

Subject: 3D Interpretation and Reporting of Imaging Studies		Original Effective Date: 12/12/2012
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PREFACE

This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the following website: <http://www.cms.hhs.gov/center/coverage.asp>.

FDA INDICATIONS

3D Interpretation and Reporting of Imaging Studies is a procedure not subject to FDA regulation.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

CMS does not have a NCD for 3D Imaging Studies. There are various LCD's that outline specific limited coverage criteria for 3D Interpretation and Reporting of Imaging Studies, CPT codes: 76376 & 76377. These LCD's indicate that CPT codes 76376 and 76377 may be considered medically unnecessary and denied if equivalent information obtained from the test has already been provided by another procedure (magnetic resonance imaging, ultrasound, angiography, etc.) or could be provided by a standard CT scan (two-dimensional) without reconstruction. CMS rules outline that no more than 20 percent of the total Computerized Tomography (CT) and Magnetic Resonance (MR) imaging of any practice be submitted with 3-D rendering or interpretation, with or without image post-processing. For non-hospital based outpatient services, CMS requires that the referring physician will generate a written request indicating the clinical need for the additional 3-D imaging, a copy of that request will be maintained by the interpreting physician, and the interpreting physician's report will address those specific clinical issues. In the event that a 3-D interpretation is deemed urgently needed by the radiologist and the referring physician is not immediately available, the radiologist must document the time of the study, the specific need for the study, and a summary of the findings that were urgently transmitted to the practitioner named as the referring physician on the radiology report. ¹

INITIAL COVERAGE CRITERIA

1. Three dimensional (3D) rendering of computed tomography (CT) or magnetic resonance imaging (MRI) requiring image postprocessing on an independent workstation (CPT code 76377) is considered medically necessary *only* under the following circumstances ¹: [ONE]
 - When the information to be obtained from the test cannot be provided by another procedure (magnetic resonance imaging, ultrasound, angiography, etc.), **or**
 - When the information could not be provided by a standard CT scan (two-dimensional) without reconstruction, **AND**
 - For preoperative planning in any of the following clinical circumstances: [ONE]
 - Congenital skull abnormalities (e.g. craniosynostosis) in infants and children ^{22 27}
 - Complex craniofacial reconstructive surgery and including facial fractures ^{8 14 15 16 27}
 - Complex pelvic joint fractures ^{7 28 29}
 - Complex spine fractures ^{18 21 26}
 - Craniocervical abnormalities ^{27 31}
 - Scoliosis surgery ^{18 27}
2. CPT code 76376 (3D rendering not requiring image post-processing on an independent workstation) should not be separately reimbursed, since this function is built into the imaging software and generally takes less than 15 minutes to perform. ^{19 20}
3. The 3D imaging service must be clearly described as a separate documentation in the radiology report and submitted for review.

CONTINUATION OF THERAPY

Not Applicable

COVERAGE EXCLUSIONS

The following services are excluded and not covered:

1. 3D rendering CPT codes 76376 & 73677 are considered an inherent component cannot be reported with ANY of the following procedures ^{2 4 5}:
 - Computed tomographic angiography (CTA) of the head, neck, chest, pelvis, upper and lower extremity, abdomen, and abdominal aorta, and bilateral iliofemoral lower extremity vessels includes CPT codes: (70496-70498, 71275, 72191, 73206, 74175, 75635)
 - Magnetic resonance angiography (MRA) of the head, neck, chest, spinal canal, pelvis, upper and lower extremities, and abdomen includes CPT codes: (70544-70549, 71555, 72159, 72198, 73225, 73725, 74185)
 - Positron emission tomography (PET) tumor imaging includes CPT codes: (78811-78816)
 - Computed tomographic (CT) colonography (virtual colonoscopy) includes CPT codes: (74261-74263)
 - Cardiac magnetic resonance imaging (MRI) includes CPT codes: (75557-75565)
 - Computed tomography (CT) heart and (CTA) heart, coronary arteries and bypass grafts includes CPT codes: (75571-75574)
 - Nuclear Medicine Series includes CPT codes: (78000-78999)
 - Computer-aided detection includes CPT code: (0159T)

2. CPT 76376 (3D rendering not requiring image post-processing on an independent workstation) should not be separately reimbursed, since this function is built into the imaging software and generally takes less than 15 minutes to perform.^{19 20}

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Three dimensional images called 3D reconstruction or 3D rendering is a distinct diagnostic procedure that describes a separate procedure or process that can be applied to computed tomography (CT), magnetic resonance imaging (MRI), ultrasound or other tomographic modality. Having 3D capability available for diagnosis and surgical planning allows the interpreting physician to first get a summary view of the entire anatomy and then refer back to the original 2D data for comparison and confirmation. 3D imaging takes multiple thin-section, usually axial, images and reconstructs them into a 3D image. The dataset then can be manipulated, rotated into different views, allowing for a better understanding of the relationship of one structure to another or of what a structure looks like along its length as opposed to just on a single transaxial image. By appropriate shading and coloring and perspective a 3D volume rendering of the information is useful in surgical planning and in identifying critical areas for avoidance or targeting. Applications of this technology include visualization of central nervous system vasculature, coronary artery imaging, enhanced imaging of the thorax to include embolic disease, inflammatory and neoplastic lesions, imaging of facial malformations, complex facial fractures/trauma, aortic aneurysms and multiple others.^{19 20}

The physician will supervise and/or create the 3D reconstructions and adjust the projection to optimize visualization of anatomy or pathology for the 3D reconstruction performed on an independent workstation and the physician will discuss with the technologist the need for 3D imaging and supervise the technologist in creating 3D images for studies not requiring image post-processing on an independent workstation. The 3D rendering codes are intended to address complex renderings such as shaded surface rendering, volumetric rendering, maximum intensity projections, fusion of images from other modalities, and quantitative analysis (segmental volumes and surgical planning).

GENERAL INFORMATION

Summary of Medical Evidence

Breast Mammography: Bernardi and colleagues (2012) prospectively evaluated the effect of integrating 3D mammography as a triage to assessment in 158 consecutive recalls to assessment (recalled in standard 2D-mammographic screening) in asymptomatic subjects. Radiologists provided 3D mammography-based opinion as to whether recall/assessment was warranted or unnecessary, and all subjects proceeded to assessment. 3D triage was positive (confirmed the need for assessment) in all 21 subjects with breast cancer (there were no false negatives), and would have avoided recall in 102 of 137 (74.4%) subjects with a negative/benign final outcome in whom 3D triage did not recommend recall. Proportion of true negative 3D triage (as a proxy for potential reduction in recalls) was slightly higher in dense than non-dense breasts, did not differ across age-groups, but was significantly associated with the type of lesion seen on imaging (being highest for distortions, asymmetric densities, and lesions with ill-defined margins). While the simulation design may have over-estimated the potential for 3D mammography triage to reduce recalls, this study clearly demonstrates its capability to improve breast screening specificity and to reduce recall rates. The authors concluded that future studies of 3D mammography should further assess its role as a recall-reducing strategy in screening practice and should include formal cost-analysis although early studies suggest that it may improve specificity.

Skaane and colleagues (2012) compared digital mammography and Digital breast tomosynthesis (DBT) in a side-by-side feature analysis for cancer conspicuity, and to assess whether there is a potential additional value of DBT to standard state-of-the-art conventional imaging work-up with respect to detection of additional malignancies. A total of 129 women underwent 2D digital mammography including supplementary cone-down and magnification views and breast ultrasonography if indicated, as well as digital breast tomosynthesis. The indication for conventional imaging in the clinical setting included a palpable lump in 30 (23%), abnormal mammographic screening findings in 54 (42%), and surveillance in 45 (35%) of the women. The women were examined according to present guidelines, including spot-magnification views, ultrasonography, and needle biopsies, if indicated. The DBT examinations were interpreted several weeks after the conventional imaging without knowledge of the conventional imaging findings. In a later session, three radiologists performed a side-by-side feature analysis for cancer conspicuity in a sample of 50 cases. Conventional imaging resulted in needle biopsy of 45 breasts, of which 20 lesions were benign and a total of 25 cancers were diagnosed. The remaining 84 women were dismissed with a normal/definitely benign finding and without indication for needle biopsy. The subsequent DBT interpretation found suspicious findings in four of these 84 women, and these four women had to be called back for repeated work-up with knowledge of the tomosynthesis findings. These delayed work-ups resulted in two cancers (increasing the cancer detection by 8%) and two false-positive findings. The side-by-side feature analysis showed higher conspicuity scores. The reviewers concluded that there is a potential for increasing the sensitivity using this new technique, especially for cancers manifesting as spiculated masses and distortions.²⁴

Gur and colleagues (2012) retrospectively compared the interpretive performance of synthetically reconstructed two-dimensional images in combination with digital breast tomosynthesis (DBT) versus full-field digital mammography (FFDM) plus DBT. Ten radiologists trained in reading tomosynthesis examinations interpreted retrospectively, under two modes, 114 mammograms. One mode included the directly acquired full-field digital mammograms combined with DBT, and the other included synthetically reconstructed projection images combined with DBT. The reconstructed images do not require additional radiation exposure. The two modes were compared with respect to sensitivity, namely, recommendation to recall a breast with either a pathology-proven cancer ($n = 48$) or a high-risk lesion ($n = 6$), and specificity, namely, no recommendation to recall a breast not depicting an abnormality ($n = 144$) or depicting only benign abnormalities ($n = 30$). Results: The average sensitivity for FFDM with DBT was 0.826, compared to 0.772 for synthetic FFDM with DBT (difference, 0.054; $P = 0.17$ and $P = 0.53$ for fixed and random reader effects, respectively). The proportions of breasts with no or benign abnormalities recommended to be recalled were virtually the same: 0.298 and 0.297 for the two modalities, respectively (95% confidence intervals for the difference, -0.028 to 0.036 and -0.070 to 0.066 for fixed and random reader effects, respectively). Sixteen additional clusters of microcalcifications ("positive" breasts) were missed by all readers combined when interpreting the mode with synthesized images versus FFDM. The authors concluded that lower sensitivity with comparable specificity was observed with the tested version of synthetically generated images compared to FFDM, both combined with DBT. Improved synthesized images with experimentally verified acceptable diagnostic quality will be needed to eliminate double exposure during DBT-based screening.²⁵

Endometriosis: Bazot and colleagues (2012) evaluated image quality and diagnostic accuracy of two- (2D) and three-dimensional (3D) T2-weighted magnetic resonance imaging (MRI) for the evaluation of deep infiltrating endometriosis (DIE). One hundred and ten consecutive patients with suspicion of endometriosis were recruited at two institutions over a 5-month period. Twenty-three women underwent surgery, 18 had DIE at histology. 3D yielded significantly lower image quality than 2D MRI ($p < 0.0001$). Acquisition time for 3D was significantly shorter than 2D MRI ($p < 0.01$). 3D offered similar accuracy to diagnose DIE compared to 2D MRI. The authors concluded that despite a lower overall image

quality, 3D provides significant time saving and similar accuracy than multiplanar 2D MRI in the diagnosis of specific DIE locations.¹⁰

Extremity Tumors: Dong and colleagues (2011) evaluated the role of three-dimensional (3D) reconstruction of extremity tumor regions for patient-specific preoperative assessment and planning by using CT and MRI image data fusion. The CT and MRI image data of five patients with solid tumors were fused together to construct 3D models of the respective tumor regions. The reconstruction time and image fusion accuracy were measured, and the tumor features and spatial relationships were analyzed to enable subject-specific preoperative assessment and planning as guidance for tumor resection. The 3D models of the tumor regions, including skin, fat, bones, tumor, muscles, internal organs, nerves and vessels were created with a mean reconstruction time of 103 minutes and fusion accuracy of 2.02mm. The 3D reconstruction clearly delineated the tumor features, and provided a vivid view of spatial relationships within the tumor region. Based on this intuitional information, the subject-specific preoperative assessment and planning were accomplished, and all tumor resections were performed as planned preoperatively. The authors concluded that three-dimensional reconstruction using CT/MRI image fusion is feasible for accurate reproduction of the complex anatomy of the tumor region with high efficiency, and can help surgeons improve the preoperative assessment and planning for effective removal of tumors.¹¹

Facial Fractures: Kaur and Chopra (2010) evaluated the role of three dimensional computed tomography in comparison to conventional radiography for the diagnosis and management of mid face fractures. A case study of 100 patients with mid face fractures were included (80 male patients, 20 female patients). After clinical examination patients were subjected to conventional radiographs. To arrive at correct diagnosis and treatment plan, each patient was subjected to 3D reconstruction. Based on the etiology road traffic accidents (75%) were the most common, followed by assault (16%), fall (7%) and sports related accidents (2%). In 28 cases (28%) 3D CT had significant bearing in final diagnosis and treatment planning of mid face fractures. The authors concluded that 3D CT is valuable in case of severe facial injury, enabling a clear perception of extent of major fracture line and resulting displacement of fragments. So this new modality permits preoperative analysis and surgical planning as compared to conventional radiography in case of mid face fractures.⁸

Kim and colleagues (2010) completed a prospective study that included 533 consecutive patients who underwent three-dimensional images with 64-section multidetector-row CT for the evaluation of a facial bone fracture between June 2007 and May 2008 (366 males; 167 females; mean age +/- standard deviation 31.1+/-21.2 years; age range 1-92 years). Two observers independently scored the possibility of a nasal bone fracture on axial and sagittal images. Receiver operating characteristic (ROC) curve analysis was performed. The results showed that the AZ values of the sagittal images were higher than those of the axial images for both observers ($p=0.002$ and 0.010 , respectively) with higher accuracy ($p<0.001$ and 0.016 , respectively). The sensitivities of sagittal images were superior to those of axial images, especially for type 1 simple nasal bone fractures with no or minimal displacement (observer 1, 98.6 versus 72.8%; observer 2, 84.9 versus 71%). The authors concluded that sagittal MPR facial bone CT images provided superior diagnostic performance, and their addition to axial images is useful for the evaluation of nasal bone fractures.¹⁴

Kwon and colleagues (2009) performed a comparative study using 2 different 3-D software programs to measure the orbital volume of unilateral pure blowout fractures with computed tomography before and after surgery. Twenty-four patients were evaluated with facial computed tomographic scans before and after surgery. Both the orbital volume and the displaced soft tissue volume were measured by 2 operators using 2 different 3-D software programs (Vitrea; Vital Images Inc, Minnetonka, Minnesota; and Dextroscope; Bracco AMT Inc, Princeton, NJ). The mean (SD) normal orbital

volumes calculated by Vitrea and Dextroscope were 25.5 (2.4) mL and 24.8 (3.0) mL, respectively. The average preoperative orbital volumes were 28.3 (2.3) mL and 27.6 (3.1) mL, while the postoperative volumes were 25.8 (2.5) mL and 24.9 (3.0) mL. Vitrea showed that the average volume of displaced orbital soft tissue was 2.8 (1.9) mL before surgery and that it was reduced to 0.3 (1.3) mL after surgery, while Dextroscope showed that the average displaced orbital soft tissue was 2.9 (1.4) mL before surgery and that it was reduced to 0.1 (1.2) mL after surgery. There was no statistical difference between the 3-D analysis programs. The author's analysis concluded that consistent volume measurements can be obtained using different 3-D image analysis programs. Measuring preoperative and postoperative volume changes and postoperative reduction can ensure a good surgical result and thereby decrease the incidence of enophthalmos.¹⁵

Jasbir and colleagues (2010) completed a comparative study to evaluate the role of three dimensional computed tomography in comparison to conventional radiography in diagnosis and management of mid face fractures. One hundred patients with mid face fractures were included in this study. After clinical examination patients were subjected to conventional radiographs. To arrive at correct diagnosis and treatment plan, each patient was subjected to 3D reconstruction. Out of hundred patients of maxillofacial trauma 80% were male and 20% were females. Based on the etiology road traffic accidents (75%) were the most common, followed by assault (16%), fall (7%) and sports related accidents (2%). In 28 cases (28%) 3D CT had significant bearing in final diagnosis and treatment planning of mid face fractures. The authors concluded that the analysis showed 3D CT is valuable in case of severe facial injury, enabling a clear perception of extent of major fracture line and resulting displacement of fragments. So this new modality permits preoperative analysis and surgical planning as compared to conventional radiography in case of mid face fractures.¹⁶

Jaw Lesions: Yuan and colleagues (2008) assessed the value of multi-slice spiral CT (MSCT) with three dimensional (3D) reconstruction in the diagnosis of neoplastic lesions in the jawbones. Thirty-three patients with neoplastic lesions of the jawbones underwent MSCT scanning with 3D reconstruction. Of these patients, 14 had ameloblastoma, 8 had hemangioma, 3 had osteosarcoma, 3 had ossifying fibroma, 2 had chondrosarcoma, 2 had fibrosarcoma, and 1 had odontogenic myxoma. Preoperative MSCT scanning was performed with the slice thickness of 2 mm, and 3D reconstruction of the images was conducted by means of multi-planar reconstruction (MPR), curved-planar reformation (CRP), and 3D volume rendering technique (VRT). The results were compared with those observed during the operations. In the 33 cases, the neoplastic lesions of the jawbones were displayed by 2D or 3D imaging and confirmed by intraoperative findings. Two-dimensional imaging allowed better observation than 3D imaging of the deep structures, whereas 3D imaging was superior in visualizing the morphological changes of the compromised bones and the spatial relationship between the tumors and surrounding structures. Two-dimensional imaging and MPR were excellent in revealing the internal structures and pathological changes of tumors, having also better performance in showing the tumors involving the soft tissues. Benign tumors were most visualized as bone expansion changes with well defined ovoid or lobulated borderlines, and malignant ones often resulted in adjacent bony destruction and soft tissue masses. The authors concluded that MSCT examination is useful in defining the scope of tumor involvement and bony changes to help in the definite diagnosis, differential diagnosis and choice of clinical treatment. Two-dimensional imaging, MPR, VRT and CRP have their respective advantages and limitations in showing jawbone tumor, and their combination can be of great clinical value.⁶

Dai and colleagues (2012) sought to demonstrate the feasibility of two- and three-dimensional (2D and 3D) models based on computed tomography-magnetic resonance imaging (CT-MRI) image fusion for the visualization of jaw tumors. Both preoperative CT and MRI image data were acquired from seven patients with jaw tumors. The structures including tumor, muscle, and vascular were segmented based on different thresholds and reconstructed in 3D texture. CT-MRI

image fusion was semi-automatically performed to obtain the fused 2D images and 3D models for the visualization of jaw tumors. The qualities of the fused 2D images and 3D models together with their potential applications in surgical management of jaw tumors were qualitatively assessed. Computed tomography-MRI image fusion showed the relationship between tumors and adjacent structures. The authors concluded that despite some limitations, the 2D images and 3D models based on CT-MRI image fusion can provide a powerful tool for the visualization of jaw tumors. It may offer surgeons an assisted tool for the subject-specific preoperative planning, surgical simulation, and intraoperative guidance for jaw tumors.¹²

Musculoskeletal: Kijowski (2011) reviewed the clinical applications of three-dimensional sequences for musculoskeletal MR imaging by comparing multiple studies with surgical correlation. The diagnostic performance of three-dimensional sequences was evaluated for detecting cartilage lesions within the knee joint. The results of these studies indicated that on 1.5T imaging systems, three-dimensional sequences have sensitivity values ranging between 85% to 45% with specificity values ranging between 78% and 97%. On 3.0T imaging systems, three-dimensional sequences have sensitivity values ranging between 66% to 73% with specificity values ranging between 89% and 94%. Other studies reviewed 3D applications in the hip, ankle, shoulder; elbow and wrist joints and similar outcomes were found. The author concluded that few studies have directly compared two-dimensional and three-dimensional sequences for detecting joint pathology. For this reason, the clinical benefits of using three-dimensional sequences remain unknown. Additional studies are needed to determine whether three-dimensional isotropic sequences resolution can be used to provide rapid comprehensive joint assessment in clinical practice.⁹

Orthognathic Surgery: Plooi and colleagues (2010) performed a systematic review of digital three-dimensional image fusion processes for planning and evaluating orthodontics and orthognathic surgery. A systematic search of current literature on image fusion in the craniofacial area was performed. 15 articles were found describing 3D digital image fusion models of two or more different imaging techniques for orthodontics and orthognathic surgery. The authors concluded that from these articles image fusion and especially the 3D virtual head are accurate and realistic tools for documentation, analysis, treatment planning and long term follow up and may provide an accurate and realistic prediction model.¹³

Pelvic Fractures: Lee and associates (2011) performed a 3-dimensional multi detector computed tomography study to analyze the optimal trajectory of the transsacral iliac screw (TSIS) to overcome the disadvantages of the conventional iliac screw. Three-dimensionally reconstructed multi detector computed tomography images on the pelvis of 60 patients (M:F=30:30, age 20 to 50) were analyzed. The virtual trajectory started from the point where the center of S2 ala met the lateral sacral crest and targeted the superior rim of acetabulum, across the sacroiliac joint. On the basis of the virtual trajectory, the oblique sagittal, oblique axial, oblique coronal plane, and 3-dimensional surface rendering images were obtained. The optimal insertion angle in the 3 planes, the maximal length and diameter of screw were measured. Relationships between the trajectory and structures under risk were analyzed. The authors concluded that the TSIS could be safely inserted without increasing the general risk of conventional iliac screw and that the TSIS technique is a useful option for lumbo-pelvic fixation to overcome disadvantages of iliac screw.²⁹

Pérez and colleagues (2010) published a retrospective review of patients who had undergone surgery for complex pelvic fractures during a 15-month period. The purpose was to determine the utility of 3D computed tomography for the preoperative planning of pelvic rim fractures assessing possible changes in fracture classification as well as in the surgical indication itself. The mechanism of injury was recorded and the availability of a multi-slice spiral volumetric CT scan was requested as a preoperative study. Ten cases (58%) were pelvic rim fractures and 7 were acetabular fractures. The mean

ISS was 23.82 (9-50), and 82.3% of cases were severe traumas (ISS > 16). After the CT scan was obtained, the initial classification of the fracture was changed in four cases (23.5%), without any changes in the surgical indication. An artifact was detected in the volumetric reconstruction but it did not limit the surgeon's interpretation. The authors concluded that tri-dimensional CT-based modeling is very helpful in the surgical planning of pelvic fractures and is a complement of the plain X-rays.⁷

Li and associates (2010) investigated the clinical value of spiral CT with multi-planar reconstruction (MPR) and three dimensions reconstruction (3D) in the diagnosis and treatment of pelvic ring fractures. Fifty-seven patients with pelvic ring fractures were examined with digital radiography and spiral CT from April 2004 to April 2009. Three days to twenty-seven months after operation, spiral CT examinations were used to evaluate the location of internal fixation. Cross-check analysis of images of digital radiography and spiral CT was performed before and after operation. Five posterior and three anterior pelvic ring fractures were diagnosed as suspected fractures. Nine posterior and three anterior pelvic ring fractures were miss-diagnosed according to plain radiographs, which were corrected by spiral CT examination. According to the postoperative imaging evaluation, the results were excellent in 15, good in 3 and poor in 1. According to clinical evaluation, 16 cases were excellent, 3 good. The reviewers concluded that spiral CT with multi-planar reconstruction (MPR) and three dimensions reconstruction (3D) has clinical values for precise diagnosis and treatment for the complex pelvic ring fractures.²⁸

Skull Abnormalities: Fatterpeckar and colleagues (2006) completed a retrospective study that included 82 patients who had undergone high-resolution CT of the temporal bone for the evaluation of complaints related to the auditory system. The temporal bone is a region of complex anatomy containing multiple small structures within a relatively compact area, which makes evaluation of this region difficult. By using 3D these images can be rotated in space and dissected in any plane, allowing assessment of the morphologic features of individual structures, including the small ossicles of the middle ear and the intricate components of the inner ear. Each scan was obtained on a 16-section spiral CT scanner. 3D VR CT images were generated from the original 2D data with TeraRecon Aquarius Workstation v3.3. The application of different soft tissue and bone algorithms to the 3D reformation permitted multiprojectional display of the various temporal bone structures, including the ossicles and the inner ear structures (eg, cochlea, vestibule, and semicircular canals). With use of a built-in 3D cut-plane software technique, individual temporal bone structures were “removed” and analyzed, allowing optimal display of microanatomic components such as the delicate osseous spiral lamina of the cochlea. Three-dimensional reformatted images were also obtained from temporal bone scans to more effectively demonstrate disease. The authors concluded that the use of submillimeter two-dimensional reconstruction from CT data in addition to 3D reformation allows depiction of microanatomic structures such as the osseous spiral lamina and hamulus. Furthermore, 3D VR CT images can be used to evaluate various conditions of the temporal bone, including congenital malformations, vascular anomalies, inflammatory or neoplastic conditions, and trauma. The additional information provided by 3D reformatted images allows a better understanding of temporal bone anatomy and improves the ability to evaluate related disease, thereby helping to optimize surgical planning.¹⁷

Spine: Jin and colleagues (2012) sought to explore the clinical application and outcomes of preoperative second measurement of 3-D CT reconstruction data for scoliosis orthopedic surgery. Between August 2006 and March 2008, 11 patients with severe rigid scoliosis received surgery treatment, including 4 males and 7 females with an average age of 17.2 years (range, 15-19 years). Preoperative second measurement of 3-D CT reconstruction data was conducted to guide the surgery, including the angle and width of pedicle, the entry point, and the choice of screws whose lengths and diameters were suitable. A total of 197 pedicle screws were implanted. The operation time, blood loss, postoperative nerve function, and Cobb's angles at sagittal and coronal view were all recorded, and the postoperative CT scan was performed to assess the accuracy of pedicle screw insertion according to Andrew classification. Pedicle screws were

implanted within 1-11 minutes (mean, 5.8 minutes), and the blood loss was 450-2 300 mL (mean, 1 520 mL). The postoperative X-ray films showed the correction rates of Cobb's angle were 68.5% in coronal view and 55.5% in sagittal view. The accuracy of pedicle screw insertion was rated as grade I in 77 screws (39.1%), grade II in 116 screws (58.9%), and grade III in 4 screws (2.0%) according to postoperative CT scan. All 11 cases were followed up 14 months to 2 years without any complications. The authors concluded preoperative second measurement of 3-D CT reconstruction data can make the surgery process easy and accurate in treatment of severe scoliosis.¹⁸

Bamba and colleagues (2011) described methods for obtaining 3D reconstructed CT-MR fusion images for preoperative planning of surgical procedures in a case series of 19 patients using the iPlan[®] (BrainLAB AG, Feldkirchen, Germany) neuronavigation software. 3D CT images of the vertebral bone were combined with heavily T(2)-weighted MR images of the spinal cord, lipoma, cerebrospinal fluid (CSF) space, and nerve root through a process of fusion, segmentation, and reconstruction of the 3D images. A procedure called image overlay was used to directly project the 3D reconstructed image onto the body surface using an LED projector. The final reconstructed 3D images took 10-30 minutes to obtain, and provided the surgeon with a representation of the individual pathological structures, so enabled the design of effective surgical plans, even in patients with bony deformity such as scoliosis. None of the 19 patients treated based on the 3D reconstruction method has had neurological complications, except for CSF leakage. The analysis by the authors concluded that 3D reconstructed imaging combined with Image Overlay, improves the visual understanding of complicated surgical situations, and should improve surgical efficiency and outcome.²¹

Lin and colleagues (2011) studied the methods and preliminary clinical efficacy of posterior lumbar minimally invasive surgery assisted by 3D-Viewer system under a direct vision and provide rationales for further clinical applications. From September 2008 to September 2009, a total of 84 lumbar degenerative disease patients were enrolled and randomly divided into 2 groups (n = 42 each). One group was treated operatively by 3D-Viewer system under a direct vision while another treated with conventional operations. The lumbar paraspinal muscle approach was employed. Surgery was assisted by 3D-Viewer system under a direct vision. The operative duration, intra-operative blood loss volume, CK (creatin kinase) levels at Days 1 & 7 post-operation, atrophic rates of cross-sectional areas of bilateral multifidus muscles on MRI (magnetic resonance imaging) at 12 months post-operation were recorded. At Month 12 post-operation, the therapeutic efficacy was evaluated by Oswestry disability index (ODI) and the post-operative clinical effects assessed. The operative duration, intra-operative blood loss volume and CK level at Days 1 & 7 post-operation were statistically different ($P < 0.05$); there was significant difference in the atrophic rates of cross-sectional areas of bilateral multifidus muscles on MRI and the improvement rates of ODI ($P < 0.001$); the therapeutic efficacy of the invasive group was significantly better than that of the group treated with traditional operations ($P < 0.05$). The authors concluded that the 3D-Viewer technique reduces the risk of damage. As an ideal minimally invasive procedure, it may achieve satisfactory outcomes for spinal diseases.²⁶

Nako and associates (2010) performed a prospective study to examine patients with L5 radiculopathy to confirm the efficacy of a new 3-dimensional computed tomography (3D CT) imaging method to diagnose extraforaminal stenosis at the lumbosacral junction. The participants were 75 consecutive patients (mean age 69.5 y) with or without cauda equina symptoms who were treated by microendoscopic spinal surgery for L5 radiculopathy. The lesion responsible for the symptoms was identified by a combination of neurologic findings, selective radiculography, (3D MRI), and intraoperative neurophysiological findings. Multislice CT scanning was carried out preoperatively from the L1 vertebral body to the sacrum in all patients. The CT scan images were transferred to a remote computer workstation, and the reconstructed images were examined after surgery by an investigator blinded to the clinical diagnoses. In the reconstructed plane, we measured the minimum cross-sectional area of the de novo bony tunnel formed by the L5 transverse process, sacral ala,

and L5 vertebral body, that is, lumbosacral bony tunnel (LSBT) and determined a cutoff value to diagnose extraforaminal stenosis. The shape of the LSBT was also evaluated in relation to the diagnosis. In 3D CT analysis, the LSBT was found on the ipsilateral side in 51 of the 75 patients. The bony tunnel was outside the foramen in all patients diagnosed clinically with extraforaminal stenosis, but in only 60% of the patients without extraforaminal stenosis. The minimum cross-sectional area of the bony tunnel was significantly smaller in patients with an extraforaminal stenosis than in those without extraforaminal stenosis. The cutoff value was set at 0.8 cm². The cross-sectional area was <0.8 cm² in all patients with extraforaminal stenosis. The specificity of this diagnostic procedure was 89.6%, and the sensitivity was 100%. All true-positive cases had the spur-type shape of the bony tunnel, and all false-positive cases had the round-type shape. The authors concluded that all patients with extraforaminal stenosis had an LSBT. The minimum cross-sectional area of the bony tunnel was significantly smaller in patients with an extraforaminal lesion than in those without an extraforaminal lesion. 3D CT is a useful tool for diagnosing extraforaminal stenosis at the lumbosacral junction.³⁰

Baumert and colleagues (2009) evaluated the morphology and visibility of craniocervical ligamentous structures in whiplash injuries with a new isotropic three-dimensional (3D) turbo-spin-echo (TSE) technique. MR (MR) images of the cervical spine of 52 subjects (27 women and 25 men; mean age=29 years; age range=18-40 years) were taken with a T2-weighted 3D TSE sequence with variable flip-angle distribution [SPACE (Sampling Perfection with Application optimized Contrasts using different flip-angle Evolution)] at 1.5 T (Magnetom Avanto, Siemens Erlangen, Germany). Two experienced musculoskeletal radiologists read the images independently on a 3D imaging and postprocessing workstation. The visibility and morphology of the alar ligaments were evaluated on a five-point scale, and inter-reader correlation was assessed with kappa statistics. Both alar ligaments were detected in all subjects. Twenty-eight (53.8%) of the alar ligaments could not be seen within one slice of the standard coronal imaging plane but could adequately be visualized in an oblique reconstruction adapted to the orientation of the ligaments on the axial slices. Inter-reader correlation for visibility on MR imaging (MRI) of the internal craniocervical ligaments was high (left+right side, kappa=0.95). Most (94%) alar ligaments presented symmetrically. In the axial plane, 60% were oriented neutral and 40% had a backward orientation. In the coronal plane, 67% were oriented caudocranially and 33% were oriented horizontally. The shape of the ligaments was parallel in half and was V-shaped in the other half. The alar ligaments had homogeneous low-signal intensity in 56% and heterogeneous low-signal intensity in 44%. The apical ligament of the dens was seen (excellent-good-moderate) in 61% (reader 1) and 52% (reader 2). The tectorial membranes and the transverse ligament of the atlas were shown (excellent-good) in all subjects. The authors concluded that MRI with acquisition of an isotropic SPACE technique allows high-resolution imaging of the craniocervical ligaments in all orientations. Reconstruction of the image data in the variable orientation of the alar ligaments allowed for excellent depiction within one slice such that partial volume artifacts that hamper image analysis can be eliminated.³¹

Hayes, Cochrane, UpToDate, MD Consult etc.: Hayes does not have a technology directory report on 3D Interpretation and Reporting of Imaging Studies.

UpToDate: In a report called Overview of Craniosynostosis the authors indicate that three-dimensional surface reconstructions using CT is routinely used to plan surgical treatment of complex craniofacial reconstructions. 3D imaging uses interactive techniques that simulate osteotomies and skeletal movements in three dimensions on computer-generated surface images. The ocular globes are marked to position the orbital segments, and then the osteotomized segments are transposed into normal anatomic relationship with respect to the eyes using animation. The measurements from the computer graphic simulation are used intraoperatively to establish the correct position of the skeletal segments.²²

In a report called Approach to neuroimaging in children²⁷ image fusion with MRI/SPECT, CT/PET using 2D reformatting, 3D volumetric and reconstruction methods, segmentation, and surface rendering technique are used for the following indications:

- CT angiography and venography
- To plan stereotactic radiotherapy and radiosurgery
- To plan craniofacial reconstructive surgery
- To plan surgical stabilization of craniocervical anomalies and scoliosis
- Real-time or stereotactic image guidance for interventional neuroradiologic and neurosurgical procedures

Professional Organizations

American College of Radiology (ACR): The American College of Radiology (ACR) outlines the definitions and billing requirements for 3D rendering services that includes the following summary³:

- The two codes for 3D rendering services distinguish between those studies in which reformatting is performed on the acquisition scanner (CPT 76376) and those performed on an independent workstation (CPT 76377).
- Both of the 3D codes require concurrent physician supervision of image post-processing, 3D manipulation of volumetric data set and image rendering. Concurrent supervision means active participation in and monitoring of the reconstruction process that includes:
 - Design of the anatomic region that is to be constructed
 - Determination of the tissue type and actual structures to be displayed
 - Determination of the images or cone loops that are to be archived
 - Monitoring and adjustment of 3D work product
- For the 3D reconstructions not requiring image post-processing on an independent workstation, the physician will discuss with the technologist the need for 3D imaging and supervise the technologist in creating 3D images.
- For studies performed on an independent workstation, the physician will supervise and/or create the 3D reconstructions and adjust the projection to optimize visualization of anatomy or pathology.
- The 3D rendering codes are intended to address complex renderings such as shaded surface rendering, volumetric rendering, maximum intensity projections (MIPs), fusion of images from other modalities, and quantitative analysis (segmental volumes and surgical planning).
- It is **not** appropriate to report the 3D rendering codes with certain selected procedures since these procedures already include the review of images in alternative display formats: CPT 76376 or CPT 76377 should not be reported in conjunction with any of the Nuclear Medicine codes (78000-78999) or with the new Category III cardiac computed tomography (CT) and coronary CT angiography (CTA) codes.
- The 3D codes should not be used when 3D is not medically necessary. When providing 3D rendering services, particularly in the outpatient setting, a specific order is especially helpful in establishing medical necessity. In addition, the ACR states that the reformatting study should be documented in a separate report or in a separate section of the radiologist's report.

American Medical Association: According to the American Medical Association, current procedural terminology (CPT)⁴, it is not appropriate to report the 3D rendering codes with certain selected procedures since these procedures already contemplate the review of images in alternative display formats. CPT codes for 3D rendering should not be billed in conjunction with computer-aided detection (CAD), MRA, CTA, nuclear medicine SPECT studies, PET, PET/CT, CT colonography (virtual colonoscopy), cardiac MRI, cardiac CT, or coronary CTA studies.

CODING INFORMATION

CPT	Description: These codes are to be reported in conjunction with the code(s) for the base imaging procedure(s):
76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality; not requiring image postprocessing on an independent workstation. (Do not report 76376 in conjunction with 31627, 70496, 70498, 70544-70549, 71275, 71555, 72159, 72191, 72198, 73206, 73225, 73706, 73725, 74174, 74175, 74185, 74261-74263, 75557, 75559, 75561, 75563, 75565, 75571-75574, 75635, 76377, 78000-78999, 0159T)
76377	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality; requiring image postprocessing on an independent workstation. (Do not report 76377 in conjunction with 31627, 70496, 70498, 70544-70549, 71275, 71555, 72159, 72191, 72198, 73206, 73225, 73706, 73725, 74174, 74175, 74185, 74261-74263, 75557, 75559, 75561, 75563, 75565, 75571-75574, 75635, 76376, 78000-78999, 0159T)

HCPSC	Description
	N/A

ICD-9	Description
737.30- 737.32	Scoliosis
756.0	Craniosynostosis
802- 802.8	Fracture of face bones
805- 806.9	Fracture of vertebral column
808- 808.9	Fracture of pelvis

ICD-10	Description
M41- M41.9	Scoliosis
Q75.0	Craniosynostosis
S02.2- S02.42	Fracture of facial bones
S02.6- S02.69	Fracture of mandible
S12-	Fracture of cervical vertebra

S12.9	
S22.0- S22.089	Fracture of thoracic vertebra
S32.0- S32.059	Fracture of Lumbar vertebra
S32.3- S32.9	Fracture of pelvis

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