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WATERSHED MOMENT FOR SUBMUCOSAL FIBROID AND POLYP REMOVAL

In the field of women's health, abnormal uterine bleeding is responsible for the majority of all gynecological consultations. Studies have indicated that in more than 40% of the cases, hysteroscopic evidence of a submucous myoma or endometrial polyp will be detected. For many decades, surgeons have been challenged using the same surgical tools to address this critical area until a new product, MyoSure, was recently introduced by Interlace Medical (Framingham, MA; http://www.myosure.com).

Many of the cases that present are women who have infertility issues, so preserving the form and function of the uterus is paramount; using a resectoscope, a tool of the 20th century, for fibroid and polyp removal has been fraught with potential complications and inefficient surgeries.

MyoSure™ Tissue Removal System

The legacy surgical technique for hysteroscopic removal of myomas has been the monopolar loop electrode, a device that uses energy to burn as it cuts through tissue. Typically, this device is used with a resectoscope for visualization and articulation. The problems associated with this are many. First, to introduce the loop electrode the endometrial cavity is distended with non-ionic solutions such as glycine, mannitol or sorbitol. This demands constant monitoring of fluid deficits to avoid serious complications. Second, since the loop electrode is a head-on device, surgeons are very cautious to avoid perforating the uterus which can bring complications to the bowel and surrounding vessels. As the loop electrode is cutting through tissue, accumulating tissue debris called chips now begin clouding the visualization field and eventually the device must be withdrawn to remove the debris. Once again the surgeon must re-enter the cervix carefully to continue the procedure. The loop electrode is slow and cumbersome at best.

With Interlace Medical's MyoSure, the product development cycle for 21st century tools for OB/GYN surgeons is now complete. MyoSure uses a side approach to cut tissue, greatly reducing the possibility of uterine perforation. It uses mechanical energy to cut tissue, eliminating issues with burning sensitive tissue especially for women who want to retain reproductive capability. One of MyoSure's best features is its ability to clear cut tissue without having to exit and enter again, but aspirating the tissue though its stem while the procedure continues, keeping the field of visualization clear. The procedure can be done in an ambulatory or an office setting, under local anesthesia, reducing patient recovery time and costs. And it's fast. 30 minute procedures now take 5-10 minutes which translates to economic advantages.

Omid Khorram, MD, PhD (Board Certified Reproductive Endocrinology, Professor UCLA, Chief of Reproductive Endocrinology and Infertility Department of Obstetrics and

Gynecology, Harbor-UCLA Medical Center, www.obgyn.humc.edu) states, "The loop electrode uses electricity and is quite cumbersome but still is the prevalent technology in the marketplace. Myosure uses mechanical energy to morcelate tissue. The Myosure avoids multiple reinsertion of the device into the cavity to remove excised tissue because it simultaneously will evacuate the cut pieces of tissue and thereby significantly reducing operating time and minimizing the risk of of fluid overload. It provides clean-cut tissue specimens for pathological examination. This technique is 5 times faster than the loop electrode."

Indeed, surgeons who use MyoSure around the country enforces the idea that a new tool has arrived that is superior to the techniques and products of the past.

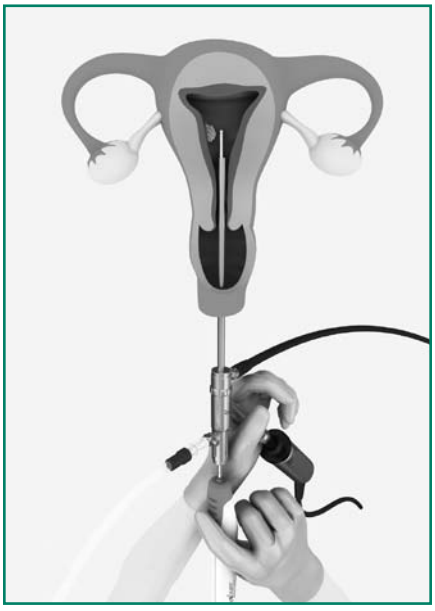
Speaking with Shahryar K. Kavoussi, MD, MPH (Board Certified Reproductive Endocrinology and Infertility Specialist, Austin Fertility & Reproductive Medicine, www.austinfertilityrm.com) about Interlace Medical's MyoSure, he comments, "The main advantages to MyoSure, in my opinion, are not having to dilate the cervix excessively as well as having good visualization and less time in the operating room per case. The MyoSure facilitates efficient removal of intrauterine lesions and not having to enter and exit the uterine cavity multiple times during the procedure is a significant advantage."

If surgeons were asked to design a near-perfect tool for hysteroscopic myomas, they would demand the following features: it would have to be small and compact. It must be easy to use to shorten the learning curve. It should use ionic media to decrease distension issues. The product must evacuate pathology that the instrument cuts and it must use mechanical energy to preserve tissue that is delicate. The device should have a very small blade with minimal or no dilation which is especially important with infertility patients and postmenopausal patients. Reduction in patient medication for office setting procedures would also be helpful.

Dr. Kavoussi continues, "With MyoSure, we can line up cases back to back easily because an intrauterine lesion that used to take 45-60 minutes to remove now takes 10-20 minutes. The product is particularly beneficial for the fertility patient since no thermal energy is used and the risk of perforating the uterus is minimized with the MyoSure design. This is a safe and cost-effective advance."

The MyoSure Tissue Removal Device is the way of the future because patients, surgeons and the medical marketplace demand it.

Dr. Khorram adds, "This provides a huge cost savings for hospitals. The procedure can be done in an ambulatory setting and can reduce the caseload in the OR. I work in a teaching hospital, so with MyoSure the learning curve is so much faster. Teaching residents with the old resectoscope technique took much longer because there are nuances that can only be mastered over time. With MyoSure,



MyoSure™ SYSTEM

the learning curve is much faster. There is no substitute for getting this procedure right the first time, reducing the need for a second procedure. Once people start using this product, they will find it so much easier and much more efficient." He continues, "With the resectoscope, the potential complication of perforation of the uterus with so much dilation is a problem; with MyoSure, this cuts down this complication. In summary, the MyoSure product brings to this procedure ease of use, reduced operating room time, less perforation complications, reduced fluid imbalance and less problems."

MyoSure… Fibroid Removal Simplified … Indeed.

For more information on Interlace Medical's MyoSure, visit www.myosure.com to fill out a contact registration form or call 508-875-1343.