Trends in Gynecology
Minimally Invasive Surgery

- 2011

- Brian D Dobbins and Kerin Draak

- Green Bay WI
What do you mean, “Minimally Invasive?”

Traditional open surgery, using a large abdominal incision, has for many years been the standard approach to gynecologic procedures. Yet, with laparotomy comes significant pain and a long recovery process. The extended time away from normal daily activities that usually follows traditional surgery can cause significant anxiety.

Therefore, there has been a trend toward developing ways to access the pelvic organs without making a large incision. These less invasive options allow less morbidity, less downtime, and less pain. They allow women to have relief of their symptoms while getting back to their usual daily activities more quickly.

MIS benefits

- Faster recovery from the procedure
- Less pain
- Equal or improved morbidity - safety
- Better cosmetics
- Equal or reduced cost to patient / insurance provider / society
- Possible improved efficiency for physician
- Improved or increased revenue for physician / clinic
- Convenience
- Allows some surgeries to become office procedures
- Provides service patients are requesting
- A good marketing opportunity for physicians / clinics
Gynecologic MIS

- Laparoscopy
- Hysteroscopy
- Robotics
- Slings and mesh
- Endometrial Ablation
- Uterine artery Embolization
- MRI-Guided Focused Ultrasonography

Why should more gynecologists choose MIS

*Over the past year, the AAGL commissioned an internet survey, compiled by Russell Research. In total, 526 women, 18 or older, completed this patient awareness survey; 53% of participants surveyed had experienced one or more of the following pelvic disorders:

- Stress urinary incontinence
- Menorrhagia
- Fibroids
- Organ prolapse

The study found that less than 40% of patients surveyed realized that hysterectomies could be greatly reduced by newer, less invasive techniques. Fewer than half of participants suffering from menorrhagia were aware of endometrial ablation; and only 47% understood that the procedure could be performed in an office setting. In addition, only 45% of patients with leiomyomata had ever heard of myomectomy; 33% of participants with stress urinary incontinence were unaware of the existence of sling procedures and less than one of five surveyed realized that sterilization could be performed in office.

Despite the fact that women involved in the survey were unaware of many of their minimally invasive surgical options, they remained steadfast in the belief that their gynecologist will provide treatment choices including the least traumatic and safest surgical procedures. Even if their doctor is currently not proficient in the technique, 98% of patients surveyed expect their gynecologist to inform them about minimally invasive treatment options, and recommend alternatives involving the least amount of pain. Furthermore, 94% of participants expect their gynecologist to promote options least affecting lifestyle.*
Office Hysteroscopy

- Diagnostic - 58555
- Polypectomy - 58558
- Directed biopsy - 58558
- Retrieval of foreign body (IUD) - 58562
- Endometrial ablation - 58563
- Hysteroscopic sterilization - 58565
Office Hysteroscopy

- About 10-15% of GYN’s in the US perform Office Hysteroscopy (of 45,000), but number is growing rapidly
- New procedures, CPT® codes and reimbursements are allowing doctors to move to the office setting

Exam Room

- Video tower
- Power Table
- IV pole and pressure bag
- Table for instruments
- Phone / Intercom
- Clean procedure
  - Minimal drapes
- Emergency supplies
Procedure is easily performed in exam room setting

Use hydro-dilation and direct visualization through cervix
Endometrial ablation - 58563

- Indicated for menorrhagia and menometorrhagia (626.2)
- It may also treat dysmenorrhea (625.3), but is not indicated for this
- It was developed as a less invasive alternative to hysterectomy

Endometrial ablation techniques

- Hysteroscopic resection
- Thermachoice
- Novasure
- HTA (hydrothermoablation)
- Introduced in 1981, requires most skill
  - “balloon method”
  - Impedance driven, fast
  - Observed thermal ablation
  - Freezed technique with ultrasound guidance, has an office code (CPT® Code 58356)
I generally use Novasure

It's Quick
- Just 90 seconds average ablation time
- Rapid recovery time - return to normal activity in 24 to 48 hours

Safe
- Evaluates integrity of uterine cavity for possible perforation prior to treatment
- Utilizes tissue impedance monitoring technology to achieve proper depth of ablation

Successful
- 91% of patients return to normal levels of menstrual bleeding or lower
- 97% of patients would recommend NovaSure to other women
- 97% of patients experience no post-procedural pain

Novasure
Steps of the procedure:
The NovaSure bipolar electrode expands from the sheath to conform to the contours of the uterine cavity. The system insufflates the uterine cavity with CO2 to perform the cavity integrity assessment.

NovaSure delivers bipolar RF energy for a complete ablation in approximately 90 seconds.

The electrode array is retracted into the sheath for removal, leaving the uterine lining desiccated down to the superficial myometrium.
Endometrial ablation

**Thermachoice**

(-) takes longer - 8 min treatment phase

(+) can be used even when the uterine cavity is distorted by submucosal fibroids
Hysteroscopic sterilization

- An alternative to laparoscopic sterilization
- Laparoscopy not minimally invasive enough?
- 2 techniques currently approved by FDA
- Essure and Adiana
- 58565 hysteroscopic tubal sterilization
- A4264 – Permanent implantable contraceptive intratubal occlusion device(s) and delivery system
What is the Essure procedure? - 58565

• First proven transcervical sterilization procedure
  • Approved by FDA in 2002
  • > 7 year commercial use
  • >450,000 procedures performed
  • 250+ publications and abstracts
  • Zero pregnancies among users in its clinical trial
  • Can be performed with local anesthesia
• Over 50% of procedures are now in the office

Micro-insert Design

PET Fiber
Dynamic Expanding
Superlastic Nitinol
Outer Coil

Stainless Steel
Innercoil

Device Length: 3.85 cm
Wound Down Outer Diameter: 0.8 mm
Expanded Outer Diameter: 1.5 – 2.0 mm

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Essure Placement is Easy

Gold Band

Essure coils give immediate visual confirmation of correct placement

ESSURE

No cutting
No general anesthesia
No hormones
15 min to perform.
Recovery time is 1 day

NOT reversible
Compliance based methods* vs Essure

% of women that will become pregnant in first 12 months of use

<table>
<thead>
<tr>
<th>Method</th>
<th>Risk of Pregnancy (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure</td>
<td>3</td>
</tr>
<tr>
<td>3 mo injectable</td>
<td>8</td>
</tr>
<tr>
<td>OC</td>
<td>15</td>
</tr>
<tr>
<td>Condom</td>
<td>27</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>0.05</td>
</tr>
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</table>


Long term methods: 5 Year failure rate comparison

Pregnancies per 1000/women

<table>
<thead>
<tr>
<th>Method</th>
<th>Risk of Pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essure</td>
<td>2.6</td>
</tr>
<tr>
<td>Progestinslip implant</td>
<td>6.3</td>
</tr>
<tr>
<td>IUD</td>
<td>7</td>
</tr>
<tr>
<td>Norplant</td>
<td>11.3</td>
</tr>
<tr>
<td>Norplant with Copper</td>
<td>13.4</td>
</tr>
<tr>
<td>Norplant with IUD</td>
<td>16.5</td>
</tr>
</tbody>
</table>

Essure Coding

ICD-9 Diagnosis Code
- V25.2 Admission for interruption of fallopian tubes or vas deferens

CPT® Codes
- 58565 With bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants
- Physicians performing the Essure procedure in a hospital, ambulatory surgical center (“ASC”), or an office setting should use CPT® Code 58565

Essure Confirmation Test

- Low pressure, slow fill
- Minimal discomfort (not an infertility HSG)
- Covered by insurance
- Provides both you and your patient peace of mind
HSG Coding

Diagnosis Codes
- V67.09 Follow-up examination following other surgery
- V26.51 Tubal ligation status

CPT® Codes
- 58340 Catheterization and introduction of saline or contrast = material for saline infusion sonohysterography (SIS) or = hysterosalpingography

<table>
<thead>
<tr>
<th>Description</th>
<th>CPT Code</th>
<th>2009 Total Non-Facility RVU</th>
<th>2009 Medicare National Average Physician Non-Facility Reimbursement $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Exam</td>
<td>00560</td>
<td>1.5A</td>
<td>60.33</td>
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<tr>
<td>Global Obstetrical Core</td>
<td>59400</td>
<td>427.51</td>
<td>1,665.49</td>
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<tr>
<td>In-office Hysteroscopic Sterilization**</td>
<td>58665</td>
<td>51.64</td>
<td>1,862.48</td>
</tr>
</tbody>
</table>

(1) Based on Medicare National Average Physician Fee Schedule. Commercial payers will negotiate based on individual physicians or group practice contracts.
(2) When performed in facility, physician uses Medicare PPS, 2011 rates will be lower.

Adiana Overview
- Track 1.4 cm into tube
- Activation of the bipolar energy source for 60 seconds per tube to deliver a cauterizing injury to 6mm fallopian tube (147°F)
- Retracting delivery catheter to release the ~1.5 mm x 3.5 mm plug in thermal injury location
- Tissue grows around the plug matrix and into pores
- Visible by ultrasound but not x-ray
- HSG at 3 mos will likely be required for reliance

<table>
<thead>
<tr>
<th></th>
<th>Essure&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Adiana&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Potential Occlusion Length</strong></td>
<td>20 mm</td>
<td>3.5 mm</td>
</tr>
<tr>
<td><strong>Distension media</strong></td>
<td>Saline</td>
<td>Glycine</td>
</tr>
<tr>
<td><strong>Generator required</strong></td>
<td>No</td>
<td>Yes – 1 min RF application in each tube</td>
</tr>
<tr>
<td><strong>Pregnancies in women relying on devices during clinical trial</strong></td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td><strong>Confirmation test</strong></td>
<td>HSG confirms both occlusion &amp; placement</td>
<td>HSG to show occlusion TVUS to show placement&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Visible on X-Ray / HSG</strong></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>Estimated number of procedures performed</strong></td>
<td>450,000+</td>
<td>645</td>
</tr>
<tr>
<td><strong>Visual confirmation of correct placement</strong></td>
<td>Yes – coils verify placement</td>
<td>No</td>
</tr>
<tr>
<td><strong>Product Shelf Life</strong></td>
<td>3 years</td>
<td>1 year&lt;sup&gt;3,4&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>1</sup> Essure Instructions for Use
<sup>3</sup> Final labeling TBD pending FDA approval.
<sup>4</sup> Cytyc Surgical Products Panel Adiana Briefing Information for December 14, 2007 FDA Panel, Page 565

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**Three-Year Failure Rates: Pregnancies per 1000 women**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Essure</th>
<th>PP salpingectomy</th>
<th>Bipolar</th>
<th>All CREST</th>
<th>Vasectomy</th>
<th>Adiana</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure Rate</td>
<td>0.84%</td>
<td>1.49%</td>
<td>0.91%</td>
<td>0.03%</td>
<td>0.76%</td>
<td>0.005%</td>
</tr>
</tbody>
</table>

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**Age-adjusted posterior cumulative Bayesian effectiveness rates (posterior means) for Essure:**

<table>
<thead>
<tr>
<th>Years</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>99.95%</td>
</tr>
<tr>
<td>2</td>
<td>99.90%</td>
</tr>
<tr>
<td>3</td>
<td>99.84%</td>
</tr>
<tr>
<td>4</td>
<td>99.80%</td>
</tr>
<tr>
<td>5</td>
<td>99.74%</td>
</tr>
</tbody>
</table>

<sup>**</sup> Age-adjusted posterior are for comparison to CREST as a reference population
<sup>**</sup> Represents 63 Phase II patients who have completed 5 years follow-up. Five years follow-up of all patients in clinical trials is currently complete.
Reported Pregnancies in Clinical Trials among subjects who have completed evaluation

<table>
<thead>
<tr>
<th></th>
<th>Year one</th>
<th>Year two</th>
<th>Year three</th>
<th>Year four</th>
<th>Year five</th>
<th>Total Pregnancies to date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Essure</strong></td>
<td>0^2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Adiana</strong></td>
<td>6^5 (excludes 1 ectopic)</td>
<td>3 (excludes 1 ectopic)</td>
<td>0</td>
<td>2'</td>
<td>1'</td>
<td>12</td>
</tr>
</tbody>
</table>

Notes:
- ^1 Essure (Xarelto Case Report, Page 10 and Provider Trial Final Report, Page 15)
- ^2 Excludes 1 ectopic pregnancy
- ^3 Adiana (Xarelto Case Report, Page 10 and Provider Trial Final Report, Page 15)
- ^4 Excludes 1 ectopic pregnancy
- ^5 Excludes 1 ectopic pregnancy
- Year three starts at 5 months after removal of Implantable Adiana system
- Year four starts at 12 months after removal of Implantable Adiana system
- Year five starts at 18 months after removal of Implantable Adiana system
Hysterectomy

- Hysterectomy is one of the most frequently performed surgery in United States (approx. 600k/year)
- Most common indications are
  - Uterine leiomyomas – 40.7%
  - Endometriosis – 17.7%
  - Prolapse – 14.5%

Hysterectomy

- US surgical data on Route
  - Abdominal – 66%
  - Vaginal – 22%
  - Laparoscopic – 12%

- ACOG considers Vaginal hysterectomy the procedure of choice whenever possible
- And laparoscopic hysterectomy is an alternative to abdominal hysterectomy
- ACOG committee opinion no. 444 Nov 2009
Why should more gynecologists choose MIS

It is the position of the AAGL that most hysterectomies for benign disease should be performed either vaginally or laparoscopically and that continued efforts should be taken to facilitate these approaches. Surgeons without the requisite training and skills required for the safe performance of VH or LH should enlist the aid of colleagues who do or should refer patients requiring hysterectomy to such individuals for their surgical care.

AAGL Position Statement: Route of Hysterectomy to Treat Benign Uterine Disease, 09 November 2010
AAGL Advancing Minimally Invasive Gynecology Worldwide
pages 1-3

ALPHABET SOUP!

TAH 58150
TVH 58260-58262 < 250g
TVH 58290-58292 > 250g
LAVH 58550-58552 < 250g
LAVH 58553-58554 > 250g
TLH 58570-58571 < 250g
TLH 58572-58573 > 250g
LSH 58541-58542 < 250g
LSH 58543-58544 > 250g
**TAH**
Total Abdominal Hysterectomy

58150

**TVH**
TRANSVAGINAL HYSTERECTOMY

58260 (2) or 58290 (1)

TVH does not require an external incision
Some feel this is the LEAST invasive type of gynecologic surgery

The first vaginal hysterectomy was in 1824

The disadvantage is that this procedure is done somewhat blindly due to the limited visual field

Removing adnexa more difficult?
Laparoscopy

- For certain surgeries, the surgeon prefers to visualize the pelvic organs, and can use laparoscopy to complete the hysterectomy.

LAVH
58550-58554

TLH
58570-58573

LSH
58541-58444
Lap Supracervical Hysterectomy

- ACOG committee opinion
- Number 388 • November 2007

“Although data from uncontrolled series may suggest a benefit from preserving the cervix, review of recently published Level I evidence reveals no advantage to the supracervical abdominal technique with regard to surgical complications, urinary symptoms, or sexual function in women undergoing hysterectomy for symptomatic uterine leiomyomata or abnormal uterine bleeding (3–5). Despite the potential advantages of shorter hospital stay and less blood loss afforded by the laparoscopic supracervical approach, there are no prospective data comparing laparoscopic supracervical hysterectomy with either LAVH or TAH.”

LSH
58541 or 58543

(+ no incision in vagina
Less pain (outpatient surgery)
Faster recovery (sad)

(-) possible continued cyclic bleeding
Continue to have pap smears.

No Randomized studies proving long/short term benefits.
Use of the Morcellator

Allows removal of large uterine fundus and/or fibroids thru the tiny incisions used in laparoscopy.

Concern for seeding of pathology.

Morcellation video
Lina loop makes for a rapid LSH
SILS

- How small can you go?
- Learning curve vs safety vs cosmetics vs results
- Does it provide better cosmetics
- Equipment advances with help this transition

Fig. 1

Source: Journal of Minimally Invasive Gynecology 2009; 16:609-611 (DOI:10.1016/j.jmig.2009.06.003)

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SILS

Single Port Hysterectomy vs. Conventional TLH
• Retrospective review (N=157)
• Benign pathology with uterus<16wk size
• No difference in age, BMI, parity, or prior surgical history

SPA-TLH (n=52) TLH (n=105)

<table>
<thead>
<tr>
<th></th>
<th>SPA-TLH</th>
<th>TLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBL (mL)</td>
<td>100</td>
<td>150</td>
</tr>
<tr>
<td>OR time (min)</td>
<td>117</td>
<td>110</td>
</tr>
<tr>
<td>Uterine weight (g)</td>
<td>162</td>
<td>123</td>
</tr>
<tr>
<td>Pain score post o</td>
<td>3.5</td>
<td>4.5</td>
</tr>
<tr>
<td>Pain scores after 48h</td>
<td>2.2</td>
<td>2.3</td>
</tr>
<tr>
<td>Complication rates (%)</td>
<td>3.8</td>
<td>9.5</td>
</tr>
</tbody>
</table>

Yim et al. AJOG 2010
ROBOTIC SURGERY

A new category of minimally invasive surgery combines the best of open and laparoscopic surgery. With the assistance of the da Vinci Robotic Surgical System surgeons can remove GYN pathology through small incisions with unmatched precision and control. Advanced optics including a 3-D view, and enhanced surgeon dexterity via “wristed” instruments. Randomized clinical trials are underway to determine clinical outcomes and cost-effectiveness, initial data proves a lower rate of conversion to laparotomy.

ROBOTIC SURGERY

- In addition to hysterectomy (TLH/LSH)
- Can do myomectomy, adnexal surgery, tubal re-anastamosis, tuboplasty, sacrocolpopexy and other highly complex surgeries that would be difficult for most GYNs using conventional laparoscopy
- No Gyn studies have found improved outcomes with use of robot compared to traditional laparoscopies
Through 1-2 cm incisions, surgeons using the da Vinci Robotic System can operate with greater precision and control, minimizing the pain and risk associated with large incisions while increasing the likelihood of a fast recovery and excellent clinical outcomes.
Coding with hysterectomies

The dictated operative note should include the specimen weight – there are scales in the operating room

Newer surgical access is still a laparoscopic hysterectomy

( TLH=SILS/TLH=robotic TLH )

There are no increases in RVUs for surgeon training and effort for new procedures even if it results in improved an patient experience

Total work values for all of our 90-day global surgical codes include not only the work of the procedure itself, but also the work involved in post-operative care

It is clear that the surgical intensity and skill required to perform this procedure laparoscopically is greater than for the open counterpart, but there is considerably less post-operative care required

The length of stay is shorter and therefore there are fewer hospital visits valued into the total service
Slings for Incontinence

- SUI is not truly a problem of the bladder. It is actually caused by an improperly functioning urethra. Normally, the urethra - when properly supported by strong pelvic floor muscles and strong connective tissue - maintains a "water tight" seal to prevent involuntary loss of urine during physical stress (e.g. coughing, sneezing, or lifting).

- When a woman suffers from SUI, weakened tissues in the pelvic floor - caused by childbirth, loss of estrogen and repetitive pelvic muscle straining - are unable to support the urethra in its correct position. As a result, as pressure is exerted on the bladder, the urethra cannot remain closed and urine escapes.

Prolapse and incontinence

- Sustained product development over that last 10-15 years
- Traditional surgeries for these problems have lousy long term success
- Industry driven or outcomes driven?
Treatment for SUI

• Old Gold Standard:
  • Burch procedure

• “Minimally Invasive” slings: 57288
  • TVT
  • TVO-T
  • Secur
  • Abbrevo

TVT (Tension-free Vaginal Tape) 57288

How does it work? Synthetic mesh tape is placed beneath the middle of the urethra in a surgical procedure that takes 30 to 50 minutes. The procedure is performed under local or general anesthesia. Cystoscopy is performed to make sure there has been no injury to the bladder during the procedure.

• Recovery takes 3 to 4 weeks. Normal daily activity can resume within 1 to 2 weeks.

• Complications include bleeding, bladder, and bowel injury; mesh erosion into vagina and urinary retention.

• What is the success rate?
  • 85% completely dry, while another 11% experienced significant improvement
  • the surgery appears to “last” as demonstrated by 5yr follow-up studies
The mesh is inserted through a small incision in the vagina and then it is passed through pelvic tissue behind the pubic bone and positioned underneath the urethra. The tape is then pulled up through two tiny incisions in the skin’s surface just above the pubic area.

Over time body tissue grows into the mesh which permanently secures it.

Other Slings (also 57288)

- Newer procedures such as **transobturator tape (TOT or TVO-T), SECUR, Abbrevo** procedure also can be used to correct stress incontinence

- These techniques may result in fewer complications than other transvaginal procedures
TVT-O
TOT
57288

TVT™ Obturator System
Tension-free Support

Suburethral sling for treatment of stress incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency

Alternate angle of the 'hammock' created, but still seems equally effective

SECUR
57288

No external incisions
Outpatient procedure - Some have moved this to the office setting

Compatible with a standard rehine driver or other appropriate instrument, per surgeon preference
Prolapse surgery

- Reason for new technique
- Training
- Benefit to patients
  - less pain
  - faster recovery
  - decreased recurrence?

Mesh for prolapse (618 series)

- A mesh procedure for treating pelvic prolapse
  - Uterine prolapse
  - Cystocele
  - Rectocele
  - Vaginal vault prolapse
  - Primary procedure or for recurrences?
### Prolapse coding

<table>
<thead>
<tr>
<th>Cpt code</th>
<th>Description</th>
<th>RVU's</th>
</tr>
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<tbody>
<tr>
<td>57240</td>
<td>Anterior Colporrhaphy</td>
<td>16.26</td>
</tr>
<tr>
<td>57250</td>
<td>Posterior colporrhaphy</td>
<td>16.00</td>
</tr>
<tr>
<td>57260</td>
<td>Combined A-P colporrhaphy</td>
<td>20.41</td>
</tr>
<tr>
<td>57265</td>
<td>Combined A-P colporrhaphy with enterocele repair</td>
<td>23.28</td>
</tr>
<tr>
<td>57268</td>
<td>Repair of enterocele vag/abd approach</td>
<td>12.47/21.09</td>
</tr>
<tr>
<td>57282</td>
<td>Colpopexy, vaginal intra-peritoneal/extra-peritoneal</td>
<td>13.34/18.34</td>
</tr>
<tr>
<td>57283</td>
<td></td>
<td></td>
</tr>
<tr>
<td>57295</td>
<td>Revision of prosthetic vaginal mesh - vaginal</td>
<td>12.98</td>
</tr>
<tr>
<td>57296</td>
<td>Revision of prosthetic vaginal mesh - abdominal</td>
<td>24.89</td>
</tr>
<tr>
<td>57267</td>
<td>Insertion of mesh for repair of pelvic floor defect</td>
<td>7.38</td>
</tr>
</tbody>
</table>

### PROLIFT Pelvic Floor Repair System

- **Guide/Cannula/Retrieval Device**
- **Total Mesh Implant**
- **Anterior Mesh Implant**
- **Posterior Mesh Implant**
Staging prolapse

Figure 66-17

Comparison of classifications of pelvic organ prolapse

Pinnacle Mesh Fixation Points

Sacrouterine Ligament

Arcus Tendineous
Insert the Capio® Device on to the sacrospinous ligament medial to the ischial spine.
Continued changes

- Prosima mesh – less mesh, less dissection, includes a vaginal support device (VSD) which is removed up to 4 weeks later
BUT...

- In October ‘08, the FDA issued a warning to physicians about complications resulting from surgical mesh devices used to treat stress incontinence.
- Complications, which include infection, pain, and mesh erosion can significantly decrease quality of life for affected patients and may require additional surgery.
- Patients who have additional health problems, patients who undergo an accompanying surgical procedure, and women who are postmenopausal may be at increased risk for complications from mesh.
Minimally Invasive Alternatives to Hysterectomy for the Treatment of Fibroids

- Hysteroscopic Myomectomy
- Laparoscopic Myomectomy
- Embolization
- MRI-focused U/S

Hysteroscopic Myomectomy 58561

- Submucosal leiomyomas are the cause of 5–10% of cases of abnormal uterine bleeding, pain, and infertility

- Steps of procedure

- Studies have shown successful removal of the leiomyoma at a rate of 85–95%. Subsequent surgery is needed in approximately 5–15% of cases

- Complication rate ranges between 1% and 12%. Complications include fluid overload, hyponatremia, pulmonary edema, cerebral edema, bleeding, uterine perforation, gas embolism, and infection
Laparoscopic Myomectomy

58545 – 1-4 fibroids or less than 250 g
58546 – 5 or more fibroids or >250g

- Eliminates a large abdominal incision, resulting in quicker post-operative recovery
- Steps of procedure
- Studies show less blood loss, reduced post-op ileus, shorter hospitalization, with overall complication rates around 10%
- Because of the complex nature of laparoscopic dissection and especially suturing, special surgical expertise is required
- Also done robotically

Uterine Artery Embolization

A procedure in which the uterine arteries are embolized via a transcervical femoral artery approach, resulting in fibroid involution. The arteries are embolized using microspheres. Supplemental metal coils also may be used.
Clinical trials comparing uterine artery embolization with myomectomy and hysterectomy showed that embolization resulted in shorter hospital stay, quicker return to activities similar rate of major complications, but a higher minor complication rate after discharge.

### Uterine Artery Embolization

- **Does it work?**
- A study of more than 500 patients reported favorable 3-month outcomes for fibroid volume reduction (42%) and decreased mean menstrual duration, dysmenorrhea, and urinary frequency or urgency.
Uterine Artery Embolization

• Does it Last?
• study comparing embolization with myomectomy reported a higher reoperation rate of 29% in the embolization group
• when subjective variables were considered, 39% in the uterine artery embolization group were considered clinical failures, compared with 30% in the myomectomy group

Focused Ultrasound Treatment

In 2004, the Food and Drug Administration approved a device called ExAblate 2000, which uses MRI-guided ultrasound to target and destroy fibroids. It’s intended only for premenopausal women who have completed childbearing. The therapy focuses ultrasound energy to destroy the fibroid tissue. The technique is very accurate, given that a real-time MRI is performed during the procedure to map out and confirm that the ultrasound waves are targeting the fibroid precisely. Because this treatment is still being investigated for long-term outcomes, most insurers do not cover it.

CPT® 0071T
Magnetic Resonance Imaging-Guided Focused Ultrasound Surgery

“Noninvasive” approach uses high-intensity ultrasound waves directed into a leiomyoma. The ultrasound energy penetrates soft tissue and produces regions of protein denaturation, irreversible cell damage, and coagulative necrosis.

- Outcomes reported at 6 months and 12 months. Although only modest uterine volume reductions were noted, 71% of patients reported symptom reduction at 6 months. At 12 months, 51% had symptom reduction.

- Adverse events included transfusion, persistent pain and bleeding; hospitalization for nausea, and leg and buttock pain. Adverse events decrease with increasing operator experience.

- Long-term studies are needed, limited availability
The End

Questions?