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Implants for surgery — Roentgen stereophotogrammetric analysis for the assessment of migration of orthopaedic implants

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National foreword

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*Implants chirurgicaux — Analyse stéréophotogrammétrique
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orthopédiques*





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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacement*.

Introduction

Since its introduction in 1974,^[1] roentgen stereophotogrammetric analysis (RSA) has been widely used to assess migration of orthopaedic implants. It is a highly accurate method of quantifying three-dimensional migration between an implant and the bone it is fixed in. RSA is also used in other applications such as measuring migration between bone fragments in e.g. bone fracture studies, and measuring wear of implants. These applications are not within the scope of this International Standard.

Several studies have found implant migration to be predictive of long-term implant survival and, for most devices, measurement over two years might therefore provide a surrogate outcome measure with relatively low numbers of subjects, e.g. less than 50 patients in each group in randomized studies.^{[2][3]} ^[4] A smaller number of subjects can be used in these studies as a consequence of the high accuracy of the measurement technique. Because of this, RSA is an important technique in early clinical trials for screening new joint replacement prostheses.

However, results from these early clinical trials are difficult to compare as different studies report their results in different formats. To facilitate comparison of outcome reported from different research groups and because the results are obtained using different methodological procedures, there is a need for standardization of RSA investigations.

The RSA method described in this International Standard requires the use of X-rays and exposes the patient to a greater X-ray exposure dose with its associated health risk. For this reason, it is neither the intention of this International Standard to recommend the routine use of RSA nor to add to existing regulatory requirements. Rather it is the intention that when RSA is used in a standardized manner, the results can be as useful and as widely applicable as possible.

