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A digital process to replicate the socket-foot alignment in below-knee running specific prostheses

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ABSTRACT

A well-fitting socket and a fine-tuned foot alignment are crucial elements in a running-specific prosthesis to allow Paralympic athletes with below-knee amputation to express their full competitive potential. For this reason, once a satisfactory socket-foot configuration is established after dynamic alignment, it is fundamental to reproduce the same conditions when constructing the definitive carbon fiber socket, and when renewing or constructing a back-up prosthesis, without dismantling the original. In addition, to cope with emerging needs of the athlete, it would be beneficial to implement fine-tuning adjustments of the alignment in a very controlled manner. At present, this requires elaborate bench procedures, which tend to be expensive, time consuming, prone to manual errors, cumbersome in use and most often require damaging or disposing of the current socket. In this study, we propose an original CAD/CAM workflow that allows replicating the desired socket-foot configuration for below-knee sprinting prostheses, as well as performing socket adaptations and introducing fine-tuning adjustments to the alignments. The workflow is exemplified with reference to two case studies involving elite Paralympic runners with transtibial and partial foot amputations, respectively.

1. Introduction

A well-fitting socket and a fine-tuned foot alignment are crucial elements in a running specific prosthesis (RSP) to allow Paralympic athletes with below-knee amputation to express their full competitive potential. For this reason, once a satisfactory socket-foot configuration is established after dynamic alignment, the possibility to reproduce the same conditions would be extremely beneficial when 1) constructing the definitive carbon fiber socket from a thermoformable check-socket, and 2) when renewing or constructing a back-up prosthesis, without dismantling the original. In both scenarios, it might also be useful to implement fine-tuning adjustments to the alignment in a very controlled manner. At present, this requires elaborate bench procedures that exploit transfer devices typically developed for everyday life prostheses and that need to be properly customized to accommodate running prosthetic feet (RPF) [1–5]. To the best of the authors' knowledge, no scientific evidence is reported in the literature regarding the pros and cons of using these devices for sport prostheses. The practical experience shows that transfer apparatuses are indeed commonly used by prosthetists for the alignment of prostheses for daily living. However, their adoption for sport application is expensive, time consuming, prone to manual errors, cumbersome in use and most often lead to damaging or breaking of the current socket. In addition, the quality and number of fine-tuning adjustments are often bound to the level of custom adaptations introduced to the transfer device and to the degrees of freedom that such adapted device is able to provide.

In this study, we propose an original CAD/CAM workflow that allows to replicate desired socket-foot configurations for below-knee RSPs for sprinting, as well as perform socket adaptations and introduce fine-tuning adjustments to existing alignments. We exemplify the new workflow by reporting the replication of the RSPs for two elite athletes, with transtibial and bilateral foot amputation, respectively.

2. Methods

Fig. 1a shows the three elements of the custom-made sprinting RSP, which is the medical device to be replicated: the socket, the RPF, and the connection distal area between these two elements. Specifically, the socket hosts the residual limb of the athlete in its inner part and is

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List of acronyms

RSP	Running specific prosthesis
RPF	Running prosthetic foot
CAD/CAM	Computer-Aided Design/Computer-Aided Manufacturing
SPB	Socket Posterior Box
FA	"Flat" area
CA	"C" area
PP	Most prominent point
SSA	"Sole & Spikes" distal Area
3DS	3D mesh editing software
SVD	Singular Value Decomposition
ICP	Iterative closest point algorithms
ABS	Acrylonitrile Butadiene Styrene
PUF	Polyurethane foam

connected to the RPF with its posterior outer part, referred herein as Socket Posterior Box (SPB), which embeds a standard (e.g. Ossur FSX50009 or Ottobock 4R420) or custom-made threaded lamination connector that is bolted to the foot (typically through two M10 bolts). The shape of the SPB sets the relative alignment between inner socket (and athlete limb) and foot. The foot is a "J" type foot, characterized by three areas (Fig. 1b): a "flat" proximal area (FA) where the foot is attached to the lamination connector embedded in the SPB, a "C area" (CA) that includes the C-bend of the foot which extends from the end of the FA to about 15 cm below its most prominent point (PP) and a "sole & spikes" distal area (SSA).

Starting from accurate scans of the socket and of the foot in their intended alignment, the workflow enables to digitally design and subsequently fabricate a so-called "alignment box" and a "coupling element" that allow a simple and repeatable bench-based implementation (replication) of the desired relative position between socket and foot. The workflow consists of two processing blocks: a *Digital design procedure* performed through scanners and 3D mesh editing software (3DS), and a *Manufacturing procedure*, implemented through a milling machine or a 3D printer.

2.1. Digital design procedure

The digital workflow consists of six steps depicted in Fig. 2 and described in detail below.

1. Scanning. Scanning the inner part of the socket and the external part of the foot, correctly assembled, and aligned with respect to one another. This step requires the use of a digital scanner with sufficient accuracy and that is capable of scanning the inner part of the socket as well as the outer part of the foot. Due to scanner limitations, these elements might need to be digitized with different devices or in separate sessions. In such a case, to allow subsequent virtual spatial registration of the two meshes, it is essential to use a common reference element visible in both scans. In this study, the Echo3D scanner (Rodin4D, Nouvelle-Aquitaine, France) was used to scan the inner part of the socket (inner socket) and the EinScan Pro 2X Plus scanner, coupled with the HD structured-light accessory (Shining3D, Zhejiang, China), was used to scan the outer shape of the foot. The "inner" scanner has an accuracy of 0.3 mm on the radius while the "outer" scanner can reach 0.05 mm. As common reference element between scans, a thin (0.1 mm thick) crumpled paper collar (0.7 mg/ m^2) was fixed around the proximal brim of the socket and was scanned by both devices; this represented a simple and unexpensive way to acquire common geometrical features by both scanners in order to facilitate subsequent spatial registration of the two meshes. As support during external scanning, it is recommended to provide a background geometry with simple and recognizable features. To this purpose, in this study a 5 mm thick cloth of Pelite ® material with irregular foam boxes glued to it was used. The part of the foot that needs to be scanned depends on the final purpose of the prosthetist. Without loss of generality, we focused here on a specific aim, i.e. to replicate the alignment or to make fine adjustments in the alignment through movements of the socket (and not of the foot). In this case, only the posterior side of the foot is needed, making sure to acquire both the FA and the CA. Through practice, we learned that scanning the foot up to approximately 20 cm below the C-bend should be sufficient to guarantee a firm interlock of the foot into the alignment box. The foot mesh was isolated from the scan using Geomagic Essential (3D Systems, Triangle Park, United States). The same software was also used to modify the mesh, i.e. delete auto-intersections and fill holes.
2) Spatial registration. Rigid spatial registration between the two scans is performed in a 3DS (e.g. MeshLab, Karnataka, India) identifying landmarks on the geometrical features of the crumpled paper collar and applying Singular Value Decomposition (SVD) [6] and Iterative Closest Point (ICP) algorithms [7].
3) Possible adjustments (*optional*). If necessary, socket modifications or fine-tuning alignment adjustments can be digitally performed in a

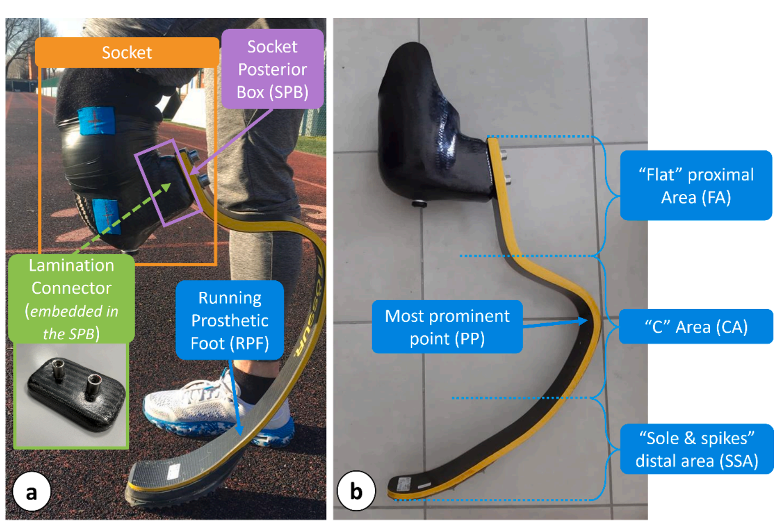

Fig. 1. (a) Custom-made sprinting RSP to be copied; (b) Foot areas.

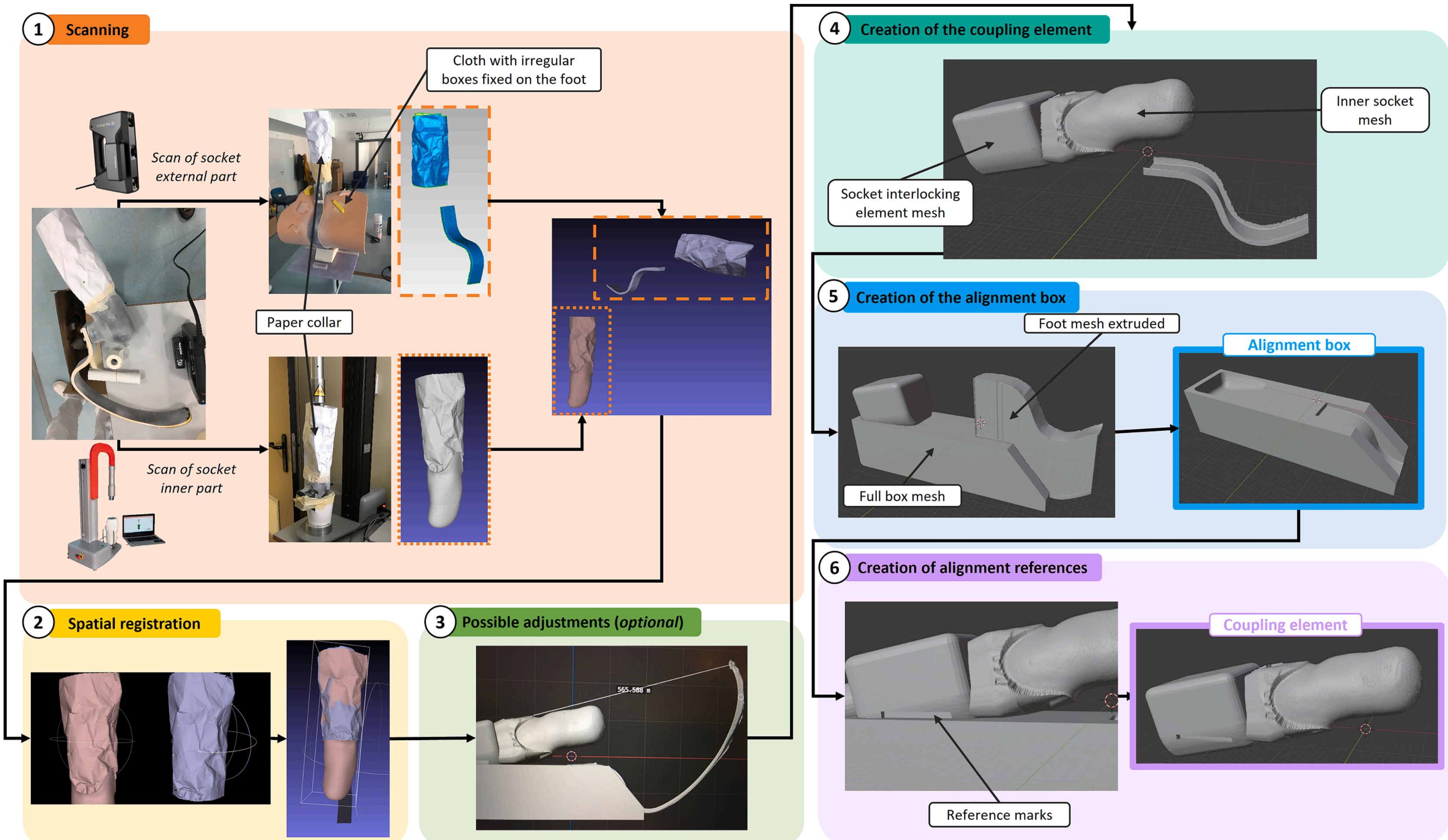

Fig. 2. Digital design procedure: 1) scanning the inner part of the socket and the external part of the foot, correctly assembled and aligned with respect to one another; 2) rigid spatial registration between the two scans; 3) if necessary, introduction of socket modifications or orientation adjustments; 4) creation of the socket interlocking element and Boolean connection to the inner socket mesh to obtain a coupling element; 5) design of the alignment box by Boolean subtraction of the socket interlocking element and of the foot, properly extruded, from a full box; 6) creation of additional reference marks in the socket interlocking element at the intersection with the alignment box.

very controlled manner in 3DS (e.g. Blender, Amsterdam, Netherlands) through rotation and translation virtual tools.

4) Creation of the coupling element. A "socket interlocking element" is generated in a 3DS and it is connected to the inner socket mesh through Boolean operations to obtain a coupling element. This assembly will later allow to position the socket with respect to the alignment box, described below. An example of interlocking element is provided in *.stl format in the supplementary online material.
5) Creation of the alignment box. An alignment box is designed in a 3DS by Boolean subtraction of the socket interlocking element and of the extruded foot from a full box. The box dimensions are established based on the dimensional limitations of the milling machine or of the 3D printing plate.
6) Creation of alignment references. To ensure an accurate coupling between the alignment box and the socket interlocking element, additional reference marks can be created on this latter component at the intersection with the alignment box. This foresight will allow, during bench alignment, to visually confirm whether the correct interlock between the two parts has been reached.

The *Digital design procedure* described above allows to obtain two digital objects, i.e. the alignment box and the coupling element. During the *Fabrication procedure*, described below, these two objects will be physically manufactured and will represent the starting point to effectively replicate the bench-based socket-foot alignment.

2.2. Fabrication procedure

For the *Fabrication procedure*, either a two-axes milling machine, or a 3D printer is required. In the case of a milling machine, the work area should be about 630 × 300 × 300 mm, to accommodate the typical size of a below-knee sprinting RSP, and it should be capable of carving a polyurethane foam (PUF) box with a recommended density of 90 kg/m^3. In this study, the 7-axes robot Ortis Essential (Roboticom, Pisa, Italy), which features an accuracy of 0.2 mm, was used to fabricate all elements. In the case of a 3D printer, the building volume can be smaller, provided that the alignment box is subdivided into smaller interconnecting sub-boxes to be coupled together. In this case we recommend ABS (Acrylonitrile Butadiene Styrene) because of its low cost and low shrinkage properties.

The procedure consists of 6 steps illustrated in Fig. 3 and described below with specific reference to the use of a milling machine.

1) Fabrication of the coupling element. Fabrication of the coupling element (i.e. inner socket connected to its interlocking element) by milling the relative digital object (obtained in step 6 of the *Digital design procedure*) from a PUF cylinder. The size of the cylinder has to be set case-by-case, depending on the size of the athlete's residual limb and on the dimension of the interlocking element.
2) Fabrication of the alignment box. Fabrication of the alignment box by milling the relative digital object (obtained in step 5 of the *Digital design procedure*) from a PUF box of customized dimensions. This PUF box can be prefabricated as follows:

a. Manufacturing of a parallelepiped mold. In this study, the mold was obtained by screwing 15 mm thick PET-G plates to create a box with internal dimensions of 170 × 195 × 800 mm. The box size was established based on the dimensional limitations of the milling machine.
b. Lubrication of the mold internal surfaces with a releasing agent.
c. Pouring the two PUF reagents (i.e. Pedilen® rigid foam and hardener, Ottobock, Duderstadt, Germany) inside the mold and mixing with a whisk. The chemical reaction is triggered and requires a few hours to reach complete solidification. In this study, 3 kg of each agent were used, and 6 h were required for curing.
d. Disassembly of the mold to obtain a solidified PUF parallelepiped.
e. Shortening of the parallelepiped to a length compatible with the milling machine dimension limitation (630 mm). This way the obtained PUF box is ready to be milled.

3) Socket lamination. The socket is laminated on the coupling element, leaving the interlocking element unaffected.
4) Socket and foot positioning in the alignment box. If a new foot is used, the foot flat area is cut to the appropriate length and the foot lamination connector is screwed to the foot in correspondence of two holes previously drilled on it in the appropriate location, to match the length and hole positions of the scanned foot. Then, the socket interlocking element and the foot (with the foot connector) are physically positioned in the dedicated housings of the alignment box. A correct socket alignment is reached when the reference marks of the socket interlocking element are aligned with the top side of the alignment box.
5) Connection creation. A physical connection between foot connector and socket distal end is created by following the typical procedure of pouring PUF between the two. Once the PUF has cured, the connector is firmly attached to the PUF. At this point, the foot is unscrewed from the foot connector and the PUF-connector combination is then embedded into the socket through a second lamination, to create the Socket Posterior Box (SPB).
6) Prosthesis assembling. The RSP is finally obtained by screwing the foot to the lamination connector embedded within the socket.

This method was adopted to replicate the socket-foot alignment of five athletes of the National Paralympic Team that practice different disciplines. In this paper, the authors decided to focus only on two athletes, representative of the treated group of subjects. Specifically, subject 1 was a 26-year-old female triathlon athlete with bilateral partial foot amputation that wore two Ottobock Sprinter 1E90 feet. Subject 2 was a 33-year-old male sprinter with a left transtibial amputation that wore an Ossur Cheetah® Xcel foot (Ossur, Reykjavík, Iceland). In all cases, athletes were asked to wear the prosthesis aligned with the described technique. The subjects were not aware of the procedure followed to fabricate their new sport devices. Firstly, the prosthetist asked them to assume an orthostatic position, then to do little jumps and finally to run on the athletic field or on the asphalt (for triathlon athletes), to assess possible misalignments or discomfort in the socket.

Finally, to assess the accuracy of the milling process, the comparison between the milled objects (coupling element and alignment box) and the respective digital objects (obtained at the end of the *digital design procedure*) was completed for subject 2. Specifically, the milled objects were scanned with Einscan Pro 2X Plus and distance maps were built between these scans and their relative digital version. To evaluate their differences, the "Distance from reference mesh" function provided by MeshLab was used, considering the digital objects as "reference meshes" and the scans as "measured meshes". Then, maps were built by means of the "quality map" MeshLab function, setting the "red-white-blue" color scale. In these maps, only the relevant surfaces for the procedure were compared, specifically, the whole coupling element and the alignment box housings for the socket interlocking element and for the foot.

3. Results

This procedure was successfully adopted to replicate the prostheses alignment of five athletes of the Italian Paralympic Team and proved to be applicable in four different types of running feet, namely Ossur Cheetah® Xtreme, Xcel, Xpand and Ottobock Sprinter 1E90.

In particular, Fig. 4 shows the application of the method to subjects 1 and 2, respectively. It reports, for subject 1, the digital versions of the right-leg coupling element (Fig. 4a) and alignment box (Fig. 4b); the digital relative positioning of these two elements (Fig. 4c); the PUF milled alignment boxes for both legs (Fig. 4d) and the two aligned prostheses worn by the athlete (Fig. 4e). For subject 2, Fig. 4 reports the

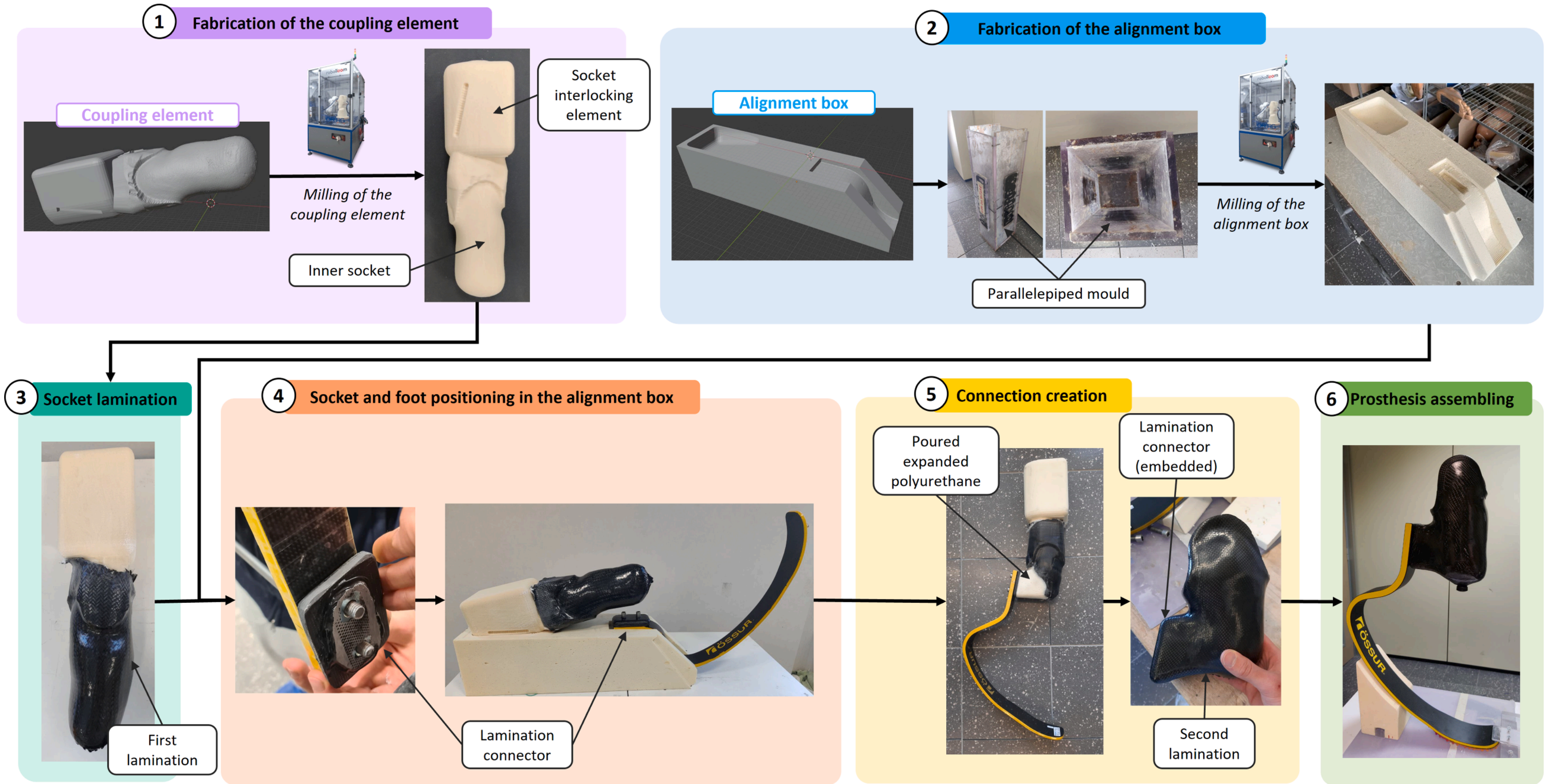

Fig. 3. Fabrication procedure: 1) fabrication of the coupling element; 2) fabrication of the alignment box by milling the digital designed shape on a pre-fabricated PUF box; 3) socket lamination leaving the interlocking element unaffected; 4) positioning of the socket interlocking element and of the foot (with the foot connector) in the dedicated housings of the alignment box; 5) connection between foot connector and socket distal end by pouring PUF and incorporation of the connector into the socket through a second lamination; (g) RSP assembly.

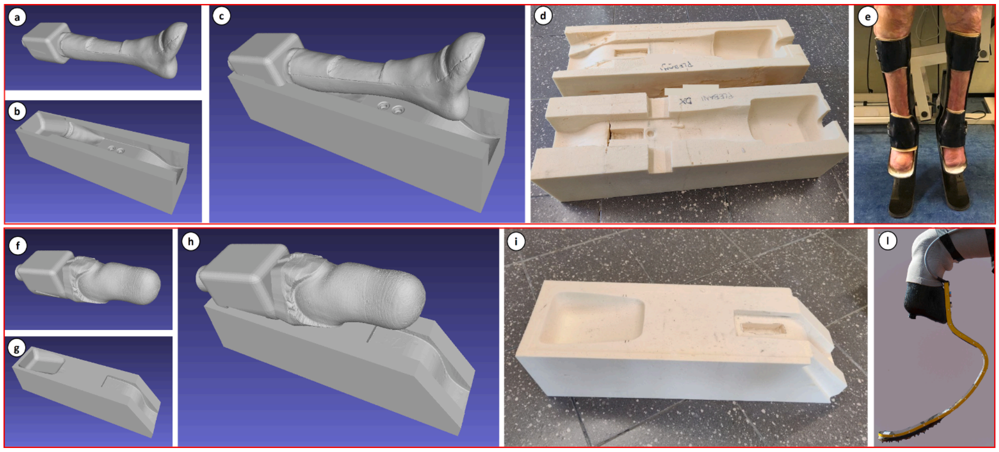

Fig. 4. Prostheses alignment of subject 1: (a) digital version of the right-leg coupling element; (b) digital version of the right-leg alignment box; (c) digital positioning of the socket interlocking element and of the foot in the dedicated housings of the alignment box; (d) milled PUF alignment boxes, for both legs; (e) aligned prostheses. Prosthesis alignment of subject 2: (f) digital version of the left-leg coupling element; (g) digital version of the alignment box; (h) digital positioning of the socket interlocking element and of the foot in the dedicated housings of the alignment box; (i) milled PUF alignment box; (l) aligned prosthesis.

digital version of the left-leg coupling element (Fig. 4f) and alignment box (Fig. 4g); the digital relative positioning of these two digital objects (Fig. 4h); the PUF milled alignment box (Fig. 4i) and the aligned prosthesis worn by the athlete (Fig. 4l). In all cases, none of the athletes reported to perceive any differences with respect to their old prosthesis during the execution of different athletic gestures and none of them asked for modifications. The prosthesis supply ended in about 1 h from the arrival of the patient in the clinic.

In addition, Fig. 5 reports the distance color maps between the digital objects (reference meshes) and the relative milled objects (measured meshes) for subject 2. Fig. 5a shows the map for the alignment box housings, while Fig. 5c reports the map for the coupling elements. For both maps, histograms related to color distributions are reported (Fig. 5b and 5d respectively). In both cases, the most intense shade of red is associated to a difference of −1 mm, the most intense shade of blue to a maximum difference of 1,5 mm and white to null distances.

4. Discussion

The procedure presented in this article proved to be a reliable tool to easily reproduce the socket-foot alignment for sprinting and running specific prostheses. As shown in the results, this method was successfully applied also to complex cases, such as a bilateral partial foot amputation subject. The comparison between the designed digital objects and their respective milled objects resulted in error values that can be considered negligible for the alignment process (range: −1 mm; 1,5 mm) since none of the athletes perceived any difference with respect to their previous prosthesis.

In general, the procedure allows to avoid using adapted transfer devices, not designed for sport applications, or other bench alignment setups that do not enable to introduce specific modifications, revealed to be unstable and could lead to manual errors and socket damages or destruction. Moreover, the use of a digital procedure allows to store all the data (i.e. scans, alignment box, coupling element) necessary to reproduce or make further modifications to the alignment. This way, there is no need to start the process from scratch (i.e. from the alignment transfer device) but it is sufficient to manufacture the alignment box and coupling element (that have been digitally stored) and use them to position a new temporary socket with respect to the foot.

It is worth mentioning that in this article we described the standard procedure to reproduce the socket foot alignment for sport prosthesis or at most to introduce minor fine-tuning adjustments through movements of the socket. Nevertheless, this method could also be used to introduce major adjustments to the alignment to meet the requests of the athlete and improve sport performance. To this aim, it could be necessary to scan the whole foot (and not only its proximal posterior part) to have the possibility to modify in a 3DS its position and orientation with respect to the socket.

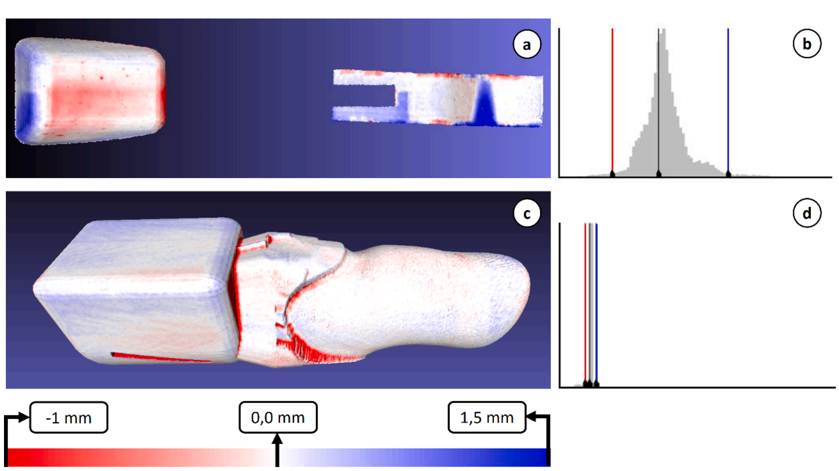

Fig. 5. Distance color maps between the milled objects and the corresponding digital objects. a) Map between alignment box housings; b) histogram related to map (a) color distribution between the set limits; c) map between coupling elements; d) histogram related to map (c) color distribution between the set limits.

During the development of the workflow, we were able to highlight some useful tips to ensure a smooth implementation of the procedure. Namely, it is important to have a sufficiently large socket interlocking element, with a considerable intersection with the alignment box. This is necessary to guarantee a firm connection between the foot and the socket during the alignment reproduction. In addition, the alignment reference marks turned out to be fundamental features to reach a correct positioning of the socket interlocking element inside the alignment box, and ultimately between socket and foot.

This method has some limitations: it requires CAD expertise and access to specific tools, i.e. 3D scanners and 3D printers or milling machines, expensive devices that involve qualified personnel.

5. Conclusions

The proposed workflow provides a novel, valid, reliable, and repeatable solution to the unsolved issue of successfully reproducing or adjusting in a very controlled manner the socket-foot alignment in below knee running specific prostheses, avoiding the adaptation of non-specific transfer devices. This workflow is easily applicable in orthotic and prosthetic facilities equipped with 3D scanners and a 3D printer or milling machine. Finally, it proved to be effective and flexible, since it was successfully adopted to replicate five athletes' socket-foot alignments, characterized by feet with different lengths and curvatures.

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Ethical approval

The two athletes, whose cases are reported here, reviewed the study manuscript before submission and gave written consent to be included. Subjects also gave permission to be acknowledged.

Declaration of competing interest

None declared.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.medengphy.2024.104106.

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