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Short communication

Radiostereometric analysis using clinical radiographic views: Development of a universal calibration object

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ABSTRACT

Radiostereometric analysis (RSA) is a highly accurate technique used to provide three-dimensional (3D) measurements of orthopaedic implant migration for clinical research applications, yet its implementation in routine clinical examinations has been limited. Previous studies have introduced a modified RSA procedure that separates the calibration examinations from the patient examinations, allowing routine clinical radiographs to be analyzed using RSA. However, in order to calibrate the wide range of clinical views, a new calibration object is required. In this study, a universal, isotropic calibration object was designed to calibrate any pair of radiographic views used in the clinic for RSA. A numerical simulation technique was used to design the calibration object, followed by a phantom validation test of a prototype to verify the performance of the novel object, and to compare the measurement reliability to the conventional calibration cage. The 3D bias for the modified calibration method using the new calibration object was 0.032 ± 0.006 mm, the 3D repeatability standard deviation was 0.015 mm, and the 3D repeatability limit was 0.042 mm. Although statistical differences were present between the universal calibration object and the conventional cage, the differences were considered to be not clinically meaningful. The 3D bias and repeatability values obtained using the universal calibration object were well under the threshold acceptable for RSA, therefore it was successfully validated. The universal calibration object will help further the adoption of RSA into a more routine practice, providing the opportunity to generate quantitative databases on joint replacement performance.

1. Introduction

Radiostereometric analysis (RSA) is a radiographic measurement technique for monitoring three-dimensional (3D) musculoskeletal movements. Its major advantage is its accuracy, unsurpassed by any other minimally invasive imaging technique, making it the gold standard in clinical orthopaedic studies (Bourne et al., 2008; Selvik, 1990; Valstar et al., 2005). Since its introduction, RSA measurement processing has advanced from time consuming X-ray film measurements to quick digital image processing (Börlin, 2000; Valstar, 2001; Yuan, 1999). However, the methodological approach has remained unchanged from its original format (Selvik, 1990).

In order to increase the accessibility of RSA, we described a modified approach which utilizes clinical patient radiographs to perform RSA (Yuan et al., 2016). This concept was accomplished by separating the calibration examination from the patient examination while keeping the examination setup unchanged, or *in-situ*. Conventionally, the calibration and patient examination are captured together and the radiographic views are restricted by the calibration cage. These views are different from diagnostic imaging in clinics. With the modified approach, the radiographic views are no longer restricted, and any views used in routine clinical patient examinations can be used for RSA. The challenges with applying this modified approach are keeping the setup *in-situ* and calibrating the wide variety of clinical views.

Maintaining the setup *in-situ* has been made easier for clinics with the development of digital radiography (DR). The DR detectors produce images that can be sent remotely to a computer,

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allowing radiographs to be obtained near real-time without moving the detector, making it possible to keep the radiographic setup *in-situ* (Bansal, 2006; Kim et al., 2008). However, clinical radiographic views differ case by case (Bontrager and Lampignano, 2010). This makes the conventional RSA calibration procedure difficult to apply to routine clinical usage, as RSA viewing angles don't always match clinical views. Clearly, a new calibration object is required with orientation independence and isotropy, meaning it has the same viewing properties and accuracy from any angle. These features will help to simplify and standardize the RSA calibration procedure for any pair of clinical views.

In this study, we designed and validated a novel calibration object. Our hypothesis is that the novel object provides similar measurement reliability with that of the conventional cage, and with RSA values from previous reports.

2. Methods

2.1. Calibration object design

First the shape of the calibration object was investigated. To make an object with isotropy, a hollow, radiolucent spherical object was selected. The numerical simulation indicates that a larger calibration object provides greater measurement accuracy. However, the object must fit within the X-ray fields of view, and therefore a 25.4 cm diameter sphere was chosen corresponding to the detectors we used. Marker placement and distribution was then investigated. Tantalum markers (diameter = 1 mm) were placed on the surface of a prototype of the calibration object evenly and symmetrically to achieve isotropy, and each marker's coordinates were accurately located using conventional RSA. These placements avoid markers overlapping in the 2D projection view, making the automatic marker detection more attainable. Finally, the influence of the number of markers was investigated using the numerical simulation previously described (Cai et al., 2008; Yuan and Ryd, 2000; Yuan et al., 1997). The simulation results revealed that an increase in the number of markers would increase the accuracy of the focal point reconstruction, but would only have minimal improvement after 32 markers. Therefore, a *pentakis dodecahedral* marker pattern was chosen because it is a pattern that contains 32 vertices and is face-transitive to provide isotropic features. After successful validation of the prototype, a final version of the calibration object was reproduced using acrylic material, similar to conventional calibration cages.

2.2. Phantom validation

An anatomical knee model (Sawbones, Pacific Research Laboratories Inc., WA, USA) with a total knee replacement (Genesis II, Smith and Nephew, TN, USA) was developed. Eight tantalum markers were inserted into both the distal femur and proximal tibia. The positioning stage was comprised of a 3D rotation positioning stage (Model TTR001, Thorlabs Incorporated, NJ, USA), with accuracy of 0.02°, attached to a 3D translation positioning stage (Model M4434, Parker Hannifin Corporation, PA, USA) with accuracy of 2 μm. The stage afforded incremental movements to introduce rotation and translation in the X (medial–lateral), Y (inferior–superior), and Z (anterior–posterior) axes, defined as Rx, Ry, and Rz for rotation and as Tx, Ty, and Tz for translation. The 3D translation is determined from the resultant of the three translational axes, and is denoted as Tr. The tibia was rigidly attached to the base and the femur was attached to the positioning stage. Therefore, all motion calculations are femur motion relative to the tibia.

A biplanar setup was used in this study (Fig. 1a). The source-to-image distance was 150 cm for both anterior-posterior (AP) and lateral views. Twelve rotation increments were sequentially applied in the X, Y, and Z axes for a total of 36 increments. Fifteen translation increments, performed separately from rotation increments, were applied in X, Y, and Z axes for a total of 45 increments. At each increment of femoral motion, double exposures of the phantom were captured (Fig. 1b). To avoid disturbing the true incremental motion, the phantom was not repositioned between double exposures. Afterwards, without changing the X-ray source and detector positions, the phantom was removed and a biplanar calibration cage (Cage 10, RSA Biomedical, Umea, Sweden) was placed within the field of view (Fig. 1c). Radiographs were captured of the cage (Fig. 1d) and later fused with each RSA image pair of the phantom for conventional calibration of the phantom radiographs. Next, the calibration cage was replaced with the novel calibration object without disturbing the radiographic setup (Fig. 1e) and radiographs were captured of the calibration object (Fig. 1f) to be used in the modified calibration procedure.

The radiographic procedures were executed in a clinical centre (Fig. 1a, c, e). A ceiling-mounted X-ray unit (XR656 Discovery, GE Medical Systems, Milwaukee, WI, USA) was used with a DR system, providing a 2022 × 2022 image matrix for a 41 × 41 cm detector, resulting in images of 0.2 mm pixel spacing and 14-bit grayscale. Also, a portable X-ray unit (DRX-Revolution, Carestream, Rochester, NY, USA) was used with a DR system providing a 2520 × 3032 image matrix for a 35 × 43 cm detector, resulting in digital images of 0.139 mm pixel spacing and 12-bit gray scale level. The exposure settings were set to standard values for routine knee examinations (60 kVp, 5 mAs). For the modified procedure, the 2D measurements were obtained using XMALab (XMALab V1.4.0, Brown University, RI, USA) by measuring the universal calibration object first, followed by measuring the phantom radiographs. For the conventional procedure, the 2D measurements were obtained using UmRSA (UmRSA V4.1, RSA Biomedical, Umea, Sweden) by measuring the fused RSA radiographs. The reconstructed 3D marker locations from each software were used to calculate the relative motion between the femur and the tibia using our in-house code.

2.3. Evaluation of bias and repeatability

To evaluate the trueness of the measurements, bias was calculated as the mean and 95% confidence intervals (CI) for absolute differences between measured and true values. Measurements of precision were given by the repeatability parameters sr and r, which are the repeatability standard deviation and 95% repeatability limit, respectively. These evaluations of trueness and precision are suggested by Langlois and Hamadouche, who followed the latest ASTM guidelines (ASTM, 2013; Langlois and Hamadouche, 2016). The root mean square error (RMSE) was also calculated as a measure of trueness for comparisons with literature using older definitions of trueness. All statistical analyses were conducted using Prism version 7.0 (GraphPad Software Inc., La Jolla, USA). A significant difference was determined when $p < 0.05$.

3. Results

Measurements of trueness are displayed in Table 1. For both the conventional and modified calibration procedure, the biases were all statistically different from zero. When comparing the two procedures, there was deemed to be no significant differences for biases in Rx ($p = 0.28$), Ry ($p = 0.16$), Rz ($p = 0.11$), and Tx ($p = 0.95$).

All measurements of precision for the conventional and modified procedure, given by the repeatability parameters, are displayed in Table 2. When comparing the two procedures, there