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A pilot study of autologous rectus fascial wrap at the time of artificial urinary sphincter placement in patients at risk of cuff erosion

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Abstract

Purpose Cuff erosion is one of the dreaded complications of artificial urinary sphincter (AUS) implantation. Patients with a history of pelvic irradiation are at increased risk of erosion. To reduce the risk of erosion we describe a novel technique and report the results in our initial series of patients.

Materials and methods A prospective analysis of patients treated with AUS and rectus fascial wrap was performed. Inclusion criteria were severe urinary incontinence (UI) and previous pelvic radiation therapy (RTX). Primary outcomes were erosion rate, complications and continence rate. Secondary outcomes were patient satisfaction.

Results Twenty-three patients were analysed. The median age was 70 years. Nine (39%) had previous surgery; 6/9 had an Advance sling, 2/9 had a Virtue sling, and 1/9 had an AUS which had eroded. Median pad use was five pads/day IQR, (4–6). Median pad weight was 630 ml, 6 cm of fascia was harvested in every case, but cuff size varied. Complications occurred in 6/23 (26%): two patients with Clavien 1 and four patients with Clavien 3B (urinary retention requiring suprapubic catheter). In all cases, the retention resolved. One patient presented at 3 months post-op with erosion (4.3% erosion rate). Median follow-up was 32 months, IQR (24–37). Excluding the patient with erosion, 17/22 (77.3%) of patients achieved complete continence, while 5/22 (22.7%) achieved social continence.

Conclusion The autologous fascial wrap technique is efficient and easy to harvest, with comparable clinical outcomes to other techniques. The medium-term results have been encouraging, but longer-term follow up is needed.

Keywords Rectus fascia · Artificial urinary sphincter · Sphincter erosion · Urinary incontinence

Introduction

The artificial urinary sphincter (AUS) is the gold standard treatment for severe stress urinary incontinence (SUI). The success rates of more than 80% are reported [1, 2]. However, AUS placement is associated with complications; these include mechanical failure, infection, urethral atrophy and erosion.

Cuff erosion is one of the more dreaded complications of sphincter implantation. Risk factors for erosion include prior AUS cuff erosion, history of urethral stent placement and conceivably prior radiotherapy. The concept that radiation increases the risk of AUS cuff erosion is still contentious with one large study demonstrating no association [3]. However, several other studies have demonstrated that explantation rates of AUS in patients with a history of pelvic irradiation are higher than in patients who never received radiotherapy. Erosion rates in the range of 6–13% have been

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reported in irradiated patients, whereas the rate is less than 4% in non-irradiated patients [1, 4–12].

To reduce the risk of erosion following AUS placement, several different techniques and modifications to AUS insertion have been tried, including transcorporeal cuff placement and small intestinal submucosa (SIS) urethral wrap. Although both procedures are associated with low risk of erosion and good continence rates, these procedures are associated with some drawbacks [13, 14].

The use of an autograft such as the rectus fascia is an alternative to both transcorporeal cuff placement and SIS. To date, there are no data reporting on the outcome of its use at the time of AUS placement in high-risk patients. This study aims to report the clinical results in our initial series of patients who have undergone autologous rectus fascial wrap at the time of AUS insertion.

Methods

Patient selection and data collection

A prospective study of patients who underwent AUS (AMS800R) implantation with rectus fascial wrap was performed. Data were collected from June 2016 to Oct 2019. Institutional ethics board approval was obtained before the collection of data and informed consent was obtained from all individual participants included in the study. All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

The procedures were performed by three separate surgeons, with a shared technique. Only patients with a history of pelvic radiation were included in this study. Data were recorded prospectively on each patient in a database, which was completed by the operating surgeon. Data collected included age, aetiology of SUI, primary and secondary treatment, previous SUI surgery, rectus fascia harvest size, cuff size, complications and hospital duration. A complication was defined as any adverse event occurring within 30 days of surgery [15]. Primary outcomes were erosion rate, complications and continence rate. Secondary outcomes were patient satisfaction.

Patients underwent pre-operative urodynamic assessment and flexible cystoscopy. If the patient had detrusor overactivity or a bladder neck contracture, each condition would have been treated and stabilised before AUS surgery. The post-operative urinary function was assessed using the Incontinence Symptom Index (ISI) questionnaire, and incontinence pad use and 24-h pad weight. Patient satisfaction was assessed using the Patient Global Impression of Improvement (PGI-I) questionnaire. All patients were

followed at 2 weeks post-AUS insertion, then at 6 weeks, 3 months, and then seen on a 6-monthly basis. A patient was defined as continent if they used no pads and had no incontinence symptoms according to questionnaires. A patient was defined as socially continent if they required one pad or less per day (safety pad) and had mild incontinence symptoms. Post-operative complications were reported and classified according to the Clavien–Dindo classification [16].

Rectus fascia harvest, placement and AUS

The patient is positioned in the dorsal lithotomy position. A 14Fr urethral catheter is placed. A vertical perineal incision is made, and this is continued down to the urethra. The proximal bulbar urethra is then carefully dissected and mobilised beneath the bulbospongiosus muscle and the circumference measured. This will be the approximate length of the rectus fascia that will be required. Next, the lower abdominal incision is made as one would place the reservoir. A strip of rectus fascia, measuring about the circumference of the urethra (6 cm in length \times 1.5 cm in height), is harvested from the same incision (Fig. 1a). The harvesting is done on the upper half of the rectus fascia incision as there is more abundant fascia here compared to the lower half. Space is then dissected out for the reservoir. The harvested fascia is de-fatted. If both layers of the rectus fascia prove to be too thick, then a single layer can be discarded to thin the graft down. The 1.5 cm side of the fascia strip is anchored at the midline ventrally to the peri-urethral tissue at the level of where the cuff will lie. Two interrupted 4-0 absorbable sutures are used to prevent movement. The fascia is then wrapped around the urethra and any excess length is then trimmed off. The trimmed end of the fascial wrap is now sutured to the anchored end of the fascia, again two interrupted 4-0 absorbable sutures are used as shown in Fig. 1b. Following graft placement, the urethra is re-measured using an AMS sizer without tension. The size of the urethra with the graft is used to determine the cuff size. An appropriate size cuff is then placed around the graft, locked in and connected as shown in Fig. 1c.

Statistics

Unless otherwise stated, data are represented as median (interquartile range [IQR]), and N represents the number of patients included in the analysis. Differences in the distribution of clinical data were evaluated using a two-sided Fisher exact test for categorical variables and the Mann–Whitney *U* test for continuous variables. Calculations were performed using STATA version 14 (StataCorp, College Station, TX, USA). All analyses were two-tailed, and significance was assessed at the 5% alpha level.

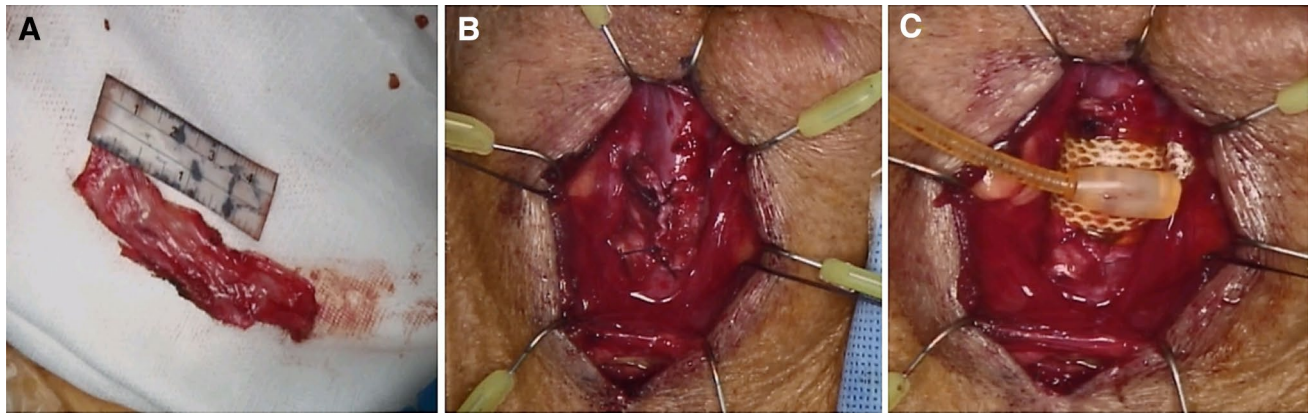


Fig. 1 a The harvested rectus fascia segment. b Rectus fascial wrap sutured in place around the urethra and c the AUS placed around the rectus fascial wrap

Results

Patient characteristics

Twenty-three male patients underwent AUS implantation with rectus fascial wrap. The median age was 70 years, IQR (62–73). All patients had pelvic radiotherapy as a primary treatment or as an adjunct for prostate cancer treatment. 15 patients (65.2%) had a radical robotic prostatectomy followed by adjuvant/salvage radiotherapy. Two patients (8.7%) had primary radiotherapy and then a salvage prostatectomy. Four patients (17.4%) had primary radiotherapy with no secondary treatment, and two patients (8.7%) had high dose brachytherapy with no secondary treatment. Nine patients (39%) had previously failed stress urinary incontinence surgery; 7/9 patients had an Advance® sling, one patient had a Virtue® sling placed and one patient had an AUS. The median time from last prostate cancer treatment to AUS implantation with rectus fascial wrap was 2 years, IQR (1–3.5).

The median 24 h pad usage was five pads/day, IQR (4–6), and the median 24 h pad weight was 630 ml, IQR (540–850). Patients with mixed lower urinary tract symptoms underwent urodynamics, and 12 patients (52.2%) were found to have DO on filling cystometry. DO was managed with anticholinergic medication in six patients (50%), beta-3 adrenergic receptor agonist in three patients (25%), intra-detrusor onabotulinumtoxin A (Botox®) injections in two patients (16.6%) and sacral neuromodulation in one patient. All patients had clinical improvement in their DO. Six (26%) patients had bladder neck contractures; a bladder neck incision was performed, and SUI surgery was only offered when the bladder neck contracture was stable and open for 6 months. Data are shown in Table 1.

Table 1 Patient data

		Total, N (%)
Patients		23
Age years, median (IRQ)		70 (65 – 73)
Treatment		
Primary	Secondary	
RRP	RTX	15 (65.2)
RTX	–	4 (17.4)
RTX	RRP	2 (8.7)
HDR	–	2 (8.7)
Previous SUI surgery		9 (39)
AUS		1 (11.1)
Advance® sling		7 (77.8)
Virtue® sling		1 (11.1)
Incontinence device		
Pads		20 (87)
Condom catheter		3 (13)
Incontinence		
Pads/24 h, median IQR		5 (4–6)
Pad weight (g)/24 h, median IQR		630 ml (540–850)
Bladder neck assessment		
No contracture		17 (74)
Contracture		6 (26)
Urodynamic assessment		6 (69.5)
DO		12 (52.2)
VLPP (cm H ₂ O), median (IRQ)		40 (30–40)
DO treatment		
Antimuscarinic medication		6 (50)
Beta3 adrenergic receptor agonist		3 (25)
Intra-detrusor Botox®		2 (16.6)
SNS		1 (8.4)

N number, IQR interquartile range, RRP retropubic radical prostatectomy, RTX radiotherapy, HDR high-dose brachytherapy, SUI stress urinary incontinence, AUS artificial urinary sphincter, VLPP Valsalva leak point pressure, DO detrusor overactivity, SNS sacral neuromodulation, Botox® onabotulinumtoxin A

Outcome and medium-term results

A 4 cm cuff was used in two patients (8.6%), 4.5 cm in 11 patients (47.8%), 5 cm in seven patients (30.4%), 5.5 cm in two patients (8.6%) and a 6 cm cuff in one patient (4.3%). The median hospital stay was 1 day, IQR (1–2). There was no increase in post-operative analgesia requirements. There were six early post-operative complications, one patient developed a haematoma (at the perineal wound site) and another patient developed a seroma (at the lower abdominal wound site). Four patients developed transient acute urinary retention. A suprapubic catheter was placed in each case, and the retention spontaneously improved. One patient (4.3%) developed a urethral cuff erosion at 3 months post-operatively, and the device was infected and was removed. This patient was one of the four patients who developed transient urinary retention. He elected not to have a second AUS reinserted.

At a median follow up of 32 months, IQR (24–37), 22/23 (95.6%) of patients are still using their AUS with fascial wrap. There were no mechanical failures, other infections or device revisions. 24 h pad usage significantly dropped with AUS with fascial wrap surgery, $p = < 0.0001$. Excluding the patient with erosion, 17/22 (77.3%) of patients achieved complete continence, while 5/22 (22.7%) achieved social continence. Post-operative ISI scores were low, and patient satisfaction was high; the median PGI-I score was 1, IQR (1–1). Data are shown in Table 2.

Discussion

Urethral erosion is the most dreaded complication of AUS cuff placement, as the device will need to be extirpated. Patients with a history of pelvic radiation, previous urethroplasty, prior AUS complications, urethral atrophy or a 3.5 cm cuff are at an increased risk of cuff erosion [4–12].

Table 2 Outcome and medium-term results

	Total, <i>N</i> (%)	<i>P</i> value
Complications	6 (26)	
Grade 1	2 (33)	
Grade 2	0 (0)	
Grade 3a	0 (0)	
Grade 3b	4 (66)	
Grade 4	0	
Grade 5	0	
Complication type		
Haematoma/seroma	2 (8.6)	
AUR	4 (17.4)	
Erosion rate*	1 (4.3%)	
Continence		
Complete	11 (78.5%)	
Socially continent	2 (14.2%)	
Failure	1 (7.3%)	
ISI score, median(IQR)		
Stress leakage	0 (0–1)	
Urge leakage	0 (0–3)	
Pad	0 (0–3)	
Severity	1 (0–7)	
Bother score	0 (0–1)	
Pad usage/24 h		
Pre-operative	5 IQR (4–6)	
Post-operative	0 IQR (0–1)	<0.0001
PGI-I, median IQR	1 (1–1)	
Follow-up (months), median IQR	32 (24–37)	

N number, *AUR* acute urinary retention, *AUS* artificial urinary sphincter, *ISI* Incontinence Symptom Index questionnaire; incontinence, *PGI-I* Patient Global Impression of Improvement

*Complication grade

**Occurred in same patient who had AUR

Erosion rates as high as 41% have been reported for irradiated patients [17]. However, a more accurate erosion rate is in the range of 6–13%; these data are represented in Table 3 [1, 18]. Despite the observation of higher erosion rates in irradiated patients, the long-term urinary continence and patient satisfaction scores were not affected [17].

To circumvent the potential increased risk of urethral erosion in irradiated patients, we conceived the idea of the rectus fascial wrap with AUS placement. Rectus fascia was chosen, because of its ease of harvest, abundance, tensile strength, low infection rate, and nil rejection risk. The versatility of the rectus fascia has already been seen in pubo-vaginal sling surgery, complex reconstructive surgery, vaginal fistula repair, urethral diverticulum excision and even the treatment of Peyronie's disease [19–21].

In this study, we utilised autologous rectus sheath fascia to increase peri-urethral tissue bulk in patients that were at increased risk of AUS cuff erosion. The procedure was well tolerated by the patients, and there was minimal additional morbidity due to fascial harvesting. One patient (4.3%) developed a urethral erosion. Complete continence was achieved in 77.3% of patients, and 22.7% achieved social continence only using one pad/day.

Transcorporal cuff placement and the use of SIS wrap have been described as alternative options to reduce the risk of urethral erosion [13, 22–25]. However, these procedures are associated with disadvantages. The transcorporal placement of AUS cuff has been associated with higher intra-operative bleeding, post-operative haematoma, and worsened erectile function and may prevent the patient from future penile prosthesis surgery. The transcorporal technique increases only the tissues surrounding the urethra dorsally and does not increase tissue thickness ventrally. An SIS wrap increases tissue thickness circumferentially around the urethra and does not preclude a patient from penile prosthesis surgery but is associated with a high rate of retention. There is also a possible risk of graft rejection that could potentially

increase the infection risk, in addition to the inherent infection risks with the xenograft material.

We believe that the use of the rectus fascial wrap technique avoids these complications. A patient who has had a rectus fascial wrap will be able to undergo a penile prosthesis implant if needed, without the risk of injuring the cuff (as in transcorporal cuff technique), and there is no risk of rejection as the tissue is an autograft. Furthermore, rectus fascia has a known durability track record, with the graft remaining viable with no signs of degeneration up to 4 years after the initial implantation [26]. Rectus fascia is also easily harvested through the same lower abdominal incision for placing the reservoir and does not add significant morbidity to the operation. The rectus fascial wrap can also be considered in patients with small urethras that need bulking up, to fit a cuff.

The potential disadvantages of the autologous rectus fascial wrap technique include a slightly more extended operating time due to graft harvesting. We estimate the added time is approximately 15 min. We did not encounter any infection or bleeding from the harvest site in this study. One patient had a small seroma at the harvest site which spontaneously resolved. One patient (4.3%) in this study did suffer an erosion which occurred early in the post-operative period. The patient had post-operative retention and presented again with retention 3 months after AUS placement. An erosion was seen at the six o'clock position during cystoscopy. At the time of surgery, it was noted that the patient had a small and atrophic urethra, and as a result, a 4 cm cuff was placed. This smaller cuff may have precipitated the cuff erosion. All the other patients in the study had larger cuffs sited, and there were no other cases of erosions. We believe that the combination of the atrophic urethra and small cuff led to premature erosion. It is important to measure the urethra for cuff size both with and without graft and the cuff that best fits the graft in place should be used. If there is any doubt about cuff size, the bigger of the two options should be chosen, in these high-risk patients.

Table 3 Erosion rate and continence of artificial urinary sphincter after radiotherapy

	Previous RTX	Previous RTX		
		Erosion, <i>N</i> (%)	Revision, <i>N</i> (%)	Continence (%)
Wang et al. [29]	16/16	2 (12.5)	–	87
Perez et al. [7]	11/75	1 (9)	6 (55)	63
Gundian et al. [8]	15/56	2 (10)	7 (32)	93
Martins et al. [19]	28/81	3 (8.8)	10 (38)	91
Elliott et al. [9]	46/313	3 (6.2)	8 (18)	–
Manunta et al. [10]	15/72	3 (20)	8 (53)	73
Gomha et al. [11]	28/86	2 (7)	7 (25)	64
Lai et al. [12]	60/218	3 (6)	16 (27)	69
Ravier et al. [1]	61/122	8 (13.1)	18 (29.5)	63.9

N number, RTX radiotherapy

Table 4 Techniques to reduce risk of erosion

	Total	Technique	Retention, <i>N</i> (%)	Erosion, <i>N</i> (%)	Continence (%)
Trost et al. [13]	8	SIS	8 (100)	3 (37.5)	75
Lee et al. [26]	15	TC	0 (0)	1 (6.67)	80
Guralnick et al. [23]	31	TC		0 (0)	83
Wiedemann et al. [24]	17	TC	3 (17.6)	1 (5.8)	76.4
Le Long et al. [25]	37	TC	5 (13.5)	3 (8.1)	81.8
Present series 2019	23	RFW	4 (17.4)	1 (4.3)	77.3*

N number, *SIS* small intestinal submucosal, *TC* transcorporal, *RFW* rectus fascial wrap

*Complete continence and no pad usage

Four patients developed acute urinary retention in the post-operative period, and this rate is less than that of the SIS wrap technique and comparable to the transcorporal cuff technique (Table 4) [23]. In each of our case of retention, a suprapubic catheter (SPC) was placed on the lower abdomen, on the contralateral side of the reservoir site and, eventually, the retention resolved spontaneously (mean time 3 weeks) [13]. Transient urinary retention is likely due to swelling and inflammation of the urethra post-operatively, which may be more common with a circumferential wrap technique. As the urinary retention rate is moderately high, the surgeon may choose to place an SPC intra-operatively as a precaution.

The limitations of this study are the small number of patients, no control group, the follow-up was relatively short and only irradiated patients were included in the study. Patients with a previous urethroplasty were not included in the study, and only one patient with a failed AUS surgery was included. It would be interesting to see if this technique is suitable for these patients too. Despite these limitations, this preliminary study gave satisfactory results and a low complication rate for this new technique.

Conclusion

The rectus fascial wrap technique at the time of AUS placement is potentially a new technique for patients who are at high risk of AUS cuff erosion. The medium-term clinical outcomes have been encouraging in this pilot study and comparable to other techniques. However, further studies with larger patient numbers, a control group and long-term data are still needed at this stage.

Author contribution JG: protocol/project development, data collection manuscript writing/editing. DBH: data analysis, manuscript writing/editing. NH: manuscript writing/editing. DL: protocol/project development, data collection. EC: protocol/project development, data collection.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest and that there was no funding for this research.

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