

Orthopaedic joint prostheses —

**Part 5: Method for determination of
endurance properties of stemmed
femoral components of hip joint
prostheses with application of torsion**

Committees responsible for this British Standard

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- British Institute of Surgical Technologists
- British Medical Association
- British Orthopaedic Association
- British Steel Industry
- British Surgical Trades Association Incorporated
- Department of Health
- Department of Trade and Industry (National Engineering Laboratory)
- Royal College of Surgeons of England
- Scottish Office
- Coopted members

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Foreword

This Part of BS 7251 has been prepared under the direction of the Health Care Standards Policy Committee at the request of the British Orthopaedic Association and the Department of Health to meet a need within the medical equipment industry to assess the endurance properties of femoral components of hip joint prostheses. It supersedes DD 91:1986, which is withdrawn.

This Part of BS 7251 is technically equivalent to ISO 7206-4:1989 "*Implants for surgery — Partial and total hip joint prostheses — Part 4: Method for determination of the endurance properties of stemmed femoral components with application of torsion*", published by the International Organization for Standardization (ISO). Attention is drawn to the corresponding method of test without the application of torsion given in BS 7251-6.

The following principles have been adopted in the development of the test method for determining the endurance properties of stemmed femoral components of hip joint prostheses described in this Part of BS 7251.

- a) The anatomical axis of the femur has been assumed to be at an angle of 10° to the load line, when viewed perpendicular to the plane that includes the stem and neck.
- b) All designs of implant should be tested under similar loading geometries, the offset angle (which introduces the torsional component of force) being set at $9 \pm 1^\circ$.
- c) Because of the complexity of the dynamic loading pattern in the patient, the diverse geometry of hip joint prostheses and the operative technique at implantation, certain factors (notably moment arm, maximum bending moment, calcar support and swing phase loading) are not referred to in this Part of BS 7251.
- d) The test conditions are based on the assumption that the stem of the prosthesis has become unsupported through breakdown of the proximal cement or bone, and therefore cannot take account of any features of a femoral component that are intended to prevent cement breakdown or to aid implantation of the component in the optimum position.

Experience in clinical practice has shown that failure of femoral components is most likely to occur at a distance of between 25 mm and 90 mm below the centre of the head of the component. It is thought that this observation reflects a combination of factors such as placement of the prosthesis, bone resorption, stem loosening and bone cement breakdown. The selected orientation of the test specimen produces a combination of direct, bending and torsional stresses in the stem.

For reproducibility of location of the prosthesis in the test rig, the embedding depth (80 ± 2 mm) has been related to point C of the component, as designated in BS 7251-3, i.e. the centre of the head of the prosthesis.

This Part of BS 7251 describes a test method for obtaining the endurance properties of the prosthesis under a constant loading range. It is generally felt that the important factors are the application of cyclic stress, the value of the mean stress, the environment and the orientation of the femoral component in relation to the applied load. It is believed that the waveform has very little effect on specimen life. A loading system has been selected comprising a mean load together with a sinusoidal dynamic load. The loading frequency has been selected to give an acceptably low cyclic rate and a reasonable duration of testing (5×10^6 cycles requires 139 h (approximately 6 days) at 10 Hz, or 278 h (approximately 11.5 days) at 5 Hz).

This Part of BS 7251 does not specify the loading range to be applied to the test prosthesis nor the number of cycles of load.

It is imperative that, after testing, the prosthesis should not be used for clinical purposes.

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Summary of pages

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This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.