Approaches to Pelvic Organ Prolapse
Workshop 7
Monday 23 August 2010, 09:00 – 12:00

<table>
<thead>
<tr>
<th>Time</th>
<th>Time</th>
<th>Topic</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>9:00</td>
<td>9:10</td>
<td>Goals of Pelvic Organ Prolapse</td>
<td>Sandip Vasavada, MD</td>
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<td>9:10</td>
<td>9:25</td>
<td>Pelvic Floor Prolapse: Anatomic, Functional and Surgical Principles</td>
<td>J. Christian Winters, MD</td>
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<td>9:25</td>
<td>09:55</td>
<td>Vaginal Repairs of Pelvic Organ Prolapse</td>
<td>Sandip Vasavada, MD</td>
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<td>09:55</td>
<td>10:05</td>
<td>Robotic Sacrocolpopexy</td>
<td>Kimberly Kenton, MD</td>
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<td>10:05</td>
<td>10:30</td>
<td>Management of recurrence and mesh complications</td>
<td>Philippe E. Zimmern, MD</td>
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<td>10:30</td>
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<td>10:50</td>
<td>11:20</td>
<td>Graft Materials in Lower Urinary Tract Reconstructin</td>
<td>J. Christian Winters, MD</td>
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<td>11:20</td>
<td>11:40</td>
<td>Assessment of outcomes after reconstructive pelvic surgery</td>
<td>Kimberly Kenton, MD</td>
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<td>12:00</td>
<td>Case discussion and Q&amp;A</td>
<td>Philippe E. Zimmern, MD</td>
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**Aims of course/workshop**
Our attendance at the recent ICS meeting was very international. The comments were overall very favorable. The main criticisms were insufficient information in the syllabus (but this cannot be changed easily since we were only given one page for each lecture) and more surgical videos to see how the procedures are being performed. The latter point will be integrated in our planning for this course at the next ICS in Toronto.

**Educational Objectives**
Key learning points:
- discussion of anatomical landmarks and indications for each described procedure
- detailed review of surgical techniques for all compartment prolapse, including robotic and meshes
- use of video clips to illustrate current techniques
- discussion on current outcome measures and how it can impact published results
- presentation of cases involving complications to discuss different approaches and their outcomes

Take home messages:
- Prolapse repair surgery entails a solid knowledge of pelvic anatomy
- Traditional techniques are being challenged by vaginal repair using mesh, but the safety of these procedures, even with elaborate kits, is not certain.
- As pointed out by the FDA (october 2008), serious complications can occur and some are difficult to correct, especially pain and dyspareunia.
- Mesh sacrocolpopexy (open, laparoscopic, or robotic) has level I evidence for its safety and long-term effectiveness.
- Complications such as erosion can occur and failures, although rare, can occur.
- Literature reviews, including Cochrane database, are helpful to discern the best procedures.
Nonetheless, outcome measures are varied and there is no consensus in the field.

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Goals of Pelvic Organ Prolapse Repair

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Pelvic Floor Disorders – U.S.

Surgery for UI and POP

Luber et al, 2001

Olson et al, Obstet Gynecol 1997;89:501

PREDISPOSE
Gender
Race
Anatomic
Neurologic
Collagen

INCITE
Childbirth
Radiation
Nerve damage
Surgery

PROMOTE
Constipation
Occupation
Smoking
COPD
Obesity
Infection
Medications

DECOMPENSE
Aging
Dementia
Decreased mobility

Pelvic Floor Disorders

Infant
Birth Weight
Prolonged 2nd Stage
Forceps

Smoking
Vacuum
Episiotomy

Prolapse
Age
Vaginal
Delivery
WHAT IS THE GOAL OF OUR REPAIR?

Goals of Repair

- Presenting complaints?
- Primary or secondary
  - Incontinence
  - Prolapse/bulge
  - Pressure
  - Pain
  - UTI
  - Constipation/defecatory dysfunction
  - Retention

Tailor Goals of Surgery to Patient Needs

- Reconstructive or Obliterative
- Vaginal or abdominal (can include lap or robotic too)
- Sexual activity
- Physical activity
- Bowel issues
- Patient expectations

A WORD ABOUT PREVENTION

POP prophylaxis at time of hysterectomy – McCall’s Culdoplasty

McCall SH, Kovac SR, Am J Obstet Gynecol, 1999

<table>
<thead>
<tr>
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<th>Moschowitz-type</th>
<th>McCall-type</th>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 0</td>
<td>30</td>
<td>33</td>
<td>26</td>
</tr>
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<tr>
<td>At 3 y</td>
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<tr>
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<td>30</td>
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<tr>
<td>Stage 2</td>
<td>6</td>
<td>0</td>
<td>5</td>
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*At 5 years patients who underwent McCall-type procedures had a significantly lower incidence of prolapse (P = .004).
When is the optimal time to assess treatment goals?

- After consultation and information
- *How much information is enough…. mesh debates etc.. and informed consent*
- Lowenstein et al. (Am J Obstet Gynecol 2007; Dec 197(6): 640 e1-3
  - Patients were more likely to focus goals from “symptoms” and “information-seeking” to “treatment” after consultations: *reassess goals after visit*

Patient Centered Surgical Outcomes

What can affect this?

  - 70% of patients reported a change in satisfaction ratings between 3 mo and 1 year
  - This was strongly associated with decreased goal achievement
  - 56% reported urge incontinence (44% de novo and 12% persistent) and represented the most common reason for dissatisfaction after surgery (p=0.04)

Other Thoughts on Patient Expectations when Undergoing Prolapse Repair

  - Disease specific QOL questionnaires help but not sensitive enough to address individual symptom bother
  - Self achievement of patient centered goals should be considered in addition to clinical and subjective data

Conclusions

- Identify patient goals at time of visit/operative planning
- Write them down (EMR etc..)
- *Mutual* understanding of what patient and physician want/need from repair
- Active re-assessment of goals in follow up period
- *Consideration of additional therapies to help achieve goal (potential road map of future therapies needed)*
Pelvic Floor Prolapse: Anatomic, Functional and Surgical Principles

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Pelvic Organ Support
- Both static and dynamic forces important
- Pelvic organ stability dependent on:
  - Bony structures
  - Pelvic floor musculature
  - Fascial condensations
  - Intact innervation
- Understanding of normal anatomy aids in restoring pelvic organ function & position

Pelvic Floor Musculature

Anterior Levator Ani group

"Pubovisceral"

- Pubococcygeus
- Directly attached to the bladder, urethra, vagina, rectum.
- Actively contribute to visceral control.
- Crucial during increased abdominal pressure.

Posterior Levator Ani Group

"Diaphragmatic"

- Iliococcygeus and coccygeus.
- Originate from more posterior portions of tendinous arc and ischial spines.
- The two sides fuse in midline posterior to the rectum and attach to the coccyx.
- This horizontal plate extends from the rectal hiatus to the coccyx, and the upper vagina and cervix are situated in this horizontal plane created by levator plate.

Levator Ani – Muscle Composition

- Type I muscle fibers – slow twitch and provide a sustained tone of pelvic floor.
  - Support pelvis in normal activity.
- Type II fibers – fast twitch fibers reflexively contract during sudden increases in intraabdominal pressure (ie cough etc).

Pelvic Floor Support

Combination of:
- Pelvic Floor Musculature
- Connective Tissue Attachments

Endopelvic Fascia

- Sheet of fibrous tissue following blood supply to visceral organs. "Retroperitoneal Mesentery"
- Attaches the cervix and vagina to the lateral pelvic sidewall.
- Composed of 2 parts:
  1. Parametrium (connected to uterus) which are the uterosacral and cardinal ligaments.
  2. Paracolpium (connected to vagina). The parametrium fuses to the paracolpium and this extends all the way to perineal body.
**Uterosacral and Cardinal Ligaments**

- Two different parts of a single mass of tissue.
- Uterosacral ligaments are the visible and palpable medial margin of this tissue complex.
  - Situate cervix and upper vagina posteriorly to sacrum.
- Cardioinal ligaments - are thick condensations of fascia originating from the greater sciatic foramen inserting into the lateral aspect of the cervix and upper vagina.
  - Important in support of bladder base as it is contiguous with perivesical fascia.
- Support cervix (uterus) and upper vagina to maintain a posterior position over the levator plate, which pulls them away from genital hiatus.

**Perineal Membrane**

- Dense, triangular sheet of fascia.
- Extends from ischial pubic rami laterally and anterior to the pubic symphysis.
- The perineal body represents the central tendon between the 2 halves of perineal membranes.
- The fibers of the perineal membranes tighten and resist against increased abdominal pressure and gravity as well as supporting the rectum.

**Levels of Vaginal Support**

- **Level I:** Uterosacral and Cardinal Ligaments
- **Level II:** Arcus Tendineus Fascia Pelvis
- **Level III:** Perineal and Rectovaginal Fascia (Perineal Body)

**Continuous layers of support**

**Delivery Induced Neural Dysfunction**

- Pelvic floor function may be altered by neuropathy in the pudendal or sacral nerves.
- Nerve injury may occur via pressure necrosis or stretching of terminal nerve endings.
  - Altered pudendal nerve terminal motor latencies (16%)
  - Evidence of partial denervation via EMG with later recovery.

**Connective Tissue Defects**

- Collagen provides tensile strength.
- Elastin provides flexibility.
  - Women with prolapse had higher proportion of Type III collagen than those without prolapse.
  - Higher activity of elastase which breaks down elastin.
  - Decreased estrogen receptors in menopausal women.

**POP – Multifactorial Nature**

- Childbirth trauma
  - Direct muscle and connective tissue injury
- Neuropathic induced pelvic floor dysfunction
  - Wide levator hiatus
- Connective tissue disorder / Menopause
- Genetics?
- Lifestyle / Weight
Pelvic Floor Defects

- Urethrocele "Urethral Hypermobility"
- Cystocele
- Uterine Prolapse
- Vaginal vault or "cuff" Prolapse
- Enterocele
- Rectocele
- Perineal Body Defects

Pelvic Floor Defects, think compartments

Anterior
- Urethrocele "Urethral Hypermobility"
- Cystocele

Middle or Apical Compartment
- Uterine Prolapse
- Vaginal vault or "cuff" Prolapse
- Enterocele

Posterior Compartment
- Enterocele
- Rectocele
- Perineal body defects

Urethral Support

A lattice-like network of the endopelvic fascia divides and supports the urethra anteriorly and posteriorly.

Anteriorly
- pubourethral = pubourethral fascia

Posteriorly
- pubocervical = pubocervical fascia

Laterally
- urethropelvic = lateral attachments

Mechanism of Stress Incontinence

- Pubourethral Ligament
- Suburethral Vaginal Hammock
- Pubococcygeus muscle

All three structures work together by drawing the urethra forward against the pubourethral ligament and closing the urethra.

The PCM muscle can only contract so much, if there is excessive vaginal laxity, it can’t draw urethra against the PUL to achieve closure.
Integral Theory

Tape placed around "high pressure" zone in mid urethra to "reinforce functional pubourethral Ligaments"
Corrects SUI without affecting hypermobility

Cystocele - Central vs. Lateral Defect

Source: JO DeLancey, Ch 21 in Female Urology, 1994

Source: Raz Textbook of Female Urology

Vaginal Vault Prolapse

Source: JO DeLancey, Ch 21 in Female Urology, 1994

Rectocele
Attenuation of rectovaginal fascia

Enterocle

* A herniation of the cul-de-sac peritoneum with or without intra-peritoneal contents into the fascial layers between the vagina and rectal walls.
* An isolated enterocle may resulting from a transverse separation of the rectovaginal septum to the Level I area of support.

Cystocele - Central Defect

Source: Raz Textbook of Female Urology

Cystocele - Lateral Defect

Source: Raz Textbook of Female Urology
Summary

P. Pelvic floor anatomy is complex, often challenging to master.

P. Proper support is achieved by a contiguous connective tissue network enhanced by properly functioning levator ani function.

P. It is important for the pelvic surgeon to understand these concepts and incorporate these principles into anatomic repair of site-specific defects.
Vaginal Repairs of Pelvic Organ Prolapse

Sandip Vasavada, MD
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The Glickman Urological and Kidney Institute
The Cleveland Clinic

“Traditional repairs vs Augmented repairs”

- Should we abandon “traditional repairs”?
- If no, then what situations to use
  - First time occurrence of prolapse
  - Thin tissues/ atrophic
  - Sexually active patients?
- Constant need to “innovate” or “keep up”

Challenges in Vaginal Prolapse Surgery

- Anterior Vaginal Wall Prolapse
- Apical Prolapse
  - At time of hysterectomy
  - Post-hysterectomy
- Posterior Vaginal Wall Prolapse

Anterior Vaginal Wall Prolapse

- Repair of central defect
  - re-approximation of widened pubocervical fascia
- Repair of lateral defect
  - Suspension/support of bladder base and apex
- Urethra and BN support
  - vaginal sling (if necessary), same or separate incision
- Cardinal ligament repair/ Bladder base/ Apex
  - dissection and approximation to midline

Anterior Vaginal Wall Prolapse

- Identify and correct all defects
- Evaluate potential other coexistent defects of pelvic organ support (e.g enterocoele, rectocele, vault mobility)
- Assess and address potential urethral incompetence
- ? Patch augmentation of repairs
2-0 PDS sutures
Anterior Colporraphy +/- Absorbable Mesh

  - 109/114 patients underwent ant colporraphy 3 techniques
    - Standard
    - Standard + mesh (polyglactin)
    - Ultralateral colporraphy
  - Evaluated by POP-Q
  - Median follow up was 23.3 months
  - 7% stage I preop, 37% stage II preop, 54% stage III preop, 2% stage IV
  - 30% satisfactory outcomes after standard colporraphy alone, 42% standard + mesh, and 46% ultralateral colporraphy
  - VAS: symptom severity improved overall (6.0 +/- 2.7 \rightarrow 1.1 +/- 0.8)
  - Addition of mesh did not seem to make a difference

Anterior Colporraphy

- Sand, PK et al. (Am J Obstet Gyn, June 2001)
  - Prospective randomized trial of stage 2 < cystocele with and without vicryl mesh
  - Follow up at 2, 6, 12, 52 weeks postop
  - 80 with mesh, 80 none
  - Technique: mesh reduction of prolapse only
  - After 1 yr, 43% patients without mesh and 25% with mesh had recurrence to mid vaginal plane (p = 0.2), concurrent slings may be protective as well
  - Mesh does make a difference

Paravaginal Defects

- Lateral support of pubocervical fascia to condensation of obturator internus and levator fascia’s (White line of arcus tendineus)
- Widespread belief that AVW prolapse patients have co-existent lateral and central defects (up to 80%)
- If so many patients have lateral defects that are not routinely corrected, why do our central defect only repairs work most of the time
**Paravaginal Defect**

*Retropubic repair*
- Can be done open or laparoscopically
- Four to six non absorbable sutures
- Success rates good for retropubic and laparoscopic
- Minimal morbidity (aside from access route)

**Paravaginal Defect Correction**

*Vaginal*
- Identify lateral defect
- Enter paravaginal space
- Re-approximate pubocervical fascia with ATFP (interrupted non absorbable sutures)

**Vaginal Correction of Lateral Defect**
Paravaginal Defect Repairs
Vaginal corrective repairs

<table>
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<tr>
<th>Study (year)</th>
<th>No. of pts</th>
<th>Study design</th>
<th>Follow-up mean</th>
<th>Cure (%)</th>
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<td>Retrospective cohort</td>
<td>11 mths</td>
<td>1 – 26 mths</td>
<td>78</td>
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</table>

Patch Augmentation for AVW Prolapse

- Poor quality tissues used for durable repair
- High recurrent prolapse rates (29-42%)
- What to do for patients with 2-3 previous failed repairs?
- Younger patient population: what will happen to results over time?
- What happens to sexual function with patch?
- "Bladder Cripples"

Rationale for Patch Augmentation for AVW Prolapse

- Simultaneous Central and Lateral Defect Support
- Reinforce weak tissues
- Materials for augmentation
  - Autologous?
  - Allograft (fascia, dermis): falling out of favor?
  - Xenograft (porcine, bovine): Cross linked vs not
  - Incisional dehiscence
  - Granulation
  - Encapsulation
  - Synthetic (prolene, soft prolene mesh, marlex, goretex, etc.)

Cystocele Conclusions

- Key to success is recognition and correction of all defects
- Address central and lateral defects
- Good apical support cannot be overemphasized
- Patch augmentation evidence is evolving (level I-II), but lack of long term data and limited prospective randomized and controlled studies
- Wide pore polypropylene mesh with anterior repair data is encouraging
- Standardized techniques of support will allow better comparisons

Apical Prolapse

Solid Support of the Vaginal Apex is the Cornerstone of a Good Vaginal Prolapse Repair
Vaginal Vault Suspension
- Vault is key to a good prolapse repair!
- Many failures because of lack of vault suspension
- Many don’t repair vault
  - Advanced procedures
  - Difficult dissection
  - Were not trained
  - Not recognized
  - Time consuming

Options for Vault Support
- Sacrospinous Ligament Fixation
  - Risks and benefits?
- Uterosacral Ligament fixation
  - Stretched out ligaments already
  - Data is good, long term?
  - Risks of ureteric injury are not insignificant
- Sacrocolpopexy
  - Approach lap or open
  - Data is the best ….. Gold standard
  - Material options ??
- Transvaginal replication of best of above approaches??

Objectives of Vaginal Vault Surgery
- Preserve normal vaginal axis
- Minimize complication rates, blood loss, postoperative discomfort, and cost
- Repair all coexistent pelvic floor defects
- Attempt to restore
  - Vaginal anatomy
  - Visceral function
  - Sexual function
  - Quality of life

Transvaginal Procedures for Vaginal Vault Prolapse
- Modified McCall's Culdoplasty
- Iliococcygeus Vaginal Vault Suspension
- Levator Myorrhaphy
- Sacrospinous fixation
- High Uterosacral Vaginal Vault Suspension (USVVS)
- Total Vaginal Mesh Apical Suspension
- Colpocleisis

Mayo/McCall culdoplasty
- Elevation of vaginal apex to high uterosacral ligament
- Proven efficacy in enterocele repair
- Wide experience in specific centers
- Reported high success rates
- Usefulness in complete prolapse in question

Iliococcygeus suspension
- Transmucosal sutures placed to coccygeus fascia, bilaterally
  - inferior to white line, anterior to ischial spine
- Reported success rates similar to sacrospinous fixation
- Simplicity and decreased morbidity
- May allow for only 6-7 cm depth

SSF technique

- Posterior or Anterior approach
- Penetrate right rectal pillar into pararectal space
- Placement of two permanent sutures 1 ½ fingerbreadths medial to ischial spine
- One end of each suture is secured to undersurface of posterior vaginal apex with “pulley stitch”
- Upper ½ of posterior colporrhaphy closed, then SSF sutures tied elevating the apex. No intervening bridge of suture

Sacrospinous Fixation vs. ASC

- ASC better than SSF with lower recurrence rates (RR: 0.23, 95% CI 0.07-0.77)
- ASC less dyspareunia
- Trend towards lower reoperation rates in ASC pts
- SSF quicker and cheaper to perform
- Return to daily activities longer with ASC
- Maher, C et al: NUU 27: 3-12, 2008 Cochrane Review

Levator Myorraphy

- Transvaginal placement of sutures through levator complex and shelf towards midline to anchor upper vagina
- Similar in concept to Mayo Culdoplasty
- Uses #1 absorbable sutures thru neovaginal apex and into levator muscles bringing them towards the midline to contralateral side. Then, 2 purse string sutures to close enterocele sac

Apical Prolapse

- Lemack, GE et al (Eur Urol Dec 2001)
  - 35 patients (mean age 71, f/u 27.0 months)
  - 5 recurrent prolapse (3 ant enterocele, 1 vault)
  - 7/35 recurrent cystoceles (5 grade 1, 2 grade 2)
  - Satisfaction > 90% in 17/35
  - One ureteral injury

Levator Myorraphy Results
Uterosacral Vaginal Vault Suspension

- Placement of sutures through "normal" vaginal apical suspension points
- Ideal at time of hysterectomy for prolapse
- Thought to be more physiologic suspension of apex
- Addresses level I and II support continuity
- Low, but not insignificant complication of ureteral injuries as the ligament is close to the ureters especially distally

Uterosacral Vaginal Vault Suspension

<table>
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<th>First Author</th>
<th>Year</th>
<th>No.</th>
<th>Follow-up Months (range)</th>
<th>Definition of anatomic success</th>
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<td>33</td>
<td>28 (6-43)</td>
<td>Stage 0 or 1</td>
<td>82%</td>
<td>Apex (15%)</td>
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</table>
Challenges of Vault Suspension Procedures

- No standardized procedure\(^1\),\(^2\)
  - More than 40 different operations for the treatment of vaginal vault prolapse have been described\(^1\)
  - Wide variation in suture materials\(^3\)
- Data on comparative efficacy and safety of different procedures are inconsistent\(^1\),\(^2\)
  - No standardized outcome measures in trials\(^1\)
  - Few randomized prospective trials\(^1,^4\)
- No routine application of tools to assess postoperative anatomical and functional outcomes\(^5\)
  - Variable impact on vaginal axis; change in axis may cause new prolapse to occur\(^6\)


Total Vaginal Mesh Kit Repairs

- Idea to replace components of normal anatomic structure and support of posterior vaginal wall and apex (may also include anterior vaginal wall)
- Typically done with wide pore polypropylene mesh (may use other substitutes)
- May offer more solid and reproducible points of fixation

If so many kits are available why is everyone not using them?

- Cost
- Is it that much better than traditional repairs?
- FDA statement?
- Risks of erosion and dyspareunia/pain is too much for comfort?
- Relies on mesh for support as opposed to any sutures

Conclusions

- Many procedures for vaginal vault suspension
- Current movement is towards use of mesh and “kits” that may reproduce native support in a minimally invasive fashion
- Cost is an issue, but hospitalization may be shorter
- Complications profile being noted with more experience
- Role for a registry for mesh use?
- Ideally suited for development of a randomized prospective trial
  - Issues of control arm: SSF, USVVS?

Posterior Repair

- Anatomical restoration
- Visceral function
- Sexual function

Rectocele repair
Narrow levator hiatus
Perineal repair
Rectocele

Rectum
Anal sphincter

Site Specific Defect Repair
Literature Review

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Follow up (months)</th>
<th>Cure Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cundiff et al. (1998)</td>
<td>43</td>
<td>12</td>
<td>81 (35/43)</td>
</tr>
<tr>
<td>Karram et al. (1999)</td>
<td>89</td>
<td>6</td>
<td>82 (73/99)</td>
</tr>
<tr>
<td>Brubaker et al. (1999)</td>
<td>44</td>
<td>12</td>
<td>77 (34/44)</td>
</tr>
<tr>
<td>Monga et al. (2000)</td>
<td>46</td>
<td>13</td>
<td>82 (38/46)</td>
</tr>
</tbody>
</table>

Graft Augmented Posterior Repairs

- **Rationale?** Recurrences to decrease?
- **Maher et al, NUU Cochrane Review**
  - Vaginal approach had lower recurrence rates than transanal
  - Higher EBL and pain
  - Data on bowel sx insufficient
  - Use of SIS and absorbable mesh insufficient but trended to not be of benefit

Conclusions

- Vaginal approach to prolapse still easiest and often most effective (esp isolated cystoceles and rectoceles)
- Use of “traditional” vs “non traditional” methods must be weighed with pros and cons of approaches with appropriate informed consent i.e “risk vs reward”
Robotic Sacrocolpopexy

Overview:
The role of robotic surgery in reconstructive pelvic surgery will be reviewed. Specifically, course participants will (1) be able list the advantages of robotic surgery when compared to other routes of access; (2) be able to discuss outcomes of robotic prolapse repair; and (3) become familiar with technique of robotic sacrocolpopexy.

Sacrocolpopexy with or without concomitant hysterectomy is the most commonly performed robotic procedure in Female Pelvic Medicine & Reconstructive Surgery. Although randomized trials demonstrate that sacrocolpopexy has more durable anatomical outcomes than vaginal approaches to apical vault suspension without mesh, open abdominal surgery has increased short-term morbidity. In a retrospective cohort analysis of laparoscopic and open sacrocolpopexy, operating room times were longer for the laparoscopic cases when compared to open cases; however, hospital stay and estimated blood loss for the laparoscopic cases was significantly less. Both cohorts had similar complication and re-operation rates.

The utilization of laparoscopy for surgeries traditionally performed via laparotomy is limited by a steep learning curve and ergonomic difficulties. Initial reports of short and long-term outcomes of robot sacrocolpopexy report comparable anatomic success, decreased hospital stay, and lower complication rates when compared with open sacrocolpopexy. A recent retrospective cohort study of robotic versus open sacrocolpopexy, the robotic group had slightly better 6 week postoperative POP-Q apical support, as noted by point “C” [-9 (-10 to -8) vs -8 (-9 to -8); p=.008]. shorter hospitalization (1.3±0.8 vs. 2.7±1.4 days; p<.001) and less intraoperative blood loss (103±96 vs. 255±155 ml; p<.001) when compared with the open group. Operative times were shorter for the open sacrocolpopexy group (225±61 vs. 328±55 minutes; p<.001). With the exception of 3 patients with postoperative fevers in the robotic group, no other significant difference in perioperative complications was seen between the groups. Concurrent hysterectomy (35 vs. 31 patients; p=.02) and anti-incontinence surgery, either synthetic midurethral sling or Burch urethropexy, (37 vs. 42; p=.17) were similar in both groups. Further studies assessing short and long-term anatomic and subjective outcomes using standardized, validated methods are imperative to determine efficacy and complications as well as identify optimal patients for robotic sacrocolpopexy.

There seem to be advantages to robotic surgery over conventional laparoscopy that may improve the generalizability and applicability of minimally invasive surgery to female pelvic surgeons who have not embraced complex laparoscopic procedures. However, with new technology comes new responsibility and only well-designed clinical trials will determine if robot surgery is the best option for patients and surgeons, who wish to offer their patients minimally invasive surgical alternatives.
Management of recurrence and mesh complications

Philippe E. ZIMMERN

My Indications for open mesh sacrocolpopexy

- Primary repair: NO!
- Secondary repair: YES (but limited data)
- Issues:
  - Young patient
  - Steroids; Diabetes
  - Vaginal wall ulcerations

Mesh Indications

- Primary repair: NO!
- Secondary repair: YES

Issues:

- Young patient
- Steroids; Diabetes
- Vaginal wall ulcerations

Mesh sacrocolpopexy Background

- First described in 1962 by Lane
- Until then, treatment options were:
  - Pessary
  - Colpocleisis
  - Vaginal repair

GOAL

Support upper vagina toward S3 and S4
Sutton et al. (1981):
Life-threatening bleeding from pre-sacral vessels

Suspension of the vagina to upper third of sacrum, near sacral promontory

Types of Synthetic meshes

- Pore > 75 micron (Marlex, Polypropylene-Prolene, Trelex)
- Pore < 10 micron/Multifilament (Gore-Tex)
- Multifilament (Teflon, Mersilene, Surgipro)
**OPEN MSC – MAJOR STEPS**

- Left ureter
- Intestinal packing

**FEET**

**RIGHT URETER**

**VAGINAL CUFF**

**PERITONEAL EDGE**

**URETER**

**VAULT**

**VALET**

**DIFFICULT BLADDER DISSECTION**

after prior anterior colporraphy

**VAULT**

**VAULT**

**DIFFICULT BLADDER DISSECTION**

after prior anterior colporraphy

**VAULT**

**Sutures to anchor the mesh to the vagina**

- Non-absorbable/Absorbable?
- 1-2 cm apart, transversely
- ± Avoid vaginal epithelium
- Knots tied over mesh

**Flyn et al. AUGS 2004 Oral poster 1**

Variable pre-sacral space vascular pattern
Final checkpoints

- Check vagina to ensure no transfixing sutures
- Cystoscopy
- Vaginal pack (molding)
- Lay graft along sigmoid
- No mesh tension

Results of abdominal sacrocolpopexy

<table>
<thead>
<tr>
<th>Authors</th>
<th>Ref.</th>
<th>Year</th>
<th>Patients (n)</th>
<th>Follow-up (months)</th>
<th>Success rate (%)</th>
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<tbody>
<tr>
<td>Angulo</td>
<td>[10]</td>
<td>1989</td>
<td>18</td>
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<td>Baker</td>
<td>[8]</td>
<td>1990</td>
<td>95</td>
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<td>Snyder</td>
<td>[9]</td>
<td>1991</td>
<td>147</td>
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<tr>
<td>van Lindert</td>
<td>[27]</td>
<td>1993</td>
<td>64</td>
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<td>Iosif</td>
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<td>1993</td>
<td>40</td>
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<td>1996</td>
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<td>—</td>
<td>2000</td>
<td>40</td>
<td>42</td>
<td>93</td>
</tr>
</tbody>
</table>

Cochrane Review 2007

- **22 RCT with 2368 patients**
- **PROS:** Lower rates of recurrence and dyspareunia compared to vaginal approach
- **CONS:** Longer procedure & recovery, and higher costs
Geomini et al  
*Eur J Obs and Gynecology* 94:234-238 2001

- 40 patients  Median F/U: 38 months  
- “Success” rate: 93% (37/40)
  - If vaginal protrusion was the only pre-operative complaint, surgery produced symptom-free results in 13/14 patients
  - If combination of complaints (protrusion plus incontinence, defecatory symptoms, or sexual dysfunction), surgery produced symptom-free results in only 10/27 (37%)

Given et al  

- Effect on **vaginal length** and sexual function
  - 59 patients
  - MSC or Sacrospinous fixation (SSF)
  - Measurements taken with a marked plastic cylinder from introitus to the posterior fourchette

Given et al

- Average vaginal length:  
  - 8.2 cm after SSF  
  - 11.3 cm after MSC

- A sexual function survey also revealed MSC to be superior

Uterine preservation  
Huguier, J. et al.  
*J.Chir.* 94:285, 1967

Repair of large cystocele with sub-urethrovessical prosthesis

Recurrent triple compartment POP

- 29 pts 2000-2006  
- Median f/up: 23 mths  
- Improved UDI and QoL  
- 2 pts: ≥gr.2 Cystocele (standing VCUG at 6 months)
- No change in sexual or defecatory functions

Gilleran JP, Zimmern, P: *BJUI* 103:1090, 2009

ROBOTIC: Indications

- BMI < 30
- Few prior abdominal surgeries
- No significant respiratory disease
- <75-80 y-old patients
- Vault prolapse alone, or with one additional compartment defect
- Consent: possible open repair (+)
ROBOTIC EQUIPMENT

Technical Pointers

- Side docking for vaginal access
- Difficult: vaginal cuff & promontory
- Mesh and suture choices
- Transfixing sutures
- Tensioning the mesh

Case 3: 62 y old – S/P vag.hyst. Wanting to resume sexual activity

Check efflux of blue

Movie

Robotic MSC-Literature review

- Several techniques described
- Few short series
- Short follow-up
- No comparative series
Elliott, DS et al. J.Urol 2006
- N=30  mean age:67
- 21 with at least 1 y follow-up
- Mean duration: 3.1 hours
- One conversion to open
- Mean hospital stay: 1,5 day
- 2 recurrences at 7 and 9 months
- 2 vaginal mesh extrusion at 6 months

Daneshgari, F et al. BJU 2007
- N=15  mean age: 64
- 3 conversion to open
- Mean duration: 317’ (> 5 hours)
- Mean blood loss: 80 ml
- Mean hospital stay: 2,4 days
- Mean follow-up: 3 months
- Mean POPQ stage: 3.1 decreased to 0

- Retrospective series
- Open (105) versus robotic MSC (78)
- More POP and supracervical hysterectomy in the robotic group
- Also less blood loss and shorter stay
- Longer operating time (mean>5h)
- Same 6 wks short term outcome (POP-Q)

- N=80
- Learning curve (3hrs down to 1h30’)
- C:cystostomy (2), enterotomy (1), ureteric injury (1)
- Erosion: 5 (6%) (mean 5 months!)
- Conversion rate: 4/80 (5%)

Conclusions
- 3 D vision
- Enhanced instrument maneuverability
- Attractive to patients
- Major cost compared to open

Future
- Single incision
- Decrease cost
- Technological improvements
  - Tactile feedback
  - Smaller units

=> New application - unproven long-term outcome and no RCT yet
**Mesh Complications**

- Bleeding (promontory ++)
- Infection
- Vaginal erosion
- Bladder erosion (stone, fistula)
- Dyspareunia
- Recurrence (< 10%)

**Snyder et al**

- One of the largest series: 147 pts
- Mean F/U: 43 months
- 78 GORE-TEX, 65 Dacron, 4 others
- Hospital stay: 2-13 days

**Iglesia et al**
*Int Urogynecol* 8: 105-115, 1997

- Review incidence of mesh erosion
  - Procedures used Marlex, Prolene, Mersilene, and Gore Tex
  - Overall incidence of erosion: 9%
    - Highest for Gore Tex

**Snyder et al**

- 108/116 (93%) who had at least 6 months F/U had a successful outcome
- No recurrent prolapse
- Complications:
  - Bleeding (>500cc EBL) in 23
  - Graft erosion (4) → Removal of graft, with 1 having recurrent prolapse
Case Discussion: 72 y old Totally incontinent after prophylactic TVT placed at time of laparoscopic mesh repair (prolene) 6 months ago

Case Discussion - Recurrence

Conclusions on MSC

- High success rate (>90%), which appears durable
- Concomitant anterior or posterior defects should be treated
- Best option for sexually active pts
- Major complications include bleeding and mesh erosion or infection

Biomechanics Analysis Methodology: Adapted from mitral valve experience

Collagen & Elastin Microstructure
Micro/macro Anatomy
Biomechanical Properties
Finite Element Analysis
Tissue Function Model

Glimpse into the Future

- Office testing (tissue signature/Cutometer)
- Finite element modeling
- Biomaterials for tissue enhancement/ replacement unique to each patient

Cutometer: Potential for Office Exam Procedure
**Graft Materials in Lower Urinary Tract Reconstruction**

J. Christian Winters, M.D.
Eustis Reily Professor of Urology and Gynecology
Chairman, Department of Urology
Louisiana State University Health Sciences Center
New Orleans, Louisiana, USA
cwinte@lsuhsc.edu

Too often we enjoy the comfort of opinion without the discomfort of facts…
John F. Kennedy

---

**Ideal Implant**

- Readily available and affordable
- Biocompatible and chemically inert
- Noncarcinogenic
- Strong, sterile
- Minimal risk of infection or rejection
- No detrimental effect on pelvic function
- More durable than autologous tissue

---

**Classification of graft materials**

- Tissue
- Tissue derivative
- Synthetic biocomposite

---

**Biologic Materials**

- An orderly arrangement of collagen fibers and connective tissue facilitates an ingrowth of host tissue.
- If an integration of host tissue occurs, the implant retains its strength.
- Does irradiation or freezing affect this arrangement?

---

**Tissue Ingrowth**

- Neovascularization and fibroblasts infiltrate the periphery and superficial surfaces of the graft.
- Central portion of graft acellular for years.
- Once entire graft infiltrated, transformation process is completed.

---

**Host Tissue Ingrowth**

- Neovascularization and fibroblasts infiltrate at periphery and superficial surfaces of the graft.
- Central portion of graft acellular for years.
- Once entire graft infiltrated, transformation process is completed.

---

**Host Tissue Incorporation**

- It appears that for long-term graft survival, host tissue incorporation must occur to facilitate a process of graft remodeling, “transformation” into host.
- Even for permanent materials!!!
- “Graft remodeling”

---

**Biologic Grafts: Lessons learned**

- Cadaveric materials:
  - harvesting technique is standardized
  - varying processing techniques
  - variance in the tensile strength and tissue quality of these graft materials (and degree of incorporation)

- Xenografts:
  - Fibrinogel:
    - ideal to facilitate tissue ingrowth
    - Cross-linking decreases degradation
    - May not allow adequate tissue integration
  - May not allow adequate tissue integration
  - Cross-linking decreases degradation

---


---

Synthetic Graft Materials

Case for Synthetics:
1. Readily available
2. Inexpensive
3. Favorable tensile strength
4. Permanent, durable material
5. No potential disease transmission

Mesh Characteristics

- Amid Classification:
  - Type 1: Macroporous and Monofilament
    - Desirable for vaginal surgery: large pores promote tissue ingrowth and host defenses against bacteria.
    - Flexible, easier to implant.
  - Type 2: Microporous with small pore size
  - Type 3: Macroporous, multifilament mesh – small interstices
  - Type 4: "Coated" biomaterials with extremely small pore size

Mesh Characteristics

- Pore size:
  - Marlex: 190-800 micron
  - Teflon: 50-1800 micron
  - GoreTex: 10-30 micron
  - Mersiline: 80-1200 micron

Microscopic Assessment:

- Time Controlled

Principles for the practicing physician

- Mesh material safe for implantation.
  - Volume of material and technique of implantation intimately related to incorporation
  - Encapsulation of grafts not beneficial (contrary to prosthetic devices)
    - Mesh does not encapsulate
    - Coated and microporous meshes or synthetics likely to elicit adverse host reaction and/or encapsulation

Sling Graft Histopathology: A Comparison

- Time Controlled


- Autologous Fascia
- Cadaveric Fascia
- Porcine Dermis
- Polypropylene mesh
- PPM
Outcomes: Comparison Difficult

- Apples vs Oranges
- Procedures differ:
  - Mesh procedures tend to be multi-compartmental repair
  - Colporraphy doesn't address the apex
  - Mesh procedures are free graft or "kit" procedures
- Definition of success not uniform

Use of Mesh in ASC

- Reports verifying benefits of synthetic mesh material during ASC
  - Patients undergoing ASC using either absorbable cadaveric fascia lata graft (Tutoplast) or non-absorbable monofilament polypropylene
  - The objective failure rate for recurrence was 14 out of 44 in the fascial group and 4 out of 45 in the mesh group (RR 3.58, 95%CI 1.28 to 10.03)

Use of mesh in vaginal surgery

- Mesh patch augmentation:
  - Free graft
  - Variable fixation: SSLF, iliococcygeus, arcus tendineus, (Sling)
  - Transvaginal kits
- Variable methodology makes comparison quite difficult.

Mesh patch

Mesh Patch

Mesh patch repair

Synthetic Mesh: Prolapse Repair

Proposed Advantages of Kits

- Standard technique
- Standard mesh
- Standard size – can be cut
- Addresses all compartments of interest?
- Straight out of the box
- Easier to compare results?

Currently Available Kits

- AMS
  - Apogee/Perigee
  - Intepro – synthetic
  - InteXen LP – biologic
- Bard
  - Avaulta
  - Palaplast/Plastipatch
- Gynecare/Ethicon Women's Health & Urology
  - Prolift
  - synthetic
**New Generation: No Trochar**

- **Pinnacle:** Boston Scientific
- **Elevate:** AMS

---

**Cost**

- **AMS**
  - Apogee - synthetic - $1295
  - Pergo - synthetic - $1595
  - Biologic - $490 more each
- **Bard - Avaulta**
  - Anterior - $1300
  - Posterior - $1300
- **Gynecare/Ethicon - Prolift**
  - Anterior - $1200
  - Posterior - $1200
  - Total - $1500

---

**Principles of TransVaginal Mesh (TVM) Technique**

- **Tension Free Placement**
- Broad coverage of the implants
- **Fixation** - of straps
- **No trimming of the vagina**
- **Mesh options:** Anterior, Posterior, and Total (with & without hysterectomy)

---

**Mesh Complications**

- Erosion
- Extrusion

---

**Synthetic Mesh Prolapse Repair:**

- **Complications**
  - Extrusion “Vaginal Erosion” rate – 8.3-11%
  - Dyspareunia:
    - Up to 20% using anterior mesh (6.3% extrusion)
    - Higher incidence expected in posterior compartment.
  - Initial Erosion rate of 17.5% using “full”

---

**Conclusions: My take home thoughts**

- Prolapse outcomes appear to be better after synthetic interposition. (No controlled data!!)
- Biologic materials are at risk of failure, and should be used sparingly.
- With higher volumes of implanted mesh, complications more likely.
- Unique complications related to synthetic materials can be significant, and disasters can (and will) occur...

---

**Pelvic Organ Prolapse**

- Surgical treatment of prolapse depends upon:
  - Severity of prolapse
  - Severity of symptoms
  - General health of the patient
  - Surgeons' preferences and skill level
- **Aims of surgical therapy**
  - Restoration of normal anatomy
  - Restore or preserve bladder, bowel and sexual function
**Surgical Procedures: POP**
- **Vaginal approach**
  - Vaginal hysterectomy
  - McCall’s culdoplasty
  - Anterior colporrhaphy
  - Posterior colporrhaphy
  - Enterocoele closure
  - Sacrospinous colpopexy
  - Colpopexy
  - Vaginal mesh kits
- **Abdominal approach**
  - Abdominal hysterectomy
  - Uterosacral suspension
  - Sacrocolpopexy
  - Sacrocolpopexy
  - Enterocoele closure
  - Paravaginal repair

**Laparoscopic Prolapse Surgery**
- **Total laparoscopic hysterectomy**
- Laparoscopic supracervical hysterectomy
- Uterosacral ligament suspension
- Sacrocolpopexy
- Sacrocolpopexy
- Enterocoele closure
- Paravaginal repair

**Re-operation rate for prolapse**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Recurrence Rate</th>
<th>Mean Follow-up</th>
<th>Mean Complication Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transvaginal</td>
<td>3.8% (range 0–28.1)</td>
<td>(26.0 ± 18.9 months)</td>
<td>10.3%</td>
</tr>
<tr>
<td>Colpopexy</td>
<td>2.2% (range 0–31.3)</td>
<td>(26.0 ± 20.8 months)</td>
<td>11.2%</td>
</tr>
<tr>
<td>Mesh Kits</td>
<td>1.3% (range 0–16.4)</td>
<td>(26.0 ± 13.8 months)</td>
<td>14.5%</td>
</tr>
</tbody>
</table>

**Cochrane Review**

Authors' Conclusion: The benefits of the Abdominal sacral colpopexy procedure must be balanced against:
- longer operating time
- longer time to return to activities of daily living
- increased cost of the abdominal approach

Summary: The trials show that abdominal sacral colpopexy may be better than vaginal sacrospinous colpopexy for uterine or vault prolapse.

**Lap vs Open Colpopexy**

- **Abdominal vs. Laparoscopic sacrocolpopexy**
  - 60 patients who underwent laparoscopic sacrocolpopexy
  - Mean follow-up: 13.3 ± 12.1 months
  - Mean operating time: 298 ± 65 minutes
  - Estimated blood loss: 172 ± 194 mL
  - Hospital stay: 1.8 ± 1.0 days

- 61 patients who underwent open sacrocolpopexy
  - Mean follow-up: 17.1 ± 18.1 months
  - Mean operating time: 218 ± 60 minutes
  - Estimated blood loss: 234 ± 149 mL
  - Hospital stay: 4.0 ± 1.8 days

Complication and reoperation rates were similar.

Conclusion: Laparoscopic and open sacral colpopexies have comparable clinical outcomes.


**Costs of Prolapse Surgery**

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th>Mean Cost (in 2005)</th>
</tr>
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<tbody>
<tr>
<td>Robotic SC</td>
<td>$25,000</td>
</tr>
<tr>
<td>Laparoscopic SC</td>
<td>$20,000</td>
</tr>
<tr>
<td>Open SC</td>
<td>$15,000</td>
</tr>
<tr>
<td>Minimally invasive SC</td>
<td>$10,000</td>
</tr>
<tr>
<td>Vaginal SC</td>
<td>$5,000</td>
</tr>
</tbody>
</table>


Sacral Colpopexy
Assessment of Outcomes after Reconstructive Pelvic Surgery

Kimberly Kenton MD, MS, FACOG, FACS
Associate Professor & Fellowship Director
Female Pelvic Medicine & Reconstructive Surgery
Departments of Obstetrics & Gynecology and Urology
Loyola University Stritch School of Medicine

Learning Objectives
- List 4 types of outcomes that should be considered when evaluating RPS.
- Provide specific examples of each dimension.
- Discuss the role of patient oriented outcomes.

Best method for assessing outcomes?
- Optimal method is unclear
- No consensus of what constitutes “success”
- Wide variety of definitions for “success”
- Results in highly variable estimates of success
- Shift toward patient centered outcomes

History of Outcomes Assessment

- Surgeon says "cured"
- Patient says "cured"

OBJECTIVE

OBJECTIVE + SUBJECTIVE
(validated instruments, QOL)

Objective + Subjective + Global Assessment
+ Goal Oriented

NIH Recommendations: Objective

2001 Workshop:
Standardization of Terminology for Pelvic Floor Researchers
- “Optimal” = Stage 0 POP
- Satisfactory = Stage I POP
- “Definitions picked arbitrarily”

(Weber A et al 2001)

Epidemiology of POP

- Women presenting for routine GYN care
  - Stage 0 = 6%
  - Stage I = 43%
  - Stage II = 48%
- Nearly half would not meet NIH definition for “optimal” or “satisfactory” anatomic outcome

(Swift S et al, 2005)
How do symptoms relate to anatomy?

- Vaginal bulge = symptom that most strongly correlates with POP-Q
- Bulge at the hymen seem to be when patients notice it and become symptomatic

(Swift S et al 2003; Bradley CA et al 2005)

Outcomes By Definition of Success

Pelvic Floor Disorders Network

- Anatomic Definitions
  - Stage 0, Stage 0/I, No descent > hymen
- Subjective Definitions
  - Absence of vaginal bulge symptoms
  - Global Impression of Improvement
- Treatment outcomes, “success” by definition
  (Barber M 2009)

Success Varied With Definition

Stage 0
19%

Stage 0/I
58%

No bulge symptoms
90%

No POP > hymen
94%
What's the Patient’s Perspective?

- Compared patient’s assessment of their outcome using PGI to each definition
- Treatment of your pelvic condition has been ___?
  - Very successful
  - Moderately successful
  - Somewhat successful
  - Not at all successful

What's the Patient’s Perspective?

- Mean Difference Between Success and Failures
- Clinical Significance

-0.9
-0.7
-0.5
-0.3
-0.1
0.1

Anatomic Criteria

Only

No Bulge

What's the Patient’s Perspective?

Bottom Line….

- Patient’s want the “bulge” gone!
- Relief of symptoms
  - NOT
  - “I want my apex at -9 or my anterior vaginal wall at -3.”

Bulge gone ≠ Patient satisfaction

- No bulge …… but, NOW has
  - SUI
  - UUI
  - Dyspareunia
  - Complication
  - Mesh erosion ………..

- Did we achieve patient’s GOALS for surgery?

Patient’s Goals & Expectations

- Always present and typically unstated
- Different
- Personal, often life-style related, and usually reasonable
- NEVER to have persistent or new post-op problems or symptoms
**Post-operative Satisfaction**
- Correlates strongly with achievement of self-described, pre-operative goals
- Dissatisfaction (3 month & 1-year) correlates strongly with
  - Feeling “unprepared” for surgery
  - Perception of routine post-operative events as “complications”
  - Development of NEW symptoms, ie: OAB
  - Elkadry E 2003, Mahajan S 2006

**Can We Help Set “Realistic” Expectations?**
- Asked women to rate their preparedness after surgical consent counseling & signing informed consent
- 42% still not completely prepared for surgery
- “Prepared” vs. “Not Prepared”
  - Higher PGI-I
  - Higher PFDI scores
  - More satisfied
  - No difference in objective measures of cure
- “Not Prepared”
  - Complications – 44%
  - Physician documentation – 8%

**Patient satisfaction**
- “No better” ≠ “worse”
- Persistent symptoms ≠ persistent symptoms + new symptom?
- We may modify expectations, more difficult to change attitudes & value
- Baseline personality
  - Happy in, happy out

**Goals Change**
- Goals can change!
  - Life intervenes, symptom control changes and a new symptom becomes predominant
- Desire for treatment changes
  - Not always based on symptom change

**Adverse Outcomes**
- Little time is spent on valuing adverse outcomes
- Side effects and complications are valued differently
- Most don’t “hear” the negative side…

**So Which Outcomes Matter? Those that Matter to That Patient**
- Counsel primarily about adverse events, especially long-lasting symptoms
- LISTEN to what your patients experience – this will help your counseling
- This will help you counsel other patient, using patient language