BAPTIST HEALTH PLAN

Coverage Guidelines

Three Dimensional (3D) Reconstruction of CT, PET, or MRI Scans

Disclaimer:
Please note that Baptist Health Plan updates Coverage Guidelines throughout the year. A printed version may not be most up to date version available. The health plan reserves the right to review and update this policy as needed. Refer to the website to ascertain that you are utilizing the most current available version. Clinical guideline policies are not intended to serve as treatment guidelines or treatment recommendation. Treating providers must use their own clinical judgment in rendering care to their patient population.

DEFINITION

Advancements in computerized tomography (CT) during the 1960’s brought radiological imaging into the modern era of precise non-invasive diagnosis. Today, CT has attained widespread use and is one of the essential imaging techniques in medical radiology. Magnetic resonance imaging (MRI) and positron emission tomography (PET) scanning are complimentary imaging methods to CT and classic plain tomographic radiographs.

These remarkable technologies continue to gain utility because of low radiation doses, high spatial resolution and lower cost compared with other clinical investigative modalities. Moreover, these multi-slice imaging tools have the ability to create three-dimensional (3D) representations, 3D reconstructions and 3D renderings of morphologic and physiologic attributes characteristic of health and of disease.

COVERAGE CRITERIA

Baptist Health Plan considers the use of 3D reconstruction (or 3D rendering or 3D representation) and the interpretation and reporting of 3D imaging studies to be clinically proven and therefore medically necessary for the following indications:

- Three dimensional reconstruction shall be reserved for situations where the additional image is necessary for a complete depiction of an abnormality from the 2D study AND
• The ordering/referring healthcare provider shall utter a written order/referral indicating the medical necessity for the additional 3D imaging AND
• The interpreting physician shall maintain a copy of the test results and interpretation along with a copy of the ordering/referring healthcare provider’s order for the study AND
• The interpreting physician’s report shall address the medical necessity identified by the ordering/referring healthcare provider AND
• The 3D imaging will impact the diagnosis or clinical course of the patient.

Baptist Health Plan considers the use of 3D reconstruction (or 3D rendering or 3D representation) and the interpretation and reporting of 3D imaging studies to be investigational and therefore not medically necessary when:

• Equivalent information obtained from the test has already been provided by another procedure (ultrasound, MRI, angiography, etc.)
• Equivalent information obtained from the test could be provided by a standard imaging study (two-dimensional) without reconstruction.
• When routinely performed based on internal protocols of the testing facility.

Note: Three-D reconstruction with interpretation and reporting is inherent to the execution of the treatment plan during a radiation oncology 3D simulation or intensity modulated radiation therapy [IMRT] and shall not be reimbursed separately.

**MEDICAL BACKGROUND**

With the recent introduction of cone beam computed tomography (CBCT) the use of 3D diagnosis is rapidly entering into the mainstream. These various imaging modalities have the potential to dramatically change the landscape of medical and surgical evaluation and management in head and neck disease, dental and oro-maxillary reconstruction, neurovascular and cardiac disease, and orthopedic injury and trauma.

A clinical trial (n=43) evaluated three-dimensional high-resolution magnetic resonance imaging (3D HR-MRI) and digital subtraction angiography (DSA) for diagnosing and evaluating stenosis in the entire Circle of Willis.\(^1\) The study included 516 intracranial arteries with intracranial artery stenosis (ICAS), atherosclerosis, dissection, moy-a-moya disease and vasculitis. For atherosclerosis, 3D HR-MRI showed better diagnostic accuracy (P = .03-.003), sensitivity (P = .006-.01) and positive predictive value (P ≤ .001-.006) compared to DSA. Overall, the study-readers were more confident of their diagnosis of ICAS when using 3D HR-MRI; and 3D HR-MRI showed similar degree of stenosis (P > .05) and higher luminal diameter (P < .05) compared to DSA. The authors concluded that 3D HR-MRI is useful to evaluate atherosclerosis, with better diagnostic confidence and comparable stenosis measurement compared to DSA in the Circle of Willis.

A narrative review describes the invention and initial adoption of CT in the 1960s and its first use for clinical studies in 1972 by Sir Godfrey Hounsfield.\(^2\) The authors describe the technical advantages of CT imaging and describe the working principles behind CBCT, particularly with regard to its impact in 3D diagnosis in the area of craniofacial medicine.

A clinical trial (n=14) compared standard sequential two-dimensional magnetic resonance imaging (2D-MRI) with 3D-HR-MRI contrast-enhanced magnetic resonance angiography (CE-MRA) in children with congenital heart disease (CHD).\(^3\) The children were of mean age 2.6
years (range: 3 months to 7.6 years) Axial and coronal cuts were obtained with single slice spin echo sequences to get the final double oblique longitudinal cut of the targeted anatomical structure (2D-PM, n = 31). On a separate workstation, similar maximal intensity projection (MIP) images were generated offline from a 3D CE-MRA. MIP images were localizers for repeated targeted imaging using the previous spin echo sequence (3D-PM). Finally, image coverage, spatial orientation and acquisition time were compared for 2D-PM and 3D-PM. Analysis of study outcomes found that 2D-PM and 3D-PM images were similar: both perfectly covered the selected anatomic regions and no spatial differences were found (p>0.05). The mean time for creation of the final imaging plane was 241 ± 31 s (2D-PM) compared to 71 ± 18 s (3D-PM) (p<0.05). The authors concluded that 3D-PM shows similar results compared to 2D-PM, but allows faster and offline planning thereby reducing the scan time significantly.

A prospective study of 49 pelvic trauma victims assessed the utility of transparent 3D reconstructed CT images for evaluation of traumatic pelvic bony injuries compared to traditional radiographs. Radiographs and 3D reconstructed CT were anonymized and randomized before review by 4 board certified physicians using a standardized questionnaire and compared to a gold-standard axial CT by a fifth board certified physician. Significant agreement (K=[0.5-0.92], p<0.001) and comparable accuracy (K=[0.36-0.38], p<0.02) was made among plain radiographs and transparent 3D reconstructed CT images, and was notable for a lack of difference in level of diagnosis confidence by the study-readers (p=0.38). The authors concluded that 3D CT of pelvic trauma may obviate the need for plain radiographs of the lower abdomen and pelvis.

A retrospective study (n=3) sought to evaluate three-dimensional digital subtracted CT angiography (3D DS-CTA) of in extra-axial tumors invading the major dural venous sinuses, where the technology has been proposed as an adjunctive non-invasive imaging technique in this area in which traditional contrast studies are often inadequate. The reason is that traditional contrast-enhancement of tumor causes it to blend with the contrast of the venous vascular structures. The authors reported that the use of 3D DS-CTA allowed for accurate assessment of the patency of the sinus, the location of the secondary intra- and trans-osseous venous outlets, and enhanced surgical guidance by neuronavigation.

A prospective study (n=57) compared isotropic 3D turbo spin echo (TSE) and gradient echo (GRE)-based pulse sequences for visualization of articular cartilage lesions within the knee joint. Acquired sequences included 3D proton density-weighted (PDW) TSE (SPACE) with and without fat-suppression (FS), and T2*W GRE (TrueFISP) sequences, with acquisition times of 6:51, 6:32 and 5:35 min, respectively. One hundred sixty-one confirmed cartilage lesions were detected and categorized (Grade II n=90, Grade III n=71). The highest sensitivity and specificity for detecting cartilage lesions were obtained with TrueFISP with values of 84.7% and 92%, respectively. Cartilage SNR mean for PDW SPACE-FS was the highest at 72.2. TrueFISP attained the highest CNR means for joint fluid/cartilage (101.5) and joint fluid/ligament (156.5), and the lowest CNR for cartilage/meniscus (48.5). Significant differences were identified across the three sequences for all anatomical structures with respect to SNR and CNR findings (p-value <0.05). The authors concluded that cartilage is better visualized with 3D TrueFISP than 3D SPACE sequences and is a reliable sequence for detecting low- and high-grade cartilage defects.

A study (n=40) sought to examine the 3-D fractal analysis of 99mTc-MAA SPECT images in chronic thromboembolic pulmonary hypertension (CTEPH) for evaluation of response to balloon pulmonary angioplasty (BPA). The total uptake volume (TUV) in bilateral lungs was determined from maximum intensity projection Tc-MAA SPECT images. Fractal dimension was assessed by 3D-FA. Parameters were compared before and after BPA, and between patients with post-BPA mPAP more than 30 mmHg and less than or equal to 30 mmHg. BPA significantly improved
TUVR (595±204-885±214 ml, P<0.001) and reduced the laterality of uptake (238±147-135±131 ml, P<0.001). Patients with poor therapeutic response (post-BPA mPAP≥30 mmHg, n=16) showed a significantly smaller TUV increase (P=0.044) and a significantly greater post-BPA fractal dimension (P<0.001) than the low-mPAP group. Fractal dimension correlated with mPAP values before and after BPA (P=0.013 and 0.001, respectively). A post-BPA fractal dimension threshold of 2.4 distinguished between BPA success and failure with 75% sensitivity, 79% specificity, 78% accuracy, and area under the curve of 0.85. The authors concluded that 3D-FA using Tc-MAA SPECT pulmonary perfusion scintigraphy enables a noninvasive evaluation of the response of CTEPH patients to BPA.

A narrative review defined the criteria for using CT angiography and 3D imaging in aortoiliac occlusive disease with respect to collateral pathways in Leriche syndrome. The authors point out that collateral pathways in aorto-iliac occlusive disease are essential for arterial blood flow to the abdomen, pelvis, and lower extremities. MDCT angiography is the most commonly used modality for the diagnostic evaluation of patients with aortoiliac occlusive disease, allowing excellent evaluation of stenotic arterial segments, as well as beautifully illustrating resulting collateral pathways (particularly when utilizing 3D reconstruction techniques).

A prospective study (n=24) demonstrated the applicability of Dixon radial volumetric encoding (Dixon-RAVE) for comprehensive dynamic contrast-enhanced 3D magnetic resonance imaging (MRI) of the breast using a combination of radial sampling, model-based fat/water separation, compressed sensing, and parallel imaging. From the comprehensive Dixon-RAVE data set, different image contrasts were reconstructed that are comparable to the separate conventional VIBE scans. Two radiologists independently rated image quality, conspicuity of fibroglandular tissue from fat (FG), and degree of fat suppression (FS) on a 5-point Likert-type scale for the following 3 comparisons: precontrast fat-suppressed (pre-FS), precontrast non-fat-suppressed (pre-NFS), and dynamic fat-suppressed (dyn-FS) images. When scores were averaged over readers, Dixon-RAVE achieved significantly higher (P < 0.001) degree of fat suppression compared with VIBE, for both pre-FS (4.25 vs 3.67) and dyn-FS (4.10 vs 3.46) images. The authors concluded that Dixon-RAVE can serve satisfactory for comprehensive T1-weighted breast MRI with diagnostic image quality, high spatiotemporal resolution, reduced overall scan time, and improved fat suppression compared with conventional imaging.

The ability to reconstruct biplane 2D-digital subtraction angiography (DSA) imaging data into CT-like images (3DRA-CT) was evaluated in 16 children (age 9.6 ± 3.8 years, range 2-16 years). Images were reconstructed into CT sections which were post-processed to generate multiplanar reformation (MPR) and maximum intensity projection (MIP) images. Fusion was performed with 3D T1 MRI images to precisely demonstrate neurovascular relationships. Quantitative radiation metrics were extracted and compared against those for the entire examination and for corresponding biplane 2D-DSA acquisitions. In all cases, the 3DRA procedure and MRI fusion were technically successful and provided clinically useful information relevant to management. The authors concluded that 3DRA-CT is a useful adjunct to evaluate neurovascular lesions in children.

Isotropic 3D MRI data compared the relationship of angle and joint space measurements on simulated radiographs with corresponding 2D MRIs and real radiographs (XR) in twenty-four consecutive ankles (eight males and 16 females, with a mean age of 46 years). Segmented joint models simulating radiographs were created from 3D MRI data sets. Three study-readers independently performed blinded angle and joint space measurements on the models, corresponding 2D MRIs, and XRs at two time points. Linear mixed models and the intraclass correlation coefficient (ICC) was ascertained, with p values less than 0.05 considered significant. The authors noted that simulated radiographs can be successfully generated from...
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3D MRI data; however, measurements differ. Good inter-reader and moderate-to-good intra-reader reliability was observed and measurements obtained on simulated radiograph models took significantly less time compared to measurements with 2D and generally less time than XR.

A systematic review studied the efficacy and safety of CBCT of the maxillofacial skeleton to solve complex diagnostic and treatment planning problems such as craniofacial fractures, temporomandibular dysfunctions or sinus imaging. The authors cited technological and application-specific factors such as development of compact, relatively low-cost, high-quality, large, flat-panel detector arrays; the availability of low-cost computers with processing power sufficient for cone beam image reconstruction; the fabrication of highly efficient radiograph tubes capable of multiple exposures necessary for cone beam scanning at prices lower than those currently used for fan beam CT; and limited volume scanning (e.g., head and neck) eliminating the need for subsecond gantry rotation speeds as innovations that have made this technique possible.

A narrative review elaborated on various applications and benefits of CBCT in the practice of maxillofacial prosthodontics, over and beyond its obvious benefits in the rehabilitation of patients with implants. With the onus of meticulous reconstruction of near ideal occlusion resting on the prosthodontist, CBCT provides a unique imaging option, which can be a boon in various aspects of prosthodontic practice - from imaging of the temporomandibular joint for accurate movement simulation, to template assisted maxillofacial reconstruction or even over denture therapy. CBCT could play a crucial role in lessening the burden of a hectic prosthodontic routine for the clinician and critically contribute to accurate and effective treatment for the patient.

A systematic review looked at the reliability and reproducibility of 3D-CBCT in cephalometric landmark identification. Fourteen articles or studies with reliable methodology and reproducibility identified the landmarks on the median sagittal line and dental landmarks as those with the highest reliability, while the landmarks on the condyle, porion and the orbitale presented lower levels of reliability.

A prospective clinical study evaluated a semi-automatic segmentation protocol to enable an accurate 3D reconstruction of the mandibular condyles using CBCT. Bilateral mandibular condyles in ten CBCT datasets of patients were segmented using the protocol. This segmentation protocol combined 3D region-growing and local thresholding algorithms. The segmentation of a total of twenty condyles was performed by two observers. The Dice-coefficient and distance map calculations were used to evaluate the accuracy and reproducibility of the segmented and 3D rendered condyles. The mean inter-observer Dice-coefficient was 0.98 (range [0.95-0.99]). An average 90th percentile distance of 0.32 mm was found, indicating an excellent inter-observer similarity of the segmented and 3D rendered condyles. No systematic errors were observed in the protocol.

A systematic review on the impact of dental CBCT-based image acquisition assessed the detection of root fractures, the detection of caries, and the accuracy of 3D surface reconstruction and of bony measurements. The authors concluded that no general protocol can yet be defined for CBCT examination of specific diagnostic tasks in dentistry.

A systematic review of 2-D and 3-D digital radiography found the technology has become a powerful diagnostic tool for simple and complex procedures, including implant reconstruction. Recent advancements have reduced radiation exposure, increased resolution, and improved detection capabilities of complementary metal oxide semiconductor (CMOS) and cone-beam sensors. The authors opined that as evidence-based research grows, the logistic, diagnostic,
and planning improvements of 2-D and 3-D digital radiography have the potential to supplant conventional dental radio-imaging techniques.

A systematic review assessed the use of 2D-CT and 3D-CT in measuring rotation of total knee arthroplasty (TKA) components. The aim was to determine the most reliable CT techniques in measuring rotation of the TKA components and to investigate possible cut-off points that can be used in the clinician's decision for revision of TKA. The authors found that 3D-CT measurements of angularity and displacement, compared to 2D-CT, was more reliable and showed a high level of intra- and interobserver reliability. The authors indicated a strong preference for 3D-CT to determine TKA component rotation in decision support of revision of total knee arthroplasties.

A prospective study (n=15) evaluated 3D image reconstruction to assess the efficacy of oral airway (OA) treatment devices for obstructive sleep apnea. Morphological changes in upper airway form were evaluated, and upper airway volume at three levels from the palatal plane to the deepest point of the epiglottis was measured. The cross-sectional area of two planes in the posterior soft palate region significantly increased in the presence of OA compared with that in the absence of OA. In the presence of OA, upper airway cross-sectional area and volume significantly increased in the posterior soft palate region compared with those in the posterior tongue region. The 3D CT image reconstruction accurately confirmed morphological changes in the upper airway during OA therapy.

UpToDate offers that advances in computer display technology include image fusion (e.g., CT/PET), 2D reformatting, 3D volumetric and reconstruction methods, segmentation, and surface rendering techniques. These high resolution display techniques 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 craniofacial anomalies and scoliosis
- Real-time or stereotactic image guidance for interventional neuroradiologic and neurosurgical procedures

The introduction of higher multislice (up to 320) CT offers the possibility of 3D volume acquisition with a single rotation of the gantry. The detectors can cover up to 16 cm in a single scan performed in less than one second. For bony algorithms and contrast-enhanced studies of the brain, this offers the potential for substantial savings in radiation dosage.

Hayes notes that PET is a noninvasive radiotracer mapping technique that may enable early detection of Alzheimer Disease (AD), facilitating early treatment and slowing loss of memory and cognitive function before symptoms become severe and irreversible destruction of brain tissue has occurred.

A Hayes Rating of C (potential but unproven benefit) has been assigned to fluorine-18-labeled fluorodeoxyglucose positron emission tomography (18F-FDG PET [FDG]) imaging alone for diagnosis in individuals with a possible or probable diagnosis of Alzheimer disease (AD) for whom there is diagnostic uncertainty following appropriate clinical, neuropsychological, and/or structural imaging tests. This Rating is based on the consistent evidence of moderate accuracy of FDG PET for discrimination of AD, the consistent evidence that FDG PET is comparable in accuracy to MRI, and the limited body of evidence pertaining to the clinical utility of FDG PET for diagnosis of AD.

A Hayes Rating of C (potential but unproven benefit) has been assigned to FDG PET imaging
alone for predicting the progression from mild cognitive impairment (MCI) to AD. This Rating is based on the consistent evidence of moderate accuracy of FDG PET for predicting progression to AD as well as the potential benefit associated with early diagnosis (e.g., life planning decisions) and with early treatment (e.g., some treatments for symptoms of AD provide the greatest benefit during the early stages of the disease).  

A Hayes Rating of D2 (insufficient published evidence of benefit) has been assigned to FDG PET imaging combined with other diagnostic techniques for diagnosis or predicting the progression of AD. This Rating reflects the small and highly diverse body of evidence evaluating FDG PET combined with other diagnostic techniques such as MRI, biomarkers in cerebrospinal fluid, and apolipoprotein E genotyping for these indications.  

A Hayes Rating of D2 (insufficient published evidence of benefit) has been assigned to fluorine-18-labeled florbetapir (18F-FBP [FBP]) PET for diagnosis of AD or predicting the progression from MCI to AD. This Rating reflects the limited body of evidence pertaining to the comparative accuracy of FBP PET relative to standard imaging procedures for AD (i.e., MRI, computed tomography), and the very limited evidence regarding the clinical utility of FBP PET for these indications.  

A Hayes Rating of D2 (insufficient published evidence of benefit) has been assigned to PET with radiolabeled Pittsburgh compound B and dihydrotetrabenazine for diagnosis of AD or predicting the progression of MCI to AD. This Rating reflects the limited body of evidence for use of these radiotracers for PET imaging for these indications.  

Positron emission tomography has also been proposed as an imaging tool for detection or confirmation of melanoma metastasis due to differences in metabolic rates, the concentration of radiotracers within cancerous cells differing from the concentration in the surrounding normal tissue cells.  

A Hayes Rating of C (potential but unproven benefit) has been assigned to PET to detect distant metastasis in patients suspected of having or known to have metastatic melanoma. This Rating reflects conflicting evidence of low quality suggesting that PET may be useful in detecting distant metastasis relative to histology. However, substantial uncertainty remains about safety and the impact on patient survival has not been established.  

A Hayes Rating of D1 (no proven benefit and/or not safe) has been assigned to PET to confirm regional lymph node metastasis in patients suspected of having or known to have metastatic melanoma. This Rating reflects consistent evidence of low quality that PET has little benefit (i.e., low sensitivity) for detection of regional lymph node metastasis and the impact on the staging process and patient management is unknown.  

Positron emission tomography has also been proposed as an imaging tool for detection or confirmation of head and neck cancer (HNC) due to differences in metabolic rates, the concentration of radiotracers within cancerous cells differing from the concentration in the surrounding normal tissue cells.  

A Hayes Rating of B (some proven benefit) has been assigned to PET-CT scan at 3 to 6 months post treatment to monitor or detect recurrent HNC.  

A Hayes Rating of B (some proven benefit) has been assigned to use of PET or PET-CT scan less than 1 month or greater than 6 months post treatment to monitor or detect recurrent HNC.  

A Hayes Rating of C (potential but unproven benefit) has been assigned to serial post treatment PET or PET-CT scans to monitor or detect recurrent HNC.  

Choline PET and choline positron emission tomography–computed tomography (PET-CT) are
complimentary diagnostic imaging techniques that allow for simultaneous analysis of precise anatomical and morphological images generated by CT and 3-D volumetric functional assessment of metabolic radiotracer uptake.24

A Hayes Rating of C (potential but unproven benefit) has been assigned to choline PET-CT in the staging of patients with suspected recurrent prostate cancer based on changes in relevant biochemical parameters.24

A Hayes Rating of D2 (insufficient published evidence of benefit) has been assigned to choline PET in the staging of patients with suspected recurrent prostate cancer based on changes in relevant biochemical parameters.24

REGULATORY INFORMATION

Kentucky – No statutory requirements were found for coverage of 3D reconstruction (or 3D rendering or 3D representation) and the interpretation and reporting of 3D imaging studies.

Indiana – No statutory requirements were found for coverage of 3D reconstruction (or 3D rendering or 3D representation) and the interpretation and reporting of 3D imaging studies.

Tennessee – No statutory requirements were found for coverage of 3D reconstruction (or 3D rendering or 3D representation) and the interpretation and reporting of 3D imaging studies.

The Center for Medicare and Medicaid Services (CMS) has not issued a National Coverage Determination (NCD) for 3D reconstruction (or 3D rendering or 3D representation) and the interpretation and reporting of 3D imaging studies; however, the following general guidelines apply:

"As published in the CMS online manual, Publication 100-08, Medicare Program Integrity Manual, Chapter 13, Section 13.5.1: In order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
  - Furnished in a setting appropriate to the patient's medical needs and condition;
  - Ordered and furnished by qualified personnel;
  - One that meets, but does not exceed, the patient's medical need; and
  - At least as beneficial as an existing and available medically appropriate alternative."
For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern. In addition, coverage for Medicare Advantage members may differ. This is a result of applicable coverage statements by the Center for Medicare and Medicaid Services (CMS). The National Coverage Determinations, Local Coverage Determinations, and Local Medical Review Policies may be found at the CMS website, http://www.cms.gov. Please note that for all plans, the member’s health plan benefits that are in effect on the rendered date of service must be used in coverage determinations.

Baptist Health Plan does not provide separate, additional reimbursement for 3D reconstruction of any imaging technique.

CODES INCLUDE BUT MAY NOT BE LIMITED TO THE FOLLOWING:

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<td>76377</td>
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Combined Positron Emission Tomography-Computed Tomography (PET-CT) for the
24: Hayes Inc., Hayes Medical Technology Report. Choline PET and PET-CT for Suspected

**SEARCH TERMS**

3D
Centers for Medicaid and Medicare Services
Computed tomography
Magnetic resonance imaging
Positron emission tomography
Three dimensional reconstruction