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# Diagnostics Assessment Programme

# EOS 2D/3D X-ray Imaging System

# Final Scope

October, 2010

## 1 Introduction

The EOS 2D/3D X-ray imaging system is manufactured by Biospace Med. The Medical Technologies Advisory Committee identified the EOS 2D/3D X-ray imaging system as potentially suitable for evaluation by the Diagnostics Assessment Programme on the basis of a briefing note that included the description of the purpose of the technology (see section 1.2). This system has a wide variety of potential uses, and analysing all of them would exceed the resources available for this assessment. The proposal arising from the early scoping phase was that the assessment should be limited to use of the system in the evaluation and monitoring of scoliosis in children and adolescents. However, the scope was broadened following the scoping workshop and the assessment subgroup meeting to include other orthopaedic conditions that would benefit from the weight bearing and full-body imaging aspects of the EOS device, as described in section 2.1.

### *1.1 Product properties*

This section describes the product's properties and is based on the manufacturer's notification to NICE. NICE has not carried out an independent evaluation of the description provided by the manufacturer.

EOS is a biplane X-ray system designed to provide fast scanning and high patient throughput with very low radiation doses and high quality images. The system is able to take full body images in an upright, weight bearing position.

The highly sensitive X-ray detector enables low-dose image capture, creating a 'head to toe' image within approximately 20 seconds for an adult and 10 seconds for shorter paediatric patients. The digital system produces front and side images of the patient, which can be viewed instantly. There is no need to adjust for distortion, or to digitally stitch together multiple images.

EOS comprises two X-ray tubes and two digital detectors mounted on a C-arm configuration. The detectors are based on the Charpak technology to allow imaging using reduced radiation levels. The images, however, have a resolution of about 2 line pairs per millimetre which is substantially less than that achieved on traditional plain film radiographs.

A vertical motor drive moves the C-arm along the full length of the patient. The patient stands or sits in the imager while the digital detectors perform a single rapid head to toe scan, or any subsection of the body as determined by the operator, capturing anteroposterior (AP) and lateral images simultaneously. Patients are scanned in a vertical position as opposed to the horizontal position used by MRI.

Digital images are immediately available on the 2D workstation. The 3D workstation generates a 3D skeletal image from the simultaneously acquired AP and lateral images. The 3D model is unique because it is weight bearing; something which is not currently possible even with CT. The 3D workstation automatically performs a variety of angle and posture calculations between individual bones, enabling new ways to globally evaluate a patient’s postural abnormality.

EOS reduces exposure to radiation, which can be significant if the patient requires multiple X-rays, for example with scoliosis. Full body scans without the need for stitching and the provision of 3D measurements can possibly improve clinical outcomes through improved evaluation of patients and subsequent clinical decision-making on diagnosis and treatment.

The EOS system is currently used in a hospital setting. It requires the same room planning and shielding as a general X-ray room, and the same radiation protection protocols apply.

EOS provides diagnostic X-ray images, which support clinical decision-making on diagnosis and treatment. No other devices or diagnostic tests are used concomitantly.

Although primarily developed for orthopaedic use, EOS can also function as a general X-ray system, capable of high image quality, speed and patient throughput at very low radiation doses.

### *1.2 Purpose of the diagnostic technology*

The purpose of the EOS X-ray system is to provide simultaneous AP and lateral, full body uninterrupted digital 2D and 3D imaging in a single scan, with low dose radiation. EOS can be beneficial for orthopaedic work, providing accurate postural assessment and examination of spine and joint alignment with the whole body in an upright, weight-bearing position. The EOS system can be used for patients requiring general X-ray imaging, although it is primarily designed for orthopaedic patients, for example, patients with spinal conditions such as scoliosis or vertebral dislocation and those requiring limb reconstructions. Paediatric patients could benefit from the low dose imaging since children are more sensitive to the harmful effects of radiation.

### *1.3 Alternative tests and comparators*

Current 2D imaging technologies consist of film, computed radiography (CR) and digital radiography (DR) imaging. These systems vary in the radiation dosage used. Some CR and DR systems have lower radiation doses than film systems, but higher than those of the EOS system. Separate AP and lateral images are taken with these systems, which means they cannot provide 3D reconstruction.

Current CT and MRI scanning can provide 3D reconstructions. CT requires high radiation exposure, while no radiation is used with MRI. Both systems generally require the patient to be recumbent, which can result in changes in spinal positioning and potentially to misleading results. Two approaches to overcome this issue exist: vertical MRI; and the use of spinal compression devices to simulate a weight-bearing stance.

For the purpose of this evaluation, the EOS device will be compared to X-ray film, CR and DR imaging. The use of CT scans and conventional MRI were excluded from the evaluation as it was considered that these techniques had different purposes to conventional radiography, and they would not replace its use. In addition, CT scans and conventional MRI produce non-weight bearing images which impact on the utility of the imaging. The use of compression devices was not considered to be a satisfactory substitute for weight bearing images.

### *1.4 Care pathways*

The care pathways for the treatment of each orthopaedic condition included in this evaluation will vary depending on the specific disease.

Scoliosis is a condition in which the spine becomes twisted and displaced. It usually develops during childhood and adolescence, and can result in loss of flexibility, pain, and cosmetic deformity. The purpose of monitoring and treating scoliosis is to prevent deterioration of the condition. Interventions to prevent deterioration include bracing and surgery. In more severe cases, corrective surgery may be used to straighten the back.

Repeated monitoring with conventional X-ray imaging increases the radiation exposure. For scoliosis monitoring, the care pathway is not well defined, and for this evaluation the outcome data deal primarily with the radiation dose and the subsequent outcomes from the radiation exposure.

Hip and knee surgery is a common procedure in the UK, however it has been indicated to NICE that in approximately 10% and 20% of cases, respectively, fully satisfactory outcomes are not achieved. This is often due to problems arising from leg length discrepancy, leg misalignment or spinal deformity in addition to local hip and knee joint problems.

# 2 Scope of the evaluation

## *2.1 Populations*

The EOS device can potentially be used for many types of radiological examinations. However, it has particular benefits where its particular features are relevant including reduced radiation dose, weight bearing imaging, full body imaging, and simultaneous AP and lateral imaging. It also produces 3D surface images, but the experts consulted did not feel that was a particularly important aspect at this time.

The experts concurred that the most important uses to be considered for this technology should include the management of spinal deformities and lower limb problems such as leg length discrepancy, leg alignment and conditions that affect the hip and knee.

The indications to be included in the assessment have been divided into those affecting younger populations (children and adolescents) and those affecting adults, as listed below.

In children and adolescents:

- Spinal deformity, principally scoliosis
- Leg length discrepancy and alignment.

In adults:

- Spinal deformity, including degenerative scoliosis, progressive kyphosis and osteoporotic fractures
- Loss of sagittal and coronal balance, including issues relating to hip and knee where full body or full leg length images are currently requested.

For children and adolescents, the most important spinal deformity for this evaluation is scoliosis because of the requirement for repeated imaging and the impact of radiation, but other deformities that occur may also be considered. Leg length discrepancy and leg alignment problems in children and adolescents will also be included in the evaluation since, for diagnosis, these often require the stitching together of multiple images.

For adults, the principal spinal deformities are those of degenerative diseases leading to arthritic changes, kyphosis or scoliosis. In some cases, problems resulting from adolescent scoliosis may also appear in adulthood. Issues relating to hip and knee include replacement planning and other degenerative changes that require full leg and hip or full body radiographs.

## *2.2 Interventions*

The only intervention being considered is the EOS 2D/3D system. As described above it does a vertical scan while recording simultaneous AP and lateral images. It has software to compute 3D reconstructions. It uses a Charpak detection system to permit significant reductions in radiation dose.

During the scoping workshop additional alternative interventions and comparators were considered and rejected including CT scanning, conventional MRI with and without compression devices, ultrasound, and contour mapping. None of these were considered to be sufficiently comparable to be included in the evaluation. The lack of comparability was based on the lack of weight bearing for CT and MRI, the insufficient visualisation of the spinal alignment for ultrasound and contour mapping, and the insufficient comparability of MRI with compression devices. Vertical MRI was also rejected because it was not considered comparable for visualising spinal curvatures and angles.

### *2.3 Comparators*

The comparator is conventional AP and lateral radiographs from either X-ray film, CR or DR imaging. In some cases, the radiographs may be stitched together to provide images covering larger portions of the body than can be done with single images. There is some variation in radiation dose among the various types of digital systems which may require breaking this comparator into subsets.

### *2.4 Outcomes*

The relevant outcomes vary by diagnosis. The relevant direct outcome from the imaging process is radiation exposure. This exposure can lead to increased risk of developing cancer in the future. Since this risk is dose dependent, it is of particular interest in conditions where multiple images are required and where imaging must be repeated over time. Since children and adolescents are developing with more frequent cell divisions, there may be an increased radiation effect compared to adults. Moreover, younger people have an increased likelihood of developing cancer because their longer life expectancy gives more time for a cancer to develop.

Outcomes related to treatment of the conditions identified vary by condition but basically relate to function, pain and cosmetic effects. For joint replacement surgeries, important additional outcomes are the likelihood of success of the replacement and its durability. Data were not found to relate these outcomes to the benefits of the EOS system during the scoping process.

Only case report and case series data were found to relate the use of the device to the actual management of scoliosis, therefore the primary analysis proposed was to consider the cost effectiveness of the reduction in the radiation dose. Additional analysis may include the use of expert elicitation to directly assess any benefits arising from changes in management.

### *2.5 Cost considerations*

The EOS system has considerable non-recurrent set-up costs. These include the purchase of the equipment (if not leased), and installation including the workstation and software. There may be some building costs to provide a suitable location that complies with radiation legislation requirements if existing rooms are not suitable. The manufacturer claims that the high throughput of the device may result in a requirement for fewer general X-ray rooms. Digital imaging reduces the need for consumables, but there are annual maintenance costs. Costs for consumables may be reduced since film and developing solutions are not required. Costs for integrating the system into extant computerised picture archiving and communications systems (PACS) would need to be explored.

The conventional film, DR, and CR systems are probably in place and will not require special implementation. Average costs that include capital and installation costs should be used for these systems.

### *2.6 Care pathway*

The care pathways vary for the conditions being considered. The pathway for scoliosis in children and adolescents may be the most critical to consider since multiple images are taken repeatedly over time. Unfortunately, the care pathway for scoliosis is not well defined. Generally the management of these patients involves taking radiographs at intervals and determining the degree of scoliosis, usually by computing the Cobb angle. Many physicians prescribe bracing to stabilise the back when the Cobb angle gets large enough. A frequently cited Cobb angle for considering bracing is 20 degrees. There is, however, disagreement about the value of bracing in preventing worsening of the scoliosis, and it is not commonly used in the UK. As the Cobb angle increases, surgery is often recommended to straighten the back and usually fuse it. Cobb angles of 40 degrees or more are often cited as justifying surgical treatment. Many patients who have mild scoliosis never require treatment.

Scoliosis usually develops during childhood or early adolescence. Patients diagnosed with scoliosis are monitored at intervals to determine whether their scoliosis has progressed to the degree requiring treatment. The frequency of monitoring can range from 4 months to almost 2 years depending on the nature of the curve, the speed of progression, the age of the patient and differences in practice. After growth stops, the patient's spinal curvature has usually stabilised and monitoring ceases.

For the other conditions, the modelling of the care pathway will likely be reduced by direct elicitation of outcomes based on the of image quality of the devices.

## 3 Equality issues

No evidence has been found to indicate variation in effectiveness according to age, gender, class and ethnicity. Nor has any differential impact on inequalities in health within and between different population groups been identified.

## 4 Implementation issues

There is some question about the number of scoliosis centres that might require systems if the technology was to be adopted. The number of centres in England has been reported in different sources, varying from16 to 37. Additionally, it has been indicated to NICE that there are two centres in Scotland, one in Wales, and one in

Northern Ireland. The number of imaging units required to cover these centres may not be justifiable. Alternatively, the impact on patients and carers of travelling to these centres may be excessive. The load for these systems may be insufficient to justify the capital costs, and alternative uses for will therefore need to be considered. The EOS systems will also require space to be made available for this new equipment, which may present a burden in some settings.

## Appendix 1 – Extant guidance

American College of Radiology, Practice Guideline for the Performance of Radiography for Scoliosis in Children, 2009

## Appendix 2 – Available literature


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