

# Cadaveric study of ACT<sup>®</sup> balloons and their impact on female sexual anatomy

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**Abstract:** The adjustable continence therapy (ACT<sup>®</sup>) device has been developed for the treatment of intrinsic sphincter deficiency (ISD) using a standardised surgical technique to optimise continence efficacy. This study examined the extent of structural disruptions caused by its insertion and the possible impact of this device on female sexual anatomy. Bilateral balloon placement was performed in a female cadaver and dissection was used to determine the effect on sexual structures. The pelves were dissected layer-by-layer to examine the structures transversed by the ACT<sup>®</sup> system, particularly the clitoral tissue, adjacent neurovascular bundles, and its position in relation of the urethra, bladder neck, urogenital diaphragm and endopelvic fascia. The trocar track was observed to have coursed through a relatively "safe" zone between the bulb of the clitoris medially, the crus and clitoral neurovascular bundle anterolaterally and the perineal branches of the pudendal neurovascular bundle posteriorly. The trocar pierced the urogenital diaphragm reaching the desired position between the pelvic diaphragm and the endopelvic fascia, posterolateral to the vesicourethral junction. This method of trocar introduction caused no significant disruption of the clitoris or its neurovascular bundles in the specimens studied. Periurethral implantation of balloon devices may be safely achieved. Insertion of the ACT<sup>®</sup> trocar device in the location, direction and depth described here did not damage the clitoris or its neurovascular supply. These observations may also be of relevance to other anti-incontinence surgeries that involve instrumentation and insertion of materials beneath or by the side of the urethra.

**Key words:** Clitoris; Anatomy; Incontinence; Sexuality; Surgery.

## INTRODUCTION

Recent anatomical studies have clarified historical accounts of female pelvic anatomy.<sup>1</sup> Dissection based and radiological studies have provided objective information about female pelvic anatomy and particularly the anatomy of the distal vagina where the urethra and clitoris form an erectile cluster of which the urethra and vaginal wall form a core (Fig. 1). The anatomy of the clitoris, particularly the anatomy of the bulbs of the clitoris has been presented erroneously in most anatomical textbooks – both modern and historical. These structures are large and highly vascular, flanking both the lateral vaginal wall directly under its mucosa and on either side of the urethra. They are of some relevance to urological and gynaecological surgeons who may have been unaware of their existence because of the previous paucity of basic scientific information about this anatomy. Interventions in the vicinity of the urethra and distal vagina could quite conceivably injure them, their vascular or nerve supply. The size of the bulbs has been shown to vary considerably according to age and presumably hormonal status in both cadaver and MRI-based studies.<sup>2</sup> Anatomical studies of peri-urethral interventions are scarce. This type of study permits screening for potential damage prior to introducing new technology. To date the anatomical impact of the ACT<sup>®</sup> device had been investigated from an intra-pelvic perspective.<sup>3</sup> The device ultimately becomes intra-pelvic and it is in the pelvis that the balloons exert their influence on continence. The device, however, reached this intra-pelvic location via a trans-perineal route. Placement of the balloons above the urogenital diaphragm appears to be a secure location in that the confined space limits movement that would otherwise result in ineffectiveness or prolapse of the device. Clinical experience has demonstrated that when the balloons eventuate in a supra-diaphragmatic location they do not prolapse below that level.<sup>3</sup> However, there are no data regarding the potential or actual impact of the devices

## MATERIALS AND METHODS

During the initial development of the device and as proof of the concept, prior radiological and dissectionbased studies determined the placement technique associated with the most effective continence impact.<sup>4</sup>

Following standard cooling techniques maintaining a temperature of 4° Celsius, the thighs of a freshly frozen (<3 days) post menopausal cadaver were abducted to expose the perineum. A Foley urethral catheter was placed and 10 cc of water instilled in the catheter balloon for easy digital identification, via the vagina, of the bladder neck when traction on the catheter was applied. Insertion of the device involves introduction of a trocar assembly unit via a small vertical incision placed at the middle of labium major of each side along the sulcus between the major and minor labia. The trocar is then directed peri urethral parallel to the urethral Foley catheter whilst palpating the tip of the trocar through the full thickness of the anterior vaginal wall. The trocar is directed so that its tip reaches a location posterolateral to the vesicourethral junction but deep to the urogenital diaphragm. A sensation of the urogenital diaphragm "giving way" indicates that the correct depth has been reached. The balloons are then placed via the trocar. In this study the position was verified with dissection rather than radiographically as per standard clinical practice.<sup>5</sup>

A dissection was then performed on each side to expose the structures that had been traversed. Commencing from mons veneris and inguinal area, the dissection firstly identified the gracilis muscle its insertion marking the adjacent location of the clitoral crus. The superficial layers overlying the clitoral crus, bulbs and body were removed to demonstrate clitoral anatomy and the relationship of its components to the inserted device. The distance between the tubing of the implanted ACT<sup>®</sup> balloon and the clitoral bulb, the crus of the clitoris and the neurovascular bundles were measured.

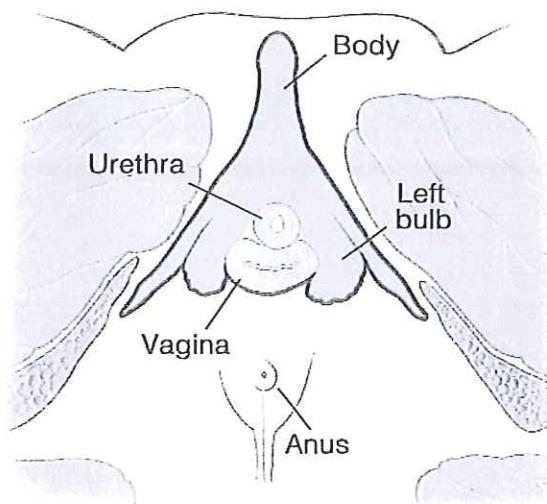
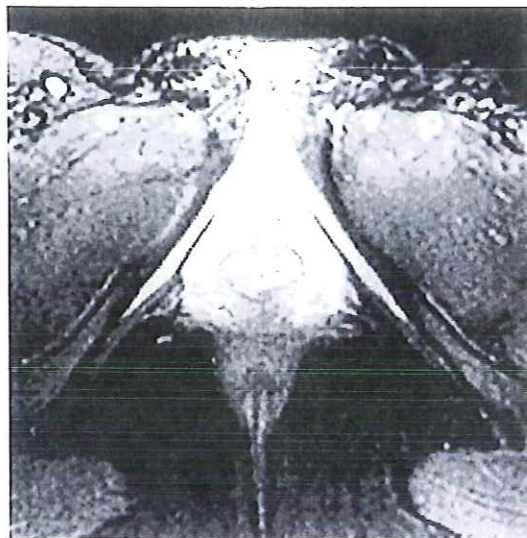


Fig. 1. – Coronal section of female erectile tissue of 76 year old fixed cadaver.

ously implanted ACT<sup>®</sup> balloon and both the vestibular bulb and the crus of the clitoris was between 1.0 cm and 1.5 cm (Fig. 2). The dorsal neurovascular structures were found to be anterior and lateral to the position of the ACT<sup>®</sup> prosthesis, at a distance of 1.5 cm or greater (Fig. 3).

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 through the midpoint of the labium majus, 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 ischiopubic rami, then disruption of the clitoral bulb or crus or the adjacent neurovascular bundle did not occur (Fig. 4). Directing the insertion instrument from a more lateral position towards the contralateral labia could produce unintended clitoral bulb disruption (Fig. 5). Existing recommendations to place the ACT<sup>®</sup> balloon device for urinary incontinence appear to avoid disruption of the clitoris, vaginal wall and neurovascular structures, preserving the structural and functional integrity of the genital anatomy. However, any deviations from recommended insertion technique, e.g. an overly medial placement or too-shallow direction of the insertion trocar may be associated with unintended clitoral injury.

The distal vaginal wall and the urogenital septum appear to be a fused structure.<sup>6</sup> The clitoral bulb attaches to it laterally. The perineal neurovascular bundle lies deep to the

clitoral bulb on the surface of this diaphragm/vaginal wall layer. Although the trocar placement pierces the urogenital membrane (vaginal wall) close to the neurovascular bundle, in both cases a safe window appeared to have been identified which spared the bulb and other clitoral components, including their neurovascular supply. These structures remained uninjured by the trocar and the tubing of the implanted device. The dorsal neurovascular bundles are not affected by placement of the trocars or other components of the ACT<sup>®</sup> system.

#### DISCUSSION

The female urethra is located in the anterior vaginal wall adjacent to the clitoris, with the body of the bulb superiorly and the bulbs and crura on either sides. The urethra should be viewed as a pelvic and perineal conduit surrounded by erectile tissue. The urethra, vagina and clitoris form a triangular cluster of tissue in the perineum in demonstrations with MRI studies.<sup>2</sup>

This anatomical study in both sides of an elderly female cadaver have demonstrated sparing of the clitoral structures, urethra and the neurovascular supply during the implantation of the ACT<sup>®</sup> device by the method described here. In the female perineum, a "safe" area or a location relatively free of genital and neurovascular structures appear to exist between the inferomedial margin of the crus of the clitoris and the lateral surface of the clitoral bulb, forming a small 'indentation'



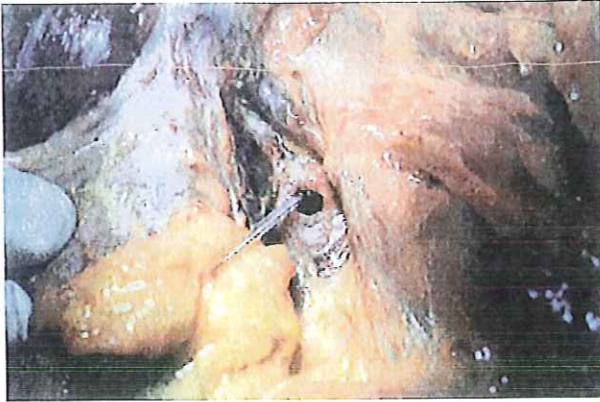
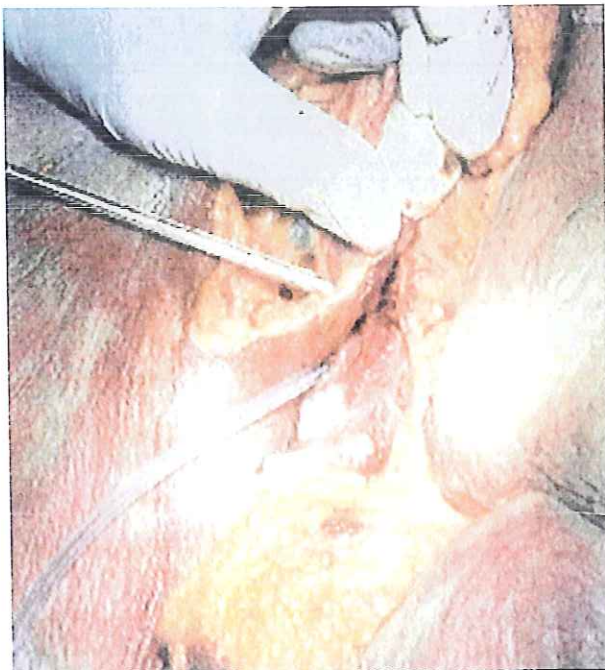


Fig. 4. – Passage of implanted device in relation to the crus, the bulbs and the dorsal neurovascular bundle showing no disruption of the clitoral bulb.

just below the inferior pubic rami. Deviations in the orientation of the trocar from the recommended are associated with anatomical evidence of probable clitoral trauma.

Erectile tissue is more extensive in premenopausal women compared to that of postmenopausal women.<sup>7, 8</sup> Further studies would include evaluation of placement of this and other surgical treatments in both pre- and post-menopausal cadavers. Clearly, access to premenopausal cadavers is very limited. It would be advisable to discuss the potential post-operative sexual dysfunction, especially in pre-menopausal women, prior to embarking on any suburethral surgery for urinary incontinence or pelvic organ prolapse. To date, there have been few systematic investigations of the effect of surgical treatments on sexual anatomy or function. Surgeries around the urethra, or insertion of materials designed to support the urethra, can potentially disrupt these structures and the adjacent neurovascular bundle during the surgery and/or due to inflammatory tissue responses to implanted artificial materials following surgery.



The literature to date relating incontinence surgery to sexuality, has been focussed primarily upon the assessment of impact of the urinary leakage on the ability to enjoy sexual relations, rather than assessing changes in sexual response potentially related to the surgical trauma. The negative impact of leaking during the act of sex seems well established.<sup>9</sup> Weber and associates in evaluating sexual function and vaginal anatomy in 165 women both before and after surgery for pelvic organ prolapse and incontinence, noted that although most women reported an improvement or no change in their sexual function and satisfaction, 38% of women who had a combination of Burch colposuspension and posterior colporrhaphy reported dyspareunia, which was not present prior to surgery.<sup>10</sup> In contrast, Lalos and associates examined the sexual impact following retropubic urethropexy or pubococcygeal repair by interviewing the patients and through patient-directed questionnaires. They concluded that the majority expressed satisfaction with their sexual live.<sup>11</sup> Following the insertion of tension-free vaginal tapes (TVT) suburethrally, Elzevier and associates<sup>12</sup> and Glavind and Tetsche<sup>13</sup> found very little or no sexual impact in those patients who responded to the mailed questionnaires (75% and 81% respectively). Those few who did report some degree of sexual dysfunction following this surgery cited loss of libido and worsening incontinence as the cause, rather than the actual surgery. In contrast, Mazouni and associates<sup>14</sup> in their prospective study, using a mailed self-administered sexual questionnaire before and after the procedure, reported that 20% of their respondents were found to have developed sexual impairment after TVT implantation surgery. Dyspareunia accounted for 14.5% (none pre-operatively versus 8/71 post-operatively,  $p < 0.01$ ) and a loss of libido in 5.4%. Yeni and associates<sup>15</sup> compared the pre- and post-operative sexual function in 32 women who were implanted with TVT, against a control of 25 matched but continent women. They used the Female Sexual Function Index (FSFI)<sup>16</sup> which specifically examines different domains of desire, arousal, orgasm, pain and overall satisfaction related to sexual function. Prior to surgery, all domains except orgasm were slightly, though not significantly, decreased in the treatment group compared to the control group. Post-operatively, all domains except for arousal and desire worsened significantly in the treatment group compared to the control group. The authors conclude that both stress urinary incontinence and the TVT procedure negatively affect sexual function in women.

Preliminary studies of the ACT® device found “discomfort during sexual intercourse” in a small number of patients, principally relating to the positioning of the injection ports dorsally in the labia majora. This experience was identified prior to the refinement of the technique as described in this study.<sup>4, 17, 18</sup> A later report by the European investigators described the complaint of dyspareunia in one patient (2% of the treated cohort) as transient.<sup>19</sup>

The ICS has recommended that sexual outcome results are to be used in the overall evaluation of all incontinence therapies.<sup>20</sup> Anatomical study prior to introduction of a new surgical procedure involving the urethra is appropriate.

Anti-incontinence surgeries can possibly injure the clitoris and its neurovascular supply. An effective method for inserting an ACT® device for intrinsic sphincter deficiency

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