FATIGUE DEVICE FOR TESTING ANKLE JOINT ENDOPROSTHESSES

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Abstract: The paper proposes a model of a fatigue device for testing dedicated to ankle prostheses. The concept of the testing device relies on two aspects: almost any type of ankle prosthesis can be tested on it and it has to work on INSTRON axial-torsion testing machine. Starting from these requirements, a 3D functional assembly that reproduces the real movement of the ankle joint during gait cycle has been designed. The device is based on a cam-follower mechanism.

KEY WORDS: ankle joint, endoprosthesis, testing device, fatigue test

1. INTRODUCTION

Nowadays, for more and more patients with ankle arthritis or osteoarthritis total ankle replacement is becoming increasingly more used as a viable alternative to fusion. Although progress in ankle arthroplasty is considerable, this type of prosthesis is still affected by a relatively high rate of intra-operative complications and revisions, generating concerns about its long-term success [1].

In general, long-term improvement of implant features aims to design new constructive solutions of implants to ensure a better fit of their components on the fractured bones or on the bones that make up the joint, appropriate mechanical strength, good wear and fatigue behavior (especially), better properties of materials that are manufactured implants / endoprostheses, less invasive techniques / procedures of implantation, precise and ergonomical surgical instruments used for fastening parts (components) of implants / endoprostheses and efficient post-operative recovery methods.

Design of the joint prostheses and related material selection are always influencing the function performance and long-term durability of endoprostheses. Wear of total joint prosthesis is an important clinical problem, because the wear of the bearing surfaces of the implant is responsible for wear debris which can cause adverse tissue reaction that may lead to the implant loosening [2].

Given the growing number of cases of total ankle prosthesis, research is oriented toward component wear, especially polyethylene components, and their long-term sustainability. Thus, improving the prosthesis sustainability is a major concern. A study of total ankle prosthesis durability relative to durability of total knee replacement based on the analysis of polyethylene wear particles recovered from joint fluid, concluded that long-term function of total ankle prosthesis can be considered similar to total knee replacement in terms of polyethylene wear and osteolysis prevalence [1].

Testing devices and simulators have become an efficient and important tool in preclinical testing stage of artificial joints. The paper presents a testing device model for ankle joint replacement designed to be used on INSTRON 8874 testing machine that is able to perform a great variety of fatigue and dynamic tests.
2. MOVEMENTS IN ANKLE JOINT

The ankle moves as a complex mechanism composed of two joints: ankle joint (tibiotalar joint) that is of type of synovial hinge joint allowing dorsi-flexion (normal range: 10-30°) and plantar flexion (normal range 20-50°) movements, and subtalar joint allowing inversion and eversion movements.

Taking into account the ankle anatomy, the device proposed in the paper aims to reproduce a real flexion-extension movement of the ankle, during a series of normal gait cycles.

A gait cycle has two main phases: stance (the foot is in contact with the ground - weight bearing) phase and swing phase (the foot is not in contact with the ground - non-weight bearing). Each of these phases consists of several events [3]:
- stance phase: Heel Strike, Mid-Stance, Toe Off;
- swing phase: Acceleration and Deceleration.

A typical flexion-extension movement of the ankle is depicted in figure 1. This graph was drawn using data collected with Zebris measuring system [4]. As it can be observed, two periods of plantar flexion and dorsi-flexion are executed during a gait cycle.

During a normal gait cycle, the following positions of the ankle joint can be mentioned:
- Heel Strike - neutral position;
- Mid-Stance - dorsiflexed;
- Toe Off - plantar flexed;
- Acceleration - neutral position;

A highly realistic simulator used in testing of the ankle joint endoprostheses must experiences the real movements in ankle joint during gait cycles.

3. MODELING OF THE TESTING DEVICE

The fatigue testing of joint endoprostheses is of a great importance when evaluation of the durability of the joint replacement components or joint endoprostheses is under concern. Wear testing machines are mostly available for many orthopaedic devices, such as hip, knee, spine implants, stabilization systems, and dental implants but not for ankle joint endoprostheses [5], [6].
Durability testing of ankle endoprostheses must accomplish the requirements of specific standards such as ISO 22675 and ISO 10328 (Testing of ankle-foot devices and Structural testing of lower-limb prostheses), and FDA guidelines. Also, the testing device must allow the application of precise loads and generate the movements according to the gait cycle [7].

The design of the fatigue test device was conducted based on the following items:
- test any ankle joint replacement having two or three components;
- allow dorsi- and plantar flexion modeled as real gait cycle movements;
- prosthesis under the test can be fixed inside the device or can be implanted into the bones which are later fixed in the device;
- allow additionally systems to ensure lubrication with biological liquid;
- loads applied to the prosthesis are either constant or cyclically.

The functional principle of the device is based on transforming the alternative axial movement of the INSTRON machine in oscillatory angular movements. The mechanism that stays at the fundamentals of the device is a cam-follower system. The follower part of the mechanism is materialized by a road fixed on the machine’s grip, which produces the active movements. The cam part can be observed in figure 2, executing a passive oscillation around the instantaneous center of rotation ICR. The ICR is placed on the conjugated surfaces of the ankle joint prosthesis.

![Fig. 2. Cam design and parameters](image)

The design of the cam follows the particularities of the ankle movements during a gait cycle. In this way, the cam shape was created by successive circle arches which by their concave or convex geometry generate dorsi or plantar flexion movement. The angular velocity of the movement is a function of the linear velocity of the follower element.

Taking into account the design items earlier defined, the assembly of the testing device was build (figure 3). It counts 18 individual elements like plates, springs, roads, screws, cam and follower, bushed bearing. The model was created part by part in SolidWorks. The main components of the testing device are:
- inferior plate - 1;
- test ankle prosthesis - 2;
- superior plate - 3;
- cam - 4;
- cam follower - 5;
- spring – 6.

The parts were than assembled, obtaining the 3D model of the testing device. By applying mechanical mates to the whole components, a functional assembly resulted.
This assembly is respecting the movement possibilities and limitations that were imposed by the task.

The ankle prosthesis represents an integrate part of the whole assembly, this having a functional demanding: the ICR of the cam must be located on the sliding surfaces of the prosthesis.

This is leading us to the conclusion that, by changing the height of the prosthesis inside the mechanism, the position of the ICR will change according to the angular movement of the cam. In order to avoid this inconvenience, the length of the cam’s cane has to be adjustable.

4. AXIAL-TORSION FATIGUE TESTING SYSTEMS

The testing device can be installed on the INSTRON - servohydraulic bi-axial testing machine 8874 (figure 4) which is ideal for performing bi-axial tests on materials and components. The combined axial-torsion actuator is in the upper crosshead and leaves the lower T-slot table free for mounting of specimens, grips, or complex fixtures and accessories. The axial force capacity is up to ±25 kN, and torque capacity up to 100 Nm [8]. The Dynacell is a patented feature used to compensate the inertial loads caused by heavy grips and fixtures.

INSTRON 8874 testing machine experiences several testing solutions in orthopedics, including static testing of raw materials, impact loading of joint components, complete simulation for evaluating the fatigue and wear properties in vivo.

The machine’s control can be made either in force or displacement. Because a specific movement is intended to be obtained rather than a specific compression force, the control of the machine will be made in displacement.
The diagram of the movement is a sine wave situated below the time axis (figure 5). For the testing device, Min. position represents the upper point of the cam while Max. position represents the lowest point of the cam.

![Fig. 4. Instron - Servohydraulic bi-axial testing machine 8874](image)

**Fig. 4. Instron - Servohydraulic bi-axial testing machine 8874**

![Displacement diagram of the testing machine](image)

**Fig. 5. Displacement diagram of the testing machine**

5. CONCLUSIONS

In order to perform wear or fatigue tests on ankle joint endoprostheses using an INSTON testing machine, a specific device has to be designed. By trying to create a versatile device adaptable for a large variety of ankle prostheses, some requirements have to be imposed. First of all, a special cam has to be designed for reproducing a realistic movement of the endoprosthesis. Second, the dimensions of the prosthesis have to be compensated by some adjustable elements of the device.

The designed testing device allows both dorsi-flexion and plantar flexion movement in ankle endoprostheses. Using the longitudinal axial rotation of the INSTON testing machine, an internal rotation of the ankle endoprostheses could be applied. Accordingly, both fatigue and wear tests of the ankle endoprostheses can be performed.

By modifying the cam profile, a customized device could be obtained. The customized profile represents the real movement in ankle joint of the patient, recorded in a Motion Analysis Laboratory.
Future work will consist in theoretical simulations, manufacturing and validation of the designed testing device. Once the designed model will be validated, the wear / fatigue behavior of some ankle endoprostheses will be investigated.

REFERENCES


