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REFINING ACT BALLOON PLACEMENT: ANATOMICAL RELATIONSHIP BETWEEN ADJUSTABLE CONTINENCE THERAPY (ACT) BALLOON (AND TROCAR) AND FEMALE ERECTILE TISSUE.

Hypothesis / aims of study

A peri-urethrally implanted prosthetic, the adjustable continence therapy device (ACT™) has been recently developed for the control of Intrinsic Sphincter Deficiency (ISD) in women. Prior to product trials, cadaveric dissections were performed to determine the best surgical approach to minimize disruption of normal tissues and optimize the chance of cure or improvement in sphincter function. Cadaveric research into the relationship between the urethra and the clitoris revealed that the clitoris and its neuro-vascular supply might be at risk in a range of stress incontinence surgical strategies [1]. We aimed to reproduce in the cadaver the recommended ACT placement and determine the exact relationship to the clitoral complex and whether points of technique could minimize any potential injury to the female sexual tissues or their neuro-vascular supply.

Study design, materials and methods

Findings from previous dissections were reviewed to determine the anatomical structures in the pathway of the ACT balloons. Two adult female cadavers were dissected in 2000 in Italy with particular emphasis on identifying the best orientation for insertion of the instrument used to achieve the implantation and the preferred position of placing the balloons and the injection ports, so as to achieve predictable support at the vesico-urethral junction. A third adult female cadaver was dissected in Australia in 2004 to examine the relationship between the clitoral tissues and their neuro-vascular bundle. At each dissection the cadavers examined were fresh and had macroscopically normal gross anatomy. All three cadavers were postmenopausal. Assessments of the positioning of the ACT devices were made following the exposure of these critical structures. Measurements and photographic recordings were made at each dissection.

Results

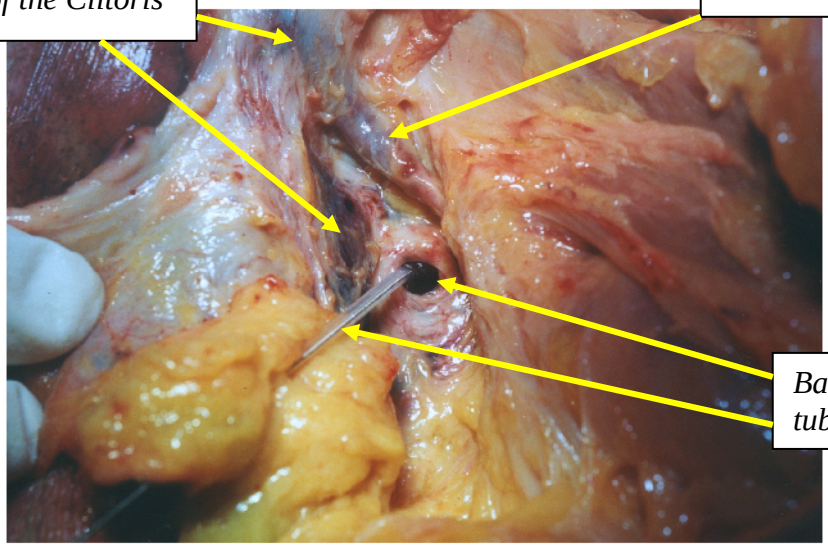
The first dissections illustrated the importance of locating the peri-urethrally placed balloons under the endo-pelvic fascia, postero-lateral to the urethra at the vesico-urethral junction and very importantly, superior to the urogenital diaphragm. This placement provides sufficient support for the device itself, and inhibits any undesired lateral or distal migration of the balloons before the pseudo-capsule formation secures it at this position. It is critical to maintain the full thickness of the vaginal wall between the surgeon's finger and the inserter instrument, in order to locate the trocar above the deeper aspect of the urogenital diaphragm, and thus achieve good placement of the prosthesis. The dissection of the external genital and underlying structures illustrated that if the initial incision is made at the sulcus between the labia majora and minora and the insertion instrument is directed from this point towards the bladder neck parallel to the urethra until passage of this instrument is made under the inferior aspect of the ischio-pubic rami, then no disruption of either the clitoral bulb, the crus of the clitoris or the dorsal neuro-vascular bundle occurred. Extreme care must be taken to avoid injury to the clitoral structure. Following the recommended procedure is likely to avoid such injury.

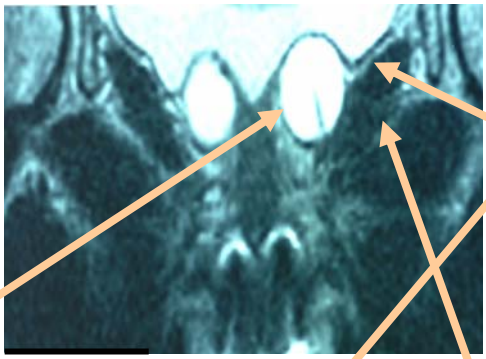
Concluding message

Implantation of this peri-urethrally positioned device for ISD can be safely achieved through a thorough understanding of the pelvic and perineal anatomy. Care should be exercised to correctly orientate the insertion instrument, so as to avoid any unintended trauma to normal structures.

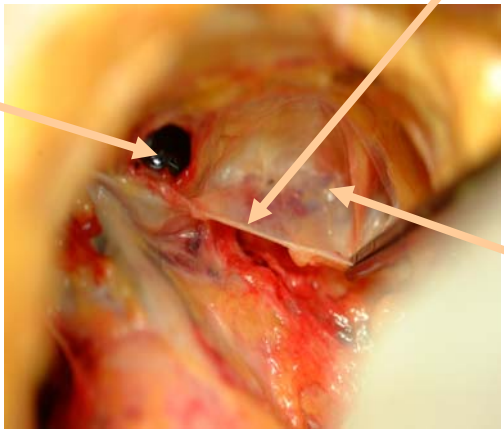
[1] Anatomical relationship between urethra and clitoris. J Urol 159: 1892-1897, 1998

Left labia majora retracted medially following ACT implantation





Impact of ACT implant on vesico-urethral structures compared by both MRI and cadaver dissection.



(Above) Endopelvic fascia detached from its lateral attachments and reflected medially to illustrate relationship between the ACT balloon and the vesico-urethral junction

(Below) Diagram of anatomical positioning of ACT balloons in a female