



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

Injectable silicone biomaterial for faecal incontinence

August 2004



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



**Royal Australasian
College of Surgeons**



© Commonwealth of Australia [2004]

This work is copyright. You may download, display, print and reproduce this material in unaltered form only (retaining this notice) for your personal, non-commercial use or use within your organisation. Apart from any use as permitted under the Copyright Act 1968, all other rights are reserved. Requests and inquiries concerning reproduction and rights should be addressed to Commonwealth Copyright Administration, Attorney General's Department, Robert Garran Offices, National Circuit, Canberra ACT 2600 or posted at <http://www.ag.gov.au/cca>

Electronic copies can be obtained from <http://www.horizonscanning.gov.au>

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

DISCLAIMER: This report is based on information available at the time of research and cannot be expected to cover any developments arising from subsequent improvements to health technologies. This report is based on a limited literature search and is not a definitive statement on the safety, effectiveness or cost-effectiveness of the health technology covered.

The Commonwealth does not guarantee the accuracy, currency or completeness of the information in this report. This report is not intended to be used as medical advice and it is not intended to be used to diagnose, treat, cure or prevent any disease, nor should it be used for therapeutic purposes or as a substitute for a health professional's advice. The Commonwealth does not accept any liability for any injury, loss or damage incurred by use of or reliance on the information.

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:

Injectable silicone biomaterial for treatment of faecal incontinence

Purpose and Target Group:

Injection of a silicon-based biomaterial into or around the internal anal sphincter is performed to improve function of the muscle for the treatment of faecal incontinence (Malouf *et al.* 2001, Kenefick *et al.* 2002). It may therefore be applicable to patients with passive faecal incontinence resulting from anatomic damage or an intact but weakened internal anal sphincter.

Stage of Development (in Australia):

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

Macroplastique and Bioplastique are registered in the Australian Register of Therapeutic Goods (ARTG) under ARTG number 53283 and 69960 respectively.

International Utilisation:

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

Impact Summary:

Background

Faecal incontinence is a condition in which patients lose control over the passage of stool or gas, most commonly as a result of damage to the pelvic floor from childbirth (for women), anorectal surgery or age-related nerve slowdown and muscle weakness (Fecal incontinence, 2004).

Conservative options for faecal incontinence such as diet management, fibre supplements or biofeedback, are only modestly effective (Fecal Incontinence 2004, Parkridge Medical Center 2004). While age-onset incontinence is less responsive to surgical treatment, surgical correction which involves sphincter repair with an overlapping sphincteroplasty can be performed in some instances, especially if the underlying cause of the incontinence is anal sphincter abnormality (Fecal Incontinence 2004).



The injection of a silicon-based biomaterial into or around the internal anal sphincter (IAS) for the treatment of faecal incontinence is a new procedure that attempts to restore functional continuity of the muscle by acting as a soft tissue bulking agent. The technology developed by Uroplasty Ltd (<http://www.uroplasty.com>) consists of the injection of textured polydimethylsiloxane particles suspended in a bioexcretable carrier hydrogel of polyvinylpyrrolidone (PVP) (Malouf *et al.* 2001). The bulking effect of the silicone enhances the action of naturally occurring anal cushions (Kenefick *et al.* 2002).

Clinical Need and Burden of Disease

The embarrassment of faecal incontinence sees many patients reluctant to seek medical attention, leading to underestimation of the problem within the community (Johanson *et al.* 1996). It is estimated that there are 1 million Australian community-dwelling adults who have some degree of faecal incontinence (Chiarelli *et al.* 2004). The prevalence of faecal incontinence increases with age, with an approximate 7-8 fold increase in the over 80-year age group compared with the under 30-year age group in both genders. The absolute values appear to be slightly higher in men than in women (Johanson *et al.* 1996, Chiarelli *et al.* 2004).

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

Malouf *et al.* (2001) published a case series report on ten patients who received silicone-based injections for the treatment of faecal incontinence. Kenefick *et al.* (2001) subsequently published a case series report on six patients who received the same treatment in 2002. Both case series were conducted from St Mark's Hospital, London, United Kingdom. The procedure has reportedly been performed on a few cases in South Australia (P. Hewett (surgeon), SA: personal communication, March 2004) but at this stage no published Australian data has been found, making the extent of diffusion difficult to estimate.

With an estimated 1 million people within the Australian population suffering from faecal incontinence (Chiarelli *et al.* 2004), and the relative simplicity of the procedure in comparison with its surgical comparators, the procedure could potentially be widely and rapidly diffusible within the health system.

Existing Comparators

- Anal sphincter, direct repair
- Delivery of radiofrequency energy to the anal sphincter
- Sphincteroplasty

Estimated Cost Impact

The costs associated with this new procedure and the cost of surgery involving direct anal sphincter repair or sphincteroplasty in Australia are not currently available. However, the Medicare Benefits Schedule reimbursement fees of direct repair of the anal sphincter (Medicare Benefits Schedule item number 32129) and Park's intersphincteric procedure



(Medicare Benefits Schedule item number 32126) is estimated to be approximately \$400 and \$530 respectively (<http://www.hic.gov.au>). According to the Health Insurance Commission, there were 311 and 8 claims processed between July 2002 and June 2003 for item numbers 32129 and 32126 respectively.

Other options available under the MBS are anal graciloplasty (32203), insertion of stimulator and electrodes following previous gastroplasty (32206), anal graciloplasty with the insertion of a stimulator and electrodes (32209), and gracilis neosphincter pacemaker (32210). The reimbursement fees are \$538, \$486, \$782 and \$216 respectively. The Health Insurance Commission reported 3, 1, 6 and 0 claims respectively between July 2002 and June 2003 for the procedures mentioned.

Efficacy and Safety Issues

Short and long-term safety and efficacy data on the use of injectable silicone biomaterial for treatment of faecal incontinence exist from two cases series (Kenefick *et al.* 2002, Malouf *et al.* 2001).

Kenefick *et al.* (2002) conducted the procedure using an 18-gauge 2.5-inch needle with injections corresponding to the positions of the anal sphincter. A marked improvement in symptoms and patient satisfaction in 5/6 (83.3%) patients was reported. Faecal incontinence scores improved significantly from a median of 14 (range 11 to 20) before the procedure to 8 (range 6 to 15) after the procedure. Quality of life scores also showed significant improvement with physical function improving from a median 26 (range 5 to 33) to 79 (range 25 to 100) ($p=0.02$) and social function improving from 10 (range 5 to 37) to 100 (range 50 to 100) ($p=0.02$). Median resting anal pressure improved from 46 cm H₂O to 75 cm H₂O, $p=0.03$ and squeeze pressure also had significantly improved from 98 cm H₂O to 142 cm H₂O, $p=0.01$. No episodes of infection or leakages were reported. Reportedly no patient experienced severe pain or constipation and erosion of the implants was not encountered.

The needle size used for the procedure by Malouf *et al.* (2001) varied from 18-gauge 2.5-inch to 18-gauge 1.0-inch. At six-week follow-up, 6/10 (60%) patients had a marked improvement in anal sphincter function. Three of ten (30%) patients did not improve after one or two injections and were found to have had a leakage of product from the injection site. One of the 10 (10%) patients improved after a second injection. At six-month follow-up, 7/10 (70%) patients reported no relief of symptoms and 3/10 (30%) reported an improvement of symptoms. Leakage and infection was experienced by patients who received the procedure using the 1-inch needle, resulting in ulceration and pain. No complications or adverse events were seen with the use of the 2.5-inch needles.

There is limited evidence for the safety and efficacy of injectable silicone biomaterial for the treatment of faecal incontinence with studies reporting on small patient numbers. The studies conducted have indicated that the procedure may enhance the function of the IAS by



providing a tissue bulking agent, resulting in an improved quality of life for patients with faecal incontinence. However, it has also been reported that the procedure may be quite painful.

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 injection of silicon-based biomaterial into or around the IAS for the treatment of faecal incontinence. Long-term safety and efficacy data with large patient numbers may be required before this procedure can be widely accepted.

With a large target population and the relative simplicity of the procedure compared with existing surgical comparators, injectable silicone biomaterial for the treatment of faecal incontinence has the potential for wide and easy uptake. Evaluation for the use of injectable silicone biomaterial for faecal incontinence has indicated its use for a range of other indications.

HealthPACT decision:

It is recommended that injectable silicone biomaterial for the treatment of all indications be assessed and a horizon scanning report to be completed.

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

References:

Chiarelli P, Bower W, Attia J, Sibbritt D, Wilson A. The prevalence of faecal incontinence: a systematic review. Available from <http://www.continence.health.gov.au/ncms/pdf/sysrevfi.pdf>
Accessed April 2004.

Fecal incontinence. Available from
http://www.columbiasurgery.org/divisions/colorectal/noncancer_fecal.html Accessed February 2004.

Johanson JF, Lafferty J. Epidemiology of faecal incontinence: the silent affliction. *American Journal of Gastroenterology* 1996; **91**(1): 33-6.



Kenefick NJ, Vaizey CJ, Malouf AJ, Norton CS, Marshall M, Kamm MA. Injectable silicone biomaterial for faecal incontinence due to internal anal sphincter dysfunction. *Gut* 2002; **51**: 225-28.

Malouf AJ, Vaizey CJ, Norton CS, Kamm MA. Internal anal sphincter augmentation for fecal incontinence using injectable silicone biomaterial. *Diseases of the Colon and Rectum* 2001; **44**: 595-600.

Parkridge Medical Center. Available from <http://www.parkridgemedicalcenter.com> Accessed February 2004.

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: 'Bioplastique', 'PTP injections for faecal incontinence', 'injectable silicone and faecal incontinence', 'perianal injection' and 'polydimethylsiloxane injections'.