Assessment of CAOS as a training model in spinal surgery: a randomised study

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Received: 29 September 2004 / Revised: 13 March 2006 / Accepted: 27 March 2006 / Published online: 9 May 2006
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Abstract The objectives of this study were (1) to quantify the benefit of computer assisted orthopaedic surgery (CAOS) pedicle screw insertion in a porcine cadaver model evaluated by dissection and computed tomography (CT); (2) to compare the effect on performance of four surgeons with no experience of CAOS, and varying experience of pedicle screw insertion; (3) to see if CT with extended windows was an acceptable method to evaluate the position of the pedicle screws in the porcine cadaver model, compared to dissection. This was a prospective, randomised, controlled and blinded porcine cadaver study. Twelve 6-month-old porcine (white skinned Landrace) lumbar spines were scanned pre-operatively by spiral CT, as required for the CAOS computer data set. Computer randomisation allocated the specimens to one of four surgeons, all new to CAOS but with different levels of experience in spinal surgery. The usual anatomical landmarks for the freehand technique were known to all four sur-

geons. Two pedicles at each vertebral level were randomly allocated between conventional free hand insertion and an electromagnetic image guided surgery (NAVITRAK[®]) and 6.5 mm cancellous AO screws inserted. Post-operatively, spiral CT was blindly evaluated by an independent radiologist and the spine fellow to assess the accuracy of pedicle screw placement, by each method. The inter- and intra-observer reliability of CT was evaluated compared to dissection. The pedicle screw placement was assessed as perfect if within the pedicle along its central axis, or acceptable (within < 2 mm from perfect), and measured in millimetres from perfect thereafter. One hundred and sixty-six of 168 pedicles in 12 porcine spines were operated on. Complete data were present for 163 pedicles (81 CAOS, 82 freehand). In the CAOS group 84% of screws were deemed acceptable or perfect, compared to 75.6% with the freehand technique. Screw misplacement was significantly reduced using CAOS ($P = 0.049$). Seventy-nine percent of CAOS screws were ideally placed compared with 64% with a conventional freehand technique ($P = 0.05$). A logistic linear regression model showed that the miss placed pedicle screw rate was significantly reduced using CAOS ($P = 0.047$). CAOS benefited the least experienced surgeons most (the research registrars acceptable rate increased from 70 to 90% and the spine fellow from 76 to 86%). CAOS did not have a statistically significant effect on the experienced consultant spine surgeon increasing from 70 to 79% ($P = 0.39$). The experienced general orthopaedic surgeon did not benefit from CAOS ($P = 0.5$). CT compared to dissection showed an intra-observer reliability of 99.4% and inter-observer reliability of 92.6%. The

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conclusions of this study were as follows: (1) an increased number of pedicle screws were ideally placed using the CAOS electromagnetic guidance system compared to the conventional freehand technique; (2) junior surgeons benefited most from CAOS; (3) we believe CAOS (Navitrak®) with porcine lumbar spines evaluated by post operative CT, represents a useful model for training junior surgeons in pedicle screw placement; (4) experienced spine surgeons, who have never used CAOS, may find CAOS less helpful than previously reported.

Keywords Pedicle screw insertion · Computer assisted orthopaedic surgery · Conventional fluoroscopic technique · Training model · Porcine cadaver lumbar spine study

Introduction

Computer assisted image guidance systems were developed in the 1990's which were optical/opto-electronic, infrared electromagnetic [1, 2, 5, 9, 11, 13, 14, 16, 18] or ultrasound based [11, 18]. The misplacement rate of conventionally inserted pedicle screws is high between 19 and 40%, even in experienced hands [4, 5, 9]. They reported the misplacement rate as being reduced to between 4.5 and 14% with computer assisted orthopaedic surgery (CAOS) in the lumbar spine, depending on the case mix [1, 6, 9, 11], with some series including scoliosis cases. There is great variation on the effect of CAOS in reducing the misplacement rate of conventionally inserted lumbar pedicle screws within an individuals practice from 14.3 to 4.3% [9] or from 42 to 8% [12]. CAOS has been shown in a randomised controlled trial of 100 consecutive patients to reduce the pedicle screw perforation rate from 13.4% for conventional fluoroscopy to 4.6% ($P = 0.006$) [8]. The misplacement rate has been accompanied by a reported drop in neurological complication, from 5% with conventional techniques to less than 1% with CAOS [1, 11, 18].

There is a learning curve with CAOS [18], and we wished to look at the early experience of CAOS, which has not previously been evaluated. This is the first paper to evaluate an electromagnetic guidance system (Navitrak®) with conventional freehand pedicle screw placement in an animal training model. We have evaluated the performance of our surgeons of varying seniority and spine surgical experience in this RCT.

Material and methods

Design

A prospective, randomised, controlled and blinded porcine cadaver study was undertaken in May and June 2001.

Porcine cadaver model

Yingling et al. [19] showed that the porcine cervical spine was a good anatomic model for the human lumbar spine with similar ligamentous structures, facet joint orientation, compression and shear values albeit with slightly smaller dimensions [19]. In a pilot study of ten porcine cervical spines, using 6.5 mm standard steel AO screws, on dissection we had a 60% technical failure rate due to pedicle fracture, suboptimal cancellous screw grip and/or subjective dissatisfaction from the surgeon [7]. The C7 vertebrae was too small to receive a screw at all. The bone was felt to be too hard, probably because the ratio of cortical to cancellous bone was high (2.25 cranio caudally and 1.8 from medial to lateral). Dissection of the porcine lumbar spines showed the vertebrae to be minimally larger, but relatively less cortical bone (Table 1). Consequently, for this paper, we used porcine lumbar spines because of their larger dimensions rather than cervical spines, in order to make the model as realistic as possible. We used standard steel 6.5 mm AO pedicle screws, which were inserted without complications and the surgeons' reported that the proprioception was realistic to that of a technically satisfactory inserted screws in a patients.

Specimen

Twelve frozen, six-month-old porcine (white skinned Landrace) lumbar spine cadaver specimens, with the appropriate veterinary certificates were used. The

Table 1 Pilot porcine spine dissection measurements

	Cervical (C3–7), <i>n</i> = 10		Lumbar (L1–6), <i>n</i> = 12	
	Mean	CC ratio	Mean	CC ratio
Supero-inf diameter	Mean 24.5 (1DP)	2.25	35.7 (1DP)	1.3
Lat-med AP	Mean 29.2 Mean 22.1	1.8	32.2 26.0	1.4

CC cortical cancellous

hospital microbiology and health and safety departments gave their approval under the standard Trust protocol. The number of pedicles chosen was based on a 10% difference between the two surgical techniques. The average length of the lumbar spine specimen was 25 cm (range 21–27 cm) from pigs weighing 68 kg (range 65–75 kg), using seven lumbar vertebrae per specimen. Each spine was frozen, stored in a commercially available freezer bag, then defrosted prior to surgery. (In the pilot we found that freezing the specimens had no effect on the spines).

Radiographic details

The spines were individually placed in a specially produced carbon fibre mould in a supine position and CT scanned on a Toshiba Xpress GX spiral CT scanner (Toshiba Medical Systems, Manor Court, Manor Royal, Crawley, West Sussex, RH10 2PY).

The CT gantry was perpendicular, with spiral 1 mm slice acquisitions, 1 mm increments and a pitch of 2.5 mm, using a bone filter (FC 01). The reconstruction was continuous and non-overlapping with slices at 1 mm, in accordance with the data set required by the CAOS system (Navitrak®) (Centrepulse Orthopaedics Medica, Basel, Switzerland subsequently taken over by Zimmer). The specimen was scanned from the top of the L1 to the bottom of the L7 vertebra. The data was stored in an uncompressed mode in 1 mm slices on a magneto optical disc. The data were used for 3D reconstruction of the lumbar spine with the software provided with the Navitrak® system.

Surgeons

None of the four surgeons had ever used CAOS before, and they had varying orthopaedic and spine surgical experience:

Experienced consultant spine surgeon (over 30 years) (JD)
 Experienced general orthopaedic consultant (CWJ)
 Spine fellow (VJ)
 Research registrar with no spinal experience (ICK)

Specimen randomisation and allocation

The porcine spines were randomly computer allocated to one of four surgeons. Each surgeon was allocated three porcine spines, and all seven lumbar vertebrae of each porcine spine were used. At every level, each pedicle was randomly allocated to either conventional

freehand surgery or computer assisted surgery starting from the left.

Table and moulds

The pedicle screw insertion was undertaken on a non-ferrous table to avoid disrupting the electromagnetic field, placed prone in a carbon fibre mould, and secured to the tabletop with a titanium screw.

Surgical procedure

Soft tissue clearance and anatomical demonstration of the facet joints was followed by calibration of the CAOS (Navitrak®) system's bone awl and screwdriver, by identifying five bony landmarks on the vertebra to register the data in the Navitrak® computer. For each vertebral level the reference clamp was applied to the spinous process.

Computer assisted orthopaedic surgical technique/image guidance

Axial, sagittal and coronal slices and a 3D reconstruction of the vertebra being operated on were displayed on the Navitrak® monitor with the bone awl superimposed as it made the track. The bone awl was driven into the pedicle while checking its position and alignment against the virtual image in three planes. Any realignment could be made in the pedicle track as required. The track was subsequently probed for integrity, the depth measured and the appropriate length pedicle screw inserted along the track, using standard stainless steel cancellous AO screw of 6.5 mm diameter.

Conventional freehand technique

The relevant superior facet joint was decorticated using a bone nibbler. The pedicle was then entered freehand with a bone awl. The track was assessed for integrity and depth using a depth gauge, and a screw of appropriate length was inserted. The position of the pedicle screws was checked at the end and redirected if required, as per the routine practice of the senior spine surgeon.

Outcome measures

To assess the accuracy of pedicle screw placement fluoroscopy, computerised tomography (CT) and dissection was carried out. The CT evaluation was carried out by an independent and blinded radiologist (PJR)

and research registrar (ICK) on two separate occasions, one week apart for inter- and intra-observer reliability. The post operative CT used: 120 mA and 50 kV scanning in seven spiral blocks through the porcine pedicles (1 mm slice thickness, pitch and increment, viewed on extreme bone windows (WW 4000, WL 1500), to minimise the metal artefact [10]. The screw position was assessed and classified as in previous studies [1, 9]. Any breach of the medial, lateral, superior or inferior cortex was recorded and measured in millimetres on CT and at dissection. Pedicle screws were ideally placed within the centre of the pedicle. A cortex perforation of less than 2 mm was regarded as acceptable [3, 9] as this appears to be clinically irrelevant, but more than 2 mm as regarded as unacceptable [17]. Two observers (ICK, AR) independently, and blinded to the imaging CT evaluations, removed the screws and replaced them with wooden dowels before the specimens were cut into sections with a band saw and dissected. The data was analysed using SPSS.

Results

Specimens and surgical procedure

Of the 168 pedicles, 166 received a pedicle screw, two placements were abandoned because of pedicle fractures and screw instability, one in each group. There was incomplete data in three screws leaving 163 screws with complete data (81 CAOS, 82 freehand). Of the 81 screws placed with the CAOS system, 79% were placed ideally, compared to 64% with the conventional technique. The difference of 15% was in favour of CAOS and is almost statistically significant ($P = 0.05$). Eighty-four percent of CAOS versus 75.6% of freehand screws were acceptably placed (ideal/or < 2 mm) ($P = 0.049$).

The most often inserted screw size was 25 mm long (Table 2). There was no formal significant difference

between the distribution of screw size ($\chi^2 = 3.83$, $df = 1$, $P > 0.05$) in the two groups, but the data suggest that longer screws were more infrequent in CAOS. A linear logistic regression model showed that the misplacement distance was significantly reduced using computer assisted surgery ($P = 0.047$).

Surgeons

Apart from the consultant general orthopaedic surgeon, each individual surgeon achieved better accuracy when using the CAOS system (Table 3). The CAOS appeared to benefit the orthopaedic research registrar, who had no previous spine experience (ICK), the most ($P = 0.11$ Fisher's Exact Test). The spine fellow (VJ) improved his accuracy from 76 to 86% with CAOS ($P = 0.34$). The consultant spine surgeon with over 30 years of experience (JD) improved his accuracy from 70 to 79% ($P = 0.39$) by using CAOS and reported that he did not always trust the CAOS. The experienced consultant general orthopaedic surgeon with no spine experience was more accurate free hand than with CAOS (86 and 81% respectively $P = 0.5$).

CT evaluation

Compared to dissection the intra-observer reliability was 99.4% and inter-observer reliability 92.6% for CT of steel screws, using extended windows. Two people independently (PJR, ICK) evaluated the fluoroscopy and showed a very high discordance (42.5 and 53.1% respectively) when compared with dissection and when compared with CT (41.4 and 52.1%).

Discussion

This study is the first prospective, randomised, controlled blinded study measuring the accuracy of the initial computer assisted surgical techniques for pedicle screw insertion for different grades of surgeon, all of whom were novices to computer assisted surgery in a training model.

The rotational and translational accuracies for image guided pedicle screw placement have been mathematically analysed on an idealised path along the central axis of the pedicle [15], however, no published clinical study yet reaches the standards set by Rampersaud [15]. For each pedicle, the margin of error is dependent on the size of the pedicle and screw, and the distance from the screw entrance point to the narrowest portion of the pedicle [18]. One in vivo randomised

Table 2 Pedicle screw size used in lumbar spine

Screw size (mm)	Conventional technique		CAOS		Total	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
25	42	51.8	48	59.3	90	55.6
30	22	27.2	25	30.9	47	29.0
35	17	21.0	8	9.8	25	15.4
Total	81	100	81	100	162	100

Table 3 Results AT the < 2 mm deviation that is an acceptable screw placement criteria

Surgeon	Surgery			
	Conventional (%)	CAOS (%)	Total	P
Experienced spine surgeon: unacceptable < 2 mm	6 14 (70%)	4 15 (79%)	10 <u>29</u> 39	0.39
General orthopaedic surgeon: unacceptable < 2 mm	3 18 (86%)	4 17 (81%)	7 <u>35</u> 42	0.5
Orthopaedic research registrar: unacceptable < 2 mm	6 14 (70%)	2 18 (90%)	8 <u>32</u> 40	0.011
Spine fellow: unacceptable < 2 mm	5 16 (76%)	3 18 (86%)	8 <u>34</u> 42	0.034
Total	82	81	163	

misled controlled trial reported pedicle perforation of more than 4 mm to be relevant [8], but most papers take less than 2 mm as the acceptable deviation [1, 9] for minimal clinical side effects [17].

This research team has developed an acceptable, realistic, cheap lumbar porcine cadaver training model for pedicle screw insertion. The model uses standard 6.5 mm AO stainless steel cancellous screws which can acceptably be evaluated using CT with extended windows to reduce the metal artefact, obviating the need, cost or time for dissection. The mean human pedicle isthmus width varies from 18 mm (L5) down to 8.7 mm (L1) [21], so 6.5 mm screws would fit humans and porcine lumbar vertebra, which were slightly larger than the cervical ones.

The animal model has the advantage in that it is inexpensive and readily available, compared to the scarcity of healthy cadaveric human lumbar spines. Pigs are also not believed to be effected by spongiform encephalopathy like sheep and cattle, and specimens can be kept frozen for convenience. We used standard stainless steel AO screws, as this was the routine of the senior spine surgeon, for financial and pragmatic reasons, although the manufacturer recommends the use of titanium screws. Our dissection showed no problems secondary to the electromagnetic devices, as the track was made with the bone awl, and the standard stainless steel screws followed the track without complications. In addition, our results are similar to those reported in the literature [6, 9, 15]. A human lumbar cadaver study showed that cobalt and even titanium screws may not always be accurately assessed by CT [20]. We therefore feel that we can support the use of stainless steel screws in this model.

Our findings confirm those of previous studies in reporting that computer assisted surgery increases the accuracy of pedicle screw placement [5, 9, 15], even

when used by surgeons new to CAOS, as in our study. The misplacement rate for the conventional technique confirms the high misplacement rates published previously [5, 9, 15]. Although this was a small study, we demonstrated that the trend in performance of surgical trainees in vitro was improved by computer assisted surgery, even after only twenty screws inserted. This initial experience appears best obtained on this pig spine training model rather than on patients. Computer assisted surgery involves a learning curve even for experienced surgeons and this model allows familiarisation with the technique in a low pressure environment. Despite the learning curve and small sample size, the accuracy results were overall significantly better in the Navitrak[®] group indicating a benefit over the conventional technique, especially during training of junior surgeons. The addition of CAOS to practising freehand techniques in a laboratory setting seems to improve safe pedicle screw placement, as shown in this study. The simulated 3D track provided by this particular guidance system can help in providing the trainee with the visuo-spatial skills required. For experienced spine surgeons CAOS may not be as helpful as previously reported. Ten years post implementation of CAOS, experienced surgeons do well with or without CAOS, (Key lecture, International Society for CAOS, Santa Fe, New Mexico, June 2002).

The involvement of four surgeons new to CAOS with differing surgical and spinal experience was a pragmatic and novel approach. However, in one respect the design was limited, in that there was only one surgeon in each training category. A maximum of 42 pedicle screws were inserted (per surgeon, half for each technique) and the results may have been more clear-cut had a larger study been conducted. In some respects these were ideal conditions: young normal spines, with no breathing artefacts on the CT

scans and no metal disturbing the electromagnetic field.

Conclusion

1. Porcine cervical spines did not prove to be a satisfactory model for pedicle screw placement.
2. The lumbar porcine cadaver model for training in pedicle screw placement is inexpensive, effective and is readily evaluated by CT with extended windows, unlike fluoroscopy.
3. Computer assisted surgery decreases the misplacement rate of pedicle screws of junior surgeons and can supplement early surgical experience. The benefit of CAOS to experienced spine surgeons may not be as great as previously reported and appears to have its own learning curve.
4. We support the use of CAOS as a training model for pedicle screw placement in spinal surgery.

Acknowledgements The impartial, unconditional free loan of the NAVITRAK[®] system and funding of the CT scans supported by Centrepulse formerly, Sulzer Medica LTD who had no input into the paper and have not seen this or any other results or documents relating to the research. The authors have no commercial relationship with the manufacturers. The authors wish to acknowledge the enthusiastic Radiography team led by Kay Jones.

References

1. Amiot L, Labelle H, De Guise JA, Sati M, Brodeur P, Rivard CH (1995) Computer assisted pedicle screw fixation: a feasibility study. *Spine* 20(10):1208–1212
2. Amiot LP, Lang K, Putzier M, Zippel H, Labelle H (2000) Comparative Results Between conventional and computer-assisted pedicle screw installation in the thoracic, lumbar, and sacral spine. *Spine* 25(5):606–614
3. Carl AL, Khanuja HS, Sachs BL, Gatto CA, vomLehn J, Vosburgh K, Schenck J, Lorensen W, Rohling K, Disler D (1997) In vitro simulation: Early results of stereotaxy for pedicle screw placement. *Spine* 22(10):1160–1164
4. Castro WH, Halm H, Jerosch J, Malms J, Steinbeck J, Blasius S (1996) Accuracy of pedicle screw placement in lumbar vertebrae. *Spine* 21(11):1320–1324
5. Gertzbein SD, Robbins SE (1990) Accuracy of pedicular screw placement in vivo. *Spine* 15:11–14
6. Kalfas IH, Kormos DW, Murphy MA, McKenzie RL, Barnett GH, Bell GR, Steiner CP, Trimbel MB, Weisenberger JP (1995) Application of frameless stereotaxy to pedicle screw fixation of the spine. *J Neurosurg* 4:641–647
7. Kurta I, Dove M, Richards P, Rahmatalla A, MacKenzie, Dove J (2002) Accuracy of pedicle screw placement: a prospective randomised laboratory study using porcine cervical spines. *J Bone Joint Surg [Br]* 84-B:96
8. Laine T, Lund T, Ylikoski M, Lohikoski J, Schlenzka D (2000) Accuracy of pedicle screw insertion with and without computer assistance: a randomised controlled clinical study in 100 consecutive patients. *Eur Spine J* 9:235–240
9. Laine T, Schlenzka D, Maekitalo K, tallroth K, Nolte LP, Visarius H (1997) Improved accuracy of pedicle screw insertion with computer assisted surgery—a prospective clinical trial of 30 patients. *Spine* 22(11):1254–1258
10. Link TM, Berning W, Scherf S, Joosten U, Joist A, Ebgele K, Daldrop-Link HE (2000) CT of metal implants: reduction of artifacts using an extended CT scale technique. *J Comput Assist Tomogr* 24(1):165–172
11. Merloz P, Tonetti J, Eid A, Faure C, Lavalley S, Troccaz J, Sautot P, Hamadeh A, Cinquin P (1997) Computer assisted spine surgery. *Clin Orthop* 337:86–96
12. Merloz P, Tonetti J, Pittet L, Coulomb M, Lavalley S, Sautot P (1998) Pedicle screw placement using image guided techniques. *Clin Orthop Relat Res* 354:39–48
13. Nolte LP, Slomezyckowski MA, Berlemann U, Strauss MJ, Hofstetter R, Schlenzka D, Laine T, Lund T (2000) A new approach to computer-aided spine surgery: fluoroscopy-based surgical navigation. *Eur Spine J* 9(1):S78–S88
14. Nolte L, Zamorano L, Arm E, Visarius H, Jiang Z, Berleman U, Schwarzenbach O (1996) Image-guided computer-assisted spine surgery: a pilot study on pedicle screw fixation. *Stereotact Funct Neurosurg* 66:108–117
15. Rampersaud YR, Simon D, Foley K (2001) Accuracy requirements for image-guided spinal pedicle screw placement. *Spine* 6(4):352–359
16. Schlenzka D, Laine T, Lund T (2000) Computer assisted spine surgery. *Eur Spine J* 9(1):S057–S064
17. Schulze CJ, Munzinger E, Weber U (1998) Clinical relevance of accuracy of pedicle screw placement—a computed tomographic-supported analysis. *Spine* 23(20):2215–2221
18. Schwarzenbach O, Berleman U, Jost B, Visarius H, Arm E, Langlotz F, Nolte LP, Ozdoba C (1997) Accuracy of computer-assisted pedicle screw placement: An in vivo computed tomography analysis. *Spine* 22(4):452–458
19. Yingling VR, Callaghan JP, McGill SM (1999) The porcine cervical spine as a model of the human lumbar spine: an anatomical, geometric and functional comparison. *J Spinal Disord* 12(5):415–423
20. Yoo JU, Ghanayem A, Petersilge C et al (1997) Accuracy of using computed tomography to identify pedicle screw placement in cadaveric human lumbar spine. *Spine* 22(22):2668–2671
21. Zindrick MR, Wiltse LL, Widell EH et al (1998) A biomechanical study of intrapeduncular screw fixation in the lumbosacral spine. *Clin Orthop Relat Res* 203:99–112