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A digital workflow for personalized design of the interface parts integrated in a powered ankle foot orthosis (PAFO)

Tom Saey[1], Veerle Creylman[1], Roy Sevit[1], Eveline De Raeve[1], Daniel Morales Arenas[1], Luiza Muraru[1]

[1]*Mobilab & Care Thomas More University of Applied Sciences, Geel, Belgium*

Abstract—
The use of actuated exoskeletons in gait rehabilitation increased significantly in recent years. Although most of these exoskeletons are produced with a generic cuff, at the foot and ankle there are a lot of bony prominences and a limited amount of soft tissue, making it less comfortable . Furthermore, a proper alignment of the actuation systems is essential for the correct functioning of the exoskeleton. Therefore, we propose a digital workflow for the design of bespoke cuffs as interface parts of a powered ankle foot orthoses (PAFO). Moreover, this digital workflow permits the creation of axis and points of reference for the anatomical features which allows not only for the creation of custom-made cuffs but also for the integration and alignment of the PAFO mechanical components and actuation unit.

I. INTRODUCTION

The use of actuated exoskeletons in gait rehabilitation increased significantly in recent years. Nowadays there exist several commercially available lower limb exoskeletons that help mobility of users with impaired gait [1] by actively assisting two or three joints. Apart from full lower limb exoskeletons there are also exoskeletons that actuate only one joint; e.g. Lerner et al. [2] developed a prototype of a powered ankle foot orthosis (PAFO) using Bowden cables.

At this time most commercially available exoskeletons have a set of generic cuffs that function as the interface between the mechanical parts of the exoskeleton and the wearer. However, at the foot and ankle there are a lot of bony prominences such as the medial and lateral malleolus, os naviculare and the metatarsal heads. The presence of these bony prominences and the limited amount of soft tissue that covers them makes it a lot harder to use generic cuffs. A poorly fitting cuff will cause discomfort to the patient and can ultimately prevent the patient from walking normally. Furthermore, to optimize the additional external torque, good alignment of the mechanical axis with respect of the anatomical ankle axis is important [3]. Given the variation of the lower leg anatomy between different patients it is not possible to guarantee a good alignment using generic cuffs.

Finally, the assembled PAFO should be as compact and lightweight as possible [4]. Using custom made 3D designed cuffs will allow for a better and more compact integration of all exoskeleton components.

The objective of this paper is to describe a design algorithm for 1) the automated generation of the trimline that defines the shank cuff and the foot plate of an articulated PAFO and 2) the automated alignment of the actuation unit with the ankle axis.

Such an algorithm allows to easily design personalized ankle exoskeleton cuffs , while ensuring an optimal alignment of all mechanical components with the individual anatomy of each test subject.

II. METHODS

In order to streamline the production of the personalized design of an ankle exoskeleton, a digital workflow was developed by using the Grasshopper visual programming language within the Rhinoceros 3D CAD software. As shown in FIG 1. this digital workflow consists of 4 steps which will be discussed in more detail below.

3D scanning and correction of the positive model

In order to design well-fitting patient specific PAFO cuffs, it is important to have a digital representation of the patients lower leg anatomy. To achieve this a 3D scanner is used to capture the shape of the patients leg. If needed, an intermediate step with plaster of Paris casting can be used. Next, similar to the conventional production workflow for custom AFOs, certain corrections are applied to the 3D model of the patient's leg by a certified prosthetist and orthotist (CPO) using specialized CAD-CAM software for orthotics and prosthetics.

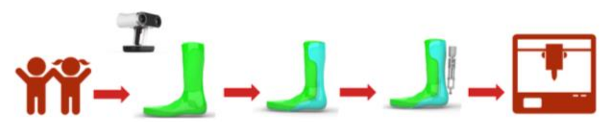

Fig. 1: Digital workflow for design and production of patient specific ankle exoskeleton cuffs

III. RESULTS

Parametric design of AFO cuffs

In order to streamline the design process of the personalized PAFO cuffs a parametric design script was written using the Rhinoceros CAD software and the grasshopper plugin.
As an input this script uses the positive corrected model of the patients leg.

1) Alignment of all positive models to the same coordinate system

In order to make it possible to use the same script for all models, independent of the scan direction, all models are aligned to the world coordinate system. Therefore the user indicates a set of anatomical landmarks on the un-oriented positive model:

- Medial malleoli (m_m) and lateral malleoli (m_l)
- Head of the fibula (f_h)
- Metatarsal head 1 (m_{1h})
- Metatarsal head 5 (m_{5h})
- Three points at the plantar forefoot surface (p_1, p_2, p_3)

Based on these points, a local coordinate system is defined, with origin (O_c) at the midpoint of the line joining m_m and m_l

Two auxiliary planes are defined on the foot:
- *transversal plane,* parallel to the *forefoot plane* (defined by p_1, p_2, p_3), and containing O_c.
- *sagittal plane*: perpendicular to the transversal plane, containing O_c and a point on the line segment joining m_{1h} *and* m_{5h} on 1/3 of the distance from m_{1h}.

The axes of the local coordinate frame are defined as follow:
- The y_c axis is the intersection between *transversal plane* and *sagittal plane*, with positive direction anterior.
- The z_c axis is lying in the *transversal plane* and perpendicular to the y_c axis, with positive direction to superior.
- The x_c axis is mutually perpendicular to y_c and z_c axis, with positive direction to the lateral side.

In a next step the local coordinative system and subsequently the positive model is rotated and translated to the world coordinate system by applying a transformation matrix.

2) Trimline definition and trimming of PAFO cuffs

The newly developed algorithm to define the trimlines is based on the same idea as the one described by Syngellakis et al. [5] but allows for a different lateral and medial trimline design at the foot level. Furthermore it is written to design a hinged (P)AFO with a separate foot and leg cuff.

As shown in Fig. 2 and Fig. 3 both the foot and calf trimline are defined by respectively a set of 8 and 9 points.

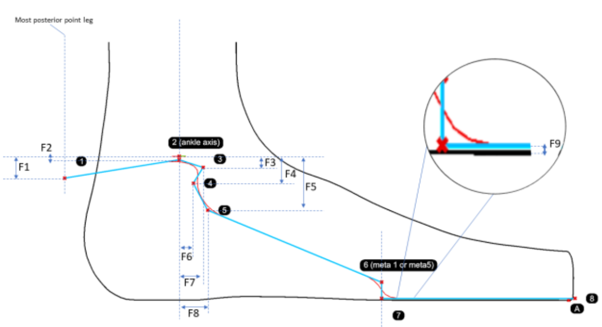

Fig. 2: sagittal view of the foot trimline and the points and parameters that define its shape

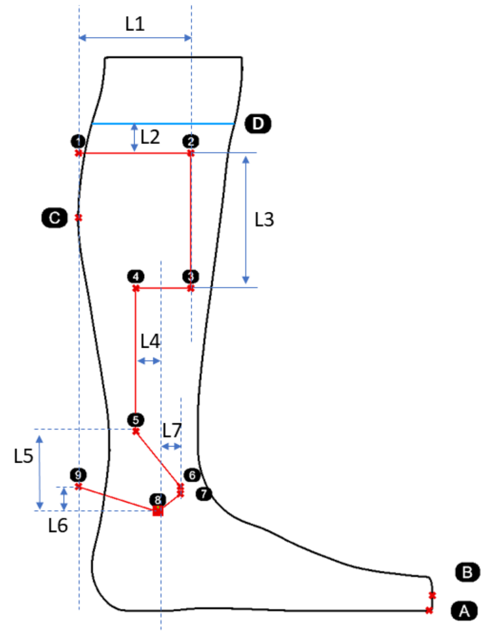

Fig. 3: sagittal view of the calf trimline and the points and parameters that define its shape

The locations of all these points are defined by parameters (L1-L7 and F1-F9) [5] that describe their location based on either indicated anatomical landmarks or calculated reference points such as: fibula head height (D), the most posterior point on the leg (C), the most distal point of the mesh (A) and the most proximal point of the mesh (B).

In order to obtain the trimline a polyline is created between the trimline points of both the calf and foot. Next the polyline is rebuild into a polyline with the same degree but defined by a higher number of control points. As a final step the rebuild polyline is smoothed to get a softer trimline curve.
In case of the foot, a similar algorithm to generate the trimline is developed. However, it is improved by using different input values [F1-F9] that define the position of the medial and lateral trimline; the result is a more precise asymmetric design.

Once the trimline curves are defined, the curves are extruded along the x-axis (Fig. 4A and B). In order to be able to combine both medial and lateral trimming surfaces of the foot into one surface, a lofted surface is created in between the middle edges of both the foot trimming surfaces (indicated in blue on Fig. 4A). Next all the trimming surfaces of the foot are joined into one surface prior to trimming the leg mesh resulting in the trimmed PAFO cuffs (Fig. 4C). Finally the forefoot plate of the foot cuff is trimmed with a trimming surface (Fig. 4D & E) that is defined by both the person's foot length and the location of the first and fifth metatarsal head.

3) Offset the trimmed PAFO cuffs to obtain cuffs with the desired thickness

In order to obtain the PAFO cuffs geometry the positive leg model is cut with the help of the previously defined trimming surface. This results in two trimmed meshes without thickness that reproduce the anatomy of the patient and need to be offset to a defined thickness in order to obtain 3D printable PAFO cuffs. Typically this can be done by applying an offset to the trimmed mesh. However the disadvantage of this approach is that it results in an offset mesh with rather sharp edges. In conventional CAD models this can be solved by applying a fillet to the sharp edge. However when working with meshes this is not straight forward. Even though there is specialized software that is able to apply fillets to mesh edges, this is not possible in Rhino grasshopper.

As a workaround the triangular mesh is converted to a quad mesh with a lower polycount. The quadrilateral mesh is then converted into a subdivision surface model (SUBD). When a SUBD surface is offset, it automatically results in a SUBD model with smooth edges, resulting in a smooth mesh when exported.

4) Alignment of ankle hinge dummies with respect of ankle axis

It is well known that the anatomical ankle axis is slightly tilted [6](Fig. 5 5). In order to be able to indicate the lateral and medial malleoli more accurately on the 3D model, the location of both malleoli is marked during initial measurement of the leg by an experienced CPO. These locations were preserved throughout the digital correction process and indicated on the corrected 3D model by means of two small mesh spheres. These spheres make it easier to indicate the right locations of both malleoli once the 3D model is imported into the design algorithm.

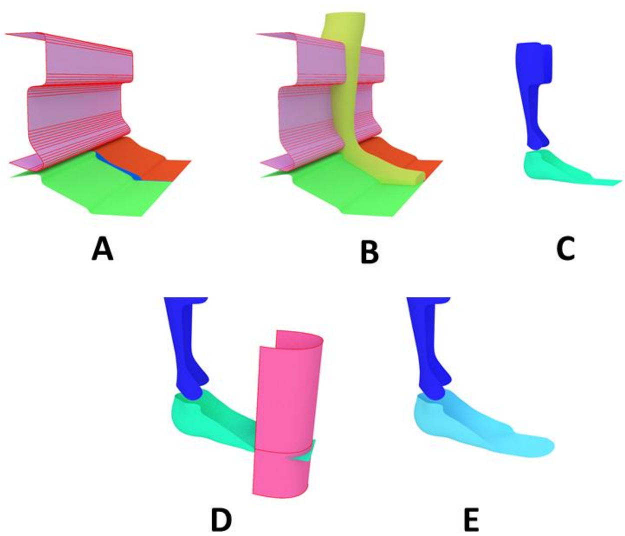

Fig. 4: Trimline generation, A) three trimming surfaces and lofted surface between medial and lateral foot surface, B) trimming surface and leg mesh, C) trimmed leg mesh, D) trimming surface to trim the forefoot plate of the PAFO based on foot length and location meta 1 and 5, E) trimmed forefoot plate

The correct positioning of the joints is made based on the points marked by the CPO. To achieve this the position of both the medial and lateral malleoli was averaged in both anterior-posterior and proximal-distal direction and a mechanical joint axis is defined. (Fig. 5).

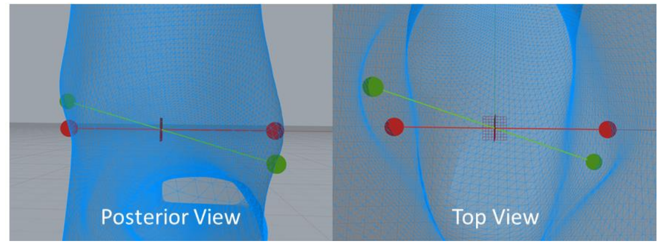

Fig. 5: Anatomical ankle axis (indicated in green), Mechanical axis used for joint placement (indicated in red)

By using the mechanical joint axis it is possible to align the selected hinges on the PAFO cuff. Reverse engineered models of the joints are used for this purpose. The main advantage of this method is that every kind of joint can be added without the need of the patient. The definition of the axis provides the guidance needed to define the correct position of the joints and to create the holes on the PAFO in order to fix the joints. The result is a joint that has an optimal orientation and there is no precision lost on manual processes as finding the location for the mechanical fixation of the joints. This process was positively evaluated by implementing two different kind of joints Tamarack (Tamarack Habilitation Technologies, Minnesota, USA) and Pivot (Launchpad, Minneapolis, USA) joints.

5) Alignment of actuation system with respect to the ankle axis

The PAFO is powered by an actuation unit, consisting of a Hebi Robotics Series Elastic Actuator (Pittsburgh, PA, USA) mounted on the calf, which is connected to the foot cuff by means of a parallel 4 bar mechanism that transmits the rotational motion to the ankle joint. To ensure that the axis of the motor and the 4 bar mechanism are parallel to the mechanical joint axis, the actuation unit is placed on the leg cuff with the help of a transformation matrix, containing the mechanical joint axis.

The lengths of the 4 bars of the mechanism are optimized for proximal placement of the heavy elements (e.g. the actuator) to minimize inertial effects that can have a negative effect on the gait pattern. They are also designed to minimize the posterior space consumed by the components (i.e. the actuator lever arm) while still maintain sufficient space to create a proper ankle cuff hinge attachment.

6) Production of personalized cuffs with additive manufacturing

The use of additive manufacturing techniques for the production of personalized AFOs is gaining relevance [7] in the field. For this application, Multi Jet Fusion (MJF, HP, Palo Alto, United states) PA12 was preferred over SLS given the low cost and reduced printing time compared to SLS [8].

7) Initial fitting

The method described above was used to design custom interface cuffs for 2 healthy adults. A pivot joint (Launchpad, Austin, TX, USA) was used to connect shank cuff with the foot plate. Further on, the cuffs were part of a newly designed PAFO.

The parts were 3D printed and assembled. First prototypes were fitted on the participants.

The weight of the PAFO with actuation unit was 1.330 kg. Fitting of the PAFO was verified visually in a similar manner as fitting of the conventional AFO.

For both participants, the ankle range of motion was not hindered while wearing the PAFO. Fig. 6 shows maximum plantar flexion and dorsiflexion from one of the participants.

IV. Discussion

The proposed digital design workflow significantly speeds up the design process of personalized PAFO cuffs. Additionally, it allows for an optimal alignment and positioning of the actuation system and hinges with respect to the ankle axis.

In order to speed up the design workflow and limit the manual input of the end user, a more automated way to generate a trimline was implemented. In the conventional manual production process of ankle foot orthosis the trimline is typically drawn by hand on the thermoplastic sheet after it is thermoformed on top of the corrected positive model of the leg.

Syngellakis et al. described a method to generate a 2D posterior leaf spring AFO trimline. This trimline was defined relative to the 2D projection of the leg model in the sagittal plane and based on a set of 10 points that could be set using parameters. One of the drawbacks of the method described by Syngellakis et al. is that it result in an AFO design with a symmetrical lateral and medial trimline. This is not consistent with the fact that in a conventional custom made AFO the medial and lateral trimline at the height of the foot often have a different shape. In order to achieve this, a new approach was proposed that allows to define the shape of both medial and lateral trimline of the foot independent from each other.

The benefit of having a scanned 3D model of the patient leg that is properly aligned with a reference coordinate system is that it allows for parametric design; by having a defined axis for the leg and ankle it is possible to introduce different kind of joints and actuation systems that are adapted to the patient leg in an optimal manner.

Adapting the external elements of an exoskeleton on a brace can be an arduous task that introduce inaccuracies due to the lack of reference points and freeform surfaces. The process presented here eliminates the inaccuracies and facilitates the optimal installation of different joints, actuation units, sensing units and allows for adaptation to the anatomy of different subjects.

In this paper, the presented digital workflow was applied for the automatic design of personalized PAFO cuffs and automatic alignment and integration of the other PAFO components.

Fig. 6: Left: PAFO assembly with cuffs and actuation system with a 4-bar mechanism Right: Test subject wearing the assembled PAFO prototype

As this work is part of a larger project, the effect of PAFO and conventional AFO on gait kinematics and kinetics of children with gait disabilities due to neurological disorders will be assessed and compared in the near future.

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