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ORIGINAL ARTICLE

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The tensile strength of Cooper's ligament suturing: comparison of abdominal and transvaginal techniques

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Abstract This study was designed to compare the strength and position of sutures anchored into Cooper's ligament utilizing a minimally invasive transvaginal suturing technique, versus the 'open' abdominal approach. In 12 fresh cadavers, Cooper's ligament was accessed via abdominal and vaginal incisions. After randomization, polytetrafluoroethylene (00) sutures were spaced along one ligament with the transvaginal device ($n = 36$). Contralaterally, sutures were placed abdominally ($n = 36$). Progressive load was applied until suture breakage or dislodgement, and tensile strength was measured using a digital tensiometer. Peak tension averaged 14.5 psi for abdominal and 12.96 psi for vaginal ($p = 0.28$). Suture breakage rather than ligament 'pullout' was more likely for abdominal (95 vs. 56%, $p = 0.0001$). Vaginal and abdominal sutures demonstrated nearly identical mean distances from mid-symphysis (4.62 vs. 4.24 cm, $p = 0.56$). Peak tension was not correlated with suture location ($r^2 = 0.17$, $p = 0.28$). We conclude that transvaginal suturing, using the minimally invasive device, achieved similar tensile strength and position to the open technique. Transvaginal sutures were associated with greater likelihood of ligament 'pullout' before suture breakage under maximal load; however, the clinical implications of this finding are uncertain.

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Introduction

In recent years, numerous minimally invasive techniques have been developed for use in pelvic reconstructive surgery, often through the modification of traditional 'open' surgical approaches. A variety of surgical devices have been designed to facilitate the placement of sutures or anchors through small incisions and limited dissection within either a vaginal or laparoscopic operating field. These instruments include bone anchors designed to either screw [1] or push [2] into pubic bone, and 'push and catch' suturing devices [3, 4] used for anchoring into ligament, muscle or other soft tissue structures. Anchored sutures can then be attached to a synthetic or biologic material fashioned as a suburethral sling for stress urinary incontinence, or as a structural graft for the repair of prolapse. As minimally invasive graft placement assumes an increasingly prominent role in pelvic reconstructive surgery, it is important to scrutinize the technical reliability of new techniques. Even before randomized controlled trials can be conducted, and in the absence of long-term clinical outcomes, cadaveric testing of new devices can provide valuable insight and enable biomechanical comparison to 'gold standard' alternatives.

The Capio CL device was specifically developed for transvaginal suturing into Cooper's ligament through small anterior vaginal incisions, using a 'push and catch' mechanism. This device has been reported as an adjunct for transvaginal suburethral sling and retropubic urethropexy procedures [5], with favorable clinical outcomes demonstrated at 1 year [6]. The implicit goal of this device is to allow for suture placement into Cooper's ligament through a limited dissection, achieving a similar location and strength to sutures placed through the ligament using an open abdominal technique. The pur-

pose of this study was to objectively compare the maximum tensile strength, and anatomic positioning, of sutures anchored into Cooper's ligament by the open abdominal and transvaginal techniques. As such, we aimed to compare the technical reliability of this newer minimally invasive anchoring technique with the 'gold standard' open abdominal approach.

Materials and methods

Twelve fresh cadavers were used for this study. In each cadaver, Cooper's ligament was accessed through an anterior vaginal incision into the retropubic space. Randomization by numbers chart was used to determine the side of transvaginal suturing, so that bias with respect to side would be minimized. The ligament designated for transvaginal suturing was then digitally palpated via dissection of a 2-cm wide retropubic tunnel. A row of three polytetrafluoroethylene (00) sutures were placed using the transvaginal suturing device, delivered through the retropubic tunnel. Transvaginal sutures ($n = 36$) were placed by one of two surgeons (R.G., S.K.) with extensive experience using the transvaginal suturing device. The technique for transvaginal suture placement using this device has been previously described [5].

Following placement of the transvaginal Cooper's ligament sutures, a low transverse abdominal incision was made in each cadaver, facilitating dissection into the contralateral retropubic space. Three polytetrafluoroethylene (00) sutures ($n = 36$) were placed along the exposed Cooper's ligament by a third surgeon (P.C.), spaced 1 cm apart using a standard tapered needle (THX-26). This surgeon was blinded to the contralateral Cooper's ligament and its existing vaginally placed sutures, using an opaque barrier. During both abdominal and transvaginal suture placement, each surgeon was instructed to simulate surgical techniques used in the operating room. Needles were placed perpendicularly into the ligament, with the typical depth and length of bite used in surgical practice. The goal was to follow the principles of usual clinical practice, rather than standardize suture placement with a fixed depth or length. The distance of sutures from mid-pubic symphysis was recorded as a measure of anatomic location.

All free suture ends were knotted into 5-cm loops, passed through their ipsilateral retropubic tunnel into the midline vaginal incision, and attached to the Omega DFG51 hand-held digital tensiometer device. Progressive tensile load was applied caudal along the axis of the vagina, until each suture either broke or was completely dislodged from the ligament. Before pullout, a flexible tape measure was placed flush against the ligament, to record the distance between each Cooper's ligament suture and the mid-pubic symphysis.

Paired *t*-tests and multivariate regression were used to compare the strength and performance of suture types, and control for potential confounding variables including the side of suture placement, and cadaver number. Pearson coefficients were used to assess correlation between suture location and biomechanical performance. Outcomes included: 'mode of failure' (breakage of the suture loop vs. dislodgment from the ligament tissue), peak tension before failure, and distance of suture placement from the mid-pubic symphysis. Statistical analyses were performed using SPSS (SPSS Inc., Chicago, IL, USA). A post-hoc power calculation—based on standard deviation of mean tensile strength of 3.2 psi, to detect a difference of 5 psi between suture techniques with 0.80 power—indicated a need for at least nine data points in each arm. Powering for the outcome of 'ligament failure', to detect a 20% difference between groups would require 16 data points in each group. Therefore, the sample size (36 in each study arm) was deemed adequate for the two major outcomes in this study.

Results

The mean peak tension averaged 14.57 psi (5.6–23.0) for abdominally placed sutures, and 12.96 psi (4.2–19.8) for the vaginal sutures ($p = 0.28$). Mean values, with 95% confidence intervals, are illustrated in Fig. 1. The paired *t*-test revealed a mean difference of 1.62 psi between abdominal and vaginal sutures ($p = 0.16$). Suture breakage rather than ligament 'pullout' was the most common failure mode for both abdominal and vaginal suturing, but was significantly more likely for abdominal sutures (95 vs. 56%, $p = 0.0001$). The average peak tension associated with ligament pullout was 11.4 psi (SD 3.6), and the average peak tension associated with suture breakage was 14.6 psi (SD 2.7). Right and left-sided sutures did not differ with statistical significance in terms of peak tension (13.35 vs. 14.14 psi) and rates of ligament failure (76 vs. 74%). Multiple logistic regression demonstrated that transvaginal suturing was indepen-

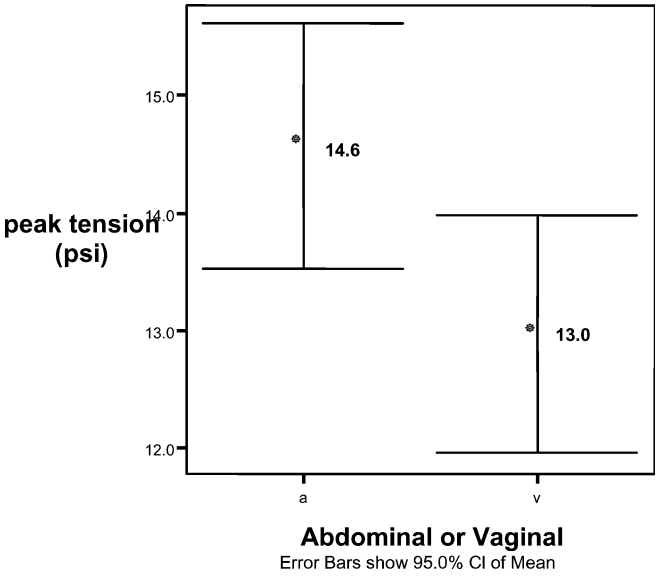

Fig. 1 Mean peak tensile strength: abdominal vs vaginal sutures

dently predictive of ligament failure after controlling for cadaver number and ligament side.

With respect to suture placement, vaginal and abdominal sutures were similarly 'targeted' along Cooper's ligament, with a nearly identical mean distance from the mid-pubic symphysis (4.62 vs. 4.24 cm, $p = 0.56$). Peak tension was not correlated with suture location along the ligament ($r^2 = 0.17$, $p = 0.28$)

Discussion

Cooper's ligament has been regarded as a particularly safe and reliable anchoring site when utilized during abdominal retropubic urethropexy, with exceedingly low rates of complication. Along with recent trends towards minimally invasive surgery, a technique for transvaginal suturing into Cooper's ligament has been introduced; however, the strength and durability of vaginally placed sutures has not been objectively assessed. This study was designed to determine if transvaginal suturing into Cooper's ligament, using a minimally invasive push and catch device, achieves the tensile strength of the traditional 'open' suturing technique.

Previous investigators have evaluated the tensile strength of pelvic anchoring sites. Klutke et al. [7] compared suture fixation between Cooper's ligament, rectus abdominis fascia and bone anchors into the pubic symphysis, in fresh cadavers using an open abdominal approach. The force required for suture breakage was no different between the bone anchoring and Cooper's fixation—leading to the conclusion that bone anchoring offered no apparent advantage. Winters et al. [8] compared periosteal suture fixation with bone anchor fixation in 21 female cadavers. Periosteal suture breakage tended to occur in the middle of the permanent monofilament suture, whereas bone anchor failures occurred at the anchor-suture interface. Furthermore, the periosteal fixation required greater mean loads to induce suture failure, compared with the bone-anchored sites. Thus, bone anchoring appeared to increase the risk of suture breakage, without any advantage with respect to maximal tensile load.

In our cadaver model, using caudally directed force, suture breakage rather than ligament pullout was the most common failure mode for both suturing techniques. However, ligament pullout was statistically less likely after the open abdominal technique (5 vs. 44%, $p = 0.0001$). It is unclear whether this biomechanical finding would bear significance for long-term success, as the maximum tension applied during this study may exceed by magnitudes the threshold of in vivo tensile strength necessary for optimal healing. In theory, long-term success may depend upon persistence of suture material only for the short term, until adequate scarring or native tissue regeneration assumes the major burden of support.

Although the biomechanical model used in this study provides initial insight into the strength and durability this transvaginal invasive anchoring technique, the study design does not allow us to infer that transvaginal reconstructive techniques are more or less effective than abdominal techniques. This question would need to be addressed through clinical trials with long-term follow up. Furthermore, our ability to assess the 'best' suturing and anchoring techniques in pelvic reconstructive surgery will remain limited until we better understand the dynamics of in vivo forces affecting surgical repairs. The caudally applied forces used in our study design provide an estimate, but not a duplication, of 'real life' physiologic stresses imposed on the anchoring site. Future research will hopefully serve to more accurately delineate these aspects of surgical wound healing, and of the dynamic forces influencing key pelvic supports after surgical reconstruction.

Conclusions

Transvaginal suturing to Cooper's ligament appears to represent a reliable technique for use in pelvic reconstructive surgery. According to this biomechanical study, transvaginal sutures achieve similar mean tensile strength to open abdominal sutures, and essentially the same anatomic positioning along Cooper's ligament. However, the transvaginal technique is associated with a greater likelihood of ligament failure before suture breakage compared with the 'gold standard' abdominal approach, when maximal tension is applied caudally. Whether this difference is clinically significant will require clinical correlation. As new surgical anchoring devices emerge, the findings of this study may provide a useful benchmark for further comparative studies.

References

1. Appell RA, Rackley RR, Dmochowski RR (1996) Vesica percutaneous bladder neck stabilization. J Endourol 10:221–225
2. Nativ O, Levine S, Madjar S, Issaq E, Moskovitz B, Beyar M (1997) Incisionless per vaginal bone anchor cystourethropexy for the treatment of female stress incontinence: experience with the first 50 patients. J Urol 158:1742–1744
3. Lind LR, Choe J, Bhatia NN (1997) An in-line suturing device to simplify sacrospinous vaginal vault suspension. Obstet Gynecol 89:129–132
4. Papasakelariou C (1996) Sacrospinous ligament fixation simplified with a new endoscopic suturing device. J Am Assoc Gynecol Laparosc 3[Suppl]:S38
5. Koduri S, Goldberg RP, Sand PK (2000) Transvaginal therapy of genuine stress incontinence. Urology 56[Suppl 1]:23–27
6. Gandhi S, Koduri S, Goldberg RP, Kwon C, Krotz S, Sand PK (2002) Transvaginal Cooper's ligament sling for genuine stress incontinence: one-year outcomes analysis. Oral presentation, International Urogynecology Association Annual Meeting, Prague
7. Klutke JJ, Bullock A, Klutke CG (1998) Comparison of anchors used in anti-incontinence surgery. Urology 52:979–981
8. Winters JC, Fontenot C, Glowacki C, Thomas KA, Scarpero H (2000) Comparison of biomechanical properties of periosteal suture fixation and bone anchor fixation to the pubic bone. Urology 55:866–869

Editorial comment

In this study, the authors compare sutures anchored to the Cooper's ligament utilizing a transvaginal technique with those placed by open abdominal approach. They conclude that transvaginal technique was comparable to the open approach with respect to tensile strength and suture position. Given the well-known advantages of vaginal approach, it is clear that there is a growing need for minimally invasive techniques in pelvic reconstructive surgery. Unfortunately most new surgical techniques are performed in patients without any prior lab evaluation, often with untoward consequences. It is commendable that the authors have tried to evaluate their technique in cadavers to verify their suture placement. While the results of this study are encouraging, we cannot conclude that transvaginal technique can replace abdominal approach. The dynamic forces influencing the surgical sites inside a human body may be very different from the caudally applied force in this biomechanical study. Further research into this interesting question is warranted.