

Title:	Placement of Acticon artificial bowel sphincters in the management of faecal incontinence
Agency:	Medical Services Advisory Committee (MSAC) MDP 106 Commonwealth Department of Health and Ageing GPO Box 9849 Canberra ACT 2601 http://www.msac.gov.au
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Aim:

To assess the safety, effectiveness and cost-effectiveness of the Acticon artificial bowel sphincters (ABS) in the management of severe faecal incontinence relative to colostomy, dynamic graciloplasty or conservative management.

Results and Conclusions:

Safety:

The placement of the Acticon ABS for severe faecal incontinence is associated with a high rate of clinically significant complications including infection, erosion, problematic pain and the requirement for device removal or surgical revision.

No evidence was identified which reported on the comparative safety of the Acticon ABS relative to colostomy.

Evidence from one good quality randomised controlled trial indicated that the Acticon ABS is not as safe as conservative management.

Two fair quality non-randomised comparative studies reported that the Acticon ABS is likely to be as safe as dynamic graciloplasty. However, the latter procedure is also associated with a substantial rate of clinically significant complications.

Effectiveness:

The effectiveness of the Acticon ABS was evaluated in terms of the severity of faecal incontinence and health related quality of life. Assessment was complicated by a lack of intention-to-treat analyses and therefore, the reported data related only to those patients who retained the device.

Published data indicated a reduction in faecal incontinence severity of 27-95 per cent and an improvement in quality of life of 44-77 per cent following implantation of the Acticon ABS.

No evidence was identified which reported on effectiveness outcomes of the Acticon ABS relative to colostomy.

One good quality randomised controlled trial indicated that the Acticon ABS was more effective than conservative management in reducing the severity of faecal incontinence and in improving quality of life.

Two fair quality non-randomised comparative studies indicated that relative to dynamic graciloplasty, the Acticon ABS was more effective in reducing the severity of incontinence and in improving patient's quality of life.

Cost Effectiveness:

Lack of appropriate incremental effectiveness data prevented a formal economic evaluation being performed. A cost comparison of the procedures indicated that the total cost per procedure for the Acticon ABS, dynamic graciloplasty, colostomy and conservative management is \$21,163, \$23,127, \$8,029, and \$984 respectively. The considerable difference

in cost between the device placement procedures (Acticon ABS and dynamic graciloplasty) and the other procedures is mainly due to the cost of the devices and equipment required. The estimated Medicare Benefits Schedule (MBS) cost per procedure for the Acticon ABS, dynamic graciloplasty, colostomy and conservative management is \$2,169, \$2,384, \$2,286 and \$746 respectively.

With the likelihood of only four procedures being performed annually, the total annual cost to the Australian healthcare system of the Acticon ABS is estimated to be \$65,658. The equivalent number of procedures for dynamic graciloplasty, colostomy and conservative management would incur costs of \$71,765, \$26,373 and \$3,698 respectively.

It should be noted that the above analysis does not include costs associated with complications following the placement of the Acticon ABS or dynamic graciloplasty.

Recommendation:

MSAC has considered the safety, effectiveness and cost-effectiveness for implantation of the Acticon artificial bowel sphincter (ABS) compared with conservative management, colostomy and dynamic graciloplasty.

MSAC finds that there is no evidence comparing the Acticon ABS with colostomy and limited evidence comparing it with conservative management and dynamic graciloplasty.

MSAC finds that the evidence suggests that Acticon ABS implantation is not as safe as conservative management and that it is likely to be at least as safe as dynamic graciloplasty.

MSAC finds that the evidence indicates that the Acticon ABS is more clinically effective than both conservative management and dynamic graciloplasty.

MSAC finds that relative cost effectiveness of the Acticon ABS and the comparators could not be assessed due to lack of data. The comparison of the estimated total costs indicates that the cost to the health system for the Acticon ABS is less than for dynamic graciloplasty.

MSAC recommends that public funding is supported for this procedure.

The Minister for Health and Ageing endorsed this recommendation on 11 April 2008.

Methods:

Medline, Embase, The Cochrane Library, and several other biomedical databases, HTA and other internet sites were searched (1996- April 2007). Specific journals were handsearched and reference lists perused. Studies were included in the review using pre-determined PICO selection criteria and reasons for exclusion were documented. Study quality was appraised, data extracted in a standardised manner, and findings synthesised qualitatively.

Prepared by Adelaide Health Technology Assessment (AHTA) on behalf of the MSAC