Radiostereometric Analysis (RSA) Studies at Massachusetts General Hospital

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INTRODUCTION

Radiostereometric analysis (RSA) was developed by Selvik *et al*. as a method for performing very accurate three-dimensional measurements *in vivo* over time from sequential radiographs [37,38]. This technique has been used for over twenty years to assess growth plate integrity [1,10-12,15,18-20,35], total joint replacement implant stability [24,25,27,36,39], spinal fusion stability [16,17,34], as well as in kinematic studies of the knee, spine, and shoulder [3,13,14,22,23,26,28,29,31-33,36,42].

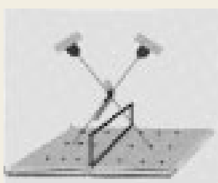

Figure 1. Schematic drawing of the radiographic set up used for obtaining the pair of radiographs. The region of interest is placed in front of the calibration cage at the point where the two x-ray beams cross.

The RSA method utilizes dual simultaneous radiographs in conjunction with a calibration cage. The calibration cage contains a number of 1.0mm tantalum beads held in fixed, well-defined positions which allows construction of a three-dimensional coordinate system. Additional tantalum bead markers are placed in the body segments to be studied. A pair of radiographs is taken with the patient in front of the cage with the x-ray sources positioned at an approximately forty degree angle (Figure 1). Analyzing the radiographic film pairs using an interactive software package, the three-dimensional position of each *in vivo* marker can be calculated and then each group of markers is treated as a three-dimensional rigid body segment. Relative displacements between two segments can then be calculated from sequential pairs of radiographs.

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Figure 2. The hip phantom allows three dimensional displacements of the femoral head within the acetabular component.

EXPERIMENTAL HIP PHANTOM STUDIES

Due to its high accuracy, RSA is considered the best technique for measuring femoral head penetration into polyethylene acetabular components *in vivo*. This penetration is a result of both plastic deformation of the polyethylene component as well as the wear of the material occurring at the articulation. However, due to the many variable parameters which can affect the outcome of an RSA study, a physical model which could be used to evaluate these parameters individually is needed. We have developed a phantom total hip replacement model in order to quantify the accuracy and precision of RSA and used it to evaluate methods of bead placement, radiographic methods, as well as to evaluate two commonly used RSA software packages [9]. The hip phantom is shown in Figure 2.

Femoral head penetration can be simulated by moving the femoral head accurately in each plane in discrete increments. Five image pairs were taken before any motion occurred. Motion was first performed in the medial direction, moving 50μm, 100μm, 150μm and finally 200μm into the acetabular component, followed by sequential posterior displacement of 50μm, 100μm, 150μm and 200μm, and thereafter followed by sequential motion in the superior direction using the same distances of 50μm, 100μm, 150μm and 200μm. This group of displacements represents one data set of the phantom. In order to calculate accuracy and precision, five data sets were created.

Using this phantom, we have shown that the *accuracy* of the radiostereometric analysis in this optimal experimental setup was 33μm for the medial direction, 22μm for the superior direction, 86μm for the posterior direction, and 55μm for the resultant three-dimensional vector length. The corresponding *precision* at the 95% confidence interval measured 8.4μm for the medial direction, 5.5μm for the superior direction, 16.0μm for the posterior direction and 13.5μm for the resultant three-dimensional vector length [9].

We have also compared the use of conventional plain radiographs to digital DICOM images. The accuracy and precision values resulting from the analysis of the digital films were consistently better than that resulting from the use of the conventional films. For both the conventional and digital radiographic methods, the poorest accuracy and precision values were for the posterior, out-of-plane vector.

There are two widely used software packages that have been developed for RSA analysis: the UmRSA™ package developed by Biomedical Innovations AB, Umeå, Sweden [7,21], and the RSA-CMS, (RSA Clinical Measurement Solution) developed at the University of Leiden, The Netherlands [2,41]. The accuracy and precision using the two different software systems was evaluated by using the same five sets of digital examinations. The accuracy values resulting from the RSA-CMS™ analysis were two times worse than those resulting from the analysis of the same films using the UmRSA™ software [8].

Finally, we have evaluated two different methods for marking the acetabular component in preparation for a clinical study. We used specially designed towers secured to the metal shell to hold the tantalum beads as well as placing a series of beads into the peripheral flange of the polyethylene insert. We found that there was no significant difference in the data resulting from the two different configurations of the tantalum markers [8].

CLINICAL STUDIES

The first clinical studies using RSA in North America have been initiated at Massachusetts General Hospital. Two studies are underway which are designed to evaluate the *in vivo* wear performance of a new form of highly crosslinked polyethylene acetabular component used in total hip replacement surgery. Each study has two patient groups. One group receives highly crosslinked acetabular components in conjunction with a 28mm cobalt chrome femoral head. The other group receives highly crosslinked acetabular components coupled with larger diameter femoral heads (36mm or 38mm) than have been routinely used in the past. These studies are designed to follow the groups of patients over a period of five years. An example of a RSA clinical radiograph is shown in Figure 3.

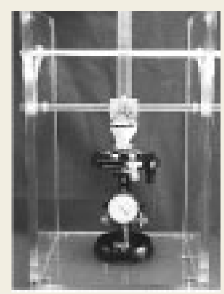
Figure 3. An example of a pair of clinical radiographs of a patient that has received a highly crosslinked polyethylene component marked with tantalum markers. The other visible markers belong to the calibration cage.

EXPERIMENTAL KNEE KINEMATIC STUDIES

Knee kinematics following total knee replacement surgery is dependant in large measure on the design of the implants. Some knee components are designed to limit anterior/posterior translation and rotation. Others are designed to enhance mobility and increase the amount of functional knee flexion. Moreover, the resulting kinematics for a particular implant design are known to be quite variable among patients. Many efforts have been made to develop techniques to measure knee kinematics *in vivo* more accurately. Two approaches have been widely used: one uses radiographic images obtained with fluoroscopy and calculates three dimensional relative motion by matching the projected profile of the implant with the computerized implant geometry. [4-6,30] The other uses RSA to calculate relative displacements from a series of radiographic film pairs [22,28,29,40]. To date, no standardized method has been developed to judge the accuracy of these techniques for measuring knee joint kinematics.

We have developed an *in vitro* model of a total knee replacement which is capable of accurate three-dimensional motions. With this model, we have begun to evaluate the RSA method of measuring knee joint kinematics. The knee phantom model was constructed using NK-II femoral and tibial components (Centerpulse Orthopaedics, Austin, TX). A mock left femur was machined from Plexiglas with the appropriately machined cuts to receive a size three left femoral component. The distal femur was held in a separate Plexiglas frame by passing a half-inch Plexiglas dowel thru the hole in the distal femur. Flexion/extension of the femur occurred around the half-inch dowel. The femoral construct could be fixed at any angle of flexion by fixation to the surrounding frame. A digital inclinometer, accurate to 0.1°, was used to measure the flexion angle relative to full extension. A sawbones proximal tibia was used to hold the tibial component. This was secured to a rotary table with rotation which was accurate to 1.0 degree. This in turn was mounted to an x, y, z table in order to control the proximal/distal positioning of the tibia and anterior/posterior translation (Figure 4). Motions in the medial/lateral plane and medial/lateral tilt were not simulated. A displacement protocol was developed to simulate flexion of the knee from full extension to 75° of flexion and back to neutral in twelve steps, while simultaneously simulating the internal/external rotation, and anterior/posterior translation.

Figure 4. The Knee Phantom capable of accurate motion of flexion, I/E rotation, and A/P translation.



For RSA evaluation, 1.0mm tantalum markers were placed in the distal femur, the proximal tibia and the side of the polyethylene liner. Simultaneous radio-pairs were obtained for each of the twelve displacements using the RSA cage, and the RSA analysis was performed using the UmRSA Biomedical software package. Relative displacements were calculated by using the first film pair as the reference. The error was calculated by subtracting the value measured by RSA from the actual known displacement.

There was good agreement between the actual displacement and the measurements of displacements measured by RSA for flexion, rotation and translation. For flexion, the error values ranged from 0.05 - 1.85 degrees, resulting in an average flexion error of 0.78 ± 0.95 degrees. For internal/external rotation, the error values ranged from 0.15 - 0.92 degrees resulting in an average rotational error of 0.52 ± 0.30 degrees. Finally, for the translation, the error values ranged from 0.29 – 2.0 millimeters resulting in an average translation error of 0.37 ± 1.26 millimeters.

SUMMARY

Radiostereometric analysis (RSA) is a powerful tool for clinical assessment. The initial focus of our studies has been to assess the performance of two designs of acetabular implants which utilize a newly developed highly crosslinked polyethylene. Likewise, the use of this new polyethylene in total knee arthroplasty may allow for innovative designs to be introduced for clinical use. These types of early clinical follow-up studies are a critical part of evidence-based medicine when new materials or implant designs are introduced for clinical use. Also important in clinical analysis are joint kinematic studies as well as implant stability studies using RSA. In order to address this a physical knee phantom for assessing various methods of measuring knee joint kinematics has been developed.

Our preliminary study has shown good agreement between the actual displacements of the knee phantom and that measured from radiographic pairs using RSA. Our results show the marker configuration used in this study appears to be adequate for kinematic analysis in a clinical setting. Finally, the capacity of performing RSA studies following spinal surgery, shoulder arthroplasty, and other orthopaedic procedures is now possible.

Don Bae, Jeannie Chung, Courtney Gobezie, and Reuben Gobezie dining at the thesis day awards dinner.

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