Aetna considers radiostereometric analysis experimental and investigational for the following indications (not an all-inclusive list) because its effectiveness has not been established.

- Assessment of migration and wear of orthopedic implants (e.g., evaluation of the migration following total knee replacement and wear measurement for reverse total shoulder arthroplasty)
- Assessment of spinal fusion, spinal motion and disorders
- Evaluation of hip joint pathomechanics (e.g., femoro-acetabular impingement)
- Evaluation of stability in lateral calcaneal lengthening osteotomies
- Evaluation of sternal instability
- Evaluation of unicompartamental knee arthroplasty
- Evaluation of upper limb arthroplasty
- Measurement of implant displacement in the shoulder
- Measurement of knee joint kinematics
- Prediction of long-term outcome in total hip arthroplasty.
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
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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 \textit{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
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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, spinal motion and disorders

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.

In a systematic review, Humadi and colleagues (2017) examined the accuracy of RSA, its assessment of spinal motion and disorders, and investigated the limitations of this technique in spine assessment. The results of this review concluded that RSA is a very powerful tool to detect small changes between 2 rigid bodies such as a vertebral segment. The technique was described for animal and human studies for cervical and lumbar spine and could be used to analyze ROM, inducible displacement, and fusion of segments. However, there are a few disadvantages with the technique; RSA percutaneous procedure needs to be performed to implant the markers (and could not be used pre-operatively), one needs a specific knowledge to handle data and interpret the results, and is relatively time-consuming and expensive. The authors concluded that RSA should be looked at as a very powerful research instrument that can be applied in limited clinical spine work.

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”.

Evaluation of Hip Joint Pathomechanics (e.g., Femoro-Acetabular Impingement)

Hansen and colleagues (2017) stated that dynamic RSA (dRSA) enables non-invasive 3D motion-tracking of bones and may be used to evaluate in-vivo hip joint kinematics including hip pathomechanics such as femoro-acetabular impingement (FAI) and the biomechanical effects of arthroscopic cheilectomy and rim trimming (ACH). These researchers evaluated the kinematic changes in the hip joint after ACH. A total of 7 non-FAI affected human cadaveric hips were CT-scanned and CT-bone models were created. Dynamic RSA recordings of the hip joints were acquired at 5 frames/s during passive flexion, adduction to stop, and internal rotation to stop (FADIR); ACH was performed and dRSA was repeated. Dynamic RSA images were analyzed using model-based RSA. Hip joint kinematics before and after ACH were compared pairwise. The volume of removed bone was quantified and compared to the post-operative range of motion (ROM). Mean hip internal rotation increased from 19.1° to 21.9° (p = 0.04, Δ2.8°, standard deviation [SD] 2.7) after ACH surgery. Mean adduction of 3.9° before and 2.7° after ACH surgery was unchanged (p = 0.48, Δ-1.2°; SD 4.3). Mean flexion angles during dRSA tests were 82.4° before and 80.8° after ACH surgery, which were similar (p = 0.18, Δ-1.6°, SD = 2.7). No correlation between volume of removed bone and ROM was observed. The authors concluded that a small increase in internal rotation, but not in adduction, was observed after arthroscopic cheilectomy and rim trimming in cadaver hips. The hip flexion angle of the FADIR test was reproducible. These researchers stated that dRSA kinematic analysis is a new and clinically applicable method with good potential to evaluate hip joint kinematics and to test FAI pathomechanics and other surgical corrections of the hip; In the future, this method may provide surgeons with the necessary insight to further improve patient outcome and satisfaction when using ACH.
Evaluation of Unicompartmental Knee Arthroplasty

Horsager and colleagues (2017) noted that implant inducible micro-motions have been suggested to reflect the quality of the fixation interface. These researchers examined the usability of dynamic RSA for evaluation of inducible micro-motions of the Oxford unicompartmental knee arthroplasty (UKA) tibial component, and evaluated factors that have been suggested to compromise the fixation, such as fixation method, component alignment, and radiolucent lines (RLLs). A total of 15 patients (12 men) with a mean age of 69 (55 to 86) years, with an Oxford UKA (7 cemented), were studied after a mean time in-situ of 4.4 (3.6 to 5.1) years; 4 had tibial RLLs. Each patient was recorded with dynamic RSA (10 frames/second) during a step-up/step-down motion. Inducible micro-motions were calculated for the tibial component with respect to the tibia bone. Post-operative component alignment was measured with model-based RSA and RLLs were measured on screened radiographs. All tibial components showed inducible micro-motions as a function of the step-cycle motion with a mean subsidence of up to -0.06 mm (95 % confidence interval [CI]: -0.10 to -0.03). Tibial component inducible micro-motions were similar for cemented fixation and cementless fixation. Patients with tibial RLLs had 0.5° (95 % CI: 0.18 to 0.81) greater inducible medio-lateral tilt of the tibial component. There was a correlation between post-operative posterior slope of the tibial plateau and inducible anterior-posterior tilt. The authors concluded that all patients had inducible micro-motions of the tibial component during step-cycle motion; RLLs and a high posterior slope increased the magnitude of inducible micro-motions suggesting that dynamic RSA is a valuable clinical tool for the evaluation of functional implant fixation.

The authors stated that this study had drawbacks including small group size (n = 15), marginal group stratification, and multiple hypothesis testing, which increased the risk of type-I and type-II error. Moreover, these investigators stated that these findings advocate the use of dynamic RSA for the evaluation of inducible micro-motions and component fixation in symptomatic implants. They stated that with further methodological advancements and the establishment of threshold values defining loose implants, dynamic RSA has the potential to become a valuable clinical tool.
Ten Brinke and colleagues (2017) stated that there have been few RSA studies of the upper limb, and the value of RSA of the upper limb is not yet clear. Thus, these investigators performed a systematic review to examine the accuracy and precision of RSA of the upper limb. PRISMA guidelines were followed and the protocol for this review was published online at PROSPERO under registration number CRD42016042014. A systematic search of the literature was performed in the databases Embase, Medline, Cochrane, Web of Science, Scopus, Cinahl, and Google Scholar on April 25, 2015 based on the keywords radiostereometric analysis, shoulder prosthesis, elbow prosthesis, wrist prosthesis, trapeziometacarpal joint prosthesis, humerus, ulna, radius, carpus. Articles concerning RSA for the analysis of early migration of prostheses of the upper limb were included. Quality assessment was performed using the MINORS score, Downs and Black checklist, and the ISO RSA; a total of 23 studies were included. Precision values were in the 0.06 to 0.88 mm and 0.05 to 10.7° range for the shoulder, the 0.05 to 0.34 mm and 0.16 to 0.76° range for the elbow, and the 0.16 to 1.83 mm and 11 to 124° range for the TMC joint. Accuracy data from marker- and model-based RSA were not reported in the studies included. The authors concluded that challenges with RSA in the upper limb include the symmetrical shape of prostheses and the limited size of surrounding bone, leading to over-projection of the markers by the prosthesis. They recommended higher adherence to RSA guidelines and encouraged investigators to publish long-term follow-up RSA studies.

The authors stated that a drawback of this review was the low number of articles included. Regarding the quality of the studies included, it was noted that the adherence to existing guidelines was poor. None of the studies that were included followed all the guidelines from the International Organization for Standardization and the European Standards Working Group on Joint Replacement Implants (ISO) standard. The most frequently ignored items were rigid body fitting error, cutoff levels for condition numbers, details of accuracy, and radiological details. To improve the methodological quality and to make it easier to compare the results of studies from different centers, better adherence to the guidelines is recommended for future studies. They noted that future research should focus on 3 main topics: (i) to learn more about...
precision and accuracy of RSA, it is important to increase the number of RSA studies in shoulder, elbow, wrist, and hand arthroplasty. (ii) Long-term results are needed to evaluate migration patterns in orthopedic implants and to examine the predictive value of early migration for future loosening. The follow-up time in all but 4 studies included in this review was 2 years or less. These researchers therefore encourage the authors of the RSA studies included to assess their patient cohorts after 5 and 10 years, to provide adequate follow-up data, and (iii) given the predictive value of early migration in total knee and hip arthroplasty, RSA is an important tool in the development, introduction, and evaluation of orthopedic implants. This predictive value has not yet been proven in the upper limb, so the value of RSA in the upper limb is not yet clear. Future research should therefore concentrate on the predictive value of early migration for loosening of prostheses in the upper limb.

Gascoyne and associates (2017) evaluated differences in the fixation and functional outcomes between pegged and keeled all-polyethylene glenoid components for standard total shoulder arthroplasty. Patients were randomized to receive a keeled or pegged all-polyethylene glenoid component. These researchers used model-based RSA to evaluate glenoid fixation and subjective outcome measures to assess patient function. Follow-up examinations were completed at 6 weeks and 6, 12 and 24 months after surgery. Modifications to the RSA surgical, imaging and analytical techniques were required throughout the study to improve the viability of the data. Stymied enrolment resulted in only 16 patients being included in this analysis. The RSA data indicated statistically greater coronal plane migration in the keeled glenoid group than in the pegged group at 12 and 24 months. Functional outcome scores did not differ significantly between the groups at any follow-up; 1 patient with a keeled glenoid showed high component migration after 24 months and subsequently required revision surgery 7 years post-operatively. The authors concluded that despite a small sample size (n = 16), they found significant differences in migration between glenoid device designs. Although clinically these findings were not robust, these investigators showed the feasibility of RSA in total shoulder arthroplasty as well as the value of a high-precision metric to achieve objective results in a small group of patients. These investigators stated that the small sample size
in their study limited its clinical relevance; moreover, they stated that improvements in the surgical, radiographic and analytical techniques of RSA described in this study will help with the feasibility of future studies of this kind.

Holm-Glad and colleagues (2018) stated that RSA is a method for measuring micro-motion in joint arthroplasties; it has never been used in total wrist arthroplasties (TWAs). These researchers evaluated the precision of model-based RSA in TWAs measured in a phantom model and in patients; the number of bone markers necessary to ensure the precision; as well as the accuracy of model-based RSA in a phantom model. Reverse engineered models of radial and carpal/metacarpal components of 2 wrist arthroplasties (ReMotion® and Motec®) were obtained by laser scanning. Precision and accuracy of each arthroplasty were analyzed with regards to translation and rotation along the 3 coordinate axes. Precision was analyzed in 10 phantom and 30 clinical double examinations for each arthroplasty, and was expressed by a repeatability coefficient. The precision of different numbers and configurations of bone markers in the phantom model were compared. Accuracy was tested in a phantom model where the implants were attached to a micrometer, and was defined as the MD between measured and true migration. In the phantom model the precision for translations ranged from 0.03 to 0.14 mm and for rotations from 0.18 to 1.52°. In patients the precision for translations ranged from 0.06 to 0.18 mm, and for rotations from 0.32 to 2.18°. Less than 4 bone markers resulted in inferior precision. Accuracy ranged from -0.06 to 0.04 mm, and from -0.38 to -0.01°; Y-rotations could not be obtained from the Motec® due to rotational symmetry about the longitudinal axis. The authors concluded that model-based RSA in TWAs was precise, accurate, and feasible to use for clinical evaluation of micro-motion in wrist arthroplasties.

Measurement of Knee Joint Kinematics

Stentz-Olesen and colleagues (2017) stated that RSA using implanted markers is considered the most accurate system for the evaluation of prosthesis migration. By using CT bone models instead of markers, combined with a dynamic RSA system, a non-invasive measurement of joint movement is enabled. These researchers evaluated the accuracy of the CT model method for measuring knee joint kinematics in static and
Radiostereometric Analysis for Migration and Wear of Orthopedic Implants

Dynamic RSA using the marker method as the benchmark. Bone models were created from CT scans, and tantalum beads were implanted into the tibia and femur of 8 human cadaver knees. Each specimen was secured in a fixture, static and dynamic stereoradiographs were recorded, and the bone models and marker models were fitted to the stereoradiographs. Results showed a mean difference between the 2 methods in all 6 degrees of freedom (DF) for static RSA to be within -0.10 mm/° and 0.08 mm/° with a 95 % limit of agreement (LoA) ranging from ±0.49 to 1.26. Dynamic RSA had a slightly larger range in mean difference (MD) of -0.23 mm/° to 0.16 mm/° with LoA ranging from ±0.75 to 1.50. The authors concluded that in a laboratory-controlled setting, the CT model method combined with dynamic RSA may be an alternative to previous marker-based methods for kinematic analyses of the knee joint. The stated that the CT model method could be the preferred method in future kinematic studies of large joints, since no implanted markers are needed.

This study had 3 main drawbacks; (i) the small sample size (n = 8) may have led to an over-estimation of the accuracy, (ii) the following processes were automated, and the reproducibility of the processes was therefore not investigated: CT segmentation of the bone model; placing the anatomical coordinate system; detection and creation of the marker model, and (iii) the comparison of the model method and the marker method was not blinded. Gudnason and associates (2017) stated that MTPM measured by RSA is widely used as a predictor of total knee arthroplasty loosening. These investigators compared the ability of different RSA measurements at different time-points to predict loosening of tibial total knee arthroplasty components in the long-term. A total of 116 total knee arthroplasties in 116 patients were included in this analysis; 16 (14.8 to 17.4) years after surgery, 5 tibial components had been revised due to aseptic loosening. Receiver operating characteristic curves were calculated in order to examine the specificity and sensitivity of different RSA parameters at different thresholds. Rotation around the transverse (x-) axis measured 2 years post-operatively had the best predictive value of all parameters, with an area under the curve (AUC) of 80 %. Using a threshold of 0.8 degrees, a specificity of 85 % and a sensitivity of 50 % were reached. The AUC for tibial component distal translation was 79 % and it was 77 % for proximal translation, whereas it was only 68 % for MTPM. The authors concluded that rotation of the
cemented tibial component around the transverse axis, proximal translation, and distal translation were slightly better at predicting aseptic loosening than MTPM, and tibial component migration measured after 2 years gave a good prediction of aseptic loosening up to 15 years. They stated that future studies on the migration of tibial components used in total knee arthroplasty should therefore direct more attention to tibial component rotation around the transverse axis, and the associated parameters proximal and distal translation of the periphery of the tibial component.

This study had several drawbacks: (i) the good long-term clinical results with few revisions reduced the precision of this statistical analyses, as reflected by wide confidence intervals. Therefore, these investigators cautioned when generalizing these findings to a general population. In the analysis of RSA data, it is important to study migration patterns over time. In this study, these researchers focused on absolute migration up to 2 years, and this limited the conclusions that can be drawn on migration patterns at later time-points, (ii) different bone densities can influence the amount of early migration, a parameter that the authors could not control for, and (iii) this study was based on historical RSA examinations performed with analog methods and analyzed with historical software. It is possible that re-analysis of the material with modern equipment would have resulted in improved precision and more exact measurements.

Evaluation of Sternal Instability

Vestergaard and co-workers (2018) proposed the use of RSA for evaluation of sternal instability and presented a method validation. Four bone analogs (phantoms) were sternotomized and tantalum beads were inserted in each half. The models were reunited with wire cerclage and placed in a radiolucent separation device. Stereoradiographs (n = 48) of the phantoms in 3 positions were recorded at 4 imposed separation points. The accuracy and precision was compared statistically and presented as translations along the 3 orthogonal axes. 7 sternotomized patients were evaluated for clinical RSA precision by double-examination stereoradiographs (n = 28). In the phantom study, these researchers found no systematic error (p > 0.3) between the 3 phantom positions, and
precision for evaluation of sternal separation was 0.02 mm. Phantom accuracy was mean 0.13 mm (SD 0.25). In the clinical study, these investigators found a detection limit of 0.42 mm for sternal separation and of 2 mm for anterior-posterior dislocation of the sternal halves for the individual patient. The authors concluded that RSA was a precise and low-dose image modality feasible for clinical evaluation of sternal stability in research.

Measurement of Implant Displacement in the Shoulder

Van de Kleut and associates (2018) determined bias in motion and bias at zero motion of RSA for evaluating implant relative displacement in reverse total shoulder arthroplasty (RTSA). A Sawbones shoulder phantom was fitted with a RTSA implant set and 13 tantalum markers. The model was fixed to a manual micrometer, providing controlled movements though 15 known increments in translation and 12 increments in rotation (0.02 to 5.00 mm and 0.1 to 6.0°), along each translation and rotation axis. Movement between the glenoid and humerus was assessed using beads versus beads (B/B), model versus beads (M/B), and model versus model (M/M) measurement methods in a model-based RSA environment. Bias in motion and bias at zero motion were defined as the difference between measured and accepted reference values, and the difference between double examinations with a theoretical displacement of zero, respectively. Bias in motion ranged from $0.054 \pm 0.010$ to $0.129 \pm 0.014$ mm and $0.076 \pm 0.025$ to $0.126 \pm 0.025°$ (B/B), $0.023 \pm 0.009$ to $0.126 \pm 0.016$ mm and $0.111 \pm 0.033$ to $0.794 \pm 0.251°$ (M/B), and $0.029 \pm 0.010$ to $0.135 \pm 0.030$ mm and $0.243 \pm 0.088$ to $0.384 \pm 0.153°$ (M/M). Bias at zero motion ranged from $0.120$ to $0.156$ mm and $0.075$ to $0.206°$ (B/B), $0.074$ to $0.149$ mm and $0.067$ to $1.953°$ (M/B), and $0.069$ to $0.259$ mm and $0.284$ to $1.273°$ (M/M). The authors concluded that this was the first RSA for RTSA study, with results comparable to those validating the use of RSA for hip and knee arthroplasties (accepted as $0.05$ to $0.50$ mm and $0.15$ to $1.15°$), justifying the potential use of RSA as a tool for measuring implant displacement in the shoulder.

Fraser and co-workers (2018) validated model-based RSA on the glenoid component of RTSA. These investigators compared 2 different modalities of model-based RSA, elementary geometrical shapes and
reversed engineering. They also explored 2 different ways to position the patient to obtain different projections of the implant, the hip-position (transversal) and shoulder-position (sagittal). Phantom accuracy was determined by performing 9 translations (x, y, z) and 5 rotations (x, y, z), and expressed as the MD between RSA measurements and micrometer values. Precision was measured using 12 double examinations of the phantom and 19 in patients, and expressed as 1.96 × SDs of the paired differences between double examinations. The accuracy was high for both modalities, but rotation around the symmetrical axis of the implant could not be measured using reversed engineering. Clinical precision ranged from 0.13 to 0.25 mm for translations, and 0.4° to 0.7° for rotations, using reversed engineering. For elementary geometrical shapes, the precision ranged from 0.18 to 0.34 mm for translations, and 0.8° to 1.8° for rotations. The hip-position was abandoned due to poor implant visualization. Model-based RSA on the glenoid component of RTSA had a high precision and accuracy, comparable to RSA results on hips and knees. Patient positioning was vital for obtaining adequate results. The authors concluded that reversed engineering was the more reliable method, and recommended reversed engineering as the method of choice for further clinical RSA investigation of the glenoid component of RTSA.

Assessment of Migration and Wear of Orthopedic Implants

In a systematic review and meta-analyses, Pijls and colleagues (2018) evaluated the early and long-term migration patterns of tibial components of total knee replacement (TKR) of all known RSA studies. Migration pattern was defined as at least 2 post-operative RSA follow-up moments. Maximal total point motion (MTPM) at 6 weeks, 3 months, 6 months, 1 year, 2 years, 5 years, and 10 years were considered. The literature search yielded 1,167 hits of which 53 studies were included, comprising 111 study groups and 2,470 knees. The majority of the early migration occurred in the first 6 months post-operatively followed by a period of stability, i.e., no or very little migration. Cemented and uncemented tibial components had different migration patterns. For cemented tibial components there was no difference in migration between all-poly and metal-backed components, between mobile bearing and fixed bearing, between cruciate retaining and posterior stabilized. Furthermore, no difference existed between TKR measured with model-based RSA or
marker-based RSA methods. For uncemented TKR there was some variation in migration with the highest migration for uncoated TKR. The authors concluded that the findings of this meta-analysis on RSA migration were in line with the results of national implant registries as well as the results of meta-analyses on revision rates, providing further proof for the association between early implant migration and late revision for aseptic loosening of TKR. The pooled migration patterns could be used both as benchmarks as well as for defining migration thresholds for future evaluation of new TKR and fixations. These researchers stated that RSA has a place for a safe pre-market approval (PMA) evaluation and as such should be part of a phased introduction of new implants. With the data from this meta-analysis it appeared possible to have a 1st evaluation of the safety (i.e., implant-bone fixation) of the implant at 6 months.

Wear Measurement for Reverse Total Shoulder Arthroplasty

Kurdziel and associates (2018) stated that polyethylene wear is a known complication in total joint arthroplasty, however, in-vivo wear rates in reverse total shoulder arthroplasty (rTSA) remain largely unknown. These researchers quantified volumetric and surface deviation changes in retrieved rTSA humeral liners using a novel micro-CT (μCT)-based technique. After institution review board (IRB)-approval, 32 humeral liners (single manufacturer and model) with term-of-service greater than 90 days were analyzed. Clinical demographics and surgical data were collected via chart review. Unworn liners were used as geometric controls. Retrieved and unworn liners underwent μCT scanning. Retrieved liner volumes were isolated, co-registered to controls of matching geometry, and surface deviations of the articulation surface and rim were computed. Differences in total volume loss (TVL), volumetric wear rate (VWR), and surface deviation were reported. Semi-quantitative grading evaluated rim damage presence and severity. Mean term-of-service for all liners was 2.07 ± 1.33 years (range of 0.30 to 4.73). Mean TVL and VWR were 181.3 ± 208.2 mm3 and 114.5 ± 160.3 mm3 per year, respectively. Mean articulation and rim surface deviations were 0.084 ± 0.65 and 0.177 ± 0.159 mm, respectively. Articulation surface deviation was positively correlated to term-of-service. Rim damage was present on 63 % of liners and correlated significantly to rim surface deviation The authors concluded that the calculation of in-vivo wear rates could help bridge the gap between clinical outcomes and experimental models such
as wear simulations and mathematical modeling. Data from this study demonstrated measurable changes in volume and surface deviations of both the articulation and rim surfaces. Wear debris produced from these changes may have an impact on implant longevity due to the inherent risks of wear debris induced osteolysis. These researchers stated that continued investigation is needed to further elucidate how specific model geometries and clinical parameters may impact implant wear and clinical outcomes.

The authors stated that this study had several limitations. Humeral liner wear was only calculated for 1 manufacturer and model type. This decision was made due to the frequency of this model within the authors' Institution's Implant Retrieval Library. Continued analysis and testing of other models and larger, multi-model populations is needed to fully elucidate the parameters that impact wear of humeral liners in rTSA. Iatrogenic damage was seen to negatively affect volume results -- surgeons should maintain caution, if possible, during revision surgery to preserve liners for subsequent retrieval damage and volume analysis. Furthermore, since all liners evaluated in this study were explanted due to failure, these data may not fully represent a well-functioning implant. The selection of liners for this study was based on available liners collected in the retrieval program and inherently created a selection bias with respect to the entire population of arthroplasty liners. It may be helpful to evaluate components post-mortem to evaluate wear rates of well-functioning rTSA systems. For this study, the surface deviation metric utilized in this study was based on Euclidean distance and thus did not distinguish directionality (i.e., recession versus protrusion of the worn surface). Also, quantitative delineation of the relative contributions of wear and plastic deformation to overall surface deviation was not feasible. Observationally, these researchers found that liners primarily exhibiting bearing surface wear had minimal evidence of plastic deformation at the edges, suggesting that limited plastic deformation occurred in these cases and that a majority of bearing surface deviation occurred due to wear. They stated that further studies should be carried out to examine these damage processes on retrieved liners. In cases of severe rim deformation, marked deformation of the original liner shape was observed along the edges of the implant, suggesting that plastic deformation was the predominant mode of rim damage.
Van de Kleut and colleagues (2019) noted that polyethylene wear measurement of rTSA is currently restricted to in-vitro, in-silico, and retrieval analysis, with no method for the quantification of in-vivo wear of well-functioning implants. These researchers validated the use of model-based RSA (MBRSA) as a measurement tool for in-vivo rTSA wear using a phantom setup. A total of 6 additively manufactured polyethylene inserts were fabricated -- 1 unworn control and 5 to represent known wear patterns, and individually fit within the rTSA components. Each insert was imaged using standard radiostereometric techniques and analyzed using MBRSA. From the position and orientation estimation provided by MBRSA, a μCT model of the control insert was virtually placed within the metaphyseal tray. The apparent intersection of the glenosphere into the insert was recorded as wear. This method enabled wear measurements with a linear precision of 0.21 mm and a bias of 0.36 ± 0.13 mm, and a volumetric precision of 49.3 mm³, with a bias of 48.9 ± 24.3 mm³. The authors concluded that this technique allowed for the in-vivo measurement of polyethylene wear without the requirement of marker beads or baseline radiographs, expanding the potential for in-vivo wear measurements to larger populations and retrospective analysis. These preliminary findings need to be validated by well-designed studies.

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 "+":*

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<th>Code</th>
<th>Code Description</th>
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<td>CPT codes not covered for indications listed in the CPB:</td>
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<tr>
<td>0348T</td>
<td>Radiologic examination, radiostereometric analysis (RSA); spine, (includes cervical, thoracic and lumbosacral, when performed)</td>
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<tr>
<td>0349T</td>
<td>Radiologic examination, radiostereometric analysis (RSA); upper extremity(ies), (includes shoulder, elbow and wrist, when performed)</td>
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Radiostereometric Analysis for Migration and Wear of Orthopedic Implants

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<th>Code</th>
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<tr>
<td>0350T</td>
<td>Radiologic examination, radiostereometric analysis (RSA); lower extremities (includes hip, proximal femur, knee and ankle, when performed)</td>
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ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):

- M25.851 - M25.859: Other specified joint disorders, hip [femoro-acetabular impingement]
- M53.2X3 - M53.2X5: Spinal instabilities [Sternal instability]
- M53.80 - M53.89: Other specified dorsopathies [Spinal motion and disorders]
- T84.020A - T84.029S: Dislocation of internal joint prosthetics
- T84.060A - T84.069S: Wear of articular bearing surface of internal prosthetic joint
- T84.110A - T84.498S: Mechanical complications of other internal fixation device
- Z47.1: Aftercare following joint replacement surgery
- Z96.651 - Z96.659: Presence of artificial knee joint
- Z96.611 - Z96.619: Presence of artificial shoulder joint

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.