Journal of Zhejiang University-SCIENCE B (Biomedicine & Biotechnology)
ISSN 1673-1581 (Print); ISSN 1862-1783 (Online)
www.zju.edu.cn/jzus; www.springerlink.com
E-mail: jzus@zju.edu.cn

Review:

Challenges faced in the clinical application of artificial anal sphincters*

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Received Sept. 10, 2014; Revision accepted Aug. 4, 2015; Crosschecked Aug. 17, 2015

Abstract: Fecal incontinence is an unresolved problem, which has a serious effect on patients, both physically and psychologically. For patients with severe symptoms, treatment with an artificial anal sphincter could be a potential option to restore continence. Currently, the Acticon Neosphincter is the only device certified by the US Food and Drug Administration. In this paper, the clinical safety and efficacy of the Acticon Neosphincter are evaluated and discussed. Furthermore, some other key studies on artificial anal sphincters are presented and summarized. In particular, this paper highlights that the crucial problem in this technology is to maintain long-term biomechanical compatibility between implants and surrounding tissues. Compatibility is affected by changes in both the morphology and mechanical properties of the tissues surrounding the implants. A new approach for enhancing the long-term biomechanical compatibility of implantable artificial sphincters is proposed based on the use of smart materials.

Key words: Fecal incontinence (FI), Artificial anal sphincter (AAS), Biomechanical compatibility, Smart materials
doi:10.1631/jzus.B1400242 **Document code:** A **CLC number:** R322.4^{+}6

1 Introduction

Fecal incontinence (FI) caused by sphincter dysfunction is a difficult medical problem, which has not been fully resolved. It can cause enormous psychological trauma and extreme discomfort for patients, and has afflicted humans for thousands of years. FI is the inability to control the passage of feces through the anus (Madoff *et al.*, 2004; Rao, 2004; Rojas *et al.*, 2014), and morbidity increases with advancing age. It is estimated that about 1.4% of adults (Perry *et al.*, 2002; Walter *et al.*, 2002), 6%–7% of elderly people, and 10% of patients in elderly nursing homes suffer from FI (Tobin and Brocklehurst, 1986; Madoff *et al.*, 2004; Teunissen *et al.*, 2006; Tan *et al.*, 2007). However, it is difficult to establish its true prevalence (Madoff *et al.*, 2004; Rojas *et al.*, 2014).

From a medical perspective, treatment methods for FI include nonsurgical and surgical treatments. Most patients prefer nonsurgical treatment, such as drug therapy or biofeedback, and surgical treatments, such as sacral nerve stimulation, sphincteroplasty, postanal repair, dynamic graciloplasty, or colostomy, are chosen only when nonsurgical treatments are ineffectual (Baig and Wexner, 2000; Tan *et al.*, 2007). Surgical repairs usually achieve only a remission of symptoms. Therefore, the medical methods are not effective enough to manage the symptoms of FI (Kaiser *et al.*, 2014; Mitchell and Sagar, 2014; Nandivada and Nagle, 2014).

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* Project supported by the Shanghai Pujiang Program (No. 09PJ1406500), the National Natural Science Foundation of China (Nos. 30970704, 51075263, 51121063, and 50821003), and the Foundation from the State Key Laboratory of Mechanical Systems and Vibration (No. MSVZD201203), China

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From an engineering perspective, an artificial device replacing the sphincter is a potential treatment method. The history of research on artificial sphincters dates back more than half a century. Initially, artificial urinary sphincters were studied, and the clinical application of such sphincters achieved by American Medical Systems (AMS) inspired some researchers to use similar devices for treating anal incontinence. The study by Christiansen and Lorentzen (1987) was the first to attempt using an AMS800 artificial urinary sphincter to treat FI, and subsequently this device was modified to meet the demands of a bowel sphincter (strengthened cuff-tab, wider cuffs, and an enlarged pressure regulating balloon). Eventually, a specific artificial anal sphincter (AAS), the Acticon Neosphincter (AMS, Minnetonka, MN, USA), was designed. In 1999, the device received a humanitarian device exemption of US Food and Drug Administration (FDA) and was formally FDA-approved in 2001 (Gregorcyk, 2005). The device has been implanted in many patients.

The Acticon Neosphincter consists of three components integrated by kink-resistant tubing: an inflatable cuff placed around the anus, a manual control pump placed under the skin of the scrotum in males or labia in females, and a pressure-regulating balloon implanted extraperitoneally (Fig. 1). The purpose of the device is to take over from the muscle to control the opening and closing of the anus (AMS, 1999).

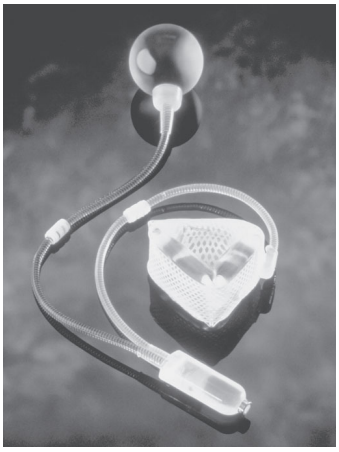

Fig. 1 Acticon Neosphincter

American Medical Systems, Inc., Minnetonka, MN, USA (https://pelvichealthsource.com/content/dam/wph/us-region/en/documents/labeling/fecal-incontinence/1006168.r03_ORMan_Acticon_en.pdf)

When a patient wishes to defecate, the bulb on the control pump is manually squeezed and released several times. This transfers the fluid from the cuff to the balloon through the tube, thereby deflating the cuff and allowing the stool to pass. Pressure from the balloon slowly forces the fluid back into the cuff over several minutes, and consequently closes the anus (AMS, 1999).

In this paper, the outcomes of the clinical application of the AMS series sphincter, in terms of both safety and efficacy, will be summarized. Some of the main researches on devices intended to achieve the continence of feces will also be discussed. Maintaining long-term biomechanical compatibility between the artificial sphincter and the surrounding tissue is the key problem of AAS in clinical application. A novel concept involving embedding smart material in the device to improve its biomechanical compatibility will be presented.

2 Results of the clinical application of the AMS series sphincter

The clinical application of AAS has been studied by many experts, and this paper summarizes and analyzes the most important 24 studies from 1996 to 2010 (Lehur *et al.*, 1996; 1998; 2000; 2002; Wong *et al.*, 1996; 2002; Vaizey *et al.*, 1998; Christiansen *et al.*, 1999; Dodi *et al.*, 2000; Malouf *et al.*, 2000; O'Brien and Skinner, 2000; Altomare *et al.*, 2001; 2004; Devesa *et al.*, 2002; Ortiz *et al.*, 2002; Michot *et al.*, 2003; Parker *et al.*, 2003; Romano *et al.*, 2003; Casal *et al.*, 2004; O'Brien *et al.*, 2004; Ruiz Carmona *et al.*, 2009; Gallas *et al.*, 2009; Meurette *et al.*, 2009; Chittawatanarat *et al.*, 2010). These studies focused chiefly on results from the clinical application of the AMS series sphincter (the unmodified AMS800, the modified version of the AMS800, and the final version, the Acticon Neosphincter) from the point of view of safety and efficacy. The longest follow-up period was 10 years after implantation (Christiansen *et al.*, 1999) and the shortest was only 6 months (O'Brien *et al.*, 2004). The largest case included 115 patients (Wong *et al.*, 2002) and the smallest only 6 (Chittawatanarat *et al.*, 2010). Five of the studies are considered to be of high quality, among which four were carried out by Lehur *et al*. (1996; 1998; 2000; 2002), in whose research the selected patients were

continuous, and one by Wong *et al.* (2002), which is the largest study with 115 patients.

2.1 Safety

2.1.1 Explantation

Twenty-two papers (Lehur *et al.*, 1996; 1998; 2000; 2002; Wong *et al.*, 1996; 2002; Vaizey *et al.*, 1998; Christiansen *et al.*, 1999; Dodi *et al.*, 2000; Malouf *et al.*, 2000; O'Brien and Skinner, 2000; Altomare *et al.*, 2001; 2004; Devesa *et al.*, 2002; Ortiz *et al.*, 2002; Michot *et al.*, 2003; Parker *et al.*, 2003; Casal *et al.*, 2004; O'Brien *et al.*, 2004; Ruiz Carmona *et al.*, 2009; Gallas *et al.*, 2009; Chittawatanarat *et al.*, 2010) reported data about the explantation rate of the device, which varied between 14% and 65% (Ruiz Carmona *et al.*, 2009). In four papers of Lehur *et al.* (1996; 1998; 2000; 2002), the explantation rates were 23%, 31%, 29%, and 31%, respectively. In the paper of Wong *et al.* (2002), the rate was 37%. The reason that explants were required varied among patients. The most common reason was infection, followed by erosion, as well as the coexistence of infection and erosion. Mechanical complications were also common. Other reasons included pain, faulty devices, and dissatisfaction of the patients (Mundy *et al.*, 2004).

2.1.2 Surgical revision

Fifteen papers (Lehur *et al.*, 1998; 2000; 2002; Christiansen *et al.*, 1999; Malouf *et al.*, 2000; O'Brien and Skinner, 2000; Altomare *et al.*, 2001; 2004; Devesa *et al.*, 2002; Wong *et al.*, 2002; Parker *et al.*, 2003; O'Brien *et al.*, 2004; Ruiz Carmona *et al.*, 2009; Gallas *et al.*, 2009; Meurette *et al.*, 2009) reported data about surgical revision, which varied between 13% (Lehur *et al.*, 2002) and 65% (Ruiz Carmona *et al.*, 2009). In three papers of Lehur *et al.* (1998; 2000; 2002), the frequencies of surgical revision were 46%, 38%, and 13%, respectively. In the paper of Wong *et al.* (2002), 51 of 97 patients underwent 73 revision surgeries. Infection, erosion, and mechanical malfunction were the main reasons for surgical revision. Other causes included fecal impaction, pain, and rupture of the perineal wound (Mundy *et al.*, 2004).

2.1.3 Infection

Seventeen papers (Lehur *et al.*, 1996; 1998; 2000; Wong *et al.*, 1996; 2002; Vaizey *et al.*, 1998; Christiansen *et al.*, 1999; Dodi *et al.*, 2000; Malouf *et al.*, 2000; O'Brien and Skinner, 2000; Altomare *et al.*, 2001; Devesa *et al.*, 2002; Ortiz *et al.*, 2002; Parker *et al.*, 2003; Casal *et al.*, 2004; Ruiz Carmona *et al.*, 2009; Chittawatanarat *et al.*, 2010) reported the infection rate, which varied between 4% (Lehur *et al.*, 2000) and 50% (Chittawatanarat *et al.*, 2010). In three papers of Lehur *et al.* (1996; 1998; 2000), the frequencies of infection were 15%, 8%, and 4%, respectively. In the paper of Wong *et al.* (2002), 38 of 112 patients were infected, and 28 of the 38 patients needed surgical revision.

The location of early infection produced before activation of the device involved mainly the perineum or abdomen. Post-activation infections were caused mainly by the erosion of the device. As the location of the artificial sphincter implant is in the anorectal region, the risk of infection is much larger than that of other operations (Christiansen, 2000; Mundy *et al.*, 2004).

2.1.4 Erosion

Sixteen papers (Lehur *et al.*, 1996; 1998; 2000; 2002; Vaizey *et al.*, 1998; Dodi *et al.*, 2000; Malouf *et al.*, 2000; O'Brien and Skinner, 2000; Altomare *et al.*, 2001; Devesa *et al.*, 2002; Ortiz *et al.*, 2002; Wong *et al.*, 2002; Michot *et al.*, 2003; Casal *et al.*, 2004; Ruiz Carmona *et al.*, 2009; Chittawatanarat *et al.*, 2010) reported the frequency of erosion, which varied between 6% (Lehur *et al.*, 2002) and 33% (Chittawatanarat *et al.*, 2010). In four papers of Lehur *et al.* (1996; 1998; 2000; 2002), the frequencies were 8%, 8%, 17%, and 6%, respectively. In the paper of Wong *et al.* (2002), the frequency was 21%. Erosion of the anal canal was most frequent, followed by cuff erosion, pump erosion, pipe erosion, rectum erosion, and erosion of other components. The causes of erosion might be infection, organizational pressure, repeated straining during defecation, inappropriate cuff size, the choice of balloon, or tissue damage.

2.1.5 Mechanical complications

Nine papers (Lehur *et al.*, 1996; Wong *et al.*, 1996; Christiansen *et al.*, 1999; Devesa *et al.*, 2002; Ortiz *et al.*, 2002; Michot *et al.*, 2003; Altomare *et al.*, 2004; Casal *et al.*, 2004; Ruiz Carmona *et al.*, 2009) mentioned mechanical complications, the frequency of which varied between 2% (Devesa *et al.*, 2002) and

29% (Ruiz Carmona *et al.*, 2009). The mechanical failure rate reported by Lehur *et al*. (1996) was 23%. These complications included rupture of the cuff, loss of fluid from the system, disconnection of any component, and malfunction or migration of the control pump. The main causes were the complexity of the device and the connectivity of its components.

2.1.6 Other complications

Evacuation difficulties were experienced by 83% of patients (Vaizey *et al.*, 1998). The frequencies of evacuation difficulties reported in three papers of Lehur *et al*. (1996; 2000; 2002) were 31%, 38%, and 31%, respectively. However, causes of this problem are still unclear. A short cuff and a short opening time of the device are correlated with poor emptying of the rectum (Savoye *et al.*, 2000; Michot *et al.*, 2003).

Other frequent complications included tissue ischemia, fecal obstruction, constipation, pain, rectal prolapse, fever, and hematoma.

2.2 Efficacy

2.2.1 Fecal incontinence score

Fifteen papers (Wong *et al.*, 1996; 2002; Lehur *et al*., 1998; 2000; 2002; Vaizey *et al*., 1998; Christiansen *et al.*, 1999; Dodi *et al.*, 2000; O'Brien and Skinner, 2000; Altomare *et al.*, 2001; Parker *et al.*, 2003; Romano *et al.*, 2003; Casal *et al.*, 2004; O'Brien *et al.*, 2004; Chittawatanarat *et al.*, 2010) used a fecal incontinence score (FIS) to assess the severity of incontinence of patients. Four scoring systems were adopted: Williams Scale (WS), AMS Fecal Incontinence Score (AMSFIS), Cleveland Continence Score (CCS), and Wexner Continence Grading Score (WCGS) (Jorge and Wexner, 1993; Vaizey *et al.*, 1999; Mundy *et al.*, 2004), as shown in Table 1.

Table 1 Fecal incontinence score (FIS)

FIS system	Normal continence score	Complete incontinence score	Number of articles using FIS
WS	0	5	1
AMSFIS	0	120	7
CCS	0	20	3
WCGS	0	20	4

WS: Williams Scale; AMSFIS: AMS Fecal Incontinence Score; CCS: Cleveland Continence Score; WCGS: Wexner Continence Grading Score

Lehur *et al*. (2000; 2002) used AMSFIS. The mean score decreased significantly from 106 (standard deviation (SD), 13) and 105 (SD, 14) in the preoperative stage, to 25 (SD, 25) and 23 (SD, 22) at the end of the follow-up period, respectively. The difference between the preoperative and postoperative stages was statistically significant ($P<0.05$). In another article using CCS (Lehur *et al*., 1998), the mean score decreased significantly from 17 (range, 14–20) in the preoperative stage to 4 (range, 0–10) at the end of the study. In the study of Wong *et al*. (2002), the AMSFIS decreased from a median of 106 (range, 71–120) preoperatively to 48 (range, 0–120) at 12 months after implantation. Statistical analysis revealed that the differences between the mean preimplantation FISs and those at 12-month follow-up were statistically significant ($P<0.0001$). In all studies, the difference between the preoperative mean score and the postoperative mean score was quite large, i.e., FI had greatly improved, but the average score did not reflect the efficacy of the device.

2.2.2 Quality of life

Twelve studies (Wong *et al.*, 1996; Vaizey *et al.*, 1998; O'Brien and Skinner, 2000; Altomare *et al.*, 2001; 2004; Lehur *et al.*, 2002; Parker *et al.*, 2003; Romano *et al.*, 2003; O'Brien *et al.*, 2004; Ruiz Carmona *et al*., 2009; Meurette *et al*., 2009; Chittawatanarat *et al.*, 2010) assessed the quality of life (QL) and ten of those (Vaizey *et al.*, 1998; O'Brien and Skinner, 2000; Altomare *et al.*, 2001; 2004; Lehur *et al.*, 2002; Parker *et al.*, 2003; O'Brien *et al.*, 2004; Ruiz Carmona *et al.*, 2009; Meurette *et al.*, 2009; Chittawatanarat *et al.*, 2010) used one of the following scores: the AMS Quality of Life Scale (AMSQLS), Rockwood FI Quality of Life Score (RFIQLS), Short-Form 36 Questionnaire (SF-36), or the Beck Depression Inventory (BDI) (Wong *et al.*, 1996; Lustman *et al.*, 1997; Lehur *et al.*, 2002; O'Brien *et al.*, 2004; Meurette *et al.*, 2009). The other two studies (Wong *et al.*, 1996; Romano *et al.*, 2003) assessed QL by questionnaire. All these FI quality of life scores showed a significant improvement from the preoperative to postoperative stages. In particular, Lehur *et al.* (2002) reported a significant improvement from a median of 0.44 (preoperative) to 0.84 (at the end of follow-up) with RFIQLS. The difference between the preoperative and postoperative values was statistically significant ($P<0.05$).

2.2.3 Anal manometry

Anorectal pressure is generally used to assess sphincter function, and the resting anal pressure reflects the function of the internal sphincter. Seventeen papers (Lehur *et al.*, 1996; 1998; 2000; 2002; Wong *et al.*, 1996; 2002; Vaizey *et al.*, 1998; Dodi *et al.*, 2000; Altomare *et al.*, 2001; 2004; Devesa *et al.*, 2002; Ortiz *et al.*, 2002; Michot *et al.*, 2003; Romano *et al.*, 2003; Casal *et al.*, 2004; Ruiz Carmona *et al.*, 2009; Chittawatanarat *et al.*, 2010) measured the anal pressure. The lowest mean resting anal pressure before operation was 16 mmHg (1 mmHg=0.133 kPa), and the corresponding postoperative resting pressure was 68 mmHg (Wong *et al.*, 1996). In three papers, Lehur *et al*. (1998; 2000; 2002) reported both preoperative and postoperative pressures and in one paper of Lehur *et al.* (1996) only postoperative values were given. Preoperative and postactivated pressures were also reported by Wong *et al*. (1996; 2002). The detailed data are shown in Table 2. The difference between preoperative and postoperative anorectal pressures was statistically significant (P<0.0001). The increase in pressure indicates an improvement in function, but a strong correlation between pressure and continence has not been confirmed.

2.2.4 Success rate of the device

Twenty-two papers, in addition to another two papers (Romano *et al.*, 2003; Meurette *et al.*, 2009), reported the success rate of the device, i.e. the proportion of functional devices, which varied between 6% (O'Brien *et al.*, 2004) and 75% (Altomare *et al.*, 2001). In the papers of Lehur *et al*. (1996; 1998; 2000; 2002), the proportions were 77%, 85%, 83%, and 75%, respectively, and in the paper of Wong *et al*. (2002), the proportion was 67%. The success rate of the device was not low; however, the function of some devices decreased gradually with time.

The clinical applications presented in the aforementioned papers show that patients suffered from a variety of postoperative complications, including infection, erosion, mechanical failure, tissue ischemia, and evacuation difficulty. These resulted in a lot of re-operations, even a large proportion of explants. With regard to efficacy, there was a large difference between preoperative and postoperative FISs but this does not necessarily indicate that the effectiveness of the device was maintained. In addition, there was a significant improvement between preoperative and postoperative quality of life scores in patients with functional devices, but in explanted patients this was not reported. The increase in pressure indicates an improvement in function, but correlation between pressure and continence is still unclear. The success rate of the device was high but its function decreased gradually with time. Generally, the device does not maintain long-term efficacy. Some new AAS devices have now been developed.

3 New studies on artificial anal sphincters

3.1 German Artificial Sphincter System

H. Schrag, from the University of Freiburg, has developed the German Artificial Sphincter System. The prosthesis employs elastic compression cuffs inside a rigid carrier ring and reservoir cuffs at its outer side. A bidirectional silicon micropump transports body compatible liquid between both cuff systems (Fig. 2a). The new concept benefits from high integration of all functional components into one device. Thus, an easy surgical implantation technique and low risk of infection can be achieved (Schrag *et al.*, 2004; Doll *et al.*, 2006; 2007). To fulfill the rigid criteria for therapy transfer and minimally invasive implantation, the various functional components of the system were redesigned. The redesign comprises the aggregation of all electric and mechanical components into one central unit (Fig. 2b) (Ruthmann *et al.*, 2010).

Table 2 Preoperative and postoperative anorectal pressures

Author	Preoperative mean pressure	Postoperative mean pressure
Lehur *et al.* (1998)	41 (SD, 10) cmH_2O (=30 (SD, 7) mmHg)	48 (SD, 10) cmH_2O (=35 (SD, 7) mmHg, cuff opened); 72 (SD, 7) cmH_2O (=53 (SD, 5) mmHg, cuff closed)
Lehur *et al.* (2000)	28 (range, 5–76) mmHg	30 (range, 9–65) mmHg (cuff opened); 60 (range, 38–96) mmHg (cuff closed)
Lehur *et al.* (2002)	42 (SD, 24) cmH_2O (=31 (SD, 18) mmHg)	35 (SD, 27) cmH_2O (=26 (SD, 20) mmHg, cuff opened); 98 (SD, 23) cmH_2O (=72 (SD, 17) mmHg, cuff closed)
Wong *et al.* (2002)	26 (range, 0–70) mmHg	46 (range, 14–77) mmHg (at the 12th month post-activation)

1 cmH_2O=0.098 kPa; 1 mmHg=0.133 kPa

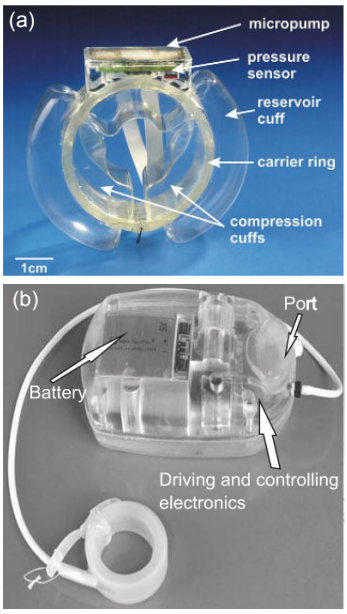

Fig. 2 German artificial sphincter system (a) and Modified prosthesis design (b)
(a) Reprinted from ref. (Doll *et al.*, 2006), Copyright 2005, with permission from Elsevier; (b) Reproduced from ref. (Ruthmann *et al.*, 2010) by permission of John Wiley and Sons

3.2 Prosthetic anal sphincter

To minimize local compression on the rectal wall, a "pillow-type" device has been developed by C.A. Hajivassiliou (Department of Paediatric Surgery, Royal Hospital for Sick Children, UK). This reproduces the action of the puborectalis by flattening and angulating the bowel muscle (Fig. 3). The design aims to reduce the stress concentration effect and overcome the risk of ischaemic complications by simulating the normal physiology of the anorectum, but the mechanical interaction between the artificial sphincter and the tissues was not discussed (Finlay *et al.*, 2004).

3.3 AAS system with sensor feedback

The research team from the School of Electrical Engineering (SEE), Shanghai Jiao Tong University (SJTU), China, has presented a highly integrated and easily implantable sphincter prosthesis with sensor feedback based on transcutaneous energy transmission. It comprises mainly a reservoir, a front cuff, a sensor cuff, and a micropump with motor gear (Fig. 4) (Zan *et al.*, 2008). Another developed AAS system is a novel machine-electrical-hydraulic muscle system that consists of an external telemetry unit, an internal AAS, and a transcutaneous energy transfer system. Its efficiency in achieving continence was confirmed *in vitro* and *in vivo* in a pig model (Ke *et al.*, 2014a; 2014b). A colonic blood flow model was presented and the electromagnetic effects on the biological tissue surrounding the transcutaneous transformer were studied (Zan *et al.*, 2008; 2010).

Fig. 3 Pillow-type prosthetic anal sphincter
Reproduced from ref. (Finlay *et al.*, 2004) by permission of John Wiley and Sons

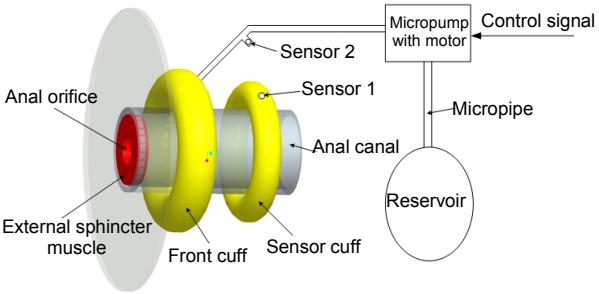

Fig. 4 Structure of AAS
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3.4 Tohoku University artificial sphincter system

Yun Luo (presently employed by SJTU) of Tohoku University proposed a novel AAS with a simple structure, using shape memory alloy (SMA). The basic design of the device is to use two elements implanted inside the body: an SMA based artificial sphincter and a secondary coil (Fig. 5) (Luo *et al.*, 2006). Although the dimensions of the artificial sphincter are comparable to those of the silicone cuff in the AMS800, the secondary coil is disk-like and drastically reduces the volume of the implant. This enables the new device to be promoted as a low invasive prosthesis. In addition, it is expected to have enhanced reliability and durability due to the simplicity of the mechanism driving the device (Luo *et al.*, 2004; 2006; Liu *et al.*, 2007).

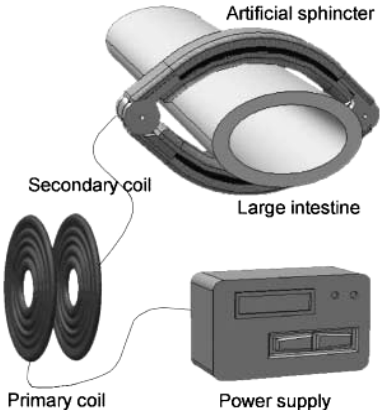

Fig. 5 Novel artificial sphincter using shape memory alloys and transcutaneous energy transmission technologies
Reprinted from ref. (Luo *et al.*, 2006) by permission of Taylor & Francis (http://www.tandfonline.com)

4 Discussion

To find the reason for the limited application of AAS and establish its rightful position in treating FI, the safety and efficacy of AAS were assessed based on 24 papers about their clinical application.

Some serious shortcomings were identified in the statistical analysis reported in these papers. First of all, assessments were based on a small number of case studies, and could not provide sufficient evidence. The number of postoperative complications was unclear, patients were not randomly selected, and the lack of control groups reduced the reliability of the results. Most papers gave only the average values of the study group, not the data for each patient. Secondly, the number of patients studied was too small. The sample number in several studies was only six, seven, or eight patients. In addition, the follow-up period was too short, with a minimum of only 6 months. There were no follow-up results on failure of operation or device explantation. Whether unsuccessful surgeries may have physical or physiological effects on the patients was unclear. There was a lack of long term data on safety and efficacy. Finally, there was no uniform standard to define whether the technology was a success or failure. For example, the effect on continence was evaluated using four different scoring systems (WS, AMSFIS, CCS, and WCGS), and the QL using four different scoring systems (AMSQLS, RFIQLS, SF-36, and BDI).

Although the data have many shortcomings, general conclusions about the efficacy and safety of artificial sphincters can still be drawn.

As far as efficacy is concerned, all studies showed that the average FIS of patients with effective devices was significantly decreased after device implantation. However, there was no strong relationship between the average score and the number of patients with an effective device. The QL of patients with effective devices improved considerably after device implantation, but the QL of patients with failed surgery and device explantation was not reported. The difference in the anal resting pressure between the preoperative and postoperative stages was statistically considerable, but no correlation between pressures and continence could be confirmed. This kind of device is effective for patients who retain the device without major complications. However, the function gradually degenerates with time. Therefore, there is not enough evidence to prove that the device is effective in the long term.

As far as safety is concerned, the device also has many problems. The operation causes a wide range of complications, such as infection, erosion, tissue ischemia, mechanical failure, and evacuation difficulties. In all studies, infection was obvious and spread to some components or the entire device. The location of infection was mainly around the anus, and the high infection rate was due mainly to the use of prosthetic material in the anoperineal area. Erosion was located mainly in the anal, rectal, cuff, pump, pipe, or other component parts. There were many causes of erosion, such as organizational pressure, infections, inappropriate cuff size, the choice of balloon, tissue damage, a change in the position of elements, and repeated defecation straining. Among these reasons, organizational pressure was the most important. Tissue ischemia was another common complication, and its main cause was that the pressure of the artificial sphincter was too high. Mechanical complications were also common, including rupture of the cuff, loss of system fluid, disconnection of any component, and malfunction or migration of the control pump. The main causes were the complexity of the device and the connectivity of its components. Another complication was the incidence of evacuation difficulties. These may be caused by the circumference of the cuff being too small or the time during which the sphincter is open being too short. Other complications were

pain, rectal prolapse, fever, and hematoma. Many complications result in surgical revision. The incidence of complications shows that the artificial sphincter can have side-effects on patients.

A perfect anal sphincter should be effective and reliable, easy to operate, and cause no harm to patients. Therefore, the current artificial sphincter cannot be widely used as a safe and effective device in clinical application. The main reason is the high infection rate, which goes hand in hand with the significant rate of explantation. Some new devices have been developed to achieve long-term safety and efficacy. The newly developed German Artificial Sphincter System is a highly integrated and efficient prosthesis with a very low risk of intestinal ischemic injury (Doll *et al*., 2006). C.A. Hajivassiliou developed a prosthetic anal sphincter, which aims to reduce stress concentration (Finlay *et al*., 2004). However, the mechanical interaction between the artificial sphincter and the tissues was not reported. The research team from SEE, SJTU highly integrated all the components with sensor feedback to make surgical implantation easy and at low risk (Zan *et al*., 2008). Yun Luo developed an AAS device with a reduced number of parts and a compact structure for a less invasive prosthesis (Luo *et al*., 2006). In preliminary studies, Yun Luo found that the thickness of tissue around the implant was changed dramatically by a stress shielding effect caused by the large mechanical stimulus. The stress shielding effect makes the force between the implant and its surrounding tissues unbalanced, causing the device to be ineffective and leading to ischemic necrosis and tissue atrophy. Therefore, the most critical issue of AAS is to maintain long-term biomechanical compatibility between the artificial sphincter and the surrounding tissue in clinical applications.

This paper presents a novel concept involving embedding smart materials in a device to improve biomechanical compatibility. Our research group is studying the use of the mechanical properties of smart materials to develop a device that remains functional under changing mechanical properties caused by the stress shielding effect and that will not damage the intestinal tissue.

5 Conclusions

Our assessment of studies on the safety and efficacy of the AMS series sphincter shows that the results are unsatisfactory. In terms of safety, the devices cause a high rate of explantation and surgical revision. The high frequency of infection, erosion, and tissue ischemia could harm patients. In terms of efficacy, there is insufficient evidence to prove that the devices can maintain a long-term functional status. Against this background, some new devices have been developed to solve the safety and efficacy issues. However, so far, no device can successfully realize the clinical application. Implantation of an artificial sphincter may lead to morphological change in the surrounding tissues. Related biomechanical imbalance could result in the loss of effectiveness of the device and various complications. Therefore, we conclude that maintaining long-term biomechanical compatibility between implants and their surrounding tissues is the key issue for achieving permanent continence in the human body. The proposed method using smart materials in the device may improve biomechanical compatibility.

Compliance with ethics guidelines

Ming-hui WANG, Ying ZHOU, Shuang ZHAO, and Yun LUO declare that they have no conflict of interest.

This article does not contain any studies with human or animal subjects performed by any of the authors.

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中文概要

题　目：人工肛门括约肌临床应用所面临的挑战

概　要：本文对目前临床使用的人工括约肌的安全性与有效性进行分析与讨论，对国内外目前正在开发的新装置和新方法进行比较，归纳出人工肛门括约肌在临床应用中遇到的关键问题是维持植入体与周围生物组织的远期力学相容性，该问题有望通过智能材料的利用得到解决。

关键词：大便失禁；人工肛门括约肌；生物力学相容性；智能材料