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A methodology for the customization of hinged ankle-foot orthoses based on in-vivo helical axis calculation with 3D printed rigid shells

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Abstract

This study aims to develop techniques for ankle joint kinematics analysis using motion capture based on stereophotogrammetry. The scope is to design marker attachments on the skin for a most reliable identification of the instantaneous helical axis, to be targeted for the fabrication of customized hinged ankle-foot orthoses. These attachments should limit the effects of the experimental artifacts, in particular the soft-tissue motion artifact, which affect largely the accuracy of any in-vivo ankle kinematics analysis. Motion analyses were carried out on two healthy subjects wearing customized rigid shells that were designed through 3D scans of the subjects' lower limbs and fabricated by additive manufacturing. Starting from stereophotogrammetry data collected during walking and dorsi-plantarflexion motor tasks, the instantaneous and mean helical axes of ankle joint were calculated. The customized shells matched accurately the anatomy of the subjects and allowed for the definition of rigid marker clusters that improved the accuracy of in-vivo kinematic analyses. The proposed methodology was able to differentiate between subjects and between the motor tasks analyzed. The observed position and dispersion of the axes were consistent with those reported in the literature. This methodology represents an effective tool for supporting the customization of hinged ankle-foot orthoses or other devices interacting with human joints functionality.

1. Introduction

In-vivo joint kinematics is relevant in many applications, such as the design of prostheses and orthoses, the optimization of exercise and sport performance and the diagnosis of pathologies affecting joint function. Relevant measurements are however critical, also using stereophotogrammetry, because of the many experimental artifacts, in particular the soft-tissue artifact.[1,2] This is a critical source of error implied in the sliding of the reflecting markers, positioned and stuck on the skin, with respect to the underlying bone. Due to its frequency content, very similar to the one of actual human joint motion, it is difficult to remove it through standard filtering techniques. In traditional gait analysis, the most critical segment is the thigh, followed by pelvis and shank segments, because of the large soft tissues around the femur. By evaluation of the relative motion between a cluster of reflective skin markers captured in stereo-photogrammetry and the underlying bone segments tracked in fluoroscopy, the deviation of skin marker trajectories on the thigh has been found about 10 mm higher than the one measured for the shank for a subject performing daily activities.[3] Furthermore, several studies[4,5] have shown that relative motion among markers within the same segment is smaller than the entire motion of the marker cluster with respect to underlying bone.

Local movement of the skin markers during walking was modeled using a linear model with up to four degrees of freedom (DOFs) so to predict markers trajectories with respect to the bone with limited approximation. [6] To reduce the effect of soft-tissue sliding, motion analysis has been also performed by inserting intracortical pins under local anesthesia in the tibia, in the talus and in the calcaneus with clusters of external markers tracked by a video analysis system, unfortunately resulting in an unnecessarily invasive technique.[7] Similarly, excessively invasive methodologies for in-vivo joint kinematics analysis are those that take advantage of X-ray based medical imaging techniques, exposing the subject to radiations.[8,9] Further attempts to remove soft-tissue artifact during walking involve multibody kinematics optimization techniques based on the estimation of the optimal position of a chosen anatomical segment by means of multibody models of the lower limb.[10]

In the present study, an experimental approach is adopted to devise a technique for the minimization of skin sliding artifacts. This is based on the design of two rigid shells for marker cluster to be fixed to the shank and the foot respectively, customized on the specific shape of the corresponding segment of the subject. In this way, since the markers are not directly placed on the skin, the deformation within the cluster can be effectively minimized. Even though the present study focused on the ankle joint, the methodology described can be easily transferred to other human joints. Several studies have demonstrated the complexity of the human ankle joint kinematics, which is often erroneously approximated as a planar hinge joint with a fixed axis of rotation passing through the two malleoli. It has been shown that the interaction between articular surfaces and ligaments leads to a rather complex relative motion between shank and foot segments, that can be described by a floating axis of rotation whose orientation and position change during motion.[10,11] This result has been consistently pointed out also with Roentgen stereo-photogrammetry based in-vivo analyses[9] as well as during in-vitro studies on cadaveric specimens by means of instantaneous helical axis theory.[11] In a former preliminary work from the present authors[12], in-vivo ankle joint kinematics confirmed the results of the aforementioned studies, even though a number of critical methodological aspects were pointed out; these are in fact addressed in the present work. The accurate kinematic analysis of ankle joint motion can provide useful information for many applications, such as the characterization of articular motion during a therapeutic treatments or the design of personalized orthoses able to cope with and to treat the specific pathological condition of each single patient.

Ankle-foot orthoses are used to totally or partially limit ankle joint motion, typically by restraining joint rotation about a fixed axis and reducing the range of motion, according to the recommendation of the physician. In particular, hinged ankle-foot orthoses (HAFO) are constituted of two shells, one on the shank and the other on the foot, connected by a mechanical hinge which typically allows some relative rotation between these two segments supposedly in the sagittal plane. The ability of an HAFO to correctly support this motion in real patients, particularly to return to normal function, has been demonstrated.[13] However, the correct placement of the mechanical hinge between the two shells is a critical aspects in the design of these devices. If not correctly designed and positioned, HAFO can contribute to unnatural gait.[14–16] For this reason, new techniques for in-vivo kinematic analysis of the ankle joint are sought to support clinicians and engineers for the design of more ergonomic and bio-mimetic HAFO. Taking advantage of recent developments in 3D scan of body segments and fabrication of high-performance plastic components by additive manufacturing, i.e. 3D printing, the functional and anatomical customization of HAFO has become feasible and relatively cheap.[17–20]

The aim of this work is to present a methodology for in-vivo kinematic evaluation of ankle joint rotations based on stereo-photogrammetry, designed to limit the impact of the main relevant sources of inaccuracies such as soft-tissue sliding and marker cluster deformation. The main outcome of the methodology is the calculation of the axis of rotation of the ankle joint, in terms of instantaneous (IHA) and mean (MHA) helical axes. These are meant to be relevant for the development of custom HAFO, tailored to the specific form and needs of each single patient. The study was carried out by performing motion analysis on two healthy subjects. In order to evaluate ankle joint kinematics in different conditions, level walking and active and passive dorsi-plantarflexion were analyzed. To limit the effects of the artifacts observed in a previous work by these authors,[21] custom-made rigid shells at the foot and shank were designed and manufactured, to be used for best marker positioning and segment tracking. The same shank and foot shells can be used both to collect kinematic trials to assess ankle joint motion, and eventually to manufacture the HAFO by designing the appropriate connection. This particular outcome, given the accurate matching between the lower limb of the subject and the shells that can be achieved with modern rapid prototyping techniques, actually represents the most relevant aspect of this methodology. Depending on the final clinical exploitation, the most appropriate kinematic reference for this design shall be decided, i.e. whether the target should be the restricted motion of the affected joint or the natural motion of the contralateral joint.

2. Methods

Two custom-made *kinematic shells*, a *shank shell* (SS) and a *foot shell* (FS), were designed and built by additive manufacturing with the methodology outlined as follows. A handheld 3D optical scanner (EinScan-Pro, Shining 3D) was used to get two separate point clouds (see Fig. 1) on each of two healthy subjects, both female, 23 and 24 years old, Body Mass Index respectively 20.2 and 19.1. In the first scan, the left shank (below the knee) and dorsal aspect of the foot were captured, with the subject barefoot in double-leg standing on a flat surface having the left foot in a phenolic foam for following footprint analysis. In the second scan, a capture of the foam itself was performed to capture the plantar aspect of the foot, in the same loaded condition. The first scan process took about 3 minutes to be completed, whereas the second scan lasted about 5 minutes. Thanks to the limited duration, the quality of the scan was not significantly affected by possible small movements of the subject. The final point clouds were smoothed to account for any noise originated during the scan process. As highlighted in Fig. 1, three to four markers were placed on the flat surface of the foam to ease the reconstruction of the full lower limb mesh by spatial matching of the two separate point clouds from the two scans. This process was carried out in MeshLab[22] with the *Align* tool. Knee and forefoot portions of the scans were removed since these were not necessary for the design of the rigid shells. Then, the mesh was processed by means of a volumetric algorithm to regenerate the skin surfaces from the scan. This was eventually smoothed and imported in Rhinoceros (version 5, McNeel Europe) to perform the design of the shells directly on top of the scanned surfaces. The result of the mesh procedure of merging and processing for one of the subjects is presented in Fig. 2.

[insert Figure 1]

Fig. 1: Scan of shank and foot body segments; markers on the foam for relevant mesh merging are circled in yellow.

[insert Figure 2]

Fig. 2: Results of 3D scan of shank and foot segments: separate shank and foam imprint scan in left and center picture, final complete model in the right picture.

The SS had an approximate length of 128 mm (Fig. 3) and was attached at the anterior aspect of the tibia, in order to limit interaction between calf muscles and the shell, thus increasing the stability of the shell to the underlying bone. The FS covered the plantar aspect of the rear- and mid-foot, and embraced the medial and lateral dorsal aspects of the mid-foot. The necessary limited length of the FS was critical to avoid its interaction with the forefoot, which undergoes relevant deformation during walking, which could worsen the stability of the shell. The length of the plantar area was about 106 mm, while the height of the posterior heel part was about 39 mm. The 3D CAD models of the two shells were defined accurately to match the original scans. In the solidification process (performed in Blender, version 2.79, Blender Foundation), the thickness of both shells was set to 1.5 mm for the first subject and 2 mm for the second one. To ease the positioning of reflective markers over the shells, four reference spots were also designed on each model. The shells were built in ABS, using a 3D printing machine based on Fused Deposition Modeling technology (uPrint SE Plus, Stratasys). The material was chosen for its adequate stiffness and common use in the fabrication of orthoses.[19,23] In this manufacturing process, both the SS and the FS were oriented with their longitudinal axis directed along the horizontal plane, possibly to minimize duration of the process and amount of support material. The choice of the orientation did not follow the optimization of mechanical performance, since the loads exerted on the shells during motion are not critical, particularly at the SS. Only the FS is subjected to relevant loads during the stance phase of walking; however, the selected thickness was considered sufficient to limit large deformations. The internal surfaces of the shells were covered with a thin soft pad just to avoid skin damage, whereas Velcro straps were used to fasten the shells to the limbs of each subject.

[insert Figure 3]

Fig. 3: Rigid shells for marker cluster positioning and kinematic analysis with stereo-photogrammetry. Shank anatomical (SAC) and technical (STC) clusters of markers, as well as foot anatomical (FAC) and technical (FTC) clusters, are depicted.

The kinematic shells were used to perform a set of motion analysis data collections aimed at evaluating the natural ankle joint kinematics, which was used then to customize the HAFO. For this purpose, a stereo-photogrammetric system (Vicon Motion Capture, Oxford UK) with 8 digital cameras was used to capture motion data at 100 Hz from the two subjects. According to the IOR-gait protocol,[24] markers on the shank (SAC) and foot (FAC) were tracked, i.e. the anatomical clusters (Fig. 3). The SAC includes the following markers: LHF, proximal tip of the head of the fibula; LTT, anterior border of the tibial tuberosity; LLM, lateral malleolus; LMM, medial malleolus. The FAC includes the following markers: LCA, calcaneus; LFM, first metatarsal head; LSM, second metatarsal head; LVM, fifth metatarsal head. A shank technical cluster (STC) was also defined as follows: SMedProx and SMedDis were placed respectively proximally and distally on the medial aspect of the SS, while SLatProx and SLatDis were located on the lateral aspect of the SS. Correspondingly, the markers of the foot technical cluster (FTC) were FMedProx, FMedDis, FLatProx and FLatDis. The effect of different positions of the markers on the joint kinematic was also analyzed. In accordance with the literature,[25] markers on the FS were positioned as near as possible to the talocrural joint (Fig. 3), therefore reducing the eccentricity of the marker set with respect to the joint rotation axis, which has been linearly correlated to the error in the calculation of IHA location.

The location of the STC markers was influenced by the SS that was positioned similarly to a typical shank shell of a HAFO. Both FS and SS positions had to be tailored appropriately to avoid covering of the malleoli. The positioning of the shells on the corresponding segment was also fundamental to ensure the precision and repeatability of kinematic analyses. The FS, enveloping the calcaneus and plantar aspect of rear- and mid-foot, was able to provide a stable positioning with respect to the foot area close to the ankle joint. To ensure the correct positioning of the SS, a direct comparison with the 3D model of the shank and foot (equipped with the shells) was necessary for each subject. Each scan provided a valuable reference to locate the SS as intended during the preliminary design on the computer model. This process was required since the SS did not embrace any specific bone protrusion or landmark, whereas the calcaneus and rear-foot provided more reliable references to the FS positioning.

The shank anatomical frame (SAF) was defined as follows: O, the origin located at the mid-point of the intermalleolar segment; v, intermalleolar axis oriented from medial to lateral malleolus; u, axis orthogonal to the quasi-frontal plane including LHF, LLM and LMM, oriented forward; w, longitudinal axis orthogonal to the plane (u,v), oriented from distal to proximal. The shank technical frame (STF), embedded in the SS, was defined as follows: O_s, the origin located at the mid-point of the SMedDis – SLatDis segment; v_s, medio-lateral axis oriented from SMedDis to SLatDis; u_s, axis orthogonal to the plane including SMedDis, SLatDis and SMedProx, oriented forward; w_s, axis orthogonal to the plane (u_s, v_s). Graphic representations of both shank frames are presented in Fig. 4.

[insert Figure 4]

Fig. 4: Shank anatomical (SAF, left) and technical (STF, right) frames.

Before data capture, both subjects had a period of accommodation to walking while wearing the kinematic shells. They confirmed that the rigid shells did not affect natural gait ability as well as these did not provide discomfort or slippage with the floor. The trials, performed in barefoot condition, were the following:

- level walking, normal speed (5 repetitions);
- level walking, high speed (5 repetitions);
- active full range dorsi-plantar flexion of the ankle with lower limb lifted in standing position (1 repetition), i.e. flexion against gravity;
- passive dorsi-plantar flexion with the subject in sitting position (4 repetitions, each with a different operator).

Normal and high walking speeds were self-selected by each subject. The trajectories of the reflective passive markers (14 mm of diameter) were used to work out joint rotations during motion;[24] from the same trajectories, the following kinematics analysis was also performed for each subject.

The methodology for IHA and MHA calculation has been already outlined in a previous work[12] from the present authors, hence it will be only briefly recalled. The global coordinates of markers (i.e. defined in the global reference frame of the motion capture system) were converted into a local shank reference frame, then a weighted least squares procedure was performed in order to limit the impact of the errors associated to skin sliding and motion artifacts, in particular related to the deformability of each marker set. In such procedure, an equivalent rigid foot model was elaborated starting from FAC or FTC markers (rigid-body fitting) and used to calculate the 6 DOFs of the foot with respect to the shank reference frame. These DOFs data, after smoothing and differentiation, were used to calculate the corresponding set of IHA (also called axode), which is representative of each single task performed. Since the IHA calculation is ill-posed when angular velocity approaches zero, only frames corresponding to an angular velocity greater than 15°/s were considered.[11] By means of a least-square minimization procedure, the MHA was then calculated, along with the linear (position) d_{eff} and angular (orientation) χ_{eff} dispersion parameters.[11] The latter are very important to quantify the changing in the shape of the axode during motion due to the floating of the IHAs. The joint rotations from the IOR-gait protocol were used to select only the data referring to an integer number of cycles of motion, in order to avoid any error given by a biased selection of the marker coordinates (e.g., in walking trials, to prevent that swing or stance phases would contribute unevenly to IHA calculation).

To evaluate the effectiveness of each marker cluster in terms of rigidity of motion, a deformability coefficient was calculated. The distances between each different couple of markers within the same cluster were computed for each time frame, then the average value μ and standard deviation σ were extracted from each distance vs time signal. Therefore, for each couple of markers in the same cluster, a deformability coefficient $CV\%$ was defined as follows:

$$CV\% = 100 \cdot \frac{\sigma}{|\mu|} \tag{1}$$

Finally, to provide a concise estimation of the deformability of the whole cluster, the mean and maximum $CV\%$ values were extracted among the set of coefficients calculated with Eq. (1). At the end of this process, mean and maximum $CV\%$ were available for each cluster of markers. This calculation was repeated for each motion trial, to evaluate task-specific differences.

Furthermore, the sliding of both rigid shells with respect to the corresponding anatomical segments was also evaluated. For the SS, the standard deviation of the time varying distance between each technical marker and the midpoint of the intermalleolar line segment was calculated and used as an indicator of the relative motion between technical and anatomical clusters of the shank. The procedure for the FS was similar and considered the relative motion between the markers directly placed on foot (FAC) and the centroid of the four FTC markers.

3. Results

The calculation of the maximum and mean *CV%* of each cluster of markers for all trials performed by the two subjects showed smaller deformability coefficients when rigid shells were used (Figs. 5 – 7). In particular, examining the *CV%* of FAC for both subjects, it was observed that the values reached an order of magnitude greater than the one given by other cluster solutions. The results from walking trials with normal and high speed were combined since differences in cluster rigidity and in helical axes parameters were found negligible.

[insert Figure 5]

Fig. 5: Maximum and mean *CV%* of each cluster of markers computed for five walking trials performed (five blue bars) by first (left) and second (right) subject.

[insert Figure 6]

Fig. 6: Maximum and mean *CV%* of each cluster of markers computed for an active dorsi-plantarflexion trial performed by first (left) and second (right) subject.

[insert Figure 7]

Fig. 7: Maximum and mean *CV%* of each cluster of markers computed for passive dorsi-plantarflexion trials performed by first (left) and second (right) subject with several operators. For each group, the four bars refer to different operators.

The analysis of standard deviations of the time varying distances computed between technical markers and the corresponding anatomical cluster (see Tables 1 and 2) showed that the shank clusters experienced the largest relative motion in both subjects. By observing the displacement of each shank technical marker with respect to the corresponding anatomical cluster, the medio-lateral coordinate (along *v* axis) was the least affected by relative motion in both subjects. Regarding the other directions, no similar trends were observed, hence relative motion along *u* and *w* axes similarly contributed to the standard deviations presented in Table 1. Similar results were obtained for the foot anatomical and technical clusters (see Table 2).

Table 1: Standard deviation, in mm, of distances between STC markers and intermalleolar midpoint obtained in walking trials for both subjects.

Marker	Subject 1	Subject 2
TMedProx	0.52	0.67
TMedDis	0.46	0.54
TLatProx	0.52	0.61
TLatDis	0.49	0.61

Table 2: Standard deviation, in mm, of distances between FAC markers and FTC midpoint obtained in walking trials for both subjects.

Marker	Subject 1	Subject 2
LCA	0.14	0.25
LFM	0.26	0.29
LSM	0.12	0.26
LVM	0.22	0.26

The bundle of IHAs and the corresponding MHA from a walking trial of a representative subject are shown in Figure 8. The IHA were found distributed in an area around the intermalleolar line segment, with the lateral portion of the bundle located posteriorly to the medial one. These axes were represented in the SAF since it allowed for a more straightforward interpretation of data with respect to the STF. However, the axis calculation was performed in two different configurations, hence by estimating relative motion between: (1) the technical kinematic shells (i.e. STC and FTC); (2) between the SAC and the FTC. Only FTC markers were considered since FAC deformability was always considerably larger (see Figs. 5 – 7). The dispersion parameters for each task and configuration were averaged (Table 3). Although these were found similar to relevant data from the literature, e.g. having the same order of magnitude of those obtained in dorsi-plantarflexion tests conducted directly on cadaveric specimens,[11] the dispersion observed was large. For instance, d_{eff} and χ_{eff} values calculated in-vitro [11] reached up to half the values reported in Table 3. This can be accounted for the different method adopted for motion analysis on cadaver, which was based on intra-cortical pins for marker attachment directly into the bones, thus removing soft tissue sliding effects on bone pose estimation. Of course, the present in-vivo techniques must imply less invasive methodologies to be accepted. Although different values of dispersion parameters were obtained for each motion trial, similar results were found for active and passive dorsi-plantarflexion trials. Nevertheless, the variability in terms of orientation and positioning of the axes was coherent with the magnitude of the dispersion parameters. Figure 9 shows the set of mean helical axes resulting from each motion trial performed by the first subject.

[insert Figure 8]

Fig. 8: Representation in the SAF transverse (left) and frontal (right) planes of the IHA (grey line segments) and of the MHA (thick black line) for a walking trial performed by the first subject. Lateral and medial malleoli are highlighted. Axes units are in mm.

[insert Figure 9]

Fig. 9: 3D views of MHA set resulting from each motion trial of the first subject. Thick black lines refer to walking trials, thin grey lines refer to passive dorsi-plantarflexion trials, dashed grey line refers to active dorsi-plantarflexion trial. Lateral and medial malleoli are highlighted. Axes units are in mm.

Table 3: d_{eff} and χ_{eff} obtained for walking, active dorsi-plantarflexion and passive dorsi-plantarflexion trials performed by the two subjects. The parameters are reported as mean ± standard deviation and are calculated in both technical (STF) and anatomical (SAF) shank reference frames.

	Subject 1		**Subject 2**	
Motion task – reference frame	**d_{eff} (mm)**	**χ_{eff} (deg)**	**d_{eff} (mm)**	**χ_{eff} (deg)**
Walking – STF	24.7 ± 5.7	29.5 ± 0.3	24.6 ± 4.6	36.5 ± 1.8
Walking – SAF	21.0 ± 4.9	31.8 ± 1.6	24.6 ± 5.5	43.3 ± 2.3
Active dorsi-plantarflexion – STF	11.7 ± 0	14.3 ± 0	6.7 ± 0	9.4 ± 0
Active dorsi-plantarflexion – SAF	8.2	15.2	9.4	19.4
Passive dorsi-plantarflexion – STF	11.2 ± 2.4	15.6 ± 5.5	7.8 ± 2.1	14.2 ± 1.2
Passive dorsi-plantarflexion – SAF	7.2 ± 0.8	12.2 ± 3.6	6.5 ± 2.1	14.9 ± 1.2

4. Discussion

The methodology presented is aimed at providing the clinician and the HAFO designer relevant information about the motion parameters of the ankle joint, so as to customize a therapeutic treatment or an external brace device based on these characteristics of the specific patient. The proposed approach is based on measurements taken by a stereophotogrammetry system, which is widely recognized as the state-of-the-art instrument for human motion analysis. However, the accuracy of kinematics analyses performed in-vivo is generally affected by soft tissue artifact, which alters the position of the markers relative to the underlying bone segments. To improve the bone-pose estimation, placing the markers on rigid shells fixed to each body segment could represent a valuable alternative. Although the use of rigid clusters does not represent an original method for in-vivo kinematic analysis by itself,[26] a relevant and original aspect of the present methodology is that the shells were designed to be used as basic elements for the design of shank and foot shells of a customized HAFO, once connected for example by a special hinge joint designed to account for the moving position and orientation of the ankle joint rotation axis. To this purpose, it is more relevant that the orthosis is able to replicate or approximate the relative motion between FS and SS rather than the natural joint functionality (bone-to-bone kinematics), whose accurate identification is critically affected by bone-to-soft tissue motion. Although the proposed methodology is intended to improve ankle joint kinematic analysis by appropriate design (i.e. shape, positioning and fastening) of the shells, the impact of soft tissue artefact on the accuracy of in-vivo measurements cannot be neglected. By targeting, for the HAFO design, the IHA patterns observed between the shells, the performance and comfort of the HAFO would also depend on the positioning and functionality (e.g. the DOFs) given to the artificial joint of the HAFO. In particular, a modular design of the orthosis (i.e. based on the connection between custom shells by means of a mechanical joint) would ease and, likely, accelerate the fabrication of customized HAFO. For this purpose, flexibility offered by modern rapid prototyping techniques can be particularly relevant. An example of a joint design able to support ankle joint variability has been presented in a previous work.[21]

As presented in Figs. 5 – 7, a reduction of the deformability coefficient for the STC with respect to SAC has been noticed in almost all the trials. This means that the markers placed directly in contact with the skin are subjected to relative motion within the cluster that cannot be neglected, unlike the markers placed on the rigid shells. However, if compared to the larger deformability of both foot clusters, the rigidities of SAC and STC appear similar. Although a SS would seem unnecessary for kinematic analysis, its implementation is fundamental for the proposed methodology targeted to the design of customized HAFO, given that both rigid shells would be combined in the final architecture. The largest cluster deformability was obtained for the FAC, and this result was confirmed by inspection of the video recorded during trials performed in laboratory. Especially during walking, the metatarsal heads, on which LFM, LSM and LVM markers are placed, undergo large relative motion due to the known deformation of forefoot. FTC showed significantly lower deformability coefficients, though these typically exceeded SAC and STC results, especially in walking and passive dorsi-plantarflexion trials: in these tasks, FS was particularly subjected to greater dynamic loads with respect to the SS, hence higher deformability coefficients were expected. It should be highlighted that, while FAC markers were placed on several bones of the foot, the FTC, enveloping only the plantar aspect of rear- and mid-foot, was essentially attached to the calcaneus. For this reason, the two marker's sets do not strictly refer to the same segments. However, similarly to the SS, the implementation of a FS is necessary to the scope of this methodology, since the same shell can be implemented in the final HAFO design. When rigid kinematic shells are used, it is fundamental to achieve accurate matching between anatomical segments and corresponding shells. For this reason, the precision in lower limb scan and meshing reconstruction is critical for the success of this procedure.

Although results presented in Figs. 5 – 7 were promising, it must be clear that marker placement on kinematic shells can limit the effect of cluster deformability only, while, as already pointed out in the literature,[26] sliding between the whole clusters of markers and the underlying bone segments is not eliminated. Data in Tables 1 and 2 show that deviations between technical and anatomical clusters for the shank were higher than the ones measured for the foot. This probably depends on shape and fastening of SS that still allowed for relative motion, though reduced, mainly along the longitudinal axis of the shank, whereas the FS was more stable likely because of its more enveloping shape. This result was confirmed by qualitative feedback from both subjects. The dispersion parameters reported in Table 3 were similar in both SAC and STC, however, in some conditions, the dispersion observed using SAC was even slightly lower than the one measured with STC. As already discussed, this variability might be related to the rigid motion occurring between SS and the shank segment. In order to limit this source of error, different shell designs and fastening solutions could be investigated in future works. Regarding the composition of each cluster, the use of more than four markers would increase the quality of the results especially regarding the effect of deformability within the marker set,[25,27] however such limited accuracy improvement is not adequately justified by a bulkier marker-set.[28] Moreover, an increase in the number of markers would not have any effect on the sliding between the cluster and the bone segment, which has been found as the major source of error. Ultimately, the accuracy of the outlined methodology in kinematic reconstruction should be assessed by comparison this with techniques able to perform true bone-pose estimation.[26]

The method adopted is able to distinguish between subjects due to both anatomy and joint functionality. A comparison between two subjects supports the ability of the methodology to provide consistent results starting from two different data sets, considering that both subjects had no defects in lower limb functionality.

In accordance with data reported in a previous work[9] about ankle dorsi-plantarflexion, the present results show that MHA has its lateral part positioned slightly behind the medial one. The same has been outlined in another study,[29] where the IHA of talocrural joint in dorsi-plantarflexion trials was estimated from an MRI (Magnetic Resonance Imaging) dataset. In the frontal plane, the orientation of the MHA resulted approximately parallel to the intermalleolar line segment.[30] Even though results compare well, the accuracy of joint axis of rotation based on IHA theory still presents some critical aspects, to be examined in depth as pointed out in the recent literature,[31,32] especially regarding the precision in the evaluation of axode location for wide movements. Alternative techniques such as finite helical axis, symmetrical axis of rotation approach (SARA)[32] or geometric fitting (GF)[33] can provide similar or even better results for motion analysis based on stereophotogrammetry. Future works should focus on this aspect, also to provide some further validation to the methodology here presented.

The selection of the most representative motion task for ankle joint kinematic identification of a subject prior to the fabrication of a customized HAFO has still to be discussed. Since an orthosis must limit ankle joint mobility, in order to avoid risks for the patient's joint capsule and ligaments in loaded condition during daily living activities, it seems reasonable to perform kinematic analysis in walking trials. For this reason, testing of ankle-foot orthoses in patients is typically performed in gait analysis.[16,34,35] On the other hand, dynamic forces can affect the quality of the kinematic reconstruction introducing noise. In our tests, although IHAs were dispersed in a similar way for both subjects, a more dispersed bundle in terms of orientation has been observed for the second subject, which was walking at higher speed with respect to the first one. This means that the shells could have been subjected to greater loads as well as to larger deformations, hence producing more dispersed IHA axodes. Passive and active dorsi-plantarflexion trials could be more easily performed by subjects with compromised foot mobility with respect to walking trials and would be significantly less affected by dynamic load effects. However, their reliability in natural joint kinematic assessment is questionable since these do not represent a realistic scenario.

5. Conclusions

Three main conclusions can be drawn from this experimental study:

- the use of two rigid shells for the ankle kinematic analysis can partially compensate for the soft tissue artifact during in-vivo motion analysis, allowing for a more accurate definition of the natural joint functionality;
- the proposed technique describes in an objective way the overall inter-segmental motion between shank and foot of a subject, and it is able to differentiate between subjects and among several motion tasks;
- a customized HAFO can be effectively realized by connecting the two experimental shells by means of a joint designed on the base of this kinematics analysis.

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