

Orthopaedic joint prostheses —

Part 8: Guide to laboratory evaluation of change of form of bearing surfaces of hip joint prostheses

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/25, upon which the following bodies were represented:

- British Institute of Surgical Technologists
- British Medical Association
- British Orthopaedic Association
- British Steel Industry
- British Surgical Trades Association
- 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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National foreword

This Part of BS 7251 has been prepared under the direction of the Health Care Standards Policy Committee and is identical with ISO/TR 9326:1989 “*Implants for surgery — Partial and total hip joint prostheses — Guidance for laboratory evaluation of change of form of bearing surfaces*”, prepared by Technical Committee 150, Implants for surgery, of the International Organization for Standardization (ISO).

Requirements for orthopaedic implants (then termed “surgical implants”) were first published in 1962 as BS 3531. In 1968 a part revision of BS 3531:1962 was issued as BS 3531-1, which dealt with surgical implants made of all materials. In 1980 the first four Parts of a multi-part version of BS 3531 were published.

A further nineteen Parts of BS 3531 were subsequently published. In view of the increase in the number of Parts, and with a view to facilitating the implementation of published or forthcoming ISO implant standards, the British Standard relating to implants has been restructured. Accordingly the number BS 3531 is reserved for standards for implants for osteosynthesis, BS 7251 covers joint prostheses, BS 7252 covers metallic materials for surgical implants, BS 7253 covers non-metallic materials for surgical implants and BS 7254 covers orthopaedic implants, i.e. aspects common to both osteosynthesis and joint replacement.

Cross-reference

International Standard	Corresponding British Standard
ISO/TR 9325:1989	BS 7251 <i>Orthopaedic joint prostheses</i> Part 7:1990 <i>Guidance on hip joint simulators</i> (Identical)

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 8, an inside back cover and a back cover.

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.

1 Scope

This Technical Report gives guidance on the methods available for the measurement of change of form (wear, creep, plastic deformation, etc.) of the bearing surfaces of hip joint prostheses when tested in hip joint simulators.

It highlights the strengths and weaknesses of the methods in an attempt to unify experimental technique and to increase the accuracy, precision and comparability of “wear test” data.

NOTE Attention is drawn to ISO/TR 9325 regarding hip joint simulators.

2 Preparation of test specimens

Test and control specimens should be prepared in accordance with the specific recommendations given in the appropriate clauses of this Technical Report and in accordance with the general recommendations in ISO/TR 9325.

3 General recommendations for measuring wear

Conventional total hip joint prostheses consist of an acetabular bearing surface of polymeric or ceramic material articulating with a femoral component made of metallic or ceramic material. A change of form of the bearing surfaces will result from wear and/or creep and/or plastic deformation. Wear products may be in solution or particulate.

Wear produces a change in the dimensions of the specimen due to the removal of material with consequent loss of mass.

Wear should be distinguished from other types of change of form common in polymeric materials, in which dimensional changes occur without loss of mass, e.g. creep. It is thus advisable or, in some instances depending on the method of assessment, essential to determine the amount of creep separately by a method such as subjecting a stationary component to the same loading cycle, number of loading cycles and environment as the test specimen.

It is known that visco-elastic deformation can occur. It is not considered in this Technical Report, but measurements of wear should be completed at the same time after the end of each test in order to minimize the effects of this factor.

The collection, inspection, and quantitative analysis of the particulate wear debris produced during a test is recommended, as it is often helpful in studying wear mechanisms. However, it is not recommended as the sole criterion for wear measurement.

It is often essential or desirable to examine the bearing surfaces of the specimens during the course of determining the wear, but such disassembly of the test rig and inspection of specimens should be kept to a minimum because the procedures involved are likely to influence subsequent wear mechanisms and rates.

Several established methods of estimating wear have been employed, all of which have some advantages whilst none are completely satisfactory or free from disadvantages. The most commonly used method is that of determining the loss in mass of a component, and this (and to a lesser extent other methods) are discussed in subsequent clauses.

Brief reference is also made to the evaluation of friction, since this is commonly determined by appropriate sensing and instrumentation during wear testing.

4 Measurement of wear by weighing

4.1 Preparation of specimens

In addition to the recommendations given in ISO/TR 9325, specimens that absorb water should be further prepared in order to minimize the deleterious effects of absorption on the accuracy of weighing the specimen.

Preparation of such specimens consists of soaking the specimen in lubricant (see ISO/TR 9325) at the temperature selected for the test until the mass of the component has stabilized as far as possible. Details are given in 4.2. The amount and duration of absorption varies considerably between different materials. A low-absorption material such as polytetrafluoroethylene may stabilize after 14 days soaking, whereas other materials may require 30 days and yet others may never reach an equilibrium mass.

Although soaking the test specimens before testing reduces errors due to absorption, it is strongly recommended that control specimens, generally known as “soak controls”, are used. These consist of control specimens which are immersed in lubricant in the same way and for the same time as the wear test specimen but which are not subjected to wear testing, thus allowing the total change in mass of the test specimen due to absorption to be estimated. The accuracy of the method may also be improved by the use of replicate test specimens and soak controls.

Specimens made of materials that do not absorb water from the lubricant to a significant amount may be treated differently, as detailed in 4.4.