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

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Evaluation of EOS® 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® 2D/3D imaging system is available on the NICE website (http://www.nice.org.uk)
The EOS® 2D/3D X-ray imaging system

- EOS® 2D/3D X-ray Imaging is a new biplane X-ray system manufactured by EOS Imaging
The EOS® 2D/3D X-ray imaging system

- EOS® 2D/3D X-ray Imaging is developed for orthopaedic imaging
- The potential benefits of EOS®:
  - 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® 2D/3D X-ray imaging in patients with orthopaedic conditions
Methods

• A systematic review was performed to assess the clinical effectiveness of the EOS® 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® 2D/3D X-ray imaging system

- **Intervention**
  - EOS® 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® 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® 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® with film X-ray imaging and one compared EOS® 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® compared with film X-ray or CR for all images

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<th>Film X-ray vs. EOS®</th>
<th>Computed radiography vs. EOS®</th>
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<tr>
<td>PA Spine</td>
<td>5.2</td>
<td>13.1</td>
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<tr>
<td>Lateral Spine</td>
<td>6.2</td>
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Image quality

- All studies found image quality to be comparable or better with EOS® 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® 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® in patients with orthopaedic conditions

• There was no evidence of clinical benefits from the innovative features of EOS® 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®.

- It is difficult to quantify the long-term health benefits associated with the reduced radiation dose seen with EOS®.
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