TESTING OF ENDOPROSTHESES ELEMENTS MADE FROM NEW BIOCOMPATIBLE MATERIALS IN SIMILAR IN VIVO POSITIONS AND CONDITIONS FOR DETERMINATION OF ENDURANCE COMPORTMENT

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Abstract

Biomaterials Applications in medical field are generated by special needs required from medical practice and by the medicine evolution as science. The biocompatibility concept, evolve the necessity to use compatible materials with the human body (biomaterials) with a wide range of properties which satisfied the necessary parameters for medical devices.

The research and development of new materials for implants and prosthetic elements lead to an increased need for verifying and testing them. This involves testing and research for biocompatibility, static and dynamic load tests and tribological investigations.

Investigation methods for medical devices are experimental tests. Testing and verification of medical devices in accordance with the applicable standards provide to manufacturers an opportunity to improve quality control. These tests and trials are not done only for validation of new materials, but also as a standard procedure in the manufacturing process, or for different case studies.

Objectives: For determination of the mechanical properties of biocompatible materials produced for medical devices, these must be tested to determine physical and mechanical characteristics (tensile test, compression, bending or endurance).

Methods: These tests are performed on stands test to determine the best reaction of biocompatible materials to the effort.

For medical devices it is essential to perform the test in the function positions like in normal conditions from the human body. So for implant hip used in arthroplasty this should be positioned on the test stand at angles that are positioned in the body. For this was made a fixture device for the endurance test samples with the possibility of rotating in two perpendicular planes.

Results: By making the device we can reproduce the anatomical positions of prosthetic implants and teste them for reaction in normal use. The two angles can be adjusted independently of each other and the device incorporates vernier bevel protractor which can indicate the angle. After angular position, the sample is tightening in the alignment and the orientation device allows maintaining the orientation after alignment device removal.

Conclusions: To shorten the certification of a new medical device, the material characterization before using it in device is necessary. For these reasons it was developed a system to guide and fixe the

specimens on the testing machine to fatigue characterization according to ASTM and ISO standards requirements for fatigue testing of medical implants.

***Keywords*:** mechanical tests, biomechanics, biomaterials characterization, endurance, orthopaedics.

Introduction

The present work discusses the orientation and fixing system designed for dynamic test in characterization of mechanical properties of biomaterials. The fixture includes load cell adapter, potting cup base, chamber and seals, chamber holder, and thrust bearing and lower housing assembly (Fig.1).

Figure 1. The specimen fixture for endurance properties determination
(Sistemul de fixare a probei pentru determinarea proprietăților de anduranță)

Objective

Endurance properties are important attributes of in vivo performance of orthopaedic implants. For determination of the performance of the implants these must be orientated so the forces should be applied similar to the anatomical position. For this reason an orientation and fixing system is necessary to provide the anatomical position for the test.

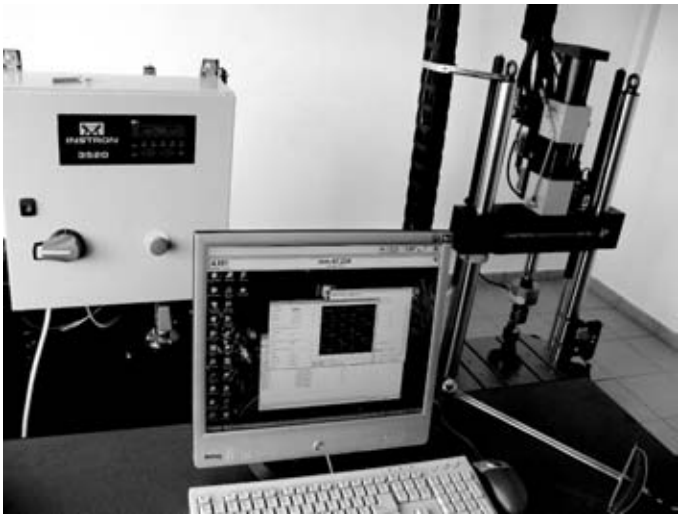

Figure 2. Testing machine (Mașina de încercare)

The testing machine must perform compressive, tensile, torsion and bending tests for material strength (Fig.2). Endurance testing can be carried out by cyclic fatigue testing. Loading curve congruent with the real use can be simulated.

The Description of the Constructive Solution

Pre-clinical endurance validation of hip femoral components is carried out under a constant loading range. A compressive sinusoidal dynamic load is applied on the head of the specimen while it is distally embedded in acrylic cement. This test condition is based on the assumption that the specimen has become unsupported through breakdown of the proximal cement or bone. The test specimen must be embedded in a solid medium to be put on the test machine. The position in the fixture must be the same like in implantable condition. For this reason an orientation and fixture system was designed.

The Orientation System of the Specimen

The system allows to define the imaginary gravitation axes of the specimens, which can be for example hip prostheses, with specific specimen parameters.

For this, the system was designed to allow the gripping of specimens with different geometrical shapes. It is composed of: a shaft (1) with V-slot at 90 degree which allows fixing, vertical positioning and the two prism (2) alignment with the specimen axes, a sitting pin (3) for the specimen tip and a gravitational system (4) to materialize the specimen axis (Fig.3).

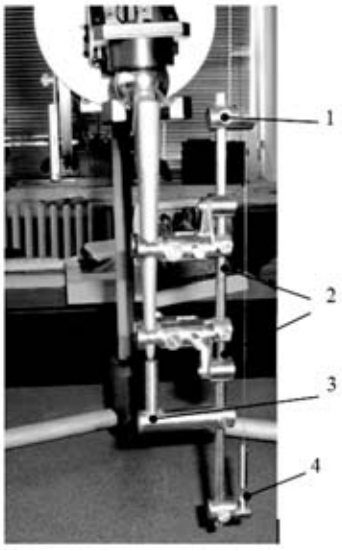

Figure 3. Specimen align device for determination of endurance properties
(Dispozitivul de aliniere a probei pentru determinarea proprietăților de anduranță)

The two prisms will be positioned at the necessary distance between them to allow a good fixture of the specimen.

The specimen head will be clamped in the gripping system and then, with the two prisms, the gravitational axis of the specimen is materialized. The vertical position is visualized utilizing a lead line.

For medical devices is necessary loading of the implant in anatomical positions. So the hip prostheses need to be positioned at a different angle in two perpendicular planes (fig. 4)

The angles are set independent of each other and are indicated by two vernier bevel protractors. After angular positioning, the specimen is fastened and keeps the orientation of the probe even after the removal of the alignment device.

Figure 4. The angular position setting device of the specimen for determination of endurance properties (Dispozitivul de aliniere unghiulară a probelor la încercarea de anduranță)

The specimen must be embedded in a casting medium which shall no crack or break under the load applied during testing, not exhibit excessive deformation or creep and are reproducible in strength and other characteristics.

The test specimen holder

The holder keeps the specimen (5) in an embedded medium (6), at the specified orientation during the test (Fig.5).

According to ISO 7206-4, the embedding medium must be a casting medium witch must have a modulus of elasticity between 3 Gpa and 6 GPa. For embedding medium our laboratory utilized bone cement.

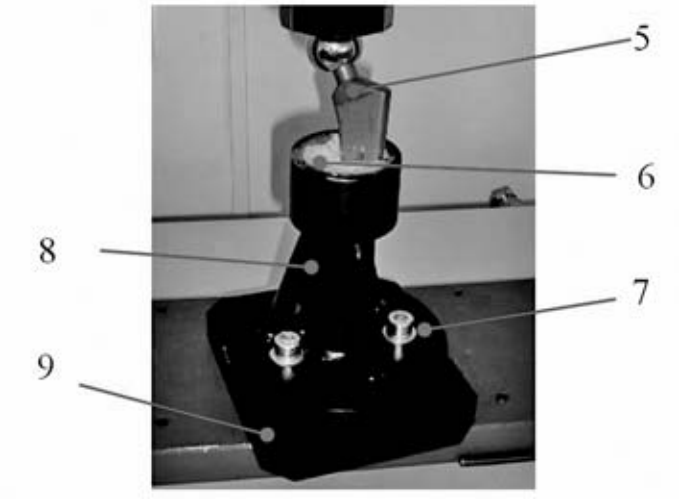

Figure 5. Specimen holder (Dispozitivul de fixare)

The holder is designed to allow specimen gripping on the endurance testing machine at the necessary load line. So the pad (7) of specimen holder (8) is provided with slotted holes to assure the necessary adjustment for proper specimen positioning on the intermediate plate (9) which is mounted on the testing machine (Fig.5). The specimen holder is designed to have the minimal possible volume to minimize the embedding medium consumption.

The loading means

The means of loading the test specimen are designed to maintain loading through the nominal centre of the specimen along the axis of testing machine. This incorporates a low-friction mechanism

to minimize loads not coincident with the axis of the testing machine. The mechanism contains a ball holder (10) and two ball groove race (11) (Fig.6).

The loading device (12) is mounted on the load cell through a connecting bolt with 8 mm diameter. To avoid the slip over of the ball holder the mechanism is provided with three elastic clamps (13), mounted at 120°, which allow cross travel of the ball holder in the necessary limits to take the offsetting of the testing load (Fig.6).

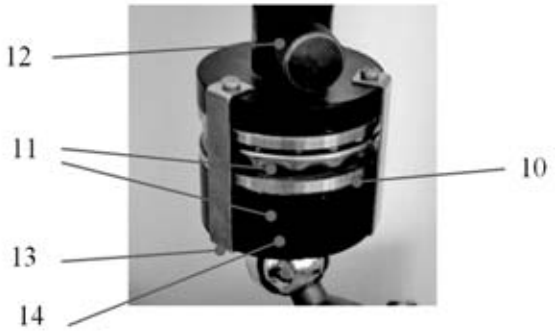

Figure 6. The loading device (Dispozitivul de încărcare)

The contact surface between the specimen head and loading mechanism is assured by an intermediate part (14) provided with a conical slot so the contact will be a circle (Fig.6).

Results

The orientation and fixing system ensures the following advantages:

- Specimen fatigue fixture was specifically designed to meet and exceed the requirements of the ISO tests
- The fixture can also be easily adapted to suit other testing machines and test set-ups.
- The flexible specimen holder is also provided to accommodate a wide variety of hip geometries, offset angles, embedding materials, and embedding depths.
- The fixture system can be used with an environmental chamber and temperature controller, for complete in vivo simulation.

Conclusions

Developing of new materials for medical implants involves new systems for mechanical properties characterization. Before clinical evaluation of implants it is necessary to test them at static and dynamic testing force. The materials characterization before their use in medical devices is essential in shortening of the necessary time for the product certification. For these reasons was developed an orientation and a fixture system for Fatigue Testing. The orientation system is designed in order to meet ASTM and ISO test criteria for implants Fatigue Testing.

The National Institute of Research and Development for Mechatronics and Measurement Technique developed a testing Laboratory for medical device with the necessary test equipments for performing mechanical characterization.