

# Quantifying the clinical benefits of new imaging technologies: A technology assessment of EOS® 2D/3D X-ray imaging system

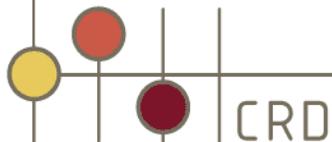
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THE UNIVERSITY *of York*

# Evaluation of EOS<sup>®</sup> 2D/3D X-ray imaging system

- The first topic for the National Institute for Health and Clinical Excellence (NICE) Diagnostic Assessment Programme
- We performed this diagnostic technology assessment as an independent research group for NICE
- The NICE guidance of EOS<sup>®</sup> 2D/3D imaging system is available on the NICE website (<http://www.nice.org.uk>)



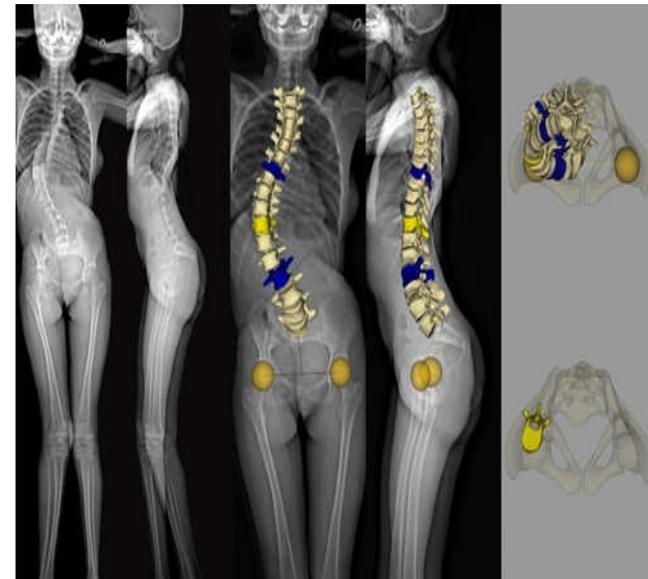
# The EOS<sup>®</sup> 2D/3D X-ray imaging system

- EOS<sup>®</sup> 2D/3D X-ray Imaging is a new biplane X-ray system manufactured by EOS Imaging



# The EOS<sup>®</sup> 2D/3D X-ray imaging system

- EOS<sup>®</sup> 2D/3D X-ray Imaging is developed for orthopaedic imaging
- The potential benefits of EOS<sup>®</sup>:
  - Weight bearing (both standing and seated positions)
  - Full body image
  - Simultaneous posteroanterior (PA) and lateral imaging
  - Three-dimensional (3D) image
  - High quality image
  - Low dose radiation

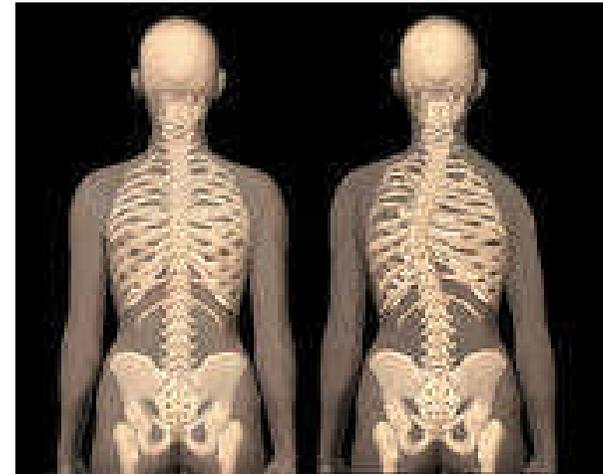


## Indications where the features of EOS® may improve patient outcomes

- In children and adolescents:
  - Spinal deformity (principally scoliosis)
  - Leg length discrepancy and alignment
- In adults:
  - Spinal deformity, including degenerative scoliosis, progressive kyphosis and osteoporotic fractures
  - Conditions involving loss of sagittal and coronal balance, including issues relating to hip and knee where full body or full length leg images are currently requested

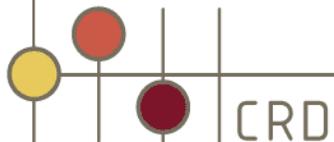
# Scoliosis

- Scoliosis is a 3D deformity of the spine, characterised by a sideways curve (coronal plane deformity) of ten degrees or more
- Patients with adolescent idiopathic scoliosis often undergo repeated X-ray scans in order to monitor the curve progression and determine the severity of the spinal deformity by measuring the degree of spinal curvature (Cobb angle)



## Objective

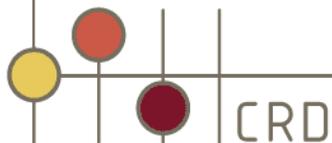
- To evaluate the clinical benefits of the EOS<sup>®</sup> 2D/3D X-ray imaging in patients with orthopaedic conditions



CRD

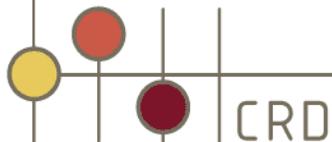
## Methods

- A systematic review was performed to assess the clinical effectiveness of the EOS<sup>®</sup> 2D/3D X-ray imaging system for the evaluation and monitoring of relevant orthopaedic conditions
- Cancer risk due to radiation exposure was assessed



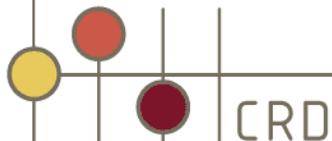
# Systematic review: clinical effectiveness of the EOS<sup>®</sup> 2D/3D X-ray imaging system

- Intervention
  - EOS<sup>®</sup> 2D/3D X-ray imaging system
- Comparators
  - Technologies used in standard practice, including X-ray film, computed radiography (CR) and digital radiography (DR)
- Participants
  - Patients with any orthopaedic condition
- Study design
  - Comparative studies (comparing EOS<sup>®</sup> with X-ray film, CR or DR)
- Primary outcome: patient health outcomes; Secondary outcomes: Radiation dose and quality of the image



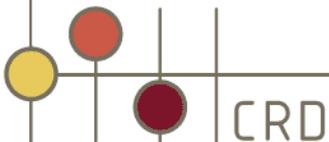
# Systematic review: clinical effectiveness of the EOS<sup>®</sup> 2D/3D X-ray imaging system

- Quality Assessment
- The quality of included studies was assessed using the QUADAS quality assessment tool for diagnostic studies
- Additional project-specific quality items were also assessed:
  - The appropriateness of the methods used for measuring radiation dose and image quality
  - Whether the execution of the technologies matched clinical practice



## Results

- Three small studies of limited quality were identified (n= 290, the sample size ranging from 50 to 176)
- Two studies compared EOS<sup>®</sup> with film X-ray imaging and one compared EOS<sup>®</sup> with standard CR
- The included patients were primarily children with scoliosis (mean age 14 years where reported)
- None of the studies reported patient health outcomes



# Radiation dose

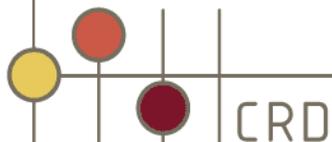
- The mean entrance surface dose was considerably lower with EOS<sup>®</sup> compared with film X-ray or CR for all images

## Ratio of mean doses

	Film X- ray vs. EOS <sup>®</sup>		Computed radiography vs. EOS <sup>®</sup>
PA Spine	5.2	13.1	5.9
Lateral Spine	6.2	15.1	8.8

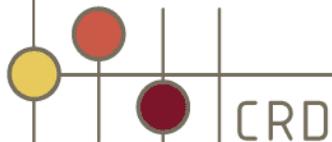
## Image quality

- All studies found image quality to be comparable or better with EOS<sup>®</sup> overall
- The image quality of studies was not assessed using standard criteria
- None of the studies compared the measurement of the Cobb angle between EOS<sup>®</sup> and film X-ray or CR
- None of the studies assessed the facility for 3D imaging



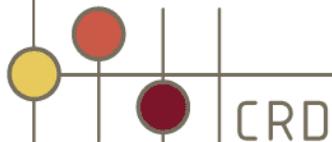
# Harmful effects due to radiation exposure

- Four major reports produced by large radiation protection and safety agencies:
  - BIER VII Phase 2
  - UNSCEAR
  - ICRP publication 103
  - Health Protection Agency (HPA) report
- A systematic review was performed to investigate what specific evidence exists of the adverse effects of diagnostic X-ray radiation in patients with orthopaedic conditions



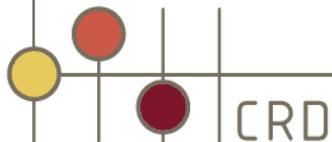
## The four major reports produced by large radiation protection and safety agencies

- Summarised the evidence of harmful effects due to radiation exposure
- Cancer risk and adverse reproductive outcomes are the adverse effects of radiation exposure of key concern
- Developed the risk models for cancer
  - The primary source of cancer risk data was derived from the Life Span Study (atomic bomb survivors)
- The lifetime cancer risk estimates being derived from the risk models in ICRP Publication 103 were used to inform the economic model of this technology assessment



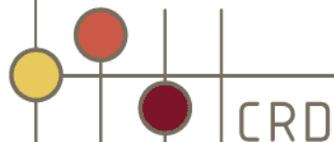
## Studies in orthopaedic patients

- Four cohort studies assessing cancer risk associated with diagnostic X-ray radiation, all based on the same cohort of US scoliosis patients (n= 5,573) diagnosed between 1912 and 1965
- The data did not show significant increases in the risk of dying from cancers such as leukaemia, liver, cervical and lung cancer compared with the general US female population
- A significant increase in the risk of dying from breast cancer in spinal curvature patients compared with the general US female population, with standardised mortality ratio (SMR) 1.68 (95% CI 1.38 to 2.02)
- However, the relevance of this result to current clinical practice is questionable



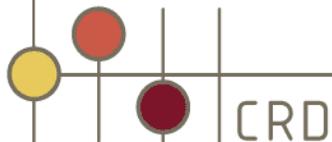
## Conclusions

- There was sparse clinical evidence to support the use of EOS<sup>®</sup> in patients with orthopaedic conditions
- There was no evidence of clinical benefits from the innovative features of EOS<sup>®</sup> in terms of:
  - changing clinicians' diagnostic reasoning
  - improving therapeutic management
  - improving patient health outcomes
- Future studies are required to assess patient health outcomes



# Conclusions

- In the absence of evidence for other clinical benefits, radiation reduction was considered to be the primary benefit for EOS<sup>®</sup>
- It is difficult to quantify the long-term health benefits associated with the reduced radiation dose seen with EOS<sup>®</sup>



# Acknowledgements

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