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# Radiostereometric Analysis for Assessment of Orthopedic Implant Position

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| Related Policies (if applicable) |
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| None |
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## Disclaimer

**Carefully check state regulations and/or the member contract.**
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

## Coverage

**This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.**

Radiostereometric analysis (RSA) for assessment of orthopedic implant position, wear, migration, soft tissue healing, and/or bone segment grafting or cement migration or loosening, with or without use of implanted markers and/or computer software aided digital views/interpretation, **is considered experimental, investigational and/or unproven**.

## Policy Guidelines

None.

## Description

Roentgen stereophotogrammetry was developed over 45 years ago to localize the position of an object in space using x-rays. Since that time, many investigators have refined the radiostereometric (RS) calculations and equivalent computer software. (1) Prior to the initial use with the introduction of computer software to produce 3-dimensional (3D) analysis, standard 2-dimensional (2D) radiographs or x-rays were first studied in 1898 and used for assessment of spinal fusion in 1911. (2, 3)

**Background**

Radiostereometric analysis (RSA) is intended to detect changes in implant position after orthopedic surgery. The process involves the insertion of spherical tantalum markers, the size of a poppy seed, into the bone during surgery to identify distinct points of measurement for each part of the implant or prosthesis involved. Following the surgical procedure, a pair of simultaneous image x-rays are taken of the surgical site together from two different directions along with a RSA calibration cage. According to the manufacturer, the markers can be precisely located relative to each other and monitored for changes in position that might indicate a problem. (4)

Halifax Biomedical (Halifax Biomedical, Inc., Mabou, Nova Scotia, Canada) provides the Halifax Bead Inserter, the Tantalum Bead Set (16 beads), the Halifax Stereo Radiography Suite (dual low-dose x-ray radiographic imaging system and calibration cage), and RSA services (evaluation and analysis of imaging). (4) The model-based RSA (MBRSA) software is the analytical software package for evaluation of orthopedic implant fixation and bone segment motion. The MBRSA assesses the 3D position calibrated stereo x-rays for measurement and/or relative motion of metal implants, marker beads, and/or bone segments. The analysis by trained physicians assists the provider to make critical patient treatment decisions, such as whether to intervene to stabilize an implant when fixation or migration concerns develop, or instability has progressed leading to additional fusion procedures. (5) Lately, RSA use in soft tissue (tendons, ligaments, and/or muscle) applications has emerged. (6)

**Regulatory Status**

The Tantalum Bead Set (Halifax Biomedical, Inc., Mabou, Nova Scotia, Canada) was cleared for marketing by the U.S. Food and Drug Administration (FDA) under the 510(k) process in August 2009. The predicate device was tantalum beads from Biomet, Inc. (Warsaw, Indiana). The FDA documentation notes that the bead inserter is a Class I device. A special 510(k) clearance was granted in June 2011 for a bead set sterilized by the manufacturer using gamma radiation. The manufacturer's indications for use are as follows: "Tantalum bead implants are used as radio-opaque markers and may be implanted into bone or soft tissue. These devices are used to measure movement in implants after surgery with the aid of an x-ray system. Implant surgery associated with the use of radiographic markers may include total joint replacement procedures, soft tissue repair and bone fracture fixation procedures." (4)

The Halifax SR Suite 1.0 (Halifax Biomedical, Inc., Mabou, Nova Scotia, Canada) was cleared for marketing by the FDA under the 510(k) process in June 2012. According to FDA documentation, the Halifax SR Suite 1.0 has "two regulatory approved x-ray imaging systems; the two systems are integrated through a synchronization switch. The switch allows the two x-ray imaging systems to fire simultaneously, providing a pair of x-ray images from different perspectives to be taken at the exact same time." The predicate device was the Sedecal Millennium Digital Radiographic System. The two systems used for the same generator. The manufacturer's labeled indications for use state, "This is a stationary digital x-ray system for general radiography and RSA." (4)

The MBRSA Software (Halifax Biomedica, Inc., Mabou, Nova Scotia, Canada), a Windows-based software only, was cleared for marketing by the FDA under the 510(k) process in March 2014 as a radiologic system image processing picture archiving and communication system. The predicate device from Medis Medical Imaging Systems (Leiden, The Netherlands), known as the Ortho-CMS (CMS=high resolution film) cleared for marketing as a 510(k) in July 2004 by the FDA. The manufacturer's indications for use are as follows: "Orthopedic specialists and/or Halifax Biomedical Inc. image processing labs use the MBRSA as a standalone analytical software package for evaluation of orthopedic implant fixation, bone segment motion… when interpreted by trained physicians these measurements may be useful to derive conclusions for patient treatment." According to the FDA information, the 3D may provide information regarding loosen of implants, wear of implants, and excessive or reduced motion between bones such as in spine instability and spine fusion. (7)

In 2018, Halifax Biomedical Inc. received 510(k) clearance from the FDA for its Halifax Radiosteometry Upgrade (K182880). The Halifax Upgrade technology adds to GE Healthcare's Discovery XR656/XR656 Plus x-ray imaging units to provide ultra-high precision in vivo 3D measurements. This is the first product to be launched under a joint development agreement between Halifax Biomedical Inc. and GE Healthcare. The procedure requires taking two simultaneous x-rays of the patient's anatomy from two different views. The HALIFAX UPGRADE comprises an L-arm imaging device with an x-ray tube that synchronizes with the XR656 x-ray tube and GE state-of-the-art imaging plates to take two high quality digital x-rays at the same time. (8)

## Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function--including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Radiostereometric Analysis (RSA)**

RSA has been increasingly utilized for the assessment of 3-dimensional (3D) migration patterns of orthopedic implants, particularly total joint prosthesis. There is an urgent need for the manufacturers, the regulators, and the research community to come together to agree on the statistical objectives of trials using RSA methodology and to provide clear guidelines for their implementation. (9)

In a 2014 systematic review, Madanat et al. evaluated adherence of hip and knee arthroplasty studies to RSA standardization guidelines. (10) 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 2017, Derbyshire et al. reviewed a new 2-D radiographic wear measurement system and compared it to current RSA practices. (11) RSA requires expensive software, special training, and a special dual X-ray machine set-up – all of which preclude its routine clinical use. The 2-D software was validated using radiographic images of a measurement jig which could vary the polyethylene (PE) cup orientation and simulate the effect of pelvic tilt/rotation. The study concluded that there is a need for surveillance of all PE cups but not all cups are manufactured with fully circular wire markers. A further limitation is that wear cannot be measured accurately if the radiographic version of the cup is very low (few degrees) because an ellipse cannot be fitted to the wire marker image due to merging of its opposite sides.

Christensen et al. (2022) conducted an assessment of knee kinematics with dynamic radiostereometry. (12) Radiostereometic analysis (RSA) is a precise method for the functional assessment of joint kinematics. Traditionally, the method is based on tracking of surgically implanted bone markers and analysis is user intensive. In recent years, new approaches using dynamic RSA (dRSA) to precisely measure the motion of bones and migration of implants have been researched. New RSA methods are based on virtual software matching of 3D models of either bones or implants to two-dimensional (2D) images of dRSA recordings, so-called model-based RSA. This study proposed an automated method of analysis based on models generated from computed tomography (CT) scans and digitally reconstructed radiographs. The automated CT bone model-based RSA method had a clinical precision comparable to that of marker-based RSA. The automated method is non-invasive, fast, and clinically applicable for functional assessment of knee kinematics and pathomechanics in patients. There is a need for an independent gold standard to perform a test of the absolute accuracy of the model-based digitally reconstructed radiographs (DRR) method. This effect inevitably becomes more evident as new methods to be validated become increasingly accurate.

**Orthopedic Implants**

Total Ankle Arthroplasty (TAA)

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 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. (13) 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. 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.

Distal Femur Fracture

A 2020 prospective cohort study by Galea and colleagues reported on 16 participants with distal femoral fracture. (14) 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.

Assessment of Spinal Fusion, Spinal Motion and Disorders

In a systematic review, Humadi et al. (2017) examined the accuracy of RSA, its assessment of spinal motion and disorders, and investigated the limitations of this technique in spine assessment. (15) 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 range of motion (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.

Extremity Fractures

Martinkevich et al. (2015) noted that lengthening osteotomies of the calcaneus in children are usually grafted with bone from the iliac crest. (16) 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.

Evaluation of Upper Limb Arthroplasty

A systematic review completed in 2017 by Ten Brinke et al. assessed early migration of prostheses of the upper limb. (17) Twenty-three studies were reviewed, and it was noted there was a lack of published studies for review. 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 International Organization for Standardization (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."

Other Uses

Early studies from the 1980's evaluated RSA for human growth measurement (Kärrholm et al. [2006] [18]). RSA has also been investigated as a tool to measure lateral calcaneal lengthening osteotomies (Martinkevich et al. [2015] [16]). These studies were all limited by a small number of participants.

Lee and Copp (2022) stated that fracture healing remains a complex process routinely evaluated in clinical practice with sequential radiographs. (19) Assessing the presence of union is a critical issue in patient care, with widespread implications in terms of overall decision-making and post-operative rehabilitation. Non-union assessment, whether it be with radiographs or more advanced imaging, has far-reaching consequences for the patient in addition to the healthcare system. These researchers examined new, emerging modalities for the assessment of fracture healing. They carried out a review of available evidence regarding the use of serologic markers and RSA, and the results were summarized. Emerging techniques to evaluate fracture healing have been evaluated, including the use of serologic markers as well as RSA; their potential applications extend beyond the simple assessment of a united fracture, with the capacity to predict non-union at earlier phases of care. The authors concluded that while early results appeared promising, the current application of serologic markers and RSA to evaluate fracture healing remains limited, and future larger-scale studies are needed to establish concrete and tailored guidelines for use.

ECRI conducted a review of RSA in 2014. (20) A review of the full text of 1 small clinical study (n=23) found that the data was insufficient to determine the efficacy of RSA (Halifax Biomedical) for assessing early implant migration. ECRI also reviewed evidence from a simulation study, and although this data may be somewhat informative, results cannot be extrapolated to actual clinical performance. "According to ECRI Institute's Health Devices engineering group, while the usefulness of RSA in a clinical setting seems limited at this time because it does not have the potential to provide an additional advantage over standard radiography, use of RSA in research setting to measure micromotion of newly developed implants/techniques seems warranted."

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in January 2024 did not identify any ongoing or unpublished trials that would likely influence this policy.

**Professional Guidelines and Position Statements**

There are no professional guidelines and position statements that would likely influence this policy.

**Summary of Evidence**

The use of radiostereometric analysis (RSA) is promising, but there is a lack of large randomized clinical trials comparing RSA to standard radiographs or computed tomography in determining implant placement, migration, bone healing, soft tissue healing that has not been established. As a result, RSA is considered experimental, investigational, and/or unproven as an alternative to current methods to monitor musculoskeletal healing and/or surgical intervention management.

## Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

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| **CPT Codes** | 0347T, 0348T, 0349T, 0350T |
| **HCPCS Codes** | None |

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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## Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

| Policy History/Revision | |
|---|---|
| **Date** | **Description of Change** |
| 12/31/2025 | Document became inactive. |
| 03/15/2025 | Document updated with literature review. Coverage unchanged. References 8, 9, and 12 added; and one removed. |
| 03/15/2024 | Reviewed. No changes. |
| 03/15/2023 | Document updated with literature review. Coverage unchanged. Reference 17 added. |
| 08/15/2022 | Reviewed. No changes. |
| 01/01/2022 | Document updated with literature review. Coverage unchanged. References 4, 9-14, and 16 added. |
| 10/15/2020 | Reviewed. No changes. |
| 04/01/2019 | Document updated with literature review. Coverage unchanged. Reference 11 added; none removed. |
| 10/15/2017 | Reviewed. No changes. |
| 10/01/2016 | Document updated with literature review. Coverage unchanged. |
| 05/15/2015 | Reviewed. No changes. |
| 07/01/2014 | New medical document. Radiostereometric analysis (RSA) for assessment of orthopedic implant position, wear, migration, soft tissue healing, and/or bone segment grafting or cement migration or loosening, with or without use of implanted markers and/or computer software aided digital views/interpretation, is considered experimental, investigational and/or unproven. |