Healthy Blue

Medical Policy

Subject:	Radiostereometric Analysis (RSA)		
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Description/Scope

This document addresses radiostereometric analysis (RSA). RSA is a method for performing three-dimensional (3-D) measurement and motion analysis using implanted markers and stereoscopic radiographs.

Position Statement

Investigational and Not Medically Necessary:

Radiostereometric analysis (RSA) is considered **investigational and not medically necessary** for all uses including, but not limited to the following:

- Determination of migration and wear of orthopedic implants;
- Assessment of spine and extremity fracture healing

Rationale

RSA has been investigated for a variety of orthopedic uses including the determination of migration and wear of orthopedic implants and the assessment of fracture segment stability during healing.

Orthopedic Implants

In 2011, Fong and colleagues performed a study with the intent of designing an 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 Model-based RSA (MBRSA) technology to provide clinically adequate precision in assessing the micromotion of the TAA prosthesis. MBRSA is a method by which implant migration can be determined without markers attached to the implants. A marker placement protocol was developed with a Phantom Protocol. A total of 20 subjects utilized the Improved Marker Placement Protocol and had postoperative RSA double examinations performed. The RSA marker insertion technique for the 20 cases provided results reported as satisfactory. The authors concluded that marker configurations used for the talus and tibia in this study can also be used for further studies. Additionally, this study indicated that the MBRSA can effectively assess the micromotion of TAA components. Study limitations included a small sample size.

A randomized controlled trial (Pijls, 2012) investigated long-term migration measured by RSA of hydroxyapatite (HA)-coated, uncoated, and cemented tibial components in total knee arthroplasty (TKA). A total of 68 knees were randomized to HA-coated (n=24), uncoated (n=20), and cemented (n=24) components. RSA was used to evaluate

migration at yearly intervals. All knees were prospectively followed for 11-16 years, or until death or revision. The study involved 742 RSA analyses. 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 as compared to uncoated components was most pronounced for subsidence and external rotation. Three 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). The authors concluded that longitudinal follow-up of TKA with RSA allows early detection of secondary loosening.

In 2014, de Vries and colleagues performed a systematic review evaluating the predictive value of RSA analysis for stem survival in total hip arthroplasty studies. A total of 32 studies describing migration of 15 different stem designs were reviewed to determine the maximum total point motion, distal migration and rotation of stem design. The RSA values were correlated to survival rates for aseptic loosening of specific stems. All stems showed 10-year survival rates of over 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 the technique to be an important tool during the phased introduction of new implant designs.

Guidelines for the standardization of RSA implants were initiated in 2005 by Valstar and colleagues in an attempt to facilitate outcome comparisons between studies. In a 2014 systematic review, Madanat evaluated adherence of hip and knee arthroplasty studies to RSA standardization guidelines. A literature search identified all articles published between January 2000 and December 2011 that used RSA in the evaluation of hip or knee prosthesis migration. Most of the evaluated studies were from Nordic countries that also had the highest level of adherence to the RSA guidelines as compared to other areas. Of the 92 studies that were published after 2005, 43 demonstrated a high methodological quality and at least partially adhered to 10 of the 13 guidelines. A total of 11 of the studies published before the guidelines had the same methodological quality. Commonly unaddressed guideline issues were related to imaging methodology, determination of precision from double examinations and also mean error of rigid-body fitting, and condition number cutoff levels. The authors indicated that the guidelines had a positive impact on the methodological quality of RSA publications, but improvement was needed. Further noted was a need "to update, simplify, and clarify the guidelines and also promote their use in the peer review process."

In a 2017 systematic review of literature, Ten Brinke and colleagues included 23 studies for which RSA was done to analyze early migration of prostheses of the upper limb. Both prospective and retrospective studies were included if they used RSA for the purpose of measuring the migration of the prostheses. Studies were evaluated for quality using the Methodological Index for Non-Randomized Studies (MINORS) index. While one study was rated a 14 (scale from 0-16), the mean score was 9 with 8 studies achieving less than half of the points available. None of the included studies reported accuracy data from marker-based and model-based RSA, despite ISO standards calling for both measurements as part of clinical studies. For the shoulder, precision values were in the 0.06-0.88 mm, 0.05-10.7° range. For the elbow, precision values were in the 0.05-0.34 mm and 0.16–0.76° range, and 0.16–1.83 mm and 11–124° range for the trapeziometacarpal joint. While the authors conclude that RSA was a highly precise method for measuring of early migration of implants, the precision of rotation in several components has been poor. The authors conclude that "…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."

Extremity Fractures

A 2010 single center study by Solomon and colleagues evaluated the accuracy and precision of RSA in a tibial plateau fracture model. Combinations of 3, 6, and 9 tantalum markers in a lateral condyle fracture were evaluated with reference to 6 proximal tibial arrangements. The results were improved using more markers in each segment. The precision (95% confidence interval) was less than ± 16 μm in all axes in vitro. Rotation had an accuracy of less than 0.123 degrees and a precision of ± 0.024 degrees. The authors reported that the use of a phantom tibia with no soft tissue coverage was a study limitation. The lack of soft tissue coverage and inferior synthetic bone density may have altered image quality.

Van Embden and colleagues (2015) performed a prospective study to quantify the movement of proximal femoral fracture fragments after fixation. Between April 2010 and April 2012, a total of 15 individuals with an undisplaced femoral neck fracture, treated with either a dynamic hip screw or three cannulated hip screws, and 16 individuals with an AO31-A2 trochanteric fracture treated with a dynamic hip screw or a Gamma Nail, were evaluated. During surgical treatment for the fractures, after or during placement of the fixation device, between three and six spherical tantalum markers were inserted into each fragment. RSA was performed at 6 weeks, 4 months and 12 months post-operatively to assess rotation and shortening. Migration could be assessed in 10 subjects with a fracture of the femoral neck and 7 with a trochanteric fracture. By 4 months post-operatively, a mean shortening of 5.4 mm (-0.04 to 16.1) was reported in the fracture of the femoral neck group and 5.0 mm (-0.13 to 12.9) in the trochanteric fracture group. A wide range of rotation occurred in both types of fracture. Right-sided trochanteric fractures seem more rotationally stable than left-sided fractures. This prospective study shows that migration at the fracture site can occur continuously during the first 4 post-operative months, after which stabilization occurs. Study limitations reported by the authors included small sample size, logistical and technical issues. There was limited access for the implantation of markers in different fracture fragments and the markers were reported to be less stable in fracture surgery. These problems resulted in fewer RSA acquisitions for analysis than were anticipated.

A 2020 prospective cohort study by Galea and colleagues reported on 16 participants with distal femoral fracture. Participants were followed for 1 year following distal femoral fracture fixation using RSA to assess for interfragmentary motion and whether RSA data are consistent with diagnosis of nonunion. Over the course of the study, 2 participants showed nonunion and required revision surgery. For the remaining 14 participants with suspected union, RSA showed interfragmentary motion between 2 and 6 weeks and between 6 and 12 weeks. No significant amount of motion was noted following 12 weeks. While this study appears to indicate the use of RSA to evaluate fracture healing, there are several limitations including a small participant size, lack of randomization and a control group. Care should be taken to interpret the results, particularly with varying types of fixation devices (for example, titanium versus stainless-steel plates). Randomized, controlled trials with larger participant sizes are necessary to effectively evaluate the use of RSA for migration following extremity fracture fixations.

Spinal Fusion

The first analysis of lumbosacral spinal fusion studied with RSA was reported by Olsson (1976) in a small case series of 3 individuals. Subsequent small studies focused on measurements of intervertebral mobility in adult

spondylolisthesis (Axelsson, 2000) and the stabilizing effect of lumbar or cervical fusions (Gunnarsson, 2000; Halldin, 2005; Pape, 2002; Zoega, 1998). A more recent 2013 study by Humadi also assessed spinal fusion; however, it was very limited in scope and was performed on 9 animals (sheep).

Other Uses

Early studies from the 1980's evaluated RSA for human growth measurement (Kärrholm, 2006). RSA has also been investigated as a tool to measure lateral calcaneal lengthening osteotomies (Martinkevich, 2015). These studies were all limited by a small number of participants.

Conclusion

Proper positioning is important during RSA and some variability can occur, especially when follow-up exams can be months to years apart. In a 2020 study by Lindgren and colleagues, the authors reported on position differences from a phantom hip-study and clinical precision of hip-RSA. There were 12 participants included who were analyzed with both a model-based and marker-based analysis. The authors noted that changes in the position of the hip between RSA exams affects the precision of measurements. Several variables can be attributed to differences in position for exams including clinical study protocol, variation in staff completing the RSA exams, and differing types of implants.

There is insufficient evidence in the published peer-reviewed literature demonstrating the efficacy of RSA. The ability of RSA and associated interstitial markers to improve clinical health outcomes has not been established. Further study to improve RSA standardization and large randomized clinical trials are needed to establish the clinical utility of this technology.

Background/Overview

RSA has been used for various orthopedic applications including assessment of bone fracture healing and evaluation of total joint replacement implant stability. The procedure typically involves the surgical implantation of at least three radio-opaque landmarks (for example, 1 mm tantalum beads) into bone or soft tissue, often surrounding an orthopedic implant, prostheses, or anatomical structures. These implanted markers are used to measure movement and overall effectiveness of implants after surgery with the aid of radiographic images. Two postoperative X-rays are taken simultaneously for the purpose of making accurate 3D measurements.

Definitions

Orthopedic implant: A medical device manufactured to replace a missing joint or bone or to support a damaged bone. The medical implant is mainly fabricated using stainless steel and titanium alloys for strength and the plastic implant coating acts as an artificial cartilage.

Phantom: A model of the body or one of its parts.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

0347T	Placement of interstitial device(s) in bone for radiostereometric analysis (RSA)
0348T	Radiologic examination, radiostereometric analysis (RSA); spine, (includes, cervical, thoracic and lumbosacral, when performed)
0349T	Radiologic examination, radiostereometric analysis (RSA); upper extremity(ies), (includes shoulder, elbow and wrist, when performed)
0350T	Radiologic examination, radiostereometric analysis (RSA); lower extremity(ies), (includes hip, proximal femur, knee and ankle, when performed)

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

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Radiostereometry Analysis
Radiostereometric Analysis
Roentgen Stereophotogrammetric Analysis

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	11/05/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections.
Reviewed	11/07/2019	MPTAC review.
Reviewed	11/08/2018	MPTAC review.
Reviewed	02/27/2018	MPTAC review. The document header wording was updated from "Current Effective Date" to "Publish Date." Updated Rationale and References sections.
Reviewed	02/02/2017	MPTAC review. Rationale and References sections updated.
New	02/04/2016	MPTAC review. Initial document development.