

Diagnostic Dynamic Spinal Visualization and Vertebral Motion Analysis (for Mississippi Only)

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Instructions for Use

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| Related Policies | |
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| None | |
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Application

This Medical Policy only applies to the state of Mississippi Only.

Coverage Rationale

The following dynamic spinal visualization techniques when used to visualize movement of the back or spine are unproven and not medically necessary due to insufficient evidence of efficacy.

- Digital motion x-ray of the spine
- Cineradiography/videofluoroscopy

Vertebral motion analysis is unproven and not medically necessary due to insufficient evidence of efficacy.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| CPT Code | Description |
|----------|---|
| 0693T | Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report |
| 76120 | Cineradiography/video radiography, except where specifically included |

| CPT Code | Description |
|----------|---|
| 76125 | Cineradiography/video radiography to complement routine examination (List separately in addition to code for primary procedure) |
| 76496 | Unlisted fluoroscopic procedure (e.g., diagnostic, interventional) [when specified as videofluoroscopy] |
| 76499 | Unlisted diagnostic radiographic procedure |

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Description of Services

Dynamic spinal visualization is a general term addressing different imaging technologies that simultaneously visualize spine (vertebrae) movements and external body movement.

Digital motion x-ray involves the use of either film x-ray or computer-based x-ray 'snapshots' taken in sequence as an individual moves in front of an x-ray camera. Film x-rays are digitized into a computer for manipulation while computer-based x-rays are automatically created in a digital format. The digitized snapshots are then put in order using a computer program and played on a video monitor, creating a moving image of the inside of the body. This moving image can then be evaluated by a physician alone or by using a computer that evaluates several aspects of the body's structure to determine the presence or absence of abnormalities.

Videofluoroscopy and cineradiography are different names for the same procedure that uses fluoroscopy to create real-time video images of internal body structures. Videofluoroscopy works like a video camera, providing motion pictures of the inside of the body. The results of these techniques can be displayed on a video monitor as the procedure is being conducted. They can also be viewed or digitally analyzed at a later time.

Vertebral motion analysis systems provide assisted bending with fluoroscopic imaging and computerized analysis. The device uses facial recognition software to track vertebral bodies across the images. Proposed benefits of the vertebral motion analysis are a reduction in patient-driven variability in bending and assessment of vertebral movement across the entire series of imaging rather than at the end range of flexion and extension bending with fluoroscopic imaging and computerized analysis.

Clinical Evidence

Cineradiography/Video Radiography

The current literature evaluating the clinical utility of dynamic spinal visualization techniques, including but not limited to digital motion x-ray and cineradiography (video fluoroscopy), for the evaluation and assessment of the spine is limited to a few studies (Lee et al., 2002; Teyhen et al., 2007; O'Sullivan et al., 2012; Yaeger et al., 2014; Qu et al., 2019) involving small numbers of participants. While these studies do indicate that there may be some benefit from the use of these technologies, further evidence from large, controlled trials is needed to demonstrate that the results have significant impact on clinical care and are superior to currently available alternatives.

ECRI (2023) performed a clinical evidence assessment for Dynamic Spinal Visualization for assessing Lumbar Spine Abnormalities. They concluded that evidence from one cohort study and two diagnostic cohorts on dynamic MRIs compared with flexion/extension radiography provide no evidence that dynamic spinal visualization improves patient outcomes or diagnoses for patients with lumbar spine abnormalities. The studies suggests that dynamic spinal visualization may identify lumbar abnormalities; however, too few data exist per dynamic visualization technique, and the studies are of too low quality to provide conclusive evidence.

Knippenberg et al. (2017) conducted a systematic review to investigate 1) which markerless motion capture systems (MCS) are used as training devices in neurological rehabilitation, 2) how they are applied, 3) in which target population, 4) what the content of the training and 5) efficacy of training with MCS. A computerized systematic literature review was conducted in four databases (PubMed, Cinahl, Cochrane Database and IEEE). The Van Tulder's Quality assessment was used to score the methodological quality of the selected studies. The descriptive analysis is reported by MCS, target population, training parameters and training efficacy. Eighteen studies were selected (mean Van Tulder score = 8.06 ± 3.67). Based on methodological quality, six studies were selected for analysis of training efficacy. The most commonly used MCS was Microsoft

Kinect, training was mostly conducted in upper limb stroke rehabilitation. Training programs varied in intensity, frequency, and content. None of the studies reported an individualized training program based on client-centered approach. The investigators concluded that markerless motion capture systems have the potential in neurological rehabilitation to increase the motivation during training and may assist improvement on one or more International Classification of Functioning, Disability and Health (ICF) levels. Future technological developments should take up the challenge to combine markerless MCS with the principles of a client-centered task-oriented approach and prove efficacy using randomized controlled trials (RCTs) with long-term follow-up. According to the investigators, because there are few RCTs and controlled clinical trials and few studies with long-term follow-up, it is difficult to prove efficacy of markerless MCS based on the studies included in this review.

Springer and Seligmann (2016) evaluated the literature describing the concurrent validity of using the Kinect as a gait analysis instrument. The Kinect consists of an array of sensors, including a camera and a depth sensor, enabling the Kinect to track and record 3D human motion without using controllers or markers. An online search of PubMed, CINAHL, and ProQuest databases was performed. Included were studies in which walking was assessed with the Kinect and another gold standard device and consisted of at least one numerical finding of spatiotemporal or kinematic measures. The search identified 366 papers, from which 12 relevant studies were retrieved. The results demonstrate that the Kinect is valid only for some spatiotemporal gait parameters. Although the kinematic parameters measured by the Kinect followed the trend of the joint trajectories, they showed poor validity and large errors. The authors concluded that Kinect may have the potential to be used as a tool for measuring spatiotemporal aspects of gait, yet standardized methods should be established, and future examinations with both healthy subjects and clinical participants are required in order to integrate the Kinect as a clinical gait analysis tool.

Vertebral Motion Analysis

For individuals who have back or spine pain who receive vertebral motion analysis, the evidence includes comparisons to standard flexion/extension radiographs. These studies reported that vertebral motion analysis reduces variability in measurement of rotational and translational spine movement compared with standard flexion/extension radiographs. Whether the reduction in variability improves diagnostic accuracy or health outcomes is uncertain. The evidence is insufficient to determine if the effects of the technology will positively impact clinical health outcomes.

Hurley et al. (2021) compared leg length measurements (LLM) and varus/valgus knee measurements (VVM) performed clinically, radiologically and using markerless motion analysis (MMA) in patients being assessed for potential total knee replacement (TKR). Twenty-three patients awaiting unilateral primary TKR were included in the study. According to the authors, the most important finding of this study was that significant differences were reported between results obtained for calculating LLM and VVM clinically, radiologically and using MMA. As much of the literature has previously validated the use of clinical and radiological in obtaining LLM, this study poses the question as to whether the results obtained using MMA for LLM and VVM can be utilized.

van Kersbergen et al. (2021) investigated whether a consumer depth camera can capture changes in gait features of Parkinson's patients. The dataset consisted of 19 patients (tested in both a practically defined OFF phase and ON phase) and 8 controls, who performed the "Timed-Up-and-Go" test multiple times while being recorded with the Microsoft Kinect V2 sensor which records Red-Green-Blue (RGB)-depth data and tracks 25 anatomical landmarks in 3D space without the need for body-attached sensors or markers. Camera-derived features were step length, average walking speed and mediolateral sway. Motor signs were assessed clinically using the Movement Disorder Society Unified Parkinson's Disease Rating Scale. The authors were able to detect group differences in gait features between people with PD and healthy controls using the Kinect depth camera. However, the current task setup and analysis approach lacks sensitivity to detect small intra-individual changes in symptom severity. According to the authors, limitations of this study include the small sample size, subjects with relatively mild symptoms and a not complete age match with the control population. The standard outcome for the TUG (task duration) could not be analyzed because of missing frames at the beginning of the recording.

In a clinical case study, Schroeder et al. (2020) evaluated whether a markerless system for three-dimensional motion capture from RGB depth sequences using a whole-body infant model can serve as the basis for automated General Movement Assessment (GMA). The 29 high risk infants that were included in the study were assessed at their clinical follow-up at 2-4 month corrected age (CA). Their neurodevelopmental outcome was assessed regularly up to 12-31 months CA. GMA was used as the study outcome measure. The GMA was completed by one of the study authors and by a masked GMA-expert of conventional and computed 3D body model ("SMIL motion") videos of the same general movements (GMs). Agreement between both GMAs was tested using dichotomous and graded scaling with Kappa and intraclass correlations, respectively. Sensitivity and specificity to predict cerebral palsy (CP) at ≥ 12 months CA were assessed. The authors concluded that this

study demonstrates that the amount of motion details captured by the Skinned Multi-Infant Linear Model (SMIL) motion video (based on a Kinect recording and the KineMAT tool) enables accurate GMA at fidgety age. According to the authors, this implies that the SMIL motion video adequately catches the movement characteristics needed for GMA of infants with movements ranging from a normal to a definitely abnormal quality, turning it into an attractive tool for automatic GMA. The authors indicated that study limitations included a small sample size, the inclusion of high-risk infants only, and short follow-up. There is no evidence from this study that the markerless motion capture system will impact patient management.

In a systematic review, Puh et al. (2019) evaluated the validity and reliability of using the Kinect camera (a markerless motion capture system) as an assessment tool for transitional movement and balance. A total of 21 research articles, published from 2012 to 2018, were included in the analysis and qualitative synthesis. Many of the included studies reported validity and did not report reliability, which limited the application to practice. According to the authors, the translation into practice for Kinect is also limited by lack of redundancy among studies and access to the software to implement the tests.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Products used for diagnostic dynamic spinal visualization and vertebral motion analysis are extensive. Refer to the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

References

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Policy History/Revision Information

| Date | Summary of Changes |
|------------|---|
| 12/01/2023 | Coverage Rationale Replaced language indicating "vertebral motion analysis is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy" with "vertebral motion analysis is unproven and not medically necessary due to insufficient evidence of efficacy" |
| | Supporting Information Updated Clinical Evidence and References sections to reflect the most current information Archived previous policy version CS254MS.A |

Instructions for Use

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