Radiostereometric Analysis for Migration and Wear of Orthopedic Implants

Policy

*A Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers radiostereometric analysis for migration and wear of orthopedic implants and for all other indications (e.g., assessment of spinal fusion, evaluation of stability in lateral calcaneal lengthening osteotomies, and prediction of long-term outcome in total hip arthroplasty) experimental and investigational because of insufficient evidence in the peer-reviewed literature.

Background

Radiostereometric analysis (RSA) has been used to determine migration and wear of orthopedic implants. Radiostereometry makes use of a cage with control marker and fiducial to calculate a three dimensional (3D) coordinate system. Spherical tantalum markers are inserted into the bone and implant to identify distinct points of measurement for each part of the skeleton and implant involved. Tantalum markers are inserted using a steel cannula, the insertion of which into cortical or...
sclerotic bone is facilitated by an awl or drill (Bottner et al, 2005).

Makinen et al (2004) reported that RSA has been a recommended technique for pre-market evaluation of new joint implant designs. The authors conducted a study of the effect of repositioning of X-ray tubes and phantom model on the precision of the RSA method. They utilized mean error of rigid body fitting (ME) values as an internal control for examinations, as ME value characterizes relative motion among the markers within each rigid body and is conventionally used to detect loosening of a bone marker. The authors performed 3 experiments as components of this study, each consisting of 10 double examinations. In the first experiment, the X-ray tubes and the phantom model were not repositioned between one double examination. However, in experiments two and three, the X-ray tubes were repositioned between one double examination and in experiment three the position of the phantom model was changed. The results illustrated that significant differences in the translation and rotation of the prosthetic components could be found in 2 of 12 comparisons. Re-positioning procedures increased ME values, mimicking deformation of rigid body segments, and therefore the authors concluded that ME value seemed to be a more sensitive parameter than migration values in this study design. They also concluded that these results confirm the importance of accurate patient positioning for RSA measurements. Standardization and calibration procedures should be performed with phantom models in order to avoid an unnecessary radiation dose to the patients. They noted that the present model gives the means to establish and follow the intra-laboratory precision of the RSA method and that the model is easily applicable in any research unit and allows the comparison of the precision values in different laboratories of multi-center trials.

Madanat et al (2007) stated that physical phantom models have conventionally been used to determine the accuracy and precision of RSA in various orthopedic applications. The
authors reported that, using a phantom model of a fracture of the distal radius, it has previously been shown that RSA is a highly accurate and precise method for measuring both translation and rotation in 3D. However, the main shortcoming of a physical phantom model is its inability to mimic complex 3D motion. Therefore, the goal of this study was to create a realistic computer model for preoperative planning of RSA studies and to use this new model to test the accuracy of RSA in measuring complex movements in fractures of the distal radius. The 3D computer model was created from a set of tomographic scans and the simulation of the radiographic imaging was performed using ray-tracing software (POV-Ray). The authors found that for simple movements in 1 axis, translations in the range of 25 microm to 2 mm could be measured with an accuracy of +/- 2 microm when using a 2-part fracture model (AO/ASIF type A2) and that rotations ranging from 16 degrees to 2 degrees could be measured with an accuracy of +/- 0.015 degrees. The corresponding values of accuracy were found to be +/- 4 microm and +/- 0.031 degrees for translation and rotation, respectively when using a 3-part fracture model. For complex 3D motion in a 3-part fracture model (AO/ASIF type C1) the accuracy was +/- 6 microm for translation and +/- 0.120 degrees for rotation. The study conclusions were that use of 3D computer modelling can provide a method for pre-operative planning of RSA studies in complex fractures of the distal radius and in other clinical situations in which the RSA method is applicable.

Cai et al (2008) conducted a study in which a new RSA calibration cage was developed. The purpose of the new RSA cage was to improve the accuracy and precision of RSA. This development consisted of 3 stages: utilization of a numerical simulation technique to design the new cage, implementation of a synthetic imaging method to predict the performance of the designed cage before it was fabricated, and conduction of an experimental phantom test to verify the actual performance of the new cage. This final phase compared two currently widely used cages. Accuracy was calculated as the 95 % prediction intervals from regression analyses between the
measured and actual displacements. Precision was defined as the standard deviation of repeated measurements. The final experimental phantom tests determined that the accuracy and precision of the new calibration cage were improved by about 40% over an existing biplanar cage. There was an improvement of approximately 70% compared to a uniplanar cage design. The authors concluded that this new cage can be used with any skeletal joints, in either static or kinematic examination, which is helpful for the standardization of the RSA application.

Fong et al (2011) conducted a study to design and evaluate a RSA marker insertion protocol to evaluate the stability of the bone-implant interface of a total ankle arthroplasty (TAA) prosthesis, and to validate that this marker insertion protocol can be combined with MBRSA technology to provide clinically adequate precision in assessing the micromotion of the TAA prosthesis. A marker placement protocol was developed with a Phantom Protocol and the Mobility™ Total Ankle System was used. The Improved Marker Placement Protocol was used in 20 patients, in whom postoperative RSA double exams were taken and condition numbers (CN) were used to assess the marker distribution, the system precision being defined as the standard deviation of the double exams (MTE, MRE). The results showed that the RSA marker insertion technique for the 20 \( \text{in vivo} \) cases provided satisfactory results and that CNs in all subjects but one were below 50 mm\((-1\). The authors concluded that system precision for these TAA implants was within the normal range identified by RSA studies, and comparable to the existing TAA RSA studies. They noted that this study demonstrated a reliable RSA marker insertion technique in both the tibia and talus and confirmed that the insertion and MBRSA technique allows the typical high precision demonstrated in other RSA studies (standard deviation less than or equal to 0.25 mm or 0.6 degrees). Thus, the authors stated, this method may allow more accurate assessment of prosthetic subsidence clinically.

Different techniques have been used to quantify the movement of sacroiliac (SI) joints, including RSA, but the accuracy and
precision of this method have not been properly evaluated and it is unclear how many markers are required and where they should be placed to achieve proper accuracy and precision. Kibsgard et al (2012) conducted a study to test accuracy and precision of RSA applied to the SI joint, in a phantom model and in patients. The authors used a plastic phantom attached to a micrometer to obtain a true value of the movement of the SI joint and compared this value with the measured value obtained by RSA with the difference representing the accuracy and the precision of the system measured by double examination in the phantom and in 5 patients. Different marker distributions were analyzed to find optimal marker placement and number of markers needed. The results illustrated that the precision of the phantom was high with a LOS less than 0.25° and 0.16 mm for all directions. In patients, the precision was less than 0.71° for rotations and 0.47 mm translations and no markers were needed in the pubic symphysis to obtain good precision. The authors therefore concluded that accuracy and precision are high when RSA is used to measure movement in the SI joint and felt that their findings support the use of RSA in research of SI joint motion.

Pijls et al (2012a) conducted a randomized controlled trial to investigate the long-term migration HA-coated, uncoated, and cemented tibial components in total knee amputation (TKA) as measured by RSA. Their rationale for this study was that, in contrast to early migration, the long-term migration of hydroxyapatite- (HA-) coated tibial components in TKA has been inadequately reported. In this study 68 knees were randomized to HA-coated (n = 24), uncoated (n = 20), and cemented (n = 24) components and all knees were prospectively followed for 11 to 16 years or until death or revision. A total of 742 RSA analyses were used to evaluate migration at yearly intervals utilizing clinical and radiographic evaluations designed according to the Knee Society system and analyzed via a generalized linear mixed model to account for the repeated measures design. Results of this study showed that the mean migration at 10 years was 1.66 mm for HA, 2.25 mm for uncoated and 0.79 mm for the cemented group (p < 0.001). The reduction of migration by HA
compared to uncoated components was greatest for subsidence and external rotation. It was noted that 3 tibial components were revised for aseptic loosening (2 uncoated and 1 cemented), 3 for septic loosening (2 uncoated and 1 cemented), and 1 for instability (HA-coated). Also of interest is that 2 of these cases were revised for secondary loosening after a period of stability, including 1 case of osteolysis and 1 case with late onset of infection. There were no statistically significant differences between the fixation groups regarding clinical or radiographic scores. The authors concluded that HA reduces migration of uncemented tibial components with this beneficial effect lasting more than 10 years. They further noted that longitudinal follow-up of TKA with RSA allows early detection of secondary loosening.

Pijls et al (2012b) performed 2 parallel systematic reviews and meta-analyses to determine the association between early migration of acetabular cups and late aseptic revision. The 2 reviews covered early migration data from RSA studies and revision rates for aseptic loosening from long-term survival studies respectively. Methodological structure of the study included thresholds for acceptable and unacceptable migration being classified according to the Swedish Hip Arthroplasty Register and the Australian National Joint Replacement Registry: less than 5 % revision at 10 years. Following an elaborate literature search, 26 studies involving 700 cups were included in the RSA review and 49 studies involving 38,013 cups were included in the survival review. Results of the study showed that for every mm increase in 2-year proximal migration, there was a 10 % increase in revision rate, which remained after correction for age, sex, diagnosis, hospital type, continent, and study quality. The authors found a clinically relevant association between early migration of acetabular cups and late revision due to loosening and concluded that the proposed migration thresholds can be implemented in a phased evidence-based introduction, given that they allow early detection of high-risk cups while exposing a small number of patients.
Although RSA has been utilized in clinical research settings, there is inadequate evidence of its effectiveness in impacting clinical outcomes regarding migration and wear of orthopedic implants. Larger scale randomized controlled trials (RCTs) comparing outcomes with RSA to outcomes alternative imaging technologies are needed to establish an evidence base for RSA for this indication.

Madanat et al (2014) stated that guidelines for standardization of RSA of implants were published in 2005 to facilitate comparison of outcomes between various research groups. In this systematic review, these investigators determined how well studies have adhered to these guidelines. These researchers performed a literature search to identify all articles published between January 2000 and December 2011 that used RSA in the evaluation of hip or knee prosthesis migration. Two investigators independently evaluated each of the studies for adherence to the 13 individual guideline items. Since some of the 13 points included more than 1 criterion, studies were assessed on whether each point was fully met, partially met, or not met. A total of 153 studies that met inclusion criteria were identified; 61 of these were published before the guidelines were introduced (2000 to 2005) and 92 after the guidelines were introduced (2006 to 2011). The methodological quality of RSA studies clearly improved from 2000 to 2011. None of the studies fully met all 13 guidelines. Nearly half (43) of the studies published after the guidelines demonstrated a high methodological quality and adhered at least partially to 10 of the 13 guidelines, whereas less than 1/5 (11) of the studies published before the guidelines had the same methodological quality. Commonly un-addressed guideline items were related to imaging methodology, determination of precision from double examinations, and also mean error of rigid-body fitting and condition number cut-off levels. The authors concluded that the guidelines have improved methodological reporting in RSA studies, but adherence to these guidelines was still relatively low. They stated that there is a need to update and clarify the guidelines for clinical hip and knee arthroplasty RSA studies.
Assessment of Spinal Fusion:

In a prospective animal study, Humadi et al (2013) evaluated the accuracy of RSA compared with computed tomographic (CT) scan in the assessment of spinal fusion after anterior lumbar interbody fusion (ALIF) using histology as a gold standard. Three non-adjacent ALIFs (L1 to L2, L3 to L4, and L5 to L6) were performed in 9 sheep, which were divided into 3 groups of 3 sheep. All the animals were humanely killed immediately after having the last scheduled RSA. The lumbar spine was removed and in-vitro fine-cut CT and histopathology were performed. Using histological assessment as the gold standard for assessing fusion, RSA demonstrated better results (100 % sensitivity and 66.7 % specificity; positive predictive value [PPV] = 27.3 %, negative predictive value [NPV] = 100.0 %) compared with CT (66.7 % sensitivity and 60.0 % specificity [PPV = 16.7 %, NPV = 93.8 %]). The authors concluded that RSA demonstrated higher sensitivity and specificity when compared with CT. Furthermore, RSA has the advantage of much lower radiation exposure compared with fine cut CT. They stated that further studies are needed to determine if RSA remains superior to CT scan for assessing spinal fusion in the clinical setting.

Choudhri et al (2014) stated that the ability to identify a successful arthrodesis is an essential element in the management of patients undergoing lumbar fusion procedures. The hypothetical gold standard of intra-operative exploration to identify, under direct observation, a solid arthrodesis is an impractical alternative. Therefore, radiographic assessment remains the most viable instrument to evaluate for a successful arthrodesis. Static radiographs, particularly in the presence of instrumentation, are not recommended. In the absence of spinal instrumentation, lack of motion on flexion-extension radiographs is highly suggestive of a successful fusion; however, motion observed at the treated levels does not necessarily predict pseudarthrosis. The degree of motion on dynamic views that would distinguish between a successful arthrodesis and pseudarthrosis has not been clearly defined. Computed
tomography with fine-cut axial images and multi-planar views is recommended and appears to be the most sensitive for assessing fusion following instrumented postero-lateral and anterior lumbar interbody fusions. For suspected symptomatic pseudarthrosis, a combination of techniques including static and dynamic radiographs as well as CT images is recommended as an option. Lack of facet fusion is considered to be more suggestive of a pseudarthrosis compared with absence of bridging posterolateral bone. Studies exploring additional non-invasive modalities of fusion assessment have demonstrated either poor potential, such as with (99m)Tc bone scans, or provide insufficient information to formulate a definitive recommendation.

**Evaluation of Stability in Lateral Calcaneal Lengthening Osteotomies:**

Martinkevich et al (2015) noted that lengthening osteotomies of the calcaneus in children are usually grafted with bone from the iliac crest. Artificial bone grafts have been introduced; however, their structural and clinical durability has not been documented. Radiostereometric analysis has been studied for the evaluation of joint implant and fracture stability, however, RSA has not previously been used in clinical studies of calcaneal osteotomies. These researchers assessed the precision of RSA as a measurement tool in a lateral calcaneal lengthening osteotomy (LCLO); LCLO was performed in 6 fixed adult cadaver feet. Tantalum markers were inserted on each side of the osteotomy and in the cuboideum. Lengthening was done with a Plexiglass wedge. A total of 24 radiological double examinations were obtained; 2 feet were excluded due to loose and poorly dispersed markers. Precision was assessed as systematic bias and 95% repeatability limits. Systematic bias was generally below 0.10 mm for translations. Precision of migration measurements was below 0.2 mm for translations in the osteotomy. The authors concluded that RSA is a precise tool for the evaluation of stability in LCLO. The findings of this small (n = 4) cadaveric study need to be validated by well-designed studies.
Prediction of Long-Term Outcome in Total Hip Arthroplasty:

de Vries and co-workers (2014) stated that the high precision of RSA has enabled researchers to predict long-term implant survival with a small sample of patients followed for a relatively short period of time. These investigators validated the predictive value of 2-year RSA results on long-term survival of different types of primary total hip arthroplasty (THA) stems. These researchers systematically reviewed literature to determine the maximum total point motion (MTPM), distal migration and rotation of stem designs and correlated these values to survival rates for aseptic loosening of these specific stems in arthroplasty registries. They included 32 studies describing migration of 15 different stem designs. The mean MTPM for straight polished cemented stems was 1.35 mm, for other cemented stems 0.83 mm and for other un-cemented stems 1.50 mm. No data were available for the un-cemented collared stem. Mean distal migration for straight polished cemented stems was 1.24 mm, for other cemented stems 0.26 mm, the un-cemented collared stem 0.40 mm and for other un-cemented stems 0.66 mm. Internal rotation was presented for 13 stems and all stems rotated into retroversion. All stems showed 10-year survival rates of greater than 97 % corrected for aseptic loosening. The authors concluded that reporting RSA results in a universal way including interpretation of outliers could improve the predictive value of RSA, allowing this technique to be an important tool during the phased introduction of new implant designs. However, a quality assessment of the data by an experienced reviewer is essential.

van der Voort and associates (2015) noted that few studies have addressed the association between early migration of femoral stems and late aseptic revision in THA. These investigators carried out a meta-regression analysis on 2 parallel systematic reviews and meta-analyses to determine the association between early migration and late aseptic revision of femoral stems. Of the 2 reviews, 1 covered early migration data obtained from RSA studies and the other covered long-term aseptic revision rates obtained from survival studies with
end-point revision for aseptic loosening. Stems were stratified according to the design concept: cemented shape-closed, cemented force-closed, and un-cemented. A weighted regression model was used to assess the association between early migration and late aseptic revision, and to correct for confounders. Thresholds for acceptable and unacceptable migration were determined in accordance with the national joint registries (less than or equal to 5 % revision at 10 years) and the National Institute for Health and Care Excellence (NICE) criteria (less than or equal to 10 % revision at 10 years). A total of 24 studies (731 stems) were included in the RSA review and 56 studies (20,599 stems) were included in the survival analysis review. Combining both reviews for the 3 design concepts showed that for every 0.1-mm increase in 2-year subsidence, as measured with RSA, there was a 4 % increase in revision rate for the shape-closed stem designs. This association remained after correction for age, sex, diagnosis, hospital type, continent, and study quality. The threshold for acceptable migration of shape-closed designs was defined at 0.15 mm; stems subsiding less than 0.15 mm in 2 years had revision rates of less than 5 % at 10 years, while stems exceeding 0.15 mm subsidence had revision rates of more than 5 %. The authors concluded that there was a clinically relevant association between early subsidence of shape-closed femoral stems and late revision for aseptic loosening. They stated that this association can be used to assess the safety of shape-closed stem designs. Moreover, they noted that the published research is insufficient to allow them to make any conclusions regarding such an association for the force-closed and un-cemented stems. Moreover, the authors stated that “Too few RSA study and survival study combinations for force-closed and un-cemented stem designs were found to give meaningful recommendations on the predictive value of early migration for aseptic revision of these designs. If more RSA migration studies are performed, the value of early migration profiles of these designs will be possible”.

Malak and colleagues (2016) stated that high failure rates of metal-on-metal (MoM) hip arthroplasty implants have
highlighted the need for more careful introduction and monitoring of new implants and for the evaluation of the safety of medical devices. The National Joint Registry and other regulatory services are unable to detect failing implants at an early enough stage. These researchers aimed to identify validated surrogate markers of long-term outcome in patients undergoing primary THA. These investigators conducted a systematic review of studies evaluating surrogate markers for predicting long-term outcome in primary THA. Long-term outcome was defined as revision rate of an implant at 10 years according to National Institute of Health and Care Excellence (NICE) guidelines. They conducted a search of Medline and Embase (OVID) databases. Separate search strategies were devised for the Cochrane database and Google Scholar. Each search was performed to include articles from the date of their inception to June 8, 2015. The search strategy identified 1,082 studies of which 115 studies were included for full article review. Following review, 17 articles were found that investigated surrogate markers of long-term outcome. These included 1 systematic review, 1 RCT, 1 case control study and 13 case series. Validated surrogate markers included RSA and Einzel-Bild-Rontgen-Analyse (EBRA), each measuring implant migration and wear. These researchers identified 5 RSA studies (1 systematic review and 4 case series) and 4 EBRA studies (1 RCT and 3 case series). Patient Reported Outcome Measures (PROMs) at 6 months have been investigated but have not been validated against long-term outcomes. The authors concluded that the findings of this systematic review identified 2 validated surrogate markers of long-term primary THA outcome: RSA and EBRA, each measuring implant migration and wear. The authors recommended the consideration of RSA in the pre-market testing of new implants. They stated that EBRA can be used to investigate acetabular wear but not femoral migration; further studies are needed to validate the use of PROMs for post-market surveillance. Moreover, these investigators stated that “The most accurate and reliable validated surrogate marker of outcome for both acetabular and femoral components is RSA. Despite this, RSA can only detect one mode of failure; aseptic loosening; and is inadequate to
detect other modes, notably in the case of MoM implants. We recommend its use to evaluate all new implants prior to their general release as part of a phased introduction”.

### CPT Codes / HCPCS Codes / ICD-10 Codes

**Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":**

**ICD-10 codes will become effective as of October 1, 2015:**

**CPT codes not covered for indications listed in the CPB:**

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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0348T</td>
<td>Radiologic examination, radiostereometric analysis (RSA); spine, (includes cervical, thoracic and lumbosacral, when performed)</td>
</tr>
<tr>
<td>0349T</td>
<td>Radiologic examination, radiostereometric analysis (RSA); upper extremity(ies), (includes shoulder, elbow and wrist, when performed)</td>
</tr>
<tr>
<td>0350T</td>
<td>Radiologic examination, radiostereometric analysis (RSA); lower extremity(ies), (includes hip, proximal femur, knee and ankle, when performed)</td>
</tr>
</tbody>
</table>

**ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>T84.020+ - T84.029+</td>
<td>Dislocation of internal joint prosthetics</td>
</tr>
<tr>
<td>T84.060+ - T84.069+</td>
<td>Wear of articular bearing surface of internal prosthetic joint</td>
</tr>
<tr>
<td>T84.110+ - T84.498+</td>
<td>Mechanical complications of other internal fixation device</td>
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The above policy is based on the following references:


Amendment to
Aetna Clinical Policy Bulletin Number: 0888
Radiostereometric Analysis for Migration and Wear of Orthopedic Implants

There are no amendments for Medicaid.

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