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

Implants chirurgicaux — Analyse stéréophotogrammétrique Roentgen pour l'évaluation de la migration des implants orthopédiques

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Foreword

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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.

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CAUTION — 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. Careful consideration of the benefits and drawbacks of this method on a case by case basis is advisable.

1 Scope

This International Standard provides requirements for the clinical assessment of migration of orthopaedic implants with roentgen stereophotogrammetric analysis (RSA).

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
absolute movement
movement of a rigid body relative to a fixed reference rigid body

2.2
accuracy
closeness of agreement between a measured quantity value and a true quantity value of a measurand

2.3
bias
estimate of a systematic measurement error

2.4
biplanar technique
RSA technique where two X-ray cassettes/films/sensors are set at an angle to each other

2.5
calibration cage
calibration box
reference frame used to create a three-dimensional coordinate system, with definition of position and orientation, and to determine the position of the two roentgen foci

2.6
condition number
calculated number used to assess the distribution of markers

Note 1 to entry: High condition numbers indicate poor marker distribution, while low condition numbers indicate appropriate marker distribution.

Note 2 to entry: See Annex A, which establishes the methodology to determine the condition number associated with the marker distribution.

2.7
crossing line error
shortest distance between the two X-rays projecting the centre of a marker in the two RSA images

2.8
double examinations
two RSA examinations of the same patient within an interval of several minutes

2.9
helical axis
screw axis
instantaneous axis about which the decomposition of the motion of an object from one position to another has a translation along and a rotation about a single axis

2.10
marker
small diameter biocompatible metal sphere having a precise size and shape used as landmark

Note 1 to entry: Spherical tantalum markers serve as well-defined landmarks.

Note 2 to entry: The diameter is commonly ≤ 1 mm.

2.11
maximum total point motion
MTPM
length of the translation vector of the marker or virtual marker in a rigid body that has the greatest migration

Note 1 to entry: It can only have positive values, and is not normally distributed.

2.12
mean error of rigid body fitting
rigid body error
measure indicating the mean change of relative positions of markers (in the same object) over time compared to the initial, reference configuration

Note 1 to entry: Annex A establishes the methodology to determine the mean error associated with the change of relative positions of markers.

2.13
migration
change in position and orientation of an implant relative to the host bone assessed between follow-up examinations

2.14
model-based RSA
RSA technique in which the position and orientation of an implant is assessed by matching a virtual projection of a three-dimensional model of the implant to the actual radiographic projection of the implant

2.15
phantom
object that is used as a representative of an anatomical part

2.16
precision
degree to which repeated measurements under unchanged conditions show the same results

2.17
reference plate
planar object holding markers used for calibration of RSA-examinations by linking its two-dimensional coordinate system to the three-dimensional global coordinate system of previous RSA-examinations that were calibrated using a three-dimensional calibration cage

2.18
reference rigid body
rigid body that defines a fixed coordinate system, the origin of which is located in that rigid body's geometrical centre

2.19
rotation matrix
mathematical expression of the three-dimensional rotation of a rigid body

2.20
RSA
roentgen stereophotogrammetric analysis
radiostereometry
radiostereometric analysis
roentgen stereophotogrammetry
measurement technique that relies on stereo X-ray images and can be used to assess relative changes in position and orientation of two rigid bodies (e.g. an orthopaedic implant and host bone) relative to each other

Note 1 to entry: In order to reach a high level of accuracy, markers are used as landmarks in the bone and a calibration object (calibration cage or reference plate) is used to assess the position of two synchronised X-ray sources in the global coordinate system defined by the calibration cage.

2.21
virtual marker
three-dimensional point from visible landmarks or calculated from known geometry to determine a specific point of an implant

Note 1 to entry: Virtual markers were formerly named fictive markers.

2.22
uniplanar technique
RSA technique where the two X-ray cassettes/films/sensors are in the same plane

3 Measurement

3.1 Size of markers

Spherical markers made of biocompatible (implant grade) metal and having a high radio-opacity (e.g. tantalum) shall be used to serve as landmarks. Marker diameters of 0,5 mm, 0,8 mm and 1,0 mm are generally used.

3.2 Virtual markers

Virtual markers indicate a specific part of the implant and facilitate comparison of migration data within and between studies.

EXAMPLE 1 Within a clinical RSA study of a specific implant, these virtual markers are valuable if one or more implant markers of a certain patient are obscured in the X-ray or have become loose.

In different RSA studies, different prosthesis designs might have markers attached at different locations. In order to compare the translation of specific points on the implant's surface between different implant designs, virtual markers can be used.

EXAMPLE 2 To compare the translation of a specific point, on the tip of different hip stems.

A virtual marker is defined by the observer. Its position is indicated in both images of a single RSA-examination, and the three-dimensional position of the virtual marker is reconstructed according to the common approach of reconstructing the position of an actual prosthesis marker. It is advised that the crossing line error is less than 1 mm. A new rigid body is formed when the position of the virtual marker is combined with the positions of at least three prosthesis markers. This enables the translation of the virtual marker to be determinable in subsequent (or previous) RSA examinations. Therefore, virtual markers are defined such that they move with the implant and they can be used to calculate the translation of this specific point of the prosthesis based on the migration of the implant itself.

3.3 Number and distribution of markers

In order to assess translations and rotations with all six degrees of freedom, markers shall be implanted on each rigid body under study so that they are not collinear. For each rigid body, at least three identical markers shall be visible on both radiographs at all examinations.

NOTE 1 In cases where only one or two markers can be used in one of the rigid bodies, only translations can be calculated.

NOTE 2 It is strongly advised to insert at least six to seven bone markers as markers may be obscured by the implant.

3.4 Mean error of rigid body fitting

The upper limit of acceptable mean error of rigid body fitting shall be related to the marker configuration of the segment (defined by its condition number). The upper limit accepted shall be reported and should typically not exceed 0,35 mm.

3.5 Condition number

For studies of hip, knee and shoulder prostheses, condition numbers shall be below 120.

For studies of small joints, such as in the fingers and the cervical spine, condition numbers shall preferably be below 150. For studies in which these high condition numbers are accepted, it is essential that the precision of the measurements is validated (see 11.2).

3.6 Three-dimensional implant models

Model-based RSA techniques do not require the attachment of metal markers to the implant but require an accurate 3D representation of the implant.[7][8] If the model-based techniques are to be used, they shall have been properly evaluated and the precision and bias of these measurements shall have been published in established journals.

4 Radiographic arrangement

It shall be indicated whether a uniplanar or a biplanar technique is used. For a biplanar technique, the angle between the recording media needs to be presented. Any other arrangement shall be described in detail.

5 Calibration cages and reference plates

Routinely, biplanar calibration cages or uniplanar calibration cages are used.

If cages are used that have not been described previously in scientific papers, this shall be stated in the report. The data shall include the dimensions of the cage, the accuracy of marker placement on the cage, and the cage material.

If calibration examinations and reference plates have been used, the equivalent data (dimensions of the plate, the accuracy of marker placement on the plate, and the plate material) shall be presented for the reference plates.

If any other type of cage is employed, these specific cages shall also be evaluated in experiments that use a phantom object holding a number of stable tantalum markers and that is positioned in a reasonable range of poses that represent the clinical range of poses that can be encountered.

6 Radiographs

6.1 General

Radiographs can either be analogue or digital.

If the authors use analogue radiographs in combination with manual measurements using a measuring table, the accuracy of the measuring table shall be stated. Information about the brand, type and manufacturer of the measuring table used shall also be given.

If analogue images have been scanned, the spatial resolution and gray-scale resolution have to be presented. Information about the brand, type and manufacturer of the film scanner used shall also be given.

If digital imaging systems have been used, information on the spatial and gray-scale resolution shall be presented. Information about the brand, type and manufacturer of the digital imaging system used shall also be given.

NOTE A minimum 150 dots per inch spatial resolution and 8 bit gray scale resolution is suggested.

6.2 Double examinations

Between two examinations, the patient shall be repositioned within limits that are expected to be encountered during a clinical follow-up study. Double examinations will be performed under unloaded or repeatable loading conditions. In this short time interval, the implant will not have moved with respect to the host bone. Due to measurement errors, however, apparent migration will be calculated. Double exam results are used to determine precision for the system as defined in 11.2.

7 Software

To compute the three-dimensional position of bone markers, implants or parts of implants, several different software packages are available. These software packages shall have appropriate documentation and validation of their accuracy and precision. This should be provided by the producer of the software, but additional independent validation studies would be valuable. If custom-made software has been used, a validation study of this software shall be fully described in an established journal before it is used in any clinical study.

8 Coordinate systems

8.1 Global coordinate system

The calibration cage defines the position and orientation of the global coordinate system. For the reference examination (usually the first examination), the body region of interest (e.g. the proximal femur), which contains the reference rigid body segment markers, should be aligned as closely as possible with the global axis system (e.g. parallel to one of the global axes). This would aid the interpretation of implant migration directions in terms of standard medical terminology (e.g. distal translation, internal rotation). In order to obtain optimum precision, it would be preferable if the region of interest for subsequent examinations were similarly aligned, as closely as possible, with the same global axis.

8.2 Implant coordinate system

The local implant coordinate system is commonly aligned with the global coordinate system with its origin either on a point of the implant or, if the implant has markers attached, at the geometric centre of the markers. When using such a coordinate system in migration calculations the migration results between patients are less influenced by patient positioning. In cases where such an implant coordinate system (that is not aligned with the global coordinate system) is used, this coordinate system shall be described, as well as the possible effects on the migration calculations.