The Use of a New Articulating Suturing Device with a Curved Needle in Bariatric and Hernia Repair; A Surgeon’s Clinical Experience of 1500 cases.

Scott Stowers, DO, FASMBS; Randall Wright, MD; Brenda McGuire, MBA, RD, CDE

January 4, 2016

Forward
Nicole Pecquex, MD, FASMBS

You are working in the abdomen doing a Laparoscopic Nissen Fundoplication with a resident attempting to suture the crus manually. While watching, you realize that learning to grip the needle to get an adequate bite is not as easy to teach as you would like. You also realize that tying a square knot laparoscopically has a learning curve. Short of sending your resident to log more hours in the skills lab, you wonder if there is a better way.

This is the exact situation that has prompted industry to come up with suturing alternatives to lessen that learning curve, speed up cases and provide a solid and safe method of suturing. There are currently few devices out there that make suturing easier. One of the devices utilizes a toggle with the suture connected at the center point. This device has certainly made intracorporeal suturing much easier and faster, but the toggle can get stuck in thick tissue and you do not have that same curved needle that you trained with in open surgery. Engineered to take the perfect bite with a twist of the wrist, penetrating tissue effortlessly. Curved needles are what we are used to, but suturing devices just didn’t have... until now.

EndoEvolution, LLC has listened to surgeons suturing needs in the OR and have come up with the first suturing device that has a curved needle, articulates and roticulates giving you access to tough angles that were difficult to suture before its arrival. The device has a pistol grip which allows more ergonomic suturing. With a simple dual click of the trigger you get a 360° degree revolution of the needle in its tract. This makes suturing and tying knots much faster than suturing manually.

Being able to articulate the tip of the instrument, allows much easier suturing in challenging angles, like suturing ventral hernia mesh to the anterior abdominal wall. It also is very useful in deep pelvic suturing and hiatal work. The needle and stitch size is also closely matched so that when the needle drives through tissue you do not create a larger hole than the suture can fill. This decreases the chance for leakage from penetration sites.

From a safety standpoint, the needle is always in its tract which allows safe entry into the abdomen without the fear that you may inadvertently get it stuck on tissue. With one click of the trigger you get smooth tissue penetration. Also, should you determine that you want to manually finish suturing for some reason; you can release the needle from the device and continue to suture laparoscopically without destroying the suture or needle.

In this Era of cost containment, the Endo360° device is reusable and often the ROI is seen, depending on case mix, in about 20-30 cases. The device is also available in three lengths for use in different areas. This device has certainly revolutionized my practice and made suturing quicker, safer, reproducible and much easier to teach to residents.
Introduction

Surgeons develop skilled hands through years of practice. Suturing is one of the skills which may be simple to learn, but requires years to master. Following the arc of a curved needle into tissue creates a natural path. The curvature of the needle provides a consistent depth of bite. The surgeon looks for the tip of the needle to protrude through the tissue, resulting in an appropriate bite; careful to approximate, but not strangulate the tissue. Extreme caution must be used to avoid excessive tension, which may break the suture and tear the tissue or lead to ischemia of the tissue. When a stitch loosens or knot slips, extra time is necessary to correct the situation. Suturing is a critical task in surgery to achieving a successful outcome– a skill surgeons continuously refine. The requirements for successful suturing are the same for open suturing as laparoscopic suturing. However, the practice of performing this suturing is markedly different.

Laparoscopic Suturing

The human hand performs many functions during surgery, which are difficult to reproduce with laparoscopic instruments. Strategically placed ports to manipulate tissue in laparoscopic surgery, rather than the surgeons’ hand, increases the risk of damaging tissue. The fulcrum effect, and a non-intuitive motor skill that is difficult to learn, adds to the complexity of suturing in laparoscopy. Laparoscopic knot tying is more challenging than manual knot tying in open surgery. Loss of depth perception and tactile feedback make placing accurate and well-tied knots challenging. For these reasons, surgeons were slow to adopt laparoscopy, despite the advances in technology and benefits to the patient. When suturing laparoscopically, surgeons still adhere to the same principles of suturing as in open surgery. Surgeons are taught to use their wrists with exaggeration, pronating and supinating to throw the needle. Exchanging the needle between the needle holder and grasper requires a surgeon use more upper body movements such as internal rotation of the shoulder, more elbow flexion, more wrist supination, and wrist ulnar and radial deviation. Laparoscopic suturing can be fatiguing for surgeons due to the repetition. An increase in arm fatigue can cause an increase in hand tremor. A study completed by the School of Engineering and Applied Sciences at Aston University found a reduction in a surgeon’s fine motor skills and reduced precision of the surgeon’s hand movement over the course of a surgical procedure. The conclusions of the study recommend surgeons should perform the most complex parts of the operation as early as possible.

Automated Suturing

Automated suturing devices have been created to reduce the complexity of manual suturing in laparoscopy. These devices increase the ability for surgeons to suture and tie knots. Many studies have shown using automated devices can decrease suturing time and operating time by as much as 50%. Data demonstrates inexperienced laparoscopic surgeons can easily learn how to suture and tie with specially designed automated devices. Yet, these devices require significant supination and pronation of the wrist, as most employ a straight or hook needle. The other downside of these devices is the inability to articulate and reach confined spaces.

Patients

Laparoscopic surgery reduces recovery times and infection rates, is superior to open surgery for post operative cosmesis and improves outcomes. Patients are now more educated about their surgical options, and will ask their surgeon about minimally invasive procedures rather than open surgery. In this fast-paced world, patients want to decrease their recovery time and return to normal activities as quickly as possible. Less scarring is another enticement of laparoscopy, as well as less post-operative pain, and outpatient surgery. Outcome studies have shown, in bariatric procedures, patients experience fewer post operative complications in the hospital and have a shorter length of stay with laparoscopy.
Curved Needle

While straight needles are the easiest to position and grasp with the jaws of a needle driver, they are difficult to drive through the tissue in an arc. Naturally, a surgeon will try to make her wrist turn like a curved needle. It is challenging to perform this motion in a perfect circle and impossible to repeat it consistently. Curved needles provide an arc which allows the wrist to complete the pronated scooping motion surgeons are trained to perform when suturing. When a surgeon drives a curved needle through tissue during suturing, the suture follows the curve of the needle. Following the natural path of the curved needle minimizes tissue trauma. Since there is no straight needles used in open surgery, there is a clinical need for a curved needle in laparoscopic surgery.

EndoEvolution, LLC

EndoEvolution, LLC developed Endo360° because the inventing engineers believed the optimal minimally invasive suturing device should mimic how surgeons traditionally suture when they do it manually, with a curved needle. Endo360° is the only automated suturing device which employs a standard curved needle and an articulating wrist for laparoscopic surgery.

Market Research

The options for surgeons suturing laparoscopically, prior to development of Endo360°, were either to suture by hand or automated suturing devices which use a straight needle. In August of 2014, a market research analysis was completed among high volume general and bariatric surgeons, to gain insight on current suturing device needs. Needle related issues topped the frustration list of the surgeons polled.

The polled surgeons identified their most desired solutions regarding suturing and tying knot devices.

- A device that automatically placed and tied the suture
- Fixed needle positioning
- A device that allows tying the knot in a single step rather than multiple passes
- A device similar to the Endo Stitch™ that would use a curved needle and be able to articulate.
- Needle holders that change angle like the robot’s wristed instruments, without the time and extra expense of the robot.

The Endo360° meets the requests most surgeons had regarding suturing devices.

Frustrations among Surgeons

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle Related</td>
<td>58%</td>
</tr>
<tr>
<td>Needle Positioning</td>
<td>33%</td>
</tr>
<tr>
<td>Knotting</td>
<td>25%</td>
</tr>
<tr>
<td>Time Consuming</td>
<td>25%</td>
</tr>
</tbody>
</table>

Intro to Endo360°

The Endo360° is a reusable automated suturing device which uses a curved needle. The distal tip is wristed.
for articulation. The handle is a pistol-like grip for ease of operation. Two full squeezes of the handle rotates the needle 360°. The needle is driven by a pawl in the needle track. The pawl moves in a 180° counter clockwise direction. This alleviates the wrist fatigue a surgeon often experiences when suturing either manually or with other automated devices. The curvature of the needle allows the surgeon to take up to an 8mm bite consistently. The device is available in three different working lengths for use in natural orifice, general laparoscopic and bariatric surgeries. Suture is available in non-absorbable and absorbable, as well as, monofilament and braided.

Clinical experience

Scott Stowers, DO, Medical Director of My Bariatric Solutions in the Dallas-Fort Worth metropolis, and his partner, Randall Wright, MD, have used Endo360°. Dr. Stowers, credits Endo360° with his ability to suture with such precision. According to Dr. Stowers, when he first saw Endo360° device, he immediately identified the device as, “A vast improvement over what we had before. We all learned to do open procedures using curved needles. This was the first time I’d seen an automated suturing tool that approximates what we do naturally.” After doing just a few cases, both surgeons felt comfortable using the device. As of July, 2015, Drs. Stowers and Wright have used Endo360° exclusively in over 1,500 bariatric and general laparoscopic procedures.

Articulation

Says Dr. Wright, “With its articulation and roticulation control, the device also allows us to access difficult-to-reach places.” The curved needle facilitates proper angulation. Because I’m able to articulate the distal tip, I feel that I am able to gain a mechanical advantage when placing sutures through the crura during hiatal hernia repair.” An added advantage, he notes, is the ability to tie intracorporeally, rather than extracorporeally using a knot pusher.

Accuracy and Precision of the Curved Needle

For both surgeons, the device’s biggest advantages include the sharp tapered tip of the needle and the ability to place the needle with precision and to control depth, which enables them to produce uniform stitches.

“When you use straight needles, there’s no control over how deep into the tissue you drive the needle; it’s more of a guess,” notes Dr. Stowers. “Squeezing the handle of the Endo360° device slightly advances the needle enough to see the tip as it passes through the tissue. And we can achieve a nice bite because of the device’s wide jaw, which allows us to control depth.” Furthermore, Dr. Stowers recalls that when he did use straight needle devices, he would typically need to twist his wrist to arrange the needle in the right direction: “As you’re driving the needle through the tissue, the needle should always follow the arc of its own curve. With Endo360°, the driver of the device mimics the scooping motion initially taught when suturing manually. So you don’t have to push the needle through; it drives like it is supposed to. You can’t hardly mess it up; it’s a perfect stitch every time,” Dr. Stowers emphasizes.
Needle-to-Suture Ratio

While the laparoscopic approach has been proven to have fewer risks of complications than traditional surgical techniques, those complications — such as digestive fluids and partially digested food leaking through the anastomosis after bypass surgery — are an ongoing concern for bariatric surgeons like Dr. Stowers. To help alleviate this critical issue, Endo360° offers a close needle-to-suture ratio, ensuring that the suture fills the hole created by the needle. Says Dr. Stowers; “The suture is not dragged through the hole alongside the needle, as with other devices, so there are far fewer incidents of leaks than when using larger needles.” In fact, Dr. Stowers says that since using Endo360°, he knows of no instance in which a patient has experienced leakage.

Safety

Because of its design, the device isatraumatic to the tissue. “When you squeeze the handle of the Endo360°, it goes through in a natural path; there’s not as much resistance, so it doesn’t traumatize the tissue,” notes Dr. Stowers. In addition, the Endo360° needle is always enclosed in the distal tip of the device, limiting needle sticks. Says Dr. Stowers: “The design of the device makes it much safer to use inside the body. The needle stays in place, so there’s much less chance of puncturing adjacent tissue or organs and causing bleeding.”

Reusability

On average, Dr. Stowers and Dr. Wright each perform 60 to 80 procedures a month using the Endo360° device. Another reason to make the switch to Endo360° is because it is reusable. As Dr. Stowers explains, “With other suturing devices, you need to dispose of them as medical waste after one procedure. With Endo360° you just purchase disposable cartridges. Wise Regional Health System recouped its original investment in less than two weeks, after about 30 cases, and that helps us keep costs down for our patients. Plus, all that medical waste is kept out of our landfills.”

Low Learning Curve

Says Dr. Wright: “Because it is intuitive to use, there’s a low learning curve. Anyone doing any type of laparoscopic procedure can get up to speed quickly.” As of June, 2015, Dr. Wright, who uses Endo360° for many types of MIS procedures from fundoplication with mesh repairs to hernia repairs, says the device makes it easier and quicker for him to sew through mesh products and thicker tissue. “With straight needle devices, I often wasn’t able to take a big bite of the tissue without getting the needle and suture caught up in the tissue. Because of the Endo360°’s wide jaw, I can get a really good bite of the fundus.”
Conclusion

The consequences of under-developed laparoscopic suturing skills in surgery can lead to long surgery times and post-operative patient complications. It is well established in the clinical literature that laparoscopic suturing is one of the most complex and time-consuming skills for a surgeon to master. The space and visualization constraints of laparoscopy make laparoscopic suturing substantially more challenging than external suturing.

To simplify the learning curve and improve the quality of laparoscopic suturing, Endo360° was designed to work the way surgeons traditionally suture. Because it uses a curved needle, Endo360° gives surgeons the same level of precision and control for MIS suturing as when they suture externally. The wristed articulation allows surgeons the ability to reach confined spaces. When compared to MIS suturing instruments, which use a straight needle, Endo360° needles are less destructive to the tissue. A curved needle decreases the potential for additional tissue trauma and, as a result, decreases the potential for post-operative leaks and tissue dehiscence.

Simple hand squeezes decrease wrist and forearm movement and simplifies laparoscopic suturing for surgeons by giving them superior precision and control of a curved needle in an articulating automated device.
References


7. Ozawa, MD, PhD, FACS, Soji, MD, PhD, Yasuhide Morikawa, MD, Junya Oguma, MD, PhD, FACS, Yuko Kitagawa, MD, PhD, Hironori Asada, and Md, PhD, FACS, Masaki Kitijima. “Development of a New Flat Needle and a Reduced Surface Coating Thread for Endoscopic Suturing.” Journal of Surgical Research, 2008: 266-271.

Acknowledgements

Dr. Scott Stowers, DO, Board certified in general surgery and an experienced bariatric surgeon, earned his Doctor of Osteopathy at the Texas College of Osteopathic Medicine. This was followed by a medical internship at the Dallas / Fort Worth Medical Center, where he also completed his residency in general surgery and ultimately served as Chief Resident from 1991 to 1992. Currently, he is the medical director of My Bariatric Solutions, located in Decatur and Fort Worth. He is also an adjunct professor of surgery at the Texas College of Osteopathic Medicine, UNT Health Science Center, Fort Worth, Texas, and member of ASMBS and an ASMBS Site Surveyor and ASMBS Fellow.

Randall A. Wright, MD, a Board certified general surgeon, graduated from the University of Texas Medical School at San Antonio in 1993. He practices medicine in Bridgeport, TX and specializes in general surgery. He is also an adjunct professor of surgery at the Texas College of Osteopathic Medicine, UNT Health Science Center, Fort Worth, Texas.

Nicole Pecquex, MD, FASMBS, is a board-certified surgeon and the Director of Bariatric surgery at St. Elizabeth’s Medical Center. She has completed an advanced laparoscopic fellowship training and has surpassed her 1,000th surgery which includes Laparoscopic Gastric Bypass and Vertical Sleeve Gastrectomy combined. Pecquex has been a member of St. Elizabeth’s surgical staff since 2004. Dr. Pecquex also has an academic appointment of Associate Professor at Tufts Medical School.

For more information about Endo360°, contact EndoEvolution at 1-855-363-6360, or visit www.endoevolution.com for surgical videos and additional product information.