Radiostereometric Analysis Using Resorbable Bioactive Radio-Opaque Ceramic Markers

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Radiostereometric analysis (RSA), was originally developed by Selvik as a method for performing highly accurate three-dimensional measurements in vivo over time from sequential radiographs. Since its introduction over twenty years ago, the RSA method has proven itself as a powerful tool with numerous orthopaedic applications. The tantalum metal landmarks used in RSA studies have an excellent radiographic opacity but have raised concern as they are permanently deposited in bone. A possible solution to this problem is the use of a resorbable biomaterial with sufficient radio-opacity to replace tantalum metal markers. In this study barium sulphate is used as an opacifier in the creation of bioactive radio-opaque ceramic spherical markers for RSA. The prediction interval of the RSA measurements for accuracy of translation in the longitudinal axis was ± 38 µm ($R2 \geq 0.99$, $P<0.001$) and the corresponding value for rotation was ± 0.64 degrees ($R2 = 0.94$, $P<0.001$). The precision of translation was found to be 9 µm and the precision of rotation was found to be 0.18°. The results of this in vitro simulation model indicate that ceramic beads with sufficient radio-opacity can be used for accurate RSA analysis.

Introduction

Radiostereometric analysis (RSA), also known as roentgen stereophotogrammetric analysis, was originally developed by Selvik as a method for performing highly accurate three-dimensional measurements in vivo over time using sequential radiographs (1). The RSA method has proven itself as a powerful tool with numerous orthopaedic applications (2) ranging from studies of skeletal kinematics and fracture healing (3,4) to the assessment of total joint replacement implant stability (5,6).

The RSA method allows very accurate measurement of three-dimensional displacements of body parts or implants in vivo (1). The method has been described extensively (1,2). It is based on implantation of metallic landmarks (tantalum beads) into the body segments to be studied. Dual simultaneous radiographs are used in association with a calibration cage. The calibration cage contains a number of tantalum beads which are held in fixed, well-defined positions enabling the construction of a three-dimensional coordinate system. The body part to be studied is either placed inside or in front of the calibration cage depending on its size. A pair of radiographs is then used to determine the location of the markers three-dimensionally, and this enables the calculation of relative displacements between different segments using special designed software. The RSA method enables highly accurate measurement of both translation and rotation in three dimensions (7,8).

The tantalum metal landmarks used in RSA studies have an excellent radiographic opacity but have raised concern as they are permanently deposited in bone. A possible solution to this problem is the use of a resorbable biomaterial with sufficient radio-opacity to replace tantalum metal markers. Bioactive glasses are resorbable and are also known to form chemical bonds with bone (9). The ability of bioactive glass to bond with bone provides the additional advantage of guaranteed marker stability when anchored in bone. Bioactive glass can also be manufactured in various morphologies such as spheres and rods.

The main shortcoming of bioactive glass is that it has a radio-opacity similar to that of cortical bone thus making it difficult to be used as such in RSA studies (10). Radio-opaque additives are of great value in surgical practice. The most commonly used opacifiers are barium sulphate (BaSO4) and zirconium dioxide (ZrO2). Barium sulphate is a commonly used radiographic contrast agent and is commonly used as an opacifier in bone cement. In this study barium sulphate is used as an opacifier in the creation of bioactive radio-opaque ceramic spherical markers for RSA. A detailed analysis of the characterization, bioactivity and biomechanical properties of this new ceramic will be presented in a separate study. The goal of this study is to verify that these markers can be used to replace tantalum markers in RSA studies.

Materials and methods

Glass spheres (bioactive glass with 10 wt % barium sulphate) with diameter of approximately 1.5 mm were manufactured. These spheres were used as markers in the RSA study. The glass was manufactured in Åbo Akademi University, Finland.

A porcine radius was used in the study. All the soft tissue was initially removed. An experimental distal extra-articular fracture (two-fragment) was created by osteotomizing the distal metaphysis of the radius. A total of ten ceramic markers (diameter 1.5 mm) were implanted with five placed proximally and five distally to the fracture site. The markers were inserted using a drill and manual placement. The markers were distributed in a way, which simulates clinical insertion of the markers through a limited surgical approach. In order to ensure no movement of the markers, the insertion holes were sealed using liquid adhesive. The proximal end of the radius was rigidly fixed to a plexiglass base plate (figure1).

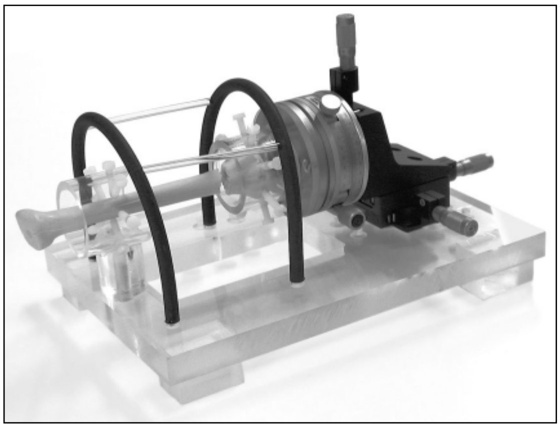

Figure 1. Placement of the radius (plastic sawbone in place of porcine radius) with translation and rotation stages on the plexiglass base plate. The proximal radius and the x,y,z translation stage were firmly fixed to the plexiglass plate.The distal fragment of the radius was allowed to move freely with respect to the proximal part, but the proximal radius and translation stage were fixed with respect to each other through their attachments to the plexiglass plate.

In the first part of the study (experiment 1) the distal fragment of the radius was rigidly attached to a high precision x,y,z translation stage (M-460A-xyz, Newport, Irvine, CA, USA) via a plastic holder connected to a high precision rotation stage (M-UTR80, Newport, Irvine, CA, USA). The translation stage was instrumented with three Vernier micrometers (model SM 13, Newport, Irvine, CA, USA). According to the manufacturer the system is accurate to 0.001 mm for translation with an angular deviation of less than 0.009° and accurate to 1/60° for rotation with a wobble of ± 0.003°. The translation stage was fixed to the same plexiglass base plate as the proximal part of the radius (figure 1). The distal fragment was then aligned with the proximal radius as before the fracture but with a clearance of at least 1 mm from it in the longitudinal axis. This experimental set-up allowed translation movements in three axes and rotation about the longitudinal axis. The porcine soft tissue initially removed from the limb was suspended around the bone on a specially designed frame to simulate accurate radiographic contrasts in the study.

The plexiglass base plate with the fracture model was then placed inside a calibration cage (Cage type 10, RSA biomedical AB, Umeå, Sweden). The base plate was visually aligned (without instrumented aid) to the RSA cage. The calibration cage had tantalum

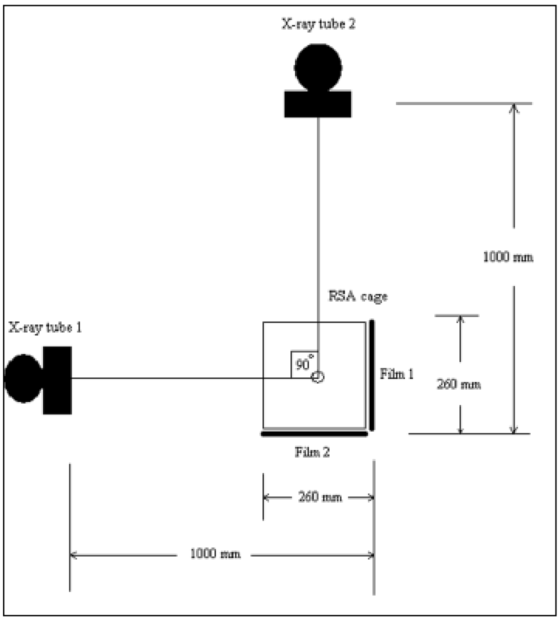

Figure 2. Schematic of the set-up (side view). The two X-ray tubes were placed so that the beams intersected at approximately 90°.

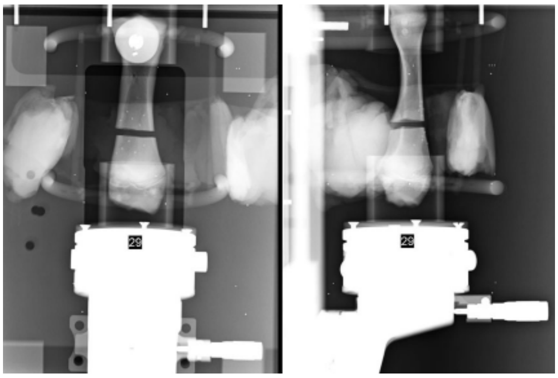

Figure 3. Anteroposterior (left) and lateral (right) stereo-radiographs of the experimental setup. The five ceramic markers, both proximal and distal to the osteotomy could be clearly visualized in both projections. The control markers in the cage are visible in the background. The soft tissue placed around the porcine radius is also visible.

markers with known positions embedded in the walls overlying two radiographic film cassettes, which were held into a built-in cassette holder for standard size film. Digital film plates (ADCC MD 10, Agfa-Gevaert AG/CAWO, Schrobenhausen, Germany) of a standard size (24 x 30 cm) were used. Two portable radiographic tubes (Siemens Mobilett Plus and Siemens Mobilett, Siemens-Elema AB, Solna, Sweden), were mounted so that the beams crossed at an angle of approximately 90° (figure 2). The distance of each radiographic tube from the film was standardized and the radiographic tubes were operated simultaneously.

First, one double examination was first performed with the distal fragment in zero rotation and translation. This was done in order to obtain baseline readings to which other movements would be compared. Isolated translation along the longitudinal axis was examined, during which no rotation was permitted. Two series were obtained, consisting of proximal and distal displacements along the longitudinal axis. For each of these directions a film pair was exposed at the following displacements: 25 µm, 50 µm, 100 µm, 500 µm, 1 mm and 2 mm. A total of 12 film pairs were obtained.

Eight double examinations were then performed in order to determine the accuracy of rotation of the distal fragment along the longitudinal axis. The distal fragment was rotated using the high precision rotation stage while allowing no translation to take place. The fragment was rotated both clockwise and anti-clockwise to the following angles: 1/6°, 1/2°, 1°, and 2°. A simultaneous film pair was exposed for each incremental rotation. A total of 8 film pairs were obtained.

In order to determine the precision of translation measurements, the model was exposed once at zero and thereafter five times after a single distal 200 µm displacement along the longitudinal axis. In order to determine the precision of rotation along the longitudinal axis the model was exposed five times after a clockwise rotation of 1/2°. Thus a total of 10 film pairs were obtained.

The digital radiographs were converted from DICOM to TIFF format for analysis. Marking of the images was performed with UmRSA Digital Measure 1.0 software (RSA Biomedical Innovations AB, Umeå, Sweden). The RSA determination of the migration of the distal fragment of the radius relative to the proximal part was performed by using the "segment motion" method of the UmRSA 4.1.0.10 software (RSA Biomedical Innovations AB, Umeå, Sweden).

The displacement of the markers in the distal fragment in relation to the markers in the proximal radius was determined for each film pair.

Linear regression analysis was used in order to relate the displacements as measured with RSA to the actual displacements measured with the micrometers. Accuracy was presented as the 95 % prediction interval (PI) as used by Önsten and co-workers (11). This interval is obtained by first determining the lower and upper bounds for the prediction interval for each observation and then calculating the mean of the intervals for each observation. Precision was calculated as the standard deviation of the five repeated measurements of the 200 μm displacement and of the five repeated 1/2 degree rotations along the longitudinal axis. All statistical analyses was performed using SigmaStat 2.03 software (SPSS Inc.,Chicago, IL).

Results

All the markers implanted into both the proximal radius and the distal fragment could be visualized in both pairs of radiographs from all film pairs (figure 3). The prediction interval of the RSA measurements for accuracy of translation in the longitudinal axis was ± 38 μm ($R2 \geq 0.99$, $P<0.001$) and the corresponding value for rotation was ± 0.64 degrees ($R2=0.94$, $P<0.001$). The precision of 200 μm translations was found to be 9 μm and the precision of 1/2 ° rotations was found to be 0.18°.

Discussion

This in vitro study shows that ceramic beads containing barium sulphate as an opacifier can be used to replace tantalum markers in RSA studies. The accuracy and precision of RSA are slightly lower than those obtained in a similar setup using tantalum markers (7), but similar to those obtained in phantom studies of hip arthroplasty (8,11). The difference in accuracy is most likely to be due to the lower radio opacity of the ceramic markers as well as to the fact that being hand-made, the markers were not perfect spheres but approximations. Lower radio-opacity and imperfect spherical shape complicate the process of marker center location and make it less accurate. Detailed analysis of the properties of this new ceramic will be published separately. Barium sulphate is one of many radio opaque substances that can be used to increase the radio opacity of bioactive glass, further studies need to be performed in order to determine which radio opacifier is best at low concentrations, thereby minimally disturbing the bioactive and chemical properties of the glass.

References

1. Selvik G: Roentgen stereophotogrammetry. A method for the study of the kinematics of the skeletal system. Acta Orthop Scand Suppl 1989;232:1-51.

2. Kärrholm J: Roentgen stereophotogrammetry. Review of orthopedic applications. Acta Orthop Scand 1989;60:491-503.

3. Weidenhielm L, Wykman A, Lundberg A, Brostrom LA: Knee motion after tibial osteotomy for arthrosis. Kinematic analysis of 7 patients. Acta Orthop Scand 1993;64:317-319.

4. Ragnarsson J I, Hansson LI, Kärrholm J: Stability of femoral neck fractures. A postoperative roentgen stereophotogrammetric analysis. Acta Orthop Scand 1989;60:283-287.

5. Kärrholm J, Borssén B, Löwenhielm G, Snorrason F: Does early micromotion of femoral stem prostheses matter? 4-7-year stereoradiographic follow-up of 84 cemented prostheses. J Bone Joint Surg Br 1994;76-B:912-917.

6. Ryd L, Albrektsson BE, Carlsson L, Dansgard F, Herberts P, Lindstrand A, et al.: Roentgen stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. J Bone Joint Surg Br 1995;77-B:377-383.

7. Madanat R, Makinen TJ, Moritz N, Mattila KT, Aro HT: Accuracy and precision of radiostereometric analysis in the measurement of three-dimensional micromotion in a fracture model of the distal radius. J Orthop Res 2005;23:481-488.

8. Bragdon CR, Malchau H, Yuan X, Perinchief R, Kärrholm J, Börlin N, et al.: Experimental assessment of precision and accuracy of radiostereometric analysis for the determination of polyethylene wear in a total hip replacement model. J Orthop Res 2002;20:688-695.

9. Hench LL, Andersson ÖH: Bioactive glasses. In: An introduction to bioceramics, editors Hench LL and Wilson J. World Scientific 1993:41-62.

10. Välimäki V-V, Moritz N, Yrjans JJ, Dalstra M, Aro HT: Peripheral quantitative computed tomography in evaluation of bioactive glass incorporation with bone. Biomaterials 2005;26:6693-6703.

11. Önsten I, Berzins A, Shott S, et al.: Accuracy and precision of radiostereometric analysis in the measurement of THR femoral component translations: human and canine in vitro models. J Orthop Res 2001;19:1162-1167.