



Australian Government
Department of Health and Ageing



Horizon Scanning Technology Prioritising Summary

Vertebral body stapling for idiopathic scoliosis

December 2005



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



**Royal Australasian
College of Surgeons**

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Enquiries about the content of the report should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by staff from the Australian safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

Horizon Scanning Technology Prioritising Summary

Name of Technology:

Vertebral Body Stapling (Nitinol Staple, Medtronic Sofamor Danek, Memphis, Tennessee).

Purpose and Target Group:

Vertebral Body Stapling is a procedure which involves the use of staples to treat patients suffering from idiopathic scoliosis. The staples are surgically inserted into the vertebrae of the patient to prevent further curvature of the spine and hence 'arresting' the progression of the disease.

Stage of Development (in Australia): Not yet emerged in Australia

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use

The Nitinol Staple is not listed or registered in the Australian Register of Therapeutic Goods.

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States	✓		

Impact Summary:

Background

Idiopathic scoliosis is the most common spinal deformity seen by orthopaedic surgeons (Lonstein, 1995). Scoliosis is essentially a disturbance to normal organisation of the 25 member intercalated series of spinal segments, resulting in curvature of the spine. It is commonly defined as greater than 10° of lateral deviation of the spine from its central axis. ([Mehlman](#) 2004).

Treatment recommendations for adolescent idiopathic scoliosis are usually determined by the severity of the curve. Non-surgical treatment for scoliosis comprises observation (watchful waiting with intermittent radiographs to check progression or absence of spinal

curvature) or orthosis (eg. braces). The Milwaukee brace was the first commonly used brace and has been reported to successfully prevent curve progression in patients with 20 to 39° curves (Lonstein and Winter, 1994). The current standard of care for immature patients with idiopathic scoliosis curves measuring 20° to 40° is a cervicothoracolumbosacral orthosis (CTLSO) or a thoracolumbosacral orthosis (TLSO). However, 18% to 50% of these curves will still progress despite bracing (Betz *et al.* 2003). Furthermore, compliance with prescribed brace wear regimens is poor with one study finding patients only wear their braces for 65% of the prescribed amount of time (Diraimondo and Green, 1988).

Surgical treatment for scoliosis using vertebral staples was developed from the use of staples to treat limb misalignment in long bones. In 1949, hemiepiphyseal stapling was used to correct lower extremity spinal curves (Nachlas and Borden, 1949). In 1997, Ogilvie began treating scoliosis patients by stapling with thoracoscopy. Curve progression was stabilised in 4/6 patients after 2 years follow-up (Betz *et al.* 2003). However, staples were partially dislodged in two patients, leading to additional surgery to replace the staples. This is a significant problem with the use of staples as they were not designed to withstand the movement of the spine. In light of this, the Nitinol Staple was developed by Medtronic Sofamor Danek. This staple has 510K approval from the FDA for its specific use as an anterior spinal staple. It is made up of 50% titanium and 50% nickel and is a memory shape alloy whereby it is straight when cooled but clamps into a 'C' shape at body temperature for a more secure fixation.

Clinical Need and Burden of Disease

In the United States, three to five of every 1,000 children (equal to ~816,000 individuals in the United States) develop spinal curves significant enough to warrant medical treatment (NIAMS 2003). Scoliosis has been shown to be present in 2% to 4% of children between 10 and 16 years of age. Scoliosis in girls tends to progress more often and girls make up the majority of scoliosis patients (Reamy *et al.* 2001).

There are no data reflecting the incidence of scoliosis in Australia, however extrapolation of prevalence data (United States and the UK) indicates that 60,000 Australians may be affected by the condition (US Census Bureau 2004).

Estimated Speed, Geographic and Practitioner Use, Patterns of Diffusion in the Health System

Vertebral Body Stapling is currently being investigated in the United States at the Shriners Hospital (Philadelphia). To date, at least 39 scoliosis patients have been treated with vertebral body stapling at this institute (Betz *et al.* 2005). This technique offers several advantages over bracing, being more comfortable and less embarrassing for the child to wear. Vertebral body stapling also offers the patients the advantage of retaining

flexibility of their spine when compared to spinal fusion. It is likely that this procedure could gain significant preference over conventional techniques if its long-term effectiveness and safety can be established.

Existing Comparators

- Spinal fusion
- Bracing
- Harrington rods
- Wedge osteotomy – A new experimental procedure where wedges of bone from the concave side of the curve is removed. The spine is straightened by closing the cut section and a temporary rod is placed for support. Patients are required to wear a brace until the bone has healed.

Estimated Cost Impact

The cost associated with this procedure is currently unavailable as it is still in the experimental stage of development. Moreover, the Shriners Hospital, currently the only institute using this technique, does not charge any fees for the treatment of children under 18 years of age. In Australia, the reimbursement fee as stated in the Medicare Benefits Schedule for the treatment of scoliosis using segmental instrumentation for spinal fusion is \$2076.95 (Item number: 48612), for anterior correction with fusion and segmental fixation (not more than 4 levels) the reimbursement is \$1358.15 (Item number: 48621), for anterior correction with fusion and segmental fixation (more than 4 levels) the reimbursement is \$1677.65 (Item number: 48624), and for vertebral resection and fusion for congenital scoliosis, \$1324.70 (Item number: 48632). From July 2003 to June 2004, there have been 235 claims for segmental instrumentation for spinal fusion, six claims for anterior correction with fusion and segmental fixation (not more than 4 levels), 23 claims for anterior correction with fusion and segmental fixation (more than 4 levels) and one claim for vertebral resection and fusion (Medicare Australia 2005).

Reimbursements for the use of Harrington rods (or other non-segmental fixation) for scoliosis/kyphosis (Item number: 48609) is \$1425.90, for segmental instruments (CD, Zielke, Luque or similar) (Item number: 48612) it is \$2118.50, while the reimbursement for reconstruction of spinal fusion for scoliosis/kyphosis using segmental instrumentation with separate anterior and posterior approaches (Item number 48613) is \$3013.35 (Medicare Australia 2005).

Efficacy and Safety Issues

List of Studies Found

Total number of studies	1
Case series studies	1 (2 articles)

The studies included in this summary are highlighted in bold in the reference list.

Safety and efficacy data from one case series study was selected for inclusion in this summary, there are two published papers on this case series (Betz *et al.* 2003 and Betz *et al.* 2005). These papers encompass the only human studies identified on vertebral body stapling.

Betz *et al.* (2005) presented the results of 39 patients (52 curves) who have received vertebral body stapling as treatment for scoliosis. There were 6/52 (11.5%) complications. A four year-old patient with infantile idiopathic scoliosis developed a rupture of a pre-existing undiagnosed diaphragmatic hernia and required emergency repair. One patient suffered a puncture in a segmental spinal vein due to a staple prong and required a mini-incision to ligate the vein after losing around 1500cc of blood (mean estimated blood loss (EBL) was 247 ± 285 cc). One patient developed chylothorax due to staple puncture of the thoracic duct at T12 and was treated with chest tube and total parenteral nutrition. Another patient suffered mild pancreatitis that was addressed by implementing a low-fat diet. Two patients experienced clinically significant atelectasis and two other patients had prolonged chest tube drainage (> 4 days) (Betz *et al.* 2005). In 31 idiopathic scoliosis patients over eight years old who were followed-up for an average of 12 months, no staple dislodgement or migration was reported from the 600 staples used. However, one four-pronged staple was fractured at the waist. One patient with a pre-operative curve $>50^\circ$ experienced pain after the procedure. In this case, stapling was not successful in preventing thoracic curve progression and fusion was performed. Two months after fusion, the patient suffered from pain again (in the lumbar spine) and two distal staples were removed (Betz *et al.* 2005).

Twenty one patients aged over eight years (25 curves stapled) had pre-operative curves $<50^\circ$ and received follow-up of 12 months or more (Betz *et al.* 2005). Three curves (3/25, 13%) progressed more than 10° , and two patients (2/21, 9%) had curves that progressed beyond or equal to 50° , both subsequently underwent spinal fusion. There were four patients aged over eight years who had pre-operative curves $>50^\circ$, three continued to experience progression of spinal curvature after stapling and required spinal fusion, while one patient remained within 5° of her pre-operative curve after 18 months (Betz *et al.* 2005).

Betz et al. (2003) highlighted three patients who experienced improvement in their spinal curves after vertebral stapling. The reduction in spinal curves was 16°, 8°, and 11° respectively, thus resulting in a success rate of 30% (3/10 patients) when assuming curve reduction as the desired end-point.

Overall, this case series present some evidence that vertebral body stapling is capable of preventing curve progression (16/21 patients with pre-operative curves <50° did not progress beyond 10°; 1/4 patients with pre-operative curves >50° did not progress beyond 5°) (Betz *et al.* 2005) and sometimes reduce spinal curvature as well (3/10 patients with pre-operative curves <50°) (Betz *et al.* 2003).

Ethical Issues

No issues were identified from the retrieved material.

Cultural or Religious Considerations

No issues were identified from the retrieved material.

Other Issues

It is important to note that the Shriners Hospital is the only institution performing this procedure and the main institute advocating the procedure. There is a need for further comparative studies between vertebral body stapling and bracing as well as the upcoming technique of wedge osteotomies to determine if stapling has significant advantages over them.

Recommendation:

Limited evidence exists on the safety and efficacy of vertebral body stapling. Current evidence of this procedure is limited to small patient numbers and short follow-up duration. Additionally, long-term safety and efficacy data from randomised controlled trials will be required before this procedure can be widely accepted. Due to the limited evidence available, it is recommended that the following be conducted.

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

References:

Betz RR, Kim J, D'Andrea LP, Mulcahey MJ, Balsara RK, Clements DH. An innovative technique of vertebral body stapling for the treatment of

patients with adolescent idiopathic scoliosis: a feasibility, safety, and utility study. *Spine* 2003; 28(20): S255-S265.

Betz RR, D'Andrea LP, Mulcahey MJ, Chafetz RS. Vertebral body stapling procedure for the treatment of scoliosis in the growing child. *Clin.Orthop Relat Res.* 2005;(434): 55-60.

DiRaimondo CV and Green NE. Brace-wear compliance in patients with adolescent idiopathic scoliosis. *Journal of Pediatric Orthopedics* 1988; 8(2): 143-146.

Hadley-Miller N, Mims B, Milewicz DM. The potential role of the elastic fiber system in adolescent idiopathic scoliosis. *J Bone Joint Surg Am* 1994; 76(8): 1193-1206.

Kindsfater K, Lowe T, Lawellin D, Weinstein D, Akmakjian J. Levels of platelet calmodulin for the prediction of progression and severity of adolescent idiopathic scoliosis. *J Bone Joint Surg Am* 1994; 76(8): 1186-1192.

Lonstein JE and Winter RB. The Milwaukee brace for the treatment of adolescent idiopathic scoliosis. A review of one thousand and twenty patients. *Journal of Bone and Joint Surgery America* 1994; 76(8): 1207-1221.

Medicare Australia (2005). Last updated 2005. <http://www9.health.gov.au/mbs/> [Accessed September 2005].

Mehlman CT. Idiopathic scoliosis. Last updated 2004. <http://www.emedicine.com/orthoped/topic504.htm> [Accessed August 2005].

Nachlas JW and Borden JN. The cure of experimental scoliosis by directed growth control. *Journal of Bone and Joint Surgery America* 1951; 33: 24-32.

NIAMS/National Institute of Arthritis and Musculoskeletal and Skin Diseases – Questions and answers about scoliosis in children and adolescents. Last updated 2003. <http://www.niams.nih.gov/hi/index.htm> [Accessed August 2005].

Reamy BV and Slakey JB. Adolescent idiopathic scoliosis: review and current concepts. *Am Fam.Physician* 2001; 64(1): 111-116.

US Census Bureau – International Data Base 2004. Last updated 2004. <http://www.wrongdiagnosis.com/s/scoliosis/stats-country.htm> [Accessed August 2005]

Search Criteria:

A search of MEDLINE, PubMed and Cochrane Library, Current Controlled Trials metaRegister, UK National Research Register, International Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in May 2005

Search terms used were: ‘vertebral body stapl\$', ‘vertebral stapl\$', ‘scoliosis stapl\$’ and ‘Nitinol stapl\$’.

This Horizon Scanning Prioritising Summary was prepared by Mr. Irving Lee from the NET-S Project, ASERNIP-S for the Health Policy Advisory Committee on Technology (Health PACT), on behalf of the Medical Services Advisory Committee (MSAC) and the Australian Health Ministers' Advisory Council (AHMAC).