

# EOS 2D/3D X-ray imaging system: a systematic review and economic evaluation

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## *Executive summary*

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# Executive summary

## Background

EOS is a biplane X-ray imaging system manufactured by EOS imaging (formerly Biospace Med, Paris, France). It uses slot-scanning technology to produce a high-quality image with less irradiation than standard imaging techniques.

The indications in which there may be potential benefit associated with EOS are those that require imaging that is weight-bearing, full body, simultaneous posteroanterior (PA) and lateral (LAT), three-dimensional (3D), and/or where radiation exposure is a concern. The relevant indications are scoliosis, kyphosis, deforming dorsopathies and congenital deformities of the spine, hips or lower limbs.

The relevant comparator imaging technologies are X-ray film, computed radiography (CR) and digital radiography (DR), although film has been replaced by CR and DR in standard UK practice. The primary outcome of interest is radiation-induced risk of cancer.

## Objective

To determine the clinical effectiveness and cost-effectiveness of the EOS two-dimensional (2D)/3D X-ray imaging system for the evaluation and monitoring of scoliosis and other relevant orthopaedic conditions.

## Methods

A systematic review of the evidence on the clinical effectiveness of EOS, compared with standard film, CR or DR, for monitoring or evaluation of any orthopaedic condition was performed. Ten electronic databases (including MEDLINE and EMBASE), two clinical trials registries and the manufacturer's website were searched up to November 2010. A narrative synthesis was undertaken.

To complement the main sources of data for adverse effects of diagnostic X-ray radiation (reports produced by the large radiation protection and safety agencies), a systematic review of the adverse effects of diagnostic radiation for patients with orthopaedic conditions was performed. Three electronic databases (MEDLINE, EMBASE and The Cochrane Library) were searched up to December 2010. A narrative synthesis was undertaken.

A systematic review was conducted to identify potentially relevant studies for inclusion in the assessment of cost-effectiveness, including full economic evaluations of EOS against any comparators and economic evaluations in the indications of interest where standard X-ray was assessed against any comparator. A decision-analytic model was developed to assess the cost-effectiveness of EOS in the relevant indications compared with standard X-ray (CR and DR imaging). The model provided a framework for the synthesis of data from the review of clinical effectiveness of EOS and adverse effects of diagnostic radiation exposure, primarily the risk of cancer, in order to evaluate the potential long-term cost-effectiveness of EOS. The model

incorporated a lifetime horizon to estimate outcomes in terms of quality-adjusted life-years (QALYs) and costs from the perspective of the NHS.

Patient throughput was expected to be a major determinant of the cost-effectiveness of EOS.

A range of scenarios was considered regarding throughput with EOS and standard X-ray, as well as threshold analyses to explore the critical throughput levels to be achieved for EOS to be considered cost-effective. Three alternative assumptions regarding patient throughput were used to examine whether or not EOS could be shown to be cost-effective:

1. Throughput assumption 1 (TA1) used patient throughput based on Hospital Episode Statistics (HES) data, which provided an estimate of the number of examinations per year for each of the various indications at national level.
2. In recognition that HES may underestimate current X-ray utilisation, throughput assumption 2 (TA2) was based on the capacity that a machine could utilise in a working day. TA2 assumed equivalent throughput for EOS and that estimated for standard X-ray at 30 patients per working day, corresponding to an annual throughput of 7530 visits for scans per year (assuming 251 working days per year).
3. Throughput assumption 3 (TA3) was based on a higher utilisation for EOS than for standard X-ray at 48 patients per working day, corresponding to an annual throughput of 12,048 visits for scans per year (assuming 251 working days per year).

Threshold analysis was also undertaken to explore the necessary size of the effects, in terms of QALYs gained from EOS as a result of the nature and quality of the EOS image, over and above those from reduced radiation, for the technology to be cost-effective.

Cost-effectiveness was assessed using incremental cost-effectiveness ratios (ICERs) for each indication. This was complemented by the threshold analyses to determine the sensitivity of the cost-effectiveness ratio to uncertainty in patient throughput and health benefits associated with EOS.

## Results

### *Clinical effectiveness*

Three comparative studies were identified for the assessment of the clinical effectiveness of EOS. Two studies compared EOS with film X-ray imaging and one study compared EOS with CR. The included studies were small and of limited quality. One study used an earlier version of the technology. No patient health outcomes were reported in any of the studies. Both studies comparing EOS with film X-ray imaging found image quality to be comparable or better with EOS overall. Radiation dose (entrance surface dose; ESD) was significantly lower with EOS for all images; ratio of means reported in the better quality study was 5.2 for PA spine and 6.2 for LAT spine.

The study comparing EOS with CR found image quality to be comparable or better with EOS for the majority of images. Radiation dose (ESD) was considerably lower with EOS than CR for all images; the ratio of means for the centre of the back was 5.9 and for the proximal LAT point was 8.8. The lowest ratio of means was at the nape of the neck, which was 2.9.

No other outcomes were reported. There was no evidence from clinical trials that the facilities offered by EOS – such as the ability to scan a full-body image, removing the need for digital

stitching, or the ability to take PA and LAT images simultaneously, so that a 3D image can be produced – translated into patient health benefits.

### **Adverse effects of diagnostic radiation**

The evidence relating to the risks of radiation exposure has been reviewed in the reports of international and UK radiation authorities. Our systematic review contributes an evaluation of the risk of cancer and adverse reproductive outcomes associated with diagnostic X-ray radiation exposure specifically for patients with orthopaedic conditions. Despite the limited data, the findings from our review showed that, when compared with the general female population, there was a clear association between increased risk of breast cancer mortality and diagnostic X-ray exposures for female scoliosis or spinal curvature patients, with a significant radiation dose–response relationship. There was a highly significant trend for increased risk of breast cancer with increased cumulative radiation dose, particularly in patients with a family history of breast cancer. Only limited poor-quality data were available regarding the risk of adverse reproductive outcomes in orthopaedic patients.

### **Cost-effectiveness**

The systematic review of existing economic evidence identified no studies of EOS that met the inclusion criteria for the review. The searches for economic evaluations in relevant indications did not identify any studies to complement the evaluation of EOS. To address these limitations, a new decision-analytic model was developed.

The base-case analysis assumed that radiation doses associated with DR were equivalent to those associated with CR. Therefore, the model assumed that there was no differential effect on health outcomes for CR and DR. Given that DR was more expensive than CR, and was assumed to produce the same outcomes, the cost-effectiveness results were presented for each indication comparing EOS with CR. The ICER for EOS was well above conventional thresholds of £20,000 and £30,000 per additional QALY in all indications. Under none of the alternative throughput assumptions – TA1, TA2 or TA3 – did EOS appear to be cost-effective at thresholds of £20,000 and £30,000 per QALY under base-case assumptions.

Threshold analysis on patient throughput showed that 17,700–27,600 scans per year (corresponding to a workload of 71–110 patient appointments per working day) were needed to achieve an ICER of £20,000 per QALY or between 15,100 and 26,500 (corresponding to a workload of 60–106 patient appointments per working day) for an ICER of £30,000 per QALY. These estimates were based on the assumption that the throughput for CR was 7530 scans per year (30 patient appointments per working day). Two-way threshold analysis examining the relationship between the cost-effectiveness of EOS and the throughput of CR and EOS suggested that EOS would not be cost-effective unless its utilisation can be assumed to be markedly greater than CR.

Threshold analysis on the incremental health benefits from sources other than reduced radiation dose suggested that EOS would have to generate significant increases in health benefits to be considered cost-effective under the three throughput assumptions. The absolute QALY gains needed over and above those from reduced radiation varied by the throughput scenario. For the lowest throughput scenario (TA1), the necessary gains ranged from 0.003 to 0.4 (an increase in the order of magnitude of 7–697); for the scenario TA2 from 0.002 to 0.003 (an increase in the order of magnitude of 4.8–35); and for TA3 from 0.0002 to 0.002 (an increase in the order of magnitude of 2.3–17). In judging the plausibility of EOS generating these health gains it should be noted that diagnostic technologies typically achieve small gains in health benefit.

This is because any change in diagnostic strategy generally results in a small proportion of patients having a change in diagnosis, and an even smaller proportion experiencing a change in therapeutic intervention, which may or may not change health outcomes.

A number of alternative scenarios were considered, which varied the assumptions used as part of the base-case analysis. In all but three of these scenarios, the ICERs were above conventional thresholds of cost-effectiveness when it was assumed that radiation dose reduction is the only source of health benefit from EOS. The scenarios in which the ICER fell below the threshold for two of the indications (late-onset scoliosis and Scheuermann's disease in adolescents) were (1) earlier age of cancer diagnosis compared with the general population; (2) 0% discount rate per annum; and (3) an alternative source (BEIR VII report instead of data from the personal communication with Paul Shrimpton from the Health Protection Agency) for the estimate of lifetime attributable risk of radiation-induced cancer.

## Conclusions

The health benefits estimated from EOS as a result of radiation dose reductions are very small. Given the higher price of the EOS equipment, patient throughput is a major determinant of the cost-effectiveness of EOS: the greater the number of procedures that can be demonstrated compared with those estimated for standard radiography, the greater the likelihood of cost-effectiveness. Using the estimates of patient throughput at national level from the HES data suggests that EOS is not cost-effective for any of the indications considered. When health benefits from EOS relate only to reduced radiation dose, patient throughput in the region of 15,100–26,500 (corresponding to a workload of 60–106 patient appointments per working day) for EOS compared with a throughput of only 7530 for CR (corresponding to a workload of 30 patient appointments per working day) is needed to achieve an ICER of £30,000 per QALY. EOS can be shown to be cost-effective when compared with CR only if the utilisation for EOS is about twice the utilisation of CR. As the throughput for CR is not tied to the particular indications for which EOS is potentially of value, as CR is routinely used for a much wider set of indications, it is unlikely that the throughput for CR would be considerably lower than for EOS. Patients from this wider set of indications could be used to increase the throughput of EOS to the required levels, but its cost-effectiveness can be ensured only if these additional patients achieve the same incremental health benefits as patients with the primary indications modelled here. If EOS were able to generate health benefits as a result of any changes in therapy as clinicians respond to any changes in the nature and quality of the EOS image compared with standard X-ray then these may be sufficient for EOS to be considered cost-effective. However, no evidence currently exists on whether or not these image-related health benefits exist, let alone whether or not they reach the magnitude necessary for EOS to be cost-effective. Furthermore, these extra health gains would be possible only if a sufficient proportion of patients experienced a change in therapeutic management, with a consequent improvement in outcomes, following the use of EOS rather than CR.

## Suggested research priorities

Estimates of likely throughput with EOS are both uncertain (there is little evidence to use for this purpose) and variable (they depend on how many EOS machines are introduced in the NHS and the relevant patient throughput in each centre). For EOS, this throughput needs to be based on the patient numbers expected for the indications for which EOS has a potential benefit. This throughput should be defined at national level, based on numbers of patients requiring scans and numbers of centres throughout the UK.

There is also a need formally to assess the implications of any changes in the quality and nature of the image with EOS compared with standard radiography for patient health outcomes, over and above the reduction in radiation. This will require research to establish, for relevant indications, the proportion of patients for whom use of EOS changes diagnosis and/or therapy, and whether or not any therapeutic changes result in improved quality-adjusted life expectancy.

### **Implications for service provision**

The cost-effectiveness of EOS depends on the feasibility of achieving the critical patient throughput levels. The economic analysis has demonstrated that the ICERs for EOS for the various indications that have been formally modelled are consistently above conventional thresholds of cost-effectiveness unless a minimum throughput of 15,100 scans per year can be achieved. This has implications for service provision. Clinics using EOS would have to be organised in such a manner to ensure that this minimum utilisation is achieved for each centre using EOS. A throughput of 15,100 scans per year is equivalent to 60 patients per working day, over 251 working days per year.

Hence, the question is whether or not such throughput is achievable with current patient numbers, and if so, how many EOS systems would be required. As the minimum throughput is in the order of 15,000 scans per year, this would require that each centre with an EOS machine would serve enough patients to ensure such utilisation. A wider set of patients, with indications other than those explicitly considered here, could have their scans with EOS to help achieve these 'target' throughput levels. However, the use of such patients would be cost-effective only if the incremental benefits they experience from EOS are similar to those estimated for patients with the indications that have been modelled.

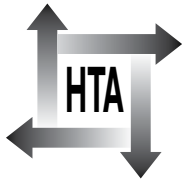
The evidence base for NHS investment in EOS is, therefore, highly uncertain. The upfront capital cost of the machine may represent an irreversible cost to the NHS if research or other information emerging in the future suggests it is not as cost-effective as existing X-ray imaging and if there is limited resale value for the equipment. For this reason, if the NHS decides to invest in EOS, there may be a case for the use of rental agreements rather than outright purchase.

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### **Publication**

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

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