

Autologous mid-urethral fascial sling for stress urinary incontinence: Long term outcomes

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Abstract

There has been an increasing interest in mesh-free surgical options for Stress Urinary Incontinence (SUI). Traditionally rectus fascia autologous slings were placed at the bladder neck but more recently they are positioned at the mid-urethra (aMUS). The long-term outcomes for these patients are described. A retrospective analysis of aMUS patients between 2009-2014 by a single surgeon for primary SUI was performed. All patients were evaluated pre-operatively with urodynamics. Patient reported outcomes were collected via postal questionnaire using the ICIQ-UI short-form questionnaire, 7-point Global Impression of Improvement score, questions on pad usage, self-catheterisation, overactive bladder treatment and re-operation rates. Results included 31 patients (response rate 63.8%). The median age was 49 years and median BMI was 27. Twenty-seven per cent (27%) of patients had stress predominant mixed urinary incontinence pre-operatively. Median length of follow up was 8 years (5-11); 60% of patients were dry and pad-free. Seventy-seven per cent (77%) found the surgery led to "much improvement" or "very much improvement" in quality of life. Thirteen per cent (13%) of patients reported a deterioration in quality of life. The median ICIQ-UI short form score was 5.5. 16.7% were taking medication and 1 patient received botulinum toxin therapy for overactive bladder symptoms. All these patients had mixed urinary incontinence on pre-operative urodynamics. The re-operation rate was 13.3%. One patient was self-catheterising. Three out of 31 (10%) had experienced pelvic pain, with 2 out of 31 (6%) experiencing dyspareunia. AMUS shows good long-term continence outcomes and is associated with low rates of de-novo overactive bladder symptoms and voiding dysfunction.

Introduction

Stress Urinary Incontinence (SUI) is perhaps more topical than ever, and remains

a common, debilitating and challenging problem to treat successfully. The success of surgical intervention has been evaluated and measured in many different ways, usually with the ultimate goal being durable long-term continence without negative complications of surgery. The potential for complications following SUI surgery is known all too well, but we must also consider patient-reported outcome measures, delayed adverse events, costs, degrees of continence and correlated sexual quality of life.

The National Institute for Health and Care Excellence (NICE) have recommended and identified that long-term outcomes of surgery using both mesh and non-mesh for SUI needs to be investigated. Currently, colposuspension, retro-pubic mid-urethral mesh slings and autologous rectus fascia slings are recommended, with the proviso that there is "limited evidence on the long-term adverse effects. In particular, the true prevalence of long-term complications is unknown."¹ One has to bear in mind that the significant press exposure that publicised the dangers of implanted mesh (including a national halt) has significantly reduced patient appetite for synthetic mesh slings.

The autologous Mid-Urethral Sling (aMUS), evolved from an initial autologous rectus fascial sling beneath the urethra at the bladder neck, popularised by Aldridge in 1942.² The tension-free aspect as well as mid-urethral placement was later revolutionised by Ulmstem in the 1990s.³ Retropubic placement of aMUS gives higher objective patient-reported cure rates when compared with the transobturator route at 8 years (no difference at 5 years) with level 1b evidence (EAU guidelines 4.3.1.3.3). Early studies assessing autologous sling outcomes positioned at the bladder neck showed that although continence remained high; patient outcomes were associated with de-novo Bladder Overactivity (OAB) and voiding dysfunction.⁴ Techniques have however moved on with adjustment of the position of the sling to the mid-urethra and modern outcomes have been published showing that short term complications are rare.⁵

UK Hospital Episode Statistics (UKHES) show that the aMUS is slowly increasing in popularity, while synthetic mesh options have fallen dramatically since 2013. Having said this, the absolute numbers for aMUS are low. UKHES data for 2018-19 state that the number of autologous sling operations was 193, with 189 on the waiting list. This is far fewer than the 620 patients who in the same year underwent colposuspension, with 615 on the waiting list. EAU guidelines clearly document and

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accept a higher risk with equivalent outcomes for colposuspension when compared with autologous sling, and therefore this disparity in popularity is difficult to explain. When compared to colposuspension, patients who undergo autologous fascial sling have greater satisfaction at 5 years (83% vs 73%, $p=0.04$).⁶ UKHES data also shows large numbers of bulking agent injections into the bladder outlet ($n=2960$). What the data does not tell us is how many patients received multiple injections over the 1-year time frame measured.

Evidence suggests that whatever method is used to treat SUI, the success diminishes with time. As mentioned, the method in which success is measured by different authors is not always consistent; but what is consistent is the finding of decreasing efficacy. What we know about long term outcomes for fascial slings include the work by Brubaker *et al.*, show-

ing continence rates at five years of only 30.8%, combined with high satisfaction rates of 83%.⁶ Khan *et al.*, showed a continence rate of 50.8% with a satisfaction rate of 70.1% at 10 years.⁷ The discrepancy between patient satisfaction and being categorised as ‘incontinent’ means that patient reported outcomes and quality of life measures are needed to qualify how we evaluate the intervention. There is a real scarcity of long-term evidence amongst the literature and that is what we aim to address with this study.

Materials and Methods

This is a retrospective case series, reviewing patients with primary stress urinary incontinence who underwent aMUS surgery by a single surgeon between 2009 and 2014. All patients who had had this surgery were invited to participate (44 in total).

The technique used in this study involves a small horizontal suprapubic incision (approximately 3cm) to harvest a minimum 6cm x 1cm strip of rectus fascia. Each end is then tied to a heavy absorbable suture (some surgeons use a non-absorbable)⁸ as a “sling on a string.” Hydro-dissection of the peri-urethral space is then carried out followed by a longitudinal incision in the anterior vaginal wall with further peri-urethral dissection. The strip of fascia is then placed in position using a retropubic needle in a “U” position at the mid-urethra, with the centre sutured in position. Cystoscopy excludes bladder injury. The two loose ends of suture are then tied over the rectus fascia without tension. A Foley catheter is inserted and removed on day 1 as described by Malde and Moore.⁵

All patients had SUI despite conservative measures including pelvic floor muscle training supervised by a specialist physiotherapist. In addition, all patients underwent a multi-channel urodynamic study prior to surgery (detrusor overactivity patients were not excluded). Patients who had undergone previous SUI surgery were excluded from this study.

Follow-up was obtained via written questionnaires posted in July 2019. The questionnaire incorporated the ICIQ-UI short form and a seven point Global Patient Impression of Improvement (PGI-I) score. The PGI-I is a validated questionnaire for evaluating treatment response.⁹ In addition there were questions to quantify pad usage, requirements for self-catheterisation, treatment for overactive bladder symptoms, the presence of chronic pelvic pain, dyspareunia and if further surgery for SUI had occurred.

Non-responders were phoned on a weekly basis for 4 weeks and if the patients were still not contactable, they were marked as non-responders. None of the patients who were successfully contacted refused to take part in the study.

Results

Thirty-one patients responded (response rate 70.5%) with a median length of follow-up of 8 years (range 5-11). The median age was 49 years (IQR 45.5, 56.5). The median BMI was 27.7 (IQR 25.5, 29.5, range 23-39). Two patients had deceased in the 8 years since surgery from unrelated causes. Mean Charlson co-morbidity index was 0.6. All patients had primary SUI in this study. Pre-operative multi-channel urodynamics demonstrated isolated SUI in 73%

of patients, with detrusor overactivity with leaks suggesting Mixed Urinary Incontinence (MUI) in the remaining 27% with proven detrusor overactivity.

At follow up, 19/31(61%) stated that urinary incontinence was no longer present (and were not wearing pads). The mean number of pads worn per 24 hours was 1.2 (Figure 1). Amongst those requiring pads the mean pad number was 3 over 24 hours. The median ICIQ-UI short form score was 5.5.

The PGI-I showed that 77% of patients reported that their lives were either ‘much improved’ or ‘very much improved’ following surgery. Four out of 31 (13%) of patients reported that their lives were subsequently poorer following the surgery. None of these patients had experienced dyspareunia, and 1 out of the 4 patients had chronic pelvic pain. The median ICIQ-UI was 18

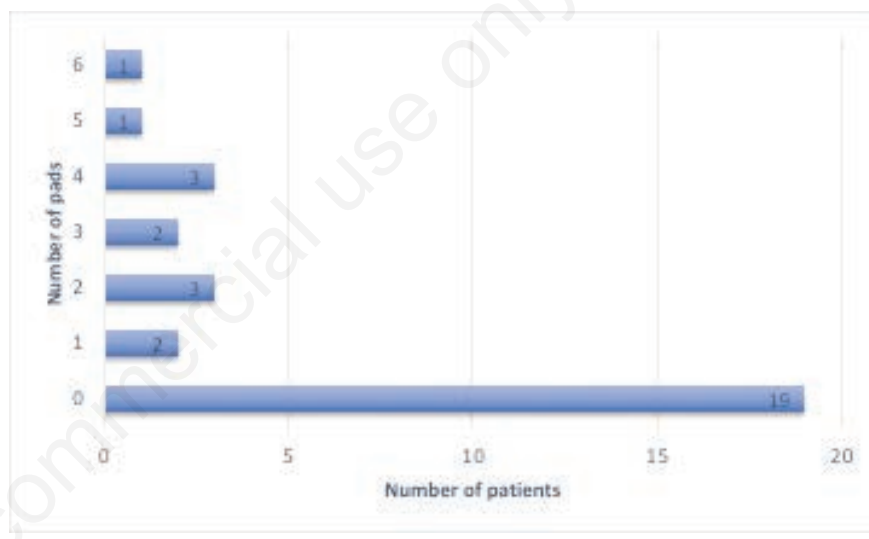


Figure 1. Number of pads used over 24 hours by these patients.

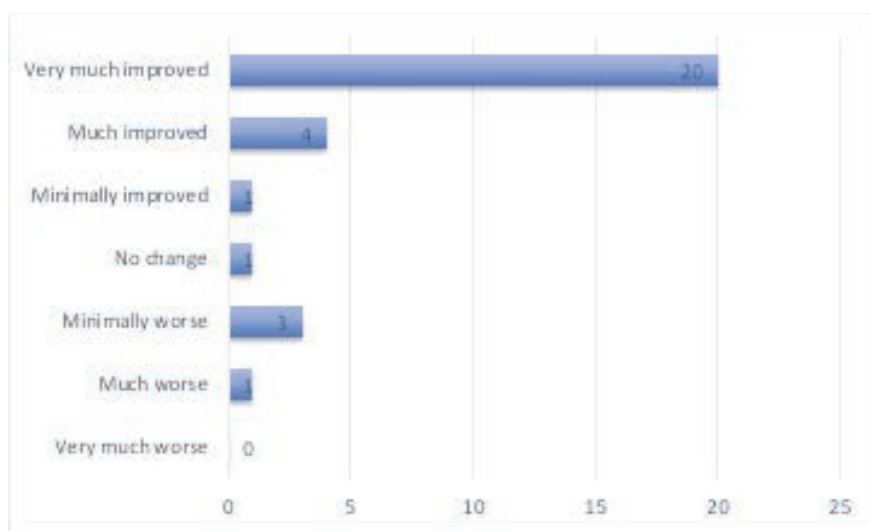


Figure 2. Global Impression of Improvement after aMUS.

(mean 15.25). All had detrusor overactivity on pre-operative urodynamics. Three out of the 4 patients experienced urinary incontinence more than once a day, with a moderate leak volume. The other one patient experience incontinence once a week or less and was no longer wearing pads, had no dyspareunia nor chronic pain. The mean interference of life score (0-10) was 8.7. Two out of the 4 patients were on anti-muscarinic medication and none had undergone subsequent botulinum toxin therapy.

Interestingly, those who described dyspareunia all documented an improved quality of life improvement. Two out of the 3 patients who described chronic pelvic pain following aMUS stated that their quality of life was 'very much improved', with 1 out of 3 that it was 'minimally worse.' *De novo* bladder overactivity was not observed. 5/31(16%) of patients were or had been taking medication for OAB symptoms – all of whom had known detrusor overactivity on pre-operative urodynamics. Voiding dysfunction was rare, with only one patient intermittently catheterising at follow-up. No revision surgery was completed as the patient was satisfied and did not want any further intervention. Three out of 31 (9.7%) patients had reported pelvic pain on most days in the preceding month. One of these patients had severe endometriosis with multiple previous pelvic operations and so couldn't determine what was exactly responsible for her pain. We cannot prove direct causation of the operation with these symptoms. Two out of 31 patients had experienced dyspareunia in the past month.

The re-operation rate was 12.9%. Two of the 4 patients had a second aMUS with a subsequent mean interference with life score of 2, and both stating that the second operation very much improved their quality of life. One patient had subsequent bulking agent injection, and one patient had subsequent colposuspension.

Discussion

This study suggests that aMUS is a good surgical option for primary SUI, with high patient satisfaction, improvements in continence and good durability at median 8-year follow-up. Current EAU guidelines suggest autologous sling as an option to treat primary SUI but the guidelines *do not take into account the positioning of the sling* (EAU Guidelines 4.3.1.4). Existing concerns surrounding the operation include the development of iatrogenic OAB, urge incontinence and voiding dysfunction,¹⁰ but our results suggest with the placement of the autologous sling at the mid-urethral level the risk of developing these complica-

tions is low.

Long-term follow up data is limited in the literature for SUI surgery, but a decline in efficacy over time is consistently seen across most papers.^{7,11} Randomized controlled trials rarely follow patients up for a prolonged period, and so we often rely on case series for answers about long term outcomes. Our study represents a 'real-world' retrospective series that will add to the literature and help to answer some of the questions posed in this area.

Other long-term studies include the paper by Khan *et al.*, with 10-year follow-up of 79 patients. This patient cohort excluded those with detrusor overactivity on pre-operative urodynamics whereas our study did not. Their results showed a decline in efficacy in the autologous fascial sling group from 90% to 75.4% at 10 years, with the dry rate actually increasing from 48% to 50.8%.⁷ At 8 years, our results show that the patients who rated themselves subsequently very much/much improved on PGI-I was 77%, with a dry rate of 61%. We have not performed prospective longitudinal data collection since date of surgery, but in a previous paper from the same surgeon evaluating 3-month outcomes of aMUS, the percentage of patients who rated 'very much/much improved' was 73%.⁵ Although not proven this alludes to durable patient satisfaction. From patient satisfaction to continence; this previous study from the same surgeon looking at 3-month outcomes (not identical patient cohort – this early study included patients with recurrent SUI), showed a mean pad number of 1. At 8 years, our mean pad number was 1.2. From the same paper, at 3-months 66% of patients were completely dry⁵ whereas as mentioned in the prior paragraph in this study at 8 years 61% were dry. The ICIQ-UI as a measuring tool has been shown to have good discriminant validity, with moderate internal consistency but high test-retest reliability.¹² There is also a proven correlation between ICIQ-UI and PGI-I, with this link described as moderate.¹³ The authors noted that there were larger reductions in overall symptom and quality of life scores associated with greater improvements in PGI-I after treatment. *De novo* OAB and voiding dysfunction are thought to be indicative of Bladder Outlet Obstruction (BOO) or injury to bladder autonomic innervation causing degrees of urinary retention. BOO is hypothesised to occur secondary to hyper-suspension of the urethra from the sling placement. Application of the sling at the mid-urethra and not at the bladder neck, combined with zero string tension means that in theory voiding dysfunction should be minimal.

Conversely, some studies have shown a cure of detrusor overactivity following autologous sling insertion, with a hypothesis that the strengthened support of the bladder neck and urethra by fascial sling may contribute to the resolution of OAB.¹⁴ This was contrary to the data from Albo *et al.*, who published their results that with autologous sling at the proximal urethra, 24% required treatment for OAB and persistent urge incontinence.¹⁵ A more recent study found de-novo storage symptoms in 8.2% of those with primary SUI treated with aMUS.¹⁶ Our results found that no patients developed de novo OAB following aMUS. 16% were on medication at 8-year follow up, all of whom had pre-existing detrusor overactivity on pre-operative urodynamics. Interestingly, the mean BMI of this group was 31.25 (obese), which follows a trend from other series noticing a possible link between obesity and post-operative OAB.¹⁷ Only one patient (3%) in our series was intermittently catheterising. The literature would suggest postoperative intermittent catheterisation rates for autologous sling in the range of 6-47%.^{16,18-21} No patient in our series required revision surgery to reverse voiding dysfunction. This differs from some studies showing a 10% rate of revision surgery,¹⁴ but is consistent with others.¹⁶

Background estimations of dyspareunia and chronic pelvic pain in women over 25 years vary, but have been measured between 11-14% and 14.8% respectively.²² This can muddy the waters when assessing iatrogenic pain from a historic operation. With these figures, even the quoted synthetic mesh related pelvic pain has a lower rate of pain than the background population. Added to this, the only tool used to illuminate this point was a single question with a binary "yes" or "no" response as has often been used in other studies. We found three patients who reported that they had pelvic pain in the last few months. One of these patients had severe endometriosis and had undergone many pelvic operations in the preceding years. Deciphering the true cause of pain between pre-existing pathology, iatrogenic cause or any other is difficult. In future studies, we would encourage authors to expand this question in a validated way to provide more detail. Interestingly, from our patients who reported dyspareunia (2/31), neither had ticked that they had continuous chronic pelvic pain. Although tiny numbers, this goes against other studies showing that chronic pelvic pain and dyspareunia often co-exist.²³ One recent study showed that with autologous transobturator tape insertion mean female sexual function index scores were seen to improve post-operatively.²⁴ Again, it is difficult to exclude other

causes of dyspareunia in a cohort of post-menopausal women. Of note - both of these patients stated that the operation had improved their quality of life on the PGI-I.

Limitations of this study include its retrospective nature, and whether the data is reproducible in different centres. It is also known that continence status can fluctuate.²⁵ Our data is a snapshot in time that may not be representative and it could display inaccuracies. With less than 100% response, we are susceptible to consumer service behavioural bias; where people are more likely to report matters if we are dissatisfied than when they are satisfied. We could hypothesise therefore that the number of people whose life was improved by the operation was possibly under-represented. Other confounding variables that influence continence were not measured in a continuous manner, or at follow up. These include level of physical activity, smoking status, ethnicity and the severity of comorbidities. We must also remember that long-term continence is also influenced by the natural history of the continence mechanism over time, with incontinence increasing with age. Finally, it has also been reported before that there is often a disparity between satisfaction and decreasing continence rate. Previous studies have shown that 63% of women categorized as incontinent were satisfied with their continence status at 5 years²⁶ and this could be investigated further.

Conclusions

These results provide real detail and information about aMUS, both for the primary SUI patient and the surgeon, with long-term follow up showing 77% of patients felt the surgery had improved their lives. This data fills a void in the literature, providing the long-term answers for this contemporary mesh-free technique. This data can now be used to benchmark surgeon's data against other 'real-world' studies looking at the alternative mesh-free surgical options for SUI and be used to properly consent patients in this litigious field of surgical practice.

References

- NICE. NICE - 1.5 Surgical management of stress urinary incontinence. 2019. Accessed: 30 December 2019. Available from: <https://www.nice.org.uk/guidance/ng123/chapter/recommendations#a-utologous-rectus-fascial-sling>
- Aldridge A. Transplantation of fascia for the relief of urinary stress incontinence. *Am J Obstet Gynecol* 1942;44:398-441.
- Ulmstem U, Henriksen L, Johnson P, Varhos G. An ambulatory surgical procedure under local anaesthetic for treatment of female urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 1996;7:81.
- McGuire E, Lytton B. Pubovaginal sling procedure for stress incontinence. *J Urol* 1978;119:82-4.
- Malde S, Moore J. Autologous mid-urethral sling for stress urinary incontinence: Preliminary results and description of a contemporary technique. *J Clin Urol* 2016;9:40-47.
- Brubaker L, Richter H, Norton P, et al. Five year continence rates, satisfaction and adverse events of burch urethropexy and fascial sling surgery for urinary incontinence. *J Urol* 2012;187:1324-30.
- Khan Z, Nambiar A, Morley R, et al. Long-term follow-up of a multicentre randomised controlled trial comparing tension-free vaginal tape, xenograft and autologous fascial slings for the treatment of stress urinary incontinence in women. *Br J Urol Int* 2015;115:968-77.
- Cubuk F, Yanaral A, Sahan A, et al. Modified autologous transobturator tape surgery - a prospective comparison with transobturator tape surgery. *Urology* 2020;146:72-8.
- Yalcin I, Bump RC. Validation of two global impression questionnaires for incontinence. *Am J Obst Gynecol* 2003;1:98-101.
- Ostergard D. Primary slings for everyone with genuine stress incontinence? The argument against. *Int Urogynecol J Pelvic Floor Dysfunct* 1997;8:321-2.
- Nilsson C, Palva K, Aarnio R, et al. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. *Int Urogynecol J* 2013;24:1265-9.
- Lim R, Long Liang M, Lau Y, Yuen K. Validity, reliability, and responsiveness of the ICIQ-UI SF and ICIQ-LUTSqol in the Malaysian population. *Neurourol Urodynam* 2015;36:2.
- Nystrom E, Sjostrom M, Stenlund H, Samuelsson E. ICIQ symptom and quality of life instruments measure clinically relevant improvements in women with stress urinary incontinence. *Neurourol Urodynam* 2015;34:747-51.
- Mitsui T, Tanaka H, Moriya K, et al. Clinical and urodynamic outcomes of pubovaginal sling procedure with autologous rectus fascia for stress urinary incontinence. *Int J Urol* 2007;14:1076-9.
- Albo M, Richter H, Brubaker L, et al. Burch colposuspension versus fascial sling to reduce urinary stress incontinence. *N Engl J Med* 2007;24:2143-55.
- Osman N, Hillary C, Mangera A, et al. The midurethral fascial "sling on a string": an alternative to midurethral synthetic tapes in the era of mesh complications. *European Urology* 2018;74:191-6.
- Zycznski H, Albo M, Goldman H, et al. Change in overactive bladder symptoms after surgery for stress urinary incontinence in women. *Obstet Gynecol* 2015;126:423-30.
- Jeon M, Jung H, Chung S, et al. Comparison of the treatment outcome of pubovaginal sling, tension-free vaginal tape, and transobturator tape for stress urinary incontinence with intrinsic sphincter deficiency. *Am J Obstet Gynecol* 2008;199:1-4.
- Fliesser AJ, Blaivas JG. Outcome of urethral reconstructive surgery in a series of 74 women. *J Urol* 2003;169:2246-9.
- Morgan T, Westney O, McGuire E. Pubovaginal sling: 4-year outcome analysis and quality of life assessment. *J Urol* 2000;163:1845-8.
- Morgan D, Dunn R, Fenner D. Comparative analysis of urinary incontinence severity after autologous fascia pubovaginal sling, pubovaginal sling and tension-free vaginal tape. *J Urol* 2007;177:604-8.
- Ayorinde AA, Bhattacharya S, Druce KL, Jones GT, Macfarlane GJ. Chronic pelvic pain in women of reproductive and post-reproductive age: a population-based study. *Eur J Pain* 2017;21:445-55.
- Zondervan KT, Yudkin P, Vessey M, et al. The prevalence of chronic pelvic pain in women in the United Kingdom: a systematic review. *Br J Obstet Gynecol* 1998;105:93-9.
- Çubuk A, Şahan A, Özkaptan O, et al. Impact of autologous transobturator sling surgery on female sexual function: a comparative study with mesh used mid-urethral sling surgeries. *Urol Int* 2021. doi: 10.1159/000514415.
- Lifford KL, Townsend MK, Curhan GC, et al. The epidemiology of urinary incontinence in older women: incidence, progression, and remission. *J Am Geriatr Soc* 2008;56:1191-8.
- Tennstedt SL, Litman HJ, Zimmern P, et al. Urinary Incontinence Treatment Network. Quality of life after surgery for stress incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2008;19:1631-8.