



Australian Government
Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

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

Horizon Scanning Technology Prioritising Summary

Non-invasive extendable prosthesis to maintain limb length equality

July 2004



ASERNIP/S

**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:

Non-invasive expandable prosthesis for the maintenance of limb length (Repiphysis® Expandable Technology).

Purpose and Target Group:

Non-invasive expandable prostheses are designed to non-invasively maintain limb length equality in growing patients after limb salvage surgery (<http://www.wmt.com> Neel 2003). It may therefore be applicable for the treatment of children who have undergone bone removal surgery for the treatment of osteosarcoma.

Stage of Development (in Australia): Yet to emerge in Australia.

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

The Repiphysis® expandable prosthesis is not listed or registered in the Australian Register of Therapeutic Goods (ARTG).

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely Diffused
UK	✓		
USA	✓		

Impact Summary:

Background

Osteosarcoma is the most common form of malignant bone tumours seen in children (Neel *et al.* 2003). These tumours frequently involve the metaphysis of the distal femur or proximal tibia and treatment often necessitates the resection of the involved segment. Amputation of the affected limb or rotationplasty has previously been the recommended treatment of choice in skeletally immature patients, as continued growth of the unaffected limb then results in significant skeletal inequality at maturity (Neel *et al.* 2003, Wilkins *et al.* 2001).

The development of endoprotheses has made limb salvage surgery an option for many children with osteosarcoma. The endoprotheses commonly take two main designs: modular design where midsections are exchanged for progressively longer sections or a minimally invasive design that requires a small incision where a screwdriver can be inserted to extend the prosthesis (Neel *et al.* 2003). Although both these designs allow salvage of the limb with



minimal limb length discrepancy at maturity, both designs require surgical procedures for the extension to occur.

Recently, a non-invasive expandable prosthesis has been released for use in skeletally immature patients after limb salvage surgery. The endoprosthesis is a custom made spring-loaded extension. Initially the patient undergoes surgical implantation of the device but subsequent limb lengthening procedures are non-invasive. The device consists of a spring which is covered in a heat-sensitive polymer within a pair of tubes. External application of electromagnetic waves softens the polymer, expanding the spring and hence stretching the limb. Once the patient becomes skeletally mature, the device is surgically removed and replaced with an alternative prosthesis that is designed to withstand long-term stress from adult weight (<http://www.wmt.com> Neel 2003, Wilkins *et al.* 2001).

Clinical Need and Burden of Disease

Malignant bone tumours are fairly uncommon, representing about 5% of cancers in childhood and adolescence (Sydney Children's Hospital 2001). Osteosarcoma is the most common form of malignant bone tumours seen in children, with more than one third of all cases occurring in children younger than 10 years of age (Neel *et al.* 2003). With the condition often affecting the growing plate, removal results in children with limb discrepancy. Frequent surgery is required in attempt to equalise limb lengths often resulting in long hospital stays and surgery provoked complications (<http://www.wmt.com>). This condition impacts not only on the physical well-being of the patient, but also on the mental and social well-being of the patient and their family.

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

Non-invasive expandable prostheses have been in development in the UK and USA since the late 1970's (<http://www.asme.org>). Stanmore Implants Worldwide Ltd. have had the bionic bone in the making for 11 years with surgeons at the Royal National Orthopaedic Hospital in Stanmore. In November 2002, they reported the insertion of the bionic bone into the lower limb of their first patient. A non-invasive expandable prosthesis called the Repiphysis system (Wright Medical Technology Inc., USA) was originally developed by Phenix Medical of France founder Arnaud Soubeiran. The device is currently sold in several European countries, and has been in use for more than six years. The Repiphysis was approved by the FDA in 2002 (<http://www.wmt.com>). Although most studies have involved implantation into lower limbs, it has shown to be implantable into upper limbs (Wilkins *et al.* 2001) with the Repiphysis inserted for the first time into the humerus in September 2003 (<http://alamenda.networkofcare.org>).

Existing Comparators

- Minimally invasive prosthesis
- Modular designed prosthesis



Estimated Cost Impact

On interview of bio-engineers and surgeons at the Royal National Orthopaedic Hospital in Stanmore, it was indicated that the custom made bionic bone cost approximately £9,000 compared to £4,000 for a mechanical prosthesis. The higher cost said to be offset by major savings in the costs of surgery and aftercare (<http://www.edgewartimes.co.uk>).

The costs associated with this new product in Australia are not currently available. The cost of modular or minimally invasive prostheses in Australia is also not available. However, reimbursement fees as stated in the Medicare Benefits Schedule for current surgery involving malignant bone tumour, enbloc resection of, with massive anatomic specific allograft or autograft, with or without prosthetic replacement (Medicare Benefits Schedule item number 50227) is approximately \$2740 (<http://www.health.gov.au>). According to HIC, 25 claims to Medicare were processed between July 2002 to June 2003 for item number 50227 (<http://www.hic.gov.au>).

Limb lengthening procedures as stated by the Medicare Benefits Schedule for up to and including 5cm, requiring slow distraction under general anesthetic in an operating theatre, with or without the use of ring fixator or similar device is approximately \$1310, payable only once in a 12 month period (<http://www.health.gov.au>).

Efficacy and Safety Issues

Short and long-term safety and efficacy data exists from two case series and five case reports.

The two case series (Neel *et al.* 2003, Wilkins *et al.* 2001) used Phenix prostheses (Phenix-Medical, Paris, France). Wilkins *et al.* (2001) had seven prostheses fitted in six patients. Twenty-one expansions occurred in the six patients with an average lengthening per procedure of 8 mm. At last follow-up, the average total amount of limb length achieved was 27 mm (range 8 to 45 mm). The average musculoskeletal tumour society functional score (MSTS) was 80% (higher scores indicate a higher level of function). No surgical complications or any acute complications due to the lengthening procedure were reported. However, two mechanical complications occurred in one patient (the prosthesis disassembled and the spring was expanding uncontrolled and the replacement prosthesis underwent pistoning with weightbearing) and another patient who required a second prosthesis due to fracture of the first, developed an infection.

Neel *et al.* (2003) had 18 devices implanted in 15 patients. The average MSTS was 90%. Patients averaged 4.3 lengthening procedures with an average extension of 8.5 mm (range 1.5 to 30 mm) each time. Eight revision procedures were required due to stem fractures or loosening and one above knee amputation was performed due to arterial thrombosis at 10 months postoperatively.



Four of the five case reports (Neel 2001, Neel 2003, Wilkins 2003a, Wilkins 2003b) utilised the Repiphysis system (Wright Medical Technology, Arlington, TN). Expansions ranged from 2.9 to 5.8 cm in total. All patients achieved equal leg lengths and reported good function. No loosening or other complications were reported. It appears that these were all publications from Wright Medical (Arlington, TN).

An additional case report (Verkerke *et al.* 1997) was only available as an abstract, which detailed six extensions in one patient, resulting in 19.5 mm of prosthetic growth. However, an ingrown toenail caused infection of the endoprosthesis and removal of the prosthesis 15 months postoperatively.

There is limited evidence for the safety and efficacy of non-invasive expandable prostheses, as an alternative to minimally invasive or modular designed prostheses. However, the studies conducted have indicated that the non-invasive expandable prostheses may enable effective extension of a limb that has undergone limb salvage surgery, without requiring additional surgery.

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 should be noted that four of the case reports were released by Wright Medical Technology, Inc. (Neel 2001, Neel 2003, Wilkins 2003a, Wilkins 2003b).

Conclusion:

Limited evidence exists on the safety and efficacy of non-invasive expandable prosthesis. Long-term safety and efficacy data from randomised controlled trials may be required before this procedure can be widely accepted.

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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 |

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<http://www.wmt.com/Physicians/Products/Oncology/REPIPHYSISExpandableTechnology.asp>
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Sources of Further Information:

No other sources of further information were identified.

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 January 2004.

Search terms used were: 'noninvasive expandable prosthesis', 'noninvasive extendable prosthesis', 'noninvasive endoprosthesis', 'Phenix prosthesis', 'bionic bone', 'Stanmore implants', 'Repiphysis system', 'non-invasive expandable prosthesis' and 'non-invasive extendable prosthesis'.