



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

Radio-frequency energy for the treatment of faecal incontinence

June 2004



ASERNIP(S)

**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).

**NAME OF TECHNOLOGY:**

Radio-frequency energy for the treatment of faecal incontinence

PURPOSE & TARGET GROUP:

The Secca® system involves the delivery of radio-frequency energy to deep mucosa of the anal canal to create thermal lesions which improve the barrier function of the muscle for the treatment of faecal incontinence (Curon Medical 2004). It may therefore be applicable to patients with faecal incontinence as a result of damage to the anal sphincter (Curon Medical 2002).

STAGE OF DEVELOPMENT (IN AUSTRALIA):

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

The Secca® system 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
USA		✓	
Mexico	✓		

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 (Parkridge Medical 2004).

Conservative options for faecal incontinence such as diet management, fibre supplements or biofeedback, produce only modest results (Parkridge Medical 2004, Fecal incontinence 2004). Injection of silicone biomaterial, around the internal anal sphincter or into a defect of the anal sphincter is also used to improve the barrier function of the muscle. 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 surgical procedure however entails a lengthy recovery with potential complications such as deep vein thrombosis (Curon Medical 2004).

The delivery of radio-frequency energy for the treatment of faecal incontinence is done via a hand held device that is placed into the anal canal. The device is connected to a radio-frequency generator, controlled levels of energy are applied to small areas of tissue, causing the collagen to contract. As the heated areas heal, additional collagen is deposited and the muscle is strengthened.

Clinical need and burden of disease:

The embarrassment of faecal incontinence sees many patients reluctant to seek medical attention, leading to under-representation within the community (Fecal incontinence 2002). It is estimated that there are 1 million Australian adults within the community who have some degree of faecal incontinence. The prevalence of faecal incontinence increases with age, with roughly 7-8 fold higher in the over 80 year age group compared to the under 30 year age group in both genders. The absolute values appear to be slightly higher in men than in women (Fecal incontinence 2002).

Estimated speed, geographic and practitioner use patterns of diffusion in the health system:

Takahashi *et al.* (2002) published a case series in 2002, where the delivery of radio-frequency energy to the anal canal was used on ten patients, with a two year follow-up (Takahashi *et al.* (2003). A multicentre case series study to evaluate the safety and efficacy of the Secca® system, (a radio-frequency energy treatment) was conducted by Efron *et al.* (2003) and results were published in December 2003. This study appears to be funded by Curon Medical, the manufacturer of the Secca® system. FDA clearance for the Secca® system was granted in March 2002 (Curon Medical 2004) and the device was launched commercially in the USA in June 2002.

Existing comparators:

- Anal sphincter, direct repair
- Sphincteroplasty

Estimated cost impact:

The costs associated with this new procedure are not currently available. The cost of surgery involving direct anal sphincter repair or sphincteroplasty in Australia is also not available. However, reimbursement fees of direct repair of the anal sphincter and Park's intersphincteric procedure as stated in the Medicare Benefits Schedule (item numbers 32126 and 32129) are estimated to be approximately \$400 and \$530 respectively (<http://www.health.gov.au>).



Efficacy and safety issues:

Short and long-term safety and efficacy data on the use of radio-frequency energy to deep mucosa of the anal canal exist from two cases series studies.

Study details	Key efficacy findings	Key safety findings
<p><i>Case series</i></p> <p>Takahashi <i>et al.</i> (2002) 10 patients Follow-up: 1 year</p> <p>Takahashi <i>et al.</i> (2003) Extended follow-up: 2 years</p> <p><i>Selection Criteria</i> Patients with faecal incontinence of varying causes.</p>	<p>At 1 year follow-up 8/10 (80%) patients were considered responders with faecal incontinence quality of life parameters improved (lifestyle (from 2.3 to 3.4), coping (from 1.4 to 2.7), depression (from 2.2 to 3.5) and embarrassment (from 1.3 to 2.8), $P < 0.05$ for all parameters).</p> <p>The median Wexner score (scale for faecal incontinence) improved from 13.5 to 5, $P < 0.001$.</p> <p>At six months post procedure there was a significant reduction in both initial and maximum tolerable rectal distention volumes.</p> <p>At two year follow-up the mean Cleveland Clinic Florida Faecal Incontinence Scale score was improved from 13.8 to 7.3 ($P = 0.002$)</p> <p>There was no statistical significant difference between the quality of life parameters at 12 months and 24 months ($P > 0.2$).</p>	<p>Median discomfort during the procedure by analogue scale was 3.8, and 0.9, two hours after the procedure.</p> <p>Bleeding occurred in 4/10 (40%) patients 14-21 days after the procedure. 3/4 (75%) had spontaneous resolution, with 1/4 (25%) requiring suture ligation.</p> <p>There were no reported long-term complications, such as stricture, pain or constipation.</p>
<p>Efron <i>et al.</i> (2003) 50 patients Follow-up: 6 months</p> <p><i>Selection Criteria</i> Patients with faecal incontinence at least once per week for three months</p>	<p>Mean treatment time 39 ± 9 (SD) minutes.</p> <p>At six months the mean Cleveland Clinic Florida Faecal Incontinence score improved from 14.5 to 11.1 ($P < 0.0001$).</p> <p>All parameters in the Faecal Incontinence Quality of Life Scales were improved, $P < 0.001$ (lifestyle from 2.5-3.1, coping from 1.9 to 2.4, depression from 2.8 to 3.3 and embarrassment from 1.9 to 2.5)</p> <p>Mean Short Form-36 social function improved from 64.3 to 76 ($P = 0.003$)</p>	<p>Complications included mucosal ulceration (1/50 (2%) superficial, 1/50 (2%) with underlying muscle injury) and delayed bleeding 1/50 (2%).</p>



There is limited evidence for the safety and efficacy of the delivery of radio-frequency energy to the anal canal, as a minimally invasive alternative to direct anal sphincter repair or sphincteroplasty. However, the studies conducted have indicated that the procedure may enable improvement of the barrier function of the muscle, whilst resulting in less discomfort and complications, improving the quality of life for patients with faecal incontinence.

Ethical issues: Not applicable

Cultural or religious considerations: Not applicable

Other issues: Not applicable

Conclusion:

Limited evidence exists on the safety and efficacy of the delivery of radio-frequency to the anal canal for the treatment of faecal incontinence. However, long-term safety and efficacy data from randomised controlled trials will be required before this procedure can be widely accepted.

Horizon Scanning Report

Full Health Technology Assessment

Monitor

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References:

Curon Medical - Products

http://www.curonmedical.com/products/secca_training.html [Accessed February 2004]

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Fecal incontinence – updated Dec 2002

<http://www.emedicine.com/med/topic3326.htm> [Accessed February 2004]

Fecal incontinence

http://www.columbiasurgery.org/divisions/colorectal/noncancer_fecal.html [Accessed February 2004]

Parkridge Medical Center

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Takahashi T, Garcia-Osogobio S, Valdovinos MA, Mass W, Jimenez R, Jauregui LA, Bobadilla J, Belmonte C, Edelstein PS, Utley DS. Radio-frequency energy delivery to the anal canal for the treatment of fecal incontinence. *Diseases of the Colon and Rectum* 2002;**45**(7):915-22.



Takahashi T, Garcia-Osogobio S, Valdovinos MA, Belmonte C, Barreto C, Velasco L. Extended two-year results of radio-frequency energy delivery for the treatment of fecal incontinence (the Secca procedure). *Diseases of the Colon and Rectum* 2003;**46**(6):711-15.

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 February 2004.

Search terms used were: ‘fecal incontinence’, ‘faecal incontinence and radio-frequency energy’ and ‘Secca procedure’.