Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Application Number: 2023-002

A slot-scanning, biplanar, digital X-ray imaging system for the evaluation and monitoring of orthopaedic conditions:

Evidence synthesis to support a generic justification decision

Date of decision: 10 July 2023

Date of publication: 21 July 2023

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services —** Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

Foreword

The European Union Basic Safety Standards for the Protection Against Dangers from Medical Exposure to Ionising Radiation (Euratom) were initially transposed into Irish law under SI 256 in January 2019.[1] These Regulations named HIQA as the competent authority for medical exposure to ionising radiation. One requirement under the Regulations is that new practices involving medical exposures must be justified by HIQA before they are generally adopted – this is known as generic justification.

This report sets out a rapid review which provides the evidence base to inform HIQA's generic justification decision. The report also includes the consideration of this evidence by HIQA's multidisciplinary Medical Exposure to Ionising Radiation Expert Advisory Group which is formally reported using an evidence to decision framework. The review considers the net benefit for this patient population in the context of the medical exposure to ionising radiation; the potential for occupational and public exposure is also considered.

This review was undertaken by the Ionising Radiation Evidence Review Team from the HTA Directorate in HIQA and was supported by HIQA's Medical Exposure to Ionising Radiation Expert Advisory Group who advised on the preparation of this report and participated in the evidence to decision exercise. HIQA would like to thank the Evidence Review Team, the members of the Expert Advisory Group and all who contributed to the preparation of this report.

Dr Máirín Ryan

Deputy Chief Executive and Director of Health Technology Assessment

Acknowledgements

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The findings of the evidence review prepared by HIQA informed the deliberations of the MEIR EAG in completing the evidence to decision framework, with the output of the framework reached through consensus.

Expert advisory group membership

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Key: * Not a member of the standing Expert Advisory Group, but attended as an ad hoc member for the meeting where this practice was discussed.

Members of the Evidence Review Team

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Conflicts of interest

None declared.

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List of abbreviations used in this report

ACR	American College of Radiology
AMSTAR	assessing the methodological quality of systematic reviews
AP	anterior-posterior
BfArM	Belgian Federal Institute for Drugs and Medical Devices
CE	Conformité Européenne
CHI	Children's Health Ireland
COI	conflict of interest
CR	computed radiography
CT	computed tomography
DAP	dose area product
DR	digital radiography
DXA	dual-energy X-ray absorptiometry
EAG	expert advisory group
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
Gy	gray
GRADE	grading of recommendations, assessment, development and evaluation
HIQA	Heath Information and Quality Authority
HTA	health technology assessment
HSE	Health Service Executive
ICC	intraclass correlation coefficient
IR-ERT	ionising radiation evidence review team
LAR	lifetime attributable risk
MEIR	medical exposure to ionising radiation
MHRA	Medicines and Health Products Regulatory Authority
MRI	magnetic resonance imaging
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
OSLD	optically stimulated luminescence dosimeters
PA	posterior-anterior
PICO	patient/problem, intervention, comparator, outcome
QUADAS	quality assessment tool for diagnostic accuracy studies
RCT	randomised controlled trial
RQ	review question
SI	statutory instrument

SIVUH	South Infirmary Victoria University Hospital
SOSORT	International Society on Scoliosis Orthopaedic and Rehabilitation Treatment
Sv	sieverts
TGA	(Australian) Therapeutic Goods Administration
THR	total hip replacement
TKR	total knee replacement
TLD	thermoluminescent dosimeter
US	United States of America
2D	two-dimensional
3D	three-dimensional

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Plain Language summary

X-ray images are an important part of the care of people with orthopaedic conditions (conditions which affect the bones, joints and soft tissues). For some of these orthopaedic conditions, it is helpful to take these X-rays when the person is weight bearing (standing up). Standard X-ray equipment, called conventional radiography can be used to take two dimensional (2D) X-rays from different angles, one after the other, while the patient is weight bearing. For imaging large areas of the body, for example, the whole spine, individual images are often digitally 'stitched' together to view the whole spine together. However, X-ray images which are three dimensional (3D), where the height, width and depth can be seen, are even more useful for assessing and planning treatment for patients with orthopaedic conditions. An example of this 3D technology are the EOS Imaging™ devices. Computed tomography (CT) scans also use X-rays to get 3D images of the bones and joints, but this usually means exposing the patient to a higher radiation dose. Since these patients may need several images as part of their care, sometimes from a young age, a method of imaging with a lower radiation dose is preferred. CT images are also usually taken when the patient is lying down (that is, not weight bearing).

Slot-scanning, biplanar, digital X-ray imaging systems such as the EOS Imaging™ devices are a type of device which are mainly used to take X-ray images for people with orthopaedic conditions. These systems can be used to take two low dose X-rays at the same time, when the person is weight bearing: one from the front or the back and one from the side. These X-rays can then be reconstructed to give 3D images of the whole body. Examples of conditions which can be imaged using these systems include: scoliosis (an abnormal curvature of the spine), leg length discrepancies (differences in the length of the legs) and images taken before and after an operation, for example a hip or knee replacement.

Slot-scanning, biplanar, digital X-ray imaging systems are new to Ireland since 2019, but have been used prior to this in other countries. Under Irish law, any new practices which involve the exposure of patients to ionising radiation must be justified by the Health Information and Quality Authority (HIQA).[(1)] Justification means making sure that the benefits of the practice outweigh the risks involved for the kind of patients undergoing this practice. To decide if this practice is justified, HIQA has reviewed the available evidence in the medical literature, and have sought input from a group of experts, including patient representatives. HIQA has also considered the occupational and public radiation safety issues in this review.

The available evidence indicates that slot-scanning, biplanar, digital X-ray imaging systems such as EOS are a safe and effective way to take X-ray images for both

children and adults with scoliosis and other orthopaedic conditions. Advantages of these systems include the low radiation dose and the ability to take 3D, weight bearing images relatively quickly.

After reviewing the risks and benefits of the practice, and considering the recommendation from its Medical Exposure to Ionising Radiation Expert Advisory Group, HIQA decided to justify this new practice of slot-scanning, biplanar, digital X-ray imaging systems for the evaluation and monitoring of orthopaedic conditions.

Key Points

Application

- This review was conducted in response to an application submitted by South Infirmary Victoria University Hospital for the generic justification of the EOS imaging™ system for use in scoliosis and other orthopaedic applications.
- The EOS imaging™ system is a slot-scanning, biplanar, digital radiography X-ray system.

Summary of evidence synthesis process

- In accordance with HIQA's Methods for generic justification of new practices in ionising radiation, a rapid review to establish the evidence base for this new type of practice was conducted.
- In total, 130 primary studies, two health technology assessments (HTAs) (each containing a relevant systematic review), two clinical guidelines, one stand-alone systematic review and one practice parameter were identified.
- While the scope of this rapid review included any CE marked slot-scanning, biplanar, digital X-ray system, all of the evidence retrieved related to the EOS Imaging™ systems.
- The identified records focused on imaging for scoliosis and other orthopaedic conditions including limb length discrepancy, and pre- and post-operative imaging.
- The studies which included a relevant comparator were assessed using a modified version of the QUADAS-2 tool and were used to inform the GRADE tables.

Clinical effectiveness evidence

- Overall, the identified studies had favourable conclusions in terms of a dose reduction with EOS relative to conventional imaging and where evaluated, had comparable image quality.
- Dose data could not be pooled as doses were reported using a variety of metrics and units, with different generations of device and protocols used, and variations in optimisation. However, almost all metrics indicated an EOS dose benefit which typically was substantial.
- A variety of radiographic parameters and image quality metrics were reported, limiting comparisons between studies.
- Considering studies where EOS was used to evaluate and monitor scoliosis:
  - In terms of dose (n=11 studies considered), on average, the reported EOS dose was approximately one fifth of the CR (computed radiography) or digital radiography (DR) dose (reported EOS doses

ranged from 4% to 50% of the CR/DR dose), while one study using a dynamic flat-panel detector system as a comparator showed similar dose area product (DAP) values between EOS (39.8 cGy.cm^2) and CR/DR (41.3 cGy.cm^2).
    - In general, reported inter- and intra-rater reliability for radiographic parameters such as Cobb angles were in the good to excellent range (>0.75) for both EOS imaging and CR/DR.
    - In terms of image quality, EOS was shown to be generally comparable to CR/DR. However, in some studies certain structures were less visible on EOS imaging, for example, lumbar spine, femoral heads and sacrum.

- Considering studies where EOS was used to evaluate and monitor patients with other orthopaedic conditions:
    - On average, the reported EOS dose was approximately half of the CR/DR dose (n= 3 studies). Mean DAP values ranged from 8 to 59 cGycm^2 for EOS and 19 to 105 cGycm^2 for CR/DR.
    - Compared with computed tomography (CT) (n=1 study), entrance skin dose, exit dose and relevant organ doses were all considerably lower with EOS.
    - Seven studies reported limb length measurements. Although there was very low certainty of the evidence, across studies there was consistent reporting of adequate agreement between radiographic measures. For example, the intra-class correlation coefficient (ICC) was generally reported to be high (≥ 0.90). Where reported, confidence intervals were narrow.
    - Eight studies investigated radiographic angular measurements. All except one study found a statistically significant difference between EOS and other imaging modalities. While the mean difference between modalities was often only as much as 2-3°, the difference between pairs ranged from -5.3° to 6.7° in one study to -29.4° to 30.2° in another.
    - For angular measurements, the reported ICCs were generally considered to be good (> 0.75). However, they varied according to the anatomical area in question with some angular measures having a better ICC than others.
    - Only one study reported on image quality, noting that 6% of EOS images were discarded due to poor image quality or poor positioning.

Adverse events and safety evidence

- Overall, identified studies did not highlight any safety concerns with EOS.

- The identified studies did not highlight any safety concerns for public and occupational exposure, and the risk is likely to be low, provided appropriate radiation protection safeguards are in place.

Certainty of the evidence

- Overall, the certainty of evidence was low to very low for the outcomes considered.
- A substantial number of studies were identified, including primary clinical studies. All included studies were observational; based on GRADE methodology, these studies start with a low certainty of evidence and can be upgraded or downgraded from this baseline based on specific criteria.
- Downgrading of the certainty of the evidence was predominantly on the basis that the included studies were at high or unclear risk of bias, while certainty was upgraded due to the large to very large dose effect.

Clinical significance of reported change in ionising radiation dose

- In general the radiation dose used in scoliosis imaging is low, and hence any related increase in long term risks of cancer are also low. However, optimising dose in the young scoliosis population where regular X-rays are acquired is important to minimise any long term risks.
- The clinical implication of a lower dose with EOS was translated to a lower estimated lifetime attributable risk (LAR) of cancer in two studies. The lower LAR is based on the assumption that EOS replaces conventional imaging and that the frequency of imaging is not increased.
- Accurate estimation of the clinical significance of dose reduction is challenging as there are many risk factors for cancer and the dose from medical imaging only forms part of a person's long-term risk of cancer. However, it is accepted that there is a clinical benefit in keeping dose, even for low dose medical exposures, as low as reasonably achievable, particularly in young patient populations.

Medical Exposure to Ionising Radiation Expert Advisory Group (MEIR EAG)

- Informed by the review of the above evidence, the MEIR EAG completed judgements under a modified evidence-to-decision making framework to arrive at a recommendation to HIQA on the generic justification of slot-scanning, biplanar, digital radiography (DR) X-ray systems (as exemplified by the EOS imaging™ systems) for use in scoliosis and other orthopaedic applications.
- The MEIR EAG judged that there was a large benefit with this practice given evidence of a consistent and potentially substantial dose reduction compared

with conventional radiography. Despite a dose reduction, there were limited concerns in relation to image quality with images obtained noted to be sufficient to inform clinical decision making. It was recognised that the dose from general X-rays used in spinal imaging is relatively low. However, the potential for further reduction is considered desirable particularly in the context of the paediatric scoliosis patient population.

- The MEIR judged the overall potential for harm to be trivial. Evidence of a lack of consistency between EOS and conventional radiography was noted for some radiographic parameters when used to evaluate and monitor other orthopaedic conditions. However, it was considered that the observed percentage differences were unlikely to be clinically significant.
- When considering the balance between the desirable and undesirable effects, the MEIR EAG agreed that the practice was favoured over conventional radiography for the evaluation and monitoring of orthopaedic conditions. This was on the basis that comparable image quality sufficient to inform clinical decision making could be achieved despite a consistent and potentially substantial reduction in ionising radiation dose.
- The MEIR EAG recognised that the identified evidence for slot-scanning, biplanar, digital X-ray imaging systems was limited to studies relating to the EOS™ imaging systems. However, while the evidence was discussed in the context of EOS, it was considered that the justification decision for this practice would apply also to other comparable technologies.
- The MEIR EAG, recommended that slot-scanning, biplanar, digital radiography (DR) X-ray systems should be generically justified for the evaluation and monitoring of orthopaedic conditions.

Decision making

- Having considered the application, the evidence review and the recommendation from the MEIR EAG, HIQA is satisfied that on consideration of the balance between the benefits and harms, this practice should be generically justified.
- The new practice of slot-scanning, biplanar, digital X-ray imaging systems for the evaluation and monitoring of orthopaedic conditions is generically justified under SI 256/2018.
- The generic justification of this practice is effective from 10 July 2023.

1. Introduction

1.1 Background to the application

EOS Imaging™ systems are biplanar digital radiography (DR) systems manufactured by EOS Imaging™ (EOS Imaging, ATEC Spine Group, Paris, France). They use slot-scanning (also referred to as slit beam technology) to acquire low dose full body weight bearing X-ray images. The systems simultaneously acquire anterior-posterior (AP) or posterior-lateral (PA) and lateral images and from these, create three-dimensional (3D) anatomical reconstructions using customised software (stereographic acquisition). As of March 2023, there are two versions of this X-ray device on the market: EOS System™ and EOSedge™. To our knowledge, these two systems, manufactured by EOS Imaging™ are the only ones of their kind. However, this generic justification would apply to other slot-scanning or slit beam technologies used for the clinical conditions outlined herein. In this report, the term 'EOS' refers to both products collectively, unless otherwise stated.

The mechanical orientation and arrangement of the system is novel in Ireland – that is, this technology was not in use in Ireland prior to January 2019. Following topic exploration and discussion with stakeholders, including members of HIQA's multidisciplinary medical exposure to ionising radiation (MEIR) expert advisory group (EAG), it was determined that use of a slot-scanning, biplanar, digital radiography X-ray system such as EOS for orthopaedic indications is a new type of practice. Therefore, consistent with the requirements under the European Union Basic Safety Standards for the Protection Against Dangers from Medical Exposure to Ionising Radiation (Euratom), which were transposed into Irish law under Statutory Instrument (SI) 256 in January 2019, it requires generic justification before it can be generally adopted.[(1)]

Topic exploration indicated that the radiation dose associated with EOS was lower than the practice it is replacing and that the use of EOS to inform the management of orthopaedic conditions is an established practice in other countries. One HTA with a relevant systematic review was identified during topic exploration. However, the review was from 2012 with the searches undertaken in 2010. The 2012 review was therefore considered of limited relevance. In accordance with HIQA's Methods for generic justification of new practices in ionising radiation[(2)] a 'rapid review' was undertaken.

EOS is primarily used in the imaging of scoliosis and of other orthopaedic conditions. There are two systems currently installed in Ireland, both commenced services after the commencement of the Regulations,[(1)] one in Children's Health Ireland (CHI) at Crumlin and the other more recently installed at South Infirmary Victoria University

Hospital (SIVUH) in Cork. CHI at Crumlin uses the system for paediatric imaging only, whereas the SIVUH applied to HIQA for generic justification for both adult and paediatric populations.

This rapid review has two review questions (RQs) which focus on the test performance, clinical benefits and safety of slot-scanning, biplanar, digital radiography X-ray systems for the evaluation and monitoring of scoliosis or other known or suspected orthopaedic conditions. Reference is also made to the potential for public and occupational exposure to ionising radiation arising from the use of these imaging systems.

1.2 Overall approach

A standing multidisciplinary MEIR expert advisory group (EAG) has been convened by HIQA comprising representation from key stakeholders. A full list of the membership of the EAG is available in the acknowledgements section of this report. The terms of reference for the EAG are published on the HIQA website.

This rapid review was prepared to provide an evidence base to inform the discussions of the MEIR EAG and its recommendation-making process as well as the subsequent decision-making by the Director of Health Technology Assessment (HTA). The following summarises the steps taken:

- A rapid review was performed to provide the evidence base for a generic justification decision by the Ionising Radiation Evidence Review Team (IR-ERT).
- This rapid review systematically identified relevant evidence which related to the test performance, clinical benefits and safety of slot-scanning, biplanar, digital radiography X-ray systems such as EOS for the imaging of scoliosis and other orthopaedic conditions.
- A draft report summarising the benefits and harms associated with this practice was produced was circulated to the EAG for review.
- Following a meeting of the MEIR EAG, the draft of the report was amended as appropriate and was circulated to MEIR EAG for review.
- The final report was sent to the Director of HTA, along with a recommendation from the MEIR EAG regarding the generic justification of the practice.
- Following HIQA's decision, the final report and generic justification decision were published on the HIQA website.

2. Description of the technology

The first EOS Imaging™ systems (EOS Imaging, ATEC Spine Group, Paris, France) were installed in Europe and North America in 2008. It is a low dose DR system which acquires X-rays using a slot-scanning (also referred to as slit beam technology), obtaining radiographs of the spine and lower extremities in a standing, weight-bearing position. EOS is used primarily in the evaluation of scoliosis for children aged six years and over, assessment of leg length discrepancy, and for the imaging of other orthopaedic conditions in adults and children. A radiolucent chair is also available to allow imaging in a seated position. EOS systems and associated software have been certified by the French notified body, GMED SAS, and CE marked as medical devices for the European market, and have also been placed on the market in Canada, Australia and the United States of America (US).

EOS is a biplanar radiography system, which can acquire orthogonal X-ray images simultaneously. It has a pair of orthogonal X-ray tubes and detectors, which produces spatially calibrated AP and lateral images. EOS's use of slot-scanning, the same technology applied in some dual-energy X-ray absorptiometry (DXA) devices, is different from conventional DR systems. Conventional computed radiography (CR) and DR systems use a single source of X-rays, which form a conical shaped beam that is divergent in all planes. Conversely, EOS uses a conical beam passed through a slit collimator which changes it into a wide fan shaped beam. The slit beam source and detector move simultaneously. This arrangement results in magnification only in the transverse plane.

In addition, the detector for the EOS uses advanced technology involving a gaseous particle detector with a multi-wire proportional chamber. This detector is based on a novel technology that is not affected by scatter, with the goal of obtaining high-quality images with low radiation doses. The manufacturer, EOS Imaging™, was provided an opportunity to confirm the accuracy of this description of technology.

The conventional device to image the spine, and primary alternative to EOS is CR or DR imaging. These technologies can be used to acquire two dimensional (2D) digital X-rays and are widely used for dental and medical diagnostics. In CR, an imaging plate made of photostimulable phosphor is irradiated and a CR reader extracts the information to create a digital image. Digital radiography is performed using a digital X-ray machine with a flat panel detector. In the case of imaging of the spine or lower limbs, CR and DR images can be acquired in a standing, weight-bearing position. However, due to limitations in the length of images that can be acquired, when imaging large areas of the body, for example, the whole spine, individual images are often digitally 'stitched' together to view the whole region of interest. The dose produced from conventional X-ray techniques, as per other medical

exposures, is dependent upon the device itself, but also optimisation of the medical exposure carried out at local level. Optimisation in general X-ray includes, but is not limited to, collimation, patient orientation, positioning, beam filtration and protocol and parameter selection.

The literature identified through topic exploration indicated that the primary use of EOS is for scoliosis imaging. Other uses include investigations of limb length discrepancies, pre-surgical planning and post-operative assessment and monitoring of orthopaedic patients. This includes imaging of the joints and lower limbs to plan spine and orthopaedic surgery, such as joint replacement surgery (arthroplasty) and as part of post-procedure follow-up. These uses include estimating the Cobb angle (the degree of spinal curvature) as part of the assessment of a patient with idiopathic scoliosis,[3] and predicting the required implant size prior to arthroplasty.[4] Data gained from 3D imaging facilitates 3D modelling which is part of the surgical planning process.[4]

3. Description of clinical indications and epidemiology

This generic justification considers the application of slot-scanning, biplanar, digital radiography X-ray systems as exemplified by EOS to children and adults with scoliosis and other orthopaedic conditions. To aid understanding, below is a brief description of the epidemiology of scoliosis and one of the most common orthopaedic indications for slot-scanning, biplanar, digital radiography X-ray systems: limb length discrepancy. The role of these systems in pre-and post-operative imaging for other orthopaedic conditions is also described.

3.1 Scoliosis

Scoliosis is an abnormal curvature of the spine (Cobb angle >10 degrees). It is usually diagnosed in childhood or adolescence, and can be classified by aetiology: congenital, neuromuscular or idiopathic.[5] Congenital scoliosis develops as a result of abnormalities in spinal curvature which are present from birth,[6] and occurs in one out of 10,000 newborns.[7] Neuromuscular scoliosis occurs with neurological or muscular diseases such as spina bifida, cerebral palsy and muscular dystrophy.[8] Its prevalence in these neuromuscular diseases can vary, affecting 20% of children born with cerebral palsy (which occurs in approximately 2 per every 1,000 live births in Ireland[9, 10] and 90% of males born with Duchenne muscular dystrophy[11] (which is estimated to occur in between 1 in every 3,600 and 1 in every 6,000 live male births in Ireland[12]). Neuromuscular scoliosis can progress relatively quickly and may require surgery.[13] Idiopathic scoliosis (meaning the cause is unknown) is the most common type of scoliosis, accounting for about 80% of all cases. It is usually evident during adolescence and is diagnosed when all other causes of scoliosis are excluded.[14] It affects between 1% and 3% of children aged 10 to 16 years, with females being more likely to develop curvature progression which requires treatment.[15, 16]

According to the Health Services Executive (HSE), scoliosis affects approximately 1% of children and adolescents in Ireland. The latest version of the International Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) guidelines, published in 2018 provide guidance on the radiographic investigations of scoliosis, and note that radiographic examinations remain the reference standard for scoliosis diagnosis. The aim of radiographic imaging is to evaluate disease progression or treatment failure, informing further management of the patients' conditions. Authors of these guidelines acknowledged at the time of writing that there is limited good-quality evidence on how often radiographic assessment is required for diagnosis, evaluation and follow-up. However, they recommend X-ray examinations are performed at the time of first evaluation and every 6-12 months thereafter, to limit

the total number of X-rays. They also recommend that the number of views taken should be limited during follow up (for example, lateral views should not be taken if not needed). Intervals between radiographic assessments may vary depending on the extent of scoliosis. For idiopathic scoliosis, guidelines suggest imaging should be carried out up to the age of 18 years. The guidelines also recommend that imaging be performed when a brace is prescribed.[17]

While the dose from general X-rays used in spinal imaging is relatively low, regular X-rays are required to monitor progression in scoliosis which means that patients are frequently exposed to radiation.[17, 18] Currently, the linear no-threshold model (LNT) is the most widely applied model to estimate the effects of ionising radiation on the human body.[19] This model assumes that every increment of radiation dose, no matter how small, constitutes an increased cancer risk for humans. While the use of this model at very low doses of radiation has been disputed, it is accepted that dose from medical exposures should be kept as low as possible. This is particularly important for younger people who are at higher risk of developing radiation-induced cancer, due to the time they live after the exposure and the rate of cell division. Scoliosis imaging involves imaging the whole spine for which the field of view could potentially include radiosensitive structures such as the thyroid, breasts and reproductive organs. In addition, females are more radiosensitive than males which impacts radiation cancer induction.[20] In the context of scoliosis, minimising radiation dose is an important consideration due to the young population, frequency of imaging and prevalence of progression in females.[15] Therefore, the selection of technology and optimisation to keep the dose as-low-as-reasonably-achievable, while achieving adequate diagnostic and clinical information from imaging, is particularly important in this population.[15]

3.2 Other orthopaedic conditions

Slot-scanning, biplanar, digital radiography X-ray systems such as EOS can be used to image a range of other orthopaedic conditions – one of these is the assessment of limb length discrepancy, which is defined as one arm or leg being shorter than the other. This phenomenon can be congenital, where a child is born with a condition that causes their bones to grow at different rates, or acquired during a person's lifetime.[21] Acquired limb length discrepancy can occur from fractures induced by infection (for example, osteomyelitis), injury, bone cancer or bone cysts.[22]

Applications of EOS to date have focused on discrepancies in the length of the legs. Limited data are available about how common leg length discrepancy is. While a 2005 review of studies suggested that only 10% of the general population have legs of exactly equal length, it highlighted that in the majority of cases, this is not clinically significant.[23] A French epidemiological study indicated that only 1 in 1,000

people had received orthopaedic treatment for leg discrepancy of ≥2cm.[23] Differences in leg length can significantly impact a child's life as they typically have to adapt their posture and walking pattern and this may cause lower back pain.[24] Leg length discrepancy can also impact the rest of the body, causing for example, functional scoliosis, and hip, knee and ankle problems.[25] Functional scoliosis means the spine has an abnormal curvature, but it is caused by a lateral (side-to-side) curvature of the spine, rather than a structural abnormality within the spine itself.[25] The aim of radiographic imaging for patients with leg length discrepancy is to determine the location and severity of the discrepancy and provide information about the cause of the discrepancy.[3] This information can then inform the management or intervention required.

Another clinical indication for slot-scanning, biplanar, digital radiography X-ray systems is the pre- and post-operative assessment of orthopaedic conditions, including conditions for which hip and knee arthroplasty may be considered. Patients undergoing knee and hip arthroplasty most commonly have severe osteoarthritis;[26] other conditions which may require arthroplasty include: rheumatoid arthritis[27] hip fracture[28] hip dysplasia.[29] X-ray imaging is used pre-surgery as part of surgical planning to gather radiographic measurements and to estimate approximate prosthesis and implant sizes.[30, 31] Pre-surgical planning can also predict measurements of femoral torsion and reconstruction of anatomical leg length, and offset and anticipate surgical difficulties. It is suggested that if the accuracy of sizing can be improved during pre-surgical planning, there is the potential to save time in the surgical theatre and to reduce costs if fewer implant options are needed.[32] Similarly, X-rays are typically used in the pre- and post-operative settings, including as part of an initial assessment should post-arthroplasty complications arise (for example, infection or dislocation of the prosthesis).[33] Advantages of conventional CR or DR include that they are generally widely available, are typically low cost and have a relatively low radiation dose.[34] CT provides 3D information, but is more expensive and involves a higher radiation dose. Slot-scanning, biplanar, digital radiography X-ray systems, in contrast, facilitate low-dose, 3D, weight-bearing images.

4. Test performance, clinical benefits and safety

4.1 Methodology

The reporting of this rapid review adheres to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria, where appropriate. Of note, the PRISMA extension for diagnostic test accuracy was not used as the primary studies identified in this rapid review did not report standard diagnostic accuracy measures. In Ireland, public and occupational exposure is primarily the responsibility of the Environmental Protection Agency (EPA). However, the Regulations require HIQA to consider public and occupational exposure as part of the justification of medical exposure. The approach taken to this issue and the two review questions (RQs) is outlined in the following sections.

4.1.1 Review questions (RQs)

RQ 1 To determine the test performance, clinical benefits and safety of imaging using slot-scanning devices (for example, EOS) compared with conventional X-ray imaging for the evaluation and monitoring of scoliosis.

RQ 2 To determine the test performance, clinical benefits and safety of imaging using slot-scanning devices (for example, EOS) compared with current practice for the evaluation and monitoring of patients with other orthopaedic conditions.

Table 1 outlines the Population, Intervention, Comparison, Outcomes, Setting (PICOS) eligibility criteria, as well as details of the eligible study designs and languages.

Table 1: PICOS table

PICOS	Description
Patient/Problem:	Adults and children (minimum age 6 years), presenting for imaging for: ▪ whole spine imaging for confirmed or suspected scoliosis (RQ1) ▪ other orthopaedic conditions (RQ2). Phantom studies were included to gather dosimetric information.
Intervention:	Any slot-scanning device or slit-beam digital radiography system, including the EOS system™ and EOSedge™.
Comparison:	Conventional digital radiography or computed tomography scanogram. No comparator.*

Outcomes:	Test performance, clinical benefit and safety: ▪ any measure of test performance (for example, sensitivity, specificity, inter-rater reliability) ▪ other stated clinical benefits (for example, time per scan, access to diagnostics, and dose reduction for patient etc.) ▪ patient safety outcomes (for example, dose per scan, long term risk of cancer).
Setting	Healthcare settings.
Study Design	Included: ▪ RCTs, observational studies, diagnostic accuracy studies, phantom studies. ▪ systematic reviews with the following key characteristics: o clearly stated set of objectives with an explicit, reproducible methodology o a systematic search of at least two databases that attempts to identify all studies that would meet the eligibility criteria o a systematic presentation, and synthesis, of the characteristics and findings of the included studies. ▪ clinical guidelines, practice parameters. Excluded: o case studies, case series, non-systematic literature reviews o studies whose sole participants were asymptomatic or healthy volunteers o dry bone and cadaver studies due to limited clinical relevance.
Languages:	Only articles for which an adequate English translation could be obtained were included.

Key: RCT - randomised controlled trial; RQ - review question
*Note: Studies without a comparator or that used an alternate comparator which is not relevant to the Irish context (for example, MRI or ultrasound) were included at title/abstract & full text screening, in order to capture data on EOS scan dose and inter-/intra-rater variability, but were not considered relevant to this generic justification.

4.1.2 Outcomes

For the purpose of this rapid review, test performance was defined as any:

- Outcome that includes measures of diagnostic accuracy (for example, sensitivity, specificity, negative and positive predictive values), or image quality (for example, contrast to noise ratio or signal to noise ratio), or any measure of radiographic parameters (Cobb angles, limb lengths and other

parameters) or measures of repeatability and reproducibility (for example, inter- and intra-rater agreement).

- Measurement of dose using patients or phantoms. (Phantoms are objects which have been specially designed to mimic the radiological characteristics of human tissues.[35] They are used in radiology and radiation oncology as part of quality control and for research purposes, and among other things can be used to test the accuracy of imaging systems and to estimate the dose to patients).
- Other stated clinical benefits (for example, comfort, time taken for scan).
- Harms (patient safety outcomes, for example, long terms cancer risk).

4.1.3 Search Strategy

Electronic searches were conducted in Medline and the Cochrane Library. The full database search strategy can be found here: https://doi.org/10.5281/zenodo.7798330

A search of the grey literature was also carried out - details of this search are outlined in Table A.1 of Appendix 1. In order to streamline this rapid review, backward and forward citation searching of returned citations of relevance was not undertaken. In order to identify any safety alerts or updates, a search of regulatory websites was also carried out, as outlined in the grey literature search (Table A.1 of Appendix 1).

4.1.4 Record selection and data extraction

Record selection

Returned records from the collective search were added to Endnote for reference management. Following de-duplication, the records were then transferred to Covidence for screening. Title and abstract screening and full text screening were performed by one reviewer, applying the pre-defined eligibility criteria, with a second reviewer checking agreement in 20% of records which were randomly selected. A small number of minor disagreements were resolved by discussion. Reasons for exclusion following full-text review were documented and summarised in the PRISMA Flowchart (see Figure 1). Of the studies which met the stated inclusion criteria, on closer review by the team, some records were found to contain data which were of limited value to this review (for example, studies which did not include a comparator or which included an alternative comparator not relevant to the Irish setting such as MRI). In order to streamline this rapid review, a full set of data were not extracted for these records, nor were they assessed for risk of bias; brief characteristics of these records are summarised in Table A.2 Appendix 1.

Data extraction

A standardised data extraction template was developed in Microsoft Excel and piloted prior to undertaking data extraction. Data extraction was performed by one reviewer, and a second reviewer data extracted 20% of these records to ensure concordance and check for quality. With the exception of a few minor disagreements which were resolved by discussion, extracted data were found to be concordant, so further duplication of data extraction was not deemed necessary.

4.1.5 Risk of bias assessment

In line with best practice, HIQA endeavours to use established and validated tools to aid the critical appraisal and risk of bias assessment of studies included in its evidence synthesis. However, the primary studies identified in this rapid review focused mainly on comparisons of radiographic measurements, assessment of inter and intra-observer variability, pre-surgical estimation of prosthesis parameters and comparisons of the radiation dose associated with EOS and CR/DR or CT. No suitable tool was identified to appraise these studies. Therefore, in line with the approach adopted by the UK's National Institute for Health and Social Care Research (NIHR) in their 2012 Health Technology Assessment (HTA),[36] a modified version of an established quality assessment tool for diagnostic accuracy studies was used. The NIHR HTA, which also assessed the use of EOS for the evaluation and monitoring of scoliosis and other orthopaedic conditions, was identified during the grey literature search. It used QUADAS as the primary tool, adding six additional items to address whether studies (where applicable) measured radiation dose in an appropriate way, and whether the intervention and comparator were used in line with clinical practice.[36] In this current rapid review, risk of bias was assessed using the QUADAS-2 tool[37] with the addition of the six items similar to the approach undertaken by the NIHR. These additional questions are outlined in Table A.3 of Appendix 1. To streamline this rapid review, only studies which underwent full data extraction were assessed for risk of bias (as described in Section 4.1.4). Each study was assessed by one reviewer with areas of uncertainty resolved following discussion with the review team. Systematic reviews were assessed for risk of bias using the Assessing the Methodological Quality of Systematic Reviews-2 (AMSTAR-2) tool.[38]

4.1.6 Data handling and presentation

Findings of the identified primary studies as well as the identified systematic reviews are reported narratively. Due to the high volume of studies which were identified as being of relevance, only the findings from the higher quality studies (those with a lower risk of bias), as assessed using the QUADAS-2 tool, are discussed in detail in

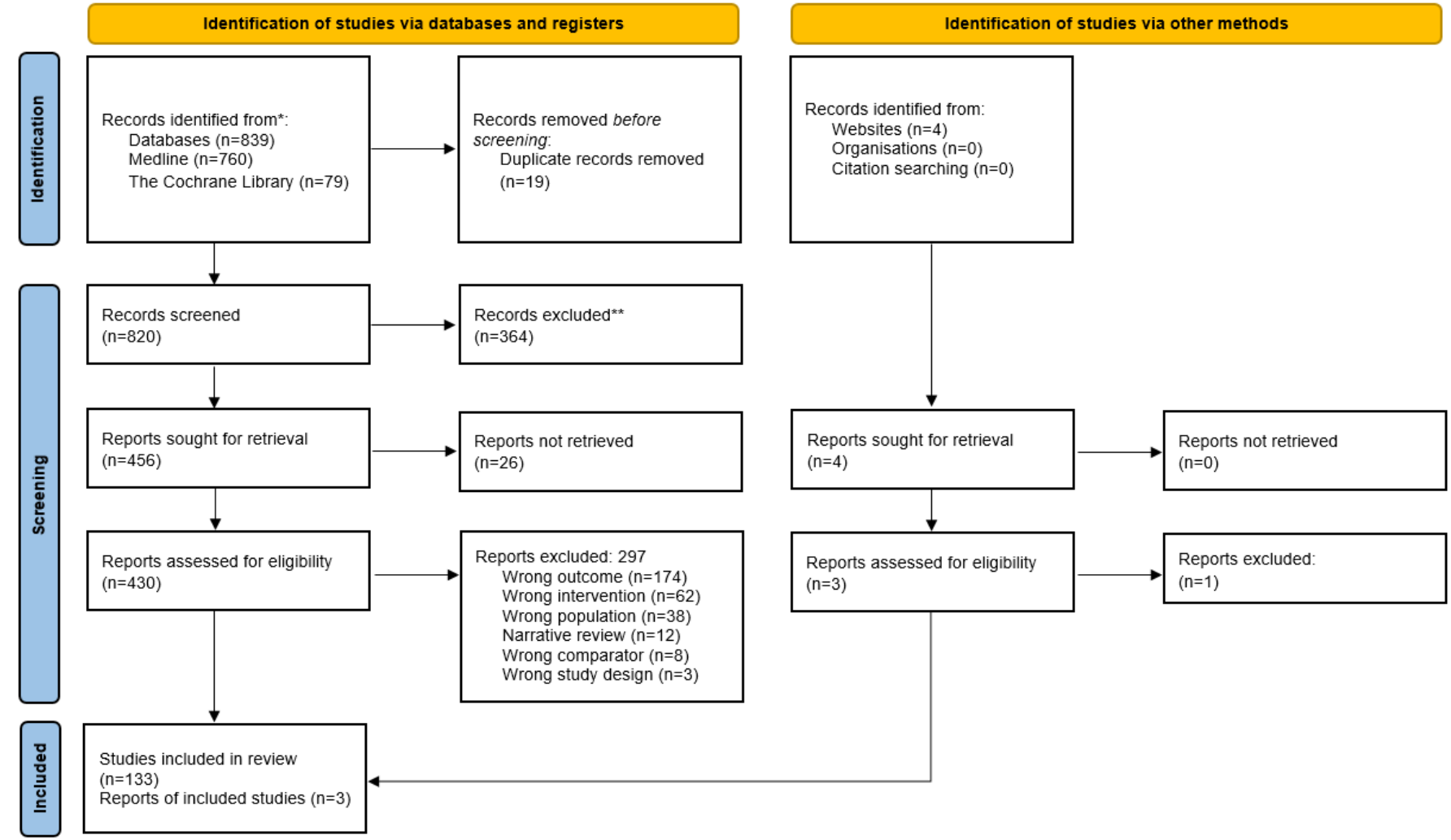
the results section. Findings from the lower quality studies are summarised briefly and any discordant findings highlighted.

4.2 Results

4.2.1 Search results

The collective search up until 22 March 2023 resulted in 839 records. Following removal of duplicates, 820 records were screened for relevance, with 430 full texts reviewed and 297 subsequently excluded. In total, 133 records met the inclusion criteria for this rapid review. A PRISMA flow-chart summarising the search process and subsequent results is provided in Figure 1.

Figure 1: PRISMA flow diagram



4.2.2 Summary of included records

A total of 136 studies and reports were identified for inclusion. Of these, 133 were identified via database searching and three were identified via other methods. Included records consisted of 130 primary studies, two HTAs (each containing a relevant systematic review), two clinical guidelines, one stand-alone systematic review, and one practice parameter. There was some overlap between the primary studies identified in this rapid review and those included within the HTAs and systematic review identified in this rapid review. Two additional primary studies were found from the HTAs,[39, 40] one of which was an unpublished study, and as such, would not have been eligible for consideration per the criteria in Table 1.[40] The findings section of this report focuses on the findings of the primary studies. The main aim in reviewing other evidence synthesis reports was to assess for areas of discordance or concordance. The two clinical guidelines and the practice parameter are discussed in Section 4.3 International practice and guidelines.

Of the 130 primary studies, 90 were deemed to be of limited value to this rapid review. This was primarily because these studies did not include a comparator or the comparator included in the study was an imaging modality not included in the application for generic justification. Examples of these alternative comparators included magnetic resonance imaging (MRI), fluoroscopy and ultrasound. Brief characteristics of these 90 studies are summarised in Table A.2 of Appendix 1. Findings from the remaining 40 primary studies, the two HTAs and the systematic review are presented in Table A.4 of Appendix 1. These findings are discussed below, according to RQ1 (scoliosis) and RQ2 (other orthopaedic conditions). Due to the high volume of primary studies which were identified as being of relevance, only the findings from the highest quality studies (those with a lower risk of bias), as assessed using the QUADAS-2 tool, are discussed in detail in the results section.

There was a lack of diagnostic accuracy outcomes in the results (for example, sensitivity and specificity, negative and positive predictive values). The test performance outcomes reported in the search results were commonly radiographic parameters (for example, Cobb angle measurements). The ERT included such radiographic parameters as surrogate outcomes for test performance.

Relevant findings from the clinical guidelines and the practice parameter are summarised in Section 4.3 International practice and guidelines.

4.2.3 Risk of bias assessment

AMSTAR 2 was used to assess the three systematic reviews included in this review. A 2012 HTA by the UK's NIHR included a systematic review of the literature, which was also subsequently published as a systematic review of clinical effectiveness in

the European Spine Journal. [36, 41] This was assessed as being of moderate quality (see Table A.5 of Appendix 1). The systematic reviews by Mahboub–Ahar[42] and Pettit[43] were assessed as being of critically low quality (see Tables A.6 and A.7 of Appendix 1).

For the 35 primary studies involving patients, the assessed risk of bias using QUADAS-2 was mostly 'high' or 'unclear' for patient selection (Appendix 2, Figure A.1 and Table A8). This was due to the nature of these studies as many of them used a clinical dataset and searched retrospectively for a particular patient group that happened to have had both image modalities within a certain time frame. In general, how the index test was conducted or interpreted was not a major source of bias, but it was sometimes unclear from the methods exactly how the test was conducted and if any sort of blinding had been used. The reference standard, conventional radiography or CT, was a potential source of bias in over 40% of studies. This was mainly due to blinding and patient positioning during image acquisition. However, it is acknowledged that it may have been difficult to blind those who interpreted the images in this situation. Another source of bias in these studies was due to the flow and timing of the tests: More than half of the studies had an unclear or high risk of bias for this domain. This was mostly due to either a gap in time between the EOS imaging and the CR/DR imaging or where not all patients received the reference standard. As most of the studies had low patient numbers and very few studies mentioned sample size calculations (15%), it is possible they were under powered. In general those studies that measured radiation dose or image quality used appropriate methods and, in general, EOS imaging and conventional radiography was used as it would be in practice. The studies discussed below in Sections 4.2.4 (15 studies) and 4.2.5 (25 studies) focus on the studies which had a lower risk of bias and were most applicable to the research questions.

Eight primary studies included phantoms, of which five used phantoms only.[44-49]. These phantom-only studies were included as they were considered an important source of dose information. To assess the risk of bias for these studies, the same tool was used as above except for Domain 1 (patient selection) and Domain 4 (flow and timing) as these were deemed not applicable. In general, these five studies had a low risk of bias for the domains and additional questions when considering assessment of dosimetric phantom data. While the dose and image quality information provided by these studies is not in-vivo and is therefore inherently limited, there are some advantages to phantom study designs, which were considered in the risk of bias assessment. Firstly, both index and references images were carried out on the same phantom, whereas in the clinical studies often a cohort of patients received EOS and a different cohort received the comparator imaging. Secondly, phantom studies allow benchmarking of various protocols, which cannot

be carried out in the same way on patients given the radiation exposure involved. Furthermore, dose can be measured both at depth and at entrance (skin) in a phantom, whereas in patients the organ or depth dose is calculated or extrapolated, rather than measured directly.

In seven of the primary studies relevant conflicts of interest or funding declarations were made.[32, 46, 50-54] The nature of these conflicts varied, but were primarily concerned with EOS as a funding source.

4.2.4 **Scoliosis** (RQ1)

Systematic reviews

Two HTAs, which were included in this rapid review reported the results of systematic reviews within them. The first HTA was published in 2012 by the UK's NIHR, and evaluated the clinical effectiveness of EOS compared with CR/DR for the monitoring and evaluation of scoliosis and other orthopaedic conditions.[36] The systematic review, which included three primary studies, concluded that the spinal imaging dose was considerably lower with EOS and the image quality better or comparable. However, the authors noted that only the basic technical abilities of EOS had been established, and its ability to improve patient outcomes had not yet been established. The searches in this review were carried out up to November 2010. The second HTA, published in 2016 was funded by the Iranian Ministry of Health and Education and mainly focused on the relative cost effectiveness of EOS versus CR/DR for any orthopaedic condition.[42] The searches in this review were carried out up to May 2013. This systematic review, which included four studies and one HTA, again reported the lack of a rigorous evidence base for EOS, but noted that primary studies did indicate a reduction in radiation dose, compared with CR/DR. The reported reduction in radiation dose ranged from two to 19-fold.

Primary clinical studies

Of the 15 primary studies describing imaging in scoliosis patients which underwent full data extraction, 14 compared EOS to CR or DR[44, 46-48, 51, 55-63] while one study compared EOS with both CR and CT scanograms.[44] A summary of the characteristics of these studies is presented in Table 2; a detailed overview is also provided in Table A.4 of Appendix 1. Seven of these studies were retrospective comparative studies, four were phantom studies, three were prospective comparative studies, and two were case control studies. Three of these 15 studies were appraised as being of higher quality and applicability and are summarised below.

Dietrich 2013 reported data on 47 and 134 patients (age and sex not specified) who had whole spine imaging for scoliosis with DR and EOS respectively, from a prospective, single centre, case control study.[56] They found that the dose area product (DAP) was significantly lower with EOS (158.4 cGycm^2 SD 103.8 versus 392.2 cGycm^2 SD 231.7 with CR, <0.001). This study did not include a funding or conflict of interest statement.

Deschênes 2010 described a prospective, single centre, comparative study involving 50 adolescents (39 females and 11 males; mean age=14.8±3.6 years) who underwent whole spine imaging for scoliosis with both EOS and CR, which assessed both image quality and dosimetry.[55] Four observers (two orthopaedic surgeons and two radiologists) rated the visibility of 19 radiographic structures using a four-point scale. On Wilcoxon analysis, the visibility of all structures on EOS was significantly better ($p<0.006$) on the PA view, and for all structures in sagittal view $p<0.003$, except for one structure (the lumbar spinous process). The entrance dose was also measured using 13 optically stimulated luminescence dosimeters (OSLDs) positioned on the surface of the patients' bodies (neck, thorax, abdomen and pelvis). The OSLD measurements showed that the mean entrance dose was consistently lower for EOS at all points, compared with CR. The dose was six to nine times lower for thoracoabdominal region and three times lower at the nape of the neck. The study authors declared no funding sources or conflicts of interest.

Luo 2015 reviewed 42 skeletally immature patients with idiopathic scoliosis (age and sex not specified) treated with bracing or spinal fusion. They estimated the cumulative radiation dose of EOS and CR (with and without a lead acrylic filter at the X-ray tube aimed to optimise the patient dose) for an entire course of serial imaging, using a computerised model based on phantom data.[58] The patient model was based on a 15 year old, height: 168cm, weight: 56kg, trunk thickness: 20cm, width: 30cm). The mean number of images was 20.9 per patient (range: 8-43). For EOS imaging, the organ dose to the thyroid, breast and testes was higher if an AP view was used, but the bone marrow dose was lower. The mean cumulative effective dose over the course of scoliosis treatment for all patients was estimated to be 5.38 mSv if standing CR is used for all imaging, 2.66 mSv, a decrease of 51% if EOS is used for all imaging with PA and lateral views and 3.40 mSv, or a decrease of 37% for EOS using AP and lateral views. The potential dosimetric advantages of PA imaging, over AP and the dose impact of using filters are discussed in Section 5 of this report. If CR was used with a filter, the estimated dose was 2.64 mSv, a decrease of 51%.This study did not include a funding or conflict of interest statement.

Findings from a number of studies which were assessed as higher risk of bias and or had lower applicability to the research question are summarised briefly now. Hui

2016[61, 64] and Abrisahm 2017[61] reported that the DAP was lower for whole spine imaging using EOS, compared with CR/DR; however, Yvert 2015 found no significant difference in DAP. Skin entrance dose measured by thermoluminescent dosimeters (TLDs) was lower in the thoracic and sacral regions for EOS, compared to CR/DR, but higher in the cervical regions.[64] Similarly, Hui 2016 found that the skin entrance dose was lower at the sternal notch, nipple line and symphysis pubis.[64] Hirsch 2021 found that the visibility of the cervicothoracic junction was superior on a lateral EOS image, compared to conventional lateral radiograph,[63] while Hui 2016 found image quality was comparable between EOS and DR, except for some blurriness at boundaries of vertebral bodies.[64] Welborn 2020 found the inter-observer intraclass correlation coefficient (ICC) was moderate to excellent for EOS, although inter-image ICC was poor.[62] Simon 2018 found no differences in coronal or sagittal plane measurements between EOS and CR; they did find motion artefacts in 19.7% of EOS images, but this did not affect measurements.[65]

Phantom studies

Pedersen 2018 assessed radiation dose measurements comparing EOS standard dose, EOS micro-dose and CR whole spine imaging in two anthropomorphic phantoms. One phantom represented an adolescent and the other a paediatric patient.[66] Dose to the phantoms was measured using TLDs placed at organ specific positions at depth and on the phantom skin surface. In the adolescent phantom, for PA and lateral images to the whole spine, the effective doses were 29µSv using the micro-dose EOS, 175 µSv using standard dose EOS and 491 µSv (456-531) for CR. Similarly, in the paediatric phantom the EOS micro-dose was 81% less than CR and 86% less than standard dose EOS. However, in the paediatric phantom the EOS standard dose settings had 38% higher absorbed dose than CR when imaged in the PA/lateral orientation. The authors attributed this to conventional imaging optimisation. EOS organs doses were found to be lower in the posterior-lateral orientation than anterior-lateral. This study did not evaluate image quality of the micro-dose EOS protocol. The study authors declared no funding sources or conflicts of interest.

In a dosimetric phantom study, Boissonnat 2023 compared organ doses between DR and EOSedge from full spine imaging.[46] Organ doses were measured in an anthropomorphic female adult phantom and a five-year-old paediatric phantom using optically stimulated luminescence (OSL) dosimeters. Comparisons made to EOS (first generation) dose were estimated from the literature. The effective dose in the female adult phantom was 92µSv for EOSedge compared with 572µSv for DR. In the paediatric phantom, the EOSedge dose was 32µSv and 179µSv for DR. All organ doses calculated were lower for EOSedge than DR. Quantitative image quality

metrics were computed on a quality assurance phantom. The contrast to noise ratio (CNR) was reported to be equal or better with EOSedge vs DR for various attenuation values. The EOSedge was also reported to show a more stable behaviour than DR in relation to contrast-to-noise. The study was sponsored by EOS and some authors were full-time employees of EOS Imaging.

Branchini 2018 carried out a phantom study to compare adolescent whole spine imaging protocols in CR and EOS.[47] TLD measurements were acquired to calculate organ dose and effective dose. CR organ doses were higher than EOS, except for testes and eyes, which were excluded from the scan in CR protocol. The effective dose from EOS was (0.43 ± 0.04 mSv) which was approximately half the dose in CR with anti-scatter grid examination (0.87 ± 0.09 mSv). The study authors did not declare a conflict of interest.

Lifetime attributable risk (LAR) of cancer

Two studies calculated estimates of cancer probability or lifetime attributable risk of cancer (LAR) from the dose data. LAR is the probability of a premature incidence of a cancer attributable to radiation exposure in a representative population.[67] Alrehily 2019 compared the dose from DR, EOS and CT scan projection radiographs (CT scout images) of the whole spine in a phantom.[44] A dosimetry phantom was used to represent a 10-year old child and doses were directly measured using TLDs. The resultant organ doses and LAR of cancer were calculated. For the CT scout images, 27 different protocols were evaluated. Organ doses were statistically higher for DR and CT scout images compared with EOS. The LAR calculated with EOS for a 10-year-old female patient (per 10^6) ranged from 0.07 to 0.86 and for a male (per 10^6) 0.03 to 0.37. The comparative results from DR protocols ranged from 1.15 to 2.26 for female and 0.64 and 1.03 for male. For CT, the LAR ranged from 0.15 up to 5.07 for a female patient depending on the protocol used. The study notes that PA projections had lower organ dose than AP projections and therefore lower resultant LAR values in the simulated male and female patients. The study authors did not declare a conflict of interest.

Branchini 2018 described in the section above, also calculated LAR for EOS and CR imaging.[47] In terms of cancer probability estimates, the study found lower LAR values with EOS compared with DR. The estimated number of cancer induction cases per 100,000 people for a male at age 20 was 5.4 from EOS imaging and 9.7 from DR, and at age 15 was 6.6 from EOS and 11.7 from DR.

4.2.5 Other orthopaedic conditions (RQ2)

Systematic review

Pettit 2022 report the results of a systematic review of studies assessing different measurement techniques for limb length discrepancy in patients who have undergone total hip replacement.[43] The search was carried out in August 2021 and of the 42 articles included, three used EOS, all of which reported excellent inter- and/or intra-rater reliability for measuring limb length discrepancy. The authors noted, however, that EOS had not been extensively compared with other imaging modalities, for example DR or CT in the context of pre and post total hip replacement.

Primary clinical studies

Of the primary studies which underwent full data extraction, 20 studies compared EOS with CR or DR in patients with other orthopaedic conditions.[32, 45, 50, 52, 56, 68-83] The anatomical region imaged in these studies included: spine (non-scoliosis imaging), pelvis, hip and lower limbs. The study types included ten retrospective comparative studies, four prospective comparative studies, one cross-sectional study, one randomised study, one retrospective case control study, one phantom study and two diagnostic studies as described by the authors. A summary of the characteristics of these studies is presented in Table 3; a detailed overview is also provided in Table A.4 of Appendix 1. Five clinical studies and two phantom studies compared EOS with CT or CT scanogram. A summary of the characteristics of these studies is presented in Table 4; a detailed overview is also provided in Table A.4 of Appendix 1. One study compared EOS with both CR and CT scanogram and is included in both Tables 4 and 5.[71] There were seven clinical studies found to be of higher quality and applicability to this RQ; these are described below.

Dietrich 2013 reported data on 68 and 134 patients (age and sex not specified), which had imaging of the lower limb with DR and EOS respectively, from a prospective, single centre, case control study.[56] They found that the DAP was significantly lower with EOS (92.1cGycm^2±45.5 versus 170.9cGycm^2±104.2 with DR, <0.001). This study did not include a funding or conflict of interest statement.

Lazennec 2011 conducted a single centre, prospective, study with 50 adults (26 females and 24 males; mean age=60.94 ± 6.1 years (50—73)) who underwent pelvic imaging with DR and EOS, in both the sitting and standing position, following total hip replacement.[79] Five radiographic parameters were measured three times each, on AP and lateral images (2D images) taken on both DR and EOS, by two independent operators. There was excellent correlation between measurements on EOS and CR for all parameters as indicated by the Spearman's correlation coefficient (range: 0.82 to 0.97); and the ICC (range: 0.90 to 0.98). However, direct measurements using the Student's t-test showed a significant difference between the measured values for all of the radiographic parameters except for pelvic

incidence and sacral slope while standing (1-2 degrees for pelvic parameters and 2-3 degrees difference for acetabular parameters). The inter- and intra-observer variability was better for EOS (ranged from ± 2.97 degrees to ± 6.46 degrees) compared with DR (ranged from ± 4.26 degrees to ± 10.22 degrees); $p < 0.05$. This study did not include a funding statement; the authors declared no conflicts of interest.

Moltó 2014 reported the results of a single-centre, observational study of 48 people with confirmed ankylosing spondylitis (13 females, 35 males; mean age=47.6 years) and 48 controls with low back pain (39 females, 9 males; mean age=49.1 years).[81] Both groups underwent CR and EOS imaging of the whole spine; two readers, who were blinded to the medical files, independently reviewed the images to assess for sacroilitis and spinal involvement. The readers also gave a subjective assessment of the ease of assessment, as rated on a visual analogue scale of zero to ten. There was excellent agreement between EOS and CR for detecting spine involvement (kappa 0.97), but agreement was lower for sacroiliitis detection (kappa of 0.50 (95% CI 0.26, 0.75) and 0.50 (95% CI 0.16, 0.84) for reader 1 and reader 2, respectively). The sensitivity (0.76) and specificity (0.84) for detection of sacroiliitis were identical with EOS and CR. Agreement between CR and EOS in the evaluation of sacroilitis was moderate (kappa 0.5). CR had higher ease of interpretation scores (8.2; SD 0.9), compared with EOS (7.2; SD 0.8, $p < 0.0001$). This study did not include a funding statement; the authors declared no conflicts of interest.

Brenneis 2021 carried out a single centre, randomised study assessing the reliability of EOS compared with DR for planning prosthesis size for 51 patients undergoing total hip replacement.[52] Twenty-three patients (13 females, 10 males; mean age=60.2 years) had EOS imaging while 28 patients (12 females, 16 males; mean ages=63.5 years) had DR. Prosthesis templating was performed using EOS or DR imaging, by two independent observers twice, four weeks apart. The intra-observer variability for both EOS (0.92-0.97) and DR (0.84 to 0.96) were excellent for both observers for stem and cup planning. Inter-observer ICC for both stem and cup planning was higher for EOS (0.91-0.92) compared with DR (0.84). The implanted stem size was predicted ±1 size in 91.3% of case for EOS compared with 85.7% of cases for DR. The exact size was predicted was in 34.8% of cases for EOS compared with 35.7% for DR. The exact implanted cup size was predicted ±1 size in 100% of cases for EOS compared with 89.3% for DR. This study received funding from EOS imaging.

Rosskopf 2019 reported the results of a single centre, prospective, comparative study with 50 adults (29 females, 21 males; mean age: 47±16.6 years) referred for hindfoot alignment angle measurement and underwent both EOS and long axial view radiographic imaging using DR on the same day.[72] The inter-observer agreement

was excellent for both modalities, with an ICC value of 0.992; 95% CI 0.986–0.995) for EOS and ICC = 0.962; 95% CI: 0.932–0.978 for DR. Inter-method agreement was good (ICC: 0.66 (−0.646 to 0.470)). The mean difference between EOS and DR was −2.4° (range −29.4° to 25.6°) for reader 1 and −2.6° (range −28.7° to 30.2°) for reader 2. This study did not include a funding statement; the authors declared no relevant conflicts of interest.

Guggenberger 2014 presented results from a single centre, prospective, comparative study of 51 adults (29 females, 22 males; mean age=68.8 years (43–92 years)) who had imaging of the lower limb with CT scanogram, standing CR and standing EOS, following total knee replacement.[71] Lower limb length, composed limb length and limb alignment were measured independently by two radiologists. The mean lower limb length was 783 ± 56.1 mm (range: 639–927 mm) on CT scanogram; 785 ± 53.0 mm (range: 655–924 mm) for CR and 780 ± 55.4 mm (range: 633–921 mm) on EOS. These differences were statistically significant ($p < 0.001$), but felt by the authors to be clinically comparable. Mean alignment angles were 2.3 degrees ± 5.5 degrees (range: −12 degrees to 20 degrees) on CT scanogram, 2.5 degrees ± 6.7 degrees (range: −17 degrees to 18 degrees) for CR, and 3.4 degrees ± 6.6 degrees (range: −14 degrees to 18 degrees) on EOS. Again these differences were statistically significant ($p < 0.001$), but felt to be clinically comparable. Inter-reader agreement was also measured – all modalities showed no statistically significant differences between readers ($p > 0.05$). Inter-reader agreement was high for all modalities, but the highest reported agreement was for EOS. This study did not include either a funding or conflict of interest statement. As this study had both CT and conventional radiography as comparators it is included in both Table 3 and Table 4 below.

Anderson 2022 carried out a single centre, prospective, comparative study of EOS images and supine CT scans to investigate femoral anteversion in 45 adults (21 females, 24 males; mean age 62.2 years (SD: 9.37)) who had undergone total hip replacement (Table 4).[54] There was no significant difference in the postoperative femoral stem measurements taken on EOS and CT, p=0.862. The measurements also strongly correlated, r=0.95; p<0.001 and the mean paired difference in measurements was -0.09 degrees (95% CI: -1.09 to 0.91). The authors declared in their conflict of interest statement that the manufacturer (EOS) provided measurements on the 3D images.

Of the 20 studies comparing EOS with CR/DR, six are described in some detail above. Fourteen studies had a higher risk of bias and or had a lower applicability. [32, 50, 68-70, 74-78, 80, 82, 83] More details can be found in the data extraction table in Appendix 1, Table A.4 and in Table 3. Findings from these studies are summarised here in brief.

Two of these studies reported dose data.[68, 80] In keeping with the findings from Dietrich 2013 above, both of these studies reported the EOS dose to be roughly half of the CR/DR dose. Of interest, Chiron 2017 reported a difference in the radiation dose with each extra BMI point for the two systems (0.20dGy for EOS versus 0.74dGy for plain X-ray).[68]

Three of the studies looked at surgical planning and found EOS to be comparable to or better than CR/DR at predicting or measuring actual implant sizes.[32, 70, 78] The other eight studies reported on radiographic parameters as well as inter- and intra-observer agreement.[50, 69, 73-76, 82, 83] . When comparing EOS to CR/DR, some studies found no differences in radiographic parameters,[50, 73, 76, 82, 83] while others reported some variation, but it was often unclear if the differences were clinically significant.[69, 75]

Five studies compared EOS to CT or CT scanogram (Table 4), two of which were described above[54, 71] and three others, which were of lower quality or applicability, are described in brief here.[53, 84, 85] Nam 2016 compared EOS with CT scout on patients after total knee arthroplasty, and found significant differences when comparing mechanical alignment after total knee arthroplasty,[53] while another study by Ma 2022 found EOS to be comparable with CT to assess post-operative component orientation following total hip arthroplasty. [84] Mayr 2021 found a high correlation between the femoral anteversion angle measured by EOS and CT scan, except in patients with torsional malalignment.[85]

Phantom studies

Two phantom studies were identified as relevant to RQ2.[45, 49] In a limb phantom study, Escott 2013 compared CT scanograms, CR and two EOS protocols for the assessment of limb length.[45] Dose was measured using TLDs on the phantom. Two EOS protocols; EOS-Slow and EOS-Fast were used with varied current (mA) and scanning speed. Skin-entrance radiation dose and standardised measurements of bone lengths were made on each image by two observers. The limb phantom was composed of a plastic left-sided hemipelvis, leg and foot bones. The mean absolute difference from the true length of the femur was significantly more accurate for the EOS-Slow (2.6 mm; 0.5%) and EOS-Fast (3.6 mm; 0.8%) protocols as compared with CT scanograms (6.3 mm; 1.3%) ($p < 0.0001$) and CR (42.2 mm; 8.8%) ($p < 0.0001$). There was no significant difference in accuracy between the EOS-Slow and EOS-Fast protocols ($p = 0.48$). Intraclass correlation coefficients showed excellent (>0.90) agreement for CR, the EOS-Slow protocol and the EOS-Fast protocol. The mean skin radiation dose was significantly lower for the EOSFast protocol (0.68 mrad; 95% confidence interval [CI], 0.60 to 0.75 mrad) compared with the EOS-Slow protocol (13.52 mrad; 95% CI, 13.45 to 13.60 mrad) ($p < 0.0001$), CT

scanograms (3.74 mrad; 95% CI, 3.67 to 3.82 mrad) ($p < 0.0001$), and conventional radiographs (29.01 mrad; 95% CI, 28.94 to 29.09 mrad) ($p < 0.0001$). The authors of this study declared no relevant conflicts of interest.

Delin 2014 used an anthropomorphic phantom and compared the EOS dose with the CT dose in the ovaries, testes, knees and ankles. They concluded that compared with EOS imaging the CT dose was 4.1 times higher in the ovaries, 24 times higher in the testicles and 13-30 times higher in the knees and ankles.[49] The authors of this study declared no relevant conflicts of interest.

Table 2: Study characteristics table for RQ1 (scoliosis) comparing EOS to CR/DR and CT scanogram

Author	Study design	Anatomical region imaged	Indication	Outcomes			
				Test performance		Dose	
				Population	Measurements	Population	Measurements
Patient only studies							
Dietrich[56] (2013)	Prospective, case control study n = 47 (DR) n = 134 (EOS)	Whole spine	Not specified	Not included	Examination time Patient comfort	Adults, unclear if adolescents also included	DAP (cGycm^2)
Hirsch[57] (2015)	Prospective comparative study n = 50	Whole spine	Pre-operative imaging	Children scheduled for scoliosis surgery	Radiographic parameters.	Children scheduled for scoliosis surgery	Dosimeter (mSv)
Luo[58] (2015)	Retrospective comparative study n = 42	Whole spine	Serial imaging	Not included	Not included	Children with scoliosis	Computerised dosing model (mSv)
Hui[64] (2016)	Prospective comparative dosimetry study n = 33 (EOS) n = 99 (EOS)	Whole spine (microdose EOS)	Not specified	Adolescents with idiopathic scoliosis.	Inter-observer variability. Radiographic parameters. Image quality.	Adolescents with idiopathic scoliosis	Effective organ dose calculated using PCXMC. TLDs (µGy).
Singhatanadgige[51] (2016)	Retrospective comparative study n = 35	Lateral whole body	Not specified	Adults with C-spine deformity, including scoliosis.	Inter-observer & intra variability. Radiographic parameters.	Not specified	Not specified
Abrisham[61] (2017)	Prospective case controlled study n = 18 (DR) n = 41 (EOS) n = 36 had both	Whole spine	Not specified	Not specified	Not specified	Children & adults with bone deformity	DAP (cGy/cm^2)

Welborn[62] (2020)	Retrospective comparative study n = 43 (55 DR images; 184 EOS images)	Whole spine	Post-operative images	Children with scoliosis	Radiographic parameters.	Not specified	Not specified
Hirsch[63] (2021)	Retrospective comparative study n = 50	Lateral cervical images	Not specified	Not specified	Radiographic parameters. Image quality.	Not specified	Not specified
Simon (2018)[65]	Retrospective comparative study n = 198	Whole spine	Post-operative images	Post-operative images	Radiographic parameters.	Not specified	Not specified
Patient & phantom studies							
Deschênes [55] (2010)	Prospective comparative study n = 50	Whole spine	Diagnostic imaging of spinal deformities	Adolescents with spinal condition	Image quality.	Anthropomorphic phantom	OSLD dose (mGy)
Yvert[59] (2015)	Retrospective comparative study n = 26 (DR) n = 33 (EOS)	Whole spine	Not specified	Children & adolescents with scoliosis + phantom	Inter-observer variability. Radiographic parameters. Image quality.	Children & adolescents with scoliosis + phantom	DAP (cGy/cm^2) TLDs to measure entrance dose (µGy)
Phantom only studies							
Boissonnat [46] (2023)	Phantom study	Whole spine	N/A	N/A	Image quality	Anthropomorphic phantoms (female adult & paediatric)	TLD dose (mGy)
Branchini [47] (2018)	Phantom study	Whole spine	N/A	N/A	Not specified	Anthropomorphic phantom	TLD dose (mGy) DAP (mSv) LAR estimated.

Alrehily[44] (2019)	Phantom study*	Whole spine	N/A	N/A	Not specified	Anthropomorphic paediatric phantom	LAR
Pedersen [66] (2018)	Phantom study (standard & microdose EOS)	Whole spine	N/A	N/A	Not specified	Anthropomorphic phantoms (female adult & male child)	TLDs (skin & at within); µGy)

Key: CR: computed radiography; DAP: dose area product; DR: digital radiography; LAR: lifetime attributable risk; OSLD: optically stimulated luminescence detector; TLD: thermoluminescence dosimeter.

Note:* CT scanogram vs EOS vs DR

Table 3: Study characteristics table for RQ2 (other orthopaedic conditions) comparing EOS with CR/DR

Author	Study design	Anatomical region imaged	Indication	Outcomes			
				Test performance		Dose	
				Population	Measurements	Population	Measurements
Patient only studies							
Chiron[68] (2017)	Prospective comparative study n = 183 (186 hips)	Femoral heads/hips	Pre-operative imaging	Adults who are undergoing THR.	Image magnification	Patients who are undergoing THR.	DAP (dGy/cm^2)
Mainard[32] (2017)	Retrospective case-control study n = 31	Femoral heads/hips	Pre-operative imaging	Adults who are undergoing THR.	Surgical planning (instruments)	Not specified	Not specified
Powell[69] (2020)	Retrospective cohort study n = 21	Femoral heads/hips	Pre-operative imaging	Children/adolescent with acetabular dysplasia	Inter-observer & intra variability. Radiographic parameters.	Not specified	Not specified
Brenneis [52] (2021)	Randomised study: EOS (standing) vs DR (supine) n = 51	Femoral heads/hips	Pre-operative imaging	Adults undergoing THR	Inter-observer & intra variability. Surgical planning (instruments).	Not specified	Not specified
Buller[70] (2021)	Retrospective comparative study n = 160	Femoral heads/hips	Pre-operative imaging	Adults undergoing THR	Intra-observer variability. Surgical planning (instruments).	Not specified	Not specified
Dietrich[56] (2013)	Prospective case control study n = 68 (DR) n = 134 (EOS)	Lower limb	Lower limb length measurement	Not specified	Time for examination. Patients' comfort (noise).	Adults, unclear if adolescents also included	DAP (cGycm^2)
Guggenberger[71] (2014)	Prospective comparative study *	Lower limb	Not specified	Adults who had undergone TKR	Inter-modality & inter-reader variability.	Not specified	Not specified

	n = 51				Radiographic parameters.		
Rosskopf [72] (2019)	Prospective comparative study n = 50	Lower limb	Not specified	Not specified	Inter-observer & intra variability. Radiographic parameters.	Not specified	Not specified
Hau[73] (2020)	Prospective comparative study n = 20	Lower limb	Pre-operative imaging	Adults with osteoarthritis	Radiographic parameters.	Not specified	Not specified
Hyun-Soo Moon[74] (2020)	Retrospective comparative study n = 90	Lower limb	Not specified	Not specified	Radiographic parameters.	Not specified	Not specified
Koliogiannis[75] (2021)	Retrospective comparative study n = 142	Lower limb	Grading of osteoarthritis	Adults with osteoarthritis	Radiographic parameters.	Not specified	Not specified
Störmann [76] (2021)	Retrospective comparative study n = 41 (43 ankles)	Lower limb	Not specified	Not specified	Inter-observer & intra variability. Radiographic parameters.	Not specified	Not specified
Choi[77] (2022)	Retrospective comparative study n = 52 (90 knees)	Lower limb	Pre-operative images	Adults with osteoarthritis.	Radiographic parameters.	Not specified	Not specified
Chua[78] (2022)	Retrospective comparative study n = 43	Lower limb	Not specified	Not specified	Surgical planning (instruments).	Not specified	Not specified
Rungprai [50] (2014)	Retrospective comparative study n = 50	Ankle & foot	Post-operative imaging	Adults who had undergone bilateral foot & ankle realignment.	Radiographic parameters.	Not specified	Not specified
Lazennec [79] (2011)	Prospective comparative study n = 50	Pelvis	Post-operative imaging	Adults who have undergone THR	Inter-observer & intra variability. Radiographic parameters.	None specified	None specified
Mussmann [80]	Retrospective comparative study	Pelvis	Not specified	Not specified	Inter-modality & inter-reader	Not specified	DAP (mGy/cm^2)

(2019)	n = 34				variability. Radiographic parameters.		
Moltó[81] (2014)	Observational study n = 96 (48 with SpA; 48 controls with low back pain)	Whole spine	SpA or low back pain	Not specified	Inter-observer & intra variability. Radiographic parameters. Ease of interpretation.	Not specified	Not specified
Wu[82] (2021)	Retrospective comparative study n = 50	Lumbar X-ray & whole spine EOS	Pre-operative imaging	Not specified	Inter-observer & intra variability. Radiographic parameters.	Not specified	Not specified
Wei[83] (2021)	Retrospective comparative study n = 50	Lumbar X-ray & whole spine EOS	Pre & post-operative imaging	Not specified	Inter-observer & intra variability. Radiographic parameters.	Not specified	Not specified
Phantom studies							
Escott[45] (2013)	Phantom study*	Phantom limb	N/A	N/A	Inter-modality variability. Radiographic parameters.	N/A	TLD (mrad)
Delin [42] (2014)	Phantom* & clinical study	Hips, knees & ankles	N/A	Adults with osteoarthritis.	Image quality.	N/A	TLD absorbed dose (mGy)

Key: DR: digital radiography; DAP: dose area product; LAR: lifetime attributable risk; SpA: spondyloarthritis; THR: total hip replacement; TKR: total knee replacement; TLD: thermoluminescent dosimeter *CT scanogram vs EOS vs DR

Table 4: Study characteristics table for RQ2 (other orthopaedic conditions) comparing EOS with CT or CT scanogram (CT scout)

Author	Study design	Anatomical region imaged	Indication	Outcomes			
				Test performance		Dose	
				Population	Measurements	Population	Measurements
Guggenberger[71] (2014)	Prospective comparative study * n = 51	Lower limb	Not specified	Adults who had undergone TKR	Inter-modality & inter-reader variability. Radiographic parameters.	Not specified	Not specified
Nam[53] (2016)	Retrospective comparative study (CT scanogram) n = 160	Lower limb	Post-operative imaging	Adults who have undergone TKR	Radiographic parameters.	Not specified	Not specified
Anderson[54](2022)	Prospective comparative study (CT) n = 45	Lower limb	Post-operative imaging	Adults who have undergone THR	Radiographic parameters.	Not specified	Not specified
Ma[84] (2022)	Retrospective comparative study (CT) n = 44 (50 hips)	Lower limb	Post-operative imaging	Adults who have undergone THR	Radiographic parameters.	Not specified	Not specified
Mayr (2021)[85]	Prospective study n = 19	Femur	Pre-operative imaging	Adults with suspected torsional malalignment of the femur	Inter-observer & intra variability. Radiographic parameters.	Not specified	Not specified

Key: CT: computed tomography; THR: total hip replacement; TKR: total knee replacement

4.2.6 Public and occupational exposure

The use of slot-scanning, biplanar, digital radiography X-ray systems such as EOS does not raise any additional concerns regarding public and occupational exposure above those considered for the comparative technologies (DR/CR, CT or CT scanograms). In accordance with Regulation 12(5) of S.I. No. 30 of 2019, all practices involving the use of ionising radiation must be authorised in advance by the Environmental Protection Agency (EPA).[86] All undertakings carrying out a radiological practice must fully comply with the relevant provisions of the S.I. No. 30 of 2019 and any conditions attached to an authorisation.

In the context of Ireland, exposure to staff, the public, carers and comforters can be minimised through a carefully considered prospective risk assessment and use of a well-developed quality management system. The design stage of the risk assessment must be completed prior to the installation and commissioning of all sources of ionising radiation.

Local policies, procedures and guidelines must be in place to protect staff and members of the public. Procedures to be followed in the event of an incident liable to have radiation safety implications for workers and members of the public must be developed. It must be ensured that dose constraints and limits for occupational and public exposure as set out in Part 3, Sections 1 and 2 of SI 30 of 2019 are adhered to.[86] In assessing compliance with the dose constraints for medical applications, account should be taken of the principles and approach set out in the EPA's guidance document "The Design of Diagnostic Medical Facilities Where Ionising Radiation Is Used" (2009).[87]

Despite the potential for relatively low doses associated with EOS, exposures to all persons in the vicinity of the radiation source must be considered including members of the public. The risk assessment must identify the operational control measures required to ensure that radiation exposure of each staff group or individual during normal operation of the system is as low as reasonably achievable. Once the required operational controls have been identified, the risk assessment should evaluate the expected and potential doses to staff. These estimates will form the basis for the categorisation of workers. One study has estimated a maximum ambient dose equivalent to 0.045mSv was obtained near the EOS cubicle, with the highest ambient dose equivalent rate was found near to the entrance of the cubicle (>10mSvh-1).[88] The undertaking must provide adequate and proportionate radiation protection training for all staff working in the vicinity of a radiation source.

Further information on the EPA requirements is provided in their guidance for undertakings on the application of the IRR19.[89] Information on the dose constraints

for carers and comforters, and individuals participating in medical or biomedical research is also available in guidance issued by HIQA.[90]

4.2.7 Alternative imaging techniques

The following comparators and alternative interventions were identified in the literature:

- CR or DR imaging
- CT scanogram
- CT (in the context of pre- and post-operative assessments).

Input from clinical experts in Ireland indicated that the use of CR and/or DR radiographs is considered to be the most usual and appropriate alternative course of investigation. However, a number of studies investigating pre-operative planning and post-operative assessment of implants used CT as the reference standard. Images obtained via CT differ from those obtained using EOS in that they are not 'weight-bearing' images, with instead the patient imaged lying flat. It is also argued that vertebral rotational information from a supine image may not reflect the situation when the patient is standing.[41] While the ability to provide weight-bearing images is noted by many to be a distinct advantage of the EOS system, none of the identified studies explicitly investigated how the use of a weight-bearing image might differentially affect further investigations or patient management. Furthermore, although optimisation techniques have reduced CT doses, these doses remain significantly higher relative to EOS and the other alternatives. It is noted however that CT scanograms are sometimes acquired for lower limb imaging. CT scanograms are low dose scout views acquired with a CT scanner, without acquiring the 3D CT scan itself.

In addition, the use of MRI was considered due to its indicated use in some of the international literature and as MRI represents a non-ionising alternative to X-rays. However, in Ireland, CR or DR X-rays are the standard of care that EOS would be replacing and hence, in the Irish context, MRI was not considered a relevant comparator for EOS. The intention to use EOS as an alternative to CR or DR X-rays was outlined by the applicant, and the other hospital using EOS in Ireland. A number of factors limit MRI use in this setting including challenges with supine positioning, access to services and time taken for an MRI scan. SOSORT recommendations do not indicate MRI as a primary diagnostic tool for idiopathic scoliosis, but suggest that MRI can be useful in the evaluation of neuroanatomy in scoliosis patients where there is a suspected neurological condition.[17]

While guidelines offer recommendations regarding the intervals between images and

regarding the use of single-plane images where both views cannot be justified on an individual basis, these issues were not within the scope of this report.

4.2.8 Additional benefits or harms

Dietrich 2013 reported that the mean examination time was shorter for EOS, compared to DR, when used for full spine imaging (248 seconds versus 449 seconds) and full length lower limb imaging (226 seconds versus 309 seconds).[56] This study also assessed patients' comfort level using a four-point Likert scale and found that the EOS was significantly noisier than the DR system ($p<0.01$); albeit noting that, the mean rating for EOS (1.7) was between 'very quiet' and 'rather quiet'. There were no significant differences in any of the other variables assessing patient comfort (overall impression, claustrophobia, ease of getting into position for imaging, feeling of safety, willingness to undergo subsequent examination). Finally, this study asked technicians to rate ease of workflow using a four-point Likert scale: ease of positioning patient; need to re-position patient; frequency of delays or problems. No significant differences in any of these variables were noted.

No safety concerns with EOS were identified in the published literature, however, a number of field safety notices and recalls were identified in the grey literature search of regulatory websites related to incorrect resizing of images on EOS-associated software. These notices and recalls originated from Canada Health, the US Food and Drug Administration (FDA), the Medicines and Health Products Regulatory Authority (MHRA), the Belgian Federal Institute for Drugs and Medical Devices (BfArM) and the Australian Therapeutic Goods Administration (TGA). No information was found that referred to product recalls for the EOS systems in Ireland.

4.3 International practice and guidelines

Primary studies identified in the database search for this rapid review originated from a range of countries, including Canada, China, Denmark, France, Germany, Hong Kong, Korea, Japan, Switzerland, Singapore, the United Kingdom (UK) and the US. Many of these studies utilised clinical databases of EOS images, indicating that this imaging system has been part of routine clinical use in these countries for a number of years.

Five relevant records were identified as part of the database and grey literature searches. These included:

- A HTA published in 2012 by the National Institute for Health and Social Care Research (NIHR) in the UK.[36] The systematic review produced as part of this HTA is discussed in Section 4.2.4 above.
- A HTA funded by the Iranian Ministry of Health and Education, published in

2016.[42] This produced as part of this HTA is discussed in Section 4.2.4 above.

- A consensus paper published by the International Scientific Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) first referenced EOS in 2012 guidelines, where the dose benefit associated with this technology was noted for spinal imaging. Updated guidelines published in 2018 noted the "excellent" and "comparable" inter-observer and intra-observer reliability documented in two primary studies, for the measurement of spinal curvature associated with idiopathic scoliosis.[91]
- A guideline published in 2010 by the National Institute for Health and Clinical Excellence (NICE).[92] This guideline noted that the most important uses of EOS were: management of spinal deformities, leg length discrepancies, leg alignment issues, and hip and knee conditions. However, the considerable set-up costs were also described, with the reporting noting that the comparator technology (DR/CR) was typically already in place in services providing care for this cohort of patients.
- A practice parameter for the performance of radiography for scoliosis in children by the American College of Radiology. This practice parameter cited primary studies which noted comparable dose and image quality with EOS when compared with a flat panel detector.[93] A more recent ACR practice parameter for the performance of spine radiography updated in 2022 indicated that EOS was used to avoid stitching error, reduce whole body dose and was becoming standard of care.[94]

5. Discussion

Slot-scanning, biplanar, digital radiography X-ray, specifically the EOS system was first used in Ireland in 2019 and therefore, in accordance with Irish regulatory requirements, it meets the requirements for a new practice that requires generic justification before it can be generally adopted.

Since its introduction, this technology has primarily been used for scoliosis-related whole spine imaging and measurements of lower limb discrepancy. The included evidence is discussed below in the context of the two research questions relevant to this review: RQ1 (evaluation and monitoring of scoliosis) and RQ2 (evaluation and monitoring of other orthopaedic conditions).

This rapid review identified 130 primary studies, two HTAs (each containing a relevant systematic review), two clinical guidelines, one stand-alone systematic review and one practice parameter for inclusion. While meeting the stated eligibility criteria, 90 of the 130 primary studies were deemed to be of limited value due to a lack of an appropriate comparator technology. The scope of the review included any CE marked slot-scanning, biplanar, digital X-ray system; however, all of the evidence retrieved related to the EOS Imaging™ systems. The identified records focused on imaging for scoliosis and other orthopaedic conditions including limb length discrepancy, and pre- and post-operative imaging.

Overall, the identified studies had favourable conclusions in terms of a dose reduction with EOS relative to conventional imaging and where evaluated, had comparable image quality. Dose data could not be pooled as doses were reported using a variety of metrics and units, with different generations of device and protocols used, and variations in optimisation. However, almost all metrics indicated an EOS dose benefit, which typically was substantial. A variety of radiographic parameters and image quality metrics were reported, limiting comparisons between studies.

Summary of RQ1 findings

The majority (11 out of 15) of the clinical studies in RQ1 focused on the dose reduction benefit of the EOS system. Dose is particularly important in the context of the young scoliosis population due to the frequency of imaging, cumulative dose and potential lifetime attributable risk of cancer.[44, 47, 95]

Many studies did not evaluate conventional image quality metrics such as contrast and noise as outcomes. The majority focused on measurements of radiographic parameters such as Cobb angles in scoliosis, which as an outcome is potentially more clinically relevant than image quality metrics given that the intent of imaging is

often to accurately determine relevant radiographic parameters in monitoring scoliosis. Cobb angle measurements are used to classify the angular degree of scoliosis, from low (up to 20 degrees) to very severe (56 degrees or more). The Cobb method is one of the decisive factors in managing idiopathic scoliosis. It is directly correlated to all treatment decisions and determines the patient's clinical pathway, for example, whether a brace needs to be applied.[91] However, in the studies in this review, the purpose for which these measurements were being made was often unclear, with a lack of clarity as to the clinical impact of the findings for patients in terms of their care.

Overall, as evident from both clinical and phantom studies,[44, 46, 47, 55, 58, 66] for whole spine imaging, both organ dose measurements and skin entrance dose consistently favoured EOS over DR/CR. [47] In some studies, the dose reductions were notable.[44, 56, 59] Dose reduction was also evident for one phantom study where EOS was compared with CT scanograms with various imaging protocols applied.[44]

Overall, clinical studies reported lower doses with EOS than CR/DR; for example, one study reported a halving of DAP measurements with EOS compared with DR.[56] Entrance skin doses are an important outcome measure as they are widely used to compare the performance of different imaging modalities and can be indicative of dose to underlying tissues. Skin entrance dose was evaluated in two of the clinical studies using dosimeters placed on the patients,[55, 59] with the studies reporting similar or lower skin doses with EOS relative to CR. [55, 59] Specifically, one study found that compared with CR, the entrance skin dose was six to nine times lower with EOS for the thoracoabdominal region, while entrance doses were three times lower at the nape of the neck. The dose performance of EOS at the cervical spine region was attributed in this study to the configuration of the system and how it is centred at the thoracolumbar junction. In the other dosimeter clinical study, the EOS skin dose was lower than conventional radiography in the thoracic and sacral regions, but not for the cervical spine region.[59]

In the phantom studies, calculated organ doses from dosimeter measurements were found to be lower with EOS compared with CR/DR.[44, 46, 47, 66] Organ doses are an important outcome measure as they are used to calculate dose to radiosensitive organs such as breast and ovaries, and can be used to estimate long-term cancer risks. The benefit of posterior-anterior (PA) versus anterior-posteriorly (AP) on organ dose was highlighted in some of the studies.[66] For example, in one of the phantom studies, the PA projections had lower organ dose than AP projections and therefore lower resultant lifetime attributable risk values in the simulated male and female patients.[44] This highlights the importance of optimisation which is carried out at institution level to meet local clinical needs. A further example of the need for optimisation was highlighted in another phantom study, which noted CR organ doses

were higher than EOS, except for testes and eyes, which were excluded from the scan in the CR protocol.[47]

In addition to dose, the outcomes in RQ1 included relevant measurements of radiographic parameters such as Cobb angles. Across the included studies, EOS was comparable to CR/DR in terms of Cobb angle measurements and inter-rater reliability for scoliosis examinations. However, there was some level of disagreement in the literature regarding image quality, with one study indicating image quality was significantly better with EOS on structure visibility while another found blurry boundaries at vertebral bodies.[55, 64]

Summary of RQ2 findings

In addition to measurements of lower limb discrepancy, a wide range of potential uses of EOS for orthopaedic imaging were found applicable to RQ2 during the systematic search. These included, for example, imaging to determine orthopaedic measurements such as femoral and tibial torsion and imaging to aid planning of arthroplasty surgeries. However, the relationship between these measures and patient relevant outcomes was somewhat unclear.

Nine studies investigating EOS products compared to CR or DR imaging in the lower limb setting focused on the measurement of radiographic parameters, inter- and intra-observer variability.[45, 56] [71-78] These measurements are used to inform surgical planning. Accurate measurement is important as over or under-correction of lower limb alignment may result in poor prognosis, while restoration of alignment may reduce the requirement for revision surgery. The studies all concluded that outcomes for EOS were comparable to CR or DR imaging except for angular measurements related to the knee where statistically significant mean differences were found between modalities.[74, 77] Similarly, a number of studies indicated that there was good inter- and intra-observer agreement with the use of EOS for pre-surgical planning of hip replacements.[32, 52, 70] One study indicated that EOS demonstrated a good ability to determine the correct cup size, however sensitivity and specificity for determining correct cup sizes compared to the available comparators was not investigated.[52]

Considerations

The purpose of this review was to synthesise evidence to inform a decision with respect to generic justification of slot-scanning, biplanar, digital radiography X-ray systems for evaluation and monitoring of orthopaedic conditions. As noted, all of the identified evidence related to the EOS™ systems. Specifically, it included studies related to both generations of EOS imaging devices currently on the market: the EOS system (first generation) and the newer generation EOSedge.[46] Most of the

included studies presented results from the first generation device, with these studies typically indicating a reduction in dose and comparable or better imaging relative to conventional imaging. Iterative development is common with medical devices, but poses challenges in terms of synthesising results from different generations of device. It is noted that the newer systems may provide further advantages in terms of dose performance. The EOSedge has new features such as embedded automatic exposure control (AEC), which has the potential to reduce dose. The AEC optimises the tube current profile along the vertical scan and the scan speed. Limited comparative data were identified for these systems. One study sponsored by EOS demonstrated a dose benefit of the EOSedge versus the first generation system, although it is noted that this was a phantom study, so the image quality metrics were not carried out on patient data.[46]

In addition to considering different generations of the device, some studies looked at different EOS protocols, such as a micro-dose protocol, and compared the doses to standard imaging protocols. These alternative protocols showed favourable results in terms of dose and comparable image quality metrics.[64, 66] Scan speed was also varied in a phantom study demonstrating the impact of varying the scan speed on lower limb measurements.[45]

In terms of contextualising dose outcomes in this review, it is noted that the national diagnostic reference levels (DRLs) for common radiological practices in Ireland include scoliosis imaging. The DRLs for whole spine scoliosis imaging using CR/DR in $mGy.cm^2$ are: AP 30≤50kg = 980, AP 50-80kg = 1630, lateral 30≤50kg = 1869, lateral 50-80kg = 1840.[18] These DRLs are determined from national census data and are described using air kerma-area product (PKA) also known as DAP. The literature identified in this review used varying methods to determine dose including DAP and actual dose measurements using dosimeters (optically stimulated luminescence dosimeters or thermoluminescent dosimeters). While DAP is a useful tool for comparing doses between services in the context of DRLs, it is an approximation of dose and actual dose measurements may be more meaningful for assessment of a new technology, particularly when determining parameters such as organ dose estimates. While noting this limitation and the lack of relevant weight categorisation in the literature for comparison, the DAP reported in studies in this review indicates that doses arising from whole spine imaging EOS are considerably lower when compared to DR/CR. For example, one study reported DAP with EOS of 158.4 $cGycm^2$±103.8, which is much lower than even the lower weight category Irish DRL.[56]

As noted in Section 2 of the report, slot-scanning, biplanar, digital radiography X-ray systems such as EOS are intended as an alternative to conventional CR and DR images. Due to limitations in the length of images that can be acquired with

conventional X-ray systems, when imaging large areas of the body, for example, the whole spine, it is often necessary to digitally 'stitch' individual CR or DR images together to view the whole region of interest. In contrast, slot-scanning biplanar digital radiography X-ray systems such as EOS enable whole-body 3D imaging in one acquisition eliminating the potential for stitching errors. This issue was not explicitly assessed in the identified studies.

While the dose from orthopaedic imaging is low, there are benefits to optimising radiation dose to reduce long-term risks to the patient, particularly in the context of the young scoliosis population. Two of the studies attempted to calculate the difference in long term potential harm from the dose associated with EOS versus conventional imaging. This was done by comparing lifetime attributable risk (LAR) which is the probability of a premature incidence of a cancer attributable to radiation exposure in a representative member of the population.[67] LAR was calculated by applying risk coefficients for specific organs to effective and organ doses. The organ doses were estimated from dosimeters placed at locations in the phantoms representing typical organ locations. Both studies demonstrated that the LAR was lower with EOS, implying that EOS is associated with a lower long term cancer risk compared with conventional imaging. However, this assumes that EOS replaces conventional imaging and that the cumulative number of images per patient is not increased. Furthermore, there are many risk factors for cancer and the dose from medical imaging only forms part of a person's risk of long term cancer. Therefore, it is difficult to accurately establish the clinical significance of the reported dose reductions that may be achieved with EOS relative to conventional CR and DR X-ray. However, it is accepted that there is a clinical benefit in keeping dose from medical exposures as low as possible, particularly in young patient populations.

Limitations

Due to the lack of recent high quality reviews or HTAs on this specific topic it was difficult to draw comparisons with other reviews. While two systematic reviews were identified in relation to RQ1, they were of limited relevance as both were older reviews (published 2012 and 2015) and were primarily concerned with cost effectiveness rather than issues relevant to the generic justification of medical practices. In addition, a rapid review was undertaken rather than a systematic review, so there is a possibility that some studies may have been missed. Despite this, a large number of studies were identified, with a broad consistency in findings reported.

While a substantial number of studies were identified, including primary clinical studies, the overall evidence base was noted to be limited with the majority of the identified studies appraised as part of this rapid review found to be at high or

unclear risk of bias. In seven of the 35 primary studies relevant conflicts of interest or funding declarations were made.[50, 51] [32, 46, 52-54] These conflicts included grant and funding support from EOS Imaging™ and in two cases authors were employees or board members of the manufacturer.[46, 51] While the findings from these studies in general favoured EOS, the findings were not found to be discordant with other studies without such conflict of interest or funding declarations.

Most primary studies in this rapid review were not conventional diagnostic test accuracy studies, for example, most did not quantify the sensitivity and specificity of EOS. In most studies, sensitivity and specificity could not be calculated as patients were not exposed to both EOS and the reference standard, as a second medical exposure may not have been justified clinically. In studies where patients were exposed to both types of imaging, there were differences in the time intervals between exposures. Nonetheless, the absence of evidence in this area is important to note, especially in informing whether such technologies are justified as diagnostic tools. However, as described above, in some instances, this imaging system is used to obtain radiographic parameters or stem cup sizes rather than as a primary diagnostic tool.

Many of the studies were limited by methodological issues, with most having unclear selection or recruitment processes, no sample size calculations, and or no blinding of those interpreting the radiographs. In addition there were unclear intervals between the acquisitions of EOS and CR or DR images particularly in the retrospective studies plus other risk of bias around funding sources in a number of studies.

A number of studies employed inappropriate statistical analyses and failed to account for the pairing of observations. Appropriate statistical tests are required to control for the fact the same patient is contributing an observation to the EOS and to the comparator data. The difference in the means of these measurement techniques was also felt to be of limited importance. Instead, for example, it would have been preferable to know whether the paired observations were significantly different from one another.

Critical appraisal of the evidence could have been enhanced by the use of a more appropriate and validated tool. However, to the best knowledge of the ERT, no such critical appraisal tool is yet available to assess studies that specifically address issues such as differential radiographic measurements between two imaging techniques or dosimetric measurements. This said, it was felt that following the approach set out by the NIHR allowed for a systematic and uniform approach to critical appraisal that addressed the main areas of concern, albeit with the additional questions considered being more applicable to some studies than others.

Conclusion

While many of the included studies contained methodological flaws, there was clear and consistent evidence from a substantial number of studies, comprising 130 primary studies, two HTAs (each containing a relevant systematic review) and one stand-alone systematic review, that EOS imaging has a dose advantage relative to conventional imaging with CR/DR and CT scanogram with at least comparable image quality.

6. Evidence to decision

A draft of this report was submitted to the MEIR EAG for their consideration and feedback. Following this, a discussion was held on 1 June 2023, in which the evidence summary and additional contextual factors were considered. As per the HIQA Methods for generic justification of new practices in ionising radiation, a modified version of the GRADE evidence to decision (EtD) framework was used to support the MEIR EAG in coming to a recommendation regarding the generic justification of a slot-scanning, biplanar digital X-ray imaging system for the evaluation and monitoring of orthopaedic conditions.[(2)]

6.1 Overview of MEIR EAG GRADE EtD discussion

The full EtD framework including a summary of the panel discussion and the final judgements can be found in Appendix 3 and Table 5, respectively.

In terms of potential benefits and harms, the MEIR EAG considered the evidence for the outcomes listed in terms of both the magnitude of the effect and the certainty of the evidence. It was recognised that the identified evidence for slot-scanning, biplanar, digital X-ray imaging systems was limited to studies relating to the EOS™ imaging systems. However, while the evidence was discussed in the context of EOS, it was considered that the justification decision for this practice would apply also to other comparable technologies.

The reduction in radiation dose was considered to be the most important benefit provided by the EOS imaging system. In the context of scoliosis imaging, the EAG noted that the evidence presented suggested a potential for a 50% or greater reduction in ionising radiation dose exposure. It was recognised that the dose from general X-rays used in spinal imaging is relatively low. However, the potential for further reductions was considered desirable in the context of this patient population. The EAG recognised the challenges and complexity of quantifying the clinical significance of the dose reduction given the potential for both dose-related and stochastic ionising radiation effects. However, the importance of the as-low-as-reasonably-achievable (ALARA) principle was highlighted particularly in the context

of a paediatric population undergoing repeated thoracic exposure for scoliosis monitoring. There were limited concerns in relation to image quality, with the images obtained sufficient to inform clinical decision making in this context. Therefore a judgement of 'large' was recorded for this criterion.

For potentially undesirable effects, the EAG considered the evidence for the outcomes listed, both in terms of the magnitude of the effect and the certainty of the evidence. It was noted that it was challenging to determine an overall judgement for harms and or risks as the evidence and considerations related to two different review questions (patients with scoliosis and patients with other orthopaedic conditions). It was agreed that the percentage difference in radiographic parameters, for example, the angular measurements, were unlikely to be clinically significant. The EAG agreed that no additional risks or safety issues had been identified for this practice. Potential issues with skin dose associated with low dose radiation were discussed. It was noted that no evidence of harms was identified within the studies and the EAG agreed this was not a concern for this imaging device. A judgement of 'trivial' was agreed upon by the EAG.

The certainty of the evidence was considered to be very low, this was mostly due to the nature of the studies. Most of the studies were observational and many were retrospective studies using a clinical database to identify patients who had both modes of imaging within a certain time period. However, across most studies there was a consistent and substantial reduction in dose with at least comparable image quality reported for the EOS imaging system compared with conventional radiography. The EAG agreed that there was probably no uncertainty or variability in how much people value the main outcome, that is, the reduction in radiation associated with this practice. When considering the balance between the desirable and undesirable effects, it was agreed that EOS imaging was favoured over conventional radiography for the evaluation and monitoring of orthopaedic conditions on the basis that comparable image quality sufficient to inform clinical decision making could be achieved despite a consistent and potentially substantial reduction in dose.

On the basis of the discussion, the MEIR EAG recommended to HIQA that the use of slot-scanning, biplanar digital X-ray imaging systems for the evaluation and monitoring of orthopaedic conditions should be generically justified.

Table 5: Modified evidence to decision table for generic justification of slot-scanning, biplanar, digital X-ray imaging systems for the evaluation and monitoring of orthopaedic conditions

	SUMMARY OF JUDGEMENTS						
DESIRABLE EFFECTS	Trivial	Small	Moderate	**Large**		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	**Trivial**		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High		No included studies	
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	**Favours the intervention**	Varies	Don't know

6.2 HIQA Decision

Having considered the application, the evidence review and the recommendation from the MEIR EAG, HIQA is satisfied that on consideration of the balance between the benefits and harms, this practice should be generically justified.

The new practice of a slot-scanning, biplanar, digital X-ray imaging system for the evaluation and monitoring of orthopaedic conditions is generically justified under SI 256/2018.

The generic justification of this practice is effective from 10 July 2023. This decision may also apply to future comparable or similar technologies for the same clinical indications. Under the Regulations, HIQA may review the generic justification of this practice if new and important evidence about the practice emerges. HIQA may also review this practice if new and important evidence about alternative techniques and technologies (including non-ionising practices) emerges.

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Appendix 1

Table A.1 Details of grey literature search

Organisation, country	Description	URL link
General grey literature sources		
Google and Google Scholar	The first five pages of each were checked. Keywords: EOS imaging; EOSimaging; EOS system; EOSsystem; EOS edge; EOSedge.	https://scholar.google.com/, https://www.google.ie
International & European organisations		
World Health Organization	N/A	www.who.int/en
European Society of Radiology	N/A	https://www.myesr.org/publications/guidelines-and-recommendations
European Network for Health Technology Assessment (EUnetHTA)	N/A	https://www.eunethta.eu/
International HTA database (INAHTA)	N/A	https://database.inahta.org/
Guidelines International Network (G-I-N)	N/A	https://g-i-n.net/international-guidelines-library
Country specific organisations		
Canada		
Canadian Agency for Drugs and Technology in Health (CADTH)	N/A	http://www.cadth.ca
Health Canada	N/A	https://www.canada.ca/en/health-canada.html
United Kingdom		
The Royal college of Radiologists	N/A	https://www.rcr.ac.uk

National Institute for Health and Care Excellence (NICE)	N/A	https://www.nice.org.uk/
National Institute for Health and Care Research (NIHR)	N/A	https://www.nihr.ac.uk/
Health Technology Wales	N/A	https://healthtechnology.wales/
SHTG, Scotland	N/A	https://shtg.scot/about-us/
Scottish SIGN		https://www.sign.ac.uk/
United States of America		
Agency for Healthcare Research and Quality (AHRQ)	N/A	https://www.ahrq.gov/
Food and Drug Administration (FDA)	N/A	http://www.fda.gov/cder/guidance/index.htm
American College of Radiologists	N/A	https://www.acr.org/
National Comprehensive Cancer Network:	N/A	https://www.nccn.org/

Table A.2 Characteristics of studies which underwent limited data extraction

Author (Year) Title	Number of participants	Study type, comparator and outcomes	Population/indication
Sapin (2008) Bone mineral density assessment using the EOS low-dose X-ray device: a feasibility study.	N/A	Phantom study. EOS vs Hologic system. Assessed accuracy in measurements of bone mineral density.	N/A
Jiang (2011) Accuracy of EOS Imaging Technology in Comparison to Computed Tomography in the Assessment of Vertebral Rotational Orientation in Instrumented Spines in Adolescent Idiopathic Scoliosis.	n = 31	Retrospective, single centre comparative study. EOS vs CT. Radiographic reliability study.	Adolescents with idiopathic scoliosis.
Noto (2011) Optimization of X-ray conditions for full spine X-ray examinations in slot-scan digital radiograph.	N/A	Phantom study, compared actual doses with manufacturer-specified doses.	N/A
Glaser (2012) Comparison of 3-dimensional spinal reconstruction accuracy: biplanar radiographs with EOS versus computed tomography.	N/A	3 synthetic scoliotic phantoms scanned upright. 3D reconstruction accuracy recorded.	N/A
Guenoun (2012) Reliability of a new method for lower-extremity measurements based on stereoradiographic three-dimensional reconstruction.	n = 25	Prospective. No comparator. Assessed inter- & intra-observer variability.	Patients were awaiting THR.
Somoskeöy (2012) Accuracy and reliability of coronal and sagittal spinal curvature data based on patient-specific three-dimensional models created by the EOS 2D/3D imaging system.	n = 201	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Patients with adolescent idiopathic scoliosis, adult degenerative scoliosis, Scheuermann hyperkyphosis, healthy participants.
Somoskeöy (2012)	n = 201	Retrospective. No comparator.	Patients with adolescent idiopathic scoliosis, adult

Clinical validation of coronal and sagittal spinal curve measurements based on three-dimensional vertebra vector parameters.		Assessed inter- & intra-observer variability.	degenerative scoliosis, Scheuermann hyperkyphosis, healthy participants.
Thelen (2012) Evaluation of a new low-dose biplanar system to assess lower-limb alignment in 3D: a phantom study.	N/A	Phantom study	N/A
Assi (2013) Three-dimensional reconstructions for asymptomatic and cerebral palsy children's lower limbs using a biplanar X-ray system: a feasibility study.	n = 10	Prospective. No comparator. Assessed intra-observer variability.	5 children with cerebral palsy; 5 patients with back pain.
Al-Aubaidi (2013) Three-dimensional imaging of the spine using the EOS system: is it reliable? A comparative study using computed tomography imaging.	n = 7	Retrospective single centre, comparative study. Assessed inter- & intra-observer variability.	Children with kyphoscoliosis, Marfan syndrome, lymphoma, scoliosis, neurofibromatosis type I & myelomeningocele.
Folinais (2013) Measuring femoral and rotational alignment: EOS system versus computed tomography.	n = 30 (43 lower limbs)	Retrospective, single centre, comparative study. EOS vs CT. Femoral torsion measurements were compared between modalities.	Adults with lower limb torsion.
Barbier (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.	n = 44	Prospective. No comparator. Assessed inter- & intra-observer variability.	Patients undergoing THR surgery for arthritis.
Ferre (2014) Evaluation of a method for the assessment of anterior acetabular coverage and hip joint space width.	n = 28 (55 hips)	Prospective. Compared EOS to a false-profile view. Assessed inter- & intra-observer variability & radiation dose.	Patients with hip pain.

Krug (2014) Comparison of image quality using an X-ray stereotactical whole-body system and a direct flat-panel X-ray device in examinations of the pelvis and knee.	n = 114	Retrospective. Compared EOS to a flat panel X-ray device. Recorded radiation dose.	Not specified but all patients were imaged for a clinical complaint.
Meyrignac (2014) Low-dose biplanar radiography can be used in children and adolescents to accurately assess femoral and tibial torsion and greatly reduce irradiation.	n = 30	Prospective, single centre, comparative study. EOS vs CT. Assessed inter- & intra-observer variability. Comparative dosimetric study also done, using an ionisation chamber in a tissue-equivalent phantom & with 5 TLDs on patients.	Children with lower limb torsional abnormalities.
Rosskopf (2014) Femoral and tibial torsion measurement in children and adolescents: comparison of 3D models based on low-dose biplanar radiography and low-dose CT.	n = 50	Prospective, single centre, comparative study. EOS vs CT. Assessed interchangeability of femoral torsion and tibial torsion.	Children with femoral & tibial torsion.
Clavé (2015) Comparison of the reliability of leg length and offset data generated by three hip replacement CAOS systems using EOS™ imaging.	n = 106	Retrospective. Compared EOS to Amplivision™ & Hip Express™. Compared leg length measurements.	Patients who underwent THR.
Lazennec (2015) Offset and anteversion reconstruction after cemented and uncemented total hip arthroplasty: an evaluation with the low-dose EOS system comparing two- and three-dimensional imaging.	n = 110	Prospective. Compared the 2D and 3D protocols using EOS. Assessed inter- & intra-observer variability.	Patients who had undergone THR.
Masquefa (2015) Change in acetabular version after lumbar pedicle subtraction osteotomy to correct post-operative flat back: EOS™ measurements of 38 acetabula.	n = 19 (38 acetabula)	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Patients who had undergone pedicle subtraction osteotomy for flat back syndrome.

Demzik (2016) Inter-Rater and Intra-Rater Repeatability and Reliability of EOS 3-Dimensional Imaging Analysis Software.	n = 25	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Patients who had underwent THR.
Ferrero (2016) Role of pelvic translation and lower-extremity compensation to maintain gravity line position in spinal deformity.	n = 336	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Patients presenting with spinal pathologies (not specified).
Hirsch (2015 Flexibility analysis in adolescent idiopathic scoliosis on side-bending images using the EOS imaging system.	n = 50	Prospective. Compared EOS with side bending X-ray. Measured reproducibility of Cobb angle and dose.	Adolescent patients with non-idiopathic scoliosis.
Hocquelet (2016) Patient-specific 3D models created by 3D imaging system or bi-planar imaging coupled with MoirÃ©-Fringe projections: a comparative study of accuracy and reliability on spinal curvatures and vertebral rotation data.	n = 62	Prospective. Images taken using EOS and then reconstructed using SterEOS® 3D workstation & B3S system. Assessed inter- & intra-observer variability.	Not specified.
Ilharreborde (2016) EOS microdose protocol for the radiological follow-up of adolescent idiopathic scoliosis.	n = 32	Prospective. No comparator. Assessed inter- & intra-observer variability.	Adolescent patients with idiopathic scoliosis.
Knafo (2016) Reproducibility of low-dose stereography measurements of femoral torsion after IM nailing of femoral shaft fractures and in intact femurs.	n = 45	Prospective. No comparator. Assessed inter- & intra-observer variability.	Patients who had a femoral fracture treated with intramedullary nailing.
Morvan (2016) Standing radiological analysis with a low-dose biplanar imaging system (EOS system) of the position of the components in total hip arthroplasty using an anterior approach: a	n = 102	Prospective. No comparator. Assessed inter- & intra-observer variability.	Patients who had undergone THR.

cohort study of 102 patients.			
Newton (2016) New EOS Imaging Protocol Allows a Substantial Reduction in Radiation Exposure for Scoliosis Patients.	n = 60	Prospective. EOS v EOS microdose protocol. Assessed inter- & intra-observer variability, and dose.	Adolescent patients with idiopathic scoliosis.
Rosskopf (2016) Assessment of two-dimensional (2D) and three-dimensional (3D) lower limb measurements in adults: Comparison of micro-dose and low-dose biplanar radiographs.	n = 100	Half prospective, half retrospective. EOS vs EOS microdose protocol. Assessed inter- & intra-observer variability, and dose.	Lower limb imaged, but indication not specified.
Ben Abdennebi (2017) Comparative dose levels between CT-scanner and slot-scanning device (EOS system) in pregnant women pelvimetry.	n = 20 + a phantom	In vivo, in vitro & Monte Carlo simulation study using dosimeters placed on the skin & phantom. Measured skin dose & effective dose to the organs. EOS v CT.	Pregnant women undergoing pelvimetry.
Buckland (2017) Sagittal Pelvic Orientation A Comparison of Two Methods of Measurement.	n = 100	Retrospective. EOS images taken & 2 and 3 D analysis compared. Assessed inter- & intra-observer variability, and dose.	Spinal pathologies, type not specified.
Ferrero (2017) Three-dimensional reconstruction using stereoradiography for evaluating adult spinal deformity: a reproducibility study.	n = 30	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Patients with scoliosis.
Kato (2017) Three-dimensional EOS Analysis of Apical Vertebral Rotation in Adolescent Idiopathic Scoliosis.	n = 55	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Adolescents with idiopathic scoliosis.
Law (2017) Evaluation of cumulative effective dose and cancer risk from repetitive full spine imaging using EOS system: Impact to adolescent patients of different populations.	N/A	LAR estimated from full spine EOS imaging, included gender specific dose. Images typically taken for patients with scoliosis.	N/A - modelling study.
Meijer (2017)	n = 56	Prospective.	Patients undergoing TKR.

Do CAS measurements correlate with EOS 3D alignment measurements in primary TKA?		EOS vs computed assisted surgery alignment measurements. Valgus valve angles measured.	
Pasha (2017) Application of Low-dose Stereoradiography in In Vivo Vertebral Morphologic Measurements: Comparison With Computed Tomography.	n = 9 (86 vertebrae)	Retrospective. EOS vs CT. Measured vertebral heights.	Children with scoliosis (early onset & congenital).
Rehm (2017) 3D-modeling of the spine using EOS imaging system: Inter-reader reproducibility and reliability.	n = 73	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Patients with adolescent idiopathic scoliosis.
Rosskopf (2017) Femoral and tibial torsion measurements in children and adolescents: comparison of MRI and 3D models based on low-dose biplanar radiographs.	n = 60	Retrospective, single centre, comparative study. EOS vs MRI. Assessed interchangeability of femoral torsion and tibial torsion.	Children with femoral & tibial torsion.
Rouissi (2017) Intra and inter-observer reliability of determining degree of pelvic obliquity in neuromuscular scoliosis using the EOS-CHAIR® protocol.	n = 36	Retrospective. No comparator. Patients seated in EOS Chair. Assessed inter- & intra-observer variability.	Neuromuscular patients with pelvic obliquity.
Schlégl (2017) Determination and correlation of lower limb anatomical parameters and bone age during skeletal growth (based on 1005 cases).	n = 1005	Retrospective. EOS vs the Hassel–Farman method to assess skeletal maturity. Assessed inter- & intra-observer variability.	Children & adolescents; exact pathology not specified.
Bagheri (2018) Reliability of Three-Dimensional Spinal Modelling of Patients With Idiopathic Scoliosis Using EOS System.	n =15	Retrospective. 3D model using sterEOS software assessed. Assessed inter- & intra-observer variability.	Children with idiopathic scoliosis.
Burkus (2018) Sagittal plane assessment of spino-pelvic complex in a Central European population with	n = 458 (+ 69 control cases)	Retrospective case control study. No comparator. Assessed intra-observer variability.	Patients with adolescent idiopathic scoliosis.

adolescent idiopathic scoliosis: a case control study.			
Clavé (2018) Reproducibility of length measurements of the lower limb by using EOS™.	n = 112	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Patients undergoing THR.
DeFrancesco (2018) Agreement Between Manual and Computerized Designation of Neutral Vertebra in Idiopathic Scoliosis.	n = 32	Prospective. No comparator. Assessed inter- & intra-observer variability.	Patients with scoliosis.
Hey (2018) Normal variation in sagittal spinal alignment parameters in adult patients: an EOS study using serial imaging.	n = 60 (120 images)	Retrospective. No comparator, but two images taken per patient. Assessed inter- & intra-observer variability.	Adults with mild back pain.
Kim (2018) Reliability of the EOS Imaging System for Assessment of the Spinal and Pelvic Alignment in the Sagittal Plane.	n = 46	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Patients randomly selected from a clinical database; indications not listed but patients with congenital spinal anomaly/deformity or spine/pelvis operation.
Law (2018) Cumulative effective dose and cancer risk for pediatric population in repetitive full spine follow-up imaging: How micro dose is the EOS microdose protocol?	N/A (phantom study: 5, 10, 15 & 18 year old phantoms)	Modelling study (Monte Carlo simulation). EOS vs EOS microdose protocols. Assessed LAR.	N/A – phantom study (full spine imaging).
Lerisson (2018) Assessment of micro-dose biplanar radiography in lower limb measurements in children	n = 260	Prospective. EOS vs EOS microdose protocols. Assessed inter- & intra-observer variability, & dose.	Children having lower limb alignment imaging.
Márkus (2018) The effect of coronal decompensation on the biomechanical parameters in lower limbs in adolescent idiopathic scoliosis.	n = 280 (+56 control images)	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Orthopaedic indication (details not specified); lower limb imaging.
Morel (2018) Dose, image quality and spine modelling assessment of biplanar EOS micro-dose radiographs for the	n = 25	Prospective. EOS vs EOS microdose protocols. Assessed intra-observer variability & dose (DAP).	Adolescents with idiopathic scoliosis, with back braces.

follow-up of in-brace adolescent idiopathic scoliosis patients.			
Obid (2018) Reliability of Rod Lengthening, Thoracic, and Spino-Pelvic Measurements on Biplanar Stereoradiography in Patients Treated With Magnetically Controlled Growing Rods.	n = 20	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Children treated with magnetically controlled growing rods for spinal deformity (whole spine imaging; random selection from database).
Pasha (2018) Considerations in sagittal evaluation of the scoliotic spine.	n = 73	Retrospective. No comparator. Assessed inter- & intra-observer variability	Children with right thoracic and left lumbar curves.
Almansour (2019) Interrater reliability of three-dimensional reconstruction of the spine.	n = 45	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Children with braces for spinal deformity.
Harold (2019) Are single plane intraoperative and biplanar postoperative radiographic measurements of acetabular cup position the same?	n = 48	Prospective, single centre, comparative study. EOS vs fluoroscopy. Acetabular cup position measured.	Patients undergoing THR.
Knafo (2019) Value of 3D Preoperative Planning for Primary Total Hip Arthroplasty Based on Biplanar Weightbearing Radiographs.	n = 33	Prospective. No comparator. Assessed predicted vs actual component size during THR operation.	Patients with primary hip osteoarthritis.
Kolta (2019) Measurement of Trabecular Bone Score of the Spine by Low-Dose Imaging System (EOS®): A Feasibility Study.	n = 122	Retrospective. Trabeclular bone score measured on DXA and EOS.	Adults not undergoing anti-osteoporotic treatment.
Pedersen (2018 A reduced micro-dose protocol for 3D reconstruction of the spine in children with scoliosis: results of a phantom-based and clinically validated study using stereo-radiography.	Phantom (paediatric) study + validation study with n= 18	Prospective. Micro-dose EOS. Assessed inter- & intra-observer variability.	Phantom study + validation with children with scoliosis (whole spine images).

Post (2019) New sagittal classification of AIS: validation by 3D characterization.	n = 93	Retrospective. No comparator. Assessed intra-observer variability.	Adolescents with idiopathic scoliosis (whole spine imaging).
Vergari (2019) Trunk Growth in Early-Onset Idiopathic Scoliosis Measured With Biplanar Radiography.	n = 36	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Children with scoliosis, measuring trunk growth.
Vergari (2019) Quasi-automatic early detection of progressive idiopathic scoliosis from biplanar radiography: a preliminary validation.	n = 55	Prospective. No comparator. Assessed inter- & intra-observer variability.	Adolescents with idiopathic scoliosis.
Berg (2020) Experiences with a new biplanar low-dose X-ray device for imaging the facial skeleton: A feasibility study.	n = 48	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Whole body images taken on children with scoliosis.
Cauchon (2020) Morphological and radiological parameters correlating to shoulder function at diagnosis for patients with rotator cuff tear.	n = 52	Prospective. MRI, clinical examination & EOS. Assessed inter- & intra-observer variability.	Adults with a rotator cuff tear.
Hey (2020) Accuracy of freehand pedicle screws versus lateral mass screws in the subaxial cervical spine.	n = 36	Prospective. No comparator. Assessed inter-observer variability.	Patients undergoing multi-level posterior instrumented fusion of the subaxial cervical spine.
Reina (2020) The Delta of Correction: a novel, more reliable variable than limb-length discrepancy at predicting outcome after total hip arthroplasty.	n = 121	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Patients undergoing unilateral primary THR.
Vergari (2020) Spine slenderness and wedging in adolescent idiopathic scoliosis and in asymptomatic population: an observational retrospective study.	n = 321 (+83 controls)	Retrospective. No comparator. Assessed inter-observer variability of spine slenderness measurements.	Adolescents with idiopathic scoliosis.
Brooks (2021) Reliability of Low-dose Biplanar Radiography in	n = 17 (34 femora & 34 tibiae)	Retrospective. EOS vs CT vs MRI. Measured intermodality discrepancies.	Children with lower extremity torsional pathology.

Assessing Pediatric Torsional Pathology.			
Cho (2021) Evaluation of the reliability of lower extremity alignment measurements using EOS imaging system while standing in an even weight-bearing posture.	n = 52 (104 lower extremities)	Retrospective, single centre, comparative study. EOS vs CT. Assessed inter- & intra-observer variability (femoro-tibial rotation & tibial torsion).	Patients with osteoarthritis.
Di Laura (2021) Reconstruction of acetabular defects greater than Paprosky type 3B: the importance of functional imaging.	n = 25	Prospective, single centre comparative study. EOS vs CT. Intra-pelvic discrepancy between right and legs measured.	Adults with limb length discrepancy.
Finsterwald (2021) Accuracy of one-dimensional templating on linear EOS radiography allows template-directed instrumentation in total knee arthroplasty.	n = 113 (141 knees)	Retrospective. No comparator. Assessed inter- & intra-observer variability of planning accuracy.	Patients undergoing TKR.
Hamzian (2021) Equivalent Dose and Risk of Exposure Induced Cancer Death of Different Organs due to Various Image Techniques of EOS Imaging System.	n = 120 simulated patients	Modelling study (Monte Carlo simulation). No comparator. Assessed risk of exposure induced cancer death in different organs of the body.	N/A – phantom study (full spine, lower limb, whole body imaging).
Hecker (2021) The EOS 3D imaging system reliably measures posterior tibial slope.	n = 29 (56 knees)	Retrospective, single centre comparative study. EOS vs CT. Assessed inter- & intra-observer variability.	Adults undergoing imaging of the lower limb.
Hey (2021) Fulcrum to Generate Maximum Extension of the Spine and Hip-Proposing A New Strategy using EOS Imaging for Patient-specific Assessment of Degenerated Lumbar Spines.	n = 100	Retrospective, single centre, comparative study. Fulcrum vs conventional extension EOS imaging. Assessed inter- & intra-observer variability.	Patients with mechanical low back pain from degenerative spinal conditions.
Hu (2021) Comparison of 3D and 2D characterization of spinal geometry from biplanar X-rays: a large cohort study.	n = 494	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Patients with scoliosis and asymptomatic individuals.

Lee (2021) 3D ultrasound imaging provides reliable angle measurement with validity comparable to X-ray in patients with adolescent idiopathic scoliosis.	n = 50 (to test intra/inter-reliability0 & n = 164 (to investigate validity between Cobb angle on EOS and ultrasound curve angle (UCA).	Unknown if prospective/retrospective. EOS vs ultrasound. Tested the reliability and the validity of the UCA, and compare the UCA with the Cobb angles on X-ray images of patients with AIS.	Children & adolescents with idiopathic scoliosis.
Nyugen (2021) Microdose Protocol Stereoradiography Has Similar Reliability to Standard Low-dose Protocol When Performing Concurrent Sanders Skeletal Maturity Staging.	n = 30	Retrospective. EOS vs EOS microdose protocols. Assessed inter- & intra-observer variability.	Hand images for adolescents with idiopathic scoliosis.
Salameh (2021) Reliability assessment of cervical spine parameters measured on full-body radiographs in asymptomatic subjects and patients with spinal deformity.	n = 70	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Asymptomatic individuals, adolescents with idiopathic scoliosis & adults with spinal deformity.
Swany (2021) Comparison of slot-scanning standing, supine, and fulcrum radiographs for assessment of curve flexibility in adolescent idiopathic scoliosis: a pilot study.	n = 224	Retrospective. No comparator. Limited data provided about dose.	Adolescents with idiopathic scoliosis.
Bar Ziv (2022) Excessive Sagittal Slope of the Tibia Component during Kinematic Alignment-Safety and Functionality at a Minimum 2-Year Follow-Up.	n = 337	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Patients undergoing TKR (images taken pre and post operatively).
Gasparutti (2022) Reliability of the pelvis and femur anatomical landmarks and geometry with the EOS system before and after total hip arthroplasty.	n = 28	Retrospective. No comparator. Assessed inter- & intra-observer variability.	Patients undergoing THR (images taken pre and post operatively).

Haffer (2022) Total Hip Replacement Influences Spinopelvic Mobility: A Prospective Observational Study.	n = 197	Prospective. No comparator. Assessed inter- & intra-observer variability.	Patients undergoing THR (images taken pre & post operatively; both sitting & standing).
Haffer (2022) Acetabular cup position differs in spinopelvic mobility types: a prospective observational study of primary total hip arthroplasty patients.	n = 197	Prospective. No comparator. Assessed inter- & intra-observer variability (determining cup anteversion & inclination).	Patients undergoing THR (images taken post operatively; both sitting & standing).
Hamzian (2022) Monte Carlo evaluation of effective dose and risk of exposure induced cancer death (REID) for common examinations in stereo radiography (EOS) imaging: Considering age and gender.	n = 555 (data from these used for the modelling)	Modelling study (Monte Carlo simulation). No comparator. Assessed risk of exposure induced cancer death in different organs of the body.	Data from patients who had lower limb, full spine, full body.
Muellner (2022) Spinopelvic mobility is influenced by pre-existing contralateral hip arthroplasty: a matched-pair analysis in patients undergoing hip replacement.	n = 197	Prospective. No comparator. Assessed inter-observer variability; measurements of spinal flexibility.	Patients who had undergone THR.
Schlégl (2022) Neck-shaft angle measurement in children: accuracy of the conventional radiography-based (2D) methods compared to 3D reconstructions.	n = 156 (312 limbs)	Retrospective. No comparator (2D images vs 3D construction, both using EOS compared). Assessed inter- & intra-observer variability.	Images accessed from clinical database – indications not specified.
Xiao (2022) Where should Scoliometer and EOS Imaging be Applied when Evaluating Spinal Rotation in Adolescent Idiopathic Scoliosis -A Preliminary Study with Reference to CT Images.	n = 47 (62 curves)	Retrospective, single centre, comparative study. EOS vs CT. Assessed apical vertebral rotation.	Adolescents with idiopathic scoliosis who are undergoing surgery.
Kouyoumdjian (2023) Influence of kinematics of the lumbopelvic complex in hip arthroplasty dislocation:	n = 80	Matched case–control study. No comparator. Assessed inter- & intra-observer variability.	Patients who had undergone primary unilateral THR.

from assessment to recommendations.			
Piai (2023) Assessment of PCXMC Monte Carlo simulations in slot-scanning-based examinations: comparison with in-phantom thermoluminescent dosimetry.	N/A (phantom study)	Modelling study (Monte Carlo simulation). No comparator. Differences between measured & calculated organ doses assessed.	N/A - 5 year old & adult phantoms.
Ries (2023) Inter-observer reliability of biplanar radiography is unaffected by clinical factors relevant to individuals at risk of pathological lower limb torsion.	n = 44	Retrospective. No comparator. Assessed inter-observer variability.	Children (lower limb images) – clinical indication not specified.

Key: DXA - dual energy X-ray absorptiometry; LAR- lifetime attributable risk; MRI - magnetic resonance imaging; N/A - not applicable; THR - total hip replacement; TKR - total knee replacement; 2D - 2 dimensional; 3D - 3 dimensional.

Table A.3 Risk of bias assessment – questions added to the QUADAS-2 tool

Additional questions used to assess the quality of primary studies, as outlined in the 2012 NIHR HTA assessing the use of EOS for the monitoring and evaluation of scoliosis and other orthopaedic conditions.[36]

Question 1:	Were withdrawals from the study explained?
Question 2:	Was a sample size calculation used?
Question 3:	Was the method for measuring radiation dose appropriate for both the intervention and comparator technologies?
Question 4:	Was the method of measuring image quality appropriate for both the intervention and comparator technologies?
Question 5:	Was the execution of the intervention technology as it would be in practice?
Question 6:	Was the execution of the comparator technology as it would be in practice?

Table A.4 Characteristics of records which underwent full data extraction & quality appraisal

Author (year) Title Region or Country	Study design Stated funding for study	Number of studies or participants included for each research question		Outcome: Any measure of test performance	Outcome: Other stated clinical benefits	Dose information for Intervention and comparator Any long term effects of dose
HTAs and systematic reviews						
Wade (2013) A systematic review of the clinical effectiveness of EOS 2D/3D X-ray imaging system. UK (NIHR)	SR evaluating clinical effectiveness of EOS for evaluation and monitoring of scoliosis & relevant orthopaedic conditions. Search up to Nov 2010. No funding statement. No relevant COIs declared.	RQ1	3 studies	Studies included which compared image quality found EOS comparable or better than CR/DR. Empirical data not provided. None of the included studies compared the measurement of the Cobb angle between EOS & CR or DR, despite including patients with scoliosis.	None specified	Radiation dose was considerably lower with EOS. Mean entrance surface dose with EOS at the centre of the back = 0.18mGy vs 1.0.4mGy for CR. At the proximal lateral point EOS = 0.27mGy vs CR = 2.38mGy. At nape of neck EOS = 0.2mGy vs CR = 0.59mGy.
		RQ2	N/A			
Mahboub-Ahari (2015) EOS imaging versus current radiography: A health technology	HTA evaluating clinical & cost effectiveness of EOS imaging compared to CR/DR. Patients with any orthopaedic condition.	RQ1	Unclear: 4 peer reviewed studies and a HTA.	None specified	Literature review showed that although the time of imaging process is lower for EOS system, patients felt discomfort inside the cabin. Estimated imaging time was longer than	The average rate of emitted dose in current imaging techniques relative to EOS has been reported in the range of 2.15 to 18.8 in SR. The highest rate belongs to

assessment study. Iran (Department of Health Service Management/Iranian Center for Evidence-Based Medicine)	Search up to 2013. No funding statement. No COIs declared.	RQ2	Unclear: 4 peer reviewed studies and a HTA.		digital radiography (1 study. No significant preference to any of the technologies related to patient ease or comfort.	the study by Kalifa et al. which has used earlier version of the device. The new technology decreases X-ray emission to patient's body from 2.15 to 18.8 fold less than conventional techniques.
Pettit (2022) Measurement techniques for leg length discrepancy in total hip arthroplasty: a systematic review of reliability and validity.	SR describing measurement techniques for limb length discrepancies in total hip replacement. Search up to August 2021. No funding received. No relevant COIs.	RQ1 RQ2	N/A 42, 5 of which investigated EOS	Reported excellent intra- and/or inter-rater reliability for measuring limb length discrepancy.	Not specified	None specified
Comparative studies: EOS vs CR/DR						
Deschênes (2010) Diagnostic imaging of spinal deformities: reducing patients radiation dose with a new	Single centre, prospective comparative study. EOS vs CR, assessing dosimetry & image quality. In-vivo dosimetry & phantom data collected. No funding provided. No COIs declared.	RQ1	n=50 Patients had both EOS and CR. 39 female, 11 males.	4 experts agreed that image quality is significantly better with EOS. On Wilcoxon analysis of structures visibility EOS was significantly better $p<0.006$ in PA view. Image quality 50% EOS = CR and 46.7% EOS>CR.	Not specified	Entrance dose calculated *in-vivo*: EOS consistently lower: 6-9 times lower for thoracoabdominal region and 3 times lower at the nape of the neck.

slot-scanning X-ray imager Canada		RQ2	N/A			
Fronnec (2011) Pelvis and total hip arthroplasty acetabular component orientations in sitting and standing positions: measurements reproducibility with EOS imaging system versus conventional radiographies France	Prospective study – case control EOS vs CR (2D vs 2D) AP & lateral images standing & sitting acquired in post op THA patients. Pelvic & acetabular measurements (performed in software) compared. 5 pelvic & acetabular measurements assessed on each sitting& standing image (repeated 3 times) by 2 observers. No funding statement. No COIs declared.	RQ1 RQ2	N/A n = 50 had both EOS & CR) Females : 26, males: 24 Mean age: 60.94 ± 6.1 (50—73)	Correlation between EOS vs CR was excellent for all parameters (Spearman's coefficient ranging from 0.82 to 0.97, ICC 0.90 to 0.98). However, direct-paired comparison using the Student's t-test demonstrated a significant difference between the measured values for all parameters except for pelvic incidence & sacral slope in the standing position. This significant difference was 1—2 degrees for pelvic parameters and 2—3 degrees for acetabular parameters. The intra- & inter-observer variability ranged from ± 2.97◦ to ± 6.46◦ using the EOS and from ± 4.26◦ to ± 10.22◦ using conventional X-rays ($p < 0.05$).	Not specified	Not specified
Dietrich (2013) Comparison of radiation dose, workflow, patient comfort and financial break-even of	Prospective, single centre, case control study. Compared data of standing full-length lower limb radiographs and whole spine radiographs of both X-ray systems. Questionnaire used for patient comfort scoring	RQ1	n = 47 (DR) n = 134 (EOS) Sex not specified. Age not specifie	Not specified	The mean examination time was significantly shorter for EOS. Whole spine: DR vs EOS (449s vs 248s Full length lower limb radiograph: DR vs EOS (309s vs	DAP (cGycm^2) significantly lower for EOS than DR for whole spine imaging. DR = 392.2±231.7 EOS = 158.4±103.8 $p < 0.001$ DAP (cGycm^2) significantly lower for EOS than DR for

standard digital radiography and a novel biplanar low-dose X-ray system for upright full-length lower limb and whole spine radiography Switzerland	and questionnaire for technicians to evaluate workflow. No funding statement. No COI statement.	 RQ2	d. n = 68 (DR) n = 198 (EOS) Sex not specified. Age not specified.		226 s) Patient comfort regarding noise significantly higher for biplanar. Subjectively patients having lower limb imaging in the biplanar X-ray system assessed the examination time as significantly longer. The biplanar X-ray unit demands a higher number of examinations per year for the financial break-even point despite the lower labour costs per examination owing to the shorter examination time.	lower limb imaging. 170.9±104.2 (DR) 92.1±45.5 (EOS) p < 0.001
Escott (2013) EOS low-dose radiography: a reliable and accurate upright assessment of lower-limb lengths. Canada	Prospective Phantom Study No funding statement. No COIs declared.	RQ1 RQ2	N/A Phantom limb composed of a plastic left-sided hemipelvis, leg, and foot bones.	Mean absolute difference from the true length of the femur was significantly lower (most accurate) for the EOS-Slow (2.6 mm; 0.5%) and EOS-Fast (3.6 mm; 0.8%) protocols as compared with CT scanograms (6.3 mm; 1.3%) (p < 0.0001), and conventional radiographs (42.2 mm; 8.8%) (p < 0.0001). There was no significant difference in accuracy between the EOS-Slow and EOS-Fast protocols (p = 0.48)	Not specified	Calibrated Unfors Xi skin-entrance dosimeter was used. The mean radiation dose was significantly lower for the EOS-Fast protocol (0.68 mrad; 95% CI, 0.60 to 0.75 mrad) compared with the EOS-Slow protocol (13.52 mrad; 95% CI, 13.45 to 13.60 mrad) (p < 0.0001), CT scanograms (3.74 mrad; 95% CI, 3.67 to 3.82 mrad) (p < 0.0001),

			Comparison of measurements of 10 images (for each modality) by 2 raters.	Intraclass correlation coefficients showed excellent (>0.90) agreement for conventional radiographs, the EOS-Slow protocol, and the EOS-Fast protocol.		and conventional radiographs (29.01 mrad; 95% CI, 28.94 to 29.09 mrad) ($p < 0.0001$).
Guggenberger (2014) Assessment of lower limb length and alignment by biplanar linear radiography: comparison with supine CT and upright full-length radiography Switzerland	Prospective, single centre comparative study. CT (scout used for this study), upright CR & EOS taken. A second limb length measurement was taken using the EOS using the 3D lengths of the femur & tibia – the composed leg length. Funding source not stated. COIs not stated.	RQ1 RQ2	N/A 51 (limb length & alignment after total knee replacement) 29 females, 22 males; mean age, 68.8 years; range, 43–92 years	1. Mean Lower limb length (EOS measurements 2.7 ± 5.5mm shorter than measurements on CT scans and 5.4 ± 13.1mm shorter than CR. But no difference in composed length & CT or CR.) CT scout: 783±56.1mm (639-927) CR:780±55.4mm (633-921) EOS: 780±55.4mm (633-921) Composed length: 783±55.9mm (636-924) 2. Mean Lower limb alignment CT scout: 2.3 degrees±5.5 (-12 to 20) CR: 2.5±6.7 (-17 to 18) EOS: 3.4±6.6 (-14 to 18) 3. Inter-modality agreement Consistent variability of measurements across all graphs was seen. But	None specified	None specified

				differences were in the order of magnitude of the measurement accuracies. 4. Inter-reader agreement All modalities showed no significant differences between both readers ($p > 0.05$). Highest agreement was for EOS.		
Hirsch (2015) EOS suspension test for the assessment of spinal flexibility in adolescent idiopathic scoliosis. France	Prospective single centre comparative study. Assessment of spine flexibility. No funding statement. No COI statement.	RQ1	n = 50 children scheduled for scoliosis surgery. 41 girls, 9 boys. Mean age: 15.6 ±1.9 years.	None specified	The ratio force/weight was significantly greater for the suspension test ($p < 0.05$). The standard deviation was significantly lower for the suspension (SD = 19) test than for the traction test (SD = 40) ($p < 0.05$). Mean VAS after suspension was 5.6 (range 0–10, SD 1.9), significantly higher than the one reported after Cotrel traction test (mean 3.1, range 0–8, SD 2.4) ($p < 0.05$). No difference was found between traction and suspension tests for the proximal curve ($p = 0.71$) and the main thoracic curve (p =	Radiation doses were about 8 times ($p < 0.05$) lower during suspension (0.45 ± 0.27 mS) than during traction (3.15 ± 0.77 mS).
		RQ2	N/A			

					0.32).	
Moltó (2014) Assessing structural changes in axial spondyloarthritis using a low-dose biplanar imaging system. France	Observational, cross-sectional, single-centre study. EOS vs CR whole spine imaging for the assessment of axial spondyloarthritis (SpA). No funding statement. No COIs declared.	RQ1 RQ2	N/A n = 96, 48 with SpA diagnosis and 48 control patients with chronic mechanical low back pain. SpA group: 13 females, 35 males. Control group: 39 females, 9 males. Mean age SpA group: 47.6 years. Mean age	Outcome agreement with non-inferiority limit of 0.7 (scale 1-10). Agreement between EOS and CR for detection of spine involvement was excellent kappa 0.97 but lower for sacroiliitis detection: kappa of 0.50 (95% CI 0.26, 0.75) and 0.50 (95% CI 0.16, 0.84) for reader 1 and reader 2, respectively. Sensitivity (0.76) & specificity (0.84) for detection of sacroiliitis were identical with EOS and CR. But study found low inter-reader agreement for both CR and EOS for the classification of sacroilitis: ICC EOS = 0.94 CR = 0.95). Inter-reader limits were rather wide (presented in graph). Ease of interpretation was greater for CR [8.2 (SD 0.9)] compared with EOS [7.2 (SD 0.8), p < 0.0001).	Not specified	Not specified

			control group: 49.1 years.			
Rungprai (2014) Validation and reproducibility of a biplanar imaging system versus conventional radiography of foot and ankle radiographic parameter Authors from US & Thailand but country where study took place not specified.	Retrospective single centre comparative study. EOS v CR Funded by a grant from EOS. No COIs declared.	RQ1	N/A	16 pre-operative radiograph parameters measured of foot an ankle alignment, as well as measurements of limb length and alignment in the standing long-leg AP view. There was no statistically significant difference associated with the image source in any of the parameters measured (all p values ≥ .05) using one-way ANOVA. No statistical difference seen between radiographic techniques when tested using paired t-tests, however there was between the staggered and non-staggered positions using EOS in the single lower limb measurement of the rear leg, & the separate tibia length and femur length measurements of the rear leg. ICCs ranging from 0.938 to 1.000 and inter-observer ICCs ranging from 0.927 to 1.000. CR vs. EOS paired t-tests: Calcaneal pitch p = 0.180, Pearson correlation = 0.977 Lateral talocalcaneal angle p = 0.067, Pearson correlation = 0.999 Lateral talo-first metatarsal angle p = 0.795, Pearson correlation = 0.933	None specified	None specified
		RQ2	n = 50 (consecutive patients) 27 females & 23 males Imaging indicated for foot and ankle realignment surgeries.			

				Medial uniform-fifth metatarsal height p = 0.068, Pearson correlation = 0.994 Anterior distal tibial angle p = 0.856, Pearson correlation = 0.799 6% (4/69) were excluded from measurement due to improper positioning.		
Luo (2015) Cumulative radiation exposure with EOS imaging compared with standard spine radiographs US	Retrospective comparative study Aim: estimate the total radiation exposure to scoliosis patients during the entire treatment course using standard imaging techniques versus EOS PA and AP views. Number of radiographs taken was recorded & modelled the expected cumulative radiation dose per patient, depending on whether EOS or CR was used. 15-year old patient model (weight, 56 kg; height, 168 cm; trunk thickness, 20 cm; width, 30 cm) was assumed. No funding statement. No COIs declared.	RQ1 RQ2	42 idiopathic scoliosis patients who were skeletally immature who had serial imaging. Sex not specified. Age not specified but skeletally immature. N/A	None specified	The radiology technologists preferred EOS over CRF (without a filter) technique for ease of use and reproducibility.	For EOS imaging, the researchers found that the organ dose to the thyroid, breast, and testes was higher for an AP view compared with a PA view. Organ dose to the bone marrow, however, was lower with an AP view. Interestingly, the standard EOS AP organ dose to thyroid, breast, and testes was higher than the estimated CR PA dose, assuming a medium-sized paediatric patient (56 kg) and dosing parameters as outlined above. The total effective dose for EOS PA was approximately a third of the dose of CR PA imaging (0.069 vs. 0.215 mSv) and comparable to CRF imaging (0.057 mSv) with much improved image quality with the EOS. An EOS AP total effective dose was

						approximately half that of a CR PA radiograph (0.121 vs. 0.215 mSv). Assuming CR technique for all imaging, mean effective dose over the course of scoliosis treatment for all patients was estimated to be 5.38 mSv. Assuming EOS PA & lateral images were used during the course of treatment, the mean cumulative estimated dose was 2.66 mSv, a decrease of 51% (Table 3). Assuming EOS AP & lateral views were used, the mean cumulative estimated dose was 3.40 mSv, or a decrease of 37%. Assuming a CRF technique was used, the estimated dose over the course of treatment was 2.64 mSv, a decrease of 51%.
Yvert (2015) Radiography of scoliosis: Comparative dose levels and image quality between a dynamic flat-	Single institution retrospective comparative study & phantom study looking at dose and image quality for EOS vs DR (dynamic flat panel with image stitching) whole spine PA images. No funding statement. No COIs declared.	RQ1	EOS = 33 DR = 26 44 females, 17 males. Mean age: 11.4	3 observers. Phantom: For each observer taken individually, IQFinv of the EOS was better than DR. EOS outperformed the DR on image quality ($p < 0.001$) and for contrast resolution ($p < 0.05$) Clinical: Results were in favour of EOS but	None specified	Clinical: DAP no significant difference between EOS and DR (0.68) note in conclusion that DAP not accurate measurement of dose TLD entrance skin dose: EOS 1.57 times higher than DR ($p < 0.001$) for cervical region but EOS 1.49 and 2.15 times lower for

panel detector and a slot-scanning device (EOS system) France			years, SD = 2.64 (EOS); 11.3 years, SD = 1.87 (DR).	overall similar, significant for one observer only. DR significantly superior for visualising lumbar spine, femoral heads & sacrum. Inter-observer reproducibility for the 3 observers was better for EOS (ICC = 0.58, 95% CI: 0.29—0.77) relative to DR (ICC = 0.35, 95%CI: —0.2—0.63). Cobb angle: ICC: 0.98 (EOS); 0.96 (DR).		thoracic and sacral regions.
		RQ2	N/A			
Hui (2016) Radiation dose of digital radiography (DR) versus micro-dose x-ray (EOS) on patients with adolescent idiopathic scoliosis: 2016 SOSORT-IRSSD "John Sevastic Award" Winner in Imaging Research. China	Prospective, single centre, in-vivo dosimetry study. Quasi-RCT. Dose from PA images of whole spine compared between EOS (micro-dose protocol) and DR. Entrance (skin) dose measured using 3 TLDs placed on bony landmarks and effective and organ doses calculated using PCXMC software. Inter-observer variation evaluated by comparing Cobb angles from two observers and image quality metrics. No commercial funding.	RQ1	n = 99 (EOS) n = 33 (DR) Adolescents with idiopathic scoliosis. 81 female; 18 male (EOS). 22 female, 11 males (DR).	1. Image quality Comparable between EOS and DR for all metrics except for details where both raters rated significantly lower scores for EOS due to blurry boundaries at the vertebral bodies and collimation where EOS scored significantly higher than DR. 2. Inter-rater reliability of covv significantly correlated ($p < 0.001$) in EOS (ICC = 0.883) and DR (ICC = 0.942)	None specified	Dose was significantly less for entrance skin dose, effective dose & organ dose between EOS micro-dose protocol and DR. 1. Entrance skin dose (µGy): At sternal notch: EOS = 25, DR = 140.9 At nipple line: EOS = 26.0, DR = 521.4 At symphysis pubis: EOS = 27.2, DR = 724.9 2. Effective dose (µSv) EOS = 2.6 DR = 67.5 3. Organ dose (µGy): Thyroid:

	No relevant COIs.	RQ2	N/A			EOS = 0.8, DR = 12.3 Lung: EOS = 5.3 DR = 108.5 Reproductive organ: EOS = 2.0, DR = 68 4. DAP (mGycm^2): EOS = 39.8 vs DR = 609.5 Estimations of long term dose effects: Females received significantly higher dose at ovaries compared to testes with both EOS and DR. This institution estimated X-rays taken for AIS = 9.2 per patient, effective dose reduction with EOS microdose estimated at 600 µSv or equivalent to approximately one third to a quarter of effective dose from natural background radiation in a year.
Singhatanadgige (2016) Correlation and reliability of cervical sagittal	Retrospective analysis. Comparison of metrics used to evaluate cervical sagittal alignment. Adult population with cervical deformity. Patients had both EOS	RQ1	n = 35 patients with c-spine deformity (not necessarily	XR vs EOS measurements significant difference for: C2–C7 sagittal vertical axis (0.68cm lower) and C1-C7 (1.02cm lower). No differences for other metrics. Intra-rater reliability for all sagittal alignment parameters (6 metrics) was	None specified	None specified

alignment parameters between lateral cervical radiograph and lateral whole-body EOS stereoradiograph. Authors from US & Thailand but country where study took place not specified.	and X-ray) Disclosures from one author in relation to board membership AOSpine and grant link		scoliosis). 23 female, 12 male. Mean age of 59 years.	excellent except for 2 metrics -neck tilt (NT), and thoracic inlet angle (TIA). Intra-rater reliability good ICC 0.799 to 0.994 for XR and 0.791 to 0.995 for EOS.		
		RQ2	N/A			
Abrisham (2017) A comparison of patients absorption doses with bone deformity due to the EOS imaging and digital radiology. Iran	Prospective, single centre, case controlled study. Children & adults. No funding statement. No COI statement.	RQ1	n = 41 (EOS) n = 18 (DR) (36 images AP + lat).	None specified	None specified	Lumbar spine DAP for DR = 4.26Gy.cm^2. EOS whole spine DAP= 0.89 Gy.cm^2.
		RQ2	N/A			
Chiron (2017)	Single institution prospective comparative study to compare image	RQ1	N/A	Image magnification: Mean magnification was zero using the EOS system, regardless of patient	None specified	Dose Mean DAP: 8.19 ± 2.63 dGy/cm2 (range, 1.77–
		RQ2	n = 183 (had			

Radiation dose and magnification in pelvic X-ray: EOS™ imaging system versus plain radiographs. France	magnification between 2D EOS and plain X-ray of femoral heads (does not state CR vs DR) in patients undergoing THR (post op imaging). No funding statement. No COI statement		both EOS and plain X-ray); 186 hips. 81 female, 104 male. Mean age 61.3 ± 13.7 years (range, 24–87 years).	weight, compared to 1.15 ± 0.05 (range, 1–1.32) on plain X-ray ($p < 10^{-5}$). Data provided for various BMI ranges for plain X-ray.		14.24) with the EOS system, vs 19.38 ± 12.37 dGy/cm2 (range, 4.77–81.75) with plain X-ray (P < 10−4). Linear regression showed that the dose increased by 0.74 dGy/cm2 per BMI point in the plain X-ray group, versus 0.20 dGy/cm2 in the EOS group (P < 0.001).
Mainard (2017) Accuracy and reproducibility of preoperative three-dimensional planning for total hip arthroplasty using biplanar low-dose radiographs: A pilot study	Retrospective single institution case-control study. Ability for EOS to predict stem and cup sizes for THA preoperative planning. EOS vs AP CR Study was supported by EOS imaging covering cost of the hipEOS planning and English writing of the manuscript.	RQ1 RQ2	N/A n = 31 (31 had EOS and DR). 21 women, 10 men. Mean age of 66 years, range 49 to 86	3D planning predicted stem size more accurately with EOS. Stem sizes were planned within one size in 26/31 (84%) of cases in EOS vs 21/31 (68%) in CR (P = 0.04). EOS vs CR not significantly different for cup size: cup sizes were planned within one size in 28/30 (92%) of cases in EOS vs 26/30 (87%) in CR (p = 0.30). ICC for stem size were 0.88 vs. 0.91 for EOS and CR respectively. Inter-operator ICCs for cup size were 0.84 vs. 0.71, respectively. Repetitions of the 3D planning were within one size (except one stem), with the majority predicting the same size.	None specifed	None specified

France			years.			
Branchini (2018) Organ doses and lifetime attributable risk evaluations for scoliosis examinations of adolescent patients with the EOS imaging system. Italy	Phantom study, EOS vs CR, adolescent protocols, TLD measurements taken for organ dose and effective dose calculations. No funding statement. No COIs declared.	RQ1	N/A Phantom study	None specified	None specified	Except for testes and eyes, which were excluded from the scan in CR protocol, CR organ doses higher than EOS. EOS effective dose (0.43 ± 0.04 mSv) is about two times less than the dose in CR with anti-scatter grid examination (0.87 ± 0.09 mSv), LAR: cancer probability is lower with EOS vs CR, number of any cancers induction cases per 100,000 person examined adolescent male: Age 20 = 5.4 vs 9.7 Age 15 = 6.6 vs 11.7
		RQ2	N/A			
Hey (2018) The effectiveness of full-body EOS compared with conventional chest x-ray in preoperative evaluation of the chest for	Prospective, single centre comparative study. CXR vs EOS in preoperative screening of thoracic conditions. No commercial funding. No COI statement.	RQ1	n = 266 patients 182 females, 84 males. Mean age 38.9 years, SD 25.0	EOS and CXR done less than 2 weeks apart (Mean time interval between imaging modalities 1.75 days, SD 3.58). High inter-observer agreement found for EOS and CXR (Gwet's AC1 0.993 and 0.988 respectively). No significant differences between imaging modalities. Common positive findings included: apical pleural thickening, cardiomegaly	2 patients had normal finding on EOS imaging but abnormal on CXR. One had Cardiomegaly on CXR and had her surgery delayed for further investigations, the other had small nodular densities in left lower zone on CXR	No empirical data

patients undergoing spine operations: a preliminary study. Singapore			years. Majority of patients had adolescent idiopathic scoliosis (46.2%). Adults had lumbar spinal stenosis (29.3%) and spondylolisthesis (20.7%)	and mediastinal clips/sternotomy wires. Not possible to assess rare diagnosis such as aortic aneurysm as these were not found in this cohort. Age stratification did not affect these results.	and normal on EOS, his surgery was not delayed.	
		RQ2	N/A			
Pedersen (2018) First full-spine radiation dose measurements in anthropomorphic phantoms and	Phantom study. Aim: To report the organ dose and effective dose measurements in anthropomorphic phantoms using the EOS micro-dose protocol; 2) to compare our results to	RQ1	N/A (2 phantoms: 1 female adult, to represent an adolescent and a paediatr	None specified	None specified	Adolescent: 17-fold reduction (94%) of absorbed dose in micro-dose settings compared to measured dose absorbed with CR. Effective dose for PAL full spine, bi planar, radiographic examination with the micro-dose

comparisons with EOS standard-dose and conventional digital radiology. Denmark	measurements in the EOS standard-dose protocol and CR. Dosimeters placed on skin surface and internally. Made comparisons with doses in Damet, 2014. No COI statement.		ic female)			protocol was 29µSv (27-31); the corresponding dose for CR PA-LAT was 491 µSv (456-531).A 6-fold reduction (83%) of effective dose was observed when comparing micro-dose with standard dose protocol. A 2.8-fold (64%) reduction of effective dose reduction was observed when comparing standard dose protocol with our CR system in PA-LAT. Paediatric phantom. Effective dose for PAL full spine, bi-planar radiographic examination with the micro-dose protocol was 22 µSv (20-23); the corresponding dose for CR PA-LAT was 114 µSv (104-127); this is equivalent to a 5-fold reduction, (81%) of absorbed dose. A 7-fold reduction (86%) of effective dose was observed when comparing micro-dose with standard-dose protocol. However, there was an increase in absorbed dose of 38% when the EOS standard dose settings were compared with our CR system in PA-LAT. For most organs, doses
		RQ2	N/A			

						were lower in PAL than in APL. Effective doses in PAL compared with APL were reduced by an average of 21% (20-22%) for the phantoms in both standard and micro-dose protocols. The adolescent mean organ dose to the breasts was reduced by 29% in PAL; this reduction was solely on the left breast where dose was reduced from 403μSv to 73μSv, a 5.5-fold reduction, whereas the right breast dose was increased from 216 μSv to 287 μSv, a 33% increase in dose
Simon (2018) Stereoradiography imaging motion artefact: does it affect radiographic measures after spinal instrumentation? Germany	Retrospective single centre study. Aim: to (1) determine the incidence of movement artefact and (2) assess objectively if motion during stereoradiography imaging (SRI) acquisition modified measurement values in patients with long spinal fusion. Coronal and sagittal views were selected and independently analysed by two orthopaedic surgeons blinded to each	RQ1	198 patients with spinal instrumentation had full spine EOS; 39 of which also had CR. Exact sex break-down not	No statistically significant differences between EOS & CR spine measurements. Good to strong correlation (Pearson's correlation ranged from 0.69 to 0.93, $p < 0.05$; intra-class correlation ranged from 0.71 to 0.93, $p<0.05$). The most reliable parameter was the pelvic incidence (49.7 vs. 49.6, $p = 0.97$, $r = 0.82$, ICC = 0.93). For the other measurements, those on the EOS images were slightly greater than CR. Sagittal and coronal T1 spinopelvic inclination showed lower correlation values ($r = 0.69$, ICC = 0.71 and $r = 0.83$, ICC = 0.37, respectively) likely due to poor standardization of patient	None specified	None specified

	other's results. Radiographic measurements were made on SRI and conventional radiographs. Both types of images were compared to see if the artefact resulted in different radiographic measures. No funding statement. No COIs declared.	 RQ2	specified. Mean age: 19.5 years. N/A	positioning during the EOS & CR. Reliability of spinal measurements across all groups was very good, with range [0.81–0.98] and p values less than 0.001 except for the coronal T1 spinopelvic inclination (intra-observer reproducibility: p = 0.03 for EOS and p = 0.06 for CR; inter-rater reliability: p = 0.03 for EOS and p = 0.9 for CCR). Intra-observer reproducibility was better than inter-rater reliability according to the standard error estimate lowest values.		
Alrehily (2019) Scoliosis imaging: An analysis of radiation risk in the CT scan projection radiograph and a comparison with projection radiography and EOS. Authors from Norway, UK and Saudi Arabia but	Paediatric phantom study looking at CT scout vs DR vs EOS and the resultant organ doses and calculated Lifetime Attributable Risk (LAR) of cancer calculated. No funding provided. No COIs declared.	RQ1 RQ2	Phantom (paediatric) N/A	None specified	None specified	Organ doses used to determine the LAR. Not all organ dose data provided in the paper. Data on Lifetime Attributable Risk (LAR) of cancer female 10-yr old patient: EOS AP+lat = 0.86 EOS AP (kV 75 mA 200) = 0.25 EOS lat (kV 80 mA 80 = 0.07 DR AP = 2.26 DR PA = 0.92 DR lat=1.15

country where study took place not specified.						Lowest CT values (mA = 10, kV p = 80) female patient: CT AP= 0.53 CT PA = 0.14 CT lat = 0.15 Male 10 year old patient: EOS AP+ lat = 0.37 EOS AP (kV 75 mA 200) = 0.09 EOS lat (kV 80 mA 80 = 0.03
Mussmann (2019) Radiographic signs of acetabular retroversion using a low-dose slot-scanning radiographic system (EOS®). Denmark	Retrospective single centre population-based cohort study. Acetabular retroversion was defined as presence of crossover sign (COS) on conventional AP X-ray of the pelvis. X-rays & EOS-images of the pelvis were assessed for COS, posterior wall sign (PWS) & ischial-spine sign (ISS) radiographic signs of retroversion (Fig. 1) & ratios for COS & PWS were calculated (Fig. 2). Dose-Area-Product (DAP) for AP conventional X-rays & EOS-images was collected after each image	RQ1 RQ2	N/A n = 34 participants & 68 hips for analysis with signs of acetabular retroversion of	The absolute agreement between the 2 modalities regarding COS, PWS & ISS were 91% (62 hips), 84% (57 hips) & 76% (52 hips) respectively (Table 3). No statistically significant differences between COS-ratios & PWS-ratios for X-ray & EOS were found (Table 4). Bland Altman Limits of Agreement were narrow, i.e. -16 to 14% for COS-ratio and -18 to 15% for PWS-ratio. COS-ratio n = 57 T-test p-value = 0.53 PWS-ratio n = 36 T-test p-value = 0.27	None specified	The X-ray mean DAP was 1053 mGy/cm^2 (range 186 to 3814) & 593 mGy/cm^2 (range 452-821) on EOS (p = 0.003), & the mean radiation dose for AP-projections was reduced by 44% when using EOS.

	was acquired. No funding statement. No relevant COIs.		CR pelvis.			
Rosskopf (2019) 3D hindfoot alignment measurements based on low-dose biplanar radiographs: a clinical feasibility study. Switzerland	Prospective, single centre comparative study. EOS & DR (long axial view radiograph) taken on the same day. All measurements taken by 2 radiologists, reader 1 & reader 2. Measurements made of hindfoot angle (HA). No funding statement. No relevant COIs.	RQ1 RQ2	N/A n = 50 adults referred for long axial view radiograph & HA measurement. 29 female, 21 males. Mean age 47 ± 16.6 years).	EOS: Mean inter-reader difference (R1-R2) was 0.07° ± 1.7° (range, −6.2° to 4.1°). Inter-reader agreement for BPR measurements was excellent, with an ICC value of 0.992 (95% confidence interval: 0.986–0.995). DR: Mean inter-reader difference (R1-R2) was 0.2° ± 2.7° (range, −5.3° to 6.7°). Inter-reader agreement for measurements was excellent, with an ICC value of 0.962 (95% confidence interval: 0.932–0.978). Inter-method agreement was good with an ICC value of 0.66 (−0.646 to 0.470). The mean difference between the 2 methods was −2.4° (range −29.4° to 25.6°) for reader 1 and −2.6° (range −28.7° to 30.2°) for reader 2. On Bland–Altman plots three measurements of reader 1 & 6 measurements of reader 2 were outside of the ±1.96 SD interval.	None specified	Not specified
Hau (2020) Two-dimensional/three-dimensional	Prospective single centre comparative study. X-ray vs 3D EOS imaging. X-ray images & EOS images taken on same day both with patients	RQ1 RQ2	N/A n = 20 osteoarthritis patients for pre-	3 measurements on 35 images = 105 measurements x 1 observer. Femoral anatomic mechanical angle (fAMA) EOS 3D (mean +/- SD) 6.61 +/- 1.98	Not specified	No empirical data

EOS™ imaging is reliable and comparable to traditional X-ray imaging assessment of knee osteoarthritis aiding surgical management. Hong Kong	weight bearing. No funding statement. No COIs declared.		operative planning (40 legs, 5 excluded due to knee prosthesis). 17 females, 3 males. Mean age: 69 years (range: 60-86 years).	X-ray (mean +/-SD) 6.29 +/- 1.11 p =0.42 Mechanical lateral distal femoral angle (mLDFA): EOS 3D (mean +/- SD) 89.95 +/- 3.13 X-ray (mean +/-SD) 89.38 +/- 3.21 p = 0.45 Medial proximal tibial angle (MPTA): EOS 3D (mean +/- SD) 84.74 +/- 3.06 X-ray (mean +/-SD) 85.74 +/- 3.98 p = 0.24 Bland-Altman analysis: Mean angles (degrees). fAMA (mean difference +/- SD) 6.04 +/- 1.25, 95% CI: 5.94 to 6.14. Min 2.30, max 9.75, range 7.45. Difference in mean angles (degrees). fAMA (mean difference +/- SD) 0.28 +/- 1.15, 95% CI: -0.99 to 4.04. Min -1.60, max 8.10, range 9.70. Overall, there were no clinically relevant differences as well as no statistically significant differences in measurements between the 2 imaging modalities. Benefits of EOS™ imaging are that: (1) it has low radiation exposure, (2) it enables whole-body standing views (simultaneous AP and lateral) & (3) it enables 3D reconstruction.		

				Apart from the higher radiation exposure, the alignment & 2D measurements are easily influenced by patient's limb position (flexion or rotation) when the image is taken and by deformities (varus or valgus, femoral or tibial bowing); ultimately affecting the accuracy of preoperative templating. Other disadvantages are that: (1) X-ray beams diverge so there can be an issue with magnification; (2) there is a risk of stitching error as two to three X-ray images are needed for long leg views; & (3) it is time consuming as the patient needs to stand for the duration of several X-ray images to be taken.		
Hyun-Soo Moon (2020) The effect of knee joint rotation in the sagittal and axial plane on the measurement accuracy of coronal alignment of the lower limb. Korea	Retrospective comparative single centre study.. Patients had both EOS & CR done on the same day Aim: to investigate the effect of knee joint rotation in the sagittal plane & axial plane to the measurement accuracy of coronal alignment of the lower limb on CR with reference to the values measured by the EOS system. No external sources of funding.	RQ1 RQ2	N/A n = 90 with knee pain & required evaluation of rotation of the lower extremity. 43 females, 47 males.	There was a significant difference between the mechanical tibiofemoral angle (mTFA) on CR & EOS ($p < 0.001$). The mean value of absolute ΔmTFA, knee flexion/extension angle, and patellar rotation in overall subjects was 1.7 ± 2.0°, 5.3 ± 5.3°, 4.6 ± 4.0%, respectively.	No empirical data	No empirical data

	No COIs declared.		Mean age: 48.0 ± 16.5 years.			
Powell (2020) Can EOS imaging substitute for conventional radiography in measurement of acetabular morphology in the young dysplastic hip? US	Diagnostic study. EOS vs CR (AP) to measure acetabular morphology. No funding statement. No COIs declared.	RQ1 RQ2	N/A n = 21 patients 14 female, 7 male. 14.4 ± 4.7 years.	Inter-rater reliability: Tönnis angle: EOS = 0.86 CR = 0.86 Lateral centre edge angle (LCEA): EOS = 0.86 CR = 0.9 Acetabular depth-width ratio (ADR): EOS = 0.74 CR = 0.82 Extrusion index (EI): EOS = 0.91 CR = 0.84 On average, raters measured Tönnis angle and EI higher on EOS images than CR (2.22 degrees, 1.09%, respectively) & LCEA & ADR lower on EOS images than CR (1.54 degrees, 1.14% respectively).	Not specified	Not specified
Welborn (2020)	Single centre, retrospective comparative study of image distortion	RQ1	n = 43 patients with rod	3 observers, rod actuator diameter = 9.02mm from the manufacturer.	Not specified	Not specified

Image distortion in biplanar slot-scanning: patient-specific factors. US	by measuring magnetically controlled growing rod length (MCGR) (surrogate) in post op patients in EOS vs DR images. No funding statement. No relevant COIs.		insertions Age & sex not specified. Images: 55 post op DR AP images, 184 follow up PA EOS images, 76 lateral images.	Overall, ICC were moderate to excellent (0.635 to 0.983), but the inter-image ICCs were poor (0.332). DR overestimated the MCGR actuator width (mean = 9.655) & EOS underestimated it (mean = 8.935). The measurement range was large with EOS PA (up to 15%) & lateral (22%) measurements & with DR (39%). Patients with abnormal muscle tone had higher degrees of measurement variability. This high degree of variability for EOS increased variability in the rod width measurements between images in patients with abnormal muscle tone due to the impact of motion artefact, which is amplified in biplanar slot-scanners due to their prolonged image acquisition time.		
		RQ2	N/A			
Auberger (2021) Pelvic position, lying on a traction table, during THA by direct anterior approach. Comparison with the standing position and	Prospective, single centre, comparative study. Pre-op: AP & lateral on EOS Lateral weight bearing image & At surgery: pelvic supine lateral X-ray. Post-op: AP & lateral EOS images.	RQ1	N/A	1. Difference in pelvic incidence measurement: No difference found. Pre-op EOS: 53.7 degrees ±12.9 (23.0-97.0) Pre-op lateral weight bearing: 54.8 degrees ±11.6 (-24-84) At surgery pelvic supine lateral X-ray: 54.2±12.2 (27-92) Post-op EOS:	None specified	None specified
		RQ2	58 (acetabular cup anteversion; post-op imaging used to position prosthesis).			

influence on the acetabular cup anteversion. France	No funding provided. No relevant COIs declared.		32 females, 26 males. Mean age: 67 years.	53.2±12.6 (20.0-96.0) p = 0.06; p = 0.23; p = 0.11; p = 0.39 2. Correlation between position of supine pelvis and anteversion of the cup. Strong correlation (p < 0.001; r = −0.51).		
Brenneis (2021) Accuracy of preoperative templating in total hip arthroplasty with special focus on stem morphology: a randomized comparison between common digital and three-dimensional planning using biplanar radiographs. Germany	Randomised study assessing the reliability of EOS (3D) & DR (2D) for planning step & cup size of prosthesis. Images taken preoperatively; standing (EOS), supine (DR). Prosthesis templating performed using the imaging, by 2 independent observers twice, 4 weeks apart. Funding sources: EOS Imaging (Paris, France) provided support for this study. EOS Imaging had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. No relevant COIs	RQ1 RQ2	N/A 51 patients having total hip replacements. EOS: 23 patients (13 female, 10 male; mean age 60.2 years). DR: 28 patients (12	Intra-observer ICC for both observers for EOS was high: 0.92-0.97 for stem & cup planning. Intra-observer ICC for DR ranged from 0.84 to 0.96 for stem & cup components. Inter-observer ICC for both stem and cup planning was higher for the EOS (0.91-0.92 for EOS v 0.84 for 2D). Planning accuracy of stem size: ±1 of the implanted size predicted in 91.3% (EOS) of cases v 85.7% of cases (DR). Exact size predicted was 34.8% (EOS) v 35.7% (DR). Planning accuracy of cup size: ±1 of the implanted size predicted in 100% of cases (EOS) v 89.3% (DR). The correlations between the mean planned component sizes of all planning per patient & the implanted	None specified	None specified

	declared, bar the above.		female, 16 male; mean ages: 63.5 years).	component sizes showed a high level of accuracy for the acetabular cup size (3D: r = 0.87, p < 0.001 vs. 2D:r = 0.88, P < 0.001) and the femoral stem size (3D:r = 0.94, P < 0.001 vs. 2D: r = 0.89, p <0.001) for both planning methods. Short stem size was planned exactly in 30.8% of cases (EOS) vs 15.4% (DR). Planned femoral short stem size corresponded to the implanted size in 92.3% of cases (EOS) vs 76.9% (DR). Planned femoral straight stem size corresponded with the implanted stem ±1 size (EOS) in 9 90% of cases v 93.3% of cases (DR). Comparing the accuracy of 3D & 2D planning of short stem prostheses, the absolute difference between implanted & mean planned component size was significantly lower in 3D planning (p = 0.030). There was no significant difference in planning accuracy of straight stem prostheses between both planning methods (p = 0.935).		
Buller (2021) EOS Imaging is Accurate and Reproducible	Retrospective single centre, comparative study. EOS vs CR. No funding provided.	RQ1 RQ2	N/A n = 160 undergoing THR. Sex not	Pearson test revealed EOS templating and conventional radiograph templating was highly correlated to the implanted acetabular component size (R^2 = 0.85 and R^2 = XX respectively). Value not stated.	None specified	None specified

for Preoperative Total Hip Arthroplasty Templating. US	No relevant COIs.		specified. Mean age of 66.4 ± 9.6 years.	EOS templating predicted femoral component size accurately in 66% of cases and to within 1 size in 98% of cases. The femoral component size was more likely to be templated to the exact size using EOS compared to conventional imaging (p = 0.008). Pearson test revealed EOS templating was highly correlated to the implanted femoral component size (R^2 = 0.88). The femoral component offset choice was accurately predicted in 84% of EOS cases compared to 80% of conventional templates (p = 0.341). EOS more often predicted the exact femoral component offset and size together (56%) compared to conventional radiographs (39%) (p = 0.02). EOS also more often predicted the exact femoral and acetabular component size together (44%) compared to conventional radiographs (26%) (p = .015). However, there was no significant difference in the ability of EOS to exactly predict both component's size and femoral offset (36%) when compared to conventional radiographs (24%) (p = 0.06). Inter-observer agreement was excellent for acetabular (Cronbach's alpha = 0.94) and femoral component (Cronbach's alpha = 0.96) sizing.		
Hirsch	Retrospective, single centre comparative study.	RQ1	n = 50 patients.	Lateral EOS vs lateral XR, both taken within 12 months.	None specified	None specified

(2021) Visualization of the cervicothoracic junction with EOS imaging is superior to conventional lateral cervical radiographs. US	Aim: compare the visibility of the vertebra (cervicothoracic junction, CTJ) on lateral EOS images to that of conventional lateral cervical radiographs (XR). In addition, The ability of EOS & conventional cervical radiographs to detect spondylolisthesis. Two fellowship trained spine surgeons, viewed assessed images. No funding provided. COIs declared but none relevant.		29 females, 21 males. Mean age: 56.7 years.	Authors' conclusion was that EOS imaging is superior at imaging the vertebra of the CTJ & may result in enhanced ability to detect spondylolisthesis in this region. Cohen's kappa demonstrated moderate inter-rater agreement on cortical visibility for both modalities (XR: 0.44; EOS: 0.42) EOS imaging is superior at imaging the vertebra of the CTJ. Vertebral body visibility was significantly better at T1 (2.8 ± 1.3 vs 2.3 ± 1.6, p = 0.03) & T2 (2.5 ± 1.4 vs 1.1 ± 1.6, p < .01) on EOS imaging as compared to XR. Visibility of the C6 & C7 vertebral bodies on EOS imaging was equivalent to XR Vertebral body visibility was inversely correlated with BMI on EOS at both T1 and T2 vertebrae (r = -0.29, p = 0.04 and r =-0.33, p = 0.02, respectively). On XR, an inverse correlation with BMI was found only at the T2 vertebral body (r = -0.35, p = 0.01) 30 patients had flexion & extension images. Superior visualization of the T1 & T2 vertebral bodies in both positions with minimal to no difference in visibility at		
		RQ2	N/A			

				C6 and C7. The incidence of spondylolisthesis was low across all levels & did not demonstrate any statistically significant differences between modalities (EOS vs XR). There was a significant difference in the incidence of insufficient visibility to detect spondylolisthesis on EOS versus XR at C7-T1 and T1-2, but not at C6-7. They found EOS superior when neck was in neutral flexed and extended positions.		
Koliogiannis (2021) Is the EOS imaging system as accurate as conventional radiography in grading osteoarthritis of the knee? Germany	Retrospective single centre comparative study. Patients had EOS vs CR long leg images for AP knee imaging for grading of osteoarthritis. Both images were taken on the same day in standing position. Step 1 EOS images reviewed without CR, step 2 EOS & CR compared. No funding provided. No relevant COIs.	RQ1 RQ2	N/A n = 142 79 females, 63 males. Mean age was 57.1 years with a median of 58.5 years, range 15 - 91 years.	3 metrics- joint space, KL score and OARSI. Joint space showed very good intra-class correlation 0.96 for single measurements & 0.98 for multiple measurements. OA grading by KL score weighted kappa EOS versus CR was excellent. 0.97 with a statistical significance of α < 0.001 & an asymptotic standard error of 0.012. 2/34 knees were staged as grade II on the EOS images but were finally staged as being grade III on conventional radiographs. OARSI score showed superb weighted kappa scores between 0.9 & 0.96 (α < 0.001) The parameter deformity showed a good agreement between EOS &	None specified	None specified

				radiographs (sensitivity 93.6%; specificity 100%). For the sclerosis parameter, an overall sensitivity of 71.3% & a specificity of 99.3% were calculated.		
Störmann (2021) Comparison of medial distal tibial angle in EOS imaging and weight bearing X-ray. Germany	Retrospective single centre comparative study. 3 observers, 2 orthopaedic surgeons & one radiologist, evaluated all images twice at an interval of 4 week. In EOS imaging MDTA was measured in two ways, called EOS low and EOS high. No funding provided. No COIs declared.	RQ1 RQ2	N/A n = 41 but 43 ankles. 19 female 21 male. Mean age = 55 years with a range of 18-78 years.	ICC 0.86 (X-ray low/EOS low), ICC 0.85 (X-ray low/EOS high) & ICC 0.97 (EOS low/EOS high). Intra and inter-observer reliability were in each case ICC > 0.95. X-ray low ICC of the 3 observers for average measures were 0.97, 0.98 & 0.98 respectively. For EOS the intra-class reliability was ICC 0.96, ICC 0.99 & ICC 0.98. For EOS high the ICC was 0.97, 0.99 & 0.98, demonstrating an excellent agreement for each observer & every measurement method. Determining the inter-observer reliability the consistent agreement was ICC 0.96 (X ray low), 0.95 (EOS low) and 0.98 (EOS high).	None specified	None specified
Wu (2021) Accuracy and reliability of standing lateral lumbar radiographs for measurements of spinopelvic	Retrospective single centre comparative study. Spinopelvic parameters compared in 50 consecutive patients with standing lateral lumbar X-rays and whole spine EOS taken 1 week apart.	RQ1 RQ2	N/A n = 50 (had EOS and radiographs). 26 females, 24	2 observers measured 4 values on each image, pelvic incidence (PI), pelvic tilt (PT), sacral slope (SS), & lumbar lordosis (LL), less than 1 degree difference between X-ray & EOS, only statistically different for PI. ICC values for evaluating intra- & inter-observer reliability were greater than 0.960 (range, 0.963–0.993), indicating excellent reliability	None specified	None specified

parameters. China	No commercial funding. No COIs declared.		males. Mean age was 57.3 ± 12.0 years, range, 22–81 years.	ICC values for EOS vs DR 0.872–0.976.		
Wei (2021) Consistency comparison of the parameters of the lumbar spine-pelvic sagittal plane between the whole-spine EOS images system and traditional X-ray. China	Retrospective single centre comparative study. EOS (pre-surgery) & CR (before outpatient clinic). No funding statement. No COI statement.	RQ1 RQ2	N/A n = 50 24 females, 26 males. Aged 22-81. Spine but no scoliosis.	The inter-group reliability analysis showed excellent agreement between the two observers using Surgimap software to measure the lateral pelvic incidence (PI)¸pelvic tilt (PT)¸sacral slope (SS)¸lumbar lordosis (LL) The intra-group reliability analysis showed that the 2 observers used Surgimap software to measure the conventional X-ray & EOS lateral PI¸PT¸SS¸LL on 2 separate occasions with excellent consistency (the first observer's ICC in the conventional X-ray group was 0.975-0.988 & the EOS group was 0.980-0.993), & the intra-group reliability analysis showed that the two observers used Surgimap software to measure the conventional X-ray & EOS lateral PI¸PT¸SS¸LL on two separate occasions with excellent consistency (the first observer's ICC in the conventional X-ray group was 0 . 975-0.988 & the EOS group was 0.980-0.993). The ICC in the conventional X-ray group was 0.974-0.996, and the ICC in the EOS group was 0.974-0.996.	None specified	None specified

				0.992; the ICC in the conventional X-ray group of the second observer was 0.964~ (0.989, ICC 0.963-0.991 in the EOS group) The error of the 2 measurements was very low & reproducible. Comparison of lumbar-pelvic sagittal equilibrium parameter measurements between the EOS & conventional X-ray groups: the difference between the PI measured by the 2 different imaging methods was statistically significant (p = 0.0200.05). (p > 0.05), & the consistency was good (ICC 0.872¸ 0.891¸ 0.949) % respectively.		
Choi (2022) Comparison of lower-limb alignment in patients with advanced knee osteoarthritis: EOS biplanar stereoradiography versus conventional scanography. Korea	Retrospective single centre comparative study. Aim: to compare radiographic parameters (hip-knee angle; HKA) between CR & EOS, both images taken while standing. No funding statement. No relevant COIs.	RQ1 RQ2	N/A n = 52 with bilateral knee osteoarthritis 48 females, 4 males. Mean age: 71.25 years (range, 57 to 83 years).	The average HKA was 10.14° ± 6.16° on conventional scanograms and 11.26° ± 6.21° in EOS. HKA was greater in EOS than on conventional scanograms, and the difference (1.12°; range, −1.07° to 3.22°) was statistically significant (p < 0.001).	None specified	None specified
Chua	5 year retrospective study	RQ1	N/A	Comparisons between the imaging &	None specified	None specified

(2022) Accuracy of biplanar linear radiography versus conventional radiographs when used for lower limb and implant measurements . Singapore	Aim: to compare between the measurements of EOS and CR with regard to lower limb length and implant measurements (right leg only). Patients had full length AP imaging & EOS (both weight bearing) done within 1 year of each other. No funding statement. No COIs declared.	RQ2	n = 43 23 females, 20 males. Median age: 49 years (range 3 to 80 years) for CR & 49 years (range 4 to 80 years for EOS).	the actual implant dimensions revealed that EOS was accurate in measuring the actual implant dimensions in terms of both the height (median difference=−0.14cm, p = 0.66), & width (median difference = − 0.13cm, p=0.71). CRs were inaccurate in measuring the actual implant height (median difference = 0.19cm, p = 0.01) and width (median difference=0.61cm, p < 0.01 with statistically significant difference between the actual implant dimensions and those measured on CR. There was statistically significant difference in all measurements taken on EOS & CR. This includes the anatomical femoral length (median difference = 3.53cm, p < 0.01) & mechanical tibial length (median difference = 2.20cm, p < 0.01. The Bland Altman plot also showed heteroscedasticity with CRs having larger measurements compared to EOS. However, strong to very strong correlation was noted between the two imaging methods for all measurements, including anatomical femoral length (Pearson's correlation=0.92), mechanical femoral length (Pearson's correlation=0.75), anatomical tibial length (Pearson's correlation=0.95) and mechanical tibial length (Pearson's correlation=0.96).		

Boissonnat (2023) Performance of automatic exposure control on dose and image quality: comparison between slot-scanning and flat-panel digital radiography systems. France	Dosimetric phantom study. EOS edge vs EOS vs DR. Organ doses calculated on female adult and 5 year old paediatric phantom and converted to effective doses. Quantitative image quality metrics were computed on a quality assurance phantom. Study was sponsored by EOS and 2nd, 3rd, 4th & 5th authors are full-time employees of EOS Imaging.	RQ1 RQ2	N/A Adult and paediatric phantom. N/A	Phantom based: CNR equal or better with EOSedge vs DR for various attenuation values. EOS-1st generation has the poorest CNR scores. EOS-1st generation had the poorest CNR scores, with CNR values always lower than 2, down to less than 0.1.DR images show excellent CNR values at low PMMA thicknesses, but they drop at 30 and 40 cm of PMMA. EOSedge shows a more stable behaviour, with CNR values almost always greater than 1 and up to 2.4.	None specified	Full spine female adult phantom effective dose: EOSedge= 92µSv DR=572µSv Paediatric phantom: EOSedge= 32µSv DR=179µSv All organ doses lower for EOSedge compared to DR. Organ doses calculated for EOSedge AP vs EOSedge PA. EOS vs EOSedge: In the adult phantom, doses to the uterus were similar between while dose to the lung was four times lower with EOSedge (0.27 mGy in EOS-1st generation, 0.055 mGy in EOSedge).
Comparative studies: EOS v computed tomography (CT) or CT scanogram						
Delin (2014) Ionizing radiation doses during lower limb	Prospective, single centre dosimetry & phantom study. Images acquired of lower limbs with EOS and with CT. Dose compared from	RQ1 RQ2	N/A N/A (Rando phantom). Retrosp	The image quality assessment of EOS, the mean of the subjective score was 1.11 ± 0.08. The inter-observer agreement was high, with a k value of 0.84.	None specified	Dose as tissue kerma (mGy) from phantom measurements Rt ovaries: EOS = 0.1; CT = 1.3

torsion and anteversion measurements by EOS stereoradiography and computed tomography France	rando phantom measurement. The CT acquired 3 acquisitions at 3 levels (hips, knees and ankles) for calculation of lower limb torsion and anteversion measurements Retrospective image quality review carried out on EOS images of lower limbs. No funding statement. No COI statement.		ective review of image quality on EOS = 31.			Lt ovaries: EOS = 0.5 ; CT = 1.1 Rt testicles: EOS = 0.3 ; CT= 8.5 Lt testicles: EOS = 0.4; CT = 8.4 Rt knees: EOS = 0.4; CT = 11 Lt knees: EOS = 0.8; CT = 10.4 Rt ankles: EOS = 0.5; CT = 15.2 Lt ankles: EOS = 0.8; CT = 15.6 Anterior pelvis max surface entrance dose= EOS = 0.57mGy CT = 0.71mGy Post exit dose: EOS = 0.15mGy CT = 1.2mGy

Nam (2016) The Impact of Imaging Modality on the Measurement of Coronal Plane Alignment After Total Knee Arthroplasty US	Retrospective single centre comparative study. EOS (standing) and scout CT (supine) both taken post primary total knee replacement (THR). 2 independent observers measured the hip-knee angle (HKA) angle, and femoral and tibial component alignment from each image No funding statement. COI declared by lead author	RQ1	N/A	24.4% (39 of 160) of patients had a HKA difference of ≥3 between the 2 images, whereas 18.8% (30 of 160) and 20.0% (32 of 160) of patients had a femoral and tibial component alignment difference of ≥2 respectively.	Not specified	Not specified
		RQ2	n = 160 undergoing THR. Sex not specified. Mean age of 66.4 ± 9.6 years.			
Mayr (2021) Anteversion angle	Prospective single centre self-controlled cohort. No commercial funding.	RQ1	N/A	Pearson's correlation co-efficient between two hip measurement methods = 0.855. No p-value <0.001 for 2-sided t-test.	Not specified	Not specified
		RQ2	34 femora measure			

measurement in suspected torsional malalignment of the femur in 3-dimensional EOS vs computed tomography - a validation study Germany	No relevant COIs.		ments from 19 patients. 15 females & 4 men. Average age of 45.5 ± 19.8 years. n = 14 patients included for determination of decreased AV angle or retroversion. n= 11 patients AV angle increase determination.	Pearson's correlation co-efficient between two methods of measuring AV angle with reduced AV = 0. 495. P-value = 0.072 for two-sided t-test. Pearson product-moment correlation of the measurements between EOS & CT for the determination of the AV angle in increased AV = 0.292. P-value 0.446 for two-sided t-test. The ICC for all 3 examiners showed a strong intra-observer reliability with Cronbach alpha of 0.955 for EOS & 0.934 for CT scan.		

Anderson (2022) Validating the use of 3D biplanar radiography versus CT when measuring femoral anteversion after total hip arthroplasty: a comparative study. US	Prospective, single centre comparative study. EOS vs CT when measuring femoral anteversion after total hip arthroplasty. COI declared and funding statement indicated that EOS provided measurements on the 3D images.	RQ1 RQ2	N/A n = 45 (had both EOS and CT). 21 females, 24 males. Mean age of 62.2 years (SD 9.37).	Mean postoperative femoral stem version measurements showed no significant difference CT vs EOS (p = 0.862). In addition, version measurements strongly correlated (r = 0.95; p < 0.001), & the mean paired difference in postoperative femoral version for CT scan & 3D biplanar radiography was -0.09° (95% confidence interval -1.09 to 0.91). Only 3 stem measurements out of the 45 patients (6.7%) were considered outliers with a > 5° difference.	None specified	None specified
Ma (2022) Assessing component orientation of total hip arthroplasty using the low-dose bi-planar	Retrospective single centre comparative study. CTs taken 1 week post-THR (supine); EOS images taken 6 weeks later (standing). Assessed the validity &	RQ1	N/A	With 3D CT reconstruction as the reference method, there was no significant difference in the cup anteversion (0.62°, 3.05° SD, p=0.160), cup inclination (0.32°, 3.21° SD, p=0.486), & stem anteversion (−0.41°, 2.34° SD, p = 0.219). With the APP as the reference plane,	None specified	None specified

radiographs. China	reliability of the component orientation assessment of EOS images in comparison with 3D CT reconstruction using the anterior pelvic plane (APP) as the reference plane & how the functional component orientation differs, when EOS, from that by supine CT scans? No commercial funding. No COIs declared.	RQ2	n = 44 (50 hips) under THR. 26 women; 18 men. Mean age: 51.3 years, range, 26–78 years.	the inter- & intra-observer reliabilities of the low-dose bi-planar radiographs were good. The ICCs were 0.945 & 0.956 for measuring cup anteversion, 0.923 & 0.928 for measuring cup inclination, & 0.981 & 0.987 for measuring stem anteversion. For the functional cup orientation & pelvic tilt (PT) assessment, significant differences were found between standing radiographs & supine CT scans with the radiographic coronal plane as reference, including the cup anteversion (1.80°, 5.89° SD, p = 0.035), the cup inclination (−1.69°, 5.35° SD, p = 0.030), & the PT (2.05°, 6.73° SD, p = 0.037), respectively. The mean absolute error was relatively high, reaching 4.76±1.07°, 4.02±1.08°, & 5.36±1.25°, respectively. With the APP as the reference plane, the mean values (measured on the low-dose bi-planar radiographs) were 35.16°(SD, 8.54°) for anatomical anteversion, 42.16°(SD, 5.16°) for radiographic inclination, & 17.68°(SD, 9.16°) for stem anteversion. The mean 3D CT values were 34.55°(SD, 8.30°) for anatomical anteversion, 41.84°(SD, 4.97°) for radiographic inclination, & 18.09°(SD, 8.67°) for stem anteversion. With the radiographic coronal plane as the reference plane, the mean values (measured on the		

				low-dose bi-planar radiographs) were 29.88° (SD, 9.45°) for anatomical functional anteversion, 39.74° (SD, 5.21°) for radiographic functional inclination, & 4.31° (SD, 7.11°) for PT. The mean supine CT values were 28.08°(SD, 7.72°) for anatomical anteversion, 41.43° (SD, 5.52°) for radiographic inclination, & 2.26° (SD, 8.57°) for PT.		
Included studies with no comparator						
Damet (2014) Occupational and patient exposure as well as image quality for full spine examinations with the EOS imaging system. Switzerland	Prospective, single centre dosimetry & phantom study. 20 consecutive scans performed in each position. No funding statement. No COI statement.	RQ1	N/A (adult female phantom to simulate adolescent & 5 year old male phantom used; whole spine scan).	None specified	None specified	Occupational/ comforter dose: Max ambient dose equivalent of 45µSv near cubicle. Highest associated ambient dose equivalent rate near entrance of cubicle was >10mSv/h. 1m away, the ambient dose equivalent was slightly higher than 5µSv; corresponding max dose rate was 2 mSv/h. Ambient dose equivalent rate was <100µSv/h behind the EOS walls. Patient dose: Effective dose: 290µSv (adult); 200 µSv (child) Organ doses varied from
		RQ2	N/A			

						0.1mGy to 0.5mGy (adult); & 0.2mGy to 0.4mGy (child) with the left side receiving higher dose in both cases.

Key: ADR: acetabular depth width ratio; AIS: idiopathic adolescent scoliosis; AP: anterior-posterior; APP: anterior pelvic plane; AV: anteversion; AVO: apical vertebral orientation; AVR apical vertebral rotation; AVT Apical vertebral translation; BMI: body mass index; CI: confidence interval; COI: conflict of interest; COS: cross-over sign; CR: computed radiography; CT: computed tomography; CTJ: cervicothoracic joint; CXR: chest X-ray; DAP: dose area product; DR: digital radiography; EI: extrusion index; fAMA: femoral anatomic mechanical angle; HKA: hip knee angle; HTA: health technology assessment; ICC: intraclass correlation coefficient; ISS: ischial-spine sign; LAR: lifetime attributable risk; LAR: long axial view radiograph; LAT: lateral; LCEA: lateral centre edge angle; LL: lumbar lordosis; MCGR: magnetically controlled growing rod; mLDFA: mechanical lateral distal femoral angle; PA: posterior-anterior; PI: pelvic incidence; PT: pelvic tilt; PWS: posterior wall sign; RQ: review question; SD: standard deviation; SpA: spondyloarthritis; SS: sacral slope; Sv: Sieverts; THR: total hip replacement; TLD: thermoluminescence dosimeter; US: United States of America; XR: X-ray

Table A.5 AMSTAR-2 Checklist (McKenna et al.)

AMSTAR 2 checklist item	
Did the research questions and inclusion criteria for the review include the components of PICO?	Yes
Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Partial yes
Did the review authors explain their selection of the study designs for inclusion in the review?	Yes
Did the review authors use a comprehensive literature search strategy?	Yes
Did the review authors perform study selection in duplicate?	Yes
Did the review authors perform data extraction in duplicate?	Partial yes
Did the review authors provide a list of excluded studies and justify the exclusions?	Yes
Did the review authors describe the included studies in adequate detail?	Yes
Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	Partial yes
Did the review authors report on the sources of funding for the studies included in the review?	Yes
If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	N/A
If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	N/A
Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes
Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Yes
If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	N/A
Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes
Quality outcome	**Moderate**

Table A.6 AMSTAR-2 Checklist (Mahboub-Ahar et al.)

AMSTAR 2 checklist item	
Did the research questions and inclusion criteria for the review include the components of PICO?	No
Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	No
Did the review authors explain their selection of the study designs for inclusion in the review?	No
Did the review authors use a comprehensive literature search strategy?	Partial yes
Did the review authors perform study selection in duplicate?	Yes
Did the review authors perform data extraction in duplicate?	No
Did the review authors provide a list of excluded studies and justify the exclusions?	No
Did the review authors describe the included studies in adequate detail?	No
Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	No
Did the review authors report on the sources of funding for the studies included in the review?	Yes
If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	N/A
If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	N/A
Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	No
Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Yes
If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	N/A
Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes
Quality outcome	**Critically low**

Table A.7 AMSTAR-2 Checklist (Pettit et al.)

AMSTAR 2 checklist item	
Did the research questions and inclusion criteria for the review include the components of PICO?	Yes
Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Yes
Did the review authors explain their selection of the study designs for inclusion in the review?	No
Did the review authors use a comprehensive literature search strategy?	No
Did the review authors perform study selection in duplicate?	Yes
Did the review authors perform data extraction in duplicate?	No
Did the review authors provide a list of excluded studies and justify the exclusions?	No
Did the review authors describe the included studies in adequate detail?	Partial yes
Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	No
Did the review authors report on the sources of funding for the studies included in the review?	No
If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	No
If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	No
Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	No
Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	No
If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	No
Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes
Quality outcome	**Critically low**

Appendix 2

Figure A.1: QUADAS 2 risk of bias and applicability

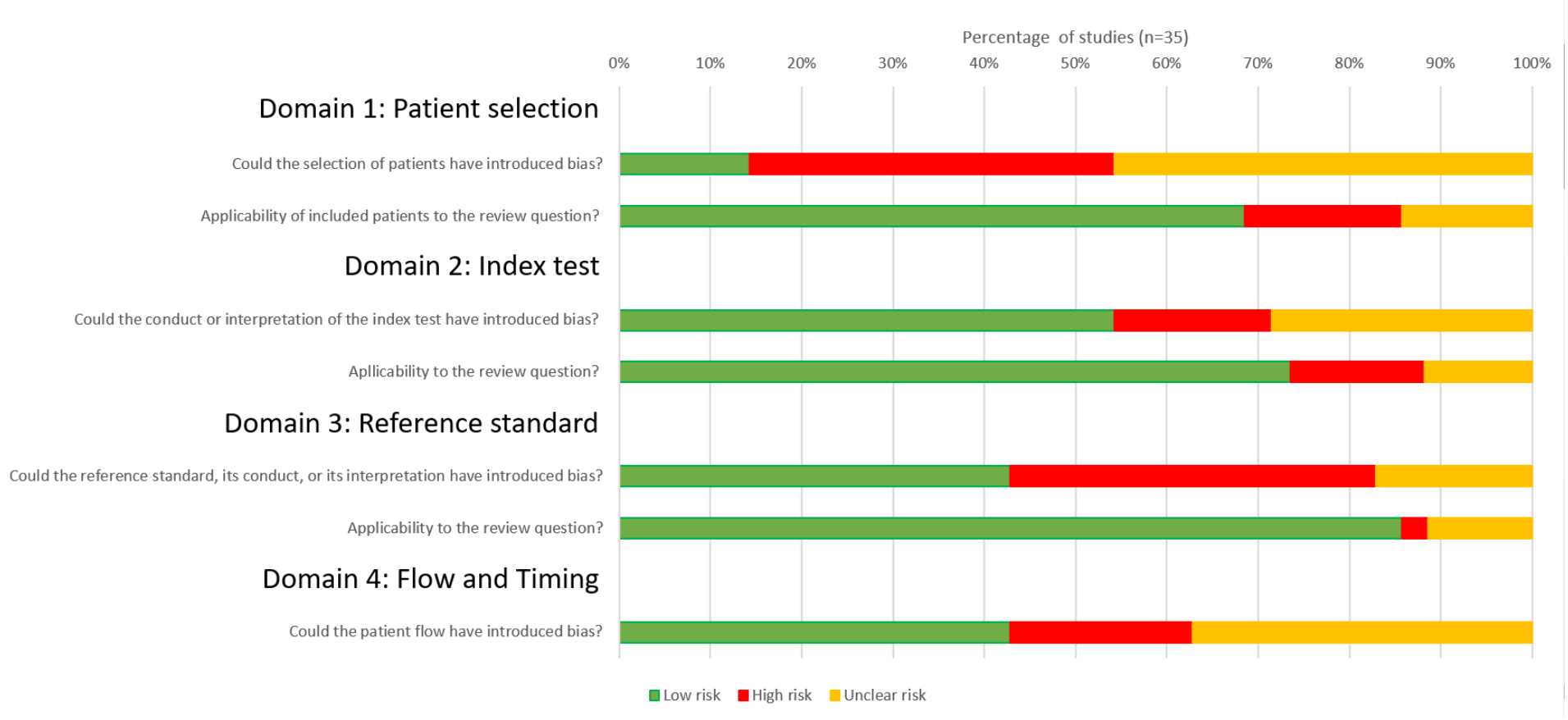

Table A.8: Additional risk of bias questions

Additional quality questions	No	Yes	N/A or N/R	Total
Were withdrawals from the study explained?	6	5	24	35
Was a sample size calculation used?	30	5	0	35
Was the method for measuring radiation dose appropriate for both the intervention and comparator technologies?	1	9	25	35
Was the method of measuring image quality appropriate for both the intervention and comparator technologies?	0	11	24	35
Was the execution of the intervention technology as it would be in practice?	2	33	0	35
Was the execution of the comparator technology as it would be in practice?	1	34	0	35

Key: N/A – not applicable; N/R – not reported.

Appendix 3

Evidence to Decision Framework Desirable Effects How substantial are the desirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ● Large ○ Varies ○ Don't know	Research Evidence <u>RQ1: Scoliosis</u> Dose: On average, the reported EOS dose was approximately one fifth of the CR/DR dose (reported EOS doses ranged from 4% to 50% of the CR/DR dose), while one study using a dynamic flat-panel detector system showed similar DAP values between EOS (39.8 cGy.cm^2) and CR/DR (41.3 cGy.cm^2). Radiographic parameters: In general, reported inter- and intra-rater reliability for radiographic parameters such as Cobb angles were in the good to excellent range (>0.75) for both EOS imaging and CR/DR. The reported inter-rater reliability for certain parameters in the neck (neck tilt and thoracic inlet angle) were only fair for both EOS and cervical radiographs. In one study there was excellent correlation between the two modalities for most sagittal alignment parameter measurements. In another the inter-rater reliability between the two modalities was significantly correlated. One study assessing spatial fidelity and reported poor inter-image ICCs for both EOS imaging and DR when measuring magnetically controlled growing rods leading to imaging error as much as 22% with EOS imaging and 39% for DR.	

	Image quality: EOS was shown to be generally comparable to CR/DR. However certain structures were less visible on EOS in certain studies, for example, lumbar spine, femoral heads and sacrum. <u>RQ2: Other orthopaedic conditions</u> Dose: All metrics indicated a dose benefit with EOS. On average the reported EOS dose was approximately half of the CR/DR dose. Mean DAP values ranged from 8 to 59 cGycm^2 for EOS and 19 to 105 cGycm^2 for CR/DR. Compared to CT (n=1) entrance skin dose, exit dose and relevant organ doses were all considerably lower. Radiographic parameters: Seven studies reported limb length measurements. Although there was very low certainty of the evidence, across studies there was consistent reporting of adequate agreement between radiographic measures. For example, the ICC was generally reported to be high (≥ 0.90). Where reported, confidence intervals were narrow. Eight studies investigated radiographic angular measurements. All except one study found a statistically significant difference between EOS and other imaging modalities. While the mean difference between modalities was often only as much as 2-3°, the difference between pairs ranged from -5.3° to 6.7° in one study to -29.4° to 30.2° in another. However, the clinical significance of these differences is uncertain. For angular measurements, the reported ICC was generally considered to be good (>0.75), however it varied according the different anatomical areas in question with some angular measures having a better ICC than others. Image quality:	

	Only one study in RQ2 reported on image quality, noting that 6% of EOS images were discarded due to poor image quality or poor positioning. Other desirable effects (both RQ1 & RQ2): One study looked at examination time, patient comfort and technician-rated ease of workflow. Examination time was shorter for EOS compared to DR for full spine (248 seconds versus 449 seconds) and full length lower limb imaging (226 seconds versus 309 seconds). EOS was significantly noisier than the DR system ($p<0.01$). There were no significant differences reported in any of the other variables assessing patient comfort. No significant difference was reported in technician-rated ease of workflow.	

Panel discussion:

The EAG considered the evidence for the outcomes listed for RQ1 and RQ2. In terms of potential benefits and harms, the MEIR EAG considered the evidence for the outcomes listed in terms of both the magnitude of the effect and the certainty of the evidence. It was recognised that the identified evidence for slot-scanning, biplanar digital X-ray imaging systems was limited to studies relating to the EOS™ imaging systems. However, while the evidence was discussed in the context of EOS, it was considered that the justification decision for this practice would apply also to other comparable technologies.

The reduction in radiation dose was considered to be the most important benefit provided by the EOS imaging system. In the context of scoliosis imaging, the EAG noted that the evidence presented suggested a potential for a 50% or greater reduction in ionising radiation dose exposure. It was recognised that the dose from general X-rays used in spinal imaging is relatively low; however, the potential for further reductions was considered desirable in the context of this patient population. The EAG recognised the challenges and complexity of quantifying the clinical significance of the dose reduction given the potential for both dose-related and stochastic ionising radiation effects. However, the importance of the as-low-as-reasonably-achievable (ALARA) principle was highlighted particularly in the context of a paediatric population undergoing repeated thoracic exposure for scoliosis monitoring. There were limited concerns in relation to image quality, with the images obtained sufficient to inform clinical decision making in this context. The EAG agreed that this judgment should be recorded as 'large'.

Undesirable Effects

How substantial are the undesirable anticipated effects?		
JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large ○ Moderate ○ Small ● Trivial ○ Varies ○ Don't know	Research Evidence <u>RQ1: Scoliosis</u> Dose: Overall, identified studies did not highlight any safety concerns with EOS. Radiographic parameters: One study assessing spatial fidelity and reported poor inter-image ICCs for both EOS imaging and DR when measuring magnetically controlled growing rods leading to imaging error as much as 22% with EOS imaging and 39% for DR. Image quality: EOS was shown to be generally comparable to CR/DR. However certain structures were less visible on EOS in certain studies, for example, lumbar spine, femoral heads and sacrum. <u>RQ2: Other orthopaedic conditions</u> Dose – Overall, identified studies did not highlight any safety concerns with EOS. Radiographic parameters: Eight studies investigated radiographic angular measurements. All except one study found a statistically significant difference between EOS and other imaging modalities. While the mean difference between modalities was often only as much as 2-3°, the difference between pairs ranged from -5.3° to 6.7° in one study to -29.4° to 30.2° in another. However, the clinical significance of these differences is uncertain.	

	For angular measurements, the reported ICC was generally considered to be good (>0.75), however it varied according the different anatomical areas in question with some angular measures having a better ICC than others. Image quality: Only one study in RQ2 reported on image quality, noting that 6% of EOS images were discarded due to poor image quality or poor positioning.	

Panel discussion:

The EAG discussion noted that it was challenging to determine an overall judgement for this criterion as the harms and or risks were being considered for two different review questions (patients with scoliosis and patients other orthopaedic conditions). The potential clinical relevance of the lack of consistency between EOS and conventional radiography for angular measurements in RQ2 was discussed. It was agreed that the percentage difference in radiographic parameters, for example, the angular measurements, were unlikely to be clinically significant. The EAG agreed that no additional risks or safety issues had been identified for this practice. Potential issues with skin dose associated with low dose radiation was discussed; it was noted that no evidence of harms were identified within the studies and the EAG agreed this was not a concern for this imaging device.

A judgement of 'trivial' was agreed upon by the EAG.

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High	Research Evidence: The certainty of the evidence for all outcomes is 'low' or 'very low'. Therefore, the overall, the certainty of the evidence is Very Low.	Additional considerations The certainty of the evidence was initially assessed as Low Certainty or was marked down for the following reasons: lack of RCTs,

○ No included studies		many of the observational studies assessed as high risk of bias due to concerns with patient selection and blinding, patient flow and timing, conduct of index and/or reference test. However, across most studies there was a consistent and substantial reduction in dose and at least comparable image quality was reported for EOS.
Panel discussion: No panel discussion around this criterion as the judgement is based on the standard GRADE methodology.		

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important		

uncertainty or variability		
Panel discussion: The panel considered the potential for important uncertainty or variability in how much people value the main outcome, that is, the ionising radiation dose. Also discussed was the potential for variability in the importance of image quality in informing decisions, depending on the clinical application. A judgement of 'probably no important uncertainty or variability' was recorded by the EAG for this criterion.		

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favours the comparison ○ Probably favours the comparison ○ Does not favour either the intervention or the comparison ○ Probably favours the intervention ● Favours the intervention ○ Varies ○ Don't know		

Panel discussion:

When considering the balance between the desirable and undesirable effects, it was agreed that the practice was favoured over conventional radiography for the evaluation and monitoring of orthopaedic conditions. This was on the basis that comparable image quality sufficient to inform clinical decision making could be achieved despite a consistent and potentially substantial reduction in ionising radiation dose. A judgement of 'favours the intervention' was recorded by the EAG for this criterion.

Recommendation

On consideration of the balance between the benefits and harms, the EAG found that the intervention is probably favoured compared to the available alternatives(s). The MEIR EAG have recommended to HIQA that a slot-scanning, biplanar, digital X-ray imaging system should be generically justified for the evaluation and monitoring of orthopaedic conditions.

Key: CR: conventional radiography; DAP: dose area product; DR: digital radiography; EAG: expert advisory group; ICC: interclass correlation coefficient; RQ: review question

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