



## **Developing Of New Systems And Test Methods For Biomaterials Testing**

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### **ABSTRACT**

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 implants must be orientated so the forces should be applied similar to the anatomical position. The fixture includes load cell adapter, potting cup base, chamber and seals, chamber holder, and thrust bearing and lower housing assembly.

### **INTRODUCTION**

The present work discusses the orientation and fixing system design for dynamic test in biomaterials mechanical properties characterization. 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*

## **THEORETICAL CONSIDERATION**

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.

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.



*Figure 2. Testing machine*

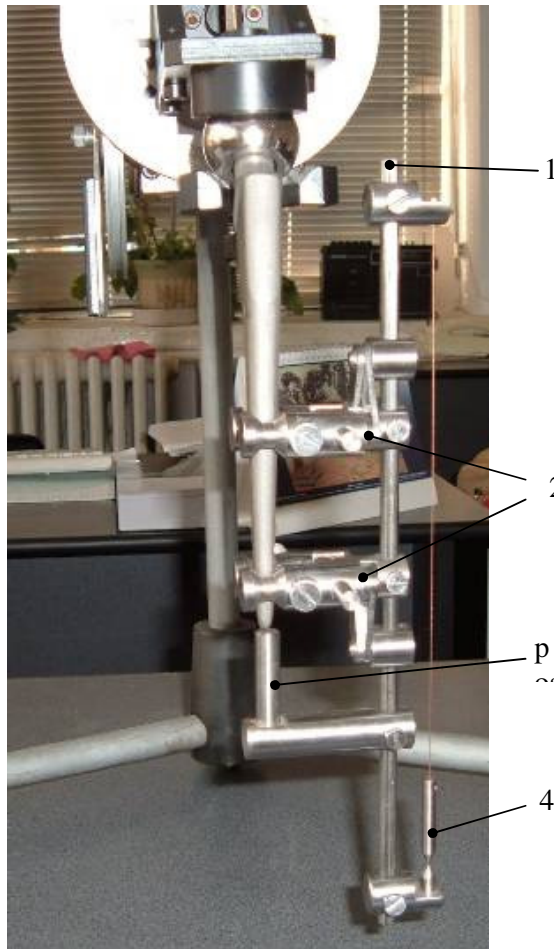
## **The Description of the Constructive Solution**

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 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)

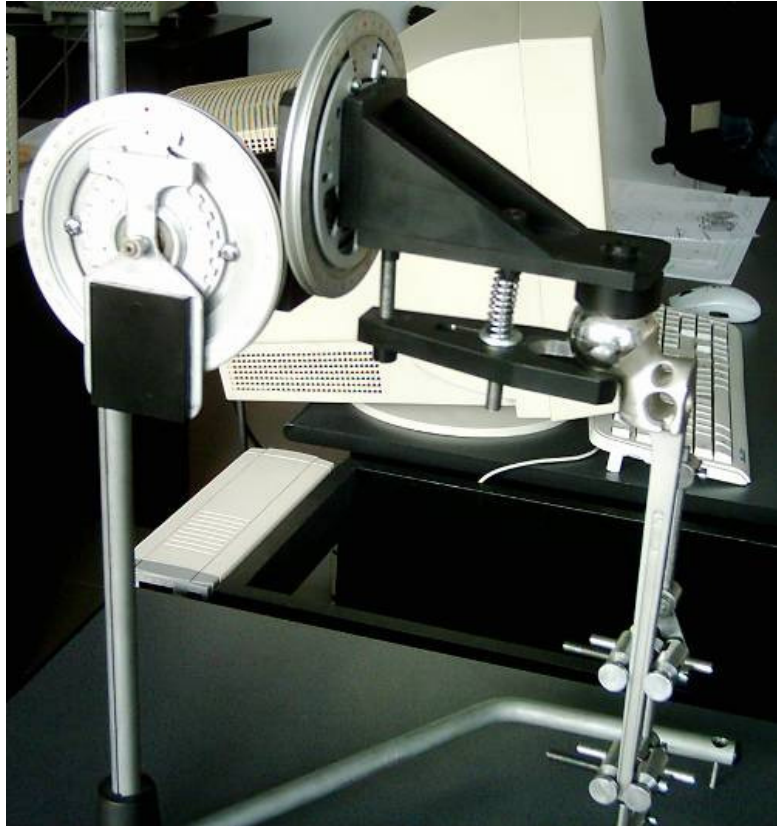


*Figure 3 Specimen align device for determination of endurance properties*

The two prisms will be positioned at the necessary distance between 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)



*Figure 4 The angular position setting device of the specimen for determination of endurance properties*

The angles are set independent 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.

The specimen must be embedded in a casting medium which shall not 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 which must have a modulus of elasticity between 3 GPa and 6 GPa. For embedding medium our laboratory utilized bone cement.

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.



Figure 5 Specimen holder

### **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)

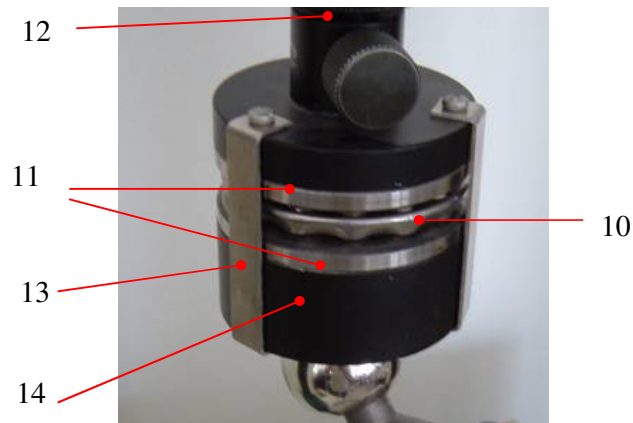


Fig.6. The loading device



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)

#### **The Advantages of the Proposed Solution**

The orientation and fixing system insures 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.

#### **REFERENCES**

- [1] ISO 7206 - 4: 2002, Implants for surgery – Partial and total hip joint prostheses – Part 4: Determination of endurance properties of stemmed femoral components.
- [2] ISO 7206 - 6: 1992, Implants for surgery – Partial and total hip joint prostheses – Part 6: Determination of endurance properties of head and neck region of femoral components.
- [3] ISO 7206 - 8: 2002, Implants for surgery – Partial and total hip joint prostheses – Part 8: Endurance properties of stemmed femoral components.