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Single incision slings: Past, present, and future

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Abstract

Pubovaginal slings have become the gold standard to treat stress urinary incontinence. Traditionally, the sling referred to a suspensory that was placed under the urethra and brought through the retropubic space and anchored on either side of the midline. Since this original concept, there have been many materials used for the sling, and there have been many different anchoring approaches. Most agree that one of the best materials is polypropylene mesh. However, the means of anchoring the device and where best to have this anchorage placed is debatable. The options for anchoring simply include using darts *vs* not to hold the sling in place. The location of this anchorage, on the other hand, is much more controversial. The main locations are retropubic, transobturator, and *via* a single incision. The obturator and retropubic slings have become the standard of care over time. The single incision sling, on the other hand, is starting to be more acceptable which has resulted in it being used more frequently. The single incision relies on mainly anchoring the sling through the obturator internus muscle with possible inclusion of the obturator membrane. The purpose of this review article is to present the data that exists for the use of the single incision sling.

Key words: Sling; Stress urinary incontinence; Incontinence; Single incision sling; Surgery

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Core tip: Polypropylene slings have become the mainstay of therapy for treating stress urinary incontinence in women. Historically, these slings have worked well, but there was always the concern of morbidity. The goal of the single incision sling (SIS) is to provide high efficacy with minimal side effects. The initial use of the SIS was mottled by confusion with the techniques for deployment. The most recent data has shown that when the SIS is used appropriately the success rates are similar to standard mid-urethral slings with minimal risk of bladder, vascular, or nerve injury as well as chronic pain.

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INTRODUCTION

Pubovaginal slings have been used for decades. However, it wasn't until the mid to late 1990's that the use expanded. This expansion was due in part to the use of polypropylene mesh. It was Ulmsten *et al*[1] who proved to the medical community that one could correct stress urinary incontinence (SUI) by using a piece of polypropylene mesh. Additionally, at the same time the synthetic sling became available, there was an enormous push by the device companies to educate the physicians. This education did not only include Urologists who were the main surgeon providing slings to their patients but it included gynecologists. This initially involved using transvaginal tape through the retropubic space. Although this worked well, there still was the potential for adverse events involving the bowel, bladder, and vascular structures[2,3]. Most of these complications were due to the use of trocars in the retropubic space. The transobturator sling was an evolutionary advancement, which attempted to preserve the high success rates of retropubic polypropylene slings while minimizing the chance of surgical complications. This sling in theory eliminated the chance of bowel injury and significantly reduced the chance of bladder injury. However, it still proved to possibly cause vascular injury to the obturator vessels or nerve injury to the obturator nerve. These patients were also at risk of groin pain either from muscular or tendon injury or perhaps neurologic irritation. Also, the medical community was looking for a sling that was the least invasive with high success rates and minimal chance of complications. In response to these desires, a polypropylene sling using a single vaginal incision was created.

The single incision sling (SIS) technique enables the user to place a piece of polypropylene mesh through a single vaginal incision. The idea of a SIS was first used approximately 7 years ago. The sling material varied in lengths from 8-9 cm. Some of these slings used fixation anchors while others relied more on scaring to provide fixation. Throughout the years, there were even variable length slings developed. The techniques for placement of many of the previous SISs were not consistently uniform. As a result, the early data for the SISs were not always comparable to those seen with transobturator and retropubic slings. However, the most recent retrospective and prospective studies on the use of second-generation SIS systems have demonstrated relatively high success rates with minimal morbidity. This review will provide evidence in support of the SIS.

SURGICAL TECHNIQUE

To enhance the understanding of the SIS, it is important to understand how it is placed. The description below provides the generalized technique for the placement of the SIS.

Prior to the surgery, IV antibiotics are administered. The patient is then given either local, general, or regional anesthesia at the discretion of the surgeon in combination with the anesthesiologist. A dorsal lithotomy position is then achieved to facilitate surgery. A foley is inserted to empty the bladder. A 1-2 cm anterior vaginal wall incision is made at the level of the midurethra. The dissection is than carried out laterally to the level of the inferior pubic rami on either side using blunt and sharp dissection. This surgical preparation provides a pathway for the delivery of the sling arms. The polypropylene mesh tip is placed onto an introducer, which is inserted into the dissected pathway and used to pass the distal arm anchors through the obturator internus muscle behind the pubic ramus. The sling is advanced using the introducer until the midline of the sling reaches the patient's midline under the urethra. This placement of the sling tip is repeated similarly on the opposite side. The polypropylene mesh sling is then brought to rest under the midurethra in a tensionless fashion. The anchors of the sling are resting in the obturator internus muscle. The goal of the surgeon is to visually see the periurethral tissue "pillowing" through the mesh material with a potential space existing between the sling and urethra such that a small instrument could easily be inserted. Cystoscopy is performed to ensure the bladder, urethra, and ureters are not compromised. The vaginal incision is then closed with a running absorbable suture.

CLINICAL STUDIES

There have been a tremendous number of articles written on the Single Incision technology. The early articles using SIS were mixed, and most early findings pertaining to their efficacy did not show equivalence to the results of the transobturator and retropubic slings[4]. Walsh[5] showed in 2011 that the use of the TVTsecur sling resulted in cure rates of 76% both subjectively and objectively. He described using both a "U" approach and a hammock approach. He concluded that more studies are needed before TVT secure could be routinely used. There were other slings such as the Ajust sling by C.R. Bard, Inc., New Providence, NJ United States, that conceptually made sense and, if used in the appropriate hands, yielded high success rates. In Jiang *et al*[6] paper, he showed that using the AJust sling resulted in subjective and objective sure rates of 82.3% and 91.2% in a 12-mo follow-up respectively. This was a single site study where there were no cases of bladder perforation or major bleeding. There were also no reported cases of groin pain at 6 and 12 mo[6].

This study exemplifies the importance of technique when placing the SISs. Although this group of researchers was able to achieve high success rates with this sling, the sling was not universally deployed successfully, and, as a result, this sling even with its high success rates is no longer being marketed by C.R. Bard Inc.

Initially, the SIS was thought to work differently than other slings and its placement and tensioning were not standardized. Surgeons were using it to go in the

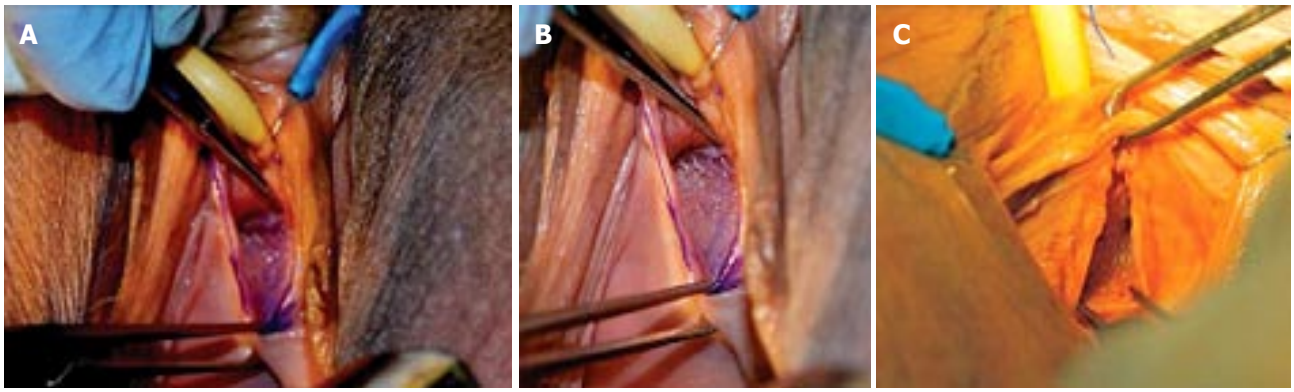

Figure 1 Placement of mid-urethal slings to alleviate stress urinary incontinence using the (A) retropubic; (B) transobturator; (C) single incision techniques.

retropubic direction as well as the obturator location. It then became accepted by most that the placement was to be in the obturator internus muscle. The tension could be set in many different ways, but the end result would be a sling that was up against the urethra with the periurethral tissues "puckering or pillowing" through the mesh openings such that a potential space existed to insinuate a small medical instrument between the urethra and the sling (Figure 1).

In the article entitled "Cadaveric Assessment of Synthetic Mid-Urethral Sling Placement", the placement of the SIS was compared to the obturator and retropubic sling[7]. It was determined that the SIS was similar to the others in appearance and furthermore was most likely at the midurethra and had the most correct tension. It is studies like this that show what is being done by the three sling approaches have different means of achieving the same endpoint.

There are presently around 26 randomized controlled trials, which are using 7 different types of SISs. In these studies approximately 3300 patients were evaluated[8].

Many of the studies have been performed comparing the SIS to the standard mid-urethral slings, which are considered to be either obturator slings or retropubic slings. The majority of these studies support the use of the SIS[9-25]. Lee *et al*[25] recently published a randomized trial comparing single incision *vs* outside-in transobturator mid-urethral sling. This paper studied the MiniArc SIS and showed an objective cure rate of 94.4% and a patient reported cure of 92.2% at 12 mo. The Monarc sling was the comparator to the MiniArc and it showed statistically similar results with a 96.7% objective sure and a 94.2% subjective cure. The operative time was reduced by 0.5 min in the SIS group. The Monarc group required more analgesia in the first 24 h and reported more short-term groin pain. The quality of life questionnaires and sexual function questionnaires revealed similar results in both groups. The patients undergoing repeat incontinence surgery were 2.7% in the MiniArc group compared to 1.8% in the Monarc group while 6.2% of the Monarc group had groin pain beyond 6 mo compared to 0% in the MiniArc group. For both patient groups, BMI and age were associated with higher failure rates[25].

Similar data was shown by Enzelsberger *et al*[26] who also looked at the MiniArc SIS and compared it to the Monarc. In this study, there was an objective cure rate of 82%. They also had shorter OR times and less groin pain. In our long-term study using the Solyx SIS, we also saw subjective success rates of 93% over a mean follow up of 43 mo[27]. There was, however, one recent article by Basu *et al*[28] that showed a lower success rate with the SIS than an obturator sling. This study also had a higher erosion rate with the SIS, which possibly implies a technical issue with using the single incision technology[28].

In the Mostafa *et al*[8] metaanalysis, he primarily looked at the MiniArc sling as compared to either retropubic or obturator slings. This study shows an aggregate objective cure rate of 88% with a subjective cure rate of 76% for the SISs. Additionally, the SIS had shorter operative times, lower incidence of groin pain, earlier return to work, and lower pain scores. There were no significant differences in subjective or objective cure rates for the SIS *vs* the standard mid-urethral slings. Also, the impact on quality of life and sexual function were similar. The TVT secur was not included in this analysis due to its poor early data and that it is now off the market as of 2012.

CONCLUSION

There are many SISs currently available. Each is different in its design and applicator as well as technique for placement. They all hope to provide the same endpoint, which is a backboard for the urethra to use with increases in abdominal pressure. Current data does suggest that if the SIS is used appropriately there would be an enhanced safety profile with less postoperative discomfort and high success rates. It is the responsibility of the medical community to provide guidelines for the use of these slings and to standardize their placement to assure reproducibility of the success rates. The correct use of SISs will ultimately lead to a treatment, which provides high success rates with low morbidity for our patients who suffer with SUI.

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