New comprehensive procedure for custom-made total ankle replacements: Medical imaging, joint modeling, prosthesis design, and 3D printing

New Comprehensive Procedure For Custom-Made Total Ankle Replacements: Medical Imaging, Joint Modeling, Prosthesis Design, and 3D Printing

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ABSTRACT: Many failures in total joint replacement are associated to prosthesis-to-bone mismatch. With recent additive-manufacturing, that is, 3D-printing, custom-made prosthesis can be created by laser-melting metal powders layer-by-layer. Ankle replacement is particularly suitable for this progress because of the limited number of sizes and the poor bone stock. In this study a novel procedure is presented for subject-specific ankle replacements, including medical-imaging, joint modelling, prosthesis design, and 3D-printing. Three shank-foot specimens were CT-scanned, and corresponding 3D bone models of the tibia, fibula, talus, and calcaneus were obtained. From these models, specimen-specific implant sets were designed according to three different concepts, and 3D-printed from cobalt-chromium-molybdenum powder. Accuracy of the overall procedure was assessed via distance map comparisons between original anatomical and final metal implants. Restoration of natural ankle joint mechanics was check after implantation of each of the three sets. In a special rig, a manually-driven dorsi/plantar-flexion was applied throughout the passive arc. Additionally, at three different joint positions, joint torques were imposed in the frontal and axial anatomical planes. Mean manufacturing errors were foundto be smaller than 0.08 mm. Consistent motion patterns were observed over repetitions, with the mean standard deviation smaller than 1.0 degree. In each ankle specimen, mobility, and stability at the replaced joints compared well with the original natural condition. For the first time, custom-made implants for total ankle replacements were designed, manufactured with additive technology and tested. This procedure is a first fundamental step toward the development of completely personalized prostheses.

Keywords: ankle joint; prosthesis design; custom-made; 3D printing; Cobalt-chromium; In-vitro validation

Joint replacement is a successful surgery, but failures and patient dissatisfaction continue to be reported.[1–3] To cope with these issues, a number of different technologies are being investigated[4,5] including computer-assisted surgery,[6,7] in-silico simulations,[8,9] and multi-instrumental analysis.[9–12] Much attention has been given to the most common replacements, such as at the hip and knee joints, whereas small joints, such as wrist, shoulder and ankle, have smaller indication and therefore have received less clinical, industrial, and scientific interest. For these joints, because of the limited market, a small number of sizes are currently produced, leading to specific issues on adaptation and fixation to the bone of the prosthesis components.[13] More specifically, large bone resections are necessary and poor bone stock are typical in these joint replacements, for which a perfect match between the component-to-bone surface of the prosthesis and the osteotomy is sought. As such, small joints appear to be particularly suitable for exploiting new technologies and prosthesis design customization. For this scope, many recent progresses can be very valuable: New knowledge in medical imaging and joint biomechanics,[14,15] motion tracking of human joints and relevant prosthesis components before, after and also during surgery,[6,8,16] and additive manufacturing technology, also known as 3D-Printing (3DP).[17,18] Orthopaedic surgical treatments are taking advantage of these, but particularly the latter is showing benefits with respect to the conventional manufacturing, in terms of accuracy, pre-operative planning, and costs,[19–21] making subject-specific customization of joint prostheses more feasible than ever.

Among small joints, Total Ankle Replacement (TAR) is still a critical treatment.[22–25] This implies the replacement of the distal tibia and the dome of the talus with metal prosthesis components, with a polyethylene insert in between. It is increasingly becoming a valuable alternative to joint arthrodesis.[3,15,26] The present patient dissatisfaction and high failure rates[27–29] are likely due to current prosthesis designs, which are not patient-specific and anatomy-based, leading to unphysiological motion at the replaced joint. Current TAR prostheses have articular surfaces that are either cylindrical or based on truncated-cone shapes with a medial apex according to a pioneering study.[30] Recent studies claim that these surfaces are best approximated by a saddle-shaped truncated skewed-cone with lateral apex,[31] and that prosthetic articulating surfaces based on this approach (Fig. 1) would result in better mechanical performances of the replaced joints.[32]

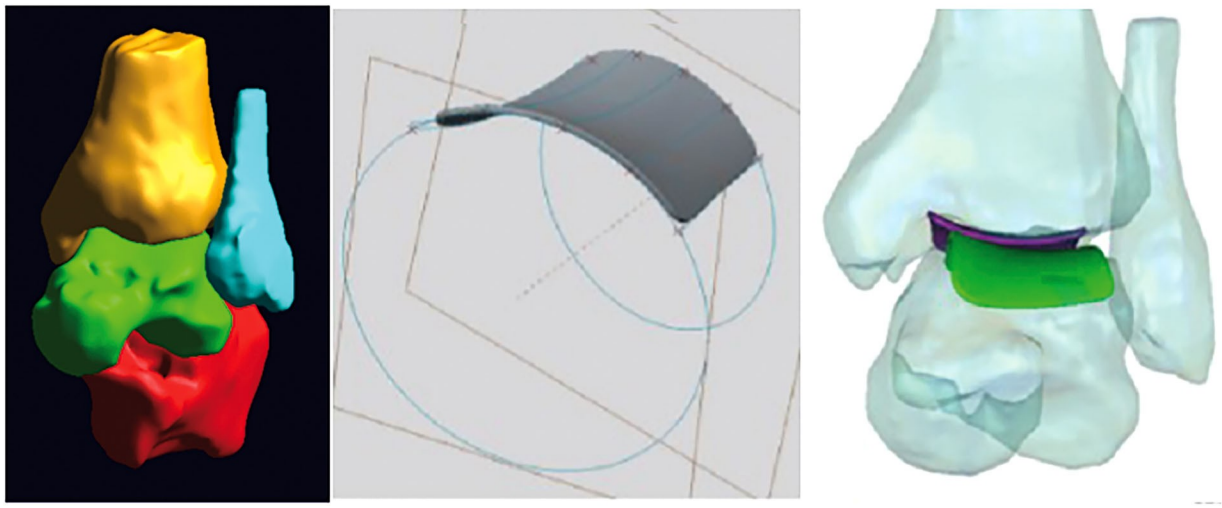

Figure 1. Snapshot taken from 3D modelling according to recent original design[31]: ankle complex anatomical reconstruction (left); morphological analysis for surface design approximating the saddle-shaped skewed-cone with lateral apex (central); the resulting 3D artificial articulating surfaces in position for possible new TAR designs (right).

Patients that undergo TAR for end-stage OA have significant degradation of the articular surfaces, in some cases even deformity of the underlying osteochondral bone, ligament stiffness, joint rigidity, or instability. TAR is meant to restore natural joint mobility and stability by replacing the patient's articular surfaces with prosthetic shapes, mimicking original anatomy, or designed to restore natural biomechanics. Both are hard to fully achieved, because of the artificial material and the general tissue degradation. This is made particularly critical because of the small number of sizes, and sometimes the wrong dimensions, of the current TARs. With the current possibility of personalized designs, the target of course would not be the degradated surfaces of the ankle to be replaced, but the contralateral, compatible with its condition. It is known that severe instability and degradation of the tissues are contraindication to TAR, to be resolved in any case before or during surgery. Correct ligament tensioning and minor problems in the nearby joints (osteophytes, impingements, etc.) are addressed and resolved during surgery, for example by choosing among different thicknesses of the polyethylene insert. As a consequence, patient-specific designs of the prosthetic articular surfaces are expected to make a considerable improvement in TAR.

Among the many different modern technologies to be exploited in the context of personalization of TAR, there is certainly medical imaging, which is improving progressively the quality of images and the identification of different tissues, as well as software for joint modelling and custom-made prosthesis design. Surgical navigation systems have been used for knee surgeries for a long time,[33–35] and have recently expanded to address also smaller joints such as the patello-femoral with successful results.[1,6,7] Patient-specific-instrumentation deals with medical imaging and 3DP using polymeric biocompatible powders,[4,36] but implies designing and manufacturing of the guides for bone cuts, still for final implantation of standard prosthesis sizes. Among these technologies, 3DP represents the most attractive advancement. Using the Selective-Laser-Melting (SLM) technique, metal prosthetic components can now be manufactured through the additive method, that is, built up layer-by-layer. This can be performed through the sintering of metal powders, such as cobalt-chromium-molybdenum alloys or titanium, exactly the same biocompatible materials that have been used in orthopaedic surgery for decades. Therefore, this represents a viable alternative to traditional manufacturing via investment casting, which is very limiting in terms of achievable complexity of both overall geometry and prosthesis-to-bone interface.[18] Pioneering clinical cases have been reported for special custom implants at the ankle, mostly total talus or talonavicular replacements,[11,37] and preliminary specific analyses in the perspective of TAR have been performed.[17,38]

After these preliminary experiences, a thorough definition and validation of a full process for the design of personalized TAR is still missing. The main aim of this study is therefore to report an original procedure of imaging, modelling, designing, and manufacturing in the context of personalized TAR, by using the best relevant technologies including SLM in CoCr. The specific goal was to assess whether this procedure is (a) viable and accurate enough and (b) capable to reproduce satisfactory results in terms of final joint mechanics. Customization of joint replacement is unlikely to embrace a single approach, therefore the present procedure has been applied to three different designs, covering a large spectrum of the TAR prostheses available in the market. The full process was validated, and these designs were tested in in-vitro experiments in a number of ankle specimens to assess final joint mobility and stability.

MATERIALS AND METHODS

The overall procedure was designed to start from real ankle joints, and for the corresponding final subject-specific design of articular surfaces replacement to be tested back on the original specimens. Three cadaver legs with normal ankle joints were analyzed: This entire process was performed on each of these specimens, and consisted of the following three steps. Validation activities were also performed as follow.

Medical Imaging Collection and Processing

Each anatomical specimen was fresh-frozen from a below knee cadaveric dissection, and thawed for at least 24 h at room temperature before imaging. Radiological and direct inspection by an orthopaedic foot and ankle surgeon confirmed the integrity of ligaments and articular surfaces. To guarantee final proper implantation of the artificial surfaces, the specimens were prepared with two antero-posterior parallel holes at the distal tibia[32] in order to host the surgical jig and guides, according to a standard operative technique.[39] The specimen was then scanned via Computer-Tomography (CT) with an in-plane resolution of 0.15 mm and a 0.4 mm inter-slice distance (Brilliance CT 16-slice system by Philips Healthcare, DA Best, The Netherlands). Eventually the leg was re-frozen, for later hosting the 3D printed custom-made artificial components.

Modelling and Designing

The CT scans were processed (Analyze Direct™, Overland Park, KS-USA) to obtain separate 3D models of the tibia, fibula, talus, and calcaneus bones by semi-automatic segmentation of the cortical contours on the DICOM images. From each of these models of the bone surface from CT scans, design parameters were extracted (GeomagicTM, Morrisville, NC-USA) to eventually produce specimen-specific artificial surface approximations of the natural joint surfaces (Fig. 2), according to three different concepts: Cylindrical (CYL), matching cylindrical surfaces with the talar dome radius equal to the average between the radii of the relevant medial and lateral crest contours; a truncated-cone with a fixed medially-oriented apex (TCM), as calculated according to the procedure by Inman[30]; and a saddle-shaped truncated skewed-cone with laterally oriented apex (TCL), as calcu- lated according to modern instruments and more careful measures.[31]

The final design of these three implants, consisting each of a tibial and a talar component, was performed (InventorTM AutoDesk, San Rafael, CA-USA) with consideration of the technique for their fixation to the bone, that is, via parallel cylinders and a screw at the tibia and via anterior screws at the talus (Fig. 3).

Manufacturing and Mechanical Testing

The two components of these three implant designs were 3D-printed using a MYSINT100 system (SISMA SpA, Piovene Rocchette, Italy), with a 10 cm platform diameter (Fig. 4). A cobalt-chromium-molybdenum powder optimized for additive manufacturing was chosen; the powder was spherical in shape with dimensions in the range of 15–45 mm. The manufacturing process had been optimized on simpler samples of the same powders to maximize density and mechanical strength, and near full density prostheses with negligible microstructural defects were obtained.[17] Tests were performed on this material to evaluate corrosion resistance in solutions simulating biological fluids and mechanical characteristics typical of TAR.[38] It was observed that the process parameters which lead to the highest mechanical resistance, also determine the worst corrosion behavior, and vice versa. Thus, for the best possible compromise, while also considering manufacturing time, a double process parameter set was recommended, one for the bulk and one for the surface. Before implantation, the components were extracted from the platform and polished with a mirror finishing.

Validation Activities

The overall process was tested initially by replicating the original anatomical surface of the talar dome with present metal manufacturing techniques. This anatomical replica was taken in a laser scan (Handyscan 700 by Creaform, Levis, QC-Canada; nominal resolution 0.05 mm, nominal accuracy 0.03 mm) and the result was compared with the corresponding computer model from the bone specimen.

For the kinematic in-vitro evaluation, each specimen was positioned in a special testing rig[40]: the tibia was fixed horizontally, and the foot secured to a plate on which loading/unloading cycles were applied in the three anatomical planes (Fig. 5). The rig guarantees rotations of the ankle joint complex about three independent axes.

Joint mobility of the specimens was tested by performing five repetitions of manually-driven dorsi/plantar-flexion along the full flexion arc, that is, passive flexion. No joint resistance is experienced in this condition, therefore the torque was not measured. Joint stability was also tested by imposing torques in the frontal and axial planes, applied with the joint complex in three ankle positions: Neutral, and maximal dorsi- and maximal plantar-flexion, that is, where the joint could not flex or extend more.

The natural joint condition (NAT) was tested first, then these tests were repeated after implantation of each of the three sets, that is, CYL, TCM, and TCL. These implant sets were secured, one at a time, to the corresponding bone by the fixation screws in front, and did not require additional cuts or drills, minimizing peripheral damage to the bones. Comparisons were eventually performed on the experimental data from these implant sets.

During these tests, a knee surgical navigation system (Stryker®, Kalamazoo, MI-USA; nominal accuracy 0.5 mm and 0.5°), suitably adapted to this study, was used to track motion of the talus, calcaneus and tibia, using corresponding trackers instrumented with active markers[1,6,14,41] (Fig. 5). Anatomically-based reference frames were defined after anatomical landmarks digitization by means of an instrumented pointer, and using a standard joint convention[42] according with the testing rig. All this results in calculation of three joint rotations, that is, dorsi/plantar-flexion, inversion/eversion, and axial internal/external rotation, for both the ankle and subtalar joints.

RESULTS

The procedure for the development of the implantable personalized TAR devices was carried out with no major problems throughout the process. The original anatomical surface of the talar dome was replicated and scanned: The comparison with the corresponding original model revealed differences smaller than 0.08 mm when averaged in the two separate directions, that is, internal and external, demonstrating there are no biases in the modeling and manufacturing of these

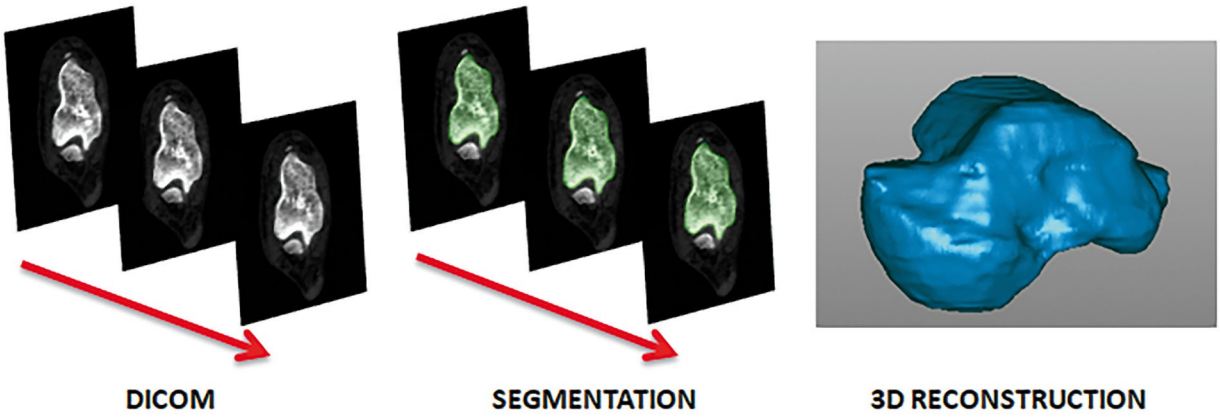

Figure 2. Medical imaging analysis: DICOM data, segmentation, and 3D reconstruction.

implant sets, and ultimately of the prosthesis components.

In the present experimental analysis, repeatable motion patterns were observed, both before and after ankle replacements with the three custom-made implant sets, the mean standard deviation over the five repetitions at each time step for all joint rotations being smaller than 1.0˚. Joint motion was therefore consistent in each of the four manual manipulations, that is, the passive flexion and the forced rotations in the three ankle positions. Generally, a good restoration of the physiological motion was found in these experimental conditions, demonstrated by the comparison of the motion patterns in the natural joint condition (NAT) with those after surface replacements by the three implant sets (CYL, TCM, and TCL; Fig. 6).

The load/displacement curves demonstrate that natural joint stability is well replicated by the three custom-made artificial surfaces, both for the internal/external rotation (Fig. 7) and inversion/eversion. Interestingly, the ankle joint after the replacements was stiffer than the natural in max Dorsi-flexion and neutral joint positions, but more lax in max Plantar-flexion, which is in fact the joint position where the articular surfaces are less congruent, due to the anatomical posterior narrowing of the talar dome.

DISCUSSION

A considerable amount of literature and concern has existed on TAR since the seventies[22,23,43] but deals only with the substitution of the osteochondral parts of the distal tibia and proximal talus by metal prostheses obtained with the standard investment casting technology. Custom ankle replacements are also reported,[11,37] but these are often massive prosthetic substitutions of large parts of the talus and/or of the distal tibia due to major bone loss. To our knowledge, the present study is the first of its kind to address the development and testing of total ankle prostheses for typical joint arthritis by exploring custom-made designs and 3DP technology. The study shows the feasibility of this process for future exploitations in the clinical contexts of TAR; this same procedure can also be exploited for small implants used in the treatment of chondral and osteochondral defects,[44] as well as for revision surgery,[45,46] for the ankle and for other human joints.

The recent rapid development of 3DP with metal powders has enabled careful personalization of prosthesis design for human joints, as sought out for many years. An original comprehensive procedure was developed for the outline and test of custom TAR, that is, designed according to the specific morphology of each ankle joint. Custom design has the advantage of obtaining final prosthesis components according to the

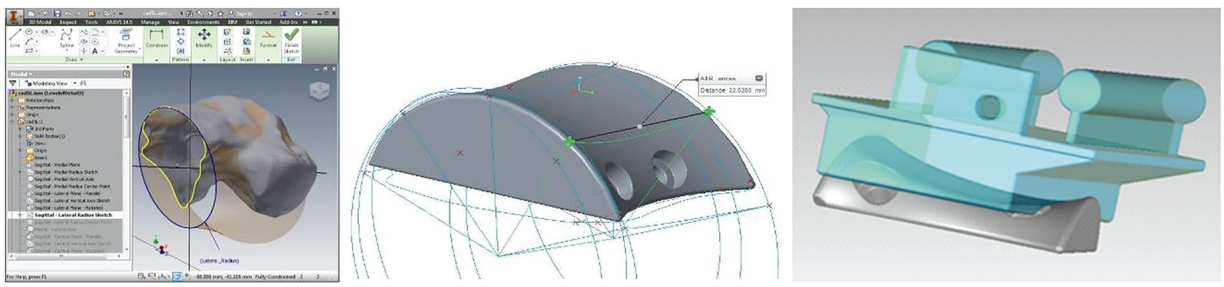

Figure 3. Snapshots from the process of bone modelling and custom prosthesis design: One of the relevant measurements performed on the talar bone model necessary to produce the surface approximation based on a skewed truncated cone with the apex located laterally (left), check of the prosthesis design parameter (centre), and two possible prosthesis components articulating in one ankle joint position (right).

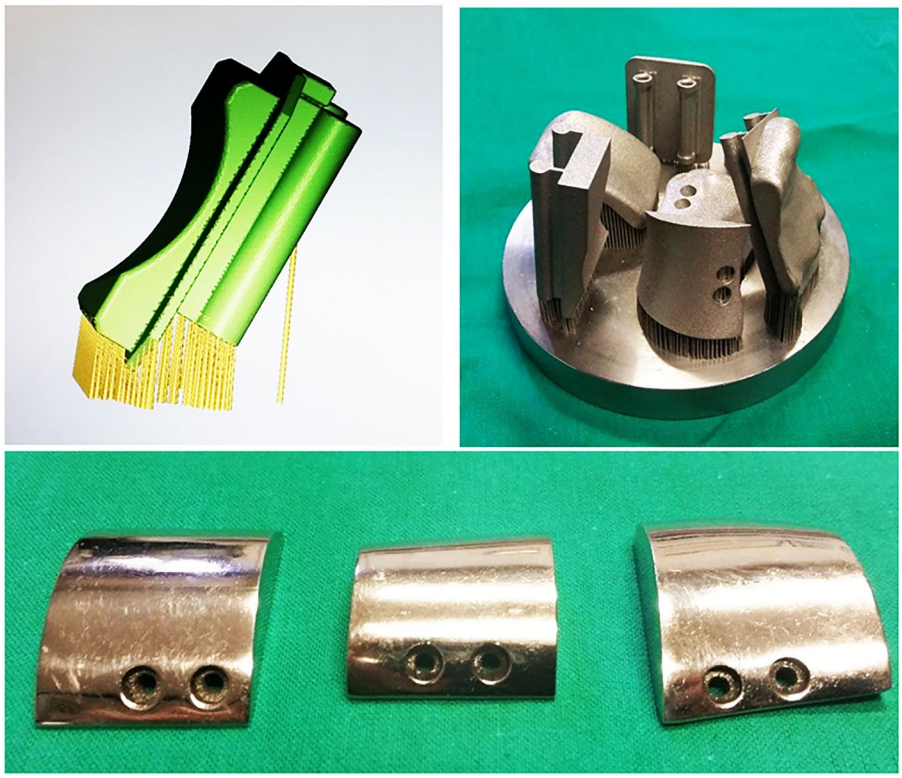

Figure 4. Once the models for the implant sets are sent for manufacturing, these are analyzed first in relevant software for optimal SLM fabrication including position parameters which are suitably set (a typical positioning of the talar component on the top left); in this configuration rough components are manufactured and a platform with a number of these components is produced (top right); these are then extracted and polished with a mirror finishing (bottom).

exact anatomy and dimensions of the specific joint to be replaced. In the present study, prosthetic articular surfaces were obtained in accordance with three different TAR design approaches, demonstrating the capacity of the overall procedure to meet any specific clinical or biomechanical preferences. The procedure implies accurate medical image acquisitions and analysis, joint modelling via modern tools, prosthesis component design, and metal manufacturing, taking advantage of the most modern technology and process optimization. The full procedure was exploited in three ankle specimens, and eventual accurate implantation and experimental measures of corresponding custom-made implant sets were performed: This showed good results in terms of joint mobility and stability, in response to external solicitations. Therefore, feasibility and efficacy of this process have been demonstrated in a few real cases.

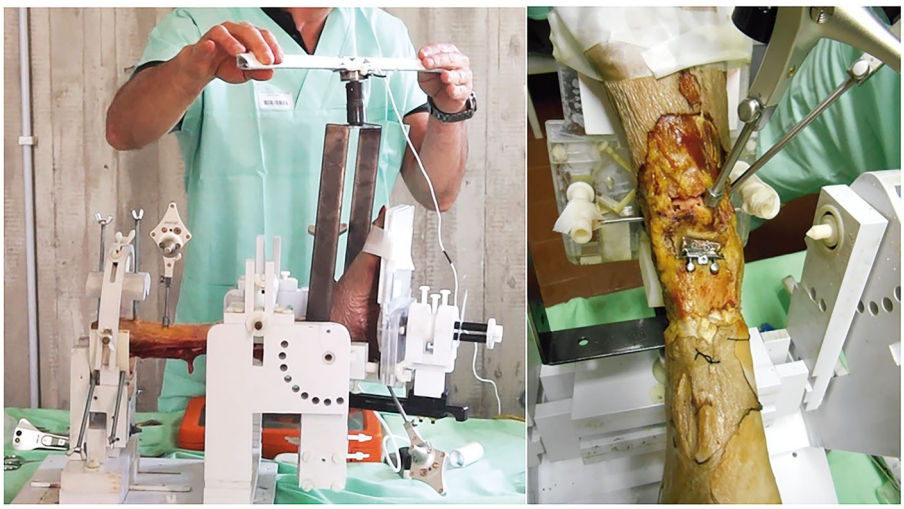

Figure 5. Pictures from the experimental set-up: The cadaver specimen mounted on testing rig (left) and close-up of the surgical site (right) showing the prosthesis components in place, together with the trackers and the pointer of navigation system.

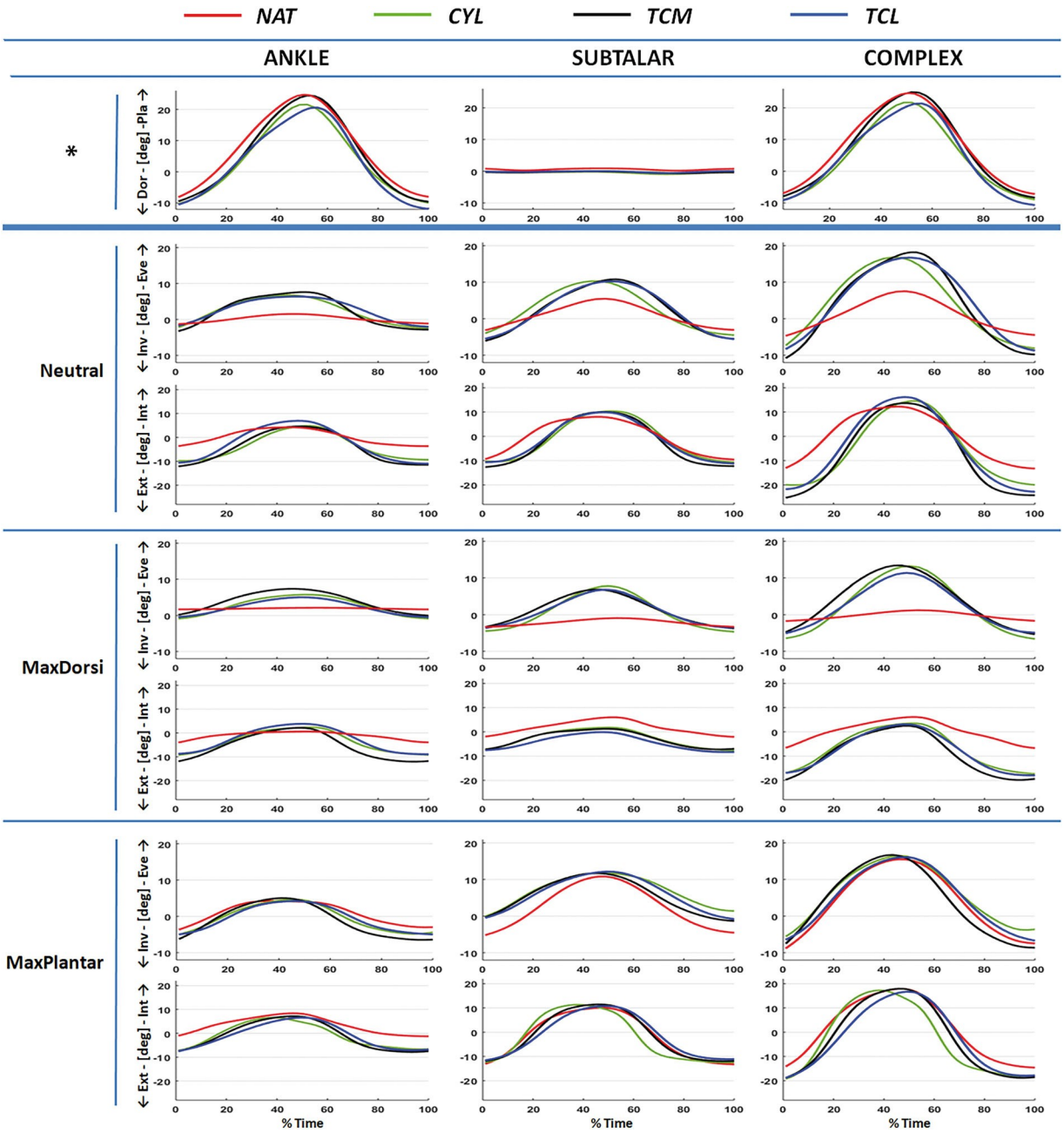

Figure 6. Cycle-to-cycle average kinematics for the ankle joint, subtalar joint, and ankle complex obtained from one representative specimen before (NAT, in red) and after the implantation of the three artificial sets (CYL, TCM, TCL). Dorsi/Plantar-flexion (Dor — Pla) is reported for its full range (ω means no torque was measured, i.e., passive flexion); Motion produced through torque application in inversion-eversion (Inv-Eve) and internal-external rotation (Int-Ext) start from the Neutral, maximum dorsi-flexion (MaxDorsi) and maximum plantar-flexion (MaxPlantar) joint positions. Joint rotations are in degrees (°); in the x-axis the percentage of the loading-unloading cycle.

A number of in-vitro studies have addressed the biomechanics of several different ankle replacement designs,[43] with inconsistent results, likely because of the variety of these designs and of the populations of specimens, as well as for the difficult sequence of standard TAR implantation. In the present study, a thorough procedure for custom-made designing and manufacturing was defined and exploited for three different designs, which shared a common support and fixation technique. A recent study[32] reported a similar procedure, but lacked the critical, final stage of additive manufacturing with metal powders via SLM. The ability to replicate anatomical shapes and to reproduce natural joint mobility and stability even using different joint replacement concepts was here demonstrated. The present observations, though on a limited sample size, supports the claimed benefits of personalization in TAR overall, independently from the design. This is expected to be of good value to reduce the mismatch between the prosthesis components and the bones, a

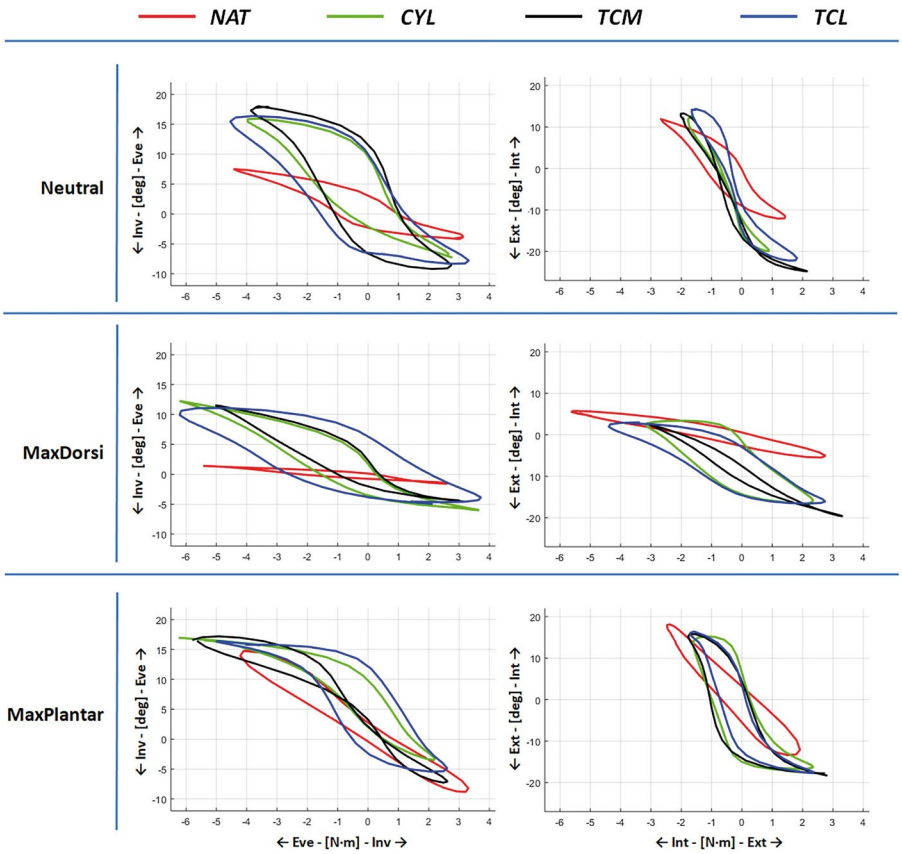

Figure 7. Rotation versus torque plots, that is, load/displacement curves, for the tibio-talar joint in Int/Ext rotation from the neutral joint position in a typical specimen: In the NAT (left), and after implant of the TCM (centre) and TCL (right) articular surface approximations. Regression lines of the loading part of the cycle are superimposed (red).

particularly critical issue at the ankle because of the small dimensions, the narrow width between the malleoli, and the general weakness of the distal tibia and proximal talus, and to eventually improve clinical outcomes. The present procedure for personalized TAR shall therefore support physicians to overcome the issues of arthrodesis and of traditional arthroplasty.

This study has several limitations. The number of specimens tested was small, but as the aim was to establish an overall new design and manufacture procedure, the specimens were sufficient here to allow for the assessment of its reliability. The three different implants were not exact full replicas of current TARs, but rather approximations of the articulating surfaces typical of a large number of the prostheses in the market; this was necessary to test in isolation mainly the effect of customization on these surfaces, based on the same support and fixation. The present experimental tests on the ankle joint are a limited spectrum of the mechanical conditions typical of daily living activities, such as, for example the absence of external compressive load. However, it was demonstrated[3,26,47] that at the ankle complex, the small compression implied in the present application of joint torques is appropriate to reveal the fundamental mechanical behaviour of both natural and replaced joints, and the relevant mutual role of the passive anatomical structures, that is, the ligaments and articulating surfaces. Thorough mechanical tests, on the metal implants themselves and on the replaced ankle joints are outside the scopes of the present paper, and are under investigation separately.[17,38]

The present analysis was performed on intact ankles, not affected by the severe degeneration of the cartilage typical of real TAR clinical cases. However, in the perspective of custom prosthesis design, it is in fact the natural contralateral joint to be targeted and mirrored in terms of replication of articular surface shapes and relevant function, still compatible with the status of the ankle to be replaced. This assumes that healthy left and right ankle joints give symmetrical geometry bilaterally. This is always given for granted in the literature, and supported with a relevant study.[48] In addition, this was investigated explicitly in the context of the present study: eight subjects underwent CT scans, relevant bone models of the full talus and of the distal tibia were reconstructed, and distance map analysis[49] between left and right models was performed. The observed maximum difference in volume and surface area for the whole talus was 7% and 5% respectively, but these figures were much smaller when only the talar dome is analyzed. For the distal tibia these figures were 3% and 3%, respectively. With the three ankle specimens of the present study this

aspect can not be addressed more deeply because of the nearly normal status of these specimens, but the literature and these preliminary results support the present assumptions.

The process of custom design for TAR addressed in this study has much potential for future exploitations, and must be developed further. First of all only prosthetic articular surfaces were here designed and manufactured; this is a preliminary yet fundamental step toward the development of complete new prostheses, which shall include appropriate interfaces with the hosting bone, fixation elements, and polyethylene inserts. 3DP however is particularly valuable to make relevant progresses also in these directions. In addition, the present computer modelling for each ankle to be replaced gives access to currently available technologies for prosthesis component implantation, such as robotic or navigation assisted surgery, or patient-specific-instrumentation. The fully digital format of all the data behind this process of custom prosthesis design allows all experts involved, that is, physicians, bioengineers, radiologists, technologists, etc. to communicate and interact despite geographical distance. In the future, modelling, and designing centres could even be located far from patients, surgeons, and manufacturers, thus reducing the movement of people and products thus saving time and costs.

With respect to the prosthetic metal components themselves, custom design and 3DP here investigated for TAR now open the door to a wide spectrum of implant-to-bone interfaces, to possibly improve the primary fixation of the components; any possible porous lattices or even trabecular-bone inspired morphologies of different densities can be investigated for their suitability for orthopaedic applications and to be carefully characterized topographically, mechanically and biologically. In combination, optimal SLM process parameters to obtain such scaffolds and structures can be investigated, as well as relevant products using other suitable powders. In fact, the present demonstrated usability of the SLM process for cobalt-chromium-molybdenum alloy unravels future usage of other different biocompatible powders, for example Titanium or Tantalum. Finally, from the same computer models obtained within this procedure, 3D biomodels can be printed with inexpensive materials to enrich medical training and teaching, as well as daily communications between physicians and patients.

AUTHORS' CONTRIBUTION

CB, SS, and AL contributed to study design; CB, SS, AF, and EL contributed in the technical development of the adopted experimental instrumentation and devices; AE, CB, and AL were involved in specimen selection; SD, CB, PC, and TK were involved in advanced imaging and segmentation; AF and EL contributed in prosthesis manufacturing via 3D printing; AE directed all surgeries with the support of CB, SS, PC and AL; CB, SS, AE, and PC contributed in data acquisition; CB, SS, AE, TK, and AL contributed in technical/kinematic data analysis and interpretation; CB, SS, AF, EL, and SD contributed in morphological data interpretation. All authors were involved in combined data interpretation, in manuscript drafting and in the critical revision of this manuscript. All authors have read and approved the final submitted manuscript.

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