

EVALUATION OF FORCE REQUIRED TO REPLACE TWO DIFFERENT, TROCAR-LESS PELVIC FLOOR REPAIR KIT MESH LEGS FROM THE SACROSPINOUS LIGAMENTS IN A CADAVER MODEL.

Hypothesis / aims of study

The purpose of this study was to evaluate the force required to replace the mesh leg of two different pelvic floor repair kits from sacrospinous ligament (SSL) in a cadaver model.

Study design, materials and methods

This study was exempt by our institutional review board. Twelve frozen female cadaver pelvises were thawed and utilized for this study. For each pelvis, the SSLs were exposed through standard sharp and blunt vaginal dissection. Following dissection, mesh legs of Pinnacle PFR Kit (Boston Scientific, Natick, MA USA) and Elevate PFR Kit (American Medical Systems, Minnetonka, MN USA) were placed according to the manufacturers' instructions through each SSL; each on separate sides of the same cadaver pelvis. The aim of the study was to determine the ease of removal of a mesh leg from the SSL which is indicated if a surgeon feels that the initial placement was not adequate and readjustment is needed. Therefore, the Pinnacle mesh arm was advanced until the dilator sleeve met the ligament, but the sleeve was not removed as this was the point at which a surgeon could replace the leg assembly, if needed. The Elevate self-fixating tip was placed into the ligament in standard fashion. A hemostat was then attached to the mesh leg. A Mark 10, Model MG-50 Tensile Gauge was then attached to the hemostat, zeroed and pulled at a slow, controlled rate in a caudal direction along a sagittal plane. The maximal load measured to remove the mesh leg from the tissue was recorded. The procedures were performed by a urogynecologist and a urologist trained in the use of the two devices.

Results

The median force required to remove the Pinnacle PFR Kit leg assembly was 2.2 pounds, with an interquartile range of 1.6 to 3.7 pounds. The median force to remove the Elevate PFR Kit leg was 7.2 pounds, with an interquartile range on 2.6 to 6.3 pounds. The median difference in pull-out force between the two products was 4.7 pounds, with an interquartile range of 2.6 to 6.3 pounds. The difference in the replacement force between the two kits is significantly different from zero with a p-value = 0.0005.

Interpretation of results

Two trocar-less pelvic floor repair kits were evaluated in this study. The mesh kit legs have to be placed via delivery devices by palpation through the SSL, as the depth of the ligament precludes direct visualization. As such, there are times when a physician will decide that a mesh leg will need to be repositioned due to poor tissue purchase or suboptimal anatomical location of the initial placement. This study demonstrates that it takes a significantly larger amount of force to remove the Elevate PFR Kit leg for replacement than a Pinnacle PFR Kit leg. This is certainly due to the design of the Pinnacle PFR Kit, which has a plastic sleeve that needs to be removed to complete deployment. This allows for easier replacement and adjustment of the Pinnacle PFR Kit as compared to Elevate PFR Kit.

Concluding message

A significantly smaller amount of force is required to replace a Pinnacle PFR Kit mesh leg from the SSL than an Elevate PFR Kit leg.

<i>Specify source of funding or grant</i>	Female cadaver pelvises and mesh kits were provided by Boston Scientific, Natick, MA USA
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Mount Auburn Hospital Institutional Review Board
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	No