Sacrospinous Fixation/Paravaginal Defect Repair

The ideal Level one/two procedure?

Calgary experience

Rationale and approach

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Paravaginal Defects

- Brought to our attention by recognized expert, Dr. Richardson, in the 1980s
- Initial high expectations for SUI; not realized
  - Found to be more useful for anterior prolapse than SUI
- Interest has somewhat waned in favor of levator avulsion
- No consistency in identification
- No consistency in repair
Paravaginal Defects
Paravaginal: Abdominal View

A. Bilateral paravaginal defects
   - Ischial spine
   - Obturator internus muscle
   - Ileooccocygeous muscle

B. Bilateral paravaginal repair

C. 
   - Fascia detaches from white line
   - White line detaches with fascia
   - Split in white line
   - Complete attenuation or disappearance of white line
Clinical correlation with intra-operative findings is poor

Intra-operative findings considered ‘gold standard’

Imaging not standardized

— Levator avulsion complicates

Ultrasound imaging of paravaginal defects in women with stress incontinence before and after paravaginal defect repair

A. MARTAN*, J. MAŠATA*, M. HALAŠKA*, M. OTČENÁŠEK* and K. SVABÍK*

*Department of Obstetrics and Gynecology, Charles University, Prague, Czech Republic
Levator Avulsion
The ‘new’ paravaginal defect?
Levator Avulsion: The Most common Trauma You Cause (and never heard of)

Paravaginal Defects

- Associated with 60-80% of anterior defects
  - (Segal et al.'s study showed only 37% prevalence)
- Causal or Casual?

Richardson AC (1990) How to correct prolapse paravaginally. Contemp OB Gyn 35(9):100–114
Controversy regarding cause of anterior prolapse
- Central defects?
- Paravaginal fascia detachment?
- Cardinal/USL defects?
- All of the above?
Confusion reigns

- Studies include multiple other procedures
- No convincing evidence that paravaginal repair makes any difference
- HOWEVER
  - Makes intuitive sense to fix observable defects
  - Makes sense to be consistent

Minassian, Vatche A., Mitesh Parekh, Deborah Poplawsky, Jennifer Gorman, and Louise Litzy. “Randomized Controlled Trial Comparing Two Procedures for Anterior Vaginal Wall Prolapse.” *Neurourology and Urodynamics* 33, no. 1

Paravaginal repair
What Is The Best Approach?

- Abdominal
  - Open
  - Laparoscopic
- Vaginal
Evaluation of three different surgical approaches in repairing paravaginal support defects: a comparative trial

Mohamed M. Hosni · Alaa E. H. El-Feky · Wael I. Agur · Essam M. Khater
First prospective cohort comparison of the three routes

Study has significant deficiencies:
- Low numbers
- High complication rate
- Abandoning of laparoscopic route
- Relatively poor anatomic outcomes in vaginal group
- Short follow up
- Many different concomitant procedures
Main Interesting Finding

- No difference between open abdominal and vaginal route
Laparoscopic Approach

- Mode of access only
- Same principles as abdominal approach
- Better visualization
- Combination with other procedures
  — Really?


Technique

- Entry of Space of Retzius
  - Trans-peritoneal
  - Extra-peritoneal
Trans-peritoneal Approaches
TOO Much Work!

- No evidence that better than vaginal approach
- Takes a long time: Access, setup, procedure
- Expensive equipment
- Often not easy to see defect/planes
- Space of Retzius entry sometimes difficult
- I refuse to do ANY operation that is anticipated to take more than a max of 2 1/2 hours combined!
What To Do?

- Vaginal approach!
  - Easier
  - Quick
  - Quick switch from/to other procedures
  - Addition to / further level one support
  - Few special devices
  - Less risk
  - Equal outcomes!
How did we get there?

- Evolution over years
- Used SIS for many years
- Improvement of technique incorporating SIS
  - Initially just bolstering colporrhaphie
  - Then wider dissection with attachment of SIS
  - Then incorporating native tissue repair first
    (apex/paravaginal - SIS secondarily)

Proof of concept: The RCT
Our Starting Point

Bolstering with SurgiSIS

www.nieuwoudt.nl
Absorbable Mesh Augmentation Compared With No Mesh for Anterior Prolapse: A Randomized Controlled Trial

Robert, Magali MD, MSc; Girard, Isabelle MD; Brennand, Erin MD; Tang, Selphée BSc; Birch, Colin MD; Murphy, Magnus MD; Ross, Sue PhD
Calgary Xenograph trial

- RCT
- 12 month follow up
- N = 57 (28 with xenograft; 29 without)
- All surgeons used same sutures and performed procedures exactly the same
- Blinded before randomization and at FU (3rd party)
- Ba 0 or greater
Success defined as $Ba \leq -1$ or less at 12 months

Secondary outcomes (various)

Assumptions for success:


- **No mesh:** 40% (Weber AM, Walters MD, Piedmonte MR, Ballard LA. Anterior colporrhaphy: a randomized trial of three surgical techniques. Am J Obstet Gynecol 2001;185:1299–304)
Power Calculations

- Based on 40% difference, 23 patients per arm would yield 80% power
- Intention to treat principles
- Primary endpoint used Fisher’s exact with RR and 95% CI
- Secondary endpoints used Mann-Whitney U test and reported
- Report according to the CONSORT 2010 Statement
Enrolled
N=58

Randomized
n=57

Allocated to Mesh Group: n=28
Received mesh procedure: 27
Received another procedure: 1

Allocated to No Mesh Group: n=29
Received no mesh procedure: 29
Received another procedure: 0

12-month follow-up
Died: n=1
Attended clinic: n=27
Responded to questionnaire: n=27

12-month follow-up
Attended clinic: n=28*
Responded to questionnaire: n=29

Withdrawn prior to surgery
n=1
<table>
<thead>
<tr>
<th>Characteristic*</th>
<th>Mesh Group (n=28)</th>
<th>No Mesh Group (n=29)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>58.8±11.8</td>
<td>56.9±12.9</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>27.2±4.1</td>
<td>27.9±3.9</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0 (0)</td>
<td>2 (7)</td>
</tr>
<tr>
<td>More than 1</td>
<td>28 (100)</td>
<td>27 (93)</td>
</tr>
<tr>
<td>Postmenopausal</td>
<td>21 (75)</td>
<td>19 (66)</td>
</tr>
<tr>
<td>Current hormone replacement therapy use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous pelvic surgery</td>
<td>19(68)</td>
<td>19 (66)</td>
</tr>
<tr>
<td>Medical conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>0 (0)</td>
<td>3 (10)</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>11 (39)</td>
<td>8 (28)</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>8 (29)</td>
<td>7 (24)</td>
</tr>
<tr>
<td>Neurologic</td>
<td>4 (14)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Other</td>
<td>17 (61)</td>
<td>14 (48)</td>
</tr>
<tr>
<td>Concomitant procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior repair alone</td>
<td>5 (18)</td>
<td>6 (21)</td>
</tr>
<tr>
<td>Anterior repair with concomitant procedure</td>
<td>22 (79)</td>
<td>23 (79)</td>
</tr>
<tr>
<td>Other repair (not anterior)†</td>
<td>1 (4)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Concomitant procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suburethral sling</td>
<td></td>
<td>18</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>Uterine suspension</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Posterior repair</td>
<td>15</td>
<td>14</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>POP-Q Outcomes</td>
<td>Preoperative</td>
<td>12 Mo Postoperatively</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td></td>
<td>Mesh Group (n=28)</td>
<td>No Mesh Group (n=29)</td>
</tr>
<tr>
<td>Cure at 12 mo (primary outcome)</td>
<td>15 (56)</td>
<td>17 (61)</td>
</tr>
<tr>
<td>Cure (Ba –1 or less)</td>
<td>12 (44)</td>
<td>11 (39)</td>
</tr>
<tr>
<td>No cure (Ba greater than –1)</td>
<td></td>
<td></td>
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<tr>
<td>Overall POP-Q stage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>I</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>II</td>
<td>16 (57)</td>
<td>16 (55)</td>
</tr>
<tr>
<td>III</td>
<td>7 (25)</td>
<td>8 (28)</td>
</tr>
<tr>
<td>IV</td>
<td>5 (18)</td>
<td>5 (17)</td>
</tr>
<tr>
<td>Median (IQR) change from baseline</td>
<td>−2 (1)</td>
<td>−2 (2)</td>
</tr>
</tbody>
</table>

POP-Q, Pelvic Organ Prolapse Quantification; RR, relative risk; CI, confidence interval; IQR, interquartile range.

Data are n (%) unless otherwise specified.

* Excludes n=1 in the Mesh Group who died and n=1 in the No Mesh Group who did not attend the 12-month follow-up appointment.

† Fisher’s exact test for all, except for Mann-Whitney U test for median change in overall POP-Q score; all tests and RRs exclude missing values.
Table 3. Patient-Reported Outcomes: Preoperative and 12 Months Postoperatively

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Preoperative</th>
<th></th>
<th>12 Mo Postoperatively</th>
<th>Statistical</th>
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<tbody>
<tr>
<td></td>
<td>Mesh Group (n=28)</td>
<td>No Mesh Group (n=29)</td>
<td>Mesh Group (n=27)</td>
<td>Comparison of</td>
</tr>
<tr>
<td>Median pelvic floor distress</td>
<td></td>
<td></td>
<td></td>
<td>Outcomes at</td>
</tr>
<tr>
<td>Inventory (20-item)</td>
<td>117 (87)</td>
<td>115 (54)</td>
<td>40 (51)</td>
<td>12 Mo* (P)</td>
</tr>
<tr>
<td>Median change from baseline</td>
<td></td>
<td></td>
<td></td>
<td>.538</td>
</tr>
<tr>
<td>Symptom of bulge, n (%)</td>
<td>25 (89%)</td>
<td>28 (97%)</td>
<td>6 (22%)</td>
<td>.544</td>
</tr>
<tr>
<td>Change from yes to no, n (%)</td>
<td>19 (70%)</td>
<td>17 (59%)</td>
<td></td>
<td>.252</td>
</tr>
<tr>
<td>Median pelvic floor impact</td>
<td></td>
<td></td>
<td></td>
<td>.412</td>
</tr>
<tr>
<td>Questionnaire (7-item)</td>
<td>43 (57)</td>
<td>86 (76)</td>
<td>14 (33)</td>
<td>.441</td>
</tr>
<tr>
<td>Median change from baseline‡</td>
<td>(missing: n=1)</td>
<td>(missing: n=2)</td>
<td>-26 (62)</td>
<td>.171</td>
</tr>
<tr>
<td>Median Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire‡</td>
<td>n=13, 31 (7)</td>
<td>n=21, 33 (8)</td>
<td>n=12, 38 (10)</td>
<td>.841</td>
</tr>
<tr>
<td>Median change from baseline‡</td>
<td>n=11, 6 (6)</td>
<td>n=19, 2 (10)</td>
<td></td>
<td>.239</td>
</tr>
</tbody>
</table>

Data are median (interquartile range) unless otherwise specified.

* Mann-Whitney U test for questionnaire scores, Fisher’s exact test for others; all tests exclude missing values; statistical tests comparing preoperative scores were not significant, except for the Pelvic Floor Impact Questionnaire (P=.04).

† Change from symptom of bulge=yes at baseline to symptom of bulge=no at 12 mo.

‡ Includes only patients who completed Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire.
- Surgical technique included apical, paravaginal repair AND standard colporrhaphy in ALL cases
- Procedure standardized
- Previous retrospective trial of same procedure (including mesh), showed presumptive cure rate (Ba 0 or less), of:
  - 69% objective
  - 69.5% subjective symptomatic improvement
Comparison With Other Techniques

- Almost impossible
- Outcome assessments depend on many parameter choices
- I would argue that you will likely not get better results than ours, or literature average
- Patient/surgeon expectations
Our Technique: Combined SSLS/Paravaginal Repair

- Essential elements
  - Capio (Boston Scientific)
  - Permanent stitches (Prolene)
  - Limited dissection (minimal disruption)
  - Feel ATLF (ramus to ischial spine)
  - Palpate obturator foramen (and stay away!)
Original Article

A review of six sacrospinous suture devices

Jane A. MANNING\textsuperscript{1} and Peter ARNOLD\textsuperscript{2}

\textsuperscript{1}John Hunter Hospital, and \textsuperscript{2}Professional Photographer, Medical Practitioner, Newcastle, NSW, Australia

Figure 1 From left to right, Miya hook, Arthrotek suture punch, Capio device, i stitch, Endostitch, Deschamp aneurysm needle.
Conclusions:

- Vascular anatomy behind the sacrospinous ligament is variable.
- Suture placement two fingerbreadths medial to the spine does not guarantee safety.
- For vascular safety, the ideal device does not penetrate behind the ligament.
- Best devices: Caspari, Capio.
- The Deschamp and Miya devices may be a good compromise for the developing world where cost is important.
Classic SSLF

Less control. Difficult visualization
pelvic diaphragm = 2 levator ani muscles & 2 coccygeus muscles

tendous arch of levator ani

puborectalis

pubococcygeus

iliococcygeus

sciatic nerve

Netter p. 340
**pelvic diaphragm** = 2 levator ani muscles & 2 coccygeus muscles

- tendous arch of levator ani
- puborectalis
- pubococcygeus
- iliococcygeus
- o.i.
- c
- p
- sciatic nerve

Netter p. 340
pelvic diaphragm = 2 levator ani muscles & 2 coccygeus muscles

tendous arch of levator ani

puborectalis

pubococygeus

iliococygeus

sciatic nerve

Netter p. 340
Trans-vaginal Approach

- Full thickness transverse dissection (no epithelial splitting)
  - Scissors/’finger –knife’
- Palpate arcus tendineus or obturator fascia/membrane
- Place Capio along line from Prespinous to pubis
- Place two or three Prolene 0 sutures
- Attach to vaginal sulcus fascia/perivaginal fascia
Integrity Of Structures

- Prespinous tissue, obturator fascia and arcus tendineus are all strong anchor points.
- The LINE is important, not the actual tissue anchored to
- Stay away from Obturator Foramen!
- Do not hook bladder with Capio

SSLS/prespinous suspension plus paravaginal
Integral part of apical and most anterior support procedures
Part of ‘whole’
   — Creates effective level One and Two support
Combined with other procedures
   — Paravaginal repair never lone procedure
     Always repair pericervical ring; sometimes midline too
   — Easy to combine with
     ▪ VH
     ▪ Slings
     ▪ Other repairs (posterior/enterocele)
What Do WE Do?

- Don’t worry about terminology
- Primary surgery always vaginal
- Always use Capio with monofilament permanent sutures
  - Transperitoneal (USLS/iliococcygeus/SSLS??)
  - Extraperitoneal
- Advance/repair retracted ant/post fascia
- Correct defective paravaginal defects (start dissection/palpate)
- ALWAYS secure the apex
- Usually bilateral if normal vaginal length and breadth
What Do We Do?

- Short vagina?
  - Secure to PRESPINOUS tissue
    - Safe
    - Strong
    - Starting point for your paravaginal repair

- Narrow vagina?
  - Unilateral fixation

- Always suture vault transversely after VH
- Anterior vaginal incision transversely
What We Do

- Minimal epithelial trimming
- Leave ALL suspension sutures (SSLS/paravaginal) untied till everything is done
- Scope before cutting any suspension sutures
- Use LoneStar
Lone Star Retractor System
‘Poor-man’ Lone Star
The Gelpi
Paravaginal Defects: Easy To Find
No Scope? No Pelvic Floor Surgery!
Calgary Experience

- We wanted consistency
- High surgical case load
- We are all experienced vaginal surgeons
- This approach works very well for us
- Admittedly not the *only* correct approach
Initially we routinely bolstered with xenograft

Now abandoned that approach

Laparoscopic approach:
  – Too much work
  – No better outcome
  – Higher risk
  – Not so easy to combine with other procedures

Open Abdominal approach:
  – We do almost no open surgery anymore
Choose Your Own Technique

Decisions

- What are your capabilities?
- Comfort level
- Convictions regarding pathogenesis of prolapse
- Available technologies/devices
- Training
- Other procedures required
Conclusion

- Combine paravaginal repair with
  - Apical suspension
  - Pericervical ring detachment repair
  - Repair of observable fascia defects
Thank You