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Force-controlled dynamic wear testing of total ankle replacements

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ABSTRACT

Currently, our knowledge of wear performance in total ankle replacements is limited. The aim of this study is to develop a scenario for force-controlled testing and wear testing of total ankle replacements. A force-controlled wear test was developed: based on cadaver measurements, the passive stabilization (ligaments and soft tissue) of the ankle joint was characterized and a restraint model for ankle stabilization was developed. Kinematics and kinetics acting at the replaced ankle joint were defined based on literature data and gait analysis. Afterwards, force-controlled wear testing was carried out on a mobile, three-component, total ankle replacement design. Wear was assessed gravimetrically and wear particles were analyzed. Wear testing resulted in a mean wear rate of 18.2 ± 1.4 $mm^3/10^6$ cycles. Wear particles showed a mean size of 0.23 µm with an aspect ratio of 1.61 ± 0.96 and a roundness of 0.62 ± 0.14. Wear testing of total ankle replacement shows that a relevant wear mass is generated with wear particles in a biologically relevant size range. The developed wear test provides a basis for future wear testing of total ankle replacements.

1. Introduction

Total ankle replacement (TAR) has become a viable option in the treatment of degenerative or inflammatory diseases of the ankle joint. This is mainly attributed to the currently used TAR generation which shows improvements in surgical technique, uncemented implant fixation and minimally constrained articulation [1,2]. Clinically, results are promising [3–5], especially when compared to earlier attempts in TAR [6]. However, TAR is still not as successful as total knee replacement (TKR) or total hip replacement (THR) [7]. It should also be noted that there are limitations surrounding our knowledge concerning the long-term performance of TAR [8].

Wear and aseptic loosening due to ultrahigh-molecular weight polyethylene (PE) wear are known to be frequent long-term complications for TKR and THR [9–11]. However, wear is not considered to be a significant problem in TARs. Clinically, aseptic loosening is considered to be a mechanical loosening procedure [12] and is the main reason for revision of TAR [4,13–15]. It is not known to what extent wear-particle-induced loss of osseous support is also involved in this loosening mechanism. Objective consideration in regards to the relevance of wear in TAR is hampered by the lack of sufficient numbers in long-term studies on modern TAR designs.

Wear simulator studies have been shown to be a powerful tool in predicting the wear performance of artificial joints for TKR and THR [16–19]. However, only a few studies have dealt with experimental wear studies on TAR [20–22]. This may partly be related to the fact that no standard exists which describes how to test TAR in vitro.

Generally, a distinction can be made between displacement-controlled and force-controlled wear testing. In both testing modes flexion (displacement-controlled) and axial loading (force-controlled) are carried out in the same way. The terms displacement-controlled and force-controlled testing refer to the simulation of the secondary motions (anterior–posterior translations and internal–external rotations). Predetermined displacements are carried out on the implant during displacement-controlled testing which are independent of resulting forces and torques. This testing mode is used especially for congruent joints like the hip. For less congruent joints that are additionally stabilized by ligaments [23] (e.g. knee joint), force-controlled testing can be defined as the best

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available technology for wear testing [24]. In this testing mode, predetermined forces and torques were carried out on the implant and resulting kinematics were dictated by the defined laxity characteristics (ligaments), implant restraint (congruence and friction restraint) and component alignment (e.g. varus alignment). Thus, force-controlled testing facilitates wear testing with a high clinical relevance. Knowledge about acting forces, torques and laxity characteristics are essential for this testing mode.

Previous wear studies used displacement-controlled testing for TAR [20–22]. Stabilization and kinematics of the replaced ankle joint rely particularly on laxity characteristics and implant restraint. Force-controlled testing therefore seems to be reliable for predicting the wear performance of TAR. The aim of this study is the development of a force-controlled testing scenario for total ankle replacements. This involved (1) the definition of kinematics and kinetics acting on the replaced ankle, (2) the characterization and definition of passive stabilization of the ankle joint (laxity characteristics), (3) definition of a wear test and (4) testing the wear performance of a currently used TAR.

2. Materials and methods

2.1. Definition of kinematics and kinetics

2.1.1. Dorsal and plantar flexion

Marker-based gait analyses of level walking, as previously described [25], were used to determine ankle flexion. Data for an extended patient collective from a previously published study [26] were used. In total, 18 ankles (HINTEGRA®, Newdeal, Lyon, France/Integra, Plainsboro, New Jersey) implanted in 17 patients (9 men, 8 women, mean age 62 ± 8 years) were analyzed. Analysis was performed on the TAR provided side as well as on the healthy contralateral side.

The determined ankle flexion is shown in Fig. 1. Patients provided with a TAR showed a reduced range of motion of 14.9° for the involved side compared to 23.1° on the contralateral side.

2.1.2. Tibio-talar loading

Determination of ankle loading is based on literature data. The literature data provide mathematical models and inverse dynamics for ankle loading. It is known that these theoretical models have limitations. Comparisons to in vivo data reveal that the quantity of loading (magnitude) is particularly prone to error [27]. It is necessary to improve the quality of these models through validation using in vivo measurements [27,28]. Because no data regarding in vivo loading of TAR exist, utilized data of tibio-talar loading in this study are scaled based on comparisons of the utilized models to in vivo loading of TKR and THR [27,29–40]. The procedure is described in the following.

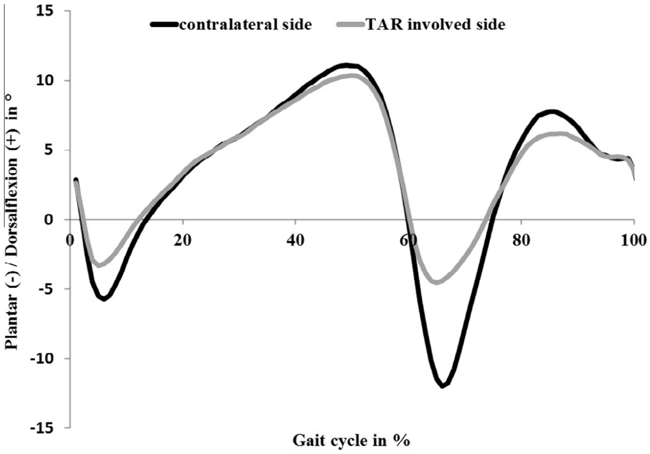

Fig. 1. Dorsal/plantar flexion of patients provided with a TAR.

Theoretical models revealed an average peak axial loading of five times the bodyweight (BW) at the healthy ankle joint [41–46]. The same models determined the axial loadings at the hip and knee joints to be two times higher than that of in vivo measurements for TKR and THR [27,29–40]. Additionally, it has to be determined if theoretical models are based on subjects with a healthy or replaced joint. It is known that loading at the replaced joint is decreased compared to the healthy joint [46–49]. For axial loading, a 30% load reduction [46] at the replaced joint compared to the healthy joint was therefore assumed. This results in an axial loading of 3.6 times BW for the healthy ankle joint and 2.5 times BW at the replaced ankle joint. Axial load progression was adapted based on data of Seireg and Arvikar [45].

Internal–external torque and anterior–posterior forces were determined in the same way. In vivo loading of TKR [38] was utilized for scaling. Details of determined loading and load progression at the replaced ankle are shown in Table 1 and Fig. 2. A detailed loading protocol is provided in Appendix 1.

2.2. Passive stabilization

To characterize the passive stabilization of the tibio-talar joint, laxity measurements were carried out on ten matched pairs of fresh-frozen cadaveric legs (20 feet). The specimens were detached at the tibia and fibula, 15 cm proximal to the ankle joint. Threaded rods were fixed using bone cement (DePuy CMW MV, DePuy Orthopaedics Ins, Warsaw, USA) into the diaphysis of the tibia and into the talus. Small incisions were made by an experienced surgeon (second author) using a posterior approach in order to gain access to the talus, which is partly restricted by ligaments and adjacent bones. Care was taken to minimize soft tissue damage and to avoid any damage of the ligamentous apparatus. Positioning of the rods into the tibia and talus was controlled via X-rays in the transversal and sagittal planes (Fig. 3).

A testing rig was used for laxity measurements (Fig. 4). The device enables anterior–posterior force and internal–external torque application in various flexion angles. Measurements were carried out in 10° dorsal flexion and 0°, 10° and 20° plantar flexion. An anterior and posterior force of 160 N and an internal and external torque of 2.5 N m were applied. Measurements were recorded after an initial loading cycle. Tibial axial loading due to the testing setup was 10 N.

After laxity measurements of each foot, the elasticity of the entire setup (testing device and bones of the cadaveric legs) was determined. Therefore, the ankle joints were fused using an internal screw fixation. Anterior–posterior forces and internal–external torques were applied in the same fashion as in the previous measurement and the determined elasticity at each loading point (force/torque) was subtracted from this initial measurement.

A motion restraint system for anterior–posterior forces and internal–external torques has been developed based on data of laxity measurements in different flexion angles. Restraint characteristics change depending on the flexion of the ankle joint. Thus, the features of the developed restraint model are the result of different restraint characteristics in different flexion angles. The procedure is described in Fig. 5. The restraint models for anterior–posterior translations and internal–external rotations are shown in Fig. 6.

2.3. Wear testing

Wear testing was run on a modified knee wear simulator (Model KS2-6-1000, Advanced Mechanical Technology Inc., Watertown, MA, USA). Kinematic and kinetic input parameters were used as defined in Section 2.1. Movements in the coronal plane (inversion/