



Trends-in-Medicine

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by D. Woods

SUMMARY

Use of robots like Intuitive Surgical's da Vinci is increasing, not only in urology but also in gynecology; 85% of hospitals checked already have at least one da Vinci, and 21% plan to get another in the next 1-2 years. ♦ Single incision surgery doesn't have tremendous appeal in gynecology because many procedures already are done laparoscopically with small incisions, but patient demand could drive a change. ♦ Better contraceptive devices, particularly Bayer's Mirena IUD, are so good and so popular that growth is projected to be relatively flat over the next year for permanent contraceptive devices – such as Hologic's Adiana or Conceptus' Essure. Mirena is even affecting endometrial ablation procedures, so no growth is expected for Hologic's NovaSure. ♦ Bayer's Yaz birth control pill remains popular despite lawyers trolling for clients who have had an adverse event. ♦ Mesh remains a useful tool in female surgery, but use of vaginal mesh is down slightly due to safety concerns. However, use of minimally invasive slings with mesh is increasing.

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Trends-in-Medicine

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38TH GLOBAL CONGRESS OF MINIMALLY INVASIVE GYNECOLOGY

hosted by the

American Association of Gynecologic Laparoscopists (AAGL)

Orlando, FL

November 16-18, 2009

HIGHLIGHTS

- Use of **Intuitive Surgical's da Vinci** is increasing, and hospitals feel compelled to buy the robot in order to be competitive. General gynecologists are trying it out and starting to use it for common procedures, but doctors experienced in laparoscopy believe it is best suited for oncologists and urogynecologists. Although procedures take longer with the device, patients spend less time in the hospital. There is no economic benefit to surgeons who use the device.
- **Single incision laparoscopic surgery** is very new, with few doctors performing the procedure yet. The procedure was described as somewhat awkward and useful for only a few procedures, but doctors predicted that patients will ask for it.
- Most doctors have little, if any, experience with **Hologic's Adiana** permanent sterilization device. Pregnancy rates for Adiana and **Conceptus' Essure** appear similar, with perhaps a slight advantage to Essure. Doctors are resisting buying new equipment to use Adiana. Doctors perform the Essure procedure in the office. Growth of both devices is expected to be flat due to other, more effective alternatives, such as **Bayer's Mirena IUD**.
- Patients and doctors like **Hologic's NovaSure** endometrial ablation procedure, an alternative to hysterectomy which provides a solution to heavy periods, but growth is expected to be flat. The Mirena IUD is a strong competitor.
- Doctors have not reduced their prescriptions for **Bayer's Yaz** birth control pill despite advertisements and commercials by personal injury lawyers advertising for clients who have suffered a deep vein thrombosis possibly related to the pill. In fact, younger women love Yaz because it reduces/eliminates menstrual periods and helps with PMS.
- The latest FDA warning about problems with **mesh for prolapse repair** is being taken seriously. Erosion is a huge concern and a subject of much discussion. Some doctors have decreased use of mesh kits, but others continue to use mesh, though they warn patients about potential problems, including pain, erosion, and voiding issues.
- There is a lot of interest in **minimally invasive slings**, although doctors worry about problems with mesh. Market share is expected to increase as mesh becomes softer, doctors get more experience, and techniques improve.

Hot topics at the meeting included robotics, pelvic floor reconstruction – including the controversy over vaginal mesh – single incision/port laparoscopic surgery, and contraceptive devices. Thirty-seven doctors were interviewed, and many said there wasn't much new at the conference and that they came mostly for the classes and hands-on workshops. A Louisiana doctor said, "There isn't anything brand new this year. Our hospital is not buying a lot. I came for the courses, and I'm looking at some hysteroscopic equipment."

Classes and sessions were generally full, and the exhibit floor was always busy, despite several attendees saying that the economy is affecting them and their hospitals, with operating room time down as much as 20%. One California urogynecologist said, "I think that every hospital in the country (has seen a drop in) operating room (OR) minutes. Our hospital is an extremely busy surgical hospital, but the OR is off in the last two years almost 20%, and if Medicare passes a 20% reduction (in reimbursement), it's going to be down even more. For some pelvic floor procedures the reimbursement is two office visits, and they're almost asking us to do the surgery for free."

ROBOTIC SURGERY: INTUITIVE SURGICAL'S da Vinci

The da Vinci robot attracted a lot of attention at the meeting. Use is increasing, and hospitals are buying a da Vinci mainly for marketing purposes, to attract gynecologists, and for training students. Few community hospitals that already have a da Vinci plan to purchase a second one, but major academic centers continue to buy additional robots. There is, however, a philosophical split between older, experienced laparoscopic surgeons and younger doctors about whether the da Vinci really advances minimally invasive surgery.

For now, da Vinci is the only robotic system in the marketplace. A few doctors at AAGL said that they heard an Italian company is close to introducing a competitor, but several Italian doctors who were at the meeting to look at or buy a machine said that they had not heard of such a company.

Impact of recent negative prostate study on da Vinci use

Most doctors questioned at AAGL did not know about the recent article in the *Journal of the American Medical Association (JAMA)* which found that a minimally invasive radical prostatectomy is less effective than retropubic radical prostatectomy, and none expected the article to affect their use of da Vinci. Doctors said that, if accurate, the results reported in the article could be due to some inexperienced doctors and that comparing male urological procedures to gynecological procedures on the robot would be like comparing apples and oranges.

- *California #1*: "You have to remember that there is a learning curve with the machine. Also, since the 3-D image is great but the tactile sense is not, perhaps some doctors get overly aggressive during the procedure."

- *California #2*: "The *JAMA* article won't have an impact because we all operate exclusively on women. There are no long-term studies to appraise it because it is still really young. You can expect more complications, and there is a learning curve. But is there any one pelvic floor surgery that you can do better with it? No. The other thing that's of great concern to a lot of us who teach is that there are time constraints on residents. Because of insurance not allowing as many people to be sent to tertiary care centers, (resident) patient loads have fallen significantly over the last decade, so we see more and more residents who haven't done an adequate number of just regular cases...Now, if you start taking up a resident's time to try to teach robotics, it will shortcut the other procedures even more."
- *Florida*: "You have to look at who complains. The more educated patients are the ones who have researched the da Vinci and say, 'That's what I want.' However, if it is true, I wouldn't use it for urology. I would still use it for gynecology because those are different procedures."
- *Kentucky #1*: "If the *JAMA* article is true, then we should (look at it with) a critical eye. Early adopters of the robot will have much better data. But if the data show that robots are not better, then you need criteria on what constitutes appropriate use of the robot. It has to be clear."
- *Kentucky #2*: "The *JAMA* article doesn't surprise me. If the only tool you have is a hammer, everything looks like a nail, and you might want to hit it really hard. Some people are overly aggressive, and the robot doesn't have the tactile feedback you might need."
- *New York #1*: "I think that doctors using the da Vinci will look at that article and consider it, but I don't think that it will have an effect, unless it is something wrong with the machine and not the surgeons...It doesn't help us if we paint with a broad brush. We need good surgeons...It depends on the hands of expert surgeons. We need studies where we can compare robotic to laparoscopic without a robot."
- *New York #2*: "The *JAMA* article doesn't make sense, and it goes against what we know at my institution."
- *New York #3*: "It is very interesting but has to be looked at carefully. We have to find out why the results aren't as good with the robot...If the ultimate results don't support the benefits of the operation, we have to be careful...The problem is that you may have done a more radical operation than you intended, perhaps because the magnification provided by the da Vinci gives a false view to the surgeon."
- *Oregon*: "I didn't see the article, but I think that surgeon experience has a lot to do with it."

The robot-is-nice-but-not-necessary view

Many older, laparoscopically-experienced doctors said that most procedures don't have to be done on the robot, and, in fact, most can be done more efficiently and faster without it. Some of these doctors do see it as useful, mostly for suturing or for more complicated procedures – for example, on obese patients. Others see it as a way to let generalists get a foot in the door in terms of doing more complicated procedures. Others believe that the da Vinci, like femtosecond lasers, is increasingly popular because of marketing and hospitals' need to compete in a very challenging economic environment.

Younger surgeons, on the other hand, are not only more open to robotics, but many of them now expect their hospital to have one. That's because their training is on a robot, which worries some old-school doctors. A Texas surgeon said, "The big hospitals will be the ones making a go of it. They will be able to do cancer on a volume basis. It will be used inappropriately in small hospitals. Right now, there is a controversy about teaching residents to use it. They're spending time they should be learning laparoscopic techniques working on the robot. That's all well and good, but they will be going to communities without robots. It's glitzy marketing, like the CO₂ laser was years ago." A Maryland hospital CEO said he recently bought a da Vinci because the younger doctors won't go to a hospital that doesn't have one, "It's what they train on, and they expect it." A Louisiana surgeon said, "We hope to have everyone graduating with some laparoscopic experience, but if you get the numbers, you get robot experience. It's a given that urologists graduate with robotic training. I hope that this will be the way it goes in gynecology." A New York surgeon said, "We have a post-graduate course in a few weeks in New York. We will be teaching 300 physicians."

Other comments on this issue included:

- *California #1*: "It opens up the field for more patients to have these procedures done because there is a definite lack of physicians with the skill set to do it laparoscopically. You can teach anyone to use the robot. I do worry about people only trained in robotics and who don't know how to do old-fashioned laparoscopy if they get into trouble...The robot has enabled people who don't have the skill set to start doing more complicated cases...My operating time is an hour or less, and with the robot no one has done it any faster than two hours, with most between three and four hours. It is time consuming to set up, extremely expensive, and extremely costly to maintain yearly (>\$100,000 a year) – all just to help people suture. Most of us who have been doing (surgery) for a long time can suture fine without a robot. There are places for robotic surgery...but other than anastomoses of a vessel or a tube, it really doesn't have any significant advantages. They talk about the 3-D view, but to get that view you give up the sensation of pressure."
- *California #2*: "I might be more enthusiastic if I hadn't been trained laparoscopically, but to me there is no benefit. It's like a toy, like playing video games, and so it has a definite attraction for younger physicians."
- *Florida*: "Robots are good for people who are less experienced with laparoscopic suturing, but really there is no advantage to it. It is very expensive, and then there is the equipment, instrumentation, and operating room personnel. What is the advantage over a good surgeon doing the same procedure?"
- *Kentucky*: "I'm being pulled into it dragging my feet. However, some of our group, especially oncology, love it and think that it's wonderful and that the da Vinci is the cat's meow. It won't be for everyone, but it will bring some people along. Those who do it (laparoscopic surgery) open will find that they make better money doing it that way (than with the da Vinci). How will they like to hear that one day out of the week they can use the robot in OR for three or four cases, and the rest they have to do in another operating room the rest of the week. I see a potential bottleneck. If the robot isn't used, you can't use the OR."
- *New Jersey*: "The instruments are flexible, but for certain bulky procedures, like bowel resection, they are not right. If you want to do operations in the pelvis and upper abdomen, you have to rotate and add more, and it gets complicated. There are procedures that you could do with regular laparoscopy that you can't do with the robot, but there is no procedure that you can do with the robot but cannot do laparoscopically...People who are good in laparoscopy don't see the advantage in the robot."
- *New York*: "This is definitely a bridge for people who are not up on laparoscopy. After endometriosis, the next areas are pelvic reconstruction or sacrocolpopexy. The last area could be tubal re-anastomosis."
- *Massachusetts*: "It has nice features and permits older surgeons to continue operating on difficult patients, but I would only use it a little bit."
- *Pennsylvania*: "For the general gynecologist it is a skill enhancer. But for people like me the added value is minimal."
- *Texas*: "For routine gynecology it isn't an advantage for an experienced doctor. For a gynecologic (GYN) oncologist it has significant advantages. Our GYN oncologist is very selective about his patients. He chooses difficult patients and difficult procedures like ovarian cancer, nodes, and sectioning. Unlike other technologies, this does have a place. But the problem is that it is such a big investment. It has no advantage over vaginal laparoscopic surgeries."

The pro-robot view

- *California*: “The jury is still out on the robot, but I use it for a lot of procedures.”
- *Florida*: “It is good for the community. My patients are in the hospital for one day and go to work two weeks later, instead of in the hospital three days and back to work six weeks later.”
- *Kentucky*: “It is great for women. They can be back at work in a day or two instead of weeks...I am a solo practitioner, and so I don’t have one, but I have access to one. I have done three out of the four sessions to get credentialed. I did two hysterectomies and the removal of tubes and ovaries in one woman, and I helped an oncologist with a 350 pound woman. I have to say that I really like it.”
- *Maryland #1*: “A good surgeon has many different ways to skin a cat, and the future has to include robotic surgery. It takes a commitment on the surgeons’ part because they get paid the same, and the same procedure on the robot can take longer. It depends where you are on the learning curve; it can take twice as long if you’re just starting. It is almost as fast and sometimes faster to do radical surgery.”
- *Maryland #2*: “It is the future of surgery. We are at the precipice of a new day in surgery, but it’s like the cell phone. The first cell phones were little suitcases, but they have gotten smaller and smaller. The newest da Vinci is better, smaller, the resolution is better, and the design with the foot pedal is improved. The console is also flatter. The robot will get smaller and smaller in the years ahead.”
- *Ohio*: “It isn’t a toy. It is very useful and will continue to be useful after the novelty wears off.”
- *Virginia*: “Research comparing the da Vinci to conventional laparoscopic and open surgery is warranted. Robotic assistance may help novice laparoscopists bypass the learning curve associated with laparoscopic suturing. For hysterectomies, patients typically feel well quickly, and in a couple of weeks they want to get back to activities. There is no heavy lifting for at least 4-6 weeks, and driving is just common sense.”

Who uses a da Vinci

The types of physicians using the robot vary widely. In hospitals serving both men and women (coed hospitals), urologists dominate the machine as much as 80% of the time, but that is starting to change. A New York doctor said, “We have one machine. Urology uses it mostly, about 40%, then cardiology, general surgery, and gynecology each use it about 20%. How do I know? Because urology has it four days, and the rest have one.” A California doctor said that its \$1.7 million robot is used by many specialties but mostly by urologists.

In women’s hospitals, gynecologists, urogynecologists, and GYN oncologists share the machine. Many physicians said that the da Vinci is most suitable for general gynecologists who want to add to their skills, as well as GYN oncologists and urogynecologists, where there is much growth. In some hospitals, general surgeons and cardiac surgeons also are starting to use the da Vinci.

Comments included:

- *California*: “Our da Vinci is used by general surgery and gynecology most, but urologists are being trained on it. Oncologists come from the University of California, San Francisco (UCSF), and Stanford, and some of them do use the robot, but right now it’s being used more by general surgeons for cholecystectomies (laparoscopic gallbladder operations) and hernia repairs, and gynecologists are using it primarily at this point for hysterectomies. They want to use it for marketing devices for their practices.”
- *Florida #1*: “The robot is really geared for general gynecologists.”
- *Florida #2*: “My hospital has one machine, and it is used by the urologists, urogynecologists, and gynecologists – about half and half between urology and gynecology. We just started colorectal.”
- *Kentucky*: “We have had it a few months, and we (gynecologists) are using it. The urogynecologists are using it a fair amount. We’re not using it too much for the routine laparoscopic procedures because we have an advanced program, and our people are pretty good on their own. There is a place for the da Vinci, but more for the subspecialties like oncology and urogynecology for the advanced techniques. The only place I see it right now... like when the first laser came out – people marketing themselves as robotic surgeons. It has a place, but I don’t think that it is appropriate for the generalists. I think that it helps people who are not particularly good at regular laparoscopic suturing.”
- *Louisiana*: “It is used for all the cancers, including uterine cancer and some ovarian cancer, and I believe it is being used for cervical cancer too.”
- *Massachusetts*: “(If we had a da Vinci) it would be used by gynecologists, surgeons, and urologists. I don’t know about general surgery. Urologists would use it the most, doing prostatectomies for cancer.”
- *New York*: “At my hospital use is almost 50-50 between urologists and gynecologists. In most hospitals, urologists are using it the most, and recently gynecologists have been using it. In certain hospitals gynecologic use may be surpassing urologists because urologists’ use has been maxed out, some aren’t doing it because of the *JAMA* article, or because gynecologists are doing more procedures.”

- *Ohio*: “(Our) robot is used half by urologists and half by gynecologists, and cardiac surgeons are starting to use it. I use it for hysterectomies and ovariectomies.”

Gynecologic procedures with da Vinci

Doctors said that the da Vinci is most useful for gynecologist oncologists and urogynecologists, and it is perhaps the area of greatest growth in gynecology. How the da Vinci is used varies widely from hospital to hospital.

Gynecological Procedures Being Done with a da Vinci

Procedure
Hysterectomies: regular and radical
Myomectomies
Cancer: endometrial, ovarian, uterine, etc., plus lymph node dissections
Sacrocolpopexy (laparoscopic)
Pelvic reconstructions
Fibroids
Endometriosis

Comments about use included:

- *California*: “I use it for hysterectomies, myomectomies, and suturing but not tubal ligation; that’s a waste of money.”
- *Florida*: “It’s used for myomectomies, hysterectomies, etc. The number of surgeons getting credentialed is increasing.”
- *Kentucky #1*: “Mostly gynecologist oncologists should use it. It’s useful for them. In oncology, lymph node dissection is easier, but it might not be as fast as traditional laparoscopy. Tubal reastomoses should be easier, and so might myomectomies, pelvic reconstruction, and sewing.”
- *Kentucky #2*: “It is mostly used by gynecologists and GYN oncologists (using it). I’d like to use it for hysterectomies, myomectomies, and removal of tubes and ovaries. It is great and allows a woman to go back to work in two weeks vs. six weeks.”
- *Louisiana*: “We got a robot in the last two years. It is primarily used by GYN oncology specialists. It is used for all the cancers, including uterine cancer and some ovarian cancer, and I believe it is being used for cervical cancer, too. For them, it is good for patient care. We’ve seen the days of multiple patient stays in the hospital. For hysterectomies it is now a one- to two-day stay in the hospital, depending on the type of cases, in comparison to four days without the robot.”
- *Maryland*: “We use it for oncology but also for reconstruction, complex laparoscopic procedures like fibroids, and endometriosis – any complex, difficult laparoscopic procedure. I use it half the time for cancer cases, such as lymph node dissections, and half for benign procedures like pelvic floor reconstruction – places that otherwise might be abdominal procedures and are difficult to do through a minimally-invasive approach if I didn’t have a robot.”
- *Massachusetts*: “The benefits include the 3-D and when you have to do suturing. It comes in handy for gynecologists. It also looks good for myomectomies and total hysterectomies. For routine endoscopy, though, I don’t think that it will help, but I suspect that its use will continue to grow.”
- *Nevada*: “Gynecologists are using it for laparoscopic hysterectomies. There are two gynecologic practices in town. One uses da Vinci, and the other doesn’t believe in it. I don’t use it now, but I’ll use it when I’m 60-years-old, sitting next to a console with my cup of coffee.”
- *Pennsylvania*: “It can be for any indication, such as hysterectomies and reconstruction.”
- *New York #1*: “Oncologists can do nodes faster and a little safer (with the robot) because of the fine movement, and they lose the tremors. There is some risk in open laparoscopy. So they are starting to convert. It is also good for endometrial cancer, and most oncologists will do these – also laparoscopic sacrocolpopexy, myomectomies, and colpopexy – within the next five years at most ...The robot can be used for all gynecologic surgery, but the debate is over its ideal role. Urologists are using it for prostatectomies, for which it is hard to do open laparoscopy. It is a small, limited space; articulation of the robot lends itself to this; and you don’t have to move the scope around a lot. The robot is not the perfect setup for gynecology because you have a larger space, and you have to move the scope around. There are a few procedures that use a lot of sutures for which the robot works well in gynecology and will take over: Laparoscopic sacrocolpopexy where it works well because of the suturing, and myomectomy where it is easy to learn on the robot and there is a very nice benefit.”
- *New York #2*: “More gynecologic oncologists are using the da Vinci compared to general gynecologists. For certain myomectomies, those which aren’t very large and which are not multiple, not complex, and a certain size, but require deep suturing, those are good for the da Vinci. If there are multiple fibroids, current available instrumentation does not fit on the da Vinci to remove the complex matter. The medium-sized intramural myomas are the best applications.”
- *Texas*: “Gynecologist oncologists use it the most. Most GYNs use it for normal hysterectomies, but it’s really useless for that.”
- *Virginia*: “The da Vinci is one of the best applications for urogynecology and reconstructive surgery.”

Use of the robot for hysterectomies

Doctors estimated that 10% - 15% of hysterectomies currently are done laparoscopically, with <1% done on the da Vinci. However, they agreed that use will grow as the procedure is marketed and as patients read about robotic surgery and ask for it. Comments included:

- *California*: “I use it for hysterectomies. It gives a greater range of motion, and suturing is easier. The learning curve is pretty short, fewer than 5 (procedures) to get it down. I think that hysterectomies are where the da Vinci is going. Our best doctor can do one in 10-15 minutes.”
- *Florida*: “Eighty percent of my hysterectomies are done on the machine. About 65% of hysterectomies are open, and 35% are laparoscopic. The reason that most people don’t do it laparoscopically is because it takes a while to do it (that way). If a competent gynecologist can do 3-5 hysterectomies over two months, after 5-10 hours of practice he can then do 3-4 a day.”
- *Kentucky*: “We use it for hysterectomies (probably with doctors used to doing open only and wanting to try the robot). It is a different mindset, and they aren’t exactly attuned to the idea. But some adapt rapidly and some don’t. The difference is that if we (experienced in laparoscopy) need to fall back, we can fall back on laparoscopy, and they fall back on open surgery. Nationwide, 15% of hysterectomies are done laparoscopically, and fewer than 1% of those are done with the da Vinci.”
- *Louisiana*: “For hysterectomies it is now one to two days stay in the hospital depending on the type of cases, in comparison to four days without the robot.”
- *New York #1*: “For regular hysterectomy it may not be advantageous to use the da Vinci. For people who are very good at laparoscopy, the robot is not cost-effective. The same goes for radical hysterectomy. Maybe it doesn’t have significant advantages for the patient, but for the surgeon it could be less tiring and may be associated with less fatigue.”
- *New York #2*: “Hysterectomies are done laparoscopically about 12% of the time. Of that, maybe 1% is done on the robot and probably not that much.”

Advantages and disadvantages of da Vinci in gynecology

Doctors said that the da Vinci has many **advantages** over traditional laparoscopy, including:

- **Less hospital time (usually an overnight stay) and faster return to work/normal activities.** A Florida doctor said, “The payoff is patients going home 24-48 hours postop from sacrocolpopexy and asking to return to work at 2-3 weeks postop. There also is reduced post-operative pain for patients. What’s left to do now that is still open? I think patients at high risk for having adhesions.” A Georgia doctor

said, “The good thing about da Vinci is that patients stay one night and go home the next day. Patients request it for hysterectomies, and we do them.”

- **Ease of suturing, small incisions, and procedure time.** A Pennsylvania doctor said, “Everyone likes it. The incisions are smaller and fewer.” A Massachusetts doctor said, “You can do a better job (with the robot) and just as quick.” A Virginia surgeon said, “The da Vinci transformed the way I approach pelvic reconstructive surgery ... I was a vaginal surgeon until I met the robot. I can take a step-by-step approach to robotic sacrocolpopexy, including detailed patient positioning, docking, instruments, and surgical approach.”
- **Less blood loss.** A Louisiana doctor said, “Blood loss in both our first and second hundred cases was cut in half to an average of 60-65 cc per procedure compared to 113 cc. The length of stay decreased, and conversion rates dropped.”
- **Ability to dissect complicated numbers of lymph nodes.**
- **Suitable for large uteri and obese patients.** A Kentucky doctor said, “One of its pluses is that you can use it for massively obese people.”
- **3-D view, providing better imaging.** A New York doctor said, “Laparoscopic robotic technology has better imaging and visualization. It is much better, and there is more opportunity to work around nerves sparingly.” Another East Coast doctor said, “It is a bridge between laparoscopy and laparotomy. The da Vinci has some elements like 3-D view that make it more intuitive. There is easy movement and more articulation of the wrist. Also, you are sitting instead of standing.”
- **Less trauma to the tissues and fewer complications.**

The biggest **disadvantages** are the cost and learning curve, but there are other disadvantages as well.

- **The size of the machine.** A Maryland doctor said, “In addition to the cost, the downside is that it is more cumbersome, and you have to set up the big machine, whereas with regular laparoscopy you don’t need as much time to set up, and there aren’t as many steps in terms of getting the procedure started. It takes a little longer to get it set up and ready to go.”

Advantages and Disadvantages of da Vinci

Advantages	Disadvantages
Less hospital time	High cost
Ease of suturing, small incisions, short procedure time	Maintenance cost
Less blood loss	Procedure preparation time
Ability to dissect complicated numbers of lymph nodes	Machine size
Suitable for large uteri and obese patients	Larger incisions
3-D imaging	Learning curve and retraining
Less trauma to tissues and fewer complications	

- **Extremely high cost, as much as \$2.5 million, plus maintenance costs of \$100,000-\$250,000 a year.** It is not just the initial cost of the robot that has to be considered, but the continuing maintenance costs. A Kentucky doctor said, “The cost is \$1.5-\$1.7 million, and it costs \$250,000-\$500,000 a year for service contracts. Probably most hospitals can’t afford this.” A Louisiana doctor said, “Cost is a real issue, and anyone who has purchased one realizes that.” A California doctor added, “The cost of startup is very expensive. We are not going to buy one. It is useful for endometriosis and hysterectomies because it makes the procedure easier, less fatigue, eliminates tremor. There is less trauma to the tissue and fewer complications.”
- **Procedure preparation time.**
- **Multiple punctures and larger incisions.** A Louisiana doctor said, “One of the negative things about the robot is that it requires so many punctures that are bigger than 5 mm in the bellybutton, and two other 5 mm incisions, and some vaginal incisions. The incisions are usually 10 cm, but some are 7 or 8 cm.”
- **Learning curve and the need to retrain.** If the robot is not used regularly, a doctor may need to be retrained on it. A Wyoming doctor said, “I moved to Wyoming, where there is no da Vinci, from San Antonio, where we had one. It cost about a million dollars. The downsides were the cost and the learning curve. You had to be retrained.”
- **Patient positioning.** Although the machine is suited to large patients, the position in which they lie (head down) can sometimes cause cardiac and pulmonary problems.

Doctors agreed that the da Vinci should not be used for tubal ligation, nor for patients at high risk for adhesions, cardiac, or pulmonary problems. Some said that it is also not appropriate for certain bulk procedures like bowel resection. Doctors were divided on the usefulness for hysterectomies, with most saying that that will be an area of huge growth, but others insisting that the procedures can be done perfectly well without the robot. A Georgia doctor said, “The contraindications are patients with a history of previous surgeries or difficult surgeries. An experienced Florida surgeon said, “The biggest contraindications are the people with cardiac and pulmonary issues. My patient has to see a primary doctor first. Pulmonary, cardiac, and adhesions are the third complication.” Another Florida doctor said, “You have to keep your skills up, and you need at least two cases every week in order to get better. You also have to know when to abandon, when necessary. You need to know the contraindications.”

Cost-benefit of da Vinci

Doctors agreed that the robot does *not* make economic sense for doctors, although it may for hospitals, and currently makes money mostly in urology because of the volume. Doctors said that they do not make more money per procedure when using

the da Vinci. In fact, because of setup time, they make less using the da Vinci than laparoscopic or open procedures.

Comments included:

- *California:* “If you are a practicing physician, you’re not going to do robotics when it takes you 2-3 hours, when you can do it in some other fashion in under an hour. You don’t get paid more robotically...One of the people in my group takes 2+ hours to do a procedure, and he’s losing money to do that.”
- *Florida:* “They say that urology is the engine for sales, and that urology makes a profit on the da Vinci, but I envision that gynecology will eventually do the same.”
- *Kentucky:* “Is it cost-effective? No. We need some cost-benefit analysis and some data...I don’t think that every hospital should have one. Some hospitals have days when the da Vinci sits around unused. A lot of surgeons don’t do hysterectomies or maybe two or three a year. They think that maybe they can get some traffic by having the da Vinci, but that’s wrong...In the current climate, I can’t see it working. If a patient copays, you’re going to be sure that the patient is going to want to know what it costs.”
- *Maryland:* “In terms of money, there really isn’t any economic benefit to the doctor because the reimbursement for laparoscopic hysterectomy is the same whether it’s done laparoscopically or robotically. The benefit from my perspective is that almost all the patients go home the same day, so I don’t need to do rounds on them the next day or the day after. If it is an abdominal procedure, they are in the hospital 2-3 days. I’d have to go see them there, so that is one of the downsides. The reimbursement is the same, even doing more complex procedures. We are really helping the patient by turning what would be an abdominal procedure into a minimally-invasive procedure, but there is no recognition of that in terms of reimbursement. In the end, it’s better for the patient. If you really keep that in mind, you’re doing what’s best for the patient, and eventually it will pay for itself many times over.”
- *Massachusetts:* “My reservation is that the applications for routine procedures aren’t cost-effective, and it costs time for setup. It takes 20-40 minutes to setup. And then there is the quarter of a million dollar service contract. But in the end it’s just hard to justify for a lot of cases.”
- *Nevada:* “Reimbursement is the same for robotic vs. laparoscopic for total laparoscopic hysterectomy (TLH). And TLH doesn’t cost \$100,000 to maintain the equipment. The average doctor would starve doing TLH on the robot. Open hysterectomy is an hour-long procedure, and you’re done and back in the office. So, the da Vinci is for people in school who can learn on it there...The cost of startup is prohibitive and so is the maintenance budget. You can also lease it, but it’s still too much money. In the current economic climate, who knows what Obamacare is

going to do to us? On the other hand, the robot is a lot of fun to play with. Everything is 3-D, and if you get distracted the instruments lock down. So there are some wonderful advantages to it. Robotics has its place, but not in a rural hospital that can't afford it...In my hospital, I couldn't even get them to get (Cooper Surgical's) RUMI Uterine Manipulator for total laparoscopic hysterectomies...These things are interesting in high volume areas at education centers. I work in a large HMO, so I get volume and I can keep my skills up, but the average person in private practice doesn't do that many procedures in a year. The learning curve is 20 cases for a robot. That's nice, but when it takes you five years to do 20 cases, it doesn't make sense."

- *New York #1*: "The real issue – globally – is that we still have to find its role in providing benefit. Is it a money maker? Only for radical prostatectomies, by volume. Cardiac surgery has also shown to be a positive revenue center for hospitals, only because of the increased volume. There is no increased reimbursement per case. There is no difference in reimbursement to the hospital, whether using the robot or not."
- *New York #2*: "It is not cost-effective for...the initial investment. It is not economically sound for hospitals because it has to be used constantly, almost five days a week."

Capacity

Most hospitals said that their da Vincis are not at full capacity yet, but that is changing as more doctors get trained and want to practice on and use the robots. At hospitals that are not women's hospitals, urologists dominate use of the robots. Comments on usage and capacity included:

- *California*: "Our capacity is probably three procedures a day. But that will increase as our time gets better on the machines."
- *Florida*: "My hospital has one machine...We want to get it utilized five days a week. For urology cases, we expect to get about three of them per day, and we are working to reduce room turnaround. Right now our capacity per day is: 4-5 procedures for gynecology and up to five or six procedures for urology...I am up to two procedures a day, and I have done 105 cases. I can do three a day if they are simple, like hysterectomies."
- *Georgia*: "We can do 8-10 procedures a day on our three machines."
- *Kentucky*: "I don't think that every hospital should have one. Our capacity is four procedures a day max...Some hospitals have days when the da Vinci sits around unused. A lot of surgeons don't do hysterectomies or do maybe two or three a year. Hospitals think that maybe they can get some traffic by having the da Vinci, but that's wrong. Also, if the robot isn't used, you can't use the operating room...I think that the adoption rate has to be slow...Is it

cost-effective? No, we need some cost-benefit analysis and some data."

- *Louisiana #1*: "We are more of a referral center, so it (the robot) is busy. It runs all day the first two days of the week, and there are people using it who have converted their regular cases to it. It's probably easier for someone who has previously done incisions to convert to that."
- *Louisiana #2*: "The major women's hospital in my town has 80 OBGYNs and one robot, and generalists have jumped on board. We went across town and trained about 10-13 people. Access became a problem, and many people couldn't get on the robot. Those who are trained are doing a great job, but there is a second wave of doctors who want to be trained. The roadblocks are cost and access issues."
- *Maryland*: "Realistically, our capacity is about three gynecologic cases a day and 15 cases a week."
- *Nevada*: "At my hospital, it is used three days a week by urologists, gynecologists, and some gynecologic oncologists."
- *New York #1*: "Actual use is not that often. Most days someone is using it, but there are cases where it is not used the entire time. General surgery is moving into the space more than the others and is the biggest increase."
- *New York #2*: "A radical prostatectomy takes about 1.5-2 hours, and a urologist can do about four a day. On the other hand, a radical hysterectomy takes 4-5 hours, so you can only do maybe one or two a day max."
- *Pennsylvania*: "An efficient system could do 4-5 procedures a day, but for complex pathology it could take as many as six hours."

da Vinci purchase plans

Doctors from 29 hospitals were questioned about their use of – and plans for – robots. Most hospitals (85%) already have a da Vinci, and all of the others hope to get one in the next two years. In addition, one-fifth (21%) of current users expect to get an additional device in the next two years. Furthermore, as other specialties and generalists start to use the da Vinci, other doctors predicted that their hospitals may be forced to buy an additional robot. Some doctors also complained that bottlenecks were already occurring as more doctors are trained on the device.

Comments on da Vinci purchase plans included:

- *California #1*: "We have two machines...and this year we are pushing for a third machine."
- *California #2*: "Right now a second one is **not** needed because the robot is not being used eight hours a day, five days a week. I imagine no more than 10 cases a week are being done on the robot – maybe 8 to 15."

Prevalence of da Vinci in Hospitals

Measurement	Number of hospitals n=29	% of hospitals
Current use		
Already have 1 da Vinci	17	59%
Already have ≥1 da Vinci	8 *	27%
Do <i>not</i> have a da Vinci but plan to get one	4	14%
Do <i>not</i> have a da Vinci and <i>do not</i> plan to get one	0	0
Purchase plans in next 1-2 years		
Planning to buy a <i>first</i> da Vinci	4	14%
Planning to buy an <i>additional</i> da Vinci	6	21%
<i>Not</i> planning to purchase a da Vinci	11	38%
Uncertain	8	27%

* 1 hospital has 4 da Vincis, 6 hospitals have 2, 1 has 3

- *Georgia*: “We have four da Vincis...We are trying to hire more gynecologists. Women’s healthcare is the most prolific area and has the most growth. Gynecologic surgery has the most demand. However, we don’t care about the money, and we think only of the patients.”
- *Kentucky*: “We have one robot, and we are *not* getting another, although the one is at capacity. It is very expensive.”
- *Louisiana*: “I don’t know if we will get a second da Vinci. A lot of the determination is based on the cost... One million dollars plus \$100,000 a year to keep it going is hard to justify. We’re at a maximum of those cases right now because of the frequency of the cancer specialists and other doctors doing it. That’s good marketing, and a lot of patients know about it or at least are aware of it.”
- *Maryland*: “We are trying to get the hospital to buy another.”
- *Massachusetts*: “We have none at the moment. Our hospital is trying to get one, and it’s mostly for marketing purposes...Our chair of minimally invasive surgery is trying to negotiate with the hospital administration.”
- *New York*: “It’s hard to say how fast it will grow. It is hard to say whether people already doing laparoscopy will turn to the da Vinci. Overall, because of the cost of the robot and because not every hospital can afford it and also the complex setup, growth will be slow.”
- *Oregon*: “We don’t have a da Vinci, but it’s coming. It’s not a question of if but when.”
- *Pennsylvania*: “I don’t think that we will get a second da Vinci. It’s very expensive. We might if it weren’t for the cost. The technology is good, but we won’t get another just yet.”

Intuitive’s marketing of da Vinci

Doctors agreed that Intuitive is doing a good marketing job, and the company appears to be working hard to convince competing hospitals in metropolitan areas that they need a robot to stay competitive.

- *California*: “Intuitive has had a brilliant marketing campaign. The hospitals see it as a big marketing device – they have to...Intuitive has a huge marketing budget ...It’s a big marketing device to say that we have robotic surgery. I have people coming into my office who want to know if I’m going to use the robot. It has that magic term about it, just as lasers did.”
- *Georgia*: “Smaller hospitals feel pressured to get it, and it will be a problem for them because you don’t need it for regular hysterectomies, for example.”
- *Kentucky #1*: “In the U.S., I think that we are creating a lot of uncertainty, and everyone is starting to think that they have to have it. (Our hospital) wants to be the robotic surgery center of the world and wants to make its reputation on robotic surgery.”
- *Kentucky #2*: “We’re lucky to have the one we have at the university hospital...All the major hospitals (in my town) have a robot. You have to have it to stay competitive. For the urologists we need it, and our oncology people are in competition. For us at the university, we need it to attract faculty and fellows.”
- *Kentucky #3*: “Last year there was one da Vinci in (our town), and now there are four, all at competing hospitals.”
- *Maryland*: “I have quite a few patients asking for the robot. They get online and look it up, and many patients know what they want.”
- *Nevada*: “In Las Vegas, there are three machines at three competing hospitals. Intuitive was very smart and went to each one, saying that the others had or were going to get one. da Vinci is hot because (Intuitive) markets it well, and it has the ‘gee whiz’ factor.”

Next generation robot

Doctors predicted that the next generation da Vinci will be smaller and less bulky.

- *New York #1*: “As the robot gets smaller and faster, more doctors will use it. The next generation will probably hang from the ceiling, be more flexible, and easier to place cannulas and trocars. It will also, I hope, be less expensive.”
- *New York #2*: “I have seen the cartoons that show it suspended from the ceiling. That would be a good thing, but I don’t know if it will really happen.”
- *Virginia #1*: “The next generation da Vinci will move to single-port instruments and will probably be more flexible and less bulky.”

- *Virginia #2:* “As the technology advances, robotic arms will become flexible and the robot will be less cumbersome. Robots will become smarter and smaller; right now, she is a beast in terms of rolling around.”

SINGLE INCISION OR PORT LAPAROSCOPIC SURGERY

Doctors are interested in single incision laparoscopic surgery, but they said that it is still too early in development to endorse. Some commented that it is ironic that laparoscopic surgery began with a single port and may be heading back that way again.

Single incision laparoscopic surgery (SILS) is also known as laparoscopic single-site surgery (LESS), single-access site (SAS), single-port access (SPA), single-site access (SSA), one-port umbilical surgery (OUS), natural orifice transumbilical surgery (NOTUS), and transumbilical endoscopic surgery (TUES). An Ohio doctor said that data presented at the European Association of Urology meeting in May 2009 showed that single incision, umbilical laparoscopy did not show benefit compared to conventional laparoscopy, but it was also not worse, “It may not be that we’re seeing significant improved outcomes, but the key is that we’re not seeing increased complications with doing this type of operation in our initial experience of 47 cases from August 2008 to September 2009...(It may be a placebo effect, but) doing this procedure, patients just do well and patient satisfaction is very high. Patients come out of the operating room, and the recovery room nurses look for bandages, and there is nothing there. It’s too early to say whether it will result in improved outcomes, more rapid return (to normal life), and less pain. I don’t know, and I can’t tell you that yet, but clearly there is a very high patient satisfaction.”

Doctors said that the instrumentation is not yet perfect, and they are experimenting with different instruments. One-handed instruments are best, with a 360 degree range. Covidien’s Endo Stitch was described as “the perfect device for SILS suturing. It can perform both intra- and extra-corporeal knots.”

Other instrumentations on the horizon include V-loc sutures, which will automatically make sutures. Covidien is the leader in this category as well, and doctors said that its SILS port has these advantages:

- Extreme flexibility that lets it separate hands and increase range of motion.
- Easy insertion.
- Removal and reinsertion can be done as often as desired.
- Changeable port size – from 5-15 mm.

Doctors said that while the technique looks awkward, patients might like it. However, most were skeptical about the idea

that it represents an advance, and some called it gimmicky. The advantages are: little pain, reduction in the number of ports needed to complete laparoscopic surgery, and reduced intraoperative complications and postoperative morbidity.

SILS procedures include lymph node dissection lymphendectomy, endometrial (type I/II, obese), and cervix (FSS, radical hysterectomy). An Ohio doctor who uses SILS for hysterectomies said, “The laparoscopic approach has an amazing cosmetic effect, which is something to take into account, because patients want it. Patients can go back to work in four days, on average. The key here, the big secret, is the uterine manipulator. Also, right now there is no articulating energy source. I hope it’s coming and it’ll be great, but for now we don’t need it.”

SILS Clinical Applications in Gynecology

Procedure
Oophorectomy/cystectomy
Total laparoscopic hysterectomy
Supracervical hysterectomy
Uterosacral vault suspension
Appendectomy
Emergency surgery for ruptured ovarian cysts, ectopic pregnancy
Excision of endometriosis
Sacrocolpopexy
Myomectomy

Comments about SILS included:

- **Possibly beneficial.** A California doctor said, “I don’t use it, but I’m open to learning about it.” A Maryland doctor said, “SILS is the next new thing on the horizon. I’m still waiting to see, but at the moment I’m not really convinced that it will have a huge application in GYN just because we’re so used to putting in multiple ports, but I think it’s a technology which has just started, and it will be interesting to see if those ports get better and smaller and instrumentation goes along with it...Patients aren’t asking for it yet, in contrast to the robot.” A Louisiana doctor said, “It looks interesting. I’m trying to determine how that would fit in with instrumentation. I think that there are going to have to be some modifications in order to have adequate visibility. I don’t think that it’s awkward, but I don’t know if putting one port with a bigger incision is that much different than making one 12 or 3 fives – it’s the same.” A California doctor added, “This is something that is definitely applicable to minor procedures, but you have to have expertise. People say that it is a gimmick, but it also leaves a small scar...It’s very easy to use for vagina suturing.”
- **Awkward.** An Ohio doctor said, “It looks awkward to me...Patients like it but the doctors don’t.” A California doctor said, “It’s awkward and sort of like chopsticks.”

- **Too early to say.** An Oregon doctor said, “It is still early. We don’t use it yet. There are pockets of people using it, just as pockets of people are using da Vinci.” A Wyoming doctor said, “This is still an emerging concept. It’s where robotics was five years ago. It is interesting, and people are tinkering with it, but whether it provides a clear benefit is still uncertain. If a patient winds up with complications, for example a hole in the bladder or in the intestine, it will end up in the trash heap. Doctors won’t want to take the risk in exchange for slightly improved cosmetic benefit. We will see some avid proponents of it over the next 5-10 years, and it will be used more for relatively simple procedures – simple gynecology, like removing simple cysts, ovaries, laparoscopic tubals, simple endometriosis – but I’m guessing that it won’t replace traditional procedures for laparoscopic hysterectomies or fibroid removal.”
- **A gimmick.** A Kentucky doctor said, “It’s ironic because the early days of laparoscopy used a single port, then we went to several ports, and I’m not convinced that a single port is better than three – 2.5 mm, a 5 mm, and a 5 mm. It’s creating a solution to a problem that may not exist. It’s okay, but then you need a new set of instruments to do SILS, and that doesn’t help keep healthcare costs down, does it? And that’s to do procedures that we’re already doing now...It’s a little gimmicky to me. That being said, I was criticized when I first started, and I was one of the first to do advanced laparoscopic surgery in the U.S. I did a lot of firsts, so I don’t want to say that some-thing is a gimmick, but why do you want to handicap yourself with one incision? To me, it makes you into a single vision, and it takes away a perspective. I tend to think that it’s more gimmicky. That being said, the more minimally invasive a procedure, the better. Time is the great evaluator here.”
- **Limited utility.** A California doctor said, “I think it’s going to have specialized situations where it will be useful. It is more minimally invasive, but sometimes you have to be careful. Sometimes you get things so small that you make it much more difficult to do, and the procedure doesn’t warrant it. We did a study several years ago on trocar size, and in 100 women using visual pain analog scores, they couldn’t distinguish between a 10-12 mm port and a 5 mm port. At that time there was a big push to go to 5 mm scopes and equipment, but that has pretty much gone by the wayside. You can do an appendectomy through a pinhole incision, but it will be more difficult, and you increase the risk of morbidity.”
- **No demand.** A Nevada doctor said, “I saw it in operation and took a class. However, if a hospital has certain laparoscopic equipment, they are reluctant to invest in other things.” A Louisiana doctor said, “We haven’t seen any demand for this. I still see people having the standard procedures. The idea of demand may not always be based on the patient having evidence of something.”

CONTRACEPTION SYSTEMS

A bilateral tubal ligation is the most common form of *permanent* contraception in the world. In the U.S., ~700,000 tubal ligations are performed annually, usually in a hospital operating room under general anesthesia. Surgeons typically make two incisions, and the patient is hospitalized 4-5 days.

Two new, minimally-invasive, incisionless, permanent contraception surgical options are now available:

- **CONCEPTUS’ Essure.** This ~13-minute procedure can be done in a physician’s office with no incisions. A small, flexible micro-insert is placed in a woman’s fallopian tubes, first one then the other, through the cervix. The body forms a natural barrier around the micro-inserts. A confirmatory dye test called a hysterosalpingogram (HSG) is performed at three months post-procedure to ensure the fallopian tubes are completely blocked. Based on 4-year follow-up, Essure claims to be 99.8% effective with no pregnancies reported in clinical trials. Essure was approved by the FDA in 2002, and >300,000 women have had the procedure.
- **HOLOGIC’S Adiana.** This two-step approach is done under local anesthesia, often in a doctor’s office. A catheter is positioned immediately inside the opening of the patient’s fallopian tube using a hysteroscope, eliminating the need for any incisions. Low-level bipolar radiofrequency (RF) energy is applied through the catheter to remove a thin layer of cells from a 1 cm section of the inside of the fallopian tube. The catheter then delivers an implantable, soft polymer, called a “matrix,” which remains within the prepared section of the tube. The matrix is smaller than a grain of rice. The procedure is then repeated on the other fallopian tube. Healthy tissue grows into the matrix, creating a complete blockage of each tube. An HSG is conducted at three months post-procedure to ensure the fallopian tubes are completely blocked. Based on 3-year follow-up, Adiana is 98.4% effective. Adiana was FDA approved in July 2009.

In May 2009, Conceptus filed suit against Hologic, claiming Adiana violates Essure patents.

Doctors at AAGL did *not* think that permanent contraceptive device use will increase much in the next few years due to better *contraceptive* devices, such as Bayer’s Mirena intrauterine device (IUD). They asked why a woman would want a permanent contraceptive device if you can still get pregnant with it. They also resisted having to purchase new equipment in order to use Adiana.

Comments about Adiana and Essure included:

- *Kentucky:* “With the failure rate of Adiana, what do doctors tell their patients? Having an unplanned pregnancy is a bigger deal than having your cervix lasered again...As a woman, would I want to have the procedure

if there is only about an 85% chance of it working? I can put Mirena in five minutes and have a much higher success rate. (Hologic) can't market this as a 98.4% efficacy rate; that is disingenuous."

- *Louisiana #1*: "Adiana probably has some advantages in terms of wanting to do an endometrial ablation for abnormal bleeding. If the patient has problems with two things, it allows you to do both procedures. Essure has metal in the coils, and you can't do ablation with (Hologic's) NovaSure (endometrial ablation system) because of that. You can't do NovaSure if you've already done Essure...I've looked at the Adiana, and I'm not sure (about it) as far as the office setting. We're not going to get it because it's going to require more equipment, and I'm not sure whether it would be worth it."
- *Louisiana #2*: "Apparently when they did the (Adiana) studies, there was a pretty high rate of failure – similar to older tubals. That would be a higher rate of tubes appearing to be open on HSG...Essure has a higher failure rate now that it is being used widely."
- *Louisiana #3*: "In my practice the number of patients who want permanent contraception has decreased because of new devices like the Mirena, which is good for five years. It has a significantly better success rate than Adiana...Mini-pills are attractive, especially in patients for whom combined oral contraceptives are contraindicated. These are lower doses and safe to use, and use in these areas is growing."
- *Missouri*: "There have been pregnancies with Adiana, but some of them were stupid. I heard that one guy put two in the same side and now they have a post-it or something that says Right and Left that you put on the monitor. I had one myself that slipped out of her tube."
- *Nevada*: "I haven't used Adiana, but the jury is still out. I'm never the first to jump on the bandwagon."
- *Ohio*: "I do 12 (Adianas) per month, and I will do 15 per month next year. The real challenge is for radiologists who have to be re-educated on what to look for. And in the real world Essure has pregnancies, too. We had three women who got pregnant after using Essure, but there is a similar placement rate and similar pregnancy rate for both. Adiana needs to get close to Essure's numbers in order to be viable, so a 1% difference in efficacy would be okay."

CONCEPTUS' Essure

Generally, doctors like Essure, are very comfortable with it, and say that their patients like it. They get from \$1,000 to \$1,500 reimbursement vs. \$1,000 for a laparoscopic tubal procedure. Essure, like Adiana, is done in the office.

Comments included:

- *California*: "The Essure is done frequently in our office. It's a good profit center for physicians, and you get paid a whole lot more for doing it in the office. I think it's \$1,200 - \$1,500 or more, whereas a laparoscopic tubal is definitely under \$1,000 anywhere, and it's much more expensive because it's outpatient. Also ablations are popular because companies are willing to pay you much more to do ablation than hysterectomy...We use Essure. It's quick and simple, and we get about \$1,000 - \$1,500 reimbursement."
- *Kentucky*: "This is a good option, and for a lot of patients it is ideal. The ideal patients are primarily abdominal surgery and obese patients. It is not reversible, no matter what they say. Reimbursement is a huge stumbling block because insurers won't pay for the HSG. Also, patients don't want to come back for the HSG. They use 3-D ultrasound in Europe, and that could be the answer. It (ultrasound) is approved in Europe but not in the U.S."
- *Louisiana*: "We've been doing it in the office for ~7 years. I have been very happy with it, and it is our main procedure for tubals. I do a varied number of Essure – ~5-6 in November and more as end of the year comes. So, I sometimes do 4 a month, sometimes 10. A lot of what people decide on depends on insurance."
- *Nevada*: "Essure is wonderful. The patients love it. It is a way to have a tubal ligation without an abdominal incision. Patients love it and tell their friends. It's a simple procedure which can be done by a doctor in a rural area."
- *New Jersey*: "I just came to look at it. The downside is the multiple insertions and having to wait three months to confirm occlusion."
- *New York*: "I love Essure. It's very easy to use, and the patients love it."
- *Oregon*: "It is a phenomenal form of contraception and avoids the complications of laparoscopy, but it's not without its potential problems, like uterine perforation. It is very effective."
- *Texas*: "Essure is minimally invasive and very quick. It is cost-effective. There is no hospital stay, and there is a very quick recovery. It costs about \$1,500."
- *Wyoming*: "I will use it, and it will wind up being 80% - 90% of the tubal market in a decade. It is incisionless, and you can do it in the office and under minimal anesthesia. The bottom line is that it's better for patients. Technology is slightly more difficult than laparoscopic tubal, and you have to learn how to do it. The other downside is that once in a while you can't get it inserted in place, or you can't find the tubal opening."

For some patients, especially younger ones, other forms of contraceptives which may be more effective than Essure may be an attractive option. A California doctor said, "For our patient population, it's hard to get them to agree to it. They have to come back in three months for the HSG, and they have

to use other forms of birth control for three months. They'd rather go with the Mirena. I do that more than anything else, especially for undergraduates."

A Nebraska doctor did a study of hysteroscopic sterilization with an IUD *in situ* in the office setting. He had six patients with IUDs who wanted Essure but didn't want to have the IUD removed until after HSG confirmation. Patients received ibuprofen 800 mg every 8 hours for 24 hours preoperatively. All patients were not fasting, and no IV or sedation was utilized. Four patients had Duramed Pharmaceuticals' ParaGard copper IUD, and two had the Mirena. All had successful placement, and no IUDs were removed at the time. There was no difference in visualization or cannulation of the tubal ostia. The doctor said, "It appears that the removal of the IUD is not necessary at the time of the hysteroscopic placement of the Essure device."

This doctor also did a retrospective study of 216 office-based gynecologic procedures performed from May 2006 to January 2009 to look at complications in the office. Of these, 62 were Essure, 72 diagnostic hysteroscopy, 33 operative hysteroscopy, and 49 endometrial ablation. All 19 complications were minor. The doctor's own complication rate was 6.4%, and there were no admissions to the hospital. There were seven minor complications with Essure (an 11% overall complication rate), including a 4.8% failure to place rate and 3.2% difficulty placing the coil. The doctor said, "The study showed ...office surgery is safe...With changes in healthcare coming, procedures performed in an office setting can improve overall care and decrease costs."

HOLOGIC's Adiana

Most doctors had not seen the Adiana device, and only a few had used it. A French doctor said that the Adiana is easier to use than Essure, "It is easier to put into place, and Essure doesn't always stay in place. Adiana is much easier." A New York doctor said, "I only heard about Adiana (at AAGL), and I'll be looking at it."

There was no pent up demand for Adiana. Most doctors did not know if they would use the device and couldn't project its use over the next year. Adiana costs \$1,300 per procedure (\$650 per side) and has the reimbursement code 58565 in office or hospital. Those doctors using it are doing the procedure in their office.

Although Hologic is not bundling Adiana with its NovaSure Endometrial Ablation System, it is heavily marketing its "Total Office Solution: Three Best-in-Class Products and One Total Solution" for doctors' offices, including Adiana, NovaSure, and Tower-free Hysteroscopy System (THS).

Several doctors questioned at AAGL said that one advantage for Adiana may be that NovaSure cannot be used after the Essure device is inserted because some of the Essure coil extends into the uterus. However, most doctors said that they

don't want to buy new equipment, which they would have to do with the Adiana System, and they said that they see no clear advantage to it.

The advantages of Adiana are:

- New generation of hysteroscopic sterilization technology.
- Does not contain metal or hormones.
- Does not protrude into the uterine cavity, so it may not interfere with future gynecologic tests or procedures.
- Well tolerated biomaterial.
- Employs the Procedure Guidance System interactive "smart" technology within the RF generator.
- No interference with the uterine cavity itself. The device is placed where the tube passes through the muscle.

The principal investigator for Adiana, Dr. Thierry Vancaillie of the University of New South Wales, Australia, said that new three-year data show that Adiana is well tolerated in 98% of patients, with most patients returning to normal activities within one or two days. Ninety-nine percent of patients reported overall comfort as very good or excellent. He said Adiana is simple to use, safe (with no perforations during the pivotal trial and no allergic reactions or need for removal), and 98.4% effective based on 3-year trial data.

Long-term efficacy of Adiana

Dr. Ted Anderson of Vanderbilt Medical Center presented three-year results of a single-arm, multicenter trial which showed that Adiana is 98.4% effective for prevention of pregnancy and similar to other permanent sterilization methods. The trial, conducted at 16 sites in the U.S., Australia, and Mexico, evaluated the efficacy of Adiana for preventing pregnancy in 645 women who wanted permanent sterilization. Doctors placed the polymer matrix hysteroscopically in patients, and tubal occlusion was confirmed by HSG at 12 weeks.

The bilateral matrix placement rate was 95%, with 88.4% bilateral occlusion by HSG, as previously published. As of July 2008, 24,968 person-months of wearing were accrued. The researcher said that the ectopic rate was <15%, consistent with tubal sterilization.

3-Year of EASE Trial Efficacy with Adiana

Measurement	12 months	24 months	36 months n=481
Number of pregnancies	6	3	0
Cumulative pregnancy prevention rate	98.9%	98.4%	98.4%

Dr. Anderson said that of the six pregnancies reported during the first year, three were due to misinterpretation of HSG results, and the remaining three were attributed to method failure, as were three pregnancies during the second year.

Two doctors were overheard discussing Adiana, and one said that one of the three failures was the result of the doctor putting two devices into one fallopian tube, leaving the other tube open.

At a Hologic breakfast on the Adiana system, Dr. Vancaillie said the HSG evaluation (by radiologists) “is an integral component of the Adiana procedure. The pivotal trial showed a 94.7% bilateral placement rate, 85.4% reliance at three months, and 88.4% reliance at six months. Fifty-three percent of the procedures are performed with minimal or no sedation, and the mean procedure time is 11 minutes and 54 seconds. The non-ionic hysteroscopic distention media used is glycerin, manitol, sorbitol, etc.”

Asked about the 15% failure rate, Dr. Vancaillie said, “The answer is that we really don’t know... There were irregularities in performance and orientation of HSGs. This has led to changes in the ways HSGs are done... This is an imperfect test. You’re asking to test something that it is not designed to show you, something that it’s not really designed to do. There is also always the question of the resolution of the test (i.e., the nature of the equipment you’re using to interpret HSG). We feel fairly confident that there is no recannulization that occurs... In looking at patients who have long-term implants in place, we don’t see cannulization, so how someone gets pregnant after an HSG shows total occlusions, we don’t know. We’d love to know the answer to these questions.”

Another doctor asked, “Since the device is not radio opaque, how can you be assured that you’re not seeing a tubal spasm because you can’t see the device?... Could it be from the 30%-60% chance of tubal spasms, especially depending on operator experience and how it’s done?” Dr. Vancaillie answered, “When you have little discomfort from procedures, I don’t think that you have that level of spasm.” The doctor who asked the question said, “Do you have the data to confirm that? I don’t see how you can say that. The whole tubal junction is muscular, and the spasm could be anywhere, so unless you have some data, I still don’t see how you can see it well enough... I suspect mostly radiologists are doing these, which is going to add another problem to the mix.” Dr. Vancaillie said, “The HSG will be a problem as long as we keep using it.”

A third doctor asked, “I wanted to clarify: on the 98.4% effectiveness rate, is that in patients who were documented complete occlusion or was that the entire population?”

- *Dr. Vancaillie*: “That is the population.”
- *Questioner*: “So if you have 12% of patients who do not have documented occlusion, do you counsel patients going in that there is only a 90% chance that it will work, and do they accept that?”
- *Dr. Vancaillie*: “That is an issue for hysteroscopic sterilization anyway and something that we will have to address.”

A skeptical physician asked, “I have been performing Essure since it came out, and I don’t see a clear advantage of Adiana. What do you think is the potential advantage of Adiana over Essure?” Dr. Vancaillie responded, “My main concern with the Essure is that it does interfere with the uterine cavity. It’s all right if the patient stays with me, but I’d be concerned with that patient going to (another doctor). So, that is my main reason – the fact that there is no portion of the (Adiana) device inside the uterine cavity.”

BAYER/SCHERING-PLOUGH’s Mirena

Doctors said their patients love the Mirena IUD, and its use is increasing, especially among younger patients. Mirena, which is made of plastic and T-shaped, contains a synthetic hormone called levonorgestrel that is released into the bloodstream. The device can remain in the uterus for up to five years. It has a 99% success rate and can result in lighter periods that sometimes go away altogether.

- *Louisiana #1*: “Our patients like Mirena. Their periods are light, or they don’t have periods. If I have patients who want permanent contraception but have bad cycles, I convince them to look at something reversible because it has such a good success rate.”
- *Louisiana #2*: “It is a great device, patients like it, and its use is increasing year-to-year.”
- *Wyoming*: “I’ve done thousands of these. As a whole, Mirena is very well tolerated, and it suits the lifestyle of the current generation. There is no maintenance, and it lasts a long time, is reliable, and is more effective than a tubal ligation. It has great efficacy, and there is low evidence of side effects. It is very popular, and I put in about 10 a month. I doubt that will change with the current generation of women of reproductive age.”

BAYER’s Yaz Birth Control Pills

Doctors and their patients like this combination drospirenone and ethinyl estradiol birth control pill, and its use is stable despite advertisements by lawyers looking for Yaz “victims.” Doctors said that Yaz works for a number of conditions, including hirsutism, premenstrual dysphoric disorder, and premenstrual syndrome (PMS). As much as 15% of birth control prescriptions are for Yaz, and that is not expected to change. Comments included:

- *California #1*: “I like it. It is useful for other things, such as acne and hirsutism.”
- *California #2*: “I use it. It causes less bleeding.”
- *Kentucky*: “I haven’t seen any contraindications in my patient population. You can get a DVT (deep vein thrombosis) from pregnancy.”
- *Louisiana*: “I prescribe it, but I’m seeing an uptick in people who are having to be practical for costs. They’re starting to see higher copays for their pharmaceuticals.”

It's a good pill, but patients are sometimes thinking that they can get the old generic at Wal-Mart for \$9-\$10 a month. There are certainly a large percentage of people who do well on it...It really helps, and a lot of people feel better, including those with acne or hirsutism, but almost all the pills will do that, too."

- *New York*: "My patients ask about the (negative) advertisements, but I tell them that all birth controls have the same risks."
- *Texas*: "I prescribe it. It has fewer side effects than other pills."
- *Wyoming*: "The potential risk of DVT has always been there from the beginning. I prescribe it. About 15% of my birth control prescriptions are Yaz."

ENDOMETRIAL ABLATION: HOLOGIC's NovaSure

Doctors use NovaSure, saying that it works well, is minimally invasive, and stops bleeding. A few doctors said that they liked Boston Scientific's Hydro ThermAblator (HTA), a hydrothermal ablation system, better. Most sources said that NovaSure is just one of many procedures in the surgeon's armamentarium. In general, doctors like NovaSure, and its use is increasing slightly.

Advantage Claims for NovaSure

Advantages
Can be done in physician's office
Increases practice diversity
Reduces OR time
Ease of access/scheduling
Increased comfort for doctors and patients
Hysteroscopy can be done at same time to look for large fibroids

Comments about NovaSure included:

- *California #1*: "NovaSure seems to be the most popular procedure."
- *California #2*: "It is simple for thermal ablation. I use it a lot because it results in less bleeding."
- *Florida*: "People like NovaSure. It works very well."
- *Kentucky #1*: "It is a good procedure. Is it the best? I can't say that it's the best. There are a lot of procedures for doing ablative techniques. I used to like the HTA systems. Some things are better in some people's hands, so it's among the many procedures (available)."
- *Kentucky #2*: "I love NovaSure, but it's not 100% successful. The data on fibroids aren't as good. I also use ThermaChoice (Gynecare's uterine balloon therapy). This market is growing, but it doesn't eliminate the risk of uterine cancer, and it doesn't address bulk symptoms."

- *Louisiana*: "The FDA approval of NovaSure said that you have to do Essure first and get a basic HSG test to show that the tubes are blocked. Then, three months later you do the procedure. You could do it at the same time off-label, but if the patient gets pregnant because the HSG isn't done, that can be a big problem. There are a lot of issues, and the costs are high for the equipment. And if you do it at the same time, you get paid as much as half of one of the procedures. In the hospital, the pay is much better, but if you do it for the patient's convenience and the convenience of doing it in the office, you may lose money, so it's a penalty to do two things. The system is set up for hospitals and not offices...We use it. I've looked at the HTA system, too. Everything is a system, and a lot of these things are not interchangeable. I've looked at small systems to check out polyps, and you have to buy separate equipment."
- *Nevada*: "It has a place. Some patients don't want to take six weeks off for a hysterectomy. Also, it works great. It is minimally invasive, stops bleeding, and is perfect for someone in a small practice who doesn't have that much learning to do. It's really wonderful. For some large fibroids, it is not the procedure to use. It is good for the small uterus and smaller fibroids."
- *New York*: "I don't love NovaSure. I like HTA better. It is good to visualize the cavity before and after the procedure."
- *Ohio*: "I do 10-12 a month. Next year it will be 15 a month. NovaSure is slick and easy to use under local anesthesia. It's important that you be careful about patient selection, (i.e., no obese patients). The worst reaction I had was a vasovaginal reaction. We do advertise NovaSure, Adiana, and THS...And the company (Hologic) markets it as a Total Office Solution."
- *Oregon*: "It (NovaSure) is a very good alternative to hysterectomies for treatment of menorrhagia. We try to avoid surgery as much as possible and try to be as minimally invasive as possible. The second-generation devices are simple to use, and there is less risk of complications. Cost, ease of use, and efficacy all come into play. You get people who are very good at it. They use HTA (hydrothermal ablation)...We use NovaSure and ThermaChoice. Patient satisfaction is very high with those. At my hospital, they tie part of our salary to patient satisfaction."
- *Wyoming*: "There are many systems for endometrial ablation, as many as for hysterectomies. NovaSure is my favorite of the third-generation ablation techniques. I've used them all except for the HTA system. I like NovaSure the most because it is fast – 90 seconds or less. It has 50% of the market now but that probably won't change because the market is saturated. Most doctors are doing ablations; they have the equipment, they have their own systems, and I'm not sure there is much growth there."

PELVIC FLOOR REPAIR

There was a lot at AAGL on pelvic floor repair and supporting systems. A California doctor said, "This group is paying a lot more attention to pelvic floor material for laparoscopic approaches and the new transvaginal minimally invasive approaches – using mesh for pelvic floor support." A New York doctor said, "(The mesh kits) are all pretty much the same in that the polypropylene is the best material for vaginal use. The pore size is good and enables more blood vessel growth...with diminished risk of infection in the vaginal area (which is not as sterile as the abdomen)...There are subtle differences in composition and some subtle differences in the way the product deploys."

Mesh kits for prolapse: the controversy

Most doctors said that the recent FDA bulletin asking doctors to discuss with patients the potential problems associated with mesh kits for pelvic organ prolapse (POP) vaginal repair has not significantly affected their practice. Several said that they are making a point of telling patients some of the potential problems associated with mesh, including pain, infection, voiding dysfunction, exposure, fistula formation, and erosion. Some doctors flat out will not use the kits, but others said that success depends on the physician's experience and technique.

This conversation about mesh took place during one of the AAGL symposia:

- *Audience member:* "In my practice I have a three-page consent form, but patients ask if I'm going to do mesh."
- *AAGL past president:* "I have the conversation (with patients) that we can use mesh or not use mesh. When it comes to SUI (stress urinary incontinence) and slings, it's different. Also, every once in a while you have a mesh-phobe."
- *Panel member #1:* "The lawyers are also definitely plugged in here."
- *AAGL past president:* "I have modified my practice partly because of the FDA. I send patients home from the post-operative visit with a copy of their pre-operative note."
- *Panel member #2:* "We need to take a long and harder look in the mirror and ask ourselves how we address this with teaching. We need to make a decision about what to do and not pick up the latest new thing. There is absolutely a learning curve, and it takes years to perfect your technique...In my opinion, vaginal mesh should be reserved for certain conditions. I don't believe that it should be used universally. It has to be a colossal or recurrent (problem) or have some other risk factor. As for age and sexual activity, it's the young person you're most concerned about. With them, it has to last the longest, and they are the most sexually active."

The concern-is-overblown view

Other doctors were less concerned about the FDA letter, saying it was just that – a caution to be sure doctors properly consented their patients. Comments included:

- *California:* "The statement was very general and misinterpreted by most people. If you read it very clearly, it was very generalized...It was written by a radiologist at the FDA, and the person didn't say that mesh was bad. It said that you need to be aware of the possible complications, patients need to be told about this in their informed consent, and people should have adequate training before starting to use it. But if you truly read it, it wasn't a condemnation of mesh at all. So, it's the kind of thing that is seen through the viewers' eyes...It didn't say anything really damning. It was put out at a time when a lot of people are trying to make the decision (to use mesh), and so it has more of an impact on generalists."
- *Florida:* "It has brought out into the open the issue with grafts, and more patients are coming into our office and ...asking if we are going to use mesh...This topic has made it into women's magazines, the internet, and other sources of information, so it has brought it out in the open. I don't know if it's affecting surgical volume, but it is impacting the need for informed consent...When addressing the risks of any procedure with synthetic mesh, erosion will occur in a certain percentage of patients even in the best of hands. I would call it expected consequences to be addressed, not a complication. The bigger matter is who should be performing these procedures – what are the training and qualifications. We are a ways away from achieving consensus on that."
- *Illinois:* "I don't know for sure whether sales have gone down as a result. I spoke to people who have stopped using certain materials as a result of the FDA public health notification. It's important what it does and doesn't say. It doesn't say, 'Don't use mesh.' It says that you should be trained and understand the complications...The problem tends to get exaggerated in people's practices."
- *Rhode Island:* "The FDA didn't say anything new that we shouldn't already be telling patients. You need to be aware of the complications specific to the materials. The erosion rate is somewhere between 5% and 10% in experienced hands; 5% require partial or total excision, 10%-17% of patients experience *de novo* dyspareunia, and that is the most difficult to discuss with patients. We have seen multiple perineal abscesses and sinus tracts as a complication of vaginal mesh...So, there are consequences for leaving materials in places where we're not used to leaving materials." He said that the problems might not be so much the mesh materials as technique.
- *Kansas:* "There are also *de novo* dyspareunia rates with non-mesh...We haven't done a good job with mesh, but we also haven't done a good job with non-mesh repairs either. What is an acceptable level (of complications)?"

- *Massachusetts*: “My colleague is a urogynecologist, and he uses various vaginal mesh. He has tried them, but he hasn’t cut down because of the controversy.”

Dr. James Ross, a California physician who is developing a mesh kit, said, “Actually, several reviews over the last two years, especially this year, have shown that there are no higher complication rates with mesh and statistically the long-term outcomes are significantly better than non-mesh repairs...One of the reasons a woman has pelvic floor descent and breakdown is that she makes poor connective tissue. So, if you use her core tissue that’s already broken down...it is a sign that the (repair) will break down again because of the poor material...like (happened with) orthopedic surgery 25 years ago when they started replacing hips. Body parts wear out, and if you can come up with a good replacement system, you’re going to be way ahead of the game. Even the people who are anti-mesh have been on some of these review papers ...and they showed quite clearly that the long-term outcome of success was significantly higher with mesh repair.”

Dr. Ross said that the hottest item in pelvic floor surgery is the development of better mesh kits. There is a group (that feels differently), but I worked in the development of mesh kits for the last five years and the use of them is growing by leaps and bounds and their success is increasing significantly. Some of the early complications that we are seeing – are being eliminated. There is less erosion – that is my specialty in developing a new mesh right now that I think will be erosion free. It is new material that is not inflammatory and is extremely soft and easy to work with and it doesn’t have the characteristic stiffness of the material most mesh kits are made of now. So pelvic floor repair is the hottest thing in gynecology right now.”

He added that those arguing against mesh “all use mid-urethral kits for urinary incontinence, and that’s made out of mesh. I’ve used mesh for pelvic floor support for more than 24 years and for all our sacrocolpopexies...I’m not saying that mesh doesn’t have its problems, but it’s like any new technology. It is in the rapid stage of development and improvement.”

Dr. Willy Davila of the University of Texas Medical School, Houston, said, “(Combined grafts) may be beneficial and may save some time in the OR. There is a lot of literature now coming from results of studies around the world. (Gynecare’s) Prolift preliminary results have been updated, but...the results are quite good, and the failure rate is quite low, only ~6%. In general, erosion rates are quite high – overall 14% – but if there is no hysterectomy, the risk of erosion is quite low at ~5%. Recognized issues with synthetic grafts include erosions and sexual dysfunction. Are they complications or expected treatable consequences? For example, in urinary retention after TVT (transvaginal tape) there may be complications, but there are also expected consequences. For example, you’ll need to transect a tape in a percentage of patients. Discussing the risk of erosion preoperatively is what the FDA recommended. The important thing is that we’re really talking about

Type 1 polypropylene mesh, not Type 2 or 3. As for sexual dysfunction, the data are actually quite reassuring. The dyspareunia rate is not increased in graft groups; it is no higher than baseline. In the anterior wall, we have a choice of synthetic (mesh), which has longevity, but erosions can be a problem, and a biologic, which may break down too quickly. There is no erosion with a biologic, while synthetics may have 3.8% - 10% erosion.”

The mesh-should-be-avoided view

Some doctors try not to use mesh kits or refuse to use them altogether.

- *California*: “Vaginal mesh kits are non-anatomic and vaginal shorting. I believe that unless graft material is improved, mesh kits should be used sparingly.”
- *Kentucky #1*: “Mesh kits aren’t such a good idea. They are creating some problems, and this is where I would lean toward using natural anatomy.”
- *Kentucky #2*: “I’m also a lawyer, and I’ll say that meshes are wonderful – in the right hands and for the right patients. A lot of doctors are not properly trained, and patients have complications. You’ll see that as cases accumulate, so will the number of major complications, and you’ll see some backing off of the procedures. There are some big problems with mesh, and urogynecologists should be the ones using them.”
- *New York*: “I use mesh kits for prolapse. I can use them for anterior, uterine, and rectal prolapse. Without mesh kits, we do well with posterior and pretty well with apical. Without them, we don’t do so well with anterior defects. I use the kits very, very rarely. For posterior we don’t have the benefit there to offset the risk. With anterior we get about 20% -25% better success rates. For apical, it’s a 14% better success rate.”
- *Virginia*: “I won’t use the kits because there are no long-term data, and they can result in pain and erosion. I can’t in good conscience recommend them, especially to younger, sexually active patients. With colpopexy, however, there are good data with mesh.”

Mesh slings

As for mesh slings for female stress urinary incontinence, most doctors said that they work well, use small incisions, are much less invasive, and are the area of greatest growth in pelvic floor surgery. However, some doctors warned that there are not enough long-term data on problems like erosion. An innovator in the field said that in the last few years researchers have been working on one-incision slings. Boston Scientific, American Medical Systems, and Gynecare all have them. CR Bard has one doing well in Europe, but it is not FDA cleared yet. He said, “Bard’s advantage over the others is that it is adjustable once it is in place, and the others truly aren’t.”

Comments about slings included:

- *California*: “The slings have been in our hospital for more than five years, and I’ve done 700-800 or more, so there have been probably way over 1,000 done, and this is the only time mesh has gotten into the bladder. That said, the market growth for sling implants continues to grow steadily. The midurethral slings now probably have >95% of the market, and our pelvic floor business is going up tremendously. It’s harder to judge how fast it is growing in the generalist population, but it is far and away the most rapid growth in pelvic floor surgery.”
- *Kentucky*: “I think that the use of mesh has reached a sort of frenzy, and we are seeing a lot of complications from slings and a lot of erosions. So, I think that some of the glamour is wearing off...TVT particularly has a lot of erosions compared to TOT (transobturator).”
- *Maryland*: “I use a variety of different types of slings, and there are some slings which are really small now and sit under the urethra to hold everything up – like the MiniArc Single-Incision sling (from American Medical Systems) – and I believe these are the future.”
- *Nevada*: “I sometimes work with a urologist who does the sling. I do the repair and let it erode on somebody else.”

Complications with transobturator (TOT) slings

As far as complications with TOT slings go, Dr. Edward Stanford of Illinois said, “You can’t trust the companies. What we have to rely on is what’s in the literature, and much of that literature is quite delayed. Doctors are not as forthcoming sometimes when things happen to patients...(Pain complications) weren’t reported much until we started using TOT slings.”

Dr. Stanford examined the literature covering 13,700 patients and found an overall 14.6% incidence (2,268 patients in 20 studies) of voiding dysfunction and detrusor overactivity as a result of slings, “Across the board, all slings taken into consideration, 15% of these patients will have voiding dysfunction as a complication or postop. That’s 1 out of 7, and I wonder how many (doctors) will tell their patients (that). As for the FDA warning...or I should say statement...we have to be better at informing patients about what is going to happen: ‘I am going to fix your incontinence, but 15% of the time you are going to have some difficulty in your voiding.’”

An examination of 14 studies with 943 patients showed an overall urinary retention incidence of 14.2%, with urethrolysis reported most commonly for TVT in 7 studies and 446 patients, Dr. Stanford said, adding, “One of the things we key on in urodynamics is extrusor pressure. If she (the patient) can’t generate more than 15 cm of water pressure to void, I’m not putting a sling in that patient because what will happen is she will retain (urine). She has to know she might have retention, and she may have to self-cath. If someone has very little

voiding pressure, that’s a red flag that she’s going to have possible retention.”

Dr. Stanford said that 4.3% of patients in two studies (175 patients) experienced dyspareunia, and about 20% had pain during sexual intercourse after a sling implant. Erosion and extrusion is “most common with Type III synthetic materials. In 16 studies (with 2,275 patients) the incidence was 5.14%...I had a couple that didn’t heal properly, and I had to take the sling mesh out. I treated them...and they did heal, but I think that this was an actual erosion...So, when you are counseling a patient, you should say that there is a 1 in 20 chance that you’ll spit some mesh out, and we’ll have to treat you in the office.”

Infections are most often uterine infections, but severe infections, such as abscess, are reported, according to Dr. Stanford. In 19 studies of 1,727 patients, there was a 6% overall incidence of infection. Hematomas “are most often pelvic or vaginal. In 4 studies of 450 patients there was 2.7% overall incidence. I put in a transobturator sling. Is it a complication? I had one patient who had a huge hematoma which tracked down her thigh all the way down to her calf. She didn’t lose that much blood, but the statement of the day that day was ‘Holy Cow.’ Now I give Coumadin (warfarin) or Plavix (Sanofi-Aventis, clopidogrel) for two weeks and operate on them in the third week.”

As for pain, Dr. Stanford said that pain is usually in the thigh and most common with TOT slings. Abdominal and pelvic organ injuries usually involve the bladder, urethra, vagina, and intestines. There was a 3.7% overall incidence in 10 studies of 2,576 patients, “You want to avoid lacerating the urethra. It’s slightly unforgiving. Lacerating the vagina isn’t too uncommon...Intestinal damage is reported most often with the retro-pubic approach, mainly the TVT, and some patients have died from delayed diagnosis. It’s avoidable with proper dissection and knowing where you are. Bladder perforation is the most common complication for TVT, with a reported incidence of 0.8% - 34%. Most commonly, it is <10%. It doesn’t affect the efficacy of the treatment, but it is a major issue if it is missed...There is an 85% success rate (with the sling)...Some studies use a lower percentage, and some a little higher. There are patients who are going to get re-operated on. I didn’t consider this a complication, and I usually tell patients that there is about an 85% success rate with these procedures.”

Mini-slings

Mini-slings are attractive because they are less invasive. One doctor said, “If you can get the same results with a smaller amount of material plus a very small minimal dissection, that could possibly be done in an outpatient setting or an office setting. That’s where the mini-slings will show up.”

Doctors consider American Medical Systems’ MiniArc to be attractive. They said it is ergonomically friendly, less invasive (single vaginal incision, no mesh beyond the obturator), done

in an outpatient setting (i.e., doctor's office), and has a 91% success rate at six months. As of November 2009, 55,000 units had been implanted.

However, doctors said there are several factors to keep in mind when using a mini-sling, including:

- There are some nuances to the procedure that require special care, such as trajectory and tensioning.
- Patients should follow simple post-procedure care instructions – no heaving, lifting, or intercourse for a minimum of four weeks.
- Success really depends on tensioning because there is no standardization.
- Sling tensioning techniques can be too tight or too loose.

Mesh for sacrocolpopexy vaginal vault prolapse

Doctors agreed that sacrocolpopexy is the gold standard for pelvic organ prolapse. However, many doctors will only do the procedure laparoscopically. A Pennsylvania doctor said, "I don't do vaginal mesh. We do it all laparoscopically. Vaginal mesh was easy to adopt and easy to learn, but it is now controversial...The problems are due in part to the technique and experience of the doctor and partly to the mesh itself. It is not the same as the abdominal prolapse procedures." A Maryland doctor said, "The gold standard for prolapse is abdominal sacrocolpopexy, where you attach it to the sacrum. That can be a big operation doing it abdominally, and it is difficult to do well laparoscopically because of all the suturing, but it is a perfect application for the robot. You can do these advanced procedures with it (da Vinci). We still do a lot of prolapse procedures vaginally, but for abdominal repairs I do all of them robotically. I use the sacrocolpopexy for holding things up. I use mesh in certain areas but not as a kit. I use mesh to hold up the bladder and hold down the rectum."

Dr. Robert O'Shea of Australia said that abdominal sacrocolpopexy (using non-mesh) is the gold standard, with good efficacy results, improved sexual function, and long-term satisfaction, "There is no doubt that we have moved on gradually from the open approach to the laparoscopic approach, and the popularity of this procedure is increasing, whereas the use of mesh in the vagina and through the vagina has provoked a lot of controversy. Using mesh in sacrocolpopexy hasn't received the same controversy...Repair of the vaginal vault is the centerpiece of prolapse repair. In our unit, we have had a number of vault failures using laparoscopic mesh sacrocolpopexy. Success depends largely on age and treatment, and results may vary. In the procedure, the vault is dissected. Then, the sacrum is dissected. Here, one has to be wary of lateral structures and peritoneal dissection...The idea is to...do it well medial to the ureter, so you don't risk kinking it later when you close the perineal. Then, suture the mesh to the vault. There are many ways to do this, and it is hard to get a consensus. I use absorbable suture, and some use monocryl. I know some non-absorbable sutures and PDS (polydi-

oxanone) is commonly used as well. I'm not sure that there is any consensus as to absorbable vs. unabsorbable. Helical screws to the sacrum are also used. There may be a case for using the helical screws to fix the mesh to the sacrum as it is somewhat safer than suturing."

Dr. O'Shea said that mesh erosion rates are ~6%, "This may reflect inexperience, but it reduces blood loss, etc. As for mesh erosion management, conservative approaches often don't work. In the end, if there is significant erosion, you have to go back in. It isn't easily treated in the office."

Dr. O'Shea said laparoscopic sacrocolpopexy with mesh:

- Is anatomically and technically achievable.
- Has an acceptable complication rate.
- Has a high objective success rate.
- Requires certain technical skills (suturing) and possibly absorbable staples. He said, "There are some absorbable staples coming on the market, and the use of them may well allow one to actually perform this procedure without actually doing any suturing in the future."

Dr. Charles Rardin of Brown Medical School talked about the debate in urogynecology over complications from laparoscopic sacrocolpopexy:

- While failure rates are high, with a 30% to 40% chance of having to do it again, the majority of patients are affirmatively fixed.
- Most patients don't need mesh, and it may cause an unsalvageable complication because of something the statistics said isn't needed in the first place.
- There is a fear of erosion, but most erosions are easily managed.
- Innovation for its own sake isn't necessary.
- Prolapse is not a form of hernia, and the abdominal wall and the vagina are not the same.
- While early adoption may be a market differentiator, doctors should choose their bandwagons carefully.

Dr. Rardin said that erosion rates vary from 2% - 25% and are often managed conservatively with topical estrogen or office-based trimming. However, he said that "Most of the data show something like 50% require a trip back to the OR to address the issues, whether it is substantial trimming with mucosal closure or complete excision. Rare but dramatic outcomes include transrectal passage, infection, and osteomyelitis."

