's 3D technology. We have already produced such braces using modified 3D products available on the commercial market. Now we have tailor-made a manufacturing process for this product by adapting OEM hardware and software from different vendors to suit our needs. The interfacing between the different software systems and customization of the hardware components has been the most demanding and time-consuming work in obtaining a functional production process.

DISCUSSION

The production process described here is p.t technologically seen up and running. However, there are stringent demands regarding both the product and the production procedure when treating patients in a clinic. The greatest challenges are connected to production time and adapting to the daily procedures in the clinic. Faster and better 3D printers are available on the market and the prices are rapidly decreasing. On the other hand, there are many benefits of the new process. The clinic can make a product that is customized to each patient. The production is flexible regarding material qualities and design of the brace. The patient will get a brace that can be removed for cleaning and adjusted to his own personal comfort. The production costs, including material and work hours, will be lower than for a traditional plaster cast. The speed of development in 3D technology today with accompanying reduction in costs, the investment in such equipment will soon be very affordable.

CONCLUSION

The aim of this research has been to use state of the art 3D technology to replace traditional procedures in the treatment of hand fractures. The result has shown that it is fully possible to replace the traditional plastering process with 3D modelling and printing of patient braces. Technologically, this new process has already been realized, and processing costs are less than for the traditional plastering process. It will not be long before investment in this kind of equipment is affordable. Processing time is closely connected to costs and the fastest 3D printers are still quite expensive. However, costs on this type of limiting technology tend to decrease very fast, so this will soon be easier to access. We are quite confident that this will be the kind of technology found in the orthopaedic clinics in most hospitals in the near future.

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