NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of DG1: The EOS 2D/3D Imaging System

This guidance was issued in October 2011

The review date for this guidance is October 2014

NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance. Other factors such as the introduction of new technologies relevant to the guidance topic, or newer versions of technologies included in the guidance, will be considered relevant in the review process, but will not in individual cases always be sufficient cause to update existing guidance.

1. Recommendation

The guidance should be transferred to the 'static guidance list'.

A list of the options for consideration, and the consequences of each option is provided in Appendix 1 at the end of this paper.

2. Original objective of guidance

To assess the clinical and cost effectiveness of the EOS 2D/3D Imaging System for the evaluation and monitoring of scoliosis and other orthopaedic conditions including leg length discrepancy and alignment and issues relating to hip and knee where full body length or full leg length images are currently requested.

3. Current guidance

Adoption recommendations

1.1 The EOS 2D/3D imaging system is an emerging technology with potentially important clinical benefits. Current evidence shows there are some patient

benefits for people with spinal deformities in terms of radiation dose reduction and increased throughput. However, those benefits alone are insufficient to justify the cost of the system. No clinical evidence was available to quantify the extent of patient benefits from the EOS system's imaging features including 3D reconstruction, weight-bearing whole-body imaging, and simultaneous posteroanterior (PA) and lateral imaging. Therefore, the EOS 2D/3D imaging system is not currently recommended for routine use in the NHS.

1.2 NICE encourages use of the EOS 2D/3D imaging system in specialist research settings to collect evidence about potentially important clinical benefits associated with 3D reconstruction, single image weight-bearing whole-body imaging and simultaneous PA and lateral imaging.

Research recommendations

7.1 Research is needed to quantify the health outcome benefits associated with imaging improvements with the EOS system. Examples of such benefits might include reduced back pain or reduced postural difficulties in people with scoliosis, or longer lasting and less painful joint replacements. Although research into the use of the EOS system is appropriate for all the indications included in the scope, the research most likely to be useful is for planning hip and knee replacement, including patient selection, device selection, and surgical approach. Joint replacement operations are more common than the other indications and the EOS system is thought to be most likely to provide benefit to these patients.

7.2 Additional methodological research is needed to determine the most appropriate model structures to assess the benefit arising from radiation dose reduction. Additional work is needed to assess when the radiation-induced cancers actually occur and the impact of the timing of the emergence of cancer on health status.

7.3 Research is needed to determine whether, and for which conditions, use of the EOS system for 3D reconstruction provides benefit for diagnosis or treatment planning.

4. Rationale

Changes in clinical practice, technology costs or evidence that would lead to a change in the recommendations of the original guidance have not been identified. No ongoing or published studies have been identified that would satisfy the research recommendations in the guidance. It is therefore proposed that the guidance is placed on the static list.

5. Implications for other guidance producing programmes

No overlaps have been identified.

6. New evidence

The search strategy from the original diagnostics assessment report was re-run on the Medline, Medline in process, Health Management Information Consortium, Embase, Cochrane Library, DARE, CENTRAL, Health Technology Assessment, NHS EED, Allied and Complementary Medicine Database, Biosis Previews, ISI Science Citation Index, CINAHL, metaRegister of Controlled Trials, ClinicalTrials.gov and EconLit databases. References from November 2010 onwards were reviewed. Additional searches of clinical trial registries were also carried out. Relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the diagnostic and care pathways. Companies were asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for their technology. Specialist Committee Members for this guidance topic were also consulted regarding changes to the technology, the evidence base and clinical practice. The results of the literature search are discussed in the 'Summary of new evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

6.1 Technologies

Searches of the grey literature and information provided by the manufacturer confirm the CE marked indication for the EOS 2D/3D Imaging System has not changed since

the publication of Diagnostics Guidance 1.

[redacted] The acquisition cost of EOS 2D/3D Imaging System used in the original modelling has changed from £400,000 to [redacted].

No new alternative technologies with a similar purpose to the EOS 2D/3D Imaging System have been identified. Advice from clinical experts identified technologies which are intended for the analysis of gait and posture, but which do not have radiological imaging capability.

6.2 Clinical practice

Searches for guidance produced by relevant professional bodies, and advice received from clinical experts, suggest that the diagnostic and care pathways relevant to Diagnostics Guidance 1 have not changed since its publication. Updated guidance on ‘practice parameters for the performance of radiography for scoliosis in children’ from the American College of Radiology recommend that high-quality radiography for scoliosis in children should be performed with the minimum radiation dose necessary to achieve a study with adequate diagnostic quality.

6.3 New studies

Twenty one studies which report outcomes relevant to the decision problem, and one study which reports an economic analysis of the EOS 2D/3D Imaging System, have been published since the searches for the systematic review were completed. The clinical studies did not specifically evaluate the clinical effectiveness of the EOS 2D/3D Imaging System, but provide information on the feasibility of using the technology for diagnostic imaging. All included studies provide information on at least 1 intermediate or clinical outcome.

Of these 21 studies:

- 12 report data on intermediate outcomes such as diagnostic accuracy and image reproducibility;
- 9 report the feasibility of using the EOS 2D/3D imaging system in the evaluation or monitoring of scoliosis and other orthopaedic conditions relevant to the decision problem.

Intermediate outcomes

Image reproducibility

Eight cohort studies (Barbier et al. 2014; Ferre et al. 2014; Guenoun et al. 2012; Kanhonou et al. 2014; Lazennec et al. 2011; Meijer et al 2014; Somoskeoy et al. 2012 and Vidal et al. 2011) and one efficacy study (Delin et al. 2014) report outcomes relating to the reproducibility of images and measurements obtained using the EOS 2D/3D Imaging System. The populations included in these studies are mixed. They include healthy volunteers, anthropomorphic phantoms and both adult and paediatric patients with a range of orthopaedic conditions such as those relating to the hip, knee and spine. The majority of these studies are small and include fewer than 50 participants. Only 4 of the 8 studies include a comparison to another imaging technique; two of which compare images from the EOS system with two comparator technologies in the guidance, x-rays and false-profile radiographs (Ferre et al. 2014 and Lazennec et al. 2011). Ferre et al. (2014) reports that inter-observer agreement was greater for false-profile radiographs than biplanar EOS images for femoral head diameter measurements, but was greater for biplanar EOS images than radiographs for the evaluation of the anterior acetabular coverage angle in patients with hip pain. Lazennec et al. (2011) reports that intra and inter-observer variability substantially improved with 2D EOS images compared with conventional x-ray in patients who had hip arthroplasty.

Image quality

One cohort study (Krug et al. 2013) evaluated the quality of images obtained using the EOS 2D/3D Imaging System compared with those obtained using flat-panel radiography technology in 114 adults who required whole leg imaging. The results of this study support the evidence included in Diagnostics Guidance 1 which suggested

that the images obtained with the EOS 2D/3D Imaging System were comparable with or better than the comparator in most cases.

Radiation dose

Three cohort studies (Ferre et al. 2014; Krug et al. 2013 and Lazennec et al. 2012) and one efficacy study (Delin et al. 2014) include outcomes relating to the radiation dose delivered by the EOS 2D/3D Imaging System. The populations included in these studies are mixed and include patients with orthopaedic conditions relating to the hip, knee and pelvis, and anthropomorphic phantoms. One study includes less than 30 patients, one includes anthropomorphic phantoms only, and none contained more than 150 patients. Two studies (Ferre et al. 2014 and Krug et al. 2013) include a comparator technology relevant to the decision problem (false-profile radiography and flat-panel radiography) and their results support the conclusions reached in Diagnostics Guidance 1, that is, compared to standard radiography techniques the EOS 2D/3D Imaging System delivers a lower dose of radiation.

Diagnostic accuracy

One cross sectional observational study (Molto et al. 2014) assesses the diagnostic accuracy of full spine and pelvis 2D imaging using the EOS 2D/3D Imaging System compared to conventional radiography. This study included 96 adults with spondyloarthritis or chronic lower back pain and assesses the accuracy of the EOS 2D/3D Imaging System for the detection of sacroilitis and ankylosis of the spine, and sacroilitis of the pelvis. Although diagnostic accuracy data were not available in the original systematic review, this study is relatively small and it is unlikely that these new data would have a significant impact on the conclusions reached in Diagnostics Guidance 1.

Feasibility studies

Eight cohort studies (Blondel et al. 2012; Courvoisier et al. 2013; Dubousset et al. 2014; Ilharreborde et al. 2013; Pailhé et al. 2014; Scherrer et al. 2013; Steffen et al. 2010 and Than et al. 2012) and one pilot study (Pellet et al. 2012) used the EOS 2D/3D imaging system in the evaluation or monitoring of scoliosis and other orthopaedic conditions relevant to the decision problem. The populations included in these studies include patients with idiopathic scoliosis, and other conditions relating

to the spine, hip or knee. These studies report surrogate clinical outcomes and do not include comparator technologies. The absence of clinical outcome data from these studies limits their applicability to the decision problem and it is unlikely that their data would contribute to reducing the substantial uncertainty surrounding the clinical benefit of the EOS 2D/3D Imaging System which is noted in Diagnostics Guidance 1.

Economic evaluation

One study (Dietrich et al. 2013) reported an economic evaluation of the EOS 2D/3D Imaging System compared to standard digital radiography in Switzerland. The aim of the study was to calculate the annual number of radiographs required to offset the level of financial investment required for each imaging modality. It is unlikely that the costing data provided by this study would contribute to reducing the uncertainty in the economic analysis presented in the original Diagnostics Assessment Report.

Ongoing studies

Five ongoing studies were identified and are detailed in Appendix 2. Of these 5 studies, 3 are currently recruiting participants, 1 is in follow up and 1 has not yet begun recruitment. None of the ongoing studies will address the research recommendations included in the original guidance.

7. Summary of new evidence and implications for review

The evidence that has emerged for the EOS 2D/3D Imaging System after the publication of Diagnostics Guidance 1 provides some new information relating to radiation dose, image quality and reproducibility, diagnostic accuracy and clinical feasibility. The emerging comparative evidence confirms that the EOS 2D/3D Imaging System delivers a low dose of radiation but it is unlikely to fully address the uncertainties identified during the assessment regarding the health outcome benefits associated with use of the system. No studies were found which address the research recommendations made in Diagnostics Guidance 1.

The cost of the EOS 2D/3D Imaging System has [redacted] since the publication of Diagnostics Guidance 1 but in view of the substantial uncertainty surrounding the

clinical effectiveness of the EOS 2D/3D Imaging System, it is unlikely that this change in cost alone would be sufficient to have a material effect on the existing guidance recommendations.

The absence of substantial new evidence to support the clinical effectiveness of the EOS 2D/3D Imaging System suggests that the guidance should be transferred to the static list.

8. Implementation

No relevant Implementation data were found. Advice received from clinical specialists suggests that the EOS 2D/3D Imaging System is not widely used in the NHS.

9. Equality issues

During the development of Diagnostics Guidance 1 it was noted that people with the conditions included in the assessment, that is scoliosis and other orthopaedic conditions including leg length discrepancy and alignment and issues relating to hip and knee where full body length or full leg length images are currently requested, may be covered by the disability provision of the Equality Act. It was also noted that, because the EOS 2D/3D Imaging System images vertically, its use may be limited to people who are able to stand or sit during image acquisition.

GE paper sign off: Carla Deakin, Associate Director 19th November 2014

Contributors to this paper:

Technical Lead: Rebecca Albrow

Technical Adviser: Sarah Byron

Project Manager: Robert Fernley

Appendix 1 – explanation of options

If the published Diagnostics Guidance needs updating NICE must select one of the options in the table below:

Options	**Consequence**	**Selected – 'Yes/No'**
A standard update of the guidance	A standard update of the Diagnostics Guidance will be planned into the NICE's work programme.	-
An accelerated update of the guidance	An accelerated update of the Diagnostics Guidance will be planned into NICE's work programme. Accelerated updates are only undertaken in circumstances where the new evidence is likely to result in minimal changes to the decision problem, and the subsequent assessment will require less time to complete than a standard update or assessment.	-
An update of the guidance within another piece of NICE guidance.	The guidance is updated according to the processes and timetable of that programme.	-

If the published Diagnostics Guidance does not need updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
The guidance should be transferred to the 'static guidance list'.	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Diagnostics Guidance on the static list should be flagged for review.	Yes
Technical supplement	A technical supplement describing newer versions of the technologies will be planned into NICE's work programme.	-
The decision to review the guidance should be deferred to [specify date or trial].	NICE will reconsider whether a review is necessary at the specified date.	-
The guidance should be withdrawn.	The Diagnostics Guidance is no longer valid and is withdrawn.	-

Appendix 2 – supporting information

Relevant Institute work

Published

The MAGEC system for spinal lengthening in children with scoliosis NICE medical technologies guidance 18 (2014)

Spasticity in children and young people with non-progressive brain disorders: Management of spasticity and co-existing motor disorders and their early musculoskeletal complications NICE clinical guideline 145 (2012)

Selective dorsal rhizotomy for spasticity in cerebral palsy NICE interventional procedures guidance 373 (2010)

Lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine NICE interventional procedures guidance 321 (2009)

Percutaneous endoscopic laser thoracic discectomy NICE interventional procedures guidance 61 (2004)

In progress

None identified.

Referred - QSs and CGs

None identified

Suspended/terminated

None identified

Details of new technologies

No new technologies were found.

Registered and unpublished trials

Trial name and registration number	Details
NCT02269657:	Prospective efficacy study investigating the effect of arms position on the clinical evaluation of spinal x-rays acquired with the EOS system in a population with adolescent idiopathic scoliosis. A new arm position (hands on the wall) in comparison to the conventional arm position (hands on the clavicles) is being used. The study is not yet open to participant recruitment
NCT01336114:	Prospective cohort study investigating the use of EOS for the 3D geometrical reconstruction of the spine and development of a model for a personalised brace in patients with adolescent idiopathic scoliosis. This study is currently in recruitment.
NCT01613989:	Randomised controlled trial investigating the use of EOS for navigation during computer-assisted prosthetic hip surgery in adult patients undergoing total hip replacement. The aim is to compare the surgical treatment of total hip prosthesis without assistance by computer and with pre-operative navigation based on EOS imaging. This study is ongoing but no longer recruiting participants.
NCT02150850:	Prospective case control study investigating the use of geometric variations of the subtrochanteric and diaphyseal regions of the femur calculated from 3D images EOS images for predicting atypical femur fractures. The Quebec Registry for atypical femur fractures is going to be used for the characterization of clinical, biomechanical, radiological and genetic predictors of AFF, associated or not with bisphosphonate and-or denosumab therapy. This study is currently in recruitment.

Trial name and registration number	Details
NCT02196415:	Prospective feasibility study investigating the role of EOS biplanar radiographs in 3D hindfoot alignment measurements in patients with congential medial deviation. The study aims to evaluate the technical feasibility and reproducibility of EOS imaging in comparison to conventional radiographs. This study is currently in recruitment.

References

American College of Radiology (2014). ACR–SPR–SSR practice parameter for the performance of radiography for scoliosis in children.

Blondel B, Lafagec V, Farcyd J-P et al. (2012) Influence of screw type on initial coronal and sagittal radiological correction with hybrid constructs in adolescent idiopathic scoliosis. Correction priorities**.** Orthopaedics & Traumatology: Surgery & Research 98: 873—878.

Barbier, O., W. Skalli, L. Mainard and D. Mainard (2014). The reliability of the anterior pelvic plane for computer navigated acetabular component placement during total hip arthroplasty: Prospective study with the EOS imaging system. Orthopaedics & Traumatology: Surgery & Research 100(6, Supplement): S287-S291.

Delin C, Silvera S, Bassinet C et al. (2013) Ionizing radiation doses during lower limb torsion and anteversion measurements by EOS stereoradiography and computed tomography. European Journal of Radiology 83(2): 371-377.

Dietrich TJ, Pfirrmann CW, Schwab A, Pankalla K, Buck FM. Comparison of radiation dose, workflow, patient comfort and financial break-even of standard digital radiography and a novel biplanar low-dose X-ray system for upright full-length lower limb and whole spine radiography. Skeletal Radiol. 2013;42(7):959-67.

Dubousset J, Ilharreborde B and Le Huec J-C (2014) Use of EOS imaging for the assessment of scoliosis deformities: application to postoperative 3D quantitative analysis of the trunk. European Spine Journal 23 (4): S397–S405.

Ferre R, Gibon E, Hamadouche M, et al. (2014) Evaluation of a method for the assessment of anterior acetabular coverage and hip joint space width. Skeletal Radiology 43(5): 599-605.

Guenoun B, Zadegan F, Aim F et al. (2012) Reliability of a new method for lower-extremity measurements based on stereoradiographic three-dimensional reconstruction. Orthopaedics, Traumatology, Surgery and Research 98(5): 506-513.

Ilharreborde B, Dubousset J, Skalli W et al. (2013) Spinal penetration index assessment in adolescent idiopathic scoliosis using EOS low-dose biplanar stereoradiography. European Spine Journal 22: 2438–2444.

Kanhonoua M, Cressona M, Lavoieb F et al. (2013) A method to study 3D knee pseudo-kinematics using low-dose stereoradiography during static squat. Computer Methods in Biomechanics and Biomedical Engineering 17(S1): 138–139.

Kim H J, Lenke L G, Oshima Y et al. (2014) Cervical Lordosis Actually Increases With Aging and Progressive Degeneration in Spinal Deformity Patients. Spine Deformity 2: 410-414.

Krug K B, Weber C, Schwabe H et al. (2013) Comparison of image quality using a X-ray stereotactical whole-body system and a direct flat-panel X-ray device in examinations of the pelvis and knee. Rofo 186(1): 67-76.

Lazennec J Y, Rousseau M A, Rangel A et al. (2011) Pelvis and total hip arthroplasty acetabular component orientations in sitting and standing positions: measurements reproducibility with EOS imaging system versus conventional radiographies. Orthopaedics, Traumatology, Surgery and Research 97(4): 373-380.

Lazennec J Y, Brusson A and Rousseau M A, (2012) THA Patients in Standing and Sitting Positions: A Prospective Evaluation Using the Low-Dose ‘‘Full-Body’’ EOSs Imaging System. Seminars in Arthroplasty 23: 220-225.

Meijer M F, Boerboom A L, Stevens M et al. (2014) Assessment of Prosthesis Alignment after Revision Total Knee Arthroplasty Using EOS 2D and 3D Imaging: A Reliability Study. PLoS ONE 9(9): e104613.

Molto A, Freire V, Feydy A et al. (2014) Assessing structural changes in axial spondyloarthritis using a low-dose biplanar imaging system. Rheumatology 53: 1669-1675.

Pailhé R, Bedes L, Sales de Gauzy J et al. (2014) Derotational femoral osteotomy technique with locking nail fixation for adotlescent femoral antetorsion: surgical technique and preliminary study. Journal of Pediatric Orthopaedics B 23: 523–528.

Pellet N, Aunoble S, Meyrat R et al. (2011) Sagittal balance parameters influence indications for lumbar disc arthroplasty or ALIF. European Spine Journal 20(5): S647–S662.

Scherrer S-A, Begon M I, Leardini a et al. (2013) Three-Dimensional Vertebral Wedging in Mild and Moderate Adolescent Idiopathic Scoliosis. PLoS ONE 8(8): e71504.

Somoskeoy S, Tunyogi-Csap M, Bogyo C et al. (2012) Clinical validation of coronal and sagittal spinal curve measurements based on three-dimensional vertebra vector parameters. The Spine Journal 12: 960–968.

Steffen J S, Obeid I, Aurouer N et al. (2010) 3D postural balance with regard to gravity line: an evaluation in the transversal plane on 93 patients and 23 asymptomatic volunteers. European Spine Journal 19: 760–767.

Than P, Szuper K, Somoskeöy S et al. (2012) Geometrical values of the normal and arthritic hip and knee detected with the EOS imaging system. International Orthopaedics 36: 1291–1297.

Vidal C, Ilharreborde B, Azoulay B et al. (2013) Reliability of cervical lordosis and global sagittal spinal balance measurements in adolescent idiopathic scoliosis. European Spine Journal 22: 1362–1367.