A meta-synthesis and meta-analysis of the functional outcome of computer assisted pedicle screw placement

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Objective
A meta-synthesis and meta-analysis of the published literature was conducted to look at the functional results after computer assisted pedicle screw placement.

Methods
A 'Dialog Datastar' search was used covering the period from 1950 to February 2008. Although 71 papers proved to be potentially eligible, only 23 met all the criteria for inclusion.

Results
We report on a total of 1288 patients with 5992 pedicle screws. The comparison of neurological complications in two groups demonstrated an odds ratio of 0.25 with a 95% CI of 0.06 to 1.14 in favour of using navigation for pedicle screw insertion (p=0.07). Comparative trials demonstrated a significant advantage in terms of accuracy of navigation over non-navigational pedicle screw insertion (p<0.00001).

Conclusion
Navigation does reduce neurological complications and provides increased accuracy for pedicle screw placement but there was insufficient data in the literature to infer a conclusion in terms of fusion rate, pain relief and health outcome scores.

Introduction

The reported pedicle screw misplacement in historical spinal literature can be as high as 20 to 39.8 % (1–3) although only a small number lead to complications (neurological, vascular or visceral injuries).

Computer assisted navigation allows for simultaneous and multi-planar visualization of spinal anatomy which helps in virtually tracking surgical instruments in relation to spinal anatomy in real time (4). This has led to its utilisation in pedicle screw placement thus increasing the accuracy of screw positioning in cadavers and patients (5–9).

The question then becomes does this increased accuracy in screw placement lead to a statistically significant decrease in the complication rates due to misplacement of pedicle screws and/or an increased

functional outcome as measured by: neurological complications, fusion rates, pain relief and health outcome scores like the Oswestry disability index, SF-36/12 in order to justify the costs incurred in the introduction of such technology?

The answers to the above questions are provided by this paper which undertakes a systematic review of the published literature (meta-synthesis) and a meta-analysis.

Materials and methods

All meta-synthesis and meta-analysis studies must define: the method by which the pertinent literature is identified, the criteria by which studies are included/excluded, the data collected and statistical methodology applied.

Literature identification and inclusion/exclusion criteria

The abstracts and titles of all the articles in: MEDLINE (1950 to February 2008), EMBASE (1974 to February 2008) and CINAHL (1982 to February 2008) were searched via 'Dialog Datastar' with the following key words: pedicle screw 'OR' navigation. Thesaurus mapping was then used to explode this search with "spine" and combining these searches with the Boolean linkage terms AND to identify relevant publications.

The complete articles identified by the above search methodology were retrieved and assessed against the inclusion/exclusion criteria outlined in table one. Additionally, the references in these publications were searched for other relevant articles.

Data collection

The data collected from the qualifying articles was: indication for surgery, number of patients, vertebral level(s) instrumented, number of pedicle screws, neurological loss and patient based outcome measures (fusion rates, Oswestry disability index, SF-36, SF-12, and pain scores) where available.

Statistical methodology

Two methodologies were required: one for randomised and case controlled studies and the other for case series.

Randomised and case controlled studies

Relevant odds ratio and relative risk along with 95% confidence intervals (CI) were undertaken and when appropriate, a meta-analysis was done as well as a summary statistics based on random effects model in RevMan 4.2 (10). Additionally, the data was also analysed for heterogeneity using I2 statistics.

Case series

The case series data was pooled using an inverse variance method weighted for the size of the study. This pooled data was analysed by random effects model and heterogeneity was assessed using I2 statistics.

Results

The electronic search methodology identified 67 possibly relevant publications while the hand search of the references of these 67 articles identified a further four articles resulting in 71 papers being reviewed. At review, 48 papers were excluded as they did not meet the inclusion criteria (Table 1). Thus 23 publications (5,6,8,9,11–29) were analyzed in this paper (Table 2 – 2 randomised controlled trials, 12 case control studies and 9 case series).

These 23 studies in essence include: 719 patients (3555 pedicle screws inserted with the help of navigation techniques) with an age range of 13 to 61.2 years and 569 patients (2437 pedicle screws inserted without the help of navigation techniques) with an age range of 15.4 to 60.2.

In order to answer the question posed in the introduction we present the results in several sections: neurological complications; fusion rate; pain relief and health outcome scores; accuracy of screw placement.

Table 1: Inclusion and Exclusion criteria

Inclusion Criteria	**Exclusion criteria**
Randomised control trials (RCT)	Case reports
Case control studies	Cadaver or model studies
Case series using navigation	Abstracts/presentations/ no articles
English language	Posters with no articles
German language	All languages other than English/German

Table 2: Publications analysed (5,6,8,9,11–29).

Author/year of publication	Type of study	Anatomic area	Number of pedicle screws	
			Cases	Controls
Rajasekaran 2007	RCT	Thoracic	242	236
Laine 2000	RCT	Thoraco-sacral	277	219
Kotani 2007	Case control	Thoraco-lumabr	57	81
Gabriel 2007	Case control	Cervico-thoracic junction	86	108
Merloz 2007	Case control	Thoraco-lumbar	140	138
Ito 2007	Case control	Cervical	25	27
Seller 2005	Case control	Thoraco-lumbar	36	24
Richter 2005	Case control	Cervical	167	93
Schnake 2004	Case control	Thoracic	211	113
Kotani 2003	Case control	Cervical	78	669
Arand 2001	Case control	Thoraco-lumbar	72	86
Amiot 2000	Case control	Thoraco-lumbar	244	544
Merloz 1998	Case control	Thoraco-lumbar	64	64
Laine 1997	Case control	Lumbo-sacral	139	35
Seichi 2005	Case series	Cervical	47	n/a
Rampersaud 2005	Case series	Thoraco-lumbar-Sacral 1	360	n/a
Bostelmann 2004	Case series	Thoraco-lumbar	348	n/a
Richter 2004	Case series	Cervico-thoracic	41	n/a
Youkilis 2001	Case series	Thoracic	224	n/a
Kamimura 2000	Case series	Cervical	36	n/a
Girardi 1999	Case series	Lumbar	330	n/a
Kamimura 1999	Case series	Thoraco-lumbar	169	n/a
Schwarzenbach 1997	Case series	Lumbar	162	n/a

Neurological complication

All of the analysed studies reported about presence or absence of neurological complications as a result of pedicle screw insertion. Navigational techniques were used to insert pedicle screws in 327 patients (9 case series) and 392 patients (2 RCTs and 12 case control studies). There were no reported cases of neurological complications in navigational group in either series. On the other hand conventional pedicle screws were inserted in 569 patients (2 RCTs, 12 case control studies) leading to 13 cases of neurological complications (2.3 %). The meta-analysis undertaken (figure 1) demonstrated an odds ratio of 0.25 with a 95% CI of 0.06 to 1.14 in favour of using navigation for pedicle screw insertion, however this result was not statistically significant (p=0.07).

It should be noted that Kotani et al (2007), reported a girl in the non-navigational group, developing a neurological loss after 4 years (28). She was included in the analysis as the cause was found to be screw perforation and symptoms resolved with screw removal. However, Seichi et al, (2005) reported a case of neurological loss (cervical myelopathy) which was due to tumour re-growth thus this was not included in the analysis (15).

Fusion rate

Six studies (11,12,18,23,25,29) reported follow-up period ranging from 15 to 34 months, while one study followed the patients to clinical and radiological bony fusion (15), but none reported on rate of fusion achieved.

Pain relief and health outcome scores

Amiot et al reported that two of their patients in the navigation group had dysesthesia in the post-operative period but a conservative approach was followed with symptom resolution at 6 months. While, Ito et al reported that the Ranawat's pain score in their ten rheumatoid arthritis patients improved from 1.4 to 1 in the navigation group and from1.6 to 1.2 in non-navigational group.

No study gave the health outcome scores like the Oswestry disability index or SF-36/12 scores.

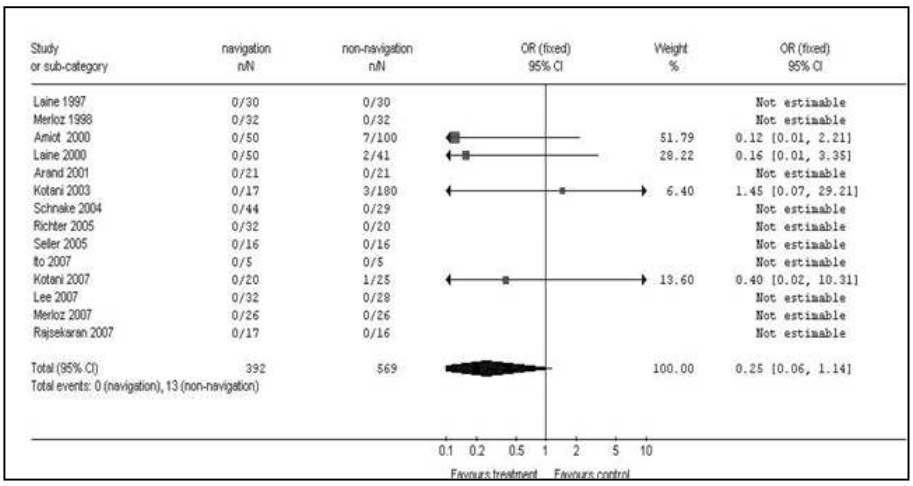

Figure 1: Meta-analysis of neurological complications in comparative trials

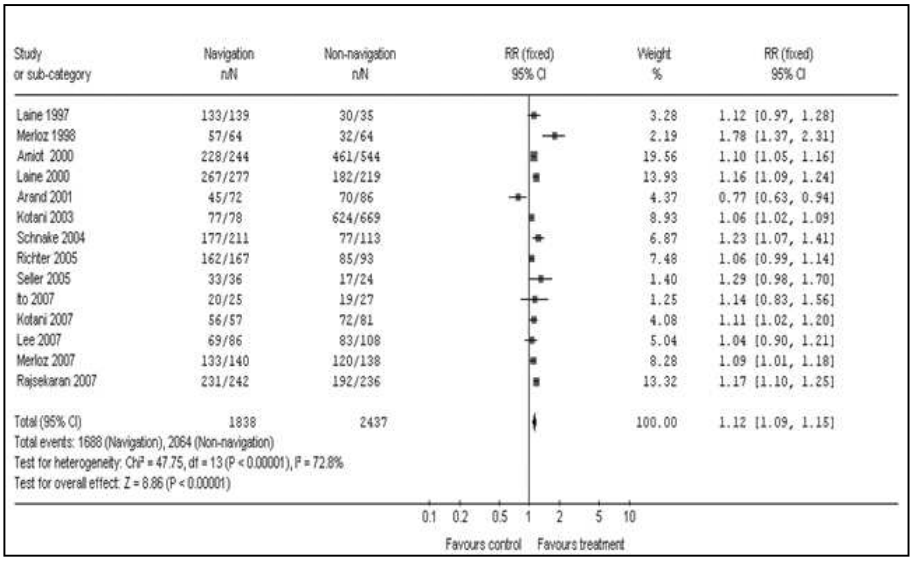

Figure 2: Meta-analysis of accurate placement of pedicle screws in comparative trials

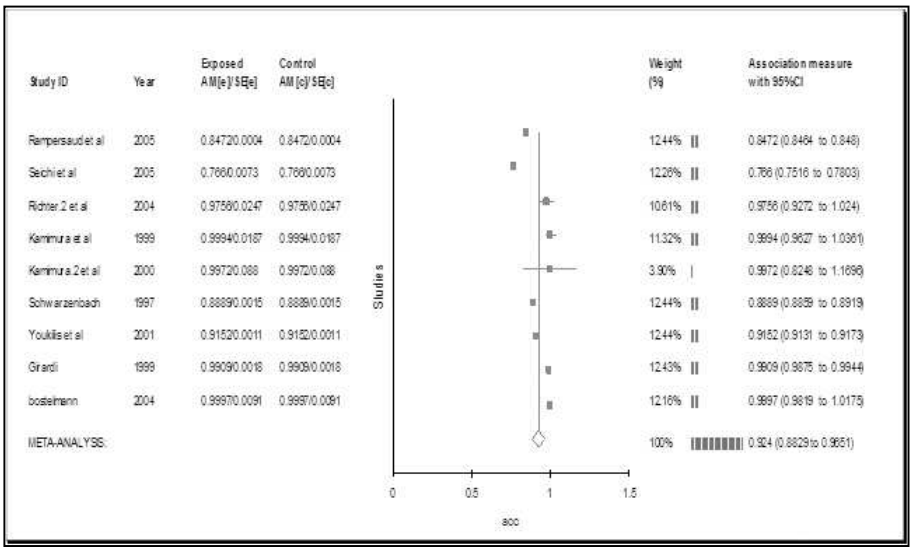

Figure 3: Meta-analysis showing pooled data from the case series using navigational techniques

Accuracy

All 23 studies (n = 5992 screws) provided accuracy data. Amiot et al and Seller et al used magnetic resonance imaging (MRI) for grading post-operative accuracy while other authors used computerised tomography techniques (CT scan) (5,6,8,9,11–29)

93.3 % (n/N=3316/3555) of the pedicle screws were inserted accurately with navigational techniques, whereas 84.7 % (n/N=2064/2437) were inserted accurately with non-navigational techniques. However, only fourteen studies – 2 RCT and 12 case control studies (1838 pedicle screws) from the navigation group (52 %) and 2437 (100 %) from the non navigational group were used for the meta-analysis, which demonstrated a significant advantage ($p<0.00001$) of navigation over non-navigation (conventional) pedicle screw insertion with a relative risk of 1.12, with a 95% CI of 1.09 to 1.15 (Fig. 2). Moreover, pooled data from the nine case series (1717 screws – 48 %) that used navigational techniques also showed accurate placement of pedicle screws (risk ratio was 0.92, with 95% CI of 0.88 to 0.96)(Fig. 3).

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Discussion and conclusion

This meta-analysis of 5992 pedicle screw placement in 1288 patients demonstrated that there is no statistical advantage to the use of navigation for pedicle screw insertion in terms of neurological loss. Further, there was insufficient data in the literature to infer a conclusion from, in so far as: fusion rate; pain relief and health outcome scores. In other words the significant increased positional accuracy achieved by navigation does not automatically impart an improved outcome as has been proposed by the premises on which the technology was developed. This is probably due to the tolerances available in the implant positioning (30). However, it is useful to remember that 'absence of evidence is not evidence of absence' (31) and hence there is a need for large multi-centre protocol driven prospective randomised trials on functional outcomes of computer assisted pedicle screw insertion.

The above conclusions must be interpreted with some caution as there were only two prospective randomised controlled trials (strongest source of evidence), the rest of the data was from controlled trials, some of which were retrospective thus suffering from possible inherent biases and confounding factors which is unavoidable given the complex nature of pedicle screw insertion.

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