Current Advances in Minimally Invasive Surgery for Female Pelvic Organ Prolapse (POP) (Didactic)

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Current Advances in Minimally Invasive Surgery for Female Pelvic Organ Prolapse (POP)
(Didactic)

C.Y. Liu, Chair
Faculty: Robert S. Furr, John B. Gebhart, Alan M. Lam, Priya S. Patel, Arnaud Wattiez

Course Description

The dynamic functional anatomy of female pelvic floor and pathophysiology of POP are still poorly understood. Currently there are numerous surgical procedures for POP available, all claiming to have high success rate. However, careful study reveals that the vast majority of them actually have either an unacceptable complication rate, low long-term success rate, or inadequate long-term follow up.

This course begins with a lecture by Dr. John DeLancey on Anatomic Factors for Successful Native Tissue Repair, which will be transmitted live from University of Michigan. A cadaver dissection to demonstrate the various mechanisms and levels of female pelvic floor support will be shown during this lecture. After focusing on sound anatomic concepts, the participants will then evaluate various commonly performed surgical procedures for POP. A presentation will be given on those procedures that have evidenced long-term success – laparoscopic, vaginal, and robotic approaches – for apical support, enterocele repair, cystocele, rectocele, and total pelvic floor reconstruction. This will be followed by a presentation by Drs. Arnaud Wattiez and Alan Lam, two pioneer surgeons from Europe and Australia, on the most commonly performed POP surgery in their respective countries. The course ends with a discussion on the prevention, recognition, and management of common complications of prolapse surgery.

Learning Objectives

At the conclusion of this course, the participant will be able to: 1) Identify the anatomy of the female pelvic floor support and important structures of pelvic sidewalls related to surgical planning for POP repair; 2) outline the anatomic defects of various conditions of POP; 3) discuss the clinical examination of the patient with enterocele, and plan the most appropriate surgical procedure for her condition; 4) evaluate the various surgical procedures for POP based upon sound anatomic principles; 5) identify the most effective surgical procedure for anterior, posterior, and apical defects; and 6) describe the prevention, and recognition, and management of complications related to POP reparative surgery.

Course Outline

1:30 Welcome, Introductions and Course Overview
   C.Y. Liu

1:35 The Role of Synthetic Mesh in the Treatment of POP
   J.B. Gebhart

1:55 How We Repair POP in Europe – Surgical Techniques and Results
   A. Wattiez

2:55 Robotic Sacro-colpopexy – Tips and Tricks
   R.S. Furr
3:25  Break
3:40  How We Repair POP in Australia – Surgical Techniques and Results  A.M. Lam/P.S. Patel
4:40  Prevention, Recognition, and Management of Complications of Surgical Repair of POP  J.B Gebhart
5:10  Questions & Answers  All Faculty
5:30  Course Evaluation
PLANNER DISCLOSURE
The following members of AAGL have been involved in the educational planning of this workshop and have no conflict of interest to disclose (in alphabetical order by last name).
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Viviane F. Connor
Consultant: Conceptus Incorporated
Frank D. Loffer, Executive Vice President/Medical Director, AAGL*
Linda Michels, Executive Director, AAGL*
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FACULTY DISCLOSURE
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John B. Gebhart
Grants/Research Support: American Medical Systems
Consultant: Astellas, Ethicon Women’s Health & Urology, Boston Scientific Corp. Inc.
Alan M. Lam*
Priya Patel*
Arnaud Wattiez
Consultant: VECTEC, Karl Storz Germany

Asterisk (*) denotes no financial relationships to disclose.
Role of Synthetic Mesh in the Treatment of POP

John B. Gebhart, M.D, M.S.
Urogynecology
Mayo Clinic

Objectives
- Recognize the options available when considering the use of mesh for POP
- Discuss management strategies and pros & cons of using mesh

Surgical mesh types
1. Non-absorbable synthetic
   - polypropylene
   - polyester
2. Absorbable synthetic
   - poly(lactic-co-glycolic acid)
   - poly(caprolactone)
3. Biologic
   - acellular collagen from bovine or porcine sources
4. Composite
   - combination of any of above

Mesh kit categories
- External trocars
  - Prolift (off market)
  - Avaulta (off market)
  - Apogee/Perigee
  - Ascend AC/PC
- Internal fixation
  - Elevate
  - Uphold
  - Pinnacle
  - Restorelle
- No fixation
  - Prosima (off market)
  - Restorelle

Apogee and Perigee™
SGS guidelines – anterior compartment

- It is suggested that nonabsorbable synthetic mesh may improve anatomic outcomes of anterior vaginal wall repair, but there are significant trade-offs in regard to the risk of adverse events.


SGS guidelines – posterior compartment

- There are no comparative studies to guide any recommendation on the use of nonabsorbable synthetic mesh in posterior vaginal wall repair when compared with native tissue repair.


SGS guidelines – multiple compartment

- There are no comparative studies to guide any recommendation on the use of nonabsorbable synthetic graft in multiple compartment repair when compared with native tissue repair.


Evidence for use of mesh - efficacy

- Mesh kits effective in restoring apical prolapse over short term, but long-term outcomes unknown.
- Mesh may improve anatomic outcomes for anterior repair:
  - May not translate to superior symptomatic outcomes or lower repeat surgery rates.
- Apical or posterior repair with mesh does not appear to provide benefit compared to traditional surgery.
- Traditional POP repair has equivalent QoL improvement compared to transvaginal mesh POP repair.

Evidence for use of mesh - safety

- 10% erosion rate within 12 months of surgery
  - Systematic review of 110 studies/11,785 patients\(^1\)
- Mesh complications are not rare
  - Vaginal erosions are most common complication\(^2\)
- SUI more common after mesh anterior repair\(^3\)
- Vaginal mesh apical suspension associated with more complications requiring repeat surgery\(^4\)
- >50% with erosion need surgery, often more than once\(^1\)

\(^1\)Abed et al. Int Urogynecol J, 2011.

FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse

- Based on evaluation of adverse event reports and assessment of the scientific literature, the FDA has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk.
- While the literature suggests an anatomic benefit to anterior repair with mesh augmentation, this anatomic benefit may not result in superior clinical outcomes, and the associated risk of adverse events should be considered.

FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse

- These products are associated with serious adverse events which can require multiple surgeries to repair and may result in continued sequelae (e.g., pain) even after mesh removal.
- Performance data fail to demonstrate improved clinical benefit over traditional non-mesh repair, particularly for transvaginal apical and posterior repair.
- The FDA is considering regulatory changes that may improve our understanding of the safety and effectiveness of these devices.

What the FDA said

- Between Jan 1, 2008 & Dec 31, 2010, the FDA received 2874 reports of complications associated with surgical mesh used to repair SUI and POP; with 1503 associated with POP.
  - The most frequent complications reported were erosion through the vagina, pain, infection, bleeding, dyspareunia, organ perforation, and urinary problems.
  - There were also reports of recurrent prolapse, neuromuscular problems, vaginal scarring or shrinkage, & emotional problems.

So, when might you consider vaginal mesh?

- Advanced prolapse
- Recurrent prolapse
- Large anterior prolapse recurrence
- Poor candidate for abdominal approach
- Demands uterine-sparing surgery?
- Patient aware of risks
- Aware of FDA warning
- Part of research protocol
**When might I avoid vaginal mesh?**

- Young patient
- Sexually active
- Athlete
- First prolapse surgery
- Candidate for standard transvaginal repair
- Candidate for sacral colpo/hysteropexy
- Medical contraindications (steroids, DM, pelvic pain)

**MESH COMPLICATIONS**

- Vaginal Exposure
- Vaginal Pain & Dyspareunia
- Vaginal Scarring and Loss of Vaginal Tissue
- Visceral Injury
- Thigh Pain and Referred Pain

**Mayo Data – Mesh Complications**

Complications specific to synthetic material use continue to increase

Multiple surgeries to address complications may be necessary, and may incompletely resolve symptoms

Potential for underreporting – only 14% referred from original treating physician

Dyspareunia and recurrent prolapse are common reasons for referral


**The Big Questions**

Severe mesh complications are occurring; but are the majority of them TECHNICAL or WOULD THEY OCCUR IN THE BEST OF HANDS

**Abdominal Sacrocolpopexy**

**The Big Questions**

- Product
- Physician
Summary

- Role for synthetic mesh
- Informed consent and documentation
- Not for everyone – patients or providers
- Stay tuned – the market is changing
- Sacrocolpopexy …… caution…..

References

- Diwadkar GB; et al. Obstet Gynecol. 2009; 113(2 Pt 1): 367-73
- Blandon RF; et al. Int Urogynecol J Pelvic Floor Dysfunct. 2009 May;20(5):523-31
How we repair POP in Europe
Surgical techniques and results

A. WATTIEZ Strasbourg University

Disclosure
✓ Consultant: VECTEC, Karl Storz Germany

History
- 1950 sacrocolpopexy with mesh (Huguier & Scali)
- 1961 Colpopexy J. Burch
- 1990 Laps Burch
- 1995 TVT
- 1998 TOT
- 2000 Vaginal mesh for prolapses

Changes in the last 15 years
- Anatomical knowledge
- Global to site specific
- Palliative to reconstructive
- Shift from laparotomy to laparoscopy
- Wide acceptance of primary repair using mesh
- Acceptance of vaginal introduction of mesh
- Tension free concept
- Trans tissue fixation
- Simplication of the laparoscopic technique
- Knowledge of the aetiology of complications

ANATOMY
The principle of an anatomical reconstruction should include a global reattachment of all the cervical ring fascial components.

Shift from laparotomy to laparoscopy

- Due to its quality laparoscopic surgery allows for:
  - Better anatomical dissection
  - A dissection with respect to the tissue
  - Access to unaccessible spaces
  - Better tolerance of the mesh
- Laparoscopy has permitted to gather global and reconstructive approaches.

Clinical Results

- Not much data
  - There is still a confusion between global and palliative. As an example the classical abdominal sacro-colpopexy is a global palliative technique as the modern laparoscopic sacro-colpopexy is a global reconstructive approach.

Wide acceptance of primary repair using mesh

- Pelvic floor defects are due to a fascial alteration
- Fascial reparation with native tissues shows bad long term results except in hernias created by fascial detachment (ex. enterocele).
- Reparation with mesh by laparotomy shows the lowest rate of recurrence even after 20 years.
- The new material used in mesh constitution allow a very good tolerance and a lower rate of complications.

New mesh according to the experience

- Theoretical specifications of an ideal mesh:
  Rapid tissue ingrowth for an efficient support ... without extensive fibrosis leading to discomfort, pains and erosion.
  A late or problematic tissue ingrowth can induce:
  - seroma, hematoma
  - erosion
  - sepsis

The exact requirements will obviously depend on the indication.
Objective: reduce intensity and time of inflammatory period

Sequence of occurrences

- Cellular appeal
- Cellular penetration

- Objective: reduce intensity and time of inflammatory period
- 2 days
- 4 days

The mesh tissue ingrowth

- 7 days
- 10 days

- Peripheral fibrous differentiation
- Central fibrous differentiation

- 15 days
- 2 years

Achieved tissue differentiation within the mesh without fibrous encapsulation

The early phase largely determines the long term tolerance

Acceptance of vaginal placement of mesh

- The good results of TVT and TOT with a low rate of complications pushed the surgeons to go further with vaginal mesh placement.
- The new material such as polypropylene monofilament is well tolerated and presents less risk for infection.
Posterior compartment

Total Prolift

BUT ......

Vaginal fistula after genital prolapse
mesh: Parietex

Prepubic abscess after retropubic sling
: Lif

Cutaneous fistulae: Obtape
Several warnings

Fda: united states
HAS: France
Germany

2012

ETHICON stops the prolift and cancel all vaginal indications...

SO...

The gold standart returns to be

SACRO-COLPO PEXY

Tension free concept

- The tension free concept opposed the elastic suspension to the fixed suspension.
- The idea is that during movement the organs should be able to move and above all in the cranio caudal direction.
- TVT≠promonto fixation
- Good results of TVT associated with a low rate of mesh complication seems to confirm the hypothesis.
- Expectations are better anatomical results associated with better functional results.
**Trans tissular fixation**

- Is the technical principle which sustain the tension free concept.
- The actual question is to know the quality of resistance of this technique during the first post-operative period.

**Simplification of the laparoscopic technique**

- Knowledge of the dissecting planes
- Knowledge of the right placement of the mesh
- Knowledge of the aetiology of complications
- Minimizing the number of sutures

**Functionnal anatomy**

- The axis of the anterior vagina is different comparing to the posterior.

**Surgical implication & access**

- The vagina is not oriented to the S1(sacro colpopexy) nor to S5 (Sacro spino fixation).
- But the restoration of the double axis of the vagina is mandatory for both the anterior and the posterior walls.
  - Low support for the posterior vaginal wall
  - Anterior attachment to the ATFP
  - Post orientation and placement of the post vagina
  - Upper orientation and reinforcement of the ant vagina

**Laparoscopic sacrocolpopexy for female genital organ prolapse: establishment of a learning curve**

- Complex and complete, that requires:
  - Knowledge of anatomy
  - Knowledge of technique
  - Suturing skills
  - Learning curve

**Need for Standardization**

- The use of Standardization is to implement guidelines, a design, or measurements in order to obtain solutions to a disorganized system (to make things easier).
Laparoscopic Sacrocolpopexy
standard technique: “The 6 points technology”

1. Placement of trocars and exposure
2. Promontory dissection
3. Preparation of spaces
4. Hysterectomy?
5. Fixation of meshes: 6 points
6. Peritonization

1. Placement of trocars and exposure

- HOW?
  - Suspension of bowel
  - Uterine manipulator
- WHY?
  - Keep a good vision
  - Keep your assistant
  - Retraction is restriction

2. Promontory dissection and preparation of mesh bed

- Palpation
- Lifting up
- Dissection

3. Preparation of spaces: rectovaginal and bladder dissections

- Rectovaginal dissection
Bladder dissection

- Bladder is dissected down to the upper part of the trigone
- Do not dissect too low: Risk of bladder inestability
- Lateral dissection stays limited to avoid ureteral injury

4. Hysterectomy?

- Not mandatory
- Allows a better distribution of the traction forces (orientation) to the anterior and posterior compartments
- **Subtotal hysterectomy** is preferred in order to avoid mesh erosion

5. Fixation of meshes

- Posterior mesh fixation: 2 points on the pubo-rectalis. « BIG bite »
- Anterior mesh fixation: 1 point. « Small bite »
- Solidarisation of meshes: 2 points
- Fixation in the promontorium: 1 point. « BIG bite ». Only one mesh!
Fixation of the mesh

Solidarisation of meshes

Fixation of the mesh to the promontory

6. Peritonization

- Fix only one mesh to avoid dead spaces between two meshes
- We turn around the mesh with the suture to enhance the fixation in the promontorium
Gynemesh as graft material

- Wide-pore polypropylene mesh seems to be an good graft material with low risk for graft infection (1.4%) or erosion. n=74
- Overall vaginal mesh erosion/extrusion rate is 1.2% (95% CI 0.5%-2.7%). Overall infection rate 0.3%. n=446
- 124 women undergoing sacral colpopexy over the 5-year observation period - overall mesh erosion rate 0.8%

Late mesh infection

- Mesh related functional disturbances
  \- Ano-rectal
    \- Constipation
    \- « False need »
  \- Urinary
    \- Stress incontinence (13–46%)
    \- Bladder instability
    \- Dyspareunia, Pain

To reduce post-operative morbidity \textbf{remember to avoid:}

- Total hysterectomy
- Very low vesico-vaginal dissection
- Transfixing sutures on the vaginal wall
- Traction on the mesh while fixing it over the promontorium
- Dead spaces (fixing only one mesh on the promontorium)

To conclude

Laparoscopic sacrocolpopexy is the “gold standard” procedure for POP repair and its standardization is justified by the difficulty. The vaginal mesh placement will probably disappear.
ROBOTIC ASSISTED SACROCLOPOPEXY
Outcomes of first thirty cases in an AAGL fellowship Program

Disclosure
- I have no financial relationships to disclose.

Introduction
- Pelvic organ prolapse (POP) affects millions of women
- Approximately 200,000 inpatient surgical procedures for prolapse are performed annually in the United States.

Introduction
- Eleven to 19 percent of women will undergo surgery for prolapse or incontinence by age 80 to 85 years.
- 30 percent of these women will require an additional prolapse repair procedure.
- Women with symptomatic POP experience daily discomfort, as well as interference with sexual function and exercise.

Introduction
- Only Symptomatic prolapse should be addressed:
  - Conservative (pessary) v. Surgical
- The choice of a primary surgical procedure for women with POP depends upon a variety of considerations, including the anatomic site of prolapse, presence of urinary or fecal incontinence, health status, and patient preferences.
The choice of surgical route for repair of apical prolapse is controversial. Open abdominal repairs are more effective in restoring vaginal topography, but vaginal repairs incur less serious morbidity and have a shorter recovery.

Laparoscopic and robotic approaches may offer the improved vaginal support associated with open procedures and the shorter recovery of vaginal procedures.

Study Objective: To report initial outcomes with six-month follow-up of our first thirty robotic-assisted sacrocolpopexy/sacrocericopexy procedures.

Design: Retrospective chart review (Level III).

Setting: Private practice patients within an AAGL Fellowship program in minimally invasive gynecologic surgery with all surgery performed at tertiary care facilities.

Patients: Thirty women who underwent either robotic-assisted sacrocolpopexy or sacrocervicopexy with or without concomitant incontinence procedure.
Abstract: Interventions

- Eight patients (26.7%) had pre-operative urodynamic stress incontinence.
  - Seven of these eight (87.5%) underwent concomitant mid-urethral sling placement (TOT).
  - One patient had a UTI at time of surgery and consequently had TOT deferred to six weeks later.

Abstract: Main Results

- No intraoperative or post-operative complications.
- 6-month follow-up data available for 22/30 patients.
- Average estimated blood loss (EBL) was 36ml.
- One (1/22=4.5%) symptomatic POP recurrence (stage 2).

Abstract: Main Results

- There were no mesh exposures or erosions.
- No complaints of dyspareunia or pelvic pain.
- All patients were discharged from the hospital either same day or in less than 24 hours.

Abstract: Main Results

- De novo USI rates were 18% (4/22) at six weeks with one additional case presenting at six months.
- Overall de novo USI rate of 22.7% (5/22).
  - CARE Trial: 3 months post-op:
    - 23.8% of Burch group had de novo USI
    - 44.1% of control group had de novo USI

Abstract: Main Results

- Of patients with pre-existing USI who underwent concomitant TOT, 2/7 (28.5%) had urge incontinence at 6 weeks that resolved at 6 months.
- At 6 months only 1/7 (14.3%) had persistent de novo urge incontinence.
  - CARE Trial: incidence of de novo urge incontinence in both arms was 32.7% (Burch) and 38.4% (controls) p=0.48.

Abstract: Main Results

- One patient underwent TOT at 6 weeks
- Second pt. had TOT placement at 6 months
- Final patient underwent TVT at 6 months due to finding of intrinsic sphincter deficiency (ISD) on urodynamic testing.
- One patient had resolution of her USI symptoms at 6 months.
- Final patient was referred for urodynamic testing and failed additional follow-up.
- In these patients with pre-operative urodynamic stress incontinence (USI), none had persistent USI at 6 months.
Requiring TOT

Symptomatic Incontinence

Symptomatic Incontinence

No New Incontinence

RSC – TOT +

De Nova Incontinence

RSC + TOT +

6 Weeks TVT

6 Months TVT

6 Months TOT

Events

1 TVT

1 TVT

Conclusions

- Robotic-assisted SCP is a good option for surgical correction of symptomatic POP without significant intraoperative or post-operative morbidity.
- Recurrent prolapse is rare.
- In our experience there are no mesh complications to date.

Discussion

- Given our initial findings compared to outcomes of the CARE Trial:
  - The pros and cons of concomitant therapeutic and/or prophylactic USI surgery may be an area for discussion and debate, warranting further randomized prospective trials with robotic SCP and TVT/TOT.

- The robotic approach to sacrocolpopexy has dramatically changed the length of hospital stay and thus may become the most accepted surgical tool with which to perform this “gold-standard” procedure for POP.

Thank You.

Robert S. Furr, MD
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How We Repair POP in Australia – Surgical Techniques and Results

Alan Lam Associate Professor
Priya Patel Clinical Fellow
Centre for Advanced Reproductive Endosurgery
Royal North Shore, Sydney University, Australia

We have no financial relationships to disclose.

Learning objectives
Based on the author’s 20 years experience in pelvic floor repair, this presentation aims to:
1. Provide the participants with tips on how the author chooses between vaginal and laparoscopic approach
2. Examine the techniques and results of laparoscopic pelvic floor suture repair from 1993 to 2002
3. Evaluate the techniques and results of laparoscopic and trans-vaginal mesh techniques from 2002 to 2012
4. Illustrate how to treat recurrent and complex prolapse and complications after transvaginal mesh repairs

We are practising in a very exciting time marked by great understanding of pelvic floor anatomy, numerous but rapidly evolving surgical techniques, promising technological breakthroughs, conflicting outcomes, few RCTs, diametrically opposed expert opinions and hence complex medico-legal environment.

Factors determining management of POP?

Surgical procedure
Surgical options?

Vaginal A/P repair

Vaginal A/P repair + Sacrospinous colpopexy

Transvaginal mesh

LSP + Vaginal fl / h

Hysterectomy?

Total or Supravaginal sacrospinous colpopexy

Laparoscopic Sacrocolpopexy

Laparoscopic SP + para-vaginal repair

Expert's opinion

Laparoscopic Suture Pelvic Floor Repair

Background

- Anatomical reconstruction of Level I and II (DeLancey 1992) pelvic floor defects
- Accessible via laparoscopic approach
Laparoscopic suture pelvic floor repair

- **Objective.**
  - To evaluate the effectiveness and safety of laparoscopic pelvic floor repair in the management of pelvic organ prolapse
- **Design.**
  - Retrospective study
  - Ongoing follow-up
- **Setting.**
  - University-affiliated hospitals (North Shore Private, Mater and St. George Hospital)
- **Patients**
  - 693 consecutive women between 1993 and December 2002

Three Pelvic Floor Repair groups

1. PFR + Uterine Suspension = 154 cases
2. PFR + Hysterectomy + Vault Suspension = 64 cases
3. PFR + Vault Suspension = 219 cases

Pelvic Floor Repair and Uterine Suspension

- **Group I**
  - Cases: 179
  - Mean Age: 51.4 ± 12.06
  - Follow-up: 13.4 months ± 15.5

Pelvic Floor Repair and Uterine Suspension

- **Presenting Symptoms**
  - Urinary Incontinence
  - Prolapse
  - Pelvic Discomfort
  - Constipation

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Pelvic Floor Repair and Uterine Suspension

Additional Procedures

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Complications

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<td></td>
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<tr>
<td>Wound infections</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>De novo constipation</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Voiding dysfunction</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Pelvic sepsis and return to OT</td>
<td>1</td>
<td>.5</td>
</tr>
<tr>
<td>UTI</td>
<td>5</td>
<td>2.5</td>
</tr>
</tbody>
</table>

Outcome of Pelvic Floor Repair and Uterine Suspension

Follow-up mean 13.4 mths SD 15.5
Repair maintained 167 93.30%
Failure (uterine descent) 6 3.5%
Failure (Vaginal prolapse) 6 3.5%

Second Procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manchester Repair</td>
<td>1</td>
</tr>
<tr>
<td>Uterine Suspension</td>
<td>1</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>4</td>
</tr>
<tr>
<td>Vaginal repairs</td>
<td>7</td>
</tr>
<tr>
<td>Colposuspension</td>
<td>1</td>
</tr>
<tr>
<td>Drainage of abscess</td>
<td>1</td>
</tr>
<tr>
<td>Removal of suture from vault</td>
<td>3</td>
</tr>
</tbody>
</table>
Hysterectomy, Pelvic Floor Repair and Vault Suspension

Group II

- Cases: 64
- Mean Age (yrs): 53.27 SD 11.7
- Follow-up (months): 9 SD 11.2

Presenting symptoms

Type of Hysterectomy Performed

<table>
<thead>
<tr>
<th>Type of Hysterectomy Performed</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Laparoscopic</td>
<td>21</td>
<td>32.8</td>
</tr>
<tr>
<td>LAVH</td>
<td>10</td>
<td>15.7</td>
</tr>
<tr>
<td>Vaginal Hysterectomy</td>
<td>33</td>
<td>51.5</td>
</tr>
</tbody>
</table>

Hysterectomy, Pelvic Floor Repair and Vault Suspension

Previous Surgery

<table>
<thead>
<tr>
<th>Previous Surgery</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colposuspension</td>
<td>6.3 (4)</td>
</tr>
<tr>
<td>Anterior repair</td>
<td>7.8 (5)</td>
</tr>
<tr>
<td>Posterior repair</td>
<td>7.8 (5)</td>
</tr>
</tbody>
</table>
Hysterectomy, Pelvic Floor Repair and Vault Suspension

### Additional Procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colposuspension/ Paravaginal</td>
<td>7</td>
</tr>
<tr>
<td>Anterior repair</td>
<td>40</td>
</tr>
<tr>
<td>Posterior repair</td>
<td>30</td>
</tr>
<tr>
<td>Perineum</td>
<td>26</td>
</tr>
<tr>
<td>Adhesiolysis</td>
<td>3</td>
</tr>
</tbody>
</table>

### Level of Repair

<table>
<thead>
<tr>
<th>Level</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I</td>
<td>19</td>
</tr>
<tr>
<td>Level II</td>
<td>41</td>
</tr>
<tr>
<td>Level III</td>
<td>4</td>
</tr>
</tbody>
</table>

### Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intra-op</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kinked ureter</td>
<td>1</td>
<td>1.5</td>
</tr>
<tr>
<td><strong>Post-op</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td>1</td>
<td>1.5</td>
</tr>
<tr>
<td>UTI</td>
<td>3</td>
<td>4.6</td>
</tr>
<tr>
<td>Voiding dysfunction</td>
<td>1</td>
<td>1.5</td>
</tr>
<tr>
<td>Wound Haematoma</td>
<td>1</td>
<td>1.5</td>
</tr>
</tbody>
</table>

### Follow-up (mean 9 mths) SD 11.2

<table>
<thead>
<tr>
<th>Repair maintained</th>
<th>58</th>
<th>90.5 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vault Prolapse</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Vaginal Prolapse</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

### Second Procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior repair</td>
<td>1</td>
</tr>
<tr>
<td>SSF</td>
<td>1</td>
</tr>
<tr>
<td>Laparoscopic Colposuspension</td>
<td>1</td>
</tr>
<tr>
<td>Laparoscopic Vault Suspension</td>
<td>1</td>
</tr>
</tbody>
</table>
Pelvic Floor Repair and Vault Suspension

- Cases: 219
- Mean Age: 60.95 ± 14.3
- Follow-up: 10.2 months ± 11.2

Presenting Symptoms

- Urinary Incontinence
- Prolapse
- Pelvic Discomfort
- Constipation

Previous Surgery

139 previous prolapse surgery = 63.5%

<table>
<thead>
<tr>
<th>Previous Surgery</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manchester</td>
<td>5</td>
<td>2.3</td>
</tr>
<tr>
<td>Colposuspension</td>
<td>35</td>
<td>16.0</td>
</tr>
<tr>
<td>Anterior repair</td>
<td>96</td>
<td>43.6</td>
</tr>
<tr>
<td>Posterior repair</td>
<td>90</td>
<td>41.1</td>
</tr>
<tr>
<td>Suspension*</td>
<td>29</td>
<td>13.2</td>
</tr>
</tbody>
</table>

* 22 previous Sacrospinous Colpopexy

Previous Hysterectomy Performed

<table>
<thead>
<tr>
<th>Performed</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Abdominal</td>
<td>124</td>
<td>57</td>
</tr>
<tr>
<td>Vaginal / LAVH / TLH</td>
<td>95</td>
<td>43</td>
</tr>
</tbody>
</table>

Level of Repair

<table>
<thead>
<tr>
<th>Level of Repair</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I</td>
<td>30</td>
</tr>
<tr>
<td>Level II</td>
<td>157</td>
</tr>
<tr>
<td>Level III</td>
<td>32</td>
</tr>
</tbody>
</table>

Group III - Colpograph
Pelvic Floor Repair and Vault Suspension
Pelvic Floor Repair and Vault Suspension

### Additional Procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colposuspension</td>
<td>71</td>
</tr>
<tr>
<td>Paravaginal</td>
<td>52</td>
</tr>
<tr>
<td>Anterior repair</td>
<td>55</td>
</tr>
<tr>
<td>Posterior repair</td>
<td>29</td>
</tr>
<tr>
<td>Perineorrhaphy</td>
<td>69</td>
</tr>
<tr>
<td>Adhesiolysis</td>
<td>84</td>
</tr>
</tbody>
</table>

### Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-op</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bladder</td>
<td>1</td>
<td>0.45</td>
</tr>
<tr>
<td>Bowel</td>
<td>1</td>
<td>0.45</td>
</tr>
<tr>
<td>Post-op</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td>5</td>
<td>2.3</td>
</tr>
<tr>
<td>UTI</td>
<td>9</td>
<td>4.1</td>
</tr>
<tr>
<td>Voiding dysfunction</td>
<td>7</td>
<td>3.2</td>
</tr>
<tr>
<td>Vesico-vaginal fistula</td>
<td>1</td>
<td>0.45</td>
</tr>
</tbody>
</table>

### Follow-up

- Mean 10.2 mths (SD 14.3)
- Repair maintained: 200 (91.7%)
- Failures: 19 (8.7%)
  - Cystocele: 4 (1.8%)
  - Rectocele: 6 (2.8%)
  - Vault Prolapse: 9 (4.1%)

- 80 patients, no previous prolapse surgery
- 4 failures = 5% recurrence

### Second Procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSF</td>
<td>3</td>
</tr>
<tr>
<td>Lap vault suspension</td>
<td>2</td>
</tr>
<tr>
<td>Vaginal repair</td>
<td>8</td>
</tr>
<tr>
<td>Lap colposuspension</td>
<td>2</td>
</tr>
<tr>
<td>Removal of sutures</td>
<td>6</td>
</tr>
<tr>
<td>VVF</td>
<td>1</td>
</tr>
</tbody>
</table>

### Conclusions

- Laparoscopic pelvic reconstructive surgery is effective
- Success rates > 90%
- Uterine preservation does not affect outcome
- Suture erosion 1-2%
- Laparoscopic approach is safe, and is associated with low peri-operative morbidity (<1% major morbidity)

---

Transvaginal Mesh for Pelvic Organ Prolapse

10 Year Experience with 674 Procedures
Objective

To review and compare the outcomes of three different transvaginal mesh (TVM) repairs performed at our centre in the last decade.

<table>
<thead>
<tr>
<th>Study Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>485 Patients</td>
</tr>
<tr>
<td>90 patients had Gynemesh (Mar 2002 – Sep 2006)</td>
</tr>
<tr>
<td>199 patients had Prolift (Feb 2006 – Mar 2010)</td>
</tr>
<tr>
<td>196 patients had Elevate (Dec 2009 – Jul 2012)</td>
</tr>
<tr>
<td>17 Post</td>
</tr>
<tr>
<td>35 Ant</td>
</tr>
<tr>
<td>35 A&amp;P</td>
</tr>
<tr>
<td>60 Post</td>
</tr>
<tr>
<td>27 ± 31 months follow-up</td>
</tr>
<tr>
<td>23 ± 21 months follow-up</td>
</tr>
<tr>
<td>7.8 ± months follow-up</td>
</tr>
</tbody>
</table>

Results

<table>
<thead>
<tr>
<th>Patient Characteristic</th>
<th>Gynemesh</th>
<th>Prolift</th>
<th>Elevate</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, y (SD)</td>
<td>63.4 (9.8)</td>
<td>62.1 (10.6)</td>
<td>60.5 (11.1)</td>
<td>0.049</td>
</tr>
<tr>
<td>Mean BMI, kg/m² (SD)</td>
<td>28.4 (4.7)</td>
<td>26.6 (4.6)</td>
<td>26.3 (5.1)</td>
<td>0.058</td>
</tr>
<tr>
<td>Mean parity, (SD)</td>
<td>2.8 (1.2)</td>
<td>2.9 (1.2)</td>
<td>2.8 (1.2)</td>
<td>0.789</td>
</tr>
<tr>
<td>Postmenopausal, n (%)</td>
<td>78 (86.7)</td>
<td>171 (85.9)</td>
<td>161 (82.1)</td>
<td>0.338</td>
</tr>
<tr>
<td>Recurrent prolapse, n (%)</td>
<td>46 (50.6)</td>
<td>93 (46.7)</td>
<td>49 (25.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mean 8 repairs, (SD)</td>
<td>1.3 (1.6)</td>
<td>0.9 (1.2)</td>
<td>0.5 (1.2)</td>
<td>0.016</td>
</tr>
<tr>
<td>Previous hysterectomy, n (%)</td>
<td>46 (51.1)</td>
<td>100 (50.3)</td>
<td>65 (33.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Baseline POP-Q Stage ≥ 3, n (%)</td>
<td>79 (87.8)</td>
<td>170 (85.4)</td>
<td>140 (71.4)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Operative Details</th>
<th>Gynemesh</th>
<th>Prolift</th>
<th>Elevate</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean duration, min (SD)</td>
<td>108 (23)</td>
<td>103 (24)</td>
<td>88 (24)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mean estimated blood loss, ml (SD)</td>
<td>129 (78)</td>
<td>196 (148)</td>
<td>157 (103)</td>
<td>0.004</td>
</tr>
<tr>
<td>Bladder perforation, n (%)</td>
<td>0 (0)</td>
<td>4 (2.0)</td>
<td>1 (0.5)</td>
<td>0.590</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>8 (8.9)</td>
<td>3 (1.5)</td>
<td>9 (4.6)</td>
<td>0.016</td>
</tr>
<tr>
<td>TVT(O)</td>
<td>10 (11.1)</td>
<td>27 (13.6)</td>
<td>50 (25.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Anterior native tissue repair</td>
<td>4 (4.4)</td>
<td>7 (3.5)</td>
<td>51 (26.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Posterior native tissue repair</td>
<td>49 (54.4)</td>
<td>26 (13.1)</td>
<td>13 (6.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Perineorrhaphy</td>
<td>43 (47.8)</td>
<td>30 (15.1)</td>
<td>106 (54.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Laparoscopic sacrocolpopexy</td>
<td>12 (13.3)</td>
<td>24 (12.2)</td>
<td>20 (10.2)</td>
<td>0.634</td>
</tr>
</tbody>
</table>
**Results**

Baseline vs. Final POP-Q Measurements

<table>
<thead>
<tr>
<th>Complications, n (%)</th>
<th>Gynemesh</th>
<th>Prolift</th>
<th>Elevate</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin drop ≥ 30 g/dL</td>
<td>8 (8.9)</td>
<td>33 (16.6)</td>
<td>13 (6.4)</td>
<td>0.011</td>
</tr>
<tr>
<td>Fecal incontinence</td>
<td>2 (2.2)</td>
<td>11 (5.4)</td>
<td>3 (1.6)</td>
<td>0.056</td>
</tr>
<tr>
<td>Skin cellulitis</td>
<td>0 (0)</td>
<td>7 (3.4)</td>
<td>0 (0)</td>
<td>0.002</td>
</tr>
<tr>
<td>Mesh infection</td>
<td>1 (1.1)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0.186</td>
</tr>
<tr>
<td>Vaginal dysfunction</td>
<td>2 (2.2)</td>
<td>5 (2.5)</td>
<td>6 (3.1)</td>
<td>0.776</td>
</tr>
<tr>
<td>Cardiovascular/thromboembolic</td>
<td>1 (1.1)</td>
<td>2 (1.0)</td>
<td>1 (0.5)</td>
<td>0.563</td>
</tr>
<tr>
<td>Readmission</td>
<td>2 (2.2)</td>
<td>7 (3.4)</td>
<td>7 (3.7)</td>
<td>0.747</td>
</tr>
<tr>
<td>Mesh exposure (per procedural site)</td>
<td>19 (20.4)</td>
<td>38 (19.5)</td>
<td>3 (1.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>at &gt; 2 months post-op</td>
<td>4 (4.5)</td>
<td>10 (4.4)</td>
<td>0 (0)</td>
<td>0.001</td>
</tr>
<tr>
<td>Mesh prominence</td>
<td>7 (7.9)</td>
<td>12 (6.4)</td>
<td>4 (2.1)</td>
<td>0.091</td>
</tr>
<tr>
<td>Mesh contraction</td>
<td>5 (5.6)</td>
<td>9 (4.6)</td>
<td>1 (0.5)</td>
<td>0.003</td>
</tr>
<tr>
<td>De novo urinary stress incontinence</td>
<td>6 (6.7)</td>
<td>26 (13.2)</td>
<td>13 (6.9)</td>
<td>0.051</td>
</tr>
<tr>
<td>De novo urinary urgency</td>
<td>8 (8.7)</td>
<td>9 (4.5)</td>
<td>12 (6.5)</td>
<td>0.318</td>
</tr>
<tr>
<td>De novo dyspareunia</td>
<td>14 (15.7)</td>
<td>24 (16.4)</td>
<td>11 (5.9)</td>
<td>0.012</td>
</tr>
<tr>
<td>Prolapse recurrence (per procedural site)</td>
<td>28 (30.1)</td>
<td>51 (25.9)</td>
<td>36 (19.2)</td>
<td>0.001</td>
</tr>
<tr>
<td>Re-operation</td>
<td>24 (27.0)</td>
<td>51 (25.9)</td>
<td>16 (8.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>for mesh exposure</td>
<td>16 (18.0)</td>
<td>27 (15.7)</td>
<td>1 (0.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>for recurrent prolapse</td>
<td>12 (13.5)</td>
<td>19 (9.6)</td>
<td>12 (6.6)</td>
<td>0.129</td>
</tr>
</tbody>
</table>

**Objective**

To compare the outcomes of laparoscopic sacrocolpopexy (LSC) with laparoscopic sacrohysteropexy (LSH) for Level I prolapse

**Methods**

- **Prospective cohort study**
- **Population**
  - Consecutive patients who underwent LSC or LSH with Gynemesh® by or under the direct supervision of the senior surgeon (AL)
- **Setting**
  - University-affiliated tertiary referral centre
- **Study period**
  - Nov 2004 – July 2012

**Methods**

- **Primary outcome**: Mesh exposure
- **Secondary outcomes**:
  - Anatomical cure
    - Defined as apical POP-Q Stage ≤ 1 at final follow-up
  - Functional improvement
    - Prolapse symptoms
    - Bladder symptoms
    - Bowel symptoms
    - Sexual symptoms

**Sexual Symptoms**

- Dyspareunia
- Decreased sensation
- Self Partner
- Altered self-image

**General Prolapse Symptoms**

- Vaginal bulging
- Pelvic pressure
- Bleeding, discharge, infection due to dependent ulceration
- Need to splint to reduce
- Low backache

**Bladder Symptoms**

- Stress incontinence
- OAB symptoms
- Nocturia
- Obstructed voiding
- Need to splint to void
- Recurrent UTIs

**Bowel Symptoms**

- Anal incontinence
- Fecal urgency
- Rectal pressure
- Constipation
- Need to splint
- Incomplete emptying

**Sexual Symptoms**

- Dyspareunia
- Decreased sensation
- Self Partner
- Altered self-image
Intra-operative Complications
- Bleeding*
- Organ injury
- Anaesthetic complication
- Cardiovascular
- Respiratory

Methods
- Secondary outcomes:
  - Surgical morbidity
    - Intra-operative
    - Post-operative
    - Mesh-related
    - De novo symptoms
    - Re-operation

Re-Operation
- For treatment of:
  - Peri-operative complications
  - Prolapse
  - Mesh complications
  - De novo GSI

Results
- 275 laparoscopic mesh sacral promontory fixation procedures
- 121 with intact uterus
- 154 who had previous hysterectomy
- 36 concurrent hysterectomy
- 85 LSH
- 1 lost to f/u
- 190 LSC
- 2 lost to f/u
- 84 LSH
- 188 LSC

Methods
- Follow-up
  - Routinely at 1, 12, and 60 months
  - Any unscheduled visits
- POP-Q measurements
  - At pre- and post-op visits
- Symptom profile
  - At pre- and post-op visits
  - Standardized questions on
    - Bladder, bowel and sexual function
    - Prolapse symptoms

Results
- Mean age, y (SD): 62.9 (10.2) vs 53.6 (10.9) \(p < 0.001\)
- Mean BMI, kg/m^2 (SD): 36.7 (4.7) vs 25.6 (5.0) \(p = 0.001\)
- Mean parity, EDY: 2.7 (1.1) vs 2.0 (5.3) \(p = 0.331\)
- Postmenopausal, n (%): 186 (93.7) vs 91 (60.0) \(p < 0.001\)
- Recurrent prolapse, n (%): 129 (66.1) vs 22 (26.9) \(p < 0.001\)
- Sexually active, n (%): 137 (72.6) vs 68 (8.0) \(p = 0.105\)
- POP-Q Stage ≥3 n (%): 129 (68.2) vs 79 (20.4) \(p = 0.001\)
- Points C ≥4: 46 (24.0) vs 50 (7.8) \(p = 0.040\)

Results
- Characteristics
  - POP-Q Stage ≤2
  - Mean follow-up 20.5 yr ± 11.6 m

Results
- Characteristics
  - Post-operative

Characteristics
- LSC
- LSH
- P-value

Mean OR time, min (SD)
- 112.2 (27)
- 111.8 (23)
- 0.423

Mean estimated blood loss, ml (SD)
- 79.5 (50)
- 105.5 (23)
- 0.000

Full repair, n (%)
- 27 (29)
- 11 (23)
- 0.749

Concurrent repair, n (%)
- 133 (94.7)
- 72 (94.7)
- 0.001

Bladder perforation, n (%)
- 1 (0.5)
- 0 (0)
- 0.543

Mesh exposure, n (%)
- 11 (6.4)
- 6 (4)
- 0.218

Mesh exposure, n (%)
- 11 (5.9)
- 7 (5.3)
- 0.621

Mesh complications, n (%)
- 1 (0.5)
- 2 (1.4)
- 0.577

Mesh exposure, n (%)
- 11 (5.9)
- 6 (4)
- 0.218
Results

Baseline vs. Final POP-Q Measurements

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Pre-Op</th>
<th>Post-Op</th>
</tr>
</thead>
<tbody>
<tr>
<td>No mesh exposure</td>
<td>29%</td>
<td>50%</td>
</tr>
<tr>
<td>1 mesh exposure</td>
<td>29%</td>
<td>26%</td>
</tr>
<tr>
<td>5 mesh exposures</td>
<td>4%</td>
<td>26%</td>
</tr>
</tbody>
</table>

Results

Baseline vs. Post-Op Symptoms

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Pre-Op</th>
<th>Post-Op</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prolapse</td>
<td>70%</td>
<td>85%</td>
</tr>
<tr>
<td>Bladder</td>
<td>60%</td>
<td>70%</td>
</tr>
<tr>
<td>Bowel</td>
<td>50%</td>
<td>60%</td>
</tr>
<tr>
<td>Sexual</td>
<td>40%</td>
<td>50%</td>
</tr>
</tbody>
</table>

Results

Complex POP cases

<table>
<thead>
<tr>
<th>Symptom</th>
<th>LSC (%)</th>
<th>LSH (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary incontinence</td>
<td>8.5</td>
<td>11.9</td>
<td>0.531</td>
</tr>
<tr>
<td>Urinary urgency</td>
<td>11.5</td>
<td>8.7</td>
<td>0.774</td>
</tr>
<tr>
<td>Dyspareunia</td>
<td>6.4</td>
<td>4.3</td>
<td>0.439</td>
</tr>
<tr>
<td>Constipation</td>
<td>4.0</td>
<td>7.4</td>
<td>0.608</td>
</tr>
</tbody>
</table>
Complications of Prolapse Surgery

John Gebhart, MD, MS
Urogynecology
Mayo Clinic

Objectives

- Recognize complications associated with prolapse procedures
- Discuss management strategies to deal with them

DISCLOSURE

- Grants/Research Support: American Medical Systems
- Consultant: Astellas, Ethicon Women's Health & Urology, Boston Scientific Corp. Inc.

Prolapse Procedure Complications
Pearls

- Avoid trouble
- Healthy paranoia – look for problems
- Cystoscopy
- Solve problems at the operating table
- Know your strengths and limitations
Pearls

- Acknowledge difficulties
- Document
- Ask a colleague for help
- Refer to a specialist
Governor Arnold Schwarzenegger signed into law **AB 1195 (eff. 7/1/06)** requiring local CME providers, such as the AAGL, to assist in enhancing the cultural and linguistic competency of California’s physicians (researchers and doctors without patient contact are exempt). This mandate follows the federal Civil Rights Act of 1964, Executive Order 13166 (2000) and the Dymally-Alatorre Bilingual Services Act (1973), all of which recognize, as confirmed by the US Census Bureau, that substantial numbers of patients possess limited English proficiency (LEP).

**California Business & Professions Code §2190.1(c)(3)** requires a review and explanation of the laws identified above so as to fulfill AAGL’s obligations pursuant to California law. Additional guidance is provided by the Institute for Medical Quality at [http://www.imq.org](http://www.imq.org).

**Title VI of the Civil Rights Act of 1964** prohibits recipients of federal financial assistance from discriminating against or otherwise excluding individuals on the basis of race, color, or national origin in any of their activities. In 1974, the US Supreme Court recognized LEP individuals as potential victims of national origin discrimination. In all situations, federal agencies are required to assess the number or proportion of LEP individuals in the eligible service population, the frequency with which they come into contact with the program, the importance of the services, and the resources available to the recipient, including the mix of oral and written language services. Additional details may be found in the Department of Justice Policy Guidance Document: Enforcement of Title VI of the Civil Rights Act of 1964 [http://www.usdoj.gov/crt/cor/pubs.htm](http://www.usdoj.gov/crt/cor/pubs.htm).

**Executive Order 13166, “Improving Access to Services for Persons with Limited English Proficiency”,** signed by the President on August 11, 2000 [http://www.usdoj.gov/crt/cor/13166.htm](http://www.usdoj.gov/crt/cor/13166.htm) was the genesis of the Guidance Document mentioned above. The Executive Order requires all federal agencies, including those which provide federal financial assistance, to examine the services they provide, identify any need for services to LEP individuals, and develop and implement a system to provide those services so LEP persons can have meaningful access.

**Dymally-Alatorre Bilingual Services Act** (California Government Code §7290 et seq.) requires every California state agency which either provides information to, or has contact with, the public to provide bilingual interpreters as well as translated materials explaining those services whenever the local agency serves LEP members of a group whose numbers exceed 5% of the general population.

If you add staff to assist with LEP patients, confirm their translation skills, not just their language skills. A 2007 Northern California study from Sutter Health confirmed that being bilingual does not guarantee competence as a medical interpreter. [http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2078538](http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2078538).