



**Australian Government**  
**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

**ANZHSN**

AN INITIATIVE OF THE NATIONAL STATE AND  
TERRITORY GOVERNMENTS OF AUSTRALIA  
AND THE GOVERNMENT OF NEW ZEALAND

# Horizon Scanning Technology Prioritising Summary

## Vertical expandable prosthetic titanium rib

August 2004



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



**Royal Australasian  
College of Surgeons**

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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).

**Name of Technology:**

Vertical Expandable Prosthetic Titanium Rib (VEPTR; Synthes)

**Purpose and Target Group:**

This procedure is intended for children suffering from Thoracic Insufficiency Syndrome (TIS), the ‘inability of the thorax to support normal respiration or lung growth’ (Campbell *et al.* 2003). ‘ Examples of TIS include unilateral hypoplastic thorax and spinal deformity associated with combined congenital scoliosis and rib fusions, and bilateral restrictive thoracic hypoplasia associated with Jeune syndrome (asphyxiating thoracic dysplasia) or Jarcho-Levin Syndrome (multiple vertebral and rib fusion anomalies’ (Lewandrowski *et al.* no date).

**Stage of Development (in Australia):** On the verge of introduction into Australia.

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

**International Utilisation:**

| COUNTRY     | LEVEL OF USE    |             |                 |
|-------------|-----------------|-------------|-----------------|
|             | Trials underway | Limited use | Widely Diffused |
| USA         | ✓               |             |                 |
| Switzerland | ✓               |             |                 |

**Impact Summary:*****Background***

In 1987, a prosthetic device constructed from Steinmann pins and a silicone sheet was implanted in a six month old infant at high risk of early death from respiratory insufficiency. Over the next two years an improvement in the curvature of the patient’s spine was observed, indicating early intervention of this type could improve scoliosis and reduce dependency on ventilator support. As a result, the first VEPTR was developed and implanted to replace the initial prosthesis. The VEPTR device has since been used in numerous subsequent patients with chest wall malformations (fused, malformed or absent ribs) as a prosthesis and distractor (Campbell *et al* 2003).

The VEPTR device is attached vertically rib-to-rib or rib-to-spine (with a lumbar extension). The telescopic arm is elongated during minor surgical procedures performed every four to six months, depending on the growth rate of the child, until the age of 13-14 years (Diamond 2002; Hell *et al.* 2003; Titanium Rib Project, no date). In children younger than 18 months old, one device usually suffices. Children older than 18 months may require two or more devices, including one with a lumbar extension to better correct and stabilise the spine (Campbell *et al.* 2004).

### ***Clinical Need and Burden of Disease***

An online eMedicine® article reports the incidence of Jeune Syndrome in the United States is estimated as 1 per 100 000 to 130 000 live births (Chen 2004). From an online *Advance Newsmagazine*, congenital severe scoliosis affects one in 10 000 in the United States (Gibbons 2004). No Australian incidence statistics could be found. Campbell *et al.* 2003 reports the incidence of major occult respiratory insufficiency in young children with thoracic deformity as unknown.

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

An FDA approved multi-centre feasibility study is currently underway in the United States. The project has been active since 1991. Currently there are only eight institutions world wide implanting VEPTR devices (seven in the USA and one in Switzerland) (Hell *et al.* 2003; Titanium Rib Project, no date). So far over 200 children have received a VEPTR device as part of this study (Titanium Rib Project, no date).

### ***Existing Comparators***

Few viable alternatives exist for patients with TIS and many children die before the age of one. The majority of children with severe scoliosis are treated with spinal fusion or convex epiphysiodesis (cessation of bone growth) and arthrodesis (fusion of joint) in order to correct abnormal curvature. Fusion prevents further spinal deformity, however it also prevents spinal growth (Campbell and Hell-Vocke 2003, Gibbons 2004, Lewandrowski *et al.* no date).

### ***Estimated Cost Impact***

The cost of the device varies between patients depending on which, and how many, 'pieces' they need. The cost of one device can reach US\$15 000 (Buegeler L, personal communication). Patients are usually hospitalised for 7 to 10 days following implantation of the device (Lewandrowski *et al.* no date).

### ***Efficacy and Safety Issues***

Three case series total the peer reviewed data available on the safety and efficacy of VEPTR. Campbell and Hell-Vocke (2003) conducted a case series study to investigate whether expansion thoracoplasty with the use of a VEPTR device in patients with

congenital scoliosis and fused ribs, allowed increased growth of the spine on both the concave and convex sides. A significant increase in the length of the thoracic spine from before the operation to the end of the follow-up period was observed in all patients.

Campbell *et al.* (2000) in a conference abstract, report the results following implantation of the VEPTR device following expansion thoracoplasty in 34 patients with progressive scoliosis and fused ribs. A statistically significant improvement in scoliosis (lateral curvature of the spine), correction of the lateral shift of the spine and average height of increase of the operated hemithorax was observed. No complications were observed in 17 patients. The remaining 17 patients experienced complications. Single incidences of spinal hook dislodgement, dural tear, spinal cord injury, device infection and postoperative death were reported. At least two cases of slow device cut out through the rib, transient upper extremity neuropraxis, adult respiratory distress syndrome and skin slough occurred.

The third tabulated case series (Campbell *et al.* no date) reports the results following implantation of a VEPTR device in 43 patients. There were four groups of patients in this experiment: group A had fused ribs, group B had absent ribs, group C had a hypoplastic thorax and group D had scoliosis only. Follow-up data was collected from 19 patients who had undergone surgery two years previously. Improvements in the degree of scoliosis was reported for all three groups. Thoracic spinal growth and width was also observed in patients from all three groups. Sixty percent (6/10) of patients previously suffering respiratory insufficiency showed improvement postoperatively. More complications were reported in patients who received a VEPTR device with lumbar extension (hybrid device) than those without the extension. One patient experienced laminar hook dislodgement, one experienced dural laceration and one infection.

### ***Ethical Issues***

No issues were identified from the retrieved material.

### ***Cultural or Religious Considerations***

No issues were identified from the retrieved material.

### ***Other Issues***

No issues were identified from the retrieved material.

### **Conclusion:**

Limited evidence exists on the safety and efficacy of the VEPTR device for the correction of Thoracic Insufficiency Syndrome. Of the three peer reviewed case series available, two studies reported the use of a VEPTR device on patients with congenital scoliosis and fused ribs (Campbell and Hell-Vocke 2003; Campbell *et al.* 2000). The other series reported the results from patients with a range of conditions (Campbell *et al.* no date). Short and long term safety and efficacy data would be required before this device

could be routinely used. As the incidence of conditions that could benefit from the implantation of a VEPTTR device is low, the introduction of VEPTTR devices into Australia would be expected to have minimal impact on the health system.

### HealthPACT decision:

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

### References:

- Buegeler L (personal communication) 7 May 2004. Case Manager, Titanium Rib Project.
- Campbell RM Jr, Hell-Vocke AK. Growth of the thoracic spine in congenital scoliosis after expansion thoracoplasty. *The Journal of Bone and Joint Surgery* 2003; **85-A**(3): 409-420.
- Campbell RM Jr, Smith MD, Hell-Vocke AK. Expansion thoracoplasty: The surgical technique of opening-wedge thoracoplasty. *The Journal of Bone and Joint Surgery* 2004; **86-A**(Suppl 1): 51-64.
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- Campbell RM Jr, Smith MD, Mayes TC, Mangos JA, Willey-Courand DB, Kose N, Pintero RF, Alder ME, Duong HL, Surber JL. The characteristics of thoracic insufficiency syndrome associated with fused ribs and congenital scoliosis. *The Journal of Bone and Joint Surgery* 2003; **85-A**(3): 399-408.
- Campbell RM Jr, Smith MD, Mayes TC, Mangos JA, Willey-Courand DB, Surber J. The treatment of thoracic insufficiency syndrome associated with scoliosis and fused ribs. *American Academy of Orthopaedic Surgeons: 67<sup>th</sup> Annual Meeting*. 2000. Paper number 191 (abstract only). Available from <http://www.aaos.org/wordhtml/anmt2000/scipro/191.htm>.
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- Diamond T (ed). Creating Room to Breathe. *Shriners Hospitals for Children, Philadelphia: Connections* 2002; **13**(3): 3-5.
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Titanium Rib Project: Thoracic Institute. Available from <http://www.theribkids.com/Hospital/Pages%20from%20Jen/Csrch.htm>. (No date). First accessed 6th May 2004.

University of Utah News Release. U of U Physicians to Teach Doctors from Around Country New Surgery for Kids with Congenital Scoliosis. Available from <http://www.utah.edu/unews/releases/02/apr/surgery.html>. Issue date 26 April 2002. First accessed 7 May 2004.

### **Sources of Further Information:**

The Titanium Rib Project is currently in the investigational/experimental status with the FDA. The Medical Director for the research project, active since 1991, is Dr. Robert Campbell.

*For further information about this study contact:*

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No published information was found to follow up from this conference abstract.

*Paediatric Orthopaedic Society of North America (POSNA)*

*2003 Annual Meeting, Florida.*

Campbell R, Smith M, Willey-Courand DB, Smith J, Gollogly S, Grohman C, Simmons JW. The treatment of jeune's asphyxiating thoracic dystrophy with a vertical expandable prosthetic titanium rib.

It was reported that a pilot study was conducted on five patients and that the results were to be presented at a conference in May (Switzerland) (University of Utah 2002). No further details could be found regarding the study. The authors were Smith J, Campbell RC, Gollogly S.

### **Search Criteria:**

A search of American College of Physicians Journal Club, Cochrane Database of Systematic Reviews, Cumulative Index to Nursing and Allied Health Literature, Current Controlled Trials metaRegister, Database of Abstracts of Reviews of Effects, EMBASE, Medline®, Medline® In-Process and Other Non-Indexed Citations, PubMed, relevant online journals and the Internet was conducted in May 2004. Search terms used were 'titanium AND rib', 'prosthetic AND rib', 'synthes AND prosthetic AND rib', 'VEPTR'.

| Study Details   | Key Safety Data   | Key Efficacy Data   |                |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
|---|---|---|----------------|----------------|---------------|---------------------------|-------------------|------------------|--------------------------|----------------|------------------------|---|----------------|----------------|--|----|---|-----------------------------------|---------|----------|----------|--------------|-------------|-----------|----------|--------------|------------|-----------|----------|--------------|-------------|-----------------------|----------|--------------|
| <p><b>Campbell and Hell-Vocke 2003. USA</b></p> <p>21 children presented with congenital scoliosis and fused ribs. Treated with expansion thoracoplasty and stabilised with VEPTR device.</p> <p>Group A (n=18): no previous spinal procedures. Average time to follow up 4.2 years.</p> <p>Group B (n=3): previous spinal fusion. Average time to follow up 2.6 years.</p> <p>VEPTR extended approximately twice a year.</p> <p>No control population of patients with congenital scoliosis that went untreated.</p> | <p>Not reported</p>   | <table border="1"> <thead> <tr> <th></th> <th>Group A (n=18)</th> <th>Group B (n=3)</th> </tr> </thead> <tbody> <tr> <td>Mean growth concave spine</td> <td>7.9mm (7.1%)</td> <td>4.6mm (3.0%)</td> </tr> <tr> <td>Mean growth convex spine</td> <td>8.3mm (6.4%)</td> <td>3.7mm (2.2%)</td> </tr> <tr> <td>Mean change in scoliosis (lateral curvature, °)</td> <td>12</td> <td>9</td> </tr> <tr> <td>Mean change in kyphosis (posterior curvature, °)</td> <td>18</td> <td>5</td> </tr> <tr> <td>Mean change in spine rotation (°)</td> <td>5</td> <td>7</td> </tr> </tbody> </table> <p>Both groups A and B showed significant (<math>p&lt;0.0001</math>) increase in the length of the thoracic spine from preoperative to postoperative.</p> <p>Increase in thoracic spinal length was a result of growth rather than of mechanical elongation due to VEPTR device.</p>  |                | Group A (n=18) | Group B (n=3) | Mean growth concave spine | 7.9mm (7.1%)      | 4.6mm (3.0%)     | Mean growth convex spine | 8.3mm (6.4%)   | 3.7mm (2.2%)           | Mean change in scoliosis (lateral curvature, °) | 12             | 9              | Mean change in kyphosis (posterior curvature, °) | 18 | 5 | Mean change in spine rotation (°) | 5       | 7        |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
|   | Group A (n=18)  | Group B (n=3)   |                |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
| Mean growth concave spine   | 7.9mm (7.1%)  | 4.6mm (3.0%)  |                |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
| Mean growth convex spine  | 8.3mm (6.4%)  | 3.7mm (2.2%)  |                |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
| Mean change in scoliosis (lateral curvature, °)   | 12  | 9   |                |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
| Mean change in kyphosis (posterior curvature, °)  | 18  | 5   |                |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
| Mean change in spine rotation (°)   | 5   | 7   |                |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
| <p><b>Campbell et al. 2000. USA</b> (conference abstract)</p> <p>34 patients with TIS secondary to progressive scoliosis associated with fused ribs. Treated with expansion thoracoplasty, primary lengthening with VEPTR prosthesis.</p> <p>Ave age at surgery: 2.3 years.</p> <p>16 patients prospectively studied. Follow up averaged 3.8 years (range 2-6 years).</p>   | <p>No complications in 17/34 (50%) patients.</p> <p><i>Complications:</i></p> <ul style="list-style-type: none"> <li>• Slow device cut out through the rib (n=4)</li> <li>• spinal hook dislodgement (n=1)</li> <li>• transient upper extremity neuropraxis (n=3)</li> <li>• dural tear (n=1)</li> <li>• spinal cord injury (n=1)</li> <li>• adult respiratory distress syndrome (n=2)</li> <li>• skin slough (n=2)</li> <li>• device infection (n=1)</li> <li>• postoperative death (n=1)</li> <li>• not reported (n=1)</li> </ul> | <p><i>Scoliosis</i> (lateral curvature)<br/>Ave preop: 73°<br/>Ave improvement: 20° (<math>p&lt;0.0001</math>).</p> <p><i>Kyphosis</i> (posterior curvature)<br/>Ave preop: 17°<br/>Improved to 33° postop</p> <p>Ave ratio (correction of the lateral shift of the spine)<br/>Preop: 2.5<br/>Postop 1.9 (normal <math>\leq 1</math>) (<math>p&lt;0.03</math>)</p> <p>Ave thoracic spinal height increase: 0.8cm/year<br/>Ave height increase of operated hemithorax: 0.8cm/year<br/>Ave height increase of non-operated hemithorax: 0.6cm/year (<math>p&lt;0.05</math>)</p> <p>Thoracic symmetry showed no significant change during treatment.</p>  |                |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
| <p><b>Campbell et al. (no date) USA.</b> (abstract only, no journal name available)</p> <p>43 patients treated with VEPTR device.</p> <p>Group A (n=20): fused ribs<br/>Group B (n=7): absent ribs<br/>Group C (n=13): hypoplastic thorax<br/>Group D (n=3): scoliosis only</p> <p>Ave age at surgery: 3.3 years (range 6 months to 15.8 years).</p> <p>Follow up: 19 patients reported after <math>\geq 2</math> years.</p>  | <p>Specific device related complications in less than 6% (2/36) patients with thoracic devices.</p> <p>Patients with hybrid devices (attached to spine) showed more significant complications:</p> <ul style="list-style-type: none"> <li>• laminar hook dislodgement (n=1)</li> <li>• dural laceration (n=1)</li> <li>• infection (n=1)</li> </ul> <p>Most common complication was respiratory distress following primary surgery (12% patients).</p>  | <p><i>Scoliosis</i></p> <table border="1"> <thead> <tr> <th>Group</th> <th>A (n=12)</th> <th>B (n=4)</th> <th>C (n=3)</th> </tr> </thead> <tbody> <tr> <td>Ave preop (range)</td> <td>74° (27 to 140°)</td> <td>35° (0 to 95°)</td> <td>40° (5 to 75°)</td> </tr> <tr> <td>Ave correction (range)</td> <td>22° (7 to 37°)</td> <td>15° (5 to 32°)</td> <td>20° (6 to 32°)</td> </tr> </tbody> </table> <p><i>Growth</i></p> <table border="1"> <thead> <tr> <th></th> <th>A</th> <th>B</th> <th>C</th> </tr> </thead> <tbody> <tr> <td>Ave TSG</td> <td>7cm/year</td> <td>7cm/year</td> <td>1.2 cm/ year</td> </tr> <tr> <td>Increase TW</td> <td>65cm/year</td> <td>8cm/year</td> <td>1.4 cm/ year</td> </tr> <tr> <td>Growth HOH</td> <td>15%/ year</td> <td>9%/ year</td> <td>Not reported</td> </tr> <tr> <td>Growth HNOH</td> <td>5%/ year (<math>p&lt;0.01</math>)</td> <td>8%/ year</td> <td>Not reported</td> </tr> </tbody> </table> <p><i>Respiratory insufficiency:</i><br/>60% (6/10) patients: improvement observed following procedure.</p> | Group          | A (n=12)       | B (n=4)       | C (n=3)                   | Ave preop (range) | 74° (27 to 140°) | 35° (0 to 95°)           | 40° (5 to 75°) | Ave correction (range) | 22° (7 to 37°)                                  | 15° (5 to 32°) | 20° (6 to 32°) |  | A  | B | C                                 | Ave TSG | 7cm/year | 7cm/year | 1.2 cm/ year | Increase TW | 65cm/year | 8cm/year | 1.4 cm/ year | Growth HOH | 15%/ year | 9%/ year | Not reported | Growth HNOH | 5%/ year ( $p<0.01$ ) | 8%/ year | Not reported |
| Group   | A (n=12)  | B (n=4)   | C (n=3)        |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
| Ave preop (range)   | 74° (27 to 140°)  | 35° (0 to 95°)  | 40° (5 to 75°) |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
| Ave correction (range)  | 22° (7 to 37°)  | 15° (5 to 32°)  | 20° (6 to 32°) |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
|   | A   | B   | C              |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
| Ave TSG   | 7cm/year  | 7cm/year  | 1.2 cm/ year   |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
| Increase TW   | 65cm/year   | 8cm/year  | 1.4 cm/ year   |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
| Growth HOH  | 15%/ year   | 9%/ year  | Not reported   |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |
| Growth HNOH   | 5%/ year ( $p<0.01$ )   | 8%/ year  | Not reported   |                |               |                           |                   |                  |                          |                |                        |   |                |                |  |    |   |                                   |         |          |          |              |             |           |          |              |            |           |          |              |             |                       |          |              |

*Abbreviations used:*

VEPTR: Vertical Expandable Prosthetic Titanium Rib

Ave: average

Preop: preoperative

Postop: Postoperative

TSG: Thoracic spinal growth

TW: Thoracic width

HOH: Height of operated hemithorax

HNOH: Height of non-operated hemithorax