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Experimental evaluation of a new morphological approximation of the articular surfaces of the ankle joint

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ABSTRACT

The mechanical characteristics of the ankle such as its kinematics and load transfer properties are influenced by the geometry of the articulating surfaces. A recent, image-based study found that these surfaces can be approximated by a saddle-shaped, skewed, truncated cone with its apex oriented laterally. The goal of this study was to establish a reliable experimental technique to study the relationship between the geometry of the articular surfaces of the ankle and its mobility and stability characteristics and to use this technique to determine if morphological approximations of the ankle surfaces based on recent discoveries, produce close to normal behavior. The study was performed on ten cadavers. For each specimen, a process based on medical imaging, modeling and 3D printing was used to produce two subject specific artificial implantable sets of the ankle surfaces. One set was a replica of the natural surfaces. The second approximated the ankle surfaces as an original saddle-shaped truncated cone with apex oriented laterally. Testing under cyclic loading conditions was then performed on each specimen following a previously established technique to determine its mobility and stability characteristics under three different conditions: natural surfaces; artificial surfaces replicating the natural surface morphology; and artificial approximation based on the saddle-shaped truncated cone concept. A repeated measure analysis of variance was then used to compare between the three conditions. The results show that (1): the artificial surfaces replicating natural morphology produce close to natural mobility and stability behavior thus establishing the reliability of the technique; and (2): the approximated surfaces based on saddle-shaped truncated cone concept produce mobility and stability behavior close to the ankle with natural surfaces.

1. Introduction

Total ankle replacement (TAR) is becoming a common surgical procedure for treatment of end-stage ankle osteoarthritis. This is primarily due to a number of drawbacks of the traditional alternative, i.e. ankle arthrodesis, including limited mobility and development of adjacent joint arthritis (Coester et al., 2001). However, while total hip and knee joint replacements have become the treatment of choice for end-stage osteoarthritis, with very low failure rates and few clinical complications, TAR is still plagued by lower survival rates (Spirt et al., 2004). The ability to reproduce the natural motion of the intact joint has been recognized as key factor for the success of implants for joint replacement. However, the surface morphology and the associated kinematics of the ankle joint are three dimensional (3D) and complex (Siegler et al., 1988; Lundberg et al., 1989; Leardini et al., 1999). A major challenge in TAR is designing and manufacturing artificial joint surfaces able to approximate this complex morphology and kinematics, and requires careful analysis of the functional morphology of the natural articular surfaces to identify their essential features.

Some of the pioneering studies on the functional morphology of the talar dome were conducted more than 60 years ago and included the seminal work by Inman and Close and their co-workers (Sewell, 1904; Barnett and Napier, 1952; Close and Inman, 1952; Hicks, 1953; Close, 1956). At that time, most investigators regarded the ankle joint as a one-degree of freedom joint with a fixed axis of rotation. Relying on this single axis assumption, direct morphological measurements of the talar

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dome and the distal tibia were performed in cadaver specimens (Close and Inman, 1952; Close, 1956; Inman, 1976). It was concluded that the trochlear surface of the talus can be approximated as a frustum of a cone, whose apex is directed medially and whose axis of revolution coincides with the line connecting the tips of the medial and lateral malleolus (Close and Inman, 1952; Inman, 1976). Relying on the validity of this postulate, the articulating surfaces of some TAR systems incorporate the truncated cone with medal apex geometry. More recently, an image-based 3D study was conducted on the morphology of the ankle joint surfaces (Siegler et al., 2014). In this study, no kinematic constraints, either translational or rotational, such as a fixed axis of rotation, were imposed. 3D models of the talus and of the tibia were produced from computer tomography (CT) images. From these models a number of geometric measurements were performed from which geometrical approximations could be produced. It was concluded that the trochlear surface of the talus, and the articulating tibial surface, can be approximated by a skewed truncated conic saddle shape, with its apex oriented laterally. These novel results were different from those reported previously (Close and Inman, 1952; Inman, 1976), and were demonstrated to be due to the fact that, unlike those early studies, no fixed axis rotation constraint was imposed.

Different geometrical approximations of the articular surfaces of the ankle may have different effects on its mechanical behavior, such as kinematic properties and load transfer characteristics. Therefore, TARs with different surface geometries may produce different ankle behavior possibly leading to significant differences in long term outcomes such as failure rates. Therefore, the first major goal of the present study was to develop and test the reliability of an in vitro experimental procedure to investigate the effect of different surface joint morphologies on the mobility and stability characteristics of the ankle. The procedure was based on producing specimen-specific 3D computer models of the articulating bones from CT scans and using these models to design and produce specimen-specific 3D printed implants. These implants were then surgically implanted and tested in the same specimens. In order to test the reliability of the technique, implant sets with artificial surfaces replicating the corresponding natural surfaces were produced and tested. The second major goal of the study was to use this technique to determine whether the implantable artificial approximation of the anatomical joint surfaces proposed recently by Siegler et al. (Siegler et al., 2014) produces mobility and stability characteristics similar to those of the natural surfaces.

2. Methodology

2.1. Summary

The experimental procedure was designed to study in-vitro the effect of different ankle surface morphologies on its mobility and stability characteristics. In this study, “mobility” is defined as the angular joint's rotation and range of motion in three planes. Stability refers to the total joint laxity which is here defined as the ratio between the range of motion in degrees in a given direction (inversion/eversion or internal/external rotation) and the total torque required to produce it. The entire process was performed on each specimen, and consisted of the following steps: pre-testing surgical preparation and CT imaging; image processing, modeling, designing and 3D printing of artificial surfaces; mechanical testing of the original intact specimen; surgical removal of the natural surfaces and implantation of the 3D printed artificial components; and repetition of the mechanical testing with each set of artificial surfaces.

2.2. Pre-testing surgical preparations and CT imaging

Ten fresh-frozen legs from below knee cadaveric dissections were used in this study. The specimens were obtained from ten subjects, three females and seven males, with an age range of 18–77 years old and an average age of 47. Each specimen was thawed for at least 24 h at room temperature. It was carefully inspected clinically and radiologically and inspected again during the subsequent surgical preparation for any observable defects or deformities. During these inspections, the integrity of ligaments and of the articular surfaces was verified. The entire surgical preparation and implantation procedure described below was performed by an orthopedic foot and ankle surgeon with large clinical experience in TAR. Using a standard anterior surgical approach, the articular surfaces were exposed. A standard surgical instrumentation jig used routinely for implantation of a currently available TAR was fixed to the distal tibia with the foot in neutral position, and with the extra-medullary rod of the jig aligned with the long axis of the tibia in both the sagittal and coronal planes (Giannini et al., 2010). The proper size tibial cutting block was selected and centered medio-laterally in the ankle mortise, providing the means to drill two parallel tunnels in the distal tibia. These tunnels were later used to fix the tibial components of the artificial surfaces as well as to provide clearly identifiable references. Three 2 mm diameter holes approximately 5 mm deep from the surface of the bones were then drilled into the tibia, talus, and calcaneus, and were used as fiduciary markers for registration. The specimen was then CT scanned (Brilliance CT 16-slice system by Philips Healthcare, DA Best, The Netherlands) with an in-plane resolution of 0.15 mm and a 0.4 mm inter-slice distance (Fig. 1a). The leg was then re-frozen while waiting for the design and production of the 3D printed artificial components.

2.3. Image processing, modeling, designing and 3D printing

The data from the CT scans (Fig. 1a) stored via Digital Imaging and Communications in Medicine (DICOM) were imported into an image processing software (Analyze Direct^{TM}, Overland Park, KS-USA) to obtain, after proper segmentation, 3D filtering and rendering, a 3D representation of the articulating bones including the tibia, fibula, talus and calcaneus (Fig. 1b). The stereo lithography (STL) files containing these 3D models of the bones were then imported into a reverse engineering program (Geomagic^{TM}, Morrisville, NC-USA) where they were further processed and where all the necessary dimensions required for the design of the artificial surfaces were performed (Fig. 1c). Two sets of these implantable surfaces were used in the study. Each set consisted of a tibial and a talar component with matching articulating surfaces. A uniform offset of 1.5 mm was introduced to account for the articular cartilage layer that was not visualized in the CT images. This value was based on an approximate average joint spacing observed in the CT images for the specimens. One implantable set consisted of articular surfaces that replicated the natural surfaces as obtained from the CT scan. This set was referred to as the ANATOMICAL set (Fig. 1d, left). The second set (Fig. 1d, right) consisted of the approximation to the natural surfaces (Siegler et al., 2014) consisting of a saddle shaped skewed truncated cone with the apex of the cone oriented laterally (from now on, referred to as SSCL). The attachment of the tibial component to the distal tibia was designed to include two 5 mm diameter cylinders that were fit into the two previously prepared 5 mm diameter tunnels in the distal tibia. A small plate in front of this component provided a means to temporarily secure the tibial