A pilot study: The anal sphincter support procedure for the treatment of anal incontinence

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Abstract: Faecal incontinence is a significant and a very debilitating condition. The true prevalence of which is unknown but up to 3% of the general population have stool incontinence which increases with age. Faecal incontinence is much more common in women, increases with parity, and up to 30% have associated urinary incontinence and/or pelvic organ prolapse. Patients who have an identifiable external sphincter defect who fail conservative treatment options are best managed by a primary repair of the defect. This study presents a novel way of supporting the external anal sphincter with a circlage tape prosthesis. Based on the success of tension-free suburethral tapes used to treat stress urinary incontinence a pilot study was devised to assess Anal Sphincter Support System (ASSP) in patients presenting with mild faecal incontinence. Fourteen patients were followed up for a mean period of eighteen months. Outcomes were very encouraging with resolution of symptoms between 70 and 100%. There were no observed complications. This pilot study demonstrates that the ASSP provides a safe and effective method of restoring anal continence and can be used successfully with concomitant procedures which may be necessary for restoration of pelvic floor anatomy and function.

Key words: Faecal incontinence; Anal Sphincter Support Procedure; Hammock hypothesis.

INTRODUCTION

Faecal incontinence is rarely due to one single factor. Vaginal childbirth and obstetric trauma are widely accepted as significant causes of faecal and flatal incontinence in women. Approximately 10-15% report symptoms following vaginal delivery culminating in 2-5% of women having faecal incontinence.\(^1\) The most common contributing cause is anal sphincter injury occurring at the time of the second stage of labour. Other significant factors are instrumental delivery, midline episiotomy and prolonged second stage of labour.\(^2,3\) Also thought to be of significance is traction or entrapment of the pudendal nerve and its branches of the perineal nerve fibres, associated with injury to the levator ani plate (iliococcygeous, pubococcygeus and puborectalis muscles).

Women with symptoms of faecal incontinence following their first pregnancy will deteriorate after their second pregnancy.\(^4\) In one study 26.9% of women had an identifiable occult anal sphincter injury on endoanal ultrasound. With each increase in parity the chance of a new defect increased by 8.5%, while 75-85% of women presenting with faecal incontinence will have an identifiable anal sphincter defect.\(^5\) Follow up of women who underwent primary repair of a third degree vaginal tear has shown that 85% will have persistent structural defects and over 50% of this group will develop faecal incontinence.\(^6-10\)

A wide range of causes may contribute to anorectal dysfunction and anal incontinence.\(^11\) Some iatrogenic causes that may result in injury to the anal sphincter complex include anorectal procedures such as fistulotomy, sphincterotomy and haemorrhoidectomy. Medical etiological factors include psychiatric conditions, chronic constipation, malabsorption syndromes, laxative overuse, diabetes, thyroid disease, gastrointestinal inflammatory conditions, neuropathies and spinal cord disease.

Anatomical distortion associated with chronic straining is commonly known as pelvic floor prolapse syndrome and may also be associated with progressive denervation of the colon, rectum and anus at the pelvic floor, in conjunction with obstructive defaecation and intussusception. Lateral, central and posterior rectal defects including rectal diverticulum may also contribute to anorectal dysfunction with incontinence.

It is difficult to know the true incidence of faecal incontinence due to variations in definitions, age distribution, underreporting due to reluctance to broach the condition, coexistence with other pelvic symptoms such as voiding dysfunction and pelvic organ prolapse.\(^12\) A complex, interactive psychological process is necessary for faecal/flatal continence including rectal motility and compliance with neurophysiology of sensation. Hyposensitivity associated with low resting pressure may indicate internal and external sphincter damage resulting in passive incontinence, whereas hypersensitivity with urge incontinence and the inability to postpone defaecation may be associated with low voluntary squeeze pressure thus indicating external anal sphincter malfunction.

The aim of this study was to explore the possibility that a circumferential mesh support for the anal sphincter would reduce symptoms in patients with faecal or flatal incontinence. This hypothesis arose from consideration of the need for additional anchoring support of the Apogee\textsuperscript{TM} (American Medical Systems, Inc, Minnetonka, MN, USA) mesh used for the repair of posterior vaginal wall prolapse (rectocele and associated perineal repair). It was found that a percentage of these patients reported a significant improvement in bowel function and in particular a reduction in severity of their previously underreported anal incontinence.\(^13\)

The use of mid urethral slings to treat Stress Urinary Incontinence (SUI) is based on the Hammock Hypothesis of DeLancey.\(^14,15\) Since the anatomy and pathophysiology of defects arising in the anterior pelvic compartment have been successfully corrected using a mid urethral sling to treat SUI it was postulated that a mesh sling prosthesis placed around the anal sphincter may improve the anal sphincter mechanism of action and address the problem of faecal and flatal incontinence. It was decided to embark on a pilot study of patients with mild faecal incontinence using such a mesh prosthesis and to monitor the outcomes of this group.

ANORECTAL ANATOMY

The anal canal extends from the anorectal junction which lies just above the level of the puborectalis sling and sphincters (internal and external) to the anus below. It is surrounded by an external sphincter of voluntary muscle fibres and an internal sphincter of involuntary muscle fibres.\(^16\) Between the two sphincters lies the longitudinal anal muscle of the rectum (LAM)\(^17\) composed of muscle fibres which receive contributions from puborectalis, pubococcygeus...
PATIENTS AND METHODS

The ASSP was performed on 14 patients between June 2005 and March 2007 with a total follow up time of 20.3 months. Mean follow up time was 18 months. Inclusion criteria for the study were symptoms of mild to moderate faecal soiling and flatal incontinence. Ten patients had a Wexner grading symptom score of 5-8 and four patients had a Wexner grading symptom score of 8-10. Past gynaecological and colorectal surgeries were as follows: Four patients had a past history of vaginal hysterectomy and anterior pelvic organ prolapse repair, six had abdominal hysterectomy (two also Burch colposuspension), four anterior and posterior vaginal repair, two had a haemorrhoidectomy, one an partial sphincterotomy for anal fissure, one an anal stretch procedure. The ages of patients ranged from 45 to 78 years, mean age 64.7 years. Obstetric history: all patients were parous. Five patients were parous 1-3, nine patients 3-5. Two patients had caesarian sections only. Interestingly both these patients had a past history of anorectal surgery. Of the 12 patients who had vaginal births more than 33% were parous. Five patients were parous 1-3, nine patients 3-5. Two patients had caesarian sections only. Interestingly both these patients had a past history of an anorectal surgery. Of the 12 patients who had vaginal births more than 33% had instrumental deliveries. Mean foetal size was 3,700 g, ranging between 4,300 to 2,800 g.

All patients were studied using Magnetic Resonance Imaging (MRI) of the anal sphincter. At imaging 5 patients had evidence of external sphincter defects mainly right, lateral or central. Defects were considered small varying from 2-3 mm. Two patients aged 75 and 78 years had evidence of external sphincter defects mainly right, lateral or central. Defects were considered small varying from 2-3 mm. Two patients aged 75 and 78 years had evidence of external sphincter defects mainly right, lateral or central. Defects were considered small varying from 2-3 mm. Two patients aged 75 and 78 years had evidence of external sphincter defects mainly right, lateral or central. Defects were considered small varying from 2-3 mm. Two patients aged 75 and 78 years had evidence of external sphincter defects mainly right, lateral or central. Defects were considered small varying from 2-3 mm. Two patients aged 75 and 78 years had evidence of external sphincter defects mainly right, lateral or central. Defects were considered small varying from 2-3 mm. Two patients aged 75 and 78 years had evidence of external sphincter defects mainly right, lateral or central. Defects were considered small varying from 2-3 mm. Two patients aged 75 and 78 years had evidence of external sphincter defects mainly right, lateral or central. Defects were considered small varying from 2-3 mm. Two patients aged 75 and 78 years had evidence of external sphincter defects mainly right, lateral or central. Defects were considered small varying from 2-3 mm. Two patients aged 75 and 78 years had evidence of external sphincter defects mainly right, lateral or central.

Operative technique: All patients had a 24 hour pre-operative bowel preparation. Systemic triple antibiotics were given intraoperatively and this combination was continued for 24 hours postoperatively. Clineamycin cream was inserted vaginally as a single dose approximately 1-2 hours preoperatively. The operation was performed in the lithotomy position. Aqueous Betadine antiseptic solution (10% w/v Povidone/Iodine) was used as skin preparation and liberally applied to inner thighs, intravaginally and to the perineal and suprapubic areas. The patient was draped in the usual fashion facilitating good exposure of the operative site with the buttocks extending just below the end of the table. Infiltration of the perianal area and perineal body including the posterior vaginal mucosa was performed using a hydro-dissection technique with dilute local anaesthetic. A stab incision of approximately 1 cm using an eleven blade was made 3 cm from the anal verge in the 5 o’clock and 7 o’clock position or a single incision was made at 6 o’clock (Fig. 4, 5).

At the vestibule of the vaginal orifice a transverse incision of approximately 4-5 cm was performed with dissection supramedially and laterally to expose the superior aspect of the perineal body. In the case of an adjuvant posterior prolapse procedure, blunt and minimal sharp tunneling dissection is continued proximally to create a pathway and identify the ischiop spine and tendinous arch of the lateral pelvic wall. This dissection is performed bilaterally (Fig. 2, 3).

Gentamicin solution 1 mg per 1cc of saline is used to liberally irrigate the operative site throughout the procedure.
was between 5 and 8 were reassessed to have
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The mesh is then gently positioned posteriorly through the
is attached to both needle tips firmly with an audible click.
tips of both needles at the perineal body, the Monarc
contra lateral side of the external anal sphincter.  With the
perineal incision.  The same technique is performed on the
perineal body enabling visualization of the needle tip at the
the external anal sphincter to emerge laterally through the
the needle through its natural arc creates a track around
directed approximately 2-3 cm in depth before rotation of
a Monarc™ (American Medical Systems, Inc, Minne-
index finger of a double gloved left hand the helical needle
approximately 1cm above the transverse perineal incision
must be in position and the excess inferior cape trimmed
before the perianal support procedure. The Apogee™ mesh
5-6 cm posterolateral to the anal verge which is 3 cm poste-
rollerateral to the incisions used for the ASSP. The posterior
compartment mesh repair Apogee™ should be performed
before the perianal support procedure. The Apogee™ mesh
must be in position and the excess inferior cape trimmed
immediately after the positioning of the ASSP is performed. The stab
incisions are then closed with 2-0 Vicryl interrupted mat-
and the mesh trimmed at the buttock incisions (Fig. 6). All
incisions are then closed with 2-0 Vicryl interrupted mat-
tress sutures.

RESULTS
All 14 patients were studied over a minimum period of 6
months. Mean average time of follow up was 18 months. During
that time there were no perioperative or postoperative
complications. In particular there were no cases of mesh
erosion or rejection and no cases of rectal perforation or
trauma. Four cases had evidence of perianal bruising which
resolved spontaneously with the judicious use of ice packs
applied to the perianal area for approximately 24 hours.
There were no cases of overt haematoma formation, infec-
tion or abscess formation. Ten patients whose initial Wexner
score was between 5 and 8 were reassessed to have
between 90 and 100% improvement in symptoms. The
other 4 patients with initial Wexner Score of 8-10 noted an
improvement of 70% or better resulting in a Wexner score
between 2 and 3.

CONCLUSIONS
The purpose of this study was primarily to evaluate the
safety and efficacy of the ASSP and its impact on quality of
life with respect to anorectal dysfunction and faecal
incontinence. The ASSP was found to be a simple proce-
dure with reproducible results and not associated with any
significant peri or post operative complications within a
mean follow up period of 18 months. In particular there
was no evidence of mesh erosion, rejection or anorectal
trauma. Subjective improvement of symptoms was noted
using the Wexner grading profile and quality of life was
maintained in all patients and improved in more than 90%.
As a consequence of this pilot study it will be important
to consider longer term prospective randomized control-
led studies, comparing outcomes of other techniques for
treating faecal incontinence with ASSP. The use of ASSP
in conjunction with other concomitant procedures for pos-
terior pelvic organ prolapse and dysfunction is efficacious
and safe. This study suggests that there is a significant
enhancement when used in conjunction with a posterior
vaginal mesh procedure using the Apogee™. Further stud-
ies in mesh design and in particular a wider dimension in
the mesh prosthesis may be desirable. Further research into
the role of pelvic floor imaging will increase our knowl-
edge into the pathogenesis and management of functional
pelvic floor disorders. There is also a need for stand-
ardized terminology and diagnostic criteria for defeca-
tory dysfunction and for a comprehensive classification of
site specific anatomical variations of the posterior pelvic
compartment. This will also need to be addressed from
a multidisciplinary perspective as recently proposed by
Farnsworth and Dodi.

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