A Prospective Randomised Controlled Clinical Trial of Placement of the Artificial Bowel Sphincter (Acticon

Running Title: RCT of the ABS and Fecal Incontinence

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Abstract

Background  Severe fecal incontinence remains a disabling condition for the patient and a major therapeutic challenge for the physician. A series of observational studies have indicated that the placement of the artificial bowel sphincter (ABS) is associated with marked improvement of continence and quality of life. We have performed a prospective randomised controlled trial to evaluate the ABS (Acticon Neosphincter®, American Medical Systems) on continence and quality of life in a group of severe incontinent adults.

Methods  Fourteen adults (M:F 1:13; age range 44 – 75) were randomised to placement of the ABS or to a program of supportive care and were followed for 6 months from operation or entry into the study. The principal outcome measure was the level of continence, measured using the Cleveland Continence Score (CCS) which provides a scale from 0 – 20 representing perfect control through to total incontinence. Secondary outcome measures were perioperative and late complications in the ABS group, and the changes in quality of life in both groups.

Results  In the control group, the CCS was not significantly altered with an initial value of 17.1 +/- 2.3 and a final value of 14.3 +/- 4.6 at 6 mth. The ABS group showed a highly significant improvement changing from 19.0 +/- 1.2 before placement to 4.8 +/- 4.0 at 6 mth after placement. One patient in the ABS group had failure of healing of the perineal wound and explantation of the device (14% explantation rate). There were two other significant perioperative events of recurring faecal impaction initially after placement in one patient and additional suturing of the perineal wound in another. There were major improvements in the quality of life for all measures in the ABS group. There was significant improvement in all 8 subscales of the SF-36 measures. The AMS quality of life score was raised from 39 +/- 6 to 83 +/- 14 and the Beck Depression Inventory showed reduction from a level of mild depression (10.8 +/- 9.3) to a normal value (6.8 +/- 8.7). No significant changes in any of the quality of life measures occurred for the control group.
Conclusions Using a prospective randomised trial format, we have shown that the placement of the ABS is safe and effective when compared with supportive care alone. Perioperative and late problems are likely to continue to occur and between 15 – 30% may require permanent explantation. For the remainder, the device is easy and discrete to use, highly effective in achieving continence and able to generate a major improvement in the quality of life.

Introduction

There are few more embarrassing events than to be incontinent of feces in public. The fear of such an event drives those at risk to severely limit their activity. They restrict their involvement in work, social interaction and physical activity. The reported prevalence varies widely, depending on the population studied and the methods used. Cross-sectional surveys of randomly selected adult subjects from the general community have reported a prevalence of 0.9 % to 15% with a median value of 3.6%\(^1\)\(^-\)\(^7\). Increased prevalence is associated with age, female sex and obstetric history including parity and mode of delivery.

The management options include modifying bowel activity with diet and medication, lifestyle changes to minimize the risk of incontinence in public, physiotherapy for the pelvic floor muscles and biofeedback techniques. If such methods are insufficient then surgical techniques need to be considered. These include direct repair of anal sphincter disruptions, post anal repair of the sphincter, replacement of the sphincter function by an artificial bowel sphincter or dynamic graciloplasty, anal encirclement procedures, sacral nerve stimulation, radiofrequency-induced thickening of the anal canal (Secca procedure), and colostomy.

For patients with a clear defect in the external anal sphincter and intact pudendal nerves, direct repair provides a high likelihood of success\(^8\) and is the procedure of choice. Postanal repair is now generally regarded as providing marginal benefit\(^8\) and therefore the patient with severe disease but unsuitable for direct repair would need to consider sphincter replacement. Two techniques of dynamic graciloplasty and placement of the artificial bowel sphincter are available. Dynamic graciloplasty has been an option for more than 15 years\(^9\) and has been shown through single and multicentre observational studies to provide objective and durable improvement in the degree of incontinence\(^8\),\(^10\).
However, broad acceptance has not occurred due to technical problems and high reoperation rates. Extensive observational studies have become available over the past 5 years reporting the use of the artificial bowel sphincter\textsuperscript{12-19} (Table 1-3) and indicate a major improvement in continence. Insufficient data are thus far available to evaluate the use of RF energy\textsuperscript{20} or sacral nerve stimulation\textsuperscript{21, 22}.

The primary hypothesis of the present study is that the use of the artificial bowel sphincter would lead to a better level of continence and an improved quality of life compared to standard clinical care. The study has been structured to use a prospective randomised controlled trial format to compare the effectiveness of placement of an artificial bowel sphincter (treatment group) with continuation of good supportive care alone (control group) in the management of severe fecal incontinence.

**Methods**

**Entry criteria**

Patients were accepted into the study if they were adults who had severe fecal incontinence, defined as a Cleveland Continence Score\textsuperscript{23} of 15 or greater, normal dexterity and a mental ability to understand the requirements for use of the ABS and were prepared to provide informed consent to be randomised to either study group. The option of direct repair of the sphincter muscle had been excluded by a history of previous repair or by endoanal ultrasound and the only alternate treatment option for these patients was of colostomy.

All patients were provided with a patient information booklet on fecal incontinence and were further informed by direct discussion of the nature of the problem, the options available for treatment and the details of the randomisation process of the trial.

Candidates were excluded from the study if they failed the entry criteria, had a history of chronic sepsis in the perianal region, were taking immunosuppressive drugs, had a history of inflammatory bowel disease, had an ongoing problem with diarrhea or were considered a high anaesthetic risk (ASA >2).
Patient Assessment

All candidates had a comprehensive clinical assessment, and anal function studies (manometry, electrophysiology, endorectal ultrasound) were performed if they had not been completed in the previous 12 months. Quality of life was measured using three methods. Firstly, the Medical Outcome Study Short Form-36 (SF-36) health survey was used. This is a 36 item questionnaire that is well validated method for measurement of general health. Population norms are well established. Subjects with a broad range of medical conditions have been surveyed. Second, the American Medical Systems (AMS) quality of life scale is a 39-item questionnaire, which specifically focuses on the questions of quality of life relevant to the problem of fecal incontinence. Third, the Beck Depression Inventory (BDI) is a validated questionnaire that has been used for more than 40 years as a measure of the characteristic attitudes and symptoms of depression. It has been validated and used in different ethnic groups and in subjects with co-existent medical conditions.

Additional investigations were performed as clinically indicated for each patient.

Randomisation and Study Group Sizes

After completion of assessment and after obtaining informed consent, patients were randomly allocated into control or treatment group on the basis of computer generated random numbers. A total of 7 patients were randomised into each group. The number of patients required for the study was derived from the change in the Cleveland Continence Score (CCS) achieved in our earlier observational study. This indicated that 7 patients per group would enable 95% confidence of detecting a difference with a power of 0.8, using a two-tailed test, assuming a mean CCS of 5 at 6-months in the surgically treated group and no change in the control group.

Endpoints

The principal endpoint was the continence score (Cleveland Continence model). This was assessed before operation and at three and six months postoperatively. Parallel assessments occurred in the control group. A single observer, who was an independent general physician (JD), conducted the assessment of continence for the treatment and control groups.
The secondary endpoints included the measures of quality of life – SF-36, AMS scale, BDI, and the complications of treatment in either group. The patients were all assessed by the independent physician before and at 3 and 6 months after randomisation.

**Treatment Methods**

Patients in the control group were managed by the Caulfield Continence Service (AK and DF) and were provided with a program of advice and supervision with respect to optimal conservative management. This included physiotherapy for the pelvic floor and anal sphincter muscle rehabilitation which may include biofeedback, electrostimulation and defecation retraining. They were also provided with dietary advice to maintain firm consistency of the stool, establishment of a regular pattern of bowel activity, judicious use of laxatives, bulking agents and antidiarrheals, and the use of aids and appliances to minimize the impact of an episode of incontinence. Advice was given as needed for skin care, odor management and lessening of anxiety.

The placement of the ABS (Acticon Neosphincter®, American Medical Systems, Minneapolis, MN) was by standard technique as previously described\(^\text{15}\). Key elements of the technique include the following:-

- Vigorous attention to antisepsis throughout the procedure including preoperative antiseptic washing, exclusion of the anal canal from the operative field, intraoperative antimicrobials and liberal and repeated use of antiseptics during the procedure.
- Transverse perineal incision in front of the anus, and not the bilateral vertical incisions alongside the anus. This transverse incision provides better exposure for the anterior dissection but has a history of poor healing postoperatively.
- Sizing of the cuff at 1cm greater than the measured dimension for the circumference around the sphincter.
- Placement of the pressure regulating balloon in the left iliac fossa extraperitoneally.
- Activation of the ABS at eight weeks after placement to allow for the postoperative swelling and tenderness around the pump to settle.

Postoperative bowel management is a critical requirement of the ABS treatment process, in particular, to avoid constipation and fecal impaction. After ABS placement, all patients were given instructions regarding appropriate diet, use of oral laxatives as
necessary, and the use of rectal washouts to avoid impaction. The washout technique was encouraged if they felt that they were not clearing the rectum fully. A Foley catheter is passed into the rectum and 300ml of tap water instilled and then passed. This process is repeated until the rectum is felt to be empty.

The trial was approved by the Alfred Hospital Human Ethics Committee.

Results

Demographics and clinical characteristics

A total of 14 patients with severe anal incontinence were enrolled: 7 in the ABS group (one male, six female) and 7 in the control group (seven female). There was no significant difference in the sex, age, severity and duration of incontinence at presentation and anal manometry and pudendal nerve motor latency (Table 4). The commonest cause for the incontinence based on clinical history was post obstetric (4 in ABS group and 5 controls). Two patients in each group had a history of anal surgery prior to onset of incontinence, one of whom also had a significant obstetric history, and one patient in each group had an apparent neurological lesion with prolonged pudendal nerve latency, secondary to lead and thallium poisoning in one and idiopathic in the other. Four patients (two treatment and two control) had had previous surgical attempts at control of the problem by direct sphincter repair and one of these patients had also had a postanal repair.

The placement of the artificial bowel sphincter required a median operating room utilization including anesthetic time of 85 min (range 75 - 100) and the length of stay was a median of 7 days (range 2 - 17).

Perioperative complications

There were three perioperative events which required additional procedures or delayed hospital discharge.

An 56 yr old women had failure of healing of the perineal wound. It was resutured under local anesthetic but remained unhealed and exposure of the cuff in the wound was noted at 15 days after placement. The device was removed at 4 weeks and a terminal colostomy performed. The perineal wound remained slow to heal with eventual closure at 8 weeks after explantation. The colostomy also failed to heal and two further revisional procedures of the colostomy were required with eventual satisfactory healing
at this site occurring at 6 weeks after formation. She gave no past history of problems with healing and no mechanism could be established.

A 75 yr woman, who had total incontinence for 32 years, had prolonged hospital stay (17 days) as she struggled to learn how to expel feces through the reduced lumen at the anus. Laxatives and rectal washouts were needed to assist evacuation. She slowly improved in the ability to defecate but, at the 6 month follow-up, she was still using the rectal washout approximately every fifth day to maintain fecal clearance. Her continence score improved from a CCS of 19 preoperatively to 9 at 6 months postoperatively.

A 64 yr female had delayed healing of the perineal wound which required resuturing under local anaesthesia. She remained in hospital for ten days after ABS placement.

**Changes in continence and quality of life.**

The changes in the various outcome measures are shown in figures 1 and 2 and in tables 4 and 5. The changes in the level of continence, as measured by the Cleveland continence score, are shown in figure 1 and table 5. Whereas no significant change in continence occurred in the control group at 3 and 6 months, there is a highly significant improvement in continence in the ABS group with a reduction from 19.1 +/- 1.2 to 4.8 +/- 4.0 (p = 0.001). While 6 of the 7 control patients showed no change at all, one patient showed a marked improvement from a CCS of 19 on admission to the study to a value of 5 at both 3 and 6 months follow-up. She had an obstetric history of 3 difficult deliveries with prolonged labour, use of forceps and tears. She later developed rectal prolapse which was treated by a Ripstein rectopexy 8 yr before, followed by transanal excision of mucosal prolapse. She had been incontinent since that procedure.

In association with the improvement in continence there is a major improvement in quality of life. The AMS QOL score improved from 38.8 +/- 5.9 % to 82.7 +/- 14% (p=0.003) where 100% represents optimal outcome. The SF-36 measures show an improvement in all 8 subscores (Figure 1) and in the physical component summary score and the mental component summary score (Table 4and 5). At the 6-month follow-up visit, SF-36 subscores for energy or vitality (p=0.04), social function (p=0.05), emotional role (p=0.04) and the mental component summary score (p=0.02) were significantly better in the surgical group than in the control group. In contrast, the control group showed no significant change in QOL as measured by the AMS score (Table 4 and 5) ( 42.5 +/- 22.9 preop; 54.7 +/- 256 at 6 months) nor in any of the SF-36 subscores (Figure 4) or the Physical or mental component summary scores (Tables 4 and 5).
The Beck depression inventory indicated the presence of a mild level of depression on average in the ABS group before operation (10.9 +/- 9.3) and normal status in the control group (7.3 +/- 5.4). At 6 months, the ABS group had improved to a mean value of 6.8 +/- 8.7, whereas the controls were unchanged at 9.3 +/- 10.

Discussion

This prospective randomised controlled trial has shown a significant improvement in anal continence and in quality of life in association with the placement of the artificial bowel sphincter (Acticon Neosphincter®) and thus provides an option other than dynamic graciloplasty and colostomy for the patient with a severe level of incontinence. Because of the powerful action of the ABS on continence, only a small sample of patient have been required to be studied to demonstrate the effect. Most have become continent not just to solid feces but also to liquid and even to flatus. To pass wind, it can be necessary to pump a small amount of fluid from the cuff. No patient had difficulty with use of the pump and, as all components are internal, it is discrete to use. For the successful patient, the only difference from normal bowel activity is the need to pump down the cuff prior to the bowel action.

The placement of the ABS appears to be a safe. Complications after the ABS are localized to the anorectal region and have not been associated with any systemic disease. Apart from the three problems discussed above, there were no perioperative complications in this study and, to our knowledge, no deaths have ever been reported in association with the use of the ABS. This contrasts with the comparator procedure of dynamic graciloplasty for which a systematic review of the literature identified an overall mortality of 2% (95% confidence intervals 1% – 3%) and a total of 387 perioperative complications in 347 patients.

The most outstanding feature of the ABS is its effectiveness in controlling incontinence. The present study shows a reduction of the Cleveland Continence scale by 75%. Tables 1 and 2 show the published data on changes in continence after ABS placement. Two continence scales have been used and therefore the results are expressed as a
percentage reduction from the preoperative level with an overall mean reduction of 81% in the degree of incontinence. Because these were all observational studies their message of effectiveness has been discounted. This study now provides level II evidence in support of this level of effectiveness.

Given the small sample size in the study, we were not expecting to demonstrate change in any of the SF-36 subscales. The study was powered to detect major improvements in fecal incontinence only, not to necessarily detect improvements in general quality of life measures. However the improvements, especially in the mental and social subscales of the SF-36, have been so great that they have reached statistical significance.

It is difficult to use existing data to compare the effectiveness of the ABS to the dynamic graciloplasty in achieving continence. No direct comparative study has been performed and only observational data (level IV) are available for the dynamic graciloplasty. In a systematic review of dynamic graciloplasty, ten of the thirteen studies examined provided no continence score. “Satisfactory” continence was described as being restored in between 42% and 85% of patients. For most studies this meant continence to solids. Reoperation rates were between 0.14 and 1.07 reoperations per patient. It would therefore appear that the level of continence achieved was inferior and that reoperation was more common. If the relative safety and effectiveness of the two procedures needed to be compared, a randomised trial would be required. However, with the expected withdrawal of the equipment support for the dynamic graciloplasty, such a study may not be relevant.

There remain two problem areas with the use of the ABS and both were evident in this trial. Explantation of the device was needed in one patient in this trial because of failure to heal of the perineal wound (14% with 6 months follow-up). The overall incidence of permanent explantation of the Acticon neosphincter in the published series varies between 17% and 31% with follow-up periods of between 10 and 58 months (table 3). In addition, revisional surgery with replacement of part or the entire device has occurred in between 7% and 25% of the patients in the published series (Table 3). The complications leading to explantation include perioperative infection, failure of wound healing, erosion of part of the device through the skin, late infection and mechanical
malfunction of the device due to cuff or balloon rupture. Lehur and coworkers have reported three consecutive series of patients between 1998 and 2002 and the total explantation/revision rates have remained constant at 31%, 29% and 31% suggesting that this rate does not reflect the learning curve but is intrinsic to the use of the device (Table 3).

The other problem which has been common in the early postoperative period is of fecal impaction. All patients require advice and assistance in the early postoperative period with modifying bowel function to cope optimally with the ABS. Whereas before operation there was advantage in having relative dry, firm stool, the presence of the ABS requires a softer, more fluid stool. Further, these patients had no need to generate pressure to pass the bowel action before operation and so a restoration of this ability is required after ABS placement. One patient in this study had particular difficulty with this task. She was elderly and had a history of severe incontinence for more than 30 years. She required repeated bowel washouts as an inpatient early after the procedure and has slowly improved. We provide instruction for all patients on the use of diet, laxatives, microenemas and tap water washout as a routine part of the postoperative educational program. Once adequate bowel function becomes established it is unusual to have further episodes of impaction.

The present study confirms that the ABS is safe from systemic complications and is effective in controlling severe fecal incontinence. Perioperative and late problems are likely to continue and between one sixth and one quarter of patients are likely to require permanent explantation. Most of these patients will go on to a permanent colostomy as the best option in light of the severity of their incontinence. For the remainder, the device is easy to use, discrete and is associated with marked improvement in their quality of life. Its use should be reserved for those with severe fecal incontinence who do not respond to conservative therapies and who are either unsuitable for or have not benefited from direct sphincter repair. For most of these patients, placement of the ABS can be expected to provide a effective solution to a most disabling problem.

References:


Table 1: Change in faecal continence after ABS placement, using the Cleveland Continence Score as the measure.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Preop</th>
<th>Postop</th>
<th>% Reduction</th>
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</thead>
<tbody>
<tr>
<td>Lehur et al, 1998\textsuperscript{12}</td>
<td>13</td>
<td>17</td>
<td>4.5</td>
<td>74%</td>
</tr>
<tr>
<td>Vaizey et al, 1998\textsuperscript{17}</td>
<td>6</td>
<td>19.5</td>
<td>4.5</td>
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<tr>
<td>O’Brien, 2000\textsuperscript{15}</td>
<td>13</td>
<td>18.7</td>
<td>2.1</td>
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<tr>
<td>Altomare et al, 2001\textsuperscript{16}</td>
<td>28</td>
<td>14.9</td>
<td>2.6</td>
<td>83%</td>
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Table 2: Changes in fecal continence after ABS placement using the AMS score as the measure

<table>
<thead>
<tr>
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<th>N</th>
<th>Preop</th>
<th>Postop</th>
<th>% Reduction</th>
</tr>
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<tr>
<td>Lehur et al, 2000&lt;sup&gt;13&lt;/sup&gt;</td>
<td>24</td>
<td>106</td>
<td>25</td>
<td>76%</td>
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<tr>
<td>Lehur et al, 2002&lt;sup&gt;14&lt;/sup&gt;</td>
<td>14</td>
<td>105</td>
<td>23</td>
<td>78%</td>
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<tr>
<td>Altomare et al, 2001&lt;sup&gt;16&lt;/sup&gt;</td>
<td>28</td>
<td>98</td>
<td>5.5</td>
<td>94%</td>
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<tr>
<td>Dodi et al, 2000&lt;sup&gt;29&lt;/sup&gt;</td>
<td>8</td>
<td>95</td>
<td>19</td>
<td>80%</td>
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### Table 3: Incidence of Explantation or Revision with reimplantation after ABS placement

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>F.U.</th>
<th>Permanent Explantation</th>
<th>Revision/Reimplantation</th>
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<td>Lehur et al, 2002(^1^4)</td>
<td>16</td>
<td>25</td>
<td>4 (25%)</td>
<td>1 (6%)</td>
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<tr>
<td>Lehur et al, 2000(^1^3)</td>
<td>24</td>
<td>20</td>
<td>4 (17%)</td>
<td>3 (12%)</td>
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<td>Lehur et al, 1998(^1^2)</td>
<td>13</td>
<td>30</td>
<td>2 (7%)</td>
<td>2 (7%)</td>
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<td>Altomare al, 2001(^1^6)</td>
<td>28</td>
<td>19</td>
<td>5 (18%)</td>
<td></td>
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<tr>
<td>Dodi et al, 2000(^2^9)</td>
<td>8</td>
<td>10</td>
<td>2 (25%)</td>
<td></td>
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<tr>
<td>O’Brien &amp; Skinner, 2000(^1^5)</td>
<td>13</td>
<td>20</td>
<td>3 (23%)</td>
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<tr>
<td>Ortiz et al, 2002(^3^0)</td>
<td>22</td>
<td>28</td>
<td>7 (31%)</td>
<td>2 (9%)</td>
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<tr>
<td>Vaizey et al, 1998(^1^7)</td>
<td>6</td>
<td>10</td>
<td>1 (17%)</td>
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<tr>
<td>Wong et al, 1996(^1^9)</td>
<td>12</td>
<td>58</td>
<td>3 (25%)</td>
<td>3 (28%)</td>
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Table 4: Patient characteristics, and initial continence, manometry and quality of life scores.

<table>
<thead>
<tr>
<th></th>
<th>Control - Medical (Mean (SD))</th>
<th>Surgical (Mean (SD))</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Number</td>
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<td>7</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>59 (range 44-75)</td>
<td>66(range 46 – 75)</td>
<td>NS</td>
</tr>
<tr>
<td>Duration of incontinence</td>
<td>11.3 yr (range 4-30)</td>
<td>7.6 yr (range 3-20)</td>
<td>NS</td>
</tr>
<tr>
<td>No of males in group</td>
<td>0</td>
<td>1</td>
<td>NS</td>
</tr>
<tr>
<td>Cleveland continence score</td>
<td>17.1 (2.3)</td>
<td>19.0(1.2)</td>
<td>0.08</td>
</tr>
<tr>
<td>AMS QOL score</td>
<td>42.4 (22)</td>
<td>38.8 (6)</td>
<td>0.78</td>
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<tr>
<td>Pudendal nerve motor latency R</td>
<td>3.05 (1.5)</td>
<td>3.20 (1.3)</td>
<td>0.84</td>
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<td>Pudendal nerve motor latency L</td>
<td>3.64 (1.1)</td>
<td>2.59 (1.4)</td>
<td>0.15</td>
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<tr>
<td>Manometry resting pressure</td>
<td>40.1 (15)</td>
<td>27.3 (14)</td>
<td>0.11</td>
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<tr>
<td>Manometry squeeze pressure</td>
<td>77.1 (35)</td>
<td>57.5 (13)</td>
<td>0.10</td>
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<tr>
<td>SF-36 Physical component summary</td>
<td>41.6 (13.2)</td>
<td>39.8 (8.5)</td>
<td>0.76</td>
</tr>
<tr>
<td>SF-36 Mental component summary</td>
<td>40.3 (9.8)</td>
<td>45.6 (9.8)</td>
<td>0.38</td>
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<tr>
<td>Beck Depression Inventory</td>
<td>7.3 (5.4)</td>
<td>10.8(9.3)</td>
<td>0.85</td>
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Mean (SD), p-value unpaired T-Test (2-tail)
Table 5: Changes in the outcome measures for the control and the ABS patients during the 6mth period of follow-up. Data are means (SD). Comparison by paired T-Test (2-tailed). The last column provides the p-values for the comparison of the final value for control group vs the final value for the ABS group

<table>
<thead>
<tr>
<th></th>
<th>Control Initial</th>
<th>Control Final</th>
<th>p-value</th>
<th>Surgical Initial</th>
<th>Surgical Final</th>
<th>p-value</th>
<th>Final – Control vs Surgical</th>
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<tr>
<td>Cleveland continence score</td>
<td>17.4(2.3)</td>
<td>14.3(4.6)</td>
<td>0.21</td>
<td>19(1.2)</td>
<td>4.8(4.0)</td>
<td>0.001</td>
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<td>AMS QOL score</td>
<td>42.5(22)</td>
<td>54.7(26)</td>
<td>0.25</td>
<td>38.8(6)</td>
<td>82.7(14)</td>
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<td>SF-36 Physical component summary</td>
<td>41.6(13)</td>
<td>41 (11)</td>
<td>0.90</td>
<td>37(10)</td>
<td>45(7)</td>
<td>0.26</td>
<td>0.43</td>
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<tr>
<td>SF-36 Mental component summary</td>
<td>40.3(10)</td>
<td>44.4(5)</td>
<td>0.27</td>
<td>45(9)</td>
<td>52(4)</td>
<td>0.25</td>
<td>0.02</td>
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<tr>
<td>Beck Depression Inventory</td>
<td>7.3(2)</td>
<td>9.3(10)</td>
<td>0.38</td>
<td>10.8(9)</td>
<td>6.8(9)</td>
<td>0.78</td>
<td>0.65</td>
</tr>
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</table>

Mean (SD), p-value unpaired T-Test (2-tail)
Figure 1:

Initial 3-months 6-months
Cleveland continence score

Surgical
Control
Figure 2

AMS QOL score

- Surgical
- Control

Initial 3-months 6-months
Figure 3:
Figure 5:
Figure 6:

![Graph showing physical function, physical role, pain, general health, vitality, social functioning, emotional role, and mental health over 6 months for controls and surgical groups.](image-url)
Legends for Figures

**Figure 1:** Cleveland continence score (mean +/- 95% CI) for the surgical and control groups at initial assessment, and 3-months and 6-months after commencing the treatment program. The difference between the groups at 6-months is significant (p=0.002).

**Figure 2:** AMS Quality of Life score (mean +/- 95% CI) for the surgical and control groups at initial assessment, and 3-months and 6-months after commencing the treatment program. The difference between the groups at 6-months is significant (p=0.040).

**Figure 3:** SF-36 Health Related QOL subscales for the surgical group before and at 6 mth after ABS placement. Higher scores were reported in all domains. but the only statistically significant change was an improvement in vitality (p=0.04).

**Figure 4:** SF-36 Health Related QOL subscales for the control group at the initial and final assessments. There is no change in any of the subscales.

**Figure 5:** SF-36 Health Related QOL subscales for the surgical and control groups at the initial assessment. There were no significant differences in the between the groups.

**Figure 6:** SF-36 Health Related QOL subscales for the surgical and control groups at 6-months. Subscores for vitality, social functioning and emotional role were significantly better in the surgical group.