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Full length article

Cadaver study of anchorless implant for the treatment of anterior and apical vaginal wall prolapse

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ABSTRACT

Objective: This cadaver study was performed in order to evaluate the feasibility and the anatomical landmarks of a Self-Retaining device, a new unanchored mesh, for the treatment of anterior and apical vaginal prolapse.
Study design: The Self-retaining device was implanted transvaginally in two cadavers. One cadaver underwent a detailed trans-abdominal dissection of the pelvis and the other cadaver, frozen after the implant placement, underwent a cross section dissection of the pelvis.
Results: The location of the device was confirmed to be in appropriate anatomical position and in safe distance from any major neurovascular structures in the pelvis.
Conclusion: The self-retaining implant, in its planned location, can be a safe procedure with respect to neighboring neurovascular and muscular pelvic structures.
Brief summery: A cadaver study of anchorless implant for safety evaluation of the distance from vital structures. The implant found anatomically safe for use.

Introduction

One of the troublesome and yet unresolved problems in female pelvic reconstructive surgery is the treatment of anterior vaginal wall defect. The classic native tissue repair – Anterior Colporrhaphy (AC) – provides poor anatomical results in long-term follow-up with a failure rate ranging from 7 to 40% [1]. The high rate of recurrence has led to the addition of synthetic material implants with higher reported cure rates. Although the use of vaginal polypropylene mesh improved the anatomical outcomes in comparison to the native tissue repair, mesh procedures are associated with longer operating time, greater blood loss, higher cystotomy, de novo dyspareunia, de novo stress urinary incontinence rate and significantly higher exposure/erosion rates compared with native tissue repair [2].

Based on evaluation of adverse event reports and assessment of the scientific literature, the FDA in 2008 and 2011 made a safety communication on the serious complications associated with transvaginal placement of surgical mesh for POP [3]. While the literature suggests an anatomic benefit to cystocele repair using synthetic mesh, this benefit may not result in superior clinical outcomes, and the associated risk of adverse events should be considered.

The current consensus is that the available mesh kits are not optimally structured. The main complications that cause the recent debate regarding the use of the current mesh kits are: 1. mesh erosions, 2. intraoperative organ injury, 3. mesh contraction, 4. chronic pelvic pain/dyspareunia and 5. prolapse recurrence.

The need to provide an alternative to the current mesh implants triggered the development of a new implanted mesh in order to challenge the shortcomings of the current mesh techniques. The device is constructed from a polypropylene mesh stretched by a solid biocompatible frame.

This is the first time a solid structure is implanted in the vagina as part of a surgical technique for the treatment of pelvic organ prolapse. In order to evaluate the anatomical risks involved with implanting a solid structure in the female pelvic floor we conducted a cadaveric lab with detailed anatomical pelvic dissection. The purpose of this study was to assess the device location in relation to pelvic nerves, blood vessels and muscles, evaluating the proximity to vital structures in the pelvis and the hypothetical risk of tissue damage of such solid structure.

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Materials and methods

The study was conducted at the Laboratoire d'anatomie de l'Université Paris-Descartes, Paris, France. The anatomy lab committee approved the study. Two cadavers were chosen with the following requirements: Adult Caucasian multiparous female, with no evidence of previous pelvic surgery and macroscopically normal uterine and cervix. The cadavers were prepared for a better visualization of pelvic structures with the following steps: *Arterial and venous vessels injection technique:* Vessel injection was carried out by cannulating the femoral vessels. The arteries were washed several times with 120–200 ml soapy water to remove serum and coagula before the injection of latex mixed with 4% red or green dye. This procedure was repeated for veins with 160–240 ml of soapy water before latex injection. Approximately 400 ml of latex mixed with 4% red or green dye and 500 ml of latex mixed with a 4% green or blue dye were used for arteries and veins, respectively Pelvic dissection started 48 h after the latex-dyeing procedure. *Device description*: The device was designed according to female pelvic anatomy to re-create the anatomical structure of the pubo-cervical fascia with a synthetic non-absorbable "neo-fascia" to support the anterior compartment of the pelvic floor. The device creates a hammock-like support positioned at the level of arcus-tendineus-fasciae-pelvis (ATFP). The device is comprised of two solid arms of a biocompatible polymer material designed to follow the ATFP, connected by a solid bridge shaped to fit the lower edge of the pubic bone. The bridge is shaped to avoid urethral pressure (Fig. 1). The device is characterized by a constant maximal latero-lateral width of 85 mm at the level of the two dorsal tips, corresponding to the bi-ischial distance and a ventro-dorsal length established in previous cadaveric studies. During these studies multiple device sizes were tested in order to reach the optimal required length and width of the solid frame. The results of these measurements revealed three possible sizes that will fit different size pelvises. The three sizes: small, medium and large differ in the length of the lateral arms: 65, 70 and 75 mm respectively with a constant size bridge. The lateral arms, which stretch down 7 cm to the ischial spine, provide the level 1 support of the uterus or vaginal apex using the proximal edge of the device as a connection between the cervix/apex to the Ischial spines. The connecting bridge profile is designed in order to allow banding only in the horizontal plan. The central portion is composed by macro-porous lightweight polypropylene mesh (16 gr/m^2) stretched under pre-determined pre-load tension. This pre-load tension was determined to keep the mesh stretched, on one hand, and to allow vaginal flexibility for intercourse on the other hand. The device is placed surgically between the bladder and the vaginal mucosa designed to retain in its implanted location without the need for anchoring technique to the surrounding pelvic structures. *Surgical procedure*: The procedure consists of a midline incision of the anterior vaginal wall, followed by a sharp and blunt dissection of the vaginal wall from the surrounding pubocervical fascia reaching the ischial spine and palpating the sacrospinous ligament bilaterally. The device is gently inserted between the bladder and the vaginal mucosa with the solid arms located along the pelvic sidewalls and the tips of the arms reaching a position cranio-lateral to the ischial spine. The connecting bridge is positioned symmetrically under the inner aspect of the pubic symphysis lower edge and under the proximal urethra/bladder neck. The two elastic arms once released in place allow a flat tension free disposition of the mesh under the bladder. After confirming the desired location of the mesh, the vaginal incision is closed using interrupted sutures under no tension. The lateral solid arms are not palpable after the closure of the vaginal incision. Subsequent pelvic dissection of both cadavers was performed. *Dissection procedures:* Before dissection, cadavers were warmed for 24 h at room temperature. Cadaver 1 and 2 underwent standard surgical procedure for the mesh implant as described above. Then, cadaver 1 was submitted to classic macroscopic dissection by performing a cross incision of the abdomen followed by a progressive cranio-caudal macroscopic dissection investigating the relationships between the implant and the pelvic organs, vessels and nerves. Cadaver 2, following the mesh placement was frozen and subsequently sagitally cut in the midline. The relationships between the implanted device and the pelvic organs, vessels and nerves were studied on both hemi-pelvises by progressive medial-to-lateral macroscopic dissection.

Anatomical terms used in this report conform to the Terminologia Anatomica proposed by the Federative Committee on Anatomical Terminology [4] and its expansion previously published.

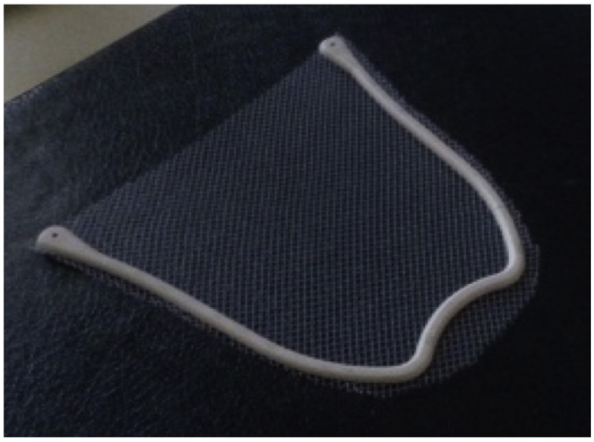

Fig. 1. shows the design of the SRM: the device is composed of a solid frame in the shape of a parallelogram consisting of a ventral arch with a midline incision for the urethra and two lateral arms ending with two dorsal tips. In between an ultra-light mesh is stretched and connected to the frame using an ultrasonic technology.

Results

The two donors' ages at death were 69 and 76 years, for cadaver 1 and cadaver 2 respectively. Dissections of cadavers 1 and 2 revealed that the insertion of the device requires the complete dissection of the vesico-vaginal cleavage plane, performed by bilateral dissection into the paravesical space from the dorsal aspect of the pubic bone up to the ischial spines on both sides. In order to evaluate the specific risks of the implanted device, the dissected area around the device was divided to 4 zones. Zones size of 2 × 2 cm allows for possible anatomic variability in different cadavers and the consideration of device movement post surgery that needs to be addressed for safety. Fig. 2 shows the area around the ischial spine keeping visible the nervous structures; zone 1 defines the area for the optimal positioning of the frame dorsal tips. The describes zones were measured at least 1.3–2 cm apart. The risks in relation to the ischial spine are:

i) The potential compression/irritation of the origin of the ischial nerve at the level of the greater sciatic foramen. The frame tips are located dorsal and cranial to the ischial spine (Fig. 2, zone 4),
ii) The potential compression/irritation of the pudendal nerve at the level of the greater ischial foramen. The frame tips are located dorsal and caudal to the ischial spine (Fig. 2, zone 3).
iii) The potential compression/irritation of the omolateral hypogastric nerve and/or inferior hypogastric plexus at the level of the uterosacral/rectovaginal ligaments. The frame tips are

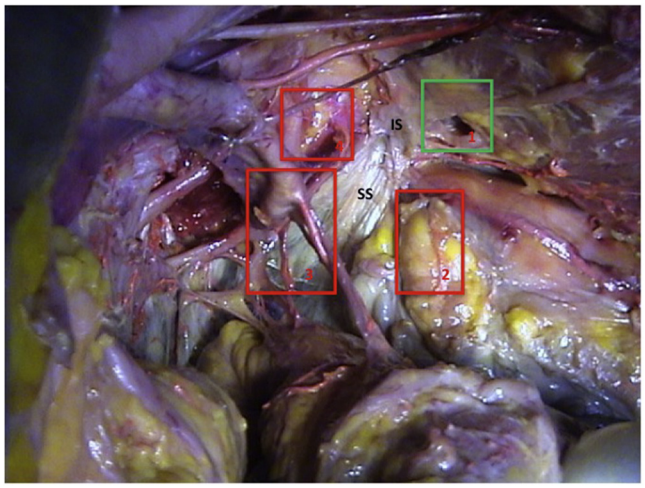

Fig. 2. Zones of possible positioning of the device's tips; Left Hemi pelvis; Zone 1 (green)- correct tip position; Zones 2,3,4 (red)-Incorrect tip position; Zone 1 = lateral to the Ischial spine mark the safe positioning of the lateral arms' tips. Zone 2 = the omolateral hypogastric nerve and/or inferior hypogastric plexus at the level of the uterosacral/rectovaginal ligaments. Zone 3 = the pudendal nerve at the level of the greater ischial foramen. Zone 4 = the origin of the ischial nerve at the level of the greater sciatic foramen. IS-Ischial Spine; SS-Sacrospinous Ligament. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

located dorsal, medial and cranial to the ischial spine (Fig. 2, zone 2).

Our dissection confirms that these risks are eliminated by appropriate device location.

The mesh could be left free except for its suggested midline fixation to the ventral aspect of the uterine cervix or vaginal apex. This fixation can be performed using absorbable suture.

As for the possible support offered by the ventral arch of the mesh to the bladder neck and urethra, the dissections showed that this effect is strictly related to the position of the device. We observed that when the ventral arch of the device faces the dorso-caudal limit of the pubic bone, its midline curvature could support the mid-urethra (Fig. 3). This is realized when the longitudinal axis of the mesh is parallel to the line connecting the dorso-caudal edge of the pubic bone to the coxis (pubo-coccygeal line).

Discussion

Surgical repair of anterior vaginal wall defect is based on reconstruction of the supporting tissue located between the bladder and the vagina. The vaginal mesh implanted between the bladder and the vaginal wall aims to replace the defective support system and provide a new support to the bladder and vaginal apex. There are different techniques to locate and secure the vaginal mesh in the appropriate location, including anchoring to a variety of anatomical structures in the pelvis. Post-surgical chronic pain in most cases develops at two areas: 1. Mesh anchoring sites where scar tissue can cause nerve entrapment, and 2. Locations where the implanted mesh is folded causing unbalanced scaring. Eliminating the anchoring points and ensuring a flat sheath of mesh might decrease the post surgery chronic pelvic pain complications. In addition, physiologic location of the mesh as a "neo-fascia" replacing the pubo-cervical fascia might provide better support to the pelvic organs. This self-retaining device was developed with these solutions in mind.

The optimal implant position — i.e. theoretically the position which offers the maximum support to the bladder base and neck while avoiding possible risks— is the one that places the dorsal tips of the solid frame ventral, lateral and cranial to the ischial spines, the lateral edges along the tendinous arch of the endopelvic fascia —ATFP – and the bridge on the dorsal aspect of the pubic bone (Fig. 3). In this position the dorsal frame tips could push over the obturator muscle with increased intra-abdominal pressure, offering adequate support to the bladder. As far as the latter aspect is concerned, our dissections showed that particular attention should be paid to the position of the dorsal frame tips ventral lateral and cranial to the ischial spine because in this position the dorsal tips of the frame should not relay on the levator-ani muscle for support since it might be damaged in case of advanced pelvic organ prolapse. Therefore, the length of the arms and the location lateral to the ischial spine offer an adequate support to the mesh and consequently, to the bladder (Fig. 4). Optimal location of the tips of both arms is depended on adequate lateral dissection to allow the fully stretched 7 cm arms reach its appropriate location.

This cadaver study confirms that the planned location of the mesh implant, specifically its rigid frame, does not increase the risk

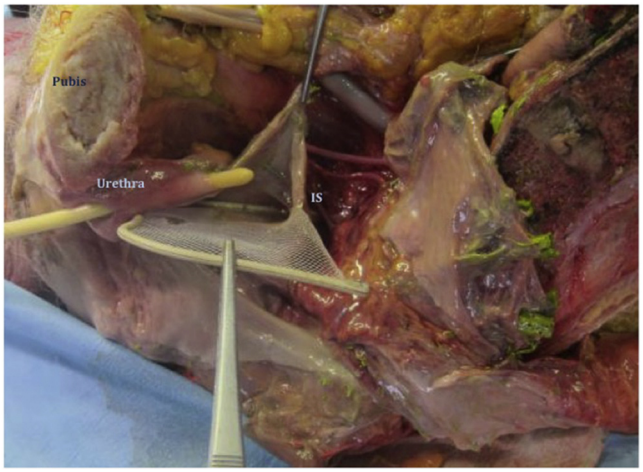

Fig. 3. Correct implant positioning; A none transected device is shown in the appropriate position with the lateral arms stretched to the Ischial spine and the connecting bridge located under the proximal urethra/bladder neck. Right Hemi pelvis; IS- Ischial Spine.

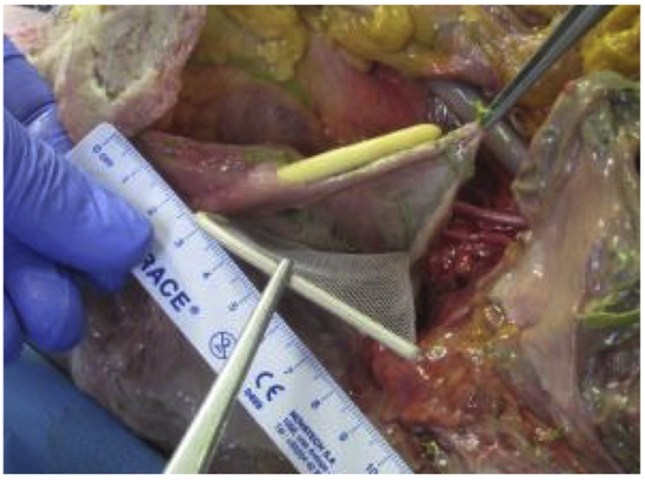

Fig. 4. Adequate device size. The size of the lateral arms of 7 cm is shown allowing the device to reach the ischial spine and provide level one support to the uterine cervix/vaginal apex.

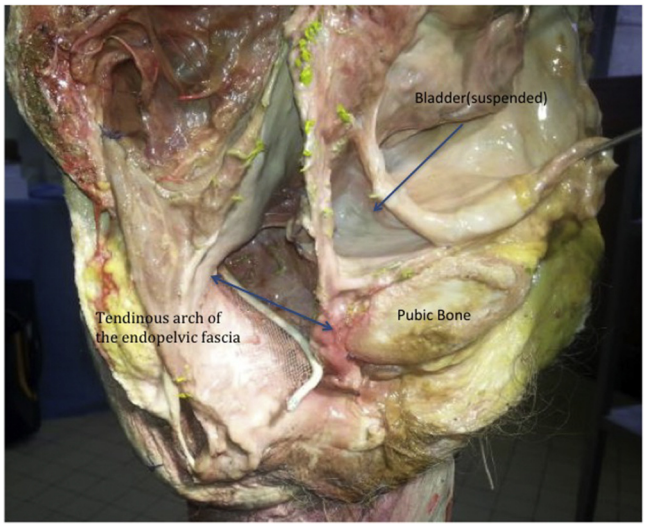

Fig. 5. Possible funneling of the pelvic floor. Dissected Hemi-pelvis is positioned in the upright position demonstrating the position of the device in the standing position.

of pressure or damage to important neurovascular structures in the pelvis. Placing the device in the same surgical space of previously used mesh implants does not risk the important zones describe previously (zones 2, 3 and 4 in Fig. 2).

Given the observed locations of the device dorsal tips, two important issues needs to be mentioned: First, the latero-lateral mesh measurement should be wide enough in order to completely avoid the possibility that the rigid tips of the mesh could stay over the levator ani muscle. Secondly, the importance of the shape of the dorsal tips of the frame so as to extend the area of support and reduce the possible muscle irritation that could be caused by the tips. The cranio-caudal mesh length is crucial to achieve the desired mesh position and function. The surgical dissection performed in preparation for the device insertion needs to fit the measurements of the distance between the apex of the dissected paravesical space and the ischial spines (Fig. 4). The dissected space needs to accommodate the length of the lateral arms measured 7 cm each fully stretched. At the distal part, under the lower aspect of the pubic bone, the dissected space needs to accommodate the connective bridge, measures 4 cm.

The solidarization between the mesh and the cervix or vaginal apex is advisable for two reasons: 1. It could help to avoid possible inclination of the plane of the mesh that should remain parallel to the plane passing through the ischial spines. 2. This fixation could help to block the uterine cervix or vaginal apex at the level of the ischial spines to avoid the possible collapse of the uterus or vaginal apex into the space comprised between the dorsal end of the mesh and the levator ani muscle (Fig. 5).

In comparison to another non-anchored mesh technique examined in cadaver study by Reisenauer et al. [5], the addition of a rigid frame was confirmed not to increase the risk for complications and to be as safe as the mesh described.

Conclusions

Considering the limitations of this cadaveric study (only 2 samples), the mesh implant with its rigid frame if placed appropriately in the desired location is safe and does not cause damage or pressure on the major neurovascular structure in the pelvic floor.

It is assumed that anterior and apical compartment prolapse repair with the non-anchored mesh device is a safe procedure with respect to neighboring anatomic structures. The use of this mesh implant may reduce the complications that are specific to the anchoring mesh techniques or the use of trocars and tunneling devices beyond the pelvic cavity. Farther clinical data is required in order to confirm the results of this cadaver study.

Conflict of Interest

Gil Levy is the inventor of the device described in the manuscript.

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Ethical approval

The project was approved by the ethical committee of the Laboratoire d'anatomie de l'Université Paris-Descartes.

Contribution to authorship

Mauro Cervgini: participated in the cadaver lab and writing the manuscript.

Alfredo Ercoli: participated in the cadaver lab and writing the manuscript.

Gil Levy: participated in the cadaver lab and writing the manuscript.

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