TITLE: O-Arm Technology in Spinal, Neurological, Orthopedic, or Trauma Surgery Settings: Clinical Effectiveness, and Benefits and Harms

DATE: 07 August 2013

RESEARCH QUESTIONS

1. What is the clinical effectiveness of O-arm technology used in spinal, neurological, orthopedic, or trauma surgery settings?

2. What are the benefits and harms associated with O-arm technology in patients undergoing spinal, neurological, orthopedic, or trauma surgeries?

3. What are the harms associated with the use of O-arm technology in operating room hospital staff?

KEY MESSAGE

One randomized controlled trial and nine non-randomized studies were identified regarding the clinical effectiveness, benefits, and harms of O-arm technology used in surgical settings.

METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2013, Issue 6), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2003 and July 29th, 2013. Internet links were provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials (RCTs), and non-randomized studies. One RCT and nine non-randomized studies were identified. Due to the large volume of relevant literature, non-comparative studies on O-arm effectiveness have been included in the appendix. Additional references of potential interest are also provided in the appendix.

OVERALL SUMMARY OF FINDINGS

Overall, studies agreed that the O-arm system was safe and accurate, with minimal radiation exposure, for spinal surgery and deep brain stimulation.[1-9] One study, on radiation exposure during orthopedic surgery, found that the O-arm delivered higher doses of radiation to operators than did the C-arm technology.[10] Further details of the included studies are provided in Table 1.

Table 1: Summary of Included Studies

Author, Year Study Type	Surgical Procedure	Comparator	Authors' Conclusions
Effectiveness			
Shin et al. 2013[1] RCT	Thoracic and lumbar spines	C-arm fluoroscopy	O-arm system was more accurate and safer than the fluoroscopy method for pedicle screw placement
Holloway et al. 2013[2] NRS	Deep brain stimulation	Computed tomography (CT)	O-arm system was as accurate as the CT scan
Hodges et al. 2012[3] NRS	Spinal surgery	C-arm	O-arm system could reduce the need for pedicle screw revision
Houten et al. 2012[4] NRS	Lumbar fusion	Fluoroscopy-guided method	O-arm system was safe and effective, improving overall accuracy and reducing operative time
Shin et al. 2012[5] NRS	Thoracic and lumbar spines	C-arm fluoroscopy	O-arm system was more accurate and safer, but surgical time was longer than with C-arm fluoroscopy
Silbermann et al. 2011[6] NRS	Lumbar and sacral spines	CT scan using free-hand	O-arm system showed greater accuracy than CT scan using free-hand
Nottmeier et al. 2010[7] NRS	Upper cervical spine and occiput	C-arm	O-arm system was as safe and accurate as the C-arm method
Radiation exposure			
Nottmeier et al. 2013[8] NRS	Spinal surgery	No comparator	Minimal radiation scatter from the O-arm system; a lead shield would protect the surgeon from any radiation exposure

Table 1: Summary of Included Studies			
Author, Year Study Type	**Surgical Procedure**	**Comparator**	**Authors' Conclusions**
Abdullah et al. 2012[9] NRS	Spinal surgery	No comparator	Minimal radiation exposure for the surgical team using O-arm system
Park et al. 2012[10] NRS	Orthopedic surgery	C-arm system	O-arm delivered higher doses of radiation to the sensitive organs of the operator

NRS = non-randomized study; RCT = randomized controlled study

REFERENCES SUMMARIZED

Health Technology Assessments
No literature identified.

Systematic Reviews and Meta-analyses
No literature identified.

Randomized Controlled Trials

1. Shin MH, Hur JW, Ryu KS, Park CK. Prospective Comparison Study Between the Fluoroscopy Guided and Navigation Coupled with O-arm(R) Guided Pedicle Screw Placement in the Thoracic and Lumbosacral Spines. J Spinal Disord Tech. 2013 Apr 3. PubMed: PM23563342

Non-Randomized Studies

Effectiveness

2. Holloway K, Docef A. A quantitative assessment of the accuracy and reliability of O-arm images for deep brain stimulation surgery. Neurosurgery. 2013 Mar;72(1 Suppl Operative):47-57. PubMed: PM22986604

3. Hodges SD, Eck JC, Newton D. Analysis of CT-based navigation system for pedicle screw placement. Orthopedics. 2012 Aug 1;35(8):e1221-e1224. PubMed: PM22868609

4. Houten JK, Nasser R, Baxi N. Clinical assessment of percutaneous lumbar pedicle screw placement using the O-arm multidimensional surgical imaging system. Neurosurgery. 2012 Apr;70(4):990-5. PubMed: PM21946509

5. Shin MH, Ryu KS, Park CK. Accuracy and Safety in Pedicle Screw Placement in the Thoracic and Lumbar Spines : Comparison Study between Conventional C-Arm Fluoroscopy and Navigation Coupled with O-Arm(R) Guided Methods. J Korean Neurosurg Soc [Internet]. 2012 Sep;52(3):204-9. [cited 2013 Aug 1]. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3483320 PubMed: PM23115662

6. Silbermann J, Riese F, Allam Y, Reichert T, Koeppert H, Gutberlet M. Computer tomography assessment of pedicle screw placement in lumbar and sacral spine: comparison between free-hand and O-arm based navigation techniques. Eur Spine J [Internet]. 2011 Jun;20(6):875-81. [cited 2013 Aug 1]. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3099154 PubMed: PM21253780

7. Nottmeier EW, Young PM. Image-guided placement of occipitocervical instrumentation using a reference arc attached to the headholder. Neurosurgery. 2010 Mar;66(3 Suppl Operative):138-42.

PubMed: PM20173564

Radiation Exposure

8. Nottmeier EW, Pirris SM, Edwards S, Kimes S, Bowman C, Nelson KL. Operating room radiation exposure in cone beam computed tomography-based, image-guided spinal surgery. J Neurosurg Spine. 2013 May 31.
PubMed: PM23725398

9. Abdullah KG, Bishop FS, Lubelski D, Steinmetz MP, Benzel EC, Mroz TE. Radiation exposure to the spine surgeon in lumbar and thoracolumbar fusions with the use of an intraoperative computed tomographic 3-dimensional imaging system. Spine (Phila Pa 1976). 2012 Aug 1;37(17):E1074-E1078.
PubMed: PM22472810

10. Park MS, Lee KM, Lee B, Min E, Kim Y, Jeon S, et al. Comparison of operator radiation exposure between C-arm and O-arm fluoroscopy for orthopaedic surgery. Radiat Prot Dosimetry. 2012 Mar;148(4):431-8.
PubMed: PM21525041

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APPENDIX – FURTHER INFORMATION:

Non-Randomized Studies – non-comparative

11. Ammirati M, Salma A. Placement of thoracolumbar pedicle screws using O-arm-based navigation: technical note on controlling the operational accuracy of the navigation system. Neurosurg Rev. 2013 Jan;36(1):157-62.
PubMed: PM22956149

12. Collins KL, Patil PG. Flat-panel fluoroscopy O-arm-guided percutaneous radiofrequency cordotomy: a new technique for the treatment of unilateral cancer pain. Neurosurgery. 2013 Mar;72(1 Suppl Operative):27-34.
PubMed: PM23037818

13. Coste C, Asloum Y, Marcheix PS, Dijoux P, Charissoux JL, Mabit C. Percutaneous iliosacral screw fixation in unstable pelvic ring lesions: the interest of O-ARM CT-guided navigation. Orthop Traumatol Surg Res. 2013 Jun;99(4 Suppl):S273-S278.
PubMed: PM23639760

14. Curto DD, Kim JS, Lee SH. Minimally invasive posterior cervical microforaminotomy in the lower cervical spine and C-T junction assisted by O-arm-based navigation. Comput Aided Surg. 2013;18(3-4):76-83.
PubMed: PM23336731

15. Ray WZ, Ravindra VM, Schmidt MH, Dailey AT. Stereotactic navigation with the O-arm for placement of S-2 alar iliac screws in pelvic lumbar fixation. J Neurosurg Spine. 2013 May;18(5):490-5.
PubMed: PM23495892

16. Bohnstedt BN, Tubbs RS, Cohen-Gadol AA. The use of intraoperative navigation for percutaneous procedures at the skull base including a difficult-to-access foramen ovale. Neurosurgery. 2012 Jun;70(2 Suppl Operative):177-80.
PubMed: PM21822157

17. Costa F, Tomei M, Sassi M, Cardia A, Ortolina A, Servello D, et al. Evaluation of the rate of decompression in anterior cervical corpectomy using an intra-operative computerized tomography scan (O-Arm system). Eur Spine J [Internet]. 2012 Feb;21(2):359-63. [cited 2013 Aug 1]. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3265603
PubMed: PM21947870

18. Dahdaleh NS, Dlouhy BJ, Menezes AH. Application of neuromuscular blockade and intraoperative 3D imaging in the reduction of basilar invagination. J Neurosurg Pediatr. 2012 Feb;9(2):119-24.
PubMed: PM22295914

19. Katisko JP, Kauppinen MT, Koivukangas JP, Heikkinen ER. Stereotactic operations using the o-arm. Stereotact Funct Neurosurg. 2012;90(6):401-9.
PubMed: PM23075522

20. Larson AN, Santos ER, Polly DW, Ledonio CG, Sembrano JN, Mielke CH, et al. Pediatric pedicle screw placement using intraoperative computed tomography and 3-dimensional image-guided navigation. Spine (Phila Pa 1976). 2012 Feb 1;37(3):E188-E194. PubMed: PM21738101

21. Larson AN, Polly DW, Guidera KJ, Mielke CH, Santos ER, Ledonio CG, et al. The accuracy of navigation and 3D image-guided placement for the placement of pedicle screws in congenital spine deformity. J Pediatr Orthop. 2012 Sep;32(6):e23-e29. PubMed: PM22892631

22. Patil S, Lindley EM, Burger EL, Yoshihara H, Patel VV. Pedicle screw placement with O-arm and stealth navigation. Orthopedics. 2012 Jan;35(1):e61-e65. PubMed: PM22229616

23. Schouten R, Lee R, Boyd M, Paquette S, Dvorak M, Kwon BK, et al. Intra-operative cone-beam CT (O-arm) and stereotactic navigation in acute spinal trauma surgery. J Clin Neurosci. 2012 Aug;19(8):1137-43. PubMed: PM22721892

24. Van de Kelft E, Costa F, Van der Planken D, Schils F. A prospective multicenter registry on the accuracy of pedicle screw placement in the thoracic, lumbar, and sacral levels with the use of the O-arm imaging system and StealthStation Navigation. Spine (Phila Pa 1976). 2012 Dec 1;37(25):E1580-E1587. PubMed: PM23196967

25. Ailawadhi P, Agrawal D, Satyarthee GD, Gupta D, Sinha S, Mahapatra AK. Use of O-arm for spinal surgery in academic institution in India: experience from JPN apex trauma centre. Neurol India. 2011 Jul;59(4):590-3. PubMed: PM21891939

26. Ishikawa Y, Kanemura T, Yoshida G, Matsumoto A, Ito Z, Tauchi R, et al. Intraoperative, full-rotation, three-dimensional image (O-arm)-based navigation system for cervical pedicle screw insertion. J Neurosurg Spine. 2011 Nov;15(5):472-8. PubMed: PM21761967

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PubMed: PM21495822

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PubMed: PM20434406

32. Park P, Foley KT, Cowan JA, Marca FL. Minimally invasive pedicle screw fixation utilizing O-arm fluoroscopy with computer-assisted navigation: Feasibility, technique, and preliminary results. Surg Neurol Int [Internet]. 2010;1:44. [cited 2013 Aug 1]. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2958329
PubMed: PM20975974

Radiation Exposure – model

33. Lange J, Karellas A, Street J, Eck JC, Lapinsky A, Connolly PJ, et al. Estimating the effective radiation dose imparted to patients by intraoperative cone-beam computed tomography in thoracolumbar spinal surgery. Spine (Phila Pa 1976). 2013 Mar 1;38(5):E306-E312.
PubMed: PM23238490

Economic Studies

34. Sanborn MR, Thawani JP, Whitmore RG, Shmulevich M, Hardy B, Benedetto C, et al. Cost-effectiveness of confirmatory techniques for the placement of lumbar pedicle screws. Neurosurg Focus. 2012 Jul;33(1):E12.
PubMed: PM22746229

Review Articles

35. Full-rotation three-dimensional intraoperative imaging during spinal procedures: a summary of ECRI Institute's Emerging Technology Evidence Report [Internet]. Plymouth Meeting (PA): ECRI Institute; 2012 Feb. [cited 2013 Aug 1]. Available from: https://www.ecri.org/Documents/Reprints/Full-Rotation_Three-Dimensional_Intraoperative_Imaging_During_Spinal_Procedures(Managed_Care)_February_2012.pdf