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Australia and New Zealand Horizon Scanning Network

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AND THE GOVERNMENT OF NEW ZEALAND

Horizon scanning technology Prioritising summary

SpineAssist® miniature robotic positioning device



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**Australian
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and Efficacy
Register
of New
Interventional
Procedures -
Surgical**

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PRIORITISING SUMMARY

REGISTER ID S000123

NAME OF TECHNOLOGY SPINEASSIST® MINIATURE ROBOTIC POSITIONING DEVICE

PURPOSE AND TARGET GROUP TO ASSIST SURGEONS IN ACCURATELY PLACING TOOLS AND IMPLANTS DURING SPINAL SURGERY (NAMELY SPINAL FUSION) TO TREAT PATIENTS WITH VARIOUS PAINFUL SPINAL CONDITIONS

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|---|-------------|----|
| <input type="checkbox"/> Yes | ARTG number | NA |
| <input checked="" type="checkbox"/> No | | |
| <input type="checkbox"/> Not applicable | | |

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials underway or completed	Limited use	Widely diffused
Germany		✓	
Israel		✓	
Russia		✓	
Switzerland		✓	
United States		✓	

IMPACT SUMMARY

The SpineAssist® miniature positioning device enables precise and accurate placement of tools and implants during a variety of open or minimally invasive spinal procedures, particularly spinal fusion. SpineAssist is a semi-active robotic system that is employed by a surgeon to perform a surgical procedure, compared with a fully automatic robotic system that performs the procedure autonomously.

BACKGROUND

Painful spinal conditions are common in industrialised countries and may occur as a result of tumour, trauma, infection, instability and deformity (Ledet et al 2006, Sukovich et al 2006). The underlying disorder is often difficult to treat, but symptom control is approached via conservative treatments such as reduced activity, analgesics and rehabilitation programs (Ledet et al 2006).

Patients who have failed conservative treatment, particularly those with degenerative disease, may be candidates for surgical interventions including spinal fusion (Sukovich et al 2006). Spinal fusion involves the surgical connection of two or more adjacent vertebrae by inserting metal screws into the pedicle (Figure 1) to immobilise one or more motion segments of the spine. Accompanying bone grafts assist the vertebrae to fuse into a solid mass. The goal is to relieve pain, correct deformity and improve stability. Traditional spinal fusion techniques include anterior lumbar interbody fusion (ALIF), posterior or posterolateral lumbar fusion (PLF), posterior lumbar interbody fusion (PLIF), and transforaminal lumbar interbody fusion (TLIF) (Sukovich et al 2006).

Regardless of the fusion technique employed, accurate positioning of pedicle screws is of utmost importance, given the proximity of the spinal cord to its branching nerve roots and major blood vessels such as the aorta and vena cava (Shoham et al 2007). Also, proper stabilisation of the area is required until bone fusion is achieved.

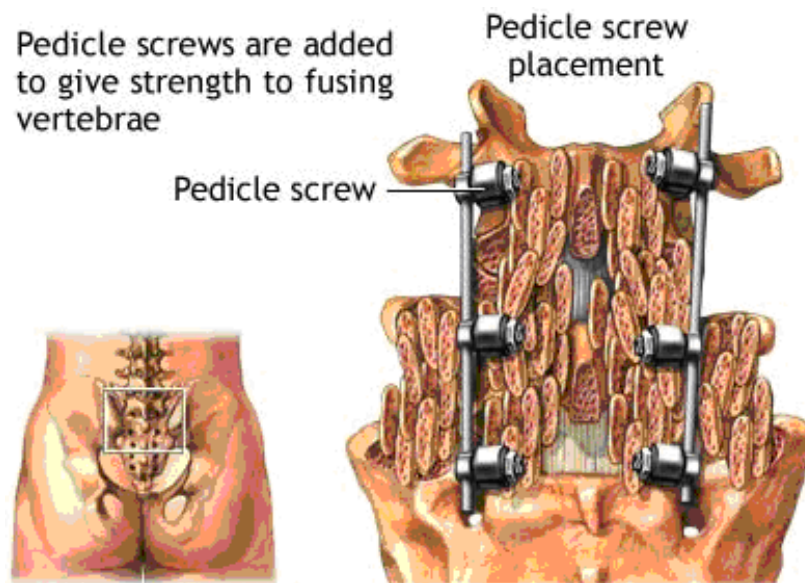


Figure 1: Illustration of the use of pedicle screws in spinal fusion (Source: "Spinal Fusion Image" 16 May 2007. HowStuffWorks.com. <<http://healthguide.howstuffworks.com/spinal-fusion-picture-a.htm>> 01 November 2010.)

Computer-assisted surgery and robotic-assisted surgery were introduced to the clinical arena in the 1990s. Surgical robots offer particular advantages when maximal accuracy is required (Shoham et al 2007). The disadvantages of surgical robots, and perhaps the reason for their slow adoption rate by most surgical disciplines, include their complexity (principally in regards to surgical technique), the large size of the devices, and the need to immobilise the patient when using active or semi-active robots.

SmartAssist® (Mazor Surgical Technologies, Caesarea, Israel) or SpineAssist® (the spinal application of SmartAssist) is the miniature robot (2.5 inches and 250 grams; size of a soft-drink can) designed to overcome these surgical robot limitations, as it is mounted directly on the patient's bony anatomy and moves in unison with the body (Shoham et al 2007). In spinal fusion procedures specifically, SpineAssist is attached to the vertebra using a specially designed disposable bone attachment component (i.e. a clamp and bridge or Hover-T frame) so that the spine and the robot become a unified rigid body, overcoming patient breathing and movement and allowing for accurate insertion of pedicle screws (Shoham et al 2007).



Figure 2: The SpineAssist miniature robot with attached surgical instrument or tool guide.
(Source: Sukovich et al 2006)

SpineAssist is a semi-active robotic system that is employed by a surgeon to perform a surgical procedure, compared to a fully automatic robotic system that performs the procedure autonomously. The device is comprised of two units: a miniature parallel robot (Figure 2) with the ability to move its end-effector with six degrees of freedom and a workstation that runs geographic user interface software and performs preoperative planning, image acquisition and registration, kinematic calculations and real-time control of the robot's motion (Shoham et al 2007).

Preoperative planning is undertaken by the operating surgeon and involves choosing the implants to be used in the procedure and planning their desired entry point and trajectory for each vertebra. The coordinates of the desired screw insertion axis are translated to the desired motion of each of the robot's six actuators (Shoham et al 2007). The surgeon then inserts a guide wire or operates surgical tools through a cannulated guide attached to the robot's moving top platform (Shoham et al 2007).

CLINICAL NEED AND BURDEN OF DISEASE

Back pain and disc disorders were the third most commonly reported long-term pain- and illness-causing conditions in Australia in 2001 with a total of nearly 4 million people affected; these disorders comprised 21% of all long-term conditions (Australian Institute of Health and Welfare 2004). According to the Institute (2003), the overall incidence of back pain (including long-term incidence) was about 9 million people, 58% being female. The peak age group was 25-64 year olds for both sexes.

The clinical need for accurate spinal fusion technology can be attributed to the rate and consequence of misplacement of pedicle screws, which ranges from 0% to 25% in patients with scoliosis and is approximately 4% in patients with degenerative diseases (Pechlivanis et al 2009). Misplacement of pedicle screws may lead to continued pain and/or permanent neurologic injury.

DIFFUSION

Between April and October 2006, the SpineAssist device was used for 65 patients in the United States, Germany and Israel (Shoham et al 2007). A recent publication revealed that the SpineAssist device has now been employed in more than 1,400 cases and for 6,000 implants and that the system is in daily use in hospitals in Switzerland and Russia, in addition to hospitals in the United States, Germany and Israel (Koren 2010).

SpineAssist obtained US Food and Drug Administration (FDA) approval on 27 August 2007 for use in precise positioning of surgical instruments or implants during thoracic and lumbar spinal surgery, in either open or percutaneous procedures (FDA 2007).

COMPARATORS

The main comparator for spinal fusion using the SpineAssist device is conventional spinal fusion using freehand techniques.

SAFETY AND EFFECTIVENESS ISSUES

Three case series studies utilising SpineAssist for spinal fusion procedures were identified (Pechlivanis et al 2009; Sukovich et al 2006; Barzilay et al 2006).

Study profiles

Authors	Country	Study period	n=	Patient mean age (yrs)
Pechlivanis et al (2009)	Germany	9/06 to 11/07	31	53 (SD 13)
Sukovich et al (2006)	United States	08/05 to 01/06	14	46
Barzilay et al (2006)	Israel	03/05 to 11/05	15	50 (for group with difficulties)

In the study by Pechlivanis et al (2009), 31 consecutive patients underwent percutaneous (minimally invasive) PLIF of the lumbar spine using the SpineAssist device. (The lumbar spine was chosen for safety reasons as the pedicles are larger than those of the thoracic or cervical spine.) Preoperative planning was carried out via computed tomography (CT) scans obtained and transferred to the SpineAssist workstation. The device was mounted onto the clamp intraoperatively and the system moved the device to facilitate accurate placement of pedicle screws. Postoperative CT determined the accuracy of screw placement: screws were measured as either perfectly within the pedicle (Group A); deviating <2 mm (Group B); deviating from 2 mm to <4 mm (Group C); deviating from 4 mm to <6 mm (Group D); or deviating >6 mm (Group E).

Sukovich et al (2006) reviewed 14 patients who underwent spinal fusion with the support of the SpineAssist system: 12 were percutaneous and two were open. The location of the fusion was the sacral spine in nine patients, lumbar spine in 14 and thoracic spine in one patient. Eight were single-level cases, four were two-level, one was five-level and one was a 14-level revision. Fully successful procedures were defined as a complete SpineAssist procedure when the system accurately pointed to the desired entry point and trajectory for all pedicles to be instrumented allowing drilling, preparing and instrumentation according to the preoperative plan. Partial success was defined as a case in which the SpineAssist robotic procedure could not be completed for one or more pedicles.

Finally, Barzilay et al (2006) reported outcomes in 15 patients who underwent spinal fusion procedures using the SpineAssist system at two medical centres in Israel. Postoperative CT confirmed the accuracy of the fusion procedure using the SpineAssist device.

Safety and effectiveness

Pechlivanis et al (2009) reported that a total of 133 pedicle screws were placed, the majority (58/133, 44%) in L5. The accuracy grade in the axial and longitudinal plane of the inserted screws is presented in Tables 1 and 2. In terms of axial accuracy, 92% (122/133) of screws satisfied Grade A criteria, 7% (9/133) Group B, and 1% (1/133) Group C. For longitudinal accuracy, 81% (108/133) satisfied Grade A criteria, 10% (13/133) Group B and 1% (1/133) Group D. It was not possible to determine the longitudinal accuracy of 11 screws due to reduced image quality. Time needed for setup and calibration was 10 minutes and average drilling and K-wire insertion time was 3 minutes per screw. Integration of the miniature robotic system was successful in 94% (29/31) of patients.

Table 1: Accuracy of screw placement in the axial plane by spinal level treated

Operated segment	# of screws per grade (measures accuracy of screw placement)				
	A	B	C	D	-
L2	1	1			
L3	6				
L4	34	5			
L5	55	2	1*		
S1	26	1			1
Total screws (n)	122	9	1	0	1

*L5 screw on the right side in case number 5, deviation probably due to screw slippage at the entry point.

Table 2: Accuracy of screw placement in the longitudinal plane by spinal level treated

Operated segment	# of screws per grade (measures accuracy of screw placement)				
	A	B	C	D	-
L2	2	1			
L3	6				
L4	30	6			3
L5	53	4		1*	
S1	17	3			8
Total screws (n)	108	14	0	1	11

*L5 screw on the right side in case number 5, deviation probably due to screw slippage at the entry point.

In the study by Sukovich et al (2006), full or partial success in utilisation of the SpineAssist system was reported for all but one patient (93%) and guidance of screw insertion was deemed to be accurate in all cases. Minor deviations (1-2mm) from the preoperative plan were identified in two procedures, secondary to unavoidable soft tissue pressure on the tool guide. In one case the use of SpineAssist was aborted due to CT-to-fluoroscopy registration failure for both vertebrae being instrumented (reasons unknown). In eight cases, registration failed for some vertebrae but not others, with S1 being the most problematic. Repeat fluoroscopy segmentation (sometimes involving multiple images) was able to achieve accurate registration. All screws remained within the pedicle, and there were no breaches of pedicle walls.

Barzilay et al (2006) reported smooth operation of the SpineAssist system in six cases (40%), resulting in accurate pedicle screw placement in accordance with the preoperative plan. Technical and surgical challenges, attributed to the system's early development stage, were encountered during nine procedures. The predominant cause of inaccurate screw placement was failure to avoid excessive pressure on the guiding arm of the SpineAssist robot caused by surrounding soft tissues. In four cases this led to a shift in entry point and trajectory of the tool guide and another case was caused by the surgeon applying too much pressure on the tool guide. In all cases the misalignment was recognised and corrected by the surgeon with no clinical implications.

Additional technical difficulties, each reported in one patient included:

- Angle of insertion on the axial plane was too wide, resulting in intraoperative plan/trajectory modification by the clinician and execution of the new plan by the robot.
- The robot was unable to reach the desired trajectory due to the angle of attachment of the clamp to the spinous process.
- Gauze pads were left in the wound during fluoro-acquisition which prevented good registration due to the pads' embedded radio-opaque markers.
- During revision surgery, old screws were found to be present during preoperative CT; these were later removed (prior to acquisition of fluoros for the SpineAssist) but resulted in a discrepancy between the CT and fluoro and prevention of registration.
- Device use was aborted due to a broken spinous process (significant force applied on the guiding arm and robot).
- Technical hardware failure required placing of three of four screws without guidance.

COST IMPACT

No cost-effectiveness studies were identified. One source reported the cost of a SpineAssist unit to be approximately US\$100 000 (Nainggolan 2004), although recent information reported US\$500 000 (Koren 2010). Disposable patient-specific clamps cost an additional \$900 (Pierce 2004, Nainggolan 2004). The device developer forecasts that purchase costs would eventually be offset due to reduced surgery time and invasiveness, expedited recovery, and minimised risks associated with traditional spinal surgery such as infection and blood loss (Nainggolan 2004).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

There were no issues identified from the retrieved material.

OTHER ISSUES

A learning curve was illustrated in the study by Barzilay et al (2006) where 15 patients underwent spinal fusion using the SpineAssist system at two medical centres. At one centre, the first four reported partial or no success but they were followed by two fully successful cases. At the second centre, four successful cases were interspersed within the initial challenging cases, but were mostly concentrated towards the end of the series. It is important to note that the time between cases was significant (mean 7 weeks), so it was difficult for the surgical teams to learn and improve from case to case.

Barzilay et al (2006) also mentioned advances in SpineAssist software and hardware following their experience with it, and retrospectively ran the original data for all of the cases in their study group (n=15) through the new software (see results in Table 3).

Table 3: Retrospective analysis of technical failures – comparing new and old software

Reason for failure using old SpineAssist version	Results using latest SpineAssist version	Explanation
Registration failed	Successful	Improved registration technology
Registration failed	Successful L5, S1 failed	Poor fluoro-image quality
Registration failed	Successful	Improved registration technology
'L5 unreachable' message	Reachable	Guidance arms were redesigned and optimised
L2 registration failed	Failed	Old metal implanted instrumentation was removed prior to fluoro-shots
T12 right side out of range	In range	Guidance arms were redesigned and optimised

SUMMARY OF FINDINGS

SpineAssist appears to provide accurate and clinically reliable guidance for placement of pedicle screws during open and percutaneous spinal fusion procedures. The most recently conducted included study demonstrated accuracy with a deviation <2 mm to the surgeon's preoperative plan in 92% to 98% of screws placed. The remaining two studies demonstrated success of the SpineAssist procedure in 93% and 40% of patients, respectively. Importantly, no cases of nerve damage as a result of misplaced pedicle screws were reported in any of the included studies; however, clinical outcomes such as symptom reduction and patient satisfaction were not reported.

HEALTHPACT ASSESSMENT

Based on the unlikelihood of additional high-quality comparative studies reporting the use of SpineAssist being published in the near future, it is recommended that no further assessment of this technology be undertaken at this time.

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor | <input checked="" type="checkbox"/> Archive |

HEALTHPACT ACTION

NUMBER OF STUDIES INCLUDED

Total number of studies	3
Level IV evidence	3

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SOURCES OF FURTHER INFORMATION

-

SEARCH CRITERIA TO BE USED

SpineAssist

Surgical robot
Miniature robot
Spinal fusion

HEALTH PACT DECISION

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor | <input type="checkbox"/> Archive |
| <input type="checkbox"/> Refer | <input type="checkbox"/> Decision pending |

PRIORITY RATING

- High** **Medium** **Low**