

# Arc to Arc minisling 1999: a critical analysis of concept and technology

PAULO PALMA

Chief Professor of Urology, UNICAMP, Brazil

**Abstract:** The aim is to critically review the Arc to Arc minisling (Palma's technique), a less invasive midurethral sling using bovine pericardium as the sling material. **Methods:** The Arc to Arc minisling, using bovine pericardium was the first published report of a minisling, in 1999. The technique was identical to the "tension-free tape" operation, midline incision and dissection of the urethra. The ATFP (white line) was identified by blunt dissection, and the minisling was sutured to the tendineous arc on both sides with 2 polypropylene 00 sutures. **Results:** The initial results were encouraging, with 9/10 patients cured at the 6 weeks post-operative visit. However, infection and extrusion of the minisling resulted in sling extrusion and removal, with 5 patients remaining cured at 12 months. **Critical analysis and conclusion:** The Arc to Arc minisling was a good concept, but failed because of the poor technology available at that time. Further research using new materials and better technology has led to new and safer alternatives for the management of stress Urinary Incontinence.

**Key words:** Urinary stress incontinence; Arc to Arc minisling, Bovine pericardium

## INTRODUCTION

The understanding of stress urinary incontinence (SUI) pathophysiology has consistently improved over the past decade, and has resulted in the development of many surgical techniques. Based on the Integral Theory, Petros and Ulmsten proposed the tension-free vaginal tape (TVT). According to this theory a midurethral tape can stabilize the urethra during straining without modifying the urethral mobility.<sup>1, 2</sup> Despite the good cure rate reported for TVT, major complications as injuries to bowel and major blood vessels have been described.<sup>3</sup>

As an alternative to the TVT procedure, the transobturator tape (TOT) technique was developed by Delorme in 2001, to reduce the perioperative complications related to the penetration in the retropubic space.<sup>4</sup> Several short-term studies reported high cure rates and low complication rates for TOT, and discussed the mechanism responsible for the success of this treatment based only on preoperative urodynamic findings and postoperative clinical examination, uroflowmetry and the cough test. The continence rate with the transobturator approach has been similar to those obtained with the transvaginal retropubic approach.<sup>5</sup> Most of the described complications are related to the blind nature of these procedures.<sup>6</sup>

The aim of this paper is to report the initial results and complications of the Arc to Arc minisling (ATAM); then to critically analyse the ATAM technique, the materials used,<sup>7</sup> and finally, to compare and contrast the ATAM as regards subsequent minislings.

## MATERIALS AND METHODS

### Patients

An open prospective non-randomized clinical trial involving SUI patient was conducted after receiving the approval of the Hospital Ethics Committee. Ten patients (mean age –58 years) underwent the Arc to Arc minisling (ATAM) procedure for SUI. The procedures were performed between March 1997 and October 1998.

### Study design

All patients were given a routine work-up for incontinence, including history, physical examination, stress test and urodynamic investigation. Urodynamic evaluation was performed with 2 urethral catheters (one 10F for filling and another 4F for bladder pressure measurement). A rectal 4F

catheter-balloon was placed above the anal sphincter to obtain abdominal pressure. The test included water cystometry, Valsalva leak point pressure (VLPP) assessment, which was performed with a intravesical volume of 200ml and Valsalva maneuvers, and pressure-flow study.

The stress test was positive in all patients. Patients who presented involuntary detrusor contractions during bladder filling or Maximum flow (Qmax) less than 15ml/s and/or post void residual urine of more than 20% of the volume voided were excluded from the study but those with irritative symptoms without urodynamically proven involuntary contractions were included. Although urodynamically proven detrusor instability does not have a significant effect on surgical outcome, this decision was based on the concept regarding the postoperative improvement of sensory urgency, as described previously.

Follow-up was performed at 1, 6 and 12 months. At these recalls, the patients were questioned about presence of spontaneous voiding, involuntary urinary leakage, lower urinary tract symptoms, vaginal and suprapubic pain, and underwent stress test. The patients were considered subjectively dry in the absence of incontinence, improved, when the incontinence episodes were less than once in two weeks and when incontinence episodes were superior to once a week the patients were recorded as subjective failures.

### Surgical technique

The procedure is performed with the patient in the lithotomy position. A 18F Foley catheter is introduced for safety. A inverted U vaginal incision is made at the level

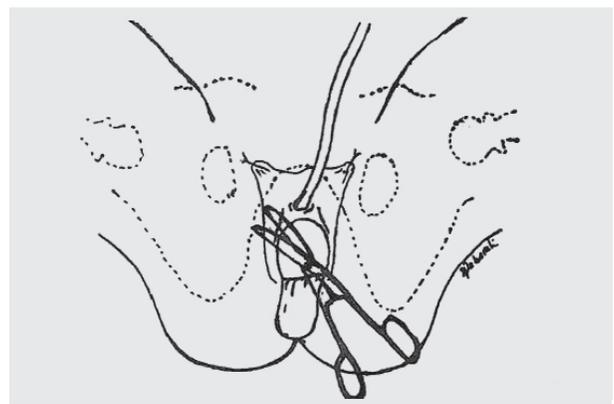


Fig. 1 – An inverted U shape incision is made and a metzenbaum scissors is used to dissect the vaginal wall (original illustrations).

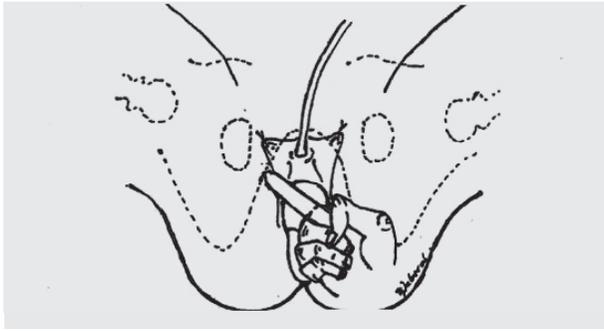


Fig. 2 – Digital identification of the Arcus tendineus fascia pelvis (ATFP).

of the bladder neck. The vaginal wall is dissected from the underlying periurethral fascia, bilaterally to the inferior ramus of the pubic bone. The urethra is identified and a small perforation of the endopelvic fascia was made at the border of the ascending ramus of the pubic bone bilaterally (fig 1).

Next, the surgeon's index finger is introduced in the Retzius space towards the obturator internus muscle in order to identify the white line (fig 2).

Once the white line is identified, 2 polypropylene 00 stitches are placed in the tendinous arc at both sides (fig 3).

Then a minisling of bovine pericardium 6 cm long and 2 cm width is used to create a ATAM, providing back board support to the urethra (fig. 4).

The vaginal incision is closed in the usual manner and and a Foley catheter is left in place overnight.

## RESULTS

There were no vascular or visceral lesions, nor urinary retention.

Nine out of 10 patients were cured of the incontinence at the first post operative month. After 2 months 2 patients presented infection of the minisling that were removed, late complications included 3 more patients that presented extrusion of the sling at 6 month. The remaining five patients did well and were continent after 12 months. All but one patient that has the minisling removed were incontinent account for 50% of good results after one year follow-up.

## DISCUSSION

The understanding of physiopatological concepts of stress urinary incontinence has consistently improved over the last years and their applications have lead to the development of many surgical techniques.

In the past decade minimally invasive synthetic slings, such as TVT, have become the preferred technique, replacing

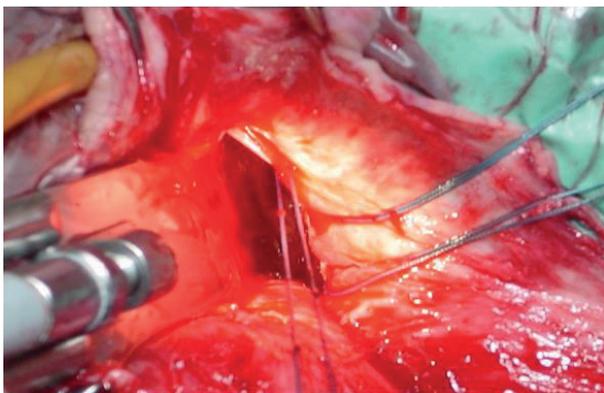


Fig. 3 – Sutures placed in the white line (ATFP).

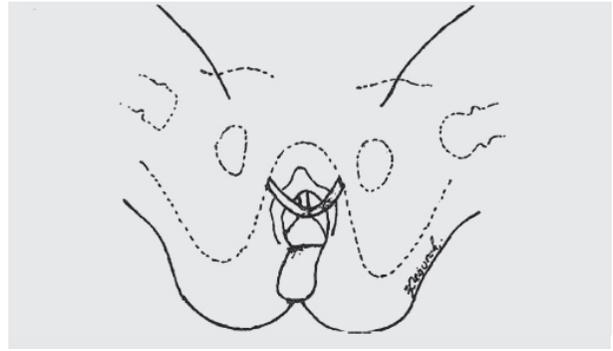


Fig. 4 – Suburethral minisling anchored to the obturator internus muscles at the level of tendinous arc bilaterally.

the Burch colposuspension for the treatment of stress urinary incontinence.<sup>8</sup>

Various factors have contributed to the popularization of slings, among them, the fact that needle suspensions have not stood the test of time, together with the various paradigm changes and the evolution of biomaterials.<sup>1</sup>

Synthetic slings present several advantages over autologous slings.

Harvesting the graft, a time consuming step of the conventional technique is eliminated along with its related morbidity and a well standardized procedure is obtained. Besides it may be performed under local anesthesia as an outpatient procedure. Not to mention less post-operative pain and shorter seek leave.<sup>2</sup>

On the other hand synthetic slings brought about new complications related to the tape and even fatal complications.<sup>3</sup>

As an alternative to the TVT procedure, the transobturator tape (TOT) technique was developed by Delorme in 2001. This procedure reduces per operative complications related to the penetration in the retropubic space.<sup>4</sup> Several short-term studies reported high cure rates and low complication rates for TOT.

But, as with any form of surgery, adverse events can occur, and the surgeon should be aware of the common complications that can accompany sling surgery, and how to best manage them.<sup>3</sup>

The most common complication reported with sling surgery is bladder perforation during needle passage. Bladder perforation usually occurs on the side opposite the surgeon's dominant hand, and with greater frequency in patients undergoing repeat procedures.

Many studies report an incidence of bladder perforation of between 1–15%, and an average perforation rate of 5%. Management of bladder perforation includes recognition of the injury during cystoscopy, withdrawal and repositioning of the needle and a Foley catheter for 24 to 48 hours.

Transobturator sling, on the other hand present a lower rate of bladder and urethral injury during the needle passage, which generally occurs in less than 1% of patients, usually during the learning curve of the procedure.

Bleeding is another important complication and can occur mainly during needle passage. Bleeding upon entry into the retropubic space can be difficult to manage, as exposure of the perivesical venous plexus is difficult.

Care must be taken during lateral replacement of needles to avoid injuring the external iliac vein for vascular injuries are usually caused by excessive lateral passage of the needle.

Despite the good results described worldwide, with cure rates of more than 80% of the cases, some major complications like bowel, vascular injuries and deaths were described.<sup>3</sup>

Most of the described major complications are related

to the blind nature of these procedures. <sup>6</sup> In fact, reducing needles diameter alone was not enough to overcome these problems that occurred even with experimented surgeons.

In an attempt to reduce major complications, mainly deaths, anatomical reconstruction of the urethral support placing a low- tension suburethral tape anchored to the obturator internus muscles bilaterally at the level of the tendineous arc, the Tissue Fixation System (TFS) were described. <sup>6</sup> By doing so, bowl lesions and major vessels injury are avoided.

A decade ago, we used this good principle, but poor technology in biomaterials at that time, lead to less than optimal results due to an unacceptable extrusion rate.

Insisting in the principle of restoring the urethropelvic ligament, we used the porcine small intestine submucosa (SIS) in 25 patients in 2001. <sup>9</sup>

Long term results with arc to arc minisling using swine intestine submucosa, produced 60% of good results after six years follow-up. <sup>10</sup>

Although the concept was good and the biomaterial improved, the absence of an appropriate anchoring system and delivery instruments were a major drawback to its widespread use.

The first commercially available kit, was the Tissue Fixation System (TFS) described by Petros. This kit contained two polypropylene anchors and a multifilament mesh. Preliminary report disclosed similar cure rates and fewer complications when compared to TOT. <sup>6</sup> This preliminary studies reported no pain, mesh exposure, vascular or visceral complications. No doubt a remarkable achievement.

Long term follow-up with TFS disclosed good cure rates after 3 years (11) and good technology available today allowed for using the TFS System to perform uterus sparing procedures as well (12).

Many other devices are available now, some of them depending on mesh integration for the fixation, like TVT-Secur and therefore presenting until 60% of failure in the first post-operative year. <sup>13</sup>

Primary fixation of mini slings is a key issue for success, and our experimental data disclosed that Ophira and TFS presents the best primary fixation when copared to others minisling. <sup>14</sup>

But needless to say that even minimally invasive procedures require a learn period and failure is an important complication as well.

At this point in time, all we can say is that after many years or research and development we now have good concepts and good technology.

## CONCLUSION

Minisling are here to stay and evidences are being building to determine its indications in the surgeon's armamentarium.

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Correspondence to:

Prof. Paulo Palma  
Coordenador Escola Superior de Urologia, SBU  
Presidente Eleito da CAU  
Prof. Titular & Chefe Disciplina Urologia-UNICAMP, Brazil  
ppalma@uol.com.br