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ANATOMICAL CADAVER STUDY OF PELVIC FLOOR RECONSTRUCTION USING A NEW POLYPROPYLENE IMPLANT VAGINAL REPAIR SYSTEM AND A VAGINAL SUPPORT DEVICE

Hypothesis / aims of study

The aim of this cadaver study was to evaluate the anatomical position of polypropylene implants after reconstruction of the anterior and posterior compartments of the pelvic floor using the GYNECARE PROSIMA™ Pelvic Floor Repair System (Ethicon, Somerville, NJ) and to determine the relations of the mesh implants to the major neighbouring neurovascular structures.

Study design, materials and methods

The anatomy of the pelvic floor is very complex and in an operative field compromised by limited visual access, prolapse surgery is often technically difficult to perform. In order to reduce the risk of potential intraoperative complications the development of minimally invasive and safe surgical techniques for pelvic floor reconstruction becomes essential. PROSIMA was developed with these considerations in mind.

Anatomical dissections of the pelvic floor of four cadavers preserved with alcohol-glycerol solution were performed after the placement of the mesh implants by a vaginal approach in accordance with instructions provided in the PROSIMA “instructions for use” document. The implants were placed over the vesicovaginal and the rectovaginal fascia with extension arms inserted into the paravaginal spaces anteriorly and onto the sacrospinous ligaments posteriorly.

In the anterior vaginal compartment, a space for the mesh straps was created on each side immediately anterior and superior to the ischial spine and superficial to the parietal fascia of the obturator internus muscle. An inserter instrument was used to place the mesh straps into these spaces so that the mesh straps laid against the parietal fascia of the obturator internus muscles.

During the posterior compartment reconstruction, dissection in a posterior direction through the rectal pillars to each ischial spine and sacrospinous ligament was performed. The mesh straps were placed onto the sacrospinous ligaments with the aid of an inserter device. A vaginal support device (VSD) was then placed into the vagina. After placement of the mesh implants was completed and the VSD inserted, the retropubic space was accessed via a laparotomy incision. The retropubic and retroperitoneal spaces were then dissected to observe the outcome of the mesh placement.

Results

The anterior implant extended from 1.5 to 2.2 cm lateral to the pubic symphysis to 1 to 1.5 cm in front of the ischial spine and spread over the entire base of the bladder, so that the anterior vaginal wall was covered by the implant. After dissecting the space of Retzius, the tip of the mesh arm could be seen anterior to the ischial spine at the level of the arcus tendineus fascia pelvis and medial to the parietal fascia of the obturator internus. The mesh connected the lateral vaginal wall with the pelvic sidewall. No paravaginal defect was caused by creation of the spaces for the anterior mesh straps **(Figure 1).**

The posterior implant lay between the posterior vaginal wall and the rectum. The lateral margins were in contact with the medial edges of the levator ani muscles. Both arms were in contact with the sacrospinous ligament 2 to 3 cm posteriomedial to the ischial spine.

A safe distance between the anterior and posterior implants and their neighbouring neurovascular structures (obturator nerve and vessels 2.8 to 3.3 cm, pudendal nerve and internal pudendal vessels 1.8 to 2.2 cm, sacral plexus 2 to 2.2 cm) was observed.

Interpretation of results

The reconstruction of the pelvic floor using the PROSIMA system is a safe and minimally invasive procedure.

Concluding message

Our cadaver study confirmed the safe and accurate anatomical placement of the mesh implants using the PROSIMA system. The important nearby neurovascular structures within the pelvis were found to be at a safe distance from the mesh implants. Clinical studies will evaluate the long-term results using this vaginal repair system.

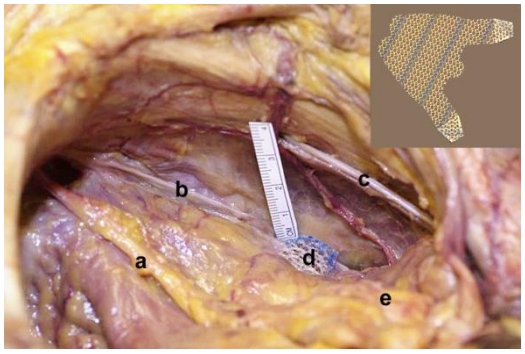

Figure 1. Reconstruction of the anterior compartment of the pelvic floor with PROSIMA.
a. Bladder. **b.** Arcus tendineus fascia pelvis. **c.** Obturator nerve and vessels. **d.** Mesh strap of anterior PROSIMA situated anterior to the ischial spine (**e**).

Specify source of funding or grant	**No**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**We performed the study using cadavers. Women spent their bodies to the Institut of Anatomy during their liftime for research.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**