

Disappointing long-term results of the artificial anal sphincter for faecal incontinence

D. F. Altomare¹, G. A. Binda², G. Dodi³,
F. La Torre⁴, G. Romano⁵, M. Rinaldi¹
and E. Melega³

¹Department of General Surgery and Liver Transplantation, University of Bari, Bari, ²Coloproctological Unit, Galliera Hospital, Genoa, ³Section of Surgical Clinic II, Department of Surgical and Oncologic Sciences, University of Padua, Padua, ⁴Department of Surgical Sciences, University of Rome 'La Sapienza', Rome and ⁵Department of Emergency Surgery, 'S. Moscati' Hospital, Avellino, Italy

Correspondence to: Dr D. F. Altomare, Department of Emergency and Organ Transplantation, Section of General Surgery and Liver Transplantation, University of Bari, Policlinico, piazza G. Cesare 11, 70124 Bari, Italy (e-mail: altomare@clichiru.uniba.it)

Paper accepted 16 March 2004

Published online 7 July 2004 in Wiley InterScience

(www.bjs.co.uk). DOI: 10.1002/bjs.4600

Introduction

Faecal incontinence can severely affect quality of life, but as it has no influence on life expectancy, the long-term efficacy of any treatment must be taken into account. Most reports on new treatments for faecal incontinence describe short-term results and are rarely followed by a later review of the same group of patients; the few long-term reviews of traditional surgery are disappointing. The authors evaluated long-term outcome after implantation of an artificial bowel sphincter (ABS) (Acticon™ Neosphincter ABS; American Medical System, Minnetonka, Minnesota, USA) to determine whether the results tend to worsen with time.

Patients and methods

In a previous report¹, seven of 28 incontinent patients treated with an ABS underwent definitive removal of the device, leaving 21 with a functioning device after a median follow-up of 50 months. An independent observer (G.A.B.), an expert on faecal incontinence but not involved in the ABS implant trial, conducted an interview and clinical examination of these patients. The patients' degree

of satisfaction with the outcome was determined using a visual analogue scale from 1 to 10. Each patient underwent examination and anal manometry. The severity of symptoms was scored using the AMS system², the Continence Grading System (CGS)³ and the constipation scoring system⁴.

Results

A further four patients had the device removed during follow-up, because of mechanical failure (two), late infection (one) or untreatable obstructed defaecation (one). Seventeen of the original 28 patients therefore continued to have an implanted device, of whom 14 were available for long-term evaluation. Five of these 14 patients had a revision operation, four to change the cuff and one to replace the pressure balloon. Eight of the 14 patients no longer activated the pump because of obstructed defaecation (seven) (in one for anal stricture) or anal pain (one). Four patients complained of anal pain. Seven patients scored their degree of satisfaction as 5 or less, and the other seven as 7 or more.

Obstructed defaecation occurred in about half of the patients with a constipation score of 10 or more, and they were unable to defaecate without an enema. Moreover, six of the 14 patients remained incontinent with a CGS score of 10 or more and an AMS score of 70 or greater. However, the AMS score decreased significantly in the 14 patients from a median of 94 to 69. Two patients complained of both constipation and incontinence. Overall, only three of the initial 25 patients for whom follow-up was available had a good functional result, whereas eight (including five constipated patients without incontinence) were fully continent.

Anal manometry was performed in four of the six patients who continued to activate the pump. Mean anal pressure was 20 mmHg with the anal cuff empty and 50 mmHg when activated.

Discussion

Enthusiasm for any new technique often leads to overemphasis of the results, and early reports are usually good. The history of the ABS is no exception and early success rates ranging from 60 to 80 per cent were reported, although most authors expressed concern over the high risks of infection and cuff erosion, and the high reoperation rate.

Only two long-term reports are available to date^{5,6}. In the first⁵, eight of 17 patients had a functioning ABS at least

The Editors have satisfied themselves that all authors have contributed significantly to this publication

5 years after implantation. However, only four patients had achieved good continence and one needed regular enemas. The second study⁶ reported the outcome in a group of ten patients with a median follow-up of 91 months and a second group of 35 patients with a median follow-up of 39 months. The rate of device explantation was four of ten in the first group and 17 of 35 in the second (overall 21 of 45). Two patients in the first group remained incontinent and one had outlet obstruction. Four patients in the second group had constipation requiring surgery. No information was given about deactivation of the ABS or about obstructed defaecation.

In the present study, obstructed defaecation was a frequent problem that led several patients to deactivate the pump. Together with the manometric findings of low anal canal resting pressure, even with the device activated, this suggests that the ABS may function as a passive obstacle to the passage of faeces in the long term, like Thiersch's sling, rather than as a dynamic sphincter. Furthermore, the ABS, like any foreign matter placed in the human body, may displace or erode, either to the rectum or to the perineum.

Overall, the present study shows that the results of anal sphincter replacement using an ABS dynamic prosthesis

deteriorate with time and that the long-term results may not be as good as reported previously.

References

- 1 Altomare DF, Dodi G, La Torre F, Romano G, Melega E, Rinaldi M. Multicentre retrospective analysis of the outcome of artificial anal sphincter implantation for severe faecal incontinence. *Br J Surg* 2001; **88**: 1481–1486.
- 2 Wong WD, Congliosi SM, Spencer MP, Corman ML, Tan P, Opelka FG *et al*. The safety and efficacy of the artificial bowel sphincter for fecal incontinence: results from a multicenter cohort study. *Dis Colon Rectum* 2002; **45**: 1139–1153.
- 3 Jorge JMN, Wexner SD. Etiology and management of fecal incontinence. *Dis Colon Rectum* 1993; **36**: 77–97.
- 4 Agachan F, Chen T, Pfeifer J, Reissman P, Wexner SD. A constipation scoring system to simplify evaluation and management of constipated patients. *Dis Colon Rectum* 1996; **39**: 681–685.
- 5 Christiansen J, Rasmussen OO, Lindorff-Larsen K. Long-term results of artificial anal sphincter implantation for severe anal incontinence. *Ann Surg* 1999; **230**: 45–48.
- 6 Parker SC, Spencer MP, Madoff RD, Jensen LL, Wong WD, Rothenberger DA. Artificial bowel sphincter: long-term experience at a single institution. *Dis Colon Rectum* 2003; **46**: 722–729.