Plenary 5: Urogynecology

MODERATOR
Neena Agarwala, MD

CO-MODERATORS
Christopher J. Pugh, MD & Ralph J. Turner, MD

Vani Dandolu, MD      Sherif A. El-Nashar, MD      Robert T. O'Shea, MD
Priya S. Patel, MD    Edward J. Stanford, MD
Professional Education Information

Target Audience
Educational activities are developed to meet the needs of surgical gynecologists in practice and in training, as well as, other allied healthcare professionals in the field of gynecology.

Accreditation
AAGL is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The AAGL designates this live activity for a maximum of 1.0 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS
As a provider accredited by the Accreditation Council for Continuing Medical Education, AAGL must ensure balance, independence, and objectivity in all CME activities to promote improvements in health care and not proprietary interests of a commercial interest. The provider controls all decisions related to identification of CME needs, determination of educational objectives, selection and presentation of content, selection of all persons and organizations that will be in a position to control the content, selection of educational methods, and evaluation of the activity. Course chairs, planning committee members, presenters, authors, moderators, panel members, and others in a position to control the content of this activity are required to disclose relevant financial relationships with commercial interests related to the subject matter of this educational activity. Learners are able to assess the potential for commercial bias in information when complete disclosure, resolution of conflicts of interest, and acknowledgment of commercial support are provided prior to the activity. Informed learners are the final safeguards in assuring that a CME activity is independent from commercial support. We believe this mechanism contributes to the transparency and accountability of CME.
# Table of Contents

Course Description ........................................................................................................................................... 1

Disclosure .......................................................................................................................................................... 2

Female Urethral Diverticulum: Population and Referral Based Incidence
S.A. El-Nashar ................................................................................................................................................... 4

National Estimate of Mesh Use at Transvaginal Pelvic Reconstructive Surgical Procedures
V. Dandolu .......................................................................................................................................................... 8

Elevate Anterior/Apical (EAA) Pelvic Organ Prolapse Repair Is Effective When Performed with Uterine Preservation
E.J. Stanford ...................................................................................................................................................... 11

Transvagal Mesh for Pelvic Organ Prolapse: 10-Year Experience with 627 Procedures
P.S. Patel .......................................................................................................................................................... 13

Laparoscopic Paravaginal Repair – Objective Outcomes at Five Years and Beyond
R.T. O’Shea ...................................................................................................................................................... 17

Cultural and Linguistics Competency ........................................................................................................... 21
Plenary 5: Urogynecology

Moderator: Neena Agarwala
Co-Moderators: Christopher J. Pugh, Ralph J. Turner

Faculty: Vani Dandolu, Sherif A. El-Nashar, Robert T. O’Shea, Priya S. Patel, Edward J. Stanford

Course Description

This session provides the attendee with an overview on a variety of urogynecological surgical aspects. This will include presentations related to urethral diverticulae, national mesh usage via the transvaginal route, use of apical and anterior suspension procedure transvaginally while preserving the uterus, comparison of various transvaginal mesh devices for POP, and laparoscopic anterior compartment repair. The use of tranvaginal mesh for pelvic prolapse repairs has been under scrutiny, therefore it is important to understand the risks and limitations including the identification of risk factors such as the graft type, trocar use, etc.

Course Objectives

At the conclusion of this session, the participant will be able to: 1) Review the risks and benefits of transvaginal mesh use, comparison of various kits, using graft density and trocar usage as important comparison factors; 2) review urethral deverticulae, an uncommon but important urogynecological condition: prevalence and treatment options; and 3) evaluate paravaginal repair for anterior compartment prolapse laparoscopically.

Course Outline

11:00 Female Urethral Diverticulum: Population and Referral Based Incidence S.A. El-Nashar
11:10 National Estimate of Mesh Use at Transvaginal Pelvic Reconstructive Surgical Procedures V. Dandolu
11:20 Elevate Anterior/Apical (EAA) Pelvic Organ Prolapse Repair Is Effective When Performed with Uterine Preservation E.J. Stanford
11:30 Transvaginal Mesh for Pelvic Organ Prolapse: 10-Year Experience with 627 Procedures P.S. Patel
11:40 Laparoscopic Paravaginal Repair – Objective Outcomes at Five Years and Beyond R.T. O’Shea
11:50 Discussion
12:00 Adjourn
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).
Art Arellano, Professional Education Manager, AAGL*
Viviane F. Connor
Consultant: Conceptus Incorporated
Frank D. Loffer, Executive Vice President/Medical Director, AAGL*
Linda Michels, Executive Director, AAGL*
Jonathan Solnik
Other: Lecturer - Olympus, Lecturer - Karl Storz Endoscopy-America

SCIENTIFIC PROGRAM COMMITTEE
Arnold P. Advincula
Consultant: CooperSurgical, Ethicon Women's Health & Urology, Intuitive Surgical
Other: Royalties - CooperSurgical
Linda Bradley
Grants/Research Support: Elsevier
Consultant: Bayer Healthcare Corp., Conceptus Incorporated, Ferring Pharmaceuticals
Speaker's Bureau: Bayer Healthcare Corp., Conceptus Incorporated, Ferring Pharm
Keith Isaacson
Consultant: Karl Storz Endoscopy
Rosanne M. Kho
Other: Honorarium - Ethicon Endo-Surgery
C.Y. Liu*
Javier Magrina*
Ceana H. Nezhat
Consultant: Intuitive Surgical, Lumenis, Karl Storz Endoscopy-America
Speaker’s Bureau: Conceptus Incorporated, Ethicon Women’s Health & Urology
William H. Parker
Grants/Research Support: Ethicon Women’s Health & Urology
Consultant: Ethicon Women’s Health & Urology
Craig J. Sobolewski
Consultant: Covidien, CareFusion, TransEnterix
Stock Shareholder: TransEnterix
Speaker’s Bureau: Covidien, Abbott Laboratories
Other: Proctor - Intuitive Surgical

FACULTY DISCLOSURE
The following have agreed to provide verbal disclosure of their relationships prior to their presentations. They have also agreed to support their presentations and clinical recommendations with the “best available evidence” from medical literature (in alphabetical order by last name).
Sherif A. El-Nashar*
Vani Dandolu*
Edward J. Stanford*
Priya S. Patel*
Robert T. O'Shea*
Neena Agarwala*
Christopher J. Pugh*
Ralph J. Turner
Speaker’s Bureau: Amgen

Asterisk (*) denotes no financial relationships to disclose.
OBJECTIVE

• To report the incidence rate of symptomatic urethral diverticulum (UD) in adult females at Olmsted County Minnesota from January 1, 1980 through December 31, 2011.
• To report incidence rate based on admission to Mayo Clinic Hospitals in the same time period
• To review the literature on the incidence rate of UD

BACKGROUND

• Urethral diverticulum (UD) is a protrusion of the urethra through the periurethral fascia
• Despite frequently quoted rates ranging from 0.6% to 6%; to date there is no population based study that validated those rates

METHODS

• An incidence study
• The study protocol was approved by Mayo Clinic and Olmsted Medical Center Institutional Review Boards
• We utilized the Rochester Epidemiologic project (REP) to ascertain cases in Olmsted County
• We also calculated admission based incidence for comparison with previous publications
• As systematic review of the literature on incidence or prevalence studies was conducted
METHODS
Statistics
• For population-based incidence:
  • Rates were calculated with the assumption that the adult female (18 years and older) population of Olmsted County was at risk.
  • The denominator was obtained from census data from 1980 through 2010.
  • Rates were adjusted to the population structure of US whites in 2000.
• For admission based incidences, denominators were obtained from admission numbers.

RESULTS
• Of 164 identified patients, there were 26 cases who resided in Olmsted County and were included in the population-based incidence analysis.
• Accordingly, the age-adjusted incidence of UD in Olmsted County was 17.9 per 1,000,000 women per year (95%CI, 10.9 to 24.9).
• There was a significant trend for increased cases through the last 3 decades (P=0.03).

<table>
<thead>
<tr>
<th>Calendar period</th>
<th>Olmsted County</th>
<th>Mayo Clinic Rochester</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>New cases</td>
<td>Incidence Rate</td>
</tr>
<tr>
<td>1980-1984</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>1985-1989</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>1990-1994</td>
<td>4</td>
<td>21</td>
</tr>
<tr>
<td>1995-1999</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>2000-2004</td>
<td>5</td>
<td>21</td>
</tr>
<tr>
<td>2005-2009</td>
<td>9</td>
<td>34</td>
</tr>
</tbody>
</table>

Test for trend
P=0.031 P=0.36 P=0.31 P=0.27
### Table 2. Systematic review results

<table>
<thead>
<tr>
<th>Study</th>
<th>Study population</th>
<th>Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Menville, 1944</td>
<td>510,585 women admitted to a hospital (1892-1943)</td>
<td>13 (25.4 per 1,000,000)</td>
</tr>
<tr>
<td>Bruning, 1959</td>
<td>500 women autopsy</td>
<td>9 (0.6%)</td>
</tr>
<tr>
<td>Adams, 1964</td>
<td>129 asymptomatic women</td>
<td>6 (4.7%)</td>
</tr>
<tr>
<td>Andersen, 1967</td>
<td>300 asymptomatic women with early cervical cancer</td>
<td>9 (3%)</td>
</tr>
<tr>
<td>Davis, 1970</td>
<td>6481 women admitted to hospital in Urology</td>
<td>110 (1.6%)</td>
</tr>
<tr>
<td>Aldridge, 1978</td>
<td>278 women with urinary incontinence undergoing cystoscopy</td>
<td>4 (1.4%)</td>
</tr>
</tbody>
</table>

### Table 3. Clinical characteristics

<table>
<thead>
<tr>
<th>Urethral Diverticulum cases</th>
<th>N=164</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, median(range)</td>
<td>46 (21,83)</td>
</tr>
<tr>
<td>Age ≥ 40 years</td>
<td>108 (65.9%)</td>
</tr>
<tr>
<td>BMI, kg/m², median(range)</td>
<td>27.8 (18,1,50.1)</td>
</tr>
<tr>
<td>BMI ≥ 30 kg/m²</td>
<td>46 (28.0%)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>142 (86.6%)</td>
</tr>
<tr>
<td>African American</td>
<td>8 (4.9%)</td>
</tr>
<tr>
<td>Others</td>
<td>14 (8.5%)</td>
</tr>
<tr>
<td>Parity, median (range)</td>
<td>2 (0.6)</td>
</tr>
<tr>
<td>Postmenopausal</td>
<td>56 (34.1%)</td>
</tr>
<tr>
<td>Previous pelvic surgery</td>
<td>56 (34.1%)</td>
</tr>
</tbody>
</table>

### Table 4. Presentation

<table>
<thead>
<tr>
<th>Urethral Diverticulum cases</th>
<th>N=164</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrent UTIs</td>
<td>95 (57.9%)</td>
</tr>
<tr>
<td>Dysuria</td>
<td>59 (36.0%)</td>
</tr>
<tr>
<td>Dyspareunia</td>
<td>34 (20.7%)</td>
</tr>
<tr>
<td>Hematuria</td>
<td>15 (9.1%)</td>
</tr>
<tr>
<td>Urinary incontinence</td>
<td></td>
</tr>
<tr>
<td>-Stress</td>
<td>12 (7.4%)</td>
</tr>
<tr>
<td>-Urgo</td>
<td>46 (28.4%)</td>
</tr>
<tr>
<td>Mixed</td>
<td></td>
</tr>
<tr>
<td>Vaginal mass on exam</td>
<td>51 (31.1%)</td>
</tr>
</tbody>
</table>

### Table 5. Diagnosis

<table>
<thead>
<tr>
<th>Urethral Diverticulum cases</th>
<th>N=164</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cystourethroscopy</td>
<td>112 (68.3%)</td>
</tr>
<tr>
<td>Urethrogram</td>
<td>46 (28.0%)</td>
</tr>
<tr>
<td>MRI</td>
<td>43(26.2%)</td>
</tr>
<tr>
<td>CT or CT urogram</td>
<td>15 (9.1%)</td>
</tr>
<tr>
<td>Only by examination (No MRI, No Urethrogram and no CT or CT urogram)</td>
<td>73 (44.5%)</td>
</tr>
</tbody>
</table>
CONCLUSION

• Acquired symptomatic female urethral diverticulum is a rare condition affecting less than 20 per 1 million women per year.

• It remains a unique condition which requires high clinical suspicion for diagnosis and frequently requires multiple surgical interventions for treatment.

ACKNOWLEDGEMENTS

Melissa Bacon, M.D.
Shunaha Kim Fine, M.D.
Amy Weaver, M.S.
John B. Gebhart, M.D.
Christopher J. Klingele, M.D.

References

2. Guzow, L. and R. Gutman, UptoDate, 2016, 16.
7. Rovner, E.S. Campbell-Walsh Urology, W.A. J., Editor 2012, W. B. Saunders Company: St. Louis, MO.
National estimate of mesh use at trans vaginal pelvic reconstructive procedures  
Vani Dandolu MD MPH MBA  
Chairperson, Dept of Obstetrics and Gynecology  
Division Director, Urogynecology  
University of Nevada School of Medicine

Disclosures  
• I have no financial relationships to disclose.

Objective  
• Estimate the frequency of use of transvaginal mesh  
• Identify differences in use by demographic and social factors

Design  
• Population based cohort study

Methods  
• Data Source: National in-patient sample dataset for year 2007  
• In women over 18 years of age surgeries for pelvic organ prolapse were identified by  
  - ICD-9-CM diagnoses codes 628.0-628.8, and  
  - procedure codes 68.3-68.9, 69.2-69.29, 70.4-70.92.  
• Abdominal, laparoscopic and obliterator procedures were excluded.

Results  
• Vaginal mesh use was reported in 7557 subjects undergoing pelvic reconstructive surgery.  
• There were an additional 126,403 subjects that underwent transvaginal reconstructive procedures without mesh use.  
• Thus the overall estimated rate of mesh use in transvaginal pelvic organ prolapse repairs was 5.6%.
Results

• Mesh use was less frequent <40 years of age (2.9%) compared to 5.9% over 40 years

• Mesh use was least frequent in NorthEast at 4.5% compared to 5.5%, 5.7% and 6.2% in Midwest, West and South respectively

Results

• Mesh use was least common among
  – Medicaid patients (2.3%) and
  – No Charge patients (2.7%) compared to
  – 5.6% of Commercial insurance and
  – 6.4% of Medicare patients

Results

• Mesh use was also less common in Asians (2.3%) compared to
  – Hispanics (3.7%), blacks (5.6%), whites (6%) and
    Native Americans (6.8%).

Results

• Mesh was used more commonly at urban teaching hospitals (5.9%) compared to rural Hospitals (5.2%).

Results

• Mesh use was more common in the highest income quartile (6.5%) compared to lower three quartiles (5.4%)

Conclusions

• National inpatient dataset is not a good data source for study of mesh use
Conclusions

- Transvaginal mesh use appears to be influenced by several demographic, geographic and social factors.

- Consumers' ability to afford the procedure and medico legal climate in different geographic areas may explain the differences noted.

THANKS!

THE END!!

QUESTIONS??
Elevate Anterior and Apical Pelvic Organ Prolapse Repair is Effective When Performed With Uterine Preservation: Two-Year Results

**Study Objective**

To evaluate efficacy of Elevate® Anterior and Apical (EAA) in the repair of pelvic organ prolapse when performed with or without uterine preservation.

**Study Design**

- Prospective, multi-center trial (10 US, 6 EU)
- Fully monitored study
- Inclusion: Anterior and/or apical prolapse ≥ stage II
- Primary endpoint: anatomic success POP-Q ≤ stage I using Last observed Failure Carried Forward
- Secondary outcomes: QOL, subjective success

**Main Results – Subject Exit Tree**

- Undertaken surgery n=542
  - Partial Hysterectomy n=1 (excluded)
  - Baseline Hysterectomy n=14
  - Concomitant Hysterectomy n=23
  - No Hysterectomy n=90
  - 24M followup n=123
  - Lost to followup from baseline n=15

**Study Design – cont’**

- 3 subgroups:
  - baseline/prior hysterectomy
  - concomitant hysterectomy
  - preserved uterus
- Kruskal-Wallis and Fisher Exact Test were used to compare differences among groups.
- A P value ≤ 0.05 was considered statistically significant.

**DISCLOSURE**

- Grants/Research Support: Contura

Presented at AIUGS Oct 3-6, 2012, Chicago, IL
Main Results - Demographics

<table>
<thead>
<tr>
<th></th>
<th>Baseline Hyst (N=61)</th>
<th>Concomitant Hyst (N=29)</th>
<th>No Hyst (N=51)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>43 (69.2%)</td>
<td>17 (58.6%)</td>
<td>26 (51.0%)</td>
<td>0.177F</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underweight (&lt;18.5)</td>
<td>3 (4.9%)</td>
<td>2 (6.9%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Median BMI (kg/m²)</td>
<td>24.4 (5.5, 30.7)</td>
<td>25.2 (5.7, 30.6)</td>
<td>24.8 (5.4, 30.8)</td>
<td></td>
</tr>
<tr>
<td>Normal (18.5 - 24.9)</td>
<td>26 (42.6%)</td>
<td>10 (34.5%)</td>
<td>16 (31.4%)</td>
<td></td>
</tr>
<tr>
<td>Obesity (&lt;40)</td>
<td>15 (24.6%)</td>
<td>8 (27.6%)</td>
<td>7 (13.7%)</td>
<td></td>
</tr>
<tr>
<td>History of Smoking</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current Smoker</td>
<td>1 (1.6%)</td>
<td>3 (10.3%)</td>
<td>1 (2.0%)</td>
<td>&lt;.001K</td>
</tr>
<tr>
<td>Previous Smoker</td>
<td>17 (27.9%)</td>
<td>4 (13.8%)</td>
<td>16 (31.4%)</td>
<td></td>
</tr>
<tr>
<td>Smoking Duration</td>
<td>43 (70.5%)</td>
<td>22 (75.9%)</td>
<td>36 (70.6%)</td>
<td>0.244F</td>
</tr>
<tr>
<td>History of Smoking</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never Smoker</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Former Smoker</td>
<td>17 (27.9%)</td>
<td>4 (13.8%)</td>
<td>16 (31.4%)</td>
<td></td>
</tr>
<tr>
<td>Current Smoker</td>
<td>1 (1.6%)</td>
<td>3 (10.3%)</td>
<td>1 (2.0%)</td>
<td></td>
</tr>
<tr>
<td>History of Diabetes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underweight (&lt;18.5)</td>
<td>0 (0.0%)</td>
<td>1 (3.4%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Median BMI (kg/m²)</td>
<td>69.4  (45.4 - 85.7)</td>
<td>60.3 (39.0 - 72.4)</td>
<td>62.8 (39.1 - 83.6)</td>
<td></td>
</tr>
<tr>
<td>Normal (18.5 - 24.9)</td>
<td>23 (37.7%)</td>
<td>10 (34.5%)</td>
<td>20 (39.2%)</td>
<td></td>
</tr>
<tr>
<td>Obesity (&gt;30)</td>
<td>1 (1.6%)</td>
<td>1 (3.4%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>History of Diabetes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underweight (&lt;18.5)</td>
<td>0 (0.0%)</td>
<td>1 (3.4%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Median BMI (kg/m²)</td>
<td>69.4 (45.4 - 85.7)</td>
<td>60.3 (39.0 - 72.4)</td>
<td>62.8 (39.1 - 83.6)</td>
<td></td>
</tr>
<tr>
<td>Normal (18.5 - 24.9)</td>
<td>23 (37.7%)</td>
<td>10 (34.5%)</td>
<td>20 (39.2%)</td>
<td></td>
</tr>
<tr>
<td>Obesity (&gt;30)</td>
<td>0 (0.0%)</td>
<td>1 (3.4%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
</tbody>
</table>

Main Results - Objective Success

There was no statistically significant difference between the groups.

<table>
<thead>
<tr>
<th></th>
<th>Baseline Hyst (N=61)</th>
<th>Concomitant Hyst (N=29)</th>
<th>No Hyst (N=51)</th>
<th>P value</th>
</tr>
</thead>
</table>

Main Results - Complications

<table>
<thead>
<tr>
<th></th>
<th>Baseline Hyst (N=61)</th>
<th>Concomitant Hyst (N=29)</th>
<th>No Hyst (N=51)</th>
<th>P Value</th>
</tr>
</thead>
</table>

Conclusions

- The results of this analysis show no statistically significant difference in efficacy in patients with a prior hysterectomy, concomitant hysterectomy, or uterine preservation with the Elevate Anterior & Apical procedure.
- **Good** long-term durability at 24-months
- Significant improvement in quality of life indicators
- **Low** complication rates

Conclusions – Cont’

- The objective and subjective outcomes were not affected when a prior hysterectomy had been done or by removing or preserving the uterus.
- The results support that a concomitant hysterectomy is not necessary in those patients for whom uterine preservation is an option.
- There may be a trend toward increased mesh extrusion when a hysterectomy is performed.
- Larger cohort studies are needed to determine if concomitant hysterectomy impact is associated with vaginal mesh extrusion.
Transvaginal Mesh for Pelvic Organ Prolapse
10 Year Experience with 674 Procedures
Patel PS, Lam A
Centre for Advanced Reproductive Endosurgery
Sydney, Australia

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

Disclosure
I have no financial relationships to disclose.

Methods
- Retrospective cohort study
- Population
  - Consecutive patients who underwent TVM repair by or under the direct supervision of the senior surgeon (AL)
- Setting
  - University-affiliated tertiary referral centre
- Study period
  - Feb 2002 – Jul 2012
Methods

- **Primary outcome:** Anatomic cure
  - Defined as POP-Q Stage ≤ 1 at final visit

- **Secondary outcomes:**
  - Subjective cure
  - Resolution of prolapse symptoms
  - Functional improvement
  - Bladder symptoms
  - Bowel symptoms
  - Sexual symptoms

---

Methods

- **Follow-up:**
  - Routinely at 1- and 12-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

---

Study Profile

- **485 Patients**
  - 90 had Gynemesh
  - 199 had Prolift
  - 196 had Elevate

- **Follow-up:**
  - 27 ± 31 months follow-up
  - 23 ± 21 months follow-up
  - 7 ± 7 months follow-up

---

Study Profile

- **Prolift® released in Australia**
- **Elevate® released in Australia**


---

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 (8.8)</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 (50.4)</td>
<td>93 (46.7)</td>
<td>49 (25.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mean # 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>70 (87.8)</td>
<td>170 (85.4)</td>
<td>140 (71.4)</td>
<td>0.001</td>
</tr>
</tbody>
</table>
### Results

<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>106 (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>106 (144)</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>
</tbody>
</table>

### Complications, n (%)  

<table>
<thead>
<tr>
<th></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 (9.5)</td>
<td>33 (16.6)</td>
<td>13 (6.4)</td>
<td>0.022</td>
</tr>
<tr>
<td>Fever mortality</td>
<td>2 (2.2)</td>
<td>11 (5.4)</td>
<td>3 (1.6)</td>
<td>0.096</td>
</tr>
<tr>
<td>Skin sedation</td>
<td>0 (0)</td>
<td>7 (3.6)</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>Urinary tract infection</td>
<td>6 (6.7)</td>
<td>13 (6.4)</td>
<td>6 (3.1)</td>
<td>0.099</td>
</tr>
<tr>
<td>Wasting 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>0.553</td>
</tr>
<tr>
<td>Readmission</td>
<td>2 (2.2)</td>
<td>7 (3.6)</td>
<td>7 (3.7)</td>
<td>0.797</td>
</tr>
<tr>
<td>Mesh exposure (per procedural site) at &lt; 2 months post-op</td>
<td>19 (20.4)</td>
<td>38 (19.0)</td>
<td>5 (5.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>De novo urinary stress incontinence</td>
<td>6 (10.0)</td>
<td>26 (19.2)</td>
<td>13 (11.9)</td>
<td>0.053</td>
</tr>
<tr>
<td>De novo urinary urgency</td>
<td>8 (15.1)</td>
<td>9 (8.2)</td>
<td>12 (10.9)</td>
<td>0.318</td>
</tr>
<tr>
<td>De novo dyspareunia</td>
<td>14 (15.7)</td>
<td>24 (16.4)</td>
<td>11 (7.3)</td>
<td>0.012</td>
</tr>
<tr>
<td>Prolapse recurrence (per procedural site)</td>
<td>28 (38.2)</td>
<td>51 (27.6)</td>
<td>30 (22.9)</td>
<td>0.001</td>
</tr>
<tr>
<td>Re-operation</td>
<td>24 (27.2)</td>
<td>51 (27.6)</td>
<td>16 (8.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>for mesh exposure</td>
<td>10 (18.6)</td>
<td>27 (19.7)</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 (6.3)</td>
<td>0.107</td>
</tr>
</tbody>
</table>

### Discussion

- **Strengths**
  - Large single-surgeon series
  - Clinically relevant outcomes
- **Drawbacks**
  - Surgeon's experience with TVM increased from one device to the next, and with it,
  - The threshold for TVM use decreased, especially with respect to
    - Primary repairs
    - Posterior compartment

### Conclusions

- It appears that trocar-less, exit-less TVM systems made of a light, flexible mesh provide a safe and effective treatment option for severe pelvic organ prolapse
- Longer follow-up necessary to confirm durability of repair and low mesh complication rates in the long term
Thank You

Questions?

Disclosure: Author AL has received educational grants from Johnson & Johnson Medical and American Medical Systems, and is currently a consultant for AMS.
Laparoscopic Paravaginal Repair
Objective Outcomes 5 years and Beyond
Robert O’Shea
Head of Unit
Nick Bedford
Fellow
Flinders Endogynaecology
Flinders University & Flinders Medical Centre
Adelaide, Australia

Disclosure
• I have no financial relationships to disclose.

Robert O’Shea
Elvis Seman
Jennifer Cook
Fariba Behnia-Willison
Nicholas Bedford
Carl Lam
Ruben Vanspauwen
Sarah Gibberd
Marc Keirse
Flinders University & Flinders Medical Centre
Flinders Endogynaecology & Urogynaecology
Adelaide, Australia

ANTERIOR COMPARTMENT

Anterior Compartment
• Anterior Colporrhaphy (Kelly 1913)
• Paravaginal Repair
  Vaginal (White 1909)
  Abdominal (Richardson 1976)

Paravaginal Repair
Abdominal
Vaginal
Laparoscopic
Paravaginal Repair (abdominal)

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Follow-up (yrs)</th>
<th>Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Richardson et al (1976)</td>
<td>60</td>
<td>1.7</td>
<td>97%</td>
</tr>
<tr>
<td>Richardson et al (1981)</td>
<td>213</td>
<td>0.5-6</td>
<td>95%</td>
</tr>
<tr>
<td>Shull &amp; Baden (1989)</td>
<td>149</td>
<td>0.5-4</td>
<td>95%</td>
</tr>
<tr>
<td>Scotti et al (1998)</td>
<td>40</td>
<td>39 m</td>
<td>97%</td>
</tr>
<tr>
<td>Bruce et al (1999)</td>
<td>25</td>
<td>17 m</td>
<td>76%</td>
</tr>
<tr>
<td>Barber et al (1999)</td>
<td>26</td>
<td>6 m</td>
<td>100%</td>
</tr>
<tr>
<td>Demirci et al (2007)</td>
<td>42</td>
<td>40 m</td>
<td>93%</td>
</tr>
</tbody>
</table>

Paravaginal Repair (vaginal)

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Follow-up (yrs)</th>
<th>Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>White (1912)</td>
<td>19</td>
<td>≤ 3</td>
<td>100%</td>
</tr>
<tr>
<td>Shull &amp; Baden (1989)</td>
<td>62</td>
<td>1.6</td>
<td>67%</td>
</tr>
<tr>
<td>Grody et al (1995)</td>
<td>72</td>
<td>0.5-3</td>
<td>99%</td>
</tr>
<tr>
<td>Barber et al (1999)</td>
<td>44</td>
<td>6 m</td>
<td>100%</td>
</tr>
<tr>
<td>Elkins et al (2000)</td>
<td>25</td>
<td>0.5-3</td>
<td>92%</td>
</tr>
<tr>
<td>Mallipeddi et al (2001)</td>
<td>35</td>
<td>1.6</td>
<td>97%</td>
</tr>
<tr>
<td>Young et al (2001)</td>
<td>100</td>
<td>11 m</td>
<td>78%</td>
</tr>
<tr>
<td>Viana et al (2006)</td>
<td>66</td>
<td>12 m</td>
<td>91%</td>
</tr>
</tbody>
</table>

Laparoscopic Paravaginal Repair

Suspension of vesicovaginal fascia to the arcus tendineus
Paravaginal Repair
(laparoscopic)

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>f/u</th>
<th>Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miklos &amp; Kohli (2000)</td>
<td>148</td>
<td>nil</td>
<td>nil</td>
</tr>
<tr>
<td>Seman, Cook, O’Shea (2003)</td>
<td>24</td>
<td>2 yrs</td>
<td>87.5% POPQ</td>
</tr>
<tr>
<td>Behnia-Willison, Seman, Cook, O’Shea, Keirse (2007)</td>
<td>212</td>
<td>≤5 yrs</td>
<td>76% POPQ</td>
</tr>
</tbody>
</table>

Outcomes: Pelvic Reconstructive Surgery
Anterior Colporraphy

A randomised trial of three surgical techniques

\[ Weber A, Walters M et al \ (2001) \]

POPQ \( (n = 114) \)

- Standard
- Standard + plus polyglactin 910
- Ultralateral anterior colporraphy


- “Cure - Aa or Ba above -1”
- Success:
  - Standard: 30%
  - Standard + Polyglactin 910: 42%
  - Ultralateral Anterior colporraphy: 46%

Many cases - ant vag wall at hymen (POPQ)

- Success low.


Success criteria reassessed

- Recurrence beyond hymen (11%)
- Symptomatic recurrence (5%)
- Repeat Surgery (1 year) - nil

Definition of Success after Surgery for Pelvic Organ Prolapse (Barber et al 2009)

- NIH (POPQ Stage 0 or 1)
- Descends beyond hymen (Aa/Ba>0)
- Reoperation rate
The cohort
279 between 1/1999 and 12/2004
105 (38%) with followup to 5+ years

3 definitions:
NIH
Aa/Ba>0
Reoperation

Outcomes – all patients (n=279)

<table>
<thead>
<tr>
<th>Failure type</th>
<th>Number (%)</th>
<th>Time in weeks (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td>139 (50%)</td>
<td>70.5 (1-340)</td>
</tr>
<tr>
<td>Anterior</td>
<td>74</td>
<td>65.5 (0-450)</td>
</tr>
<tr>
<td>Apical</td>
<td>14</td>
<td>96 (0-450)</td>
</tr>
<tr>
<td>Protrusion</td>
<td>43</td>
<td>84 (0-450)</td>
</tr>
<tr>
<td>Global</td>
<td>6</td>
<td>65 (1.3-177)</td>
</tr>
<tr>
<td>Aa/Ba&gt;0</td>
<td>42 (15%)</td>
<td>194 (50-543)</td>
</tr>
<tr>
<td>Anterior reop</td>
<td>51 (18%)</td>
<td>144 (46-570)</td>
</tr>
<tr>
<td>Apex reop</td>
<td>79 (28%)</td>
<td>300.5 (50-820)</td>
</tr>
</tbody>
</table>

De novo posterior compartment prolapse in 41/279 (15%)

Outcomes – five year data (n=105)

<table>
<thead>
<tr>
<th></th>
<th>1 year</th>
<th>3 years</th>
<th>5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td>25%</td>
<td>53%</td>
<td>62%</td>
</tr>
<tr>
<td>Aa/Ba&gt;0</td>
<td>4%</td>
<td>12%</td>
<td>22%</td>
</tr>
<tr>
<td>Anterior</td>
<td>9%</td>
<td>16%</td>
<td>23%</td>
</tr>
</tbody>
</table>

What can we tell our patients?
YOUR chance of reoperation at 5 years: 20%

PARAVAGINAL REPAIR
1. Paravaginal repair - effective
2. Paravaginal repair (1909) – has not gained wide acceptance
3. Paravaginal repair – technically difficult vaginally and abdominally
4. Laparoscopic approach – some disadvantages but considerable advantages
5. Success – subjective vs objective
CULTURAL AND LINGUISTIC COMPETENCY

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.

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.

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 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.