Review Article

The male slings: an effective and safe alternative surgical treatment to the artificial urinary sphincter for male stress urinary incontinence?—a narrative review

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Background and Objective: The ideal candidate for a male sling (MS) should have a mild to moderate degree of stress urinary incontinence (SUI). This narrative review article evaluates the current MS devices in the commercial market and examines the role of MS as an effective and safe alternative treatment option for male SUI.

Methods: The available literature on MS was reviewed and relevant clinical studies pertaining to each MS were summarised with emphasis on device design and technology as well as specific surgical findings relating to clinical outcomes.

Key Content and Findings: Over the past two decades, there have been considerable scientific advances in MS design and technology, and MS is an attractive alternative for patients who might not require or want an artificial urinary sphincter. The modern MS can be classified as adjustable or non-adjustable types and is placed either through a retropubic or transobturator (TO) approach. Strict patient selection and counselling, selection of MS with proven clinical records, and safe surgical practice are paramount to ensure a high continence rate, good patient satisfaction, and low postoperative complications. Published data on various MS materials and devices showed reasonable clinical efficacy and safety outcomes, although many of these synthetic MS devices may not be available worldwide due to a lack of regulatory approval in many countries. While the ideal MS is probably yet to be developed, continued scientific advances in slings design, mesh technology, and more refined surgical techniques will improve the continence rate and deliver better safety records.

Conclusions: As clinical data matures with longer-term outcomes coupled with advances in scientific designs and technology, the ability to have and select the optimal MS for a particular patient will come to fruition.

Keywords: Male sling (MS); artificial urinary sphincter; clinical outcomes; device designs; surgical techniques

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Introduction

The first external bulbar urethral compressive device to treat male stress urinary incontinence (SUI) was developed in the late 1960s although the "true" modern male sling (MS) was created in the late 1980s (1,2). By the early 2000s, several bulbourethral composite slings with various material types were designed and marketed with varying degrees of commercial success in certain countries (3,4). While the InVance MS (American Medical Systems, MN, USA) bone anchor sling fixation managed to gain considerable popularity and commercial success (5,6), potential device morbidity related to bone screws such as pubic bone osteitis and bone-anchor dislodgement, coupled with the emergence of more effective alternative MS devices has resulted in its discontinuation.

Over the last two decades, scientific advances in MS design and technology have led to a plethora of MS devices in the commercial market. The ideal candidate for MS should report a mild to moderate degree of SUI, has an adequate residual external urinary sphincter function, and is able to generate reasonable detrusor contraction to overcome the fixed resistance of the sling to void. While the current AMS 800 device AMS 800 (Boston Scientific, previously the American Medical Systems, Minnetonka, MN, USA), has been considered the gold standard of treatment for male SUI (7-9), it is not without limitations such as the need for the patient to manipulate the device to void. Hence, there exists a need for MS as an attractive alternative to the AMS 800 to treat male SUI. However, the current MS devices are different in terms of design, surgical approaches, and whether they can be "adjusted". These confounders can significantly impact actual clinical efficacy and/or safety outcomes, and these parameters are often difficult to compare and probably it is not appropriate to do so since each device technology treats a different degree of SUI and is highly dependent on the patient factors (such as the presence of radiation, need to operate a device, and mental competency), surgeon's preference and availability of the device in the institution or country.

The following narrative review article evaluates the current MS devices in the commercial market and examines the role of MS as an effective and safe alternative treatment option for male SUI. We present this article in accordance with the Narrative Review reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-23-13/rc).

Methods

The available literature on MS was reviewed on PubMed and EMBASE databases between 1 January 2000 and 1 December 2022 and available literature about MS was reviewed and the following terms "urinary sling", "urinary incontinence", "continence device", and "continence surgery" were searched (*Table 1*). Relevant clinical studies pertaining to each MS were summarised with emphasis on device design and technology as well as specific surgical findings relating to clinical outcomes. This paper is not intended to provide a comprehensive review of each MS nor a full surgical description of the surgical techniques, potential complications, and/or troubleshooting for potential complications relating to MS. Since there are limited published comparative studies among these slings in a head-to-head trial, a narrative review is undertaken instead of a proper systematic review or meta-analysis, a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) protocol was not implemented. This narrative review serves as an extension to the recent 7th International Consultation on Incontinence report on male surgery for urinary incontinence chapter (10).

Clinical findings

MS: device design and technology

The modern MS can be classified as adjustable or non-adjustable types and is placed either through a retropubic or transobturator (TO) approach. The current adjustable MS are Argus (Promedon, Cordoba, Argentina), ReMeex (Neomedic, Barcelona, Spain), and ATOMS (Adjustable TO Male System) (A.M.I. GmbH, Feldkirch, Austria) while available non-adjustable MS are AdVance (Boston Scientific), I-STOP TOMS (CL Medical, Sainte-Foy-lès-Lyon, France) and Virtue (Coloplast, Minneapolis, USA) slings (2) (*Table 2*). While the adjustable MS provides a theoretical benefit over non-adjustable MS in that it can be revised (adjusted) in a relatively simple surgery to provide additional urethral compression if the patient has persistent or develops recurrent SUI after the initial surgery, there are reports to suggest that adjustable MS can be associated with higher complication and explant rates following the revision procedure(s) (42). A recent study (43) reported that more men chose an adjustable MS over a non-adjustable MS when given the options despite no significant difference observed in the clinical outcomes and similar patient satisfaction rates.

The Argus sling (Promedon) was one of the modern

Table 1 The search strategy summary

Items	Specification
Date of search	1st December 2022
Databases and other sources searched	PubMed and EMBASE databases
Search terms used	"urinary sling", "urinary incontinence", "continence device", and "continence surgery"
Timeframe	From 1st January 2000 to 1st December 2022
Inclusion and exclusion criteria	Inclusion: relevant clinical studies pertaining to each MS were summarised with emphasis on device design and technology as well as specific surgical findings relating to clinical outcomes
	Exclusion: this paper is not intended to provide a comprehensive review of each MS nor a full surgical description of the surgical techniques, potential complications, and/or troubleshooting for potential complications relating to MS
Selection process	The first author conducted the selection and all the co-authors approved the included studies
Any additional considerations, if applicable	This narrative review serves as an extension to the recent 7th International Consultation on Incontinence report on male surgery for urinary incontinence chapter

MS, male sling.

Table 2 Male slings: device design and technology

Male sling	Manufacturer	Types	Specifications	References
Argus	Promedon	Adjustable	A silicone foam pad connected by two silicone columns with multiple conical elements	(11-13)
Remeex	Neomedic	Adjustable	A polypropylene suburethral sling suspended by traction threads that are connected to a mechanical regulator (known as a varitensor)	(14-16)
ATOMS	A.M.I. GmbH	Adjustable	An adjustable inflatable silicone cushion with polypropylene mesh arms that is connected to a refillable titanium port	(16-20)
AdVance	Boston Scientific	Non-adjustable	A polypropylene mesh with 2 arms	(21-31)
Virtue	Coloplast	Non-adjustable	A polypropylene mesh with 4 arms	(32-36)
I-STOP TOMS	CL Medical	Non-adjustable	A polypropylene mesh with 4-arms	(37-39)
Surgimesh M-sling	Aspide Medical	Non-adjustable	A polypropylene mesh with 4 arms	(40,41)

MS developed in 2004 (11). This adjustable MS consists of a silicone foam pad connected by two silicone columns with multiple conical elements where silicone washers can be placed to regulate the desired tension between the suburethral pad and the bulbar urethra. It was first released as a retropubic device, and the newer Argus-T version can be placed through a TO approach (12,13). Around the same time, another adjustable MS called the Remeex sling (Neomedic), which denotes Readjustable Mechanical External device was developed (14). This device has a polypropylene suburethral sling suspended by traction threads which are connected to a mechanical regulator (known as a varitensor) that can adjust the tension of the sling (15).

The non-adjustable AdVance sling (Boston Scientific formerly American Medical Systems) was introduced around 2006 (21) and comprises a polypropylene material with 2 arms (22,23). The second generation AdVanceXP sling was released in 2010 with improved features such as tension fibre within the sling and chevron anchors on each arm as

well as a more ergonomic trocar (24-29). The Virtue sling (Coloplast, Humlebaek, Denmark) was released in 2009 (32,33). It was marketed as a non-adjustable MS although the mesh can be "tightened" (adjusted) later with additional imbricating non-absorbable fixation sutures between the prepubic mesh arms and underlying pubic bone for further mesh compression (34,35).

The I-STOP TOMS sling (CL Medical) was developed based on the female I-STOP TO sling to incorporate a central monofilament polypropylene mesh component with 4-arms back in 2009 (37-39). The Surgimesh M-sling (Aspide Medical, La Talaudière, France) is another non-adjustable MS manufactured in France by the Aspide Medical company around the mid-2010s (40). Its design is similar to that of Virtue MS with a quadratic 4-arm polypropylene urethral sling that consisted of both TO and prepubic arms (41).

The ATOMS (A.M.I. GmbH) is designed by the Agency for Medical Innovations in 2010 (17). The ATOMS system is made of a TO-placed polypropylene mesh tape and an adjustable soft inflatable silicone cushion that is connected to a refillable titanium port. In the earlier model, the refillable port is larger in size and placed in the inguinal region, but the newer version of ATOMS has a smaller port that can be inserted in the scrotum (18,19).

Published data on various MS materials and devices showed reasonable clinical efficacy and safety outcomes (2,42,44), although many of these synthetic MS devices may not be available worldwide due to a lack of regulatory approval in many countries (2,16). While there is no convincing evidence to support that one type of MS is superior to another device (16,43,45), the TO approach for sling placement is the preferred technique and has largely replaced the retropubic MS placement since it is safer and avoids the risk of bladder injury (2,46).

History of urethral stricture (30), pelvic radiation (31), severe SUI (36), low abdominal leak point pressure (47), and previous incontinence surgery (48-50) are associated with higher MS failure and complication rates. Critical success factors for MS are good urethral mobility and the presence of a residual sphincter activity so that MS can provide good proximal urethral relocation and compression with ensuing urethral coaptation (2,8,9,20,42).

There is limited literature comparing nonadjustable and adjustable MS. It is difficult and not possible to compare the various MS efficacy due to the heterogeneous study population, the definition of urinary continence, inconsistent use of validated outcome measures, and relatively short follow-up study (8,9). In terms of MS composition, the use of organic (resorbable) material is less efficacious than synthetic (permanent) sling material (2,44). Furthermore, failure to adhere to strict surgical principles and manufacturer's guidelines such as placement and suture fixation of the TO sling arms could contribute to an inferior outcome (44,50). More recently, a systematic review and meta-analysis comparing ATOMS and ProACT devices (20) reported higher continence (68% *vs.* 55%, P=0.01) and improvement (91% *vs.* 80%, P=0.007) rates for ATOMS than ProACT device based on a combined data from 41 observation studies. Furthermore, the satisfaction rate was higher for ATOMS (87% *vs.* 56%, P=0.002) and the explant rate was higher for ProACT (5% *vs.* 24%, P<0.0001) although significant heterogeneity was evidenced due to various factors such as incontinence severity baseline, difficulties for common reporting of complications, different number of adjustments and time of follow-up and the absence of proper randomized studies.

In recent times, MS has been shown to be an effective treatment for climacturia in males following radical prostatectomy (51) and the use of polypropylene mini-sling mesh provides a feasible surgical adjunct at the time of inflatable penile prosthesis surgery in a subset of patients with climacturia and/or minimal incontinence (52). Furthermore, a recent study reported that MS can enhance male sexual function with regard to erectile and orgasm domains in addition to urinary continence (25).

MS or artificial urinary sphincter?

In recent times, synthetic MS has gained significant popularity over AUS due to its relatively low cost, being less invasive in nature, and being a simpler procedure. Furthermore, the patient can void spontaneously without the need to manipulate a pump. Published systematic reviews and meta-analyses on MS showed fixed slings had an objective cure rate that varies between 8.3% and 87% [pooled estimate 0.50; 95% confidence interval (CI): 0.45–0.56; I^2=82%], and the subjective cure was achieved in 33–94.4% of patients, while adjustable slings showed objective cure rates between 17% and 92% (pooled estimate 0.61; 95% CI: 0.51–0.71; I^2=88%) and subjective cure rate varies between 28% and 100% (42). While the MS is often considered less effective than the AMS 800 device and is recommended for males with mild to moderate SUI and without prior radiation therapy (8,9,48), most patients will choose an MS over the AMS 800 device when given

an option (53). Nonetheless, two systematic reviews and meta-analyses of various surgical treatments for male SUI concluded that AMS 800 device is superior to MS for moderate male SUI (54,55).

The recent publication of a randomized, non-inferiority clinical trial comparing MS surgery to AUS in men, has demonstrated that MS provides similar continence rates as an AUS [difference 3.6% (95% CI: −11.6% to 4.6%, P_{NI}=0.003)], showing noninferiority in terms of improvement in incontinence symptoms (56). Nonetheless, post hoc analysis demonstrated better clinical outcomes for the AMS 800 device than MS in almost all secondary outcome measures including postoperative continence, overall satisfaction, and complication rates. Furthermore, the perceived potential advantages of MS over the AMS 800 device such as shorter hospital stays, and lower costs were not confirmed in the MASTER trial.

At present, published guidelines and expert consensus support the AMS 800 device as the standard of care for the treatment of male SUI (8,9,42). Furthermore, the AMS 800 device remains the most effective salvage treatment option for recurrent SUI following MS failure. It is very rare for a patient to receive a MS after an AMS 800 failure (8,9).

Conclusions

Presently, the perceived advantages of adjustable MS did not translate to significant continence outcomes over complication rates when compared to non-adjustable MS. While the ideal MS is probably yet to be developed, continued scientific advances in slings design, mesh technology, and more refined surgical techniques will improve continence rate and deliver better safety records. As clinical data matures with longer-term outcomes coupled with advances in scientific designs and technology, the ability to have and select the optimal MS for a particular patient will come to fruition. It is critical that patients understand that MS may not provide complete continence, but MS offers some advantages over AUS. Strict patient selection and informed consent, selection of MS with proven long-term clinical data, and adherence to safe surgical practice are paramount to ensure an excellent continence rate, high patient satisfaction rate, and minimal postoperative complications.

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Footnote

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