



INTERNATIONAL JOURNAL OF PURE AND APPLIED RESEARCH IN ENGINEERING AND TECHNOLOGY

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FATIGUE TESTING OF HIP IMPLANTS WITH THE ISO 7206 STANDARDS: A REVIEW

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Accepted Date: 15/03/2016; Published Date: 01/05/2016

Abstract: Hip implants experienced large cyclic loads during service condition. Pre-clinical analysis must be performed to withstand millions of loading cycles. The fatigue failure of hip implant significantly reduces now a day due to improvements in technology. However, instances of fatigue failure of the hip replacement, resulting in the revision of the patient. Proximal aseptic loosening is the most common cause of stem fracture. ISO 7206-4 fatigue testing of hip implants reproduced this scenario. This test must be applied to avoid fracture of the stem. In order to assess the fatigue reliability of the hip prosthesis, the ISO 7206 international standard has been developed. The ISO 7206 test describes the fatigue test equipment and procedure. It is currently approved by several laboratories worldwide. This paper discusses literature on ISO 7206-4 fatigue testing of hip implants.

Keywords: Fatigue, Hip implant, ISO 7206, Experimental Testing.



PAPER-QR CODE

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Access Online On:

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How to Cite This Article:

Mangesh Dharme, IJPRET, 2016; Volume 4 (9): 317-325

INTRODUCTION

The patients suffering from hip diseases are treated successfully by Total hip prosthesis [5-8]. Fatigue failure of the hip replacement may occur as a result of the forces exerted on the prosthesis by human activity. So it is important to make hip replacements against fatigue failure. In the past two decades, fatigue failure of hip implants was significantly reduced [9, 10]. Even so, fatigue fractures of hip implants continue to be reported [11-14]. Therefore as part of fatigue design approval, testing of hip implants should be performed. ISO 7206-3 [15] fatigue testing of hip implants specified vertical load applied to the head of the hip implant. In this test, the hip implant is fixed at a height of 80 mm below the center of the head (Fig. 1). This standard test was replaced by ISO 7206-4 [16] to include out-of-plane bending and torsion. The free length of 80mm was replaced by 40% of the stem length (Fig. 1). In this test hip implant must survive to 5 million cycles up to 2KN force. ISO 7206-4 fatigue testing of hip implants reproduced proximally loosened condition of hip stem, which is the common cause of fatigue failure [17, 18]. Fatigue tests hip implant resulted in the development of a product higher quality through design optimization, including proximal loosened materials, methods of geometry, coatings, surface finish, and manufacturing. Fatigue resistance of the material has been compared to the analysis of hip implant finite element (FEA) results [19]. Life expectancy of hip implants can be greatly reduced due to surface structures such as porous coating, the imperfections of material, manufacturing or implantation [20]. In the Food and Drug Administration, FEA combined with mechanical testing of orthopedic components is beginning to be accepted for pre market approval. The risks of fatigue failure of hip implants can be reduced greatly by accurate FEA models and validated fatigue test prediction methods.

The objective of this review is to examine the available literature on the fatigue test ISO 7206-4 of hip implant.

2. METHODOLOGY

2.1 ISO 7206-4 FATIGUE TESTING STANDARD FOR HIP IMPLANTS

For fatigue testing of hip implants some of the significant variables that must be addressed to include the support levels of the prosthesis, the selection of the angles of load application, frequency of testing and appropriate environment. The main purpose of any testing is to duplicate prominent in-vivo loading and environmental conditions. However, the limitations of cost, time, knowledge and resources often result in compromises for testing. ISO 7206-4 fatigue test method of hip implant standard was developed in response to a fatigue failure of hip implants and the need to test designs before use. This test includes profiles of constant

amplitude sinusoidal load, fixed orientation hip implant and a test environment can be in the air or saline fluid 37°C environment [21-28]. This test is validated by correlation of reasonably good test results with historical clinical data [26-29]. In this test portion of the proximal stem 40% is not supported and assume that load sharing by the stem and the femur. In this test protocol, the unsupported portion must resist a predetermined number of cycles. As shown in Figure 1, The International Organization for Standardization (ISO) has published a standard that is representative of many of the current test methods for femoral hip prostheses (Implants for Surgery-Partial and Total Hip Joint Prosthesis. Part 4: Determination of endurance properties of stemmed femoral components with application of torsion, International Organization for Standardization 7206-4). In this test, the basic assumptions are that the implant is very rigid in relation to the bone. And failure can occur due to tensile fatigue fracture initiated in the implant surface. ISO 7206-4 fatigue testing of hip implants considers the worst-case test. For boundary condition, it assumes the complete loss of proximal bone support.

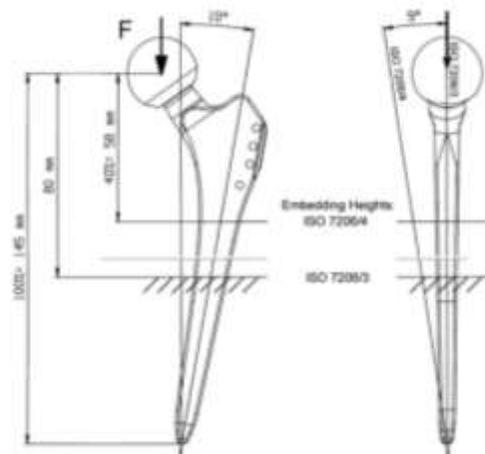


Fig. 1. ISO standard fatigue test arrangements for hip stems [15, 16]. ISO 7206/3 causes planar bending and compression, whereas ISO 7206/4 results in out-of-plane bending, torsion and compression of the hip stem.

2.2 EXPERIMENTAL FATIGUE ANALYSIS

Many researchers worked on experimentally to determine the stresses and fatigue life for different prosthetic materials. Styles et al. [30] made an attempt to develop fatigue accelerated procedures to improve the methodology for life prediction hip implant testing. McCormack et al. [31] studied the fatigue replacements under torsional loads. They found that the pores in the PMMA have fewer cracks initiated compared to PMMA / metal interfaces and PMMA / bone. Nallaa et al. [32] studied the fatigue in vitro in human cortical bone. Lennon et al. [33]

developed an experimental model implanted proximal femur. This model allowed the visualization of growth damage the cement layer to study the effect of surface finish on the accumulation of fatigue damage in a mantle of bone cement. Valle et al. [34] show a case study of 10 patients with cemented forged cobalt chrome stem under fatigue fracture for total hip arthroplasty. Santis et al. [35] manufactured and characterized a composite hip prosthesis made from poly ether-amide reinforced with carbon and glass fibers and evaluated the effect of fiber orientation on the mechanical properties of the composite femoral implant and compared with the bone. Humphreys et al carried out a fatigue testing on Howse II hip replacements. Figures 2 and 3 illustrate the mechanical testing device used in the fatigue tests. SKF rod end bearing supports a Moog E851 servo drive in the vertical position. A Moog E760-233 high response control valve is connected to the cylinder and regulates the oil flow and thus cylinder pressure and the resulting force. Novatech 15 kN load cell between the drive and the ram acetabular component, which confirmed the loaded sample. The force is operated on the prosthesis with a closed-loop system as shown in Fig. 2. A microcomputer the input waveform supplies via a digital-to-analog converter. The voltage output of this unit is then amplified by an inverting amplifier and the signal to a Moog E082-300-100 servo controller. This command input signal is compared with the electrical signal from the load cell, and the resulting error signal is amplified and used to control the actuator. The computer is also used to record the number of load cycles, and is coupled to a displacement transducer within the actuator piston rod via an analog-to-digital converter. This allows measurement of the prosthesis deflection and thus severe deformation and fatigue failure can be detected.

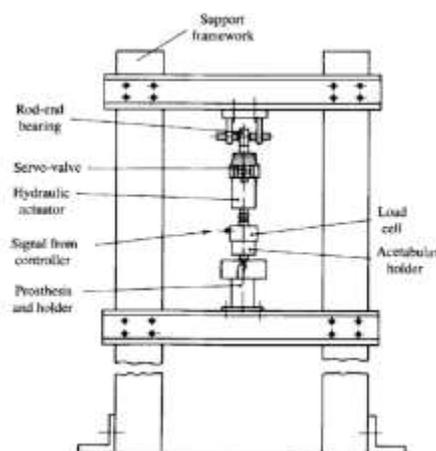


Fig. 2 Diagrammatic illustration of mechanical testing [36]

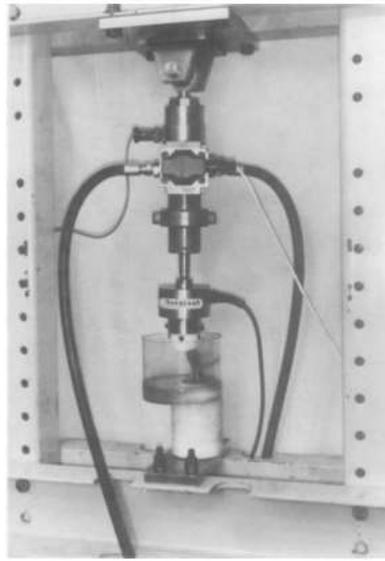


Fig. 3 Main features of mechanical testing machine[36]

3. DISCUSSION

The aim of ISO 7206-4 fatigue testing of hip implants is to get the confidence that the prosthesis will not break or fail under any circumstance during its lifetime. To achieve this requirement, the test condition should be similar to those likely to occur in service. If the condition is too severe, the hip implant may be over-strong and over-sized.

4. CONCLUSIONS

The available literature shows that the ISO 7206 standard used to test the fatigue resistance of hip prosthesis femoral components. Hip implants were much weaker in the 1970s as a result of several factors mainly related to the design and manufacturing technology. Therefore, the need for a standardized fatigue test protocol originated. Initially based on clinical experience with cemented Co-Cr-Mo sems test parameters are assigned. The lifetime of the hip prostheses greatly increased by the introduction of forged titanium alloy as a starting material for the production of hip implant and the development of better surface finishing techniques. The available literature shows that fatigue testing conducted according to the ISO 7206 protocol can prevent fatigue failure of the hip implants.

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