Laparoscopic TAPP Inguinal Hernia Repair Using ENDOEVOLUTION Endo 360° Suture Device

– *A CQI project to improve value for the patient and the healthcare system*

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Introduction:

Until recently, the tools used in healthcare outcomes research have been based on reductionist science principles. In this paper, clinical quality improvement (CQI) principles were used to attempt to improve the value of care for patients who underwent a laparoscopic transabdominal preperitoneal (TAPP) inguinal hernia repair. Applying value-based CQI allows for a more complete understanding of our world through the application of complex systems science which helps to identify the factors that contribute to both positive and negative outcomes from definable patient processes and patient subpopulations. These factors are constantly changing and are interconnected with other factors that contribute to outcomes. If they are tested in isolation, as attempted in a prospective, randomized, ***controlled*** trial, the potential measurement of the impact of any one factor will be likely inaccurate. It would also only apply to the selected group of people in which that factor was tested and only in the environment in which that experiment was completed. The tools we have used to attempt to discover static truths in healthcare will need to be replaced by tools from complex systems science (also known as information or data science) which should be applied to all patients (no inclusion or exclusion criteria) in many different local environments.

Where the reductionist scientific method, which attempts to prove or disprove a hypothesis, assumes the test environment is static, the complex systems tools for discovery are intended to be applied to a constantly changing world. Basic principles in complex systems science include the assumption that many factors that are constantly changing and interacting can have a variety of impacts on the subject (a person/patient) who is considering a variety of treatment options and will have a variety of potential outcomes based on the interaction of the factors related to the patient and the treatment process in any particular local environment at one particular moment in time. A change in any one or more of these factors can lead to a similar or potentially different outcome from the same treatment option. Rather than attempting to prove or disprove a hypothesis, tools for discovery in complex systems science are simply designed to improve whatever is measured within a definable process.

The laparoscopic TAPP inguinal hernia repair was described in the early 1990's and is similar to the laparoscopic total extraperitoneal (TEP) inguinal hernia repair in that the dissection and mesh coverage are essentially identical. However, in the TAPP approach, the procedure is performed from inside the true abdominal cavity so the peritoneum must be transected to enter the preperitoneal space to perform the dissection and mesh placement. After mesh placement, the peritoneum must be closed if the mesh is a typical macroporous inguinal hernia mesh to minimize the chance for adherence and ingrowth from the bowel. Alternatively, the peritoneum can be left open if a mesh designed for intraperitoneal placement is used, however this type of mesh is significantly more expensive than the standard macroporous inguinal hernia mesh. Cost has often been an issue with laparoscopic inguinal hernia repair where mesh fixation strategies (tacks and glue), dissection balloons (for the TEP approach) and now the surgical robot, can add

hundreds or even thousands of dollars to the direct materials cost for the procedure. As we move into the era of value-based healthcare, the tools from complex systems science will help us to measure and improve the value of care we provide for patients.

This CQI project initiated an attempt at value-based improvement for patients who underwent a laparoscopic TAPP inguinal hernia repair at two locations, Daytona Beach, FL and North Carolina. This attempt to improve the value of care included the use of a laparoscopic suturing device using a curved needle for the peritoneal closure and in some cases, for mesh fixation. The Endo 360 device being used to close the peritoneum as part of a laparoscopic TAPP inguinal hernia repair is shown in Figure 1.

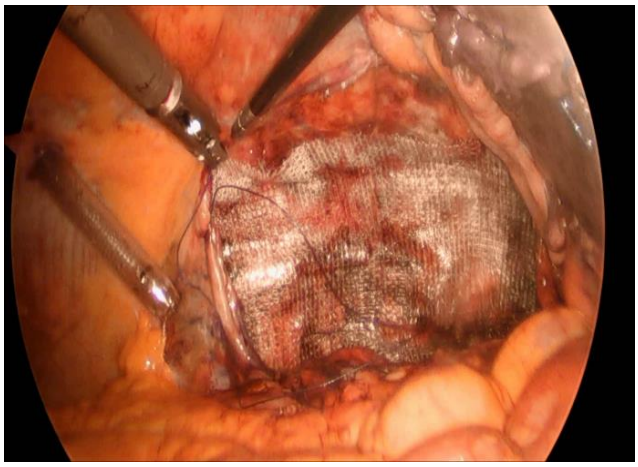

Figure 1: Laparoscopic TAPP inguinal hernia repair using the Endo 360 device to close the peritoneum.

The potential opportunities to improve value, included the ability to replace the mesh fixation device, the ability to use a less expensive mesh if a more expensive mesh designed for intraabdominal use has previously been used and/or to decrease the time and improve the efficiency of peritoneal closure with the use of the new suturing device. A comparison of using this device for a laparoscopic TAPP inguinal hernia repair with a standard TAPP technique and with a TEP technique for laparoscopic inguinal hernia repair is demonstrated in Table 1.

Table 1

	Previous TEP	TAPPWR (without reperitonealization)	Lap Suture device TAPP
Dissection	Balloon Dissector	Scissors	Scissors
Mesh	Low cost	High cost	Low cost
Fixation	Tacking device	Tacking device	Endoscopic suturing device
Peritoneal closure	N/A	Not done	Endoscopic suturing device
Potential advantage	Does not enter true abdominal cavity	Does not require peritoneal closure	Efficient and cost effective mesh fixation and peritoneal closure
OR Time	Slight decrease (especially bilateral)	Slight increase (especially bilateral)	Mod increase (especially bilateral)
Cost differences	$$	$$$	$

Table 1: Comparison of using Endo 360 for a laparoscopic TAPP inguinal hernia repair with a standard TAPP technique and with a TEP technique

Patients who underwent laparoscopic TAPP inguinal hernia repair between 9/14 and 7/15 (10 months) were included in this dataset if the laparoscopic suturing device (EndoEvolution 360) was used for a portion of the procedure. The factors thought to be important to contribute to value-based outcome measures were collected. Outcome measures such as pain, return to activity and patient satisfaction were collected in an attempt to measure the value of care. Due to the difficulty of measuring costs for the entire cycle of care, the cost measurements are specific to the materials used and to the devices replaced by the laparoscopic suturing device.

Patients included in this evaluation had prior lower abdominal surgery, mesh previously placed in the extraperitoneal space or a recurrence after mesh removal for chronic pain as indications for the laparoscopic TAPP approach.

Results:

Patient demographics are included in Table 2. Hernia characteristics and procedure details are included in Table 3

Table 2	
Patient Demographics	**N= 28**
Gender	
Female (%)	7 (25%)
Male (%)	21 (75%)
Age	
Mean (SD)	56.25 (15.66)
Range	(25-80)
BMI	
Mean (SD)	26.19 (4.74)
Range	(18.2-36)
Smoking	
Current (%)	6 (21%)
Former (%)	10 (36%)
Never (%)	12 (43%)
Employment	
Full-time (%)	15 (54%)
Retired (%)	11 (39%)
Unemployed (%)	1 (3.5%)
Not Collected (%)	1 (3.5%)

Table 2: Patient demographics

Table 3	
Hernia and Treatment Characteristics	**N=28**
Location:	**Totals (%)**
Bilateral (%)	7 (25%)
Right (%)	9 (32%)
Left (%)	12 (43%)
Pain	
Mean (SD)	5.3 (3.3)
(range)	(0-10)
Hernia size	
Mean(cm^2) (SD)	
(range)	4.72 (22.3)
	(1-12)
Mesh size	
Mean (cm^2) (SD)	
(range)	227.83 (116.8)
	(96-570)
OR Time	
Mean (min) (SD)	70.36 (38.86)
(range)	(16-155)

Table 3: Hernia characteristics

Post-operative outcomes are presented in Table 4. There were 21 patients available for follow-up. One patient died of a myocardial infarction, three people declined to be contacted for follow-up and three people were not able to be contacted for follow-up, leaving 21/28 (75%) available for follow-up. The mean length of maximum follow-up is 167.68 days (21-641). A cost comparison for a variety of laparoscopic inguinal hernia repair techniques is presented in Table 5.

Discussion:

This project is an example of the application of the principles of CQI to improve the value of a specific technique- the laparoscopic transabdominal preperitoneal (TAPP) inguinal hernia repair. We have typically used the TAPP approach when patients have significant prior lower abdominal midline surgery, have prior mesh located in the preperitoneal space and for patients with large scrotal hernias. For patients with prior

Table 4	
Follow-up Short-term: initial office visit	N=28 patients
Complications short-term (total): Seroma Nausea Burning w/ urination No Complications	**Totals (%)** 5 (18%) 3 (11%) 1 (4%) 1 (4%) 23(82%)
Pain (0-10 scale): Mean (SD) (range)	 3.31 (2.46) (0-8)
Rehospitalization Recurrent hernia Re-operation (related to hernia)	0 (0%) 0 (0%) 0 (0%)
Follow-up **Longer-term (d) mean, (range)**	**N=21 patients** **167.68 (21-641)**
Return to work: Completely Not completely **Return to exercise:** Completely Not completely	Totals (%) 13/14 (93%) 1/14 (7%) Totals (%) 17/21 (81%) 4/21 (19%)
Pain (0-10 scale): Mean (SD) (range)	 1.21 (1.85) (0-6)

Table 4. Post-operative outcomes

lower abdominal surgery or with prior mesh in the preperitoneal space, the reason for choosing a TAPP approach is due to the risk of injury to bowel or bladder with total extraperitoneal (TEP) approach and the potential to tear scar tissue resulting in an injury while dissecting the potential extraperitoneal space either with a balloon dissector or with an instrument dissection. The choice of a TAPP approach for a large scrotal hernia is for an easier and safer reduction of herniated contents and the difficulty of reducing the large indirect sac when using a TEP approach.

Using CQI to improve the value of care for a definable patient care process is a relatively new concept in medicine. Although principles of CQI have been used in medicine for several decades, they have often been applied to process improvement for administrative purposes, rather than actual patient care. Some of the first published attempts at process improvement in real patient care include the effort to reduce central line infection rates led by Peter Pronovost and the implementation of surgical checklists led by Atul Gawande in partnership with the World Health Organization (WHO). There are various improvement tools and methods that can be applied to healthcare. The general principles include the need to measure a definable process. Ideally, the measurement should define value for a whole, definable patient care process or pathway. A multidisciplinary team should determine what is best for a value measurement for a particular process and what factors in the process should be identified that matter most to the outcomes that determine value. In the case of this project, an attempt to improve value was focused on the opportunity to use a new non-disposable laparoscopic suturing device applied to a specific surgical process that would allow for a reduction in the costs of the procedure by eliminating other devices used for the procedure in the past. Table 1 presents the difference in the products used for different procedures in the past (laparoscopic TEP and TAPP without reperitonealization for inguinal hernia repair) compared with using the new suturing device in a laparoscopic TAPP inguinal hernia repair beginning with this project.

Another potential benefit of using the automated laparoscopic suturing device instead of the use of tacks for mesh fixation and/or peritoneal closure is the potential benefit of decreased post-operative pain. Although it is difficult to determine a benefit for mesh fixation- the literature shows little difference between no fixation, glue fixation or use of tacks or sutures, there is one study with over 200 patients that shows a benefit of sutures over tacks or staples. Ross et. al. published a study in Surgical Endoscopy in 2015 comparing suture, tacks and staples for the peritoneal closure during a laparoscopic TAPP inguinal hernia repair. Using the Carolinas Comfort Scale, they showed that suture closure of the peritoneum had significantly less early post-operative pain compared to the tack group ($p= 0.030$) and less activity limitation at two weeks post-operatively compared to the staple group ($p= 0.005$). These patient-centered benefits will become more valuable to clinicians as payment models that incorporate patient reported outcomes continue to be adopted.

The laparoscopic automated suturing device with a curved needle is a unique option compared with other laparoscopic suture assist devices. The use of a curved needle allows for easier purchase of tissue and the automatic passing of the needle ensures safety and ease of performing the suture pass. Although there is a learning curve, as with almost all new devices, it is relatively short and competence with device was achieved within the first few cases. There is a slightly longer learning curve to use the device to tie a surgical knot. However, for the application of this device to a laparoscopic TAPP inguinal hernia repair, we found that it was easier to just pass the suture several times in one location to anchor the suture at the beginning and end of a running suture (closing the peritoneum) and for point fixation (mesh fixation). Actual surgical knots were not required for either closing the peritoneum or mesh fixation with this device. One potential negative is that this device is a 12 mm instrument. To use this in our standard laparoscopic TAPP inguinal hernia repair, we did use a 5 mm scope through one of the working trocars while the suturing device was placed through the 12 mm umbilical trocar. Alternatively, one of the working trocars could have been replaced with a 12 mm trocar.

Table 5: Cost comparison for different laparoscopic inguinal hernia repair techniques

Table 5			
	TEP	**TAPPWR**	**TAPP Endo 360°**
Dissection Balloon Costs	$319.88	0	0
Tack Fixation Costs	$509.15	Unilateral- $509.15 Bilateral- $1018.30	0
Mesh Costs	$113.36	$757.00 (19x15 cm) $843.50 (20x15 cm)	$113.36
Suturing Device Costs	0	0	$58.25/suture cartridge
Scissors	0	$40.00	$40.00
Trocars	$61.00	Unilateral- $61.00 Bilateral- $79.00	Unilateral- $61.00 Bilateral- $79.00
TOTALS Unilateral Bilateral	**$1003.39 $1116.75**	**$1367.15 $2651.30**	**$330.86 $578.72**
Total 28 cases (21 unilat, 7 bilat)	**$28,888.44**	**$47,269.25 (+$18,380.81) (+656.46/case)**	**$10,999.10 (-$17,889.34) (-$638.91/case)**

About the Continuous Quality Improvement Approach

Clinical Quality Improvement (CQI) provides real world clinical knowledge through collection of data from process improvement projects that help care providers, medical device companies and other stakeholders in the healthcare value stream to gain a better understanding of the value of products within the clinical process and where these products may not add value or may be harmful.

Using well defined processes and a diverse team of physicians, nurses, care coordinators, engineers, patients, family, and others, CQI projects allow stakeholders the ability to analyze clinical data as it is produced by the actual patient care processes and to use this data to attempt to positively impact patient care.

Summary:

A CQI project was implemented to attempt to improve the value of care for patients who underwent a laparoscopic TAPP inguinal hernia repair using a new laparoscopic suturing device. This attempt at process improvement was successfully implemented and other costlier methods for laparoscopic inguinal hernia repair were avoided. The potential cost savings for this 28 patient project include a total of $17,889.34 ($638.94/case) compared with a laparoscopic TEP approach and $36,270.15 ($1295.37/case) compared with the laparoscopic TAPP without reperitonealization approach. The principles of CQI can be used to improve the value of care for any definable patient care process. CQI is ideally implemented using a multi-disciplinary team, including the patient and family.