Low Impact Laparoscopic Ventral Hernia Surgery using AirSeal® System

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

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Summary:

By creating a uniquely stable pneumoperitoneum, the AirSeal® System allows for the routine application of lower insufflation pressures during laparoscopy which has been shown to reduce post-operative pain, medication use, and length of stay [1]. This report presents preliminary evidence showing that application of Low Impact Surgery enabled by the AirSeal® System can improve overall patient and provider value in laparoscopic ventral hernia repair.

The results of the current manuscript stem from an ongoing clinical quality improvement (CQI) project. In this project, the AirSeal® System has been introduced as a part of a value-based quality improvement effort for patients who have complex ventral/incisional hernias and choose to have a laparoscopic ventral/incisional hernia repair. The use of AirSeal® was identified as an improvement opportunity in this group of patients after our hernia program experienced a patient who had a CO_2 embolus during the initial insufflation for a laparoscopic ventral/incisional hernia repair when a standard insufflation system was used at a pressure of 15 mmHg. The patient experienced severe respiratory distress and the operation was abandoned. After a review of the literature and assessment of insufflation options, the hernia team felt that adding the AirSeal® System to the patient process might contribute to an increased value for the patient, surgical staff and healthcare system through the following metrics:

- Equal or better outcomes in terms of less pain, quicker recovery and diminished likelihood of pulmonary and cardiac complications related to insufflation pressure (including CO_2 embolus)
- Potential to decrease costs through less pain (measured by use of opioids in PACU and during the hospital stay) and quicker immediate recovery (measured by PACU time)
- Improved visualization due to the automatic smoke evacuation provided by the AirSeal® System
- Shorter hospital stay

As part of the CQI methodology, alterations to the treatment process during this project, beyond using the AirSeal® System include giving the patient a choice of mesh and technique (laparoscopic or open hernia repair or abdominal wall reconstruction, where appropriate, as a part of a shared decision process). Another attempt at process improvement was to offer patients a preoperative bilateral transversus abdominis plane (TAP) block with long-acting local anesthetic as a part of a multi-modal pain management and enhanced recovery program for process improvement.

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.

In this patient series, the objective is to find ways to improve patient care processes and value-based outcomes. This will include but is not limited to addressing the following questions:

- Which patient subset benefits the most from the use of the AirSeal® System?
- Is there a subset of patients that should avoid using the AirSeal® System?
- What other ways can the AirSeal® System add value to the patient, the surgeon and the hospital?
- What impact does the AirSeal® System have on the costs for the entire cycle of care?

Introduction:

The CQI effort presented in this paper demonstrates an attempt at process improvement for patients with ventral/incisional hernias who choose to undergo a laparoscopic ventral hernia repair. As the fifth leading general surgical procedure resulting in hospital complications and disappointing long-term recurrence rates, there is a significant opportunity to improve the outcomes for this population of hernia patients while improving cost-effectiveness, thus increasing overall value [2].

Hospital stay for patients undergoing laparoscopic repair of ventral/incisional hernia has been reported to range from 1 to over 4 days. Post-operative complications such as pain and ileus often contribute to a prolonged hospital stay[3]. Traditionally, improvements in patient care have been dependent on established clinical research tools such as prospective, randomized, controlled studies. However, using traditional research tools for a complex dynamic process such as ventral/incisional hernia, with inherent uncontrollable variables, can be inadequate to improve value for patients. In fact, recent evidence-based guidelines suggest that complex systems science tools, such as CQI would be more appropriate [4]. Recently, principles of CQI have been introduced to improve clinical care. The value of applying these principles has already been established for portions of a patient's cycle of care: reducing central line infection, for example [5]. Implementing the principles of CQI for a patient's entire cycle of care has not yet been demonstrated.

The use of the AirSeal® System as an attempt at value-based process improvement for patients undergoing laparoscopic ventral/incisional hernia repair was considered an evidenced based option including the following considerations:

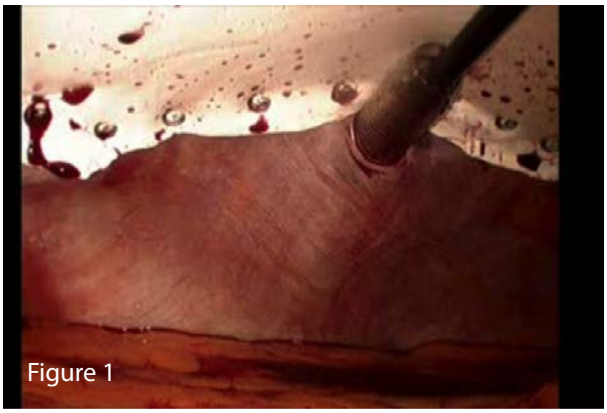
Stable, lower pressure pneumoperitoneum may help to reduce complications and potentially improve patient safety

Integrated smoke evacuation can result in a clearer surgical field with the potential for less complications

Real-time intra-abdominal pressure management avoids unnecessary spikes and drops in intra-abdominal pressures during respiration and variation in relaxation

Cost of care may be decreased with a quicker recovery and less use of opioid pain medication

Utilizing the principles of CQI rather than a traditional reductionist approach starts with defining the dynamic cycle of care for a definable patient population. Using a multi-disciplinary team, including patients and family members, evidence based care processes were introduced and process improvement ideas were generated and implemented in a hernia practice. In this study, the defined process included patients with ventral hernias who chose to undergo a laparoscopic ventral hernia repair. One of the initial attempts at process improvement was the use of a shared decision process giving the patient and family more information and alternatives in the choice for techniques and mesh options for ventral hernia repair. In most cases, the options described included watchful waiting and non-operative strategies for managing a ventral/incisional hernia. Another attempt at process improvement is offering patients a preoperative bilateral transversus abdominis plane (TAP) block with long-acting local anesthetic for post-operative pain control as a part of a multi-modal pain management strategy [6]. Adding the AirSeal® System as a part of the multi-modal pain management strategy because the TAP block using long-acting local anesthetic would hopefully block the musculoskeletal (somatic) pain related to surgical abdominal wall and mesh fixation trauma, but would not address the visceral pain (including shoulder pain) and abdominal soreness that can be due to high insufflation pressure, abdominal wall distention and retained CO_2 gas.



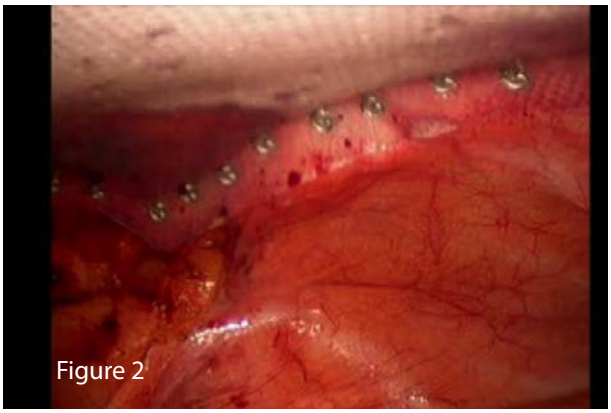


Figure 1 & 2: Lap assisted injection of long acting local anesthetic after complete mesh fixation using the AirSeal® System at a pressure of 8 mmHg.

Patients and Clinical Results

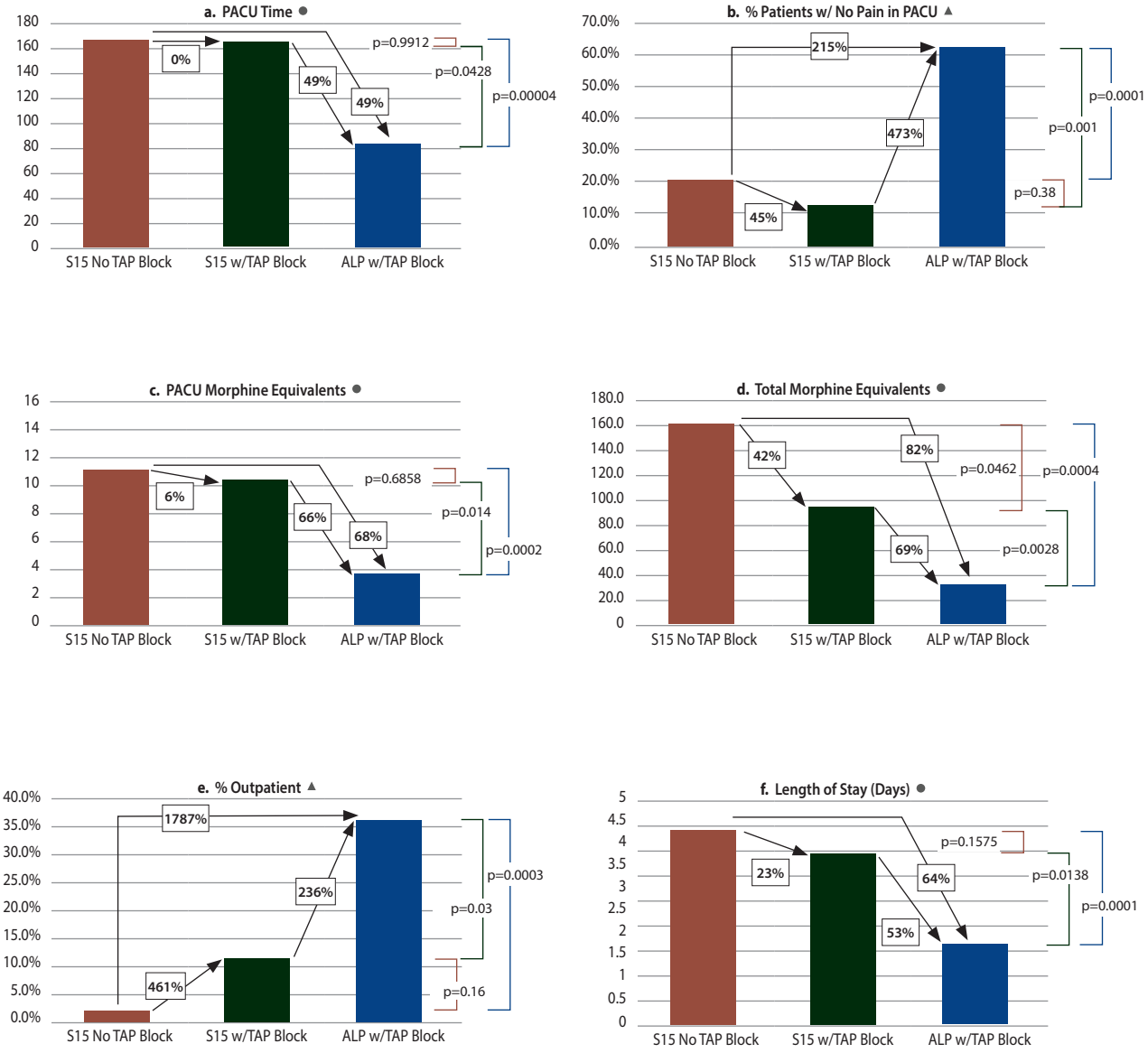
To date, 20 patients have undergone laparoscopic ventral/incisional hernia repair using the AirSeal® System. However, our hernia team has been using the AirSeal System on all laparoscopic cases to measure both the clinical and economic value in various laparoscopic procedures. The use of the AirSeal System in various laparoscopic procedures is listed in Table 1:

	10 mmHg	8 mmHg	Total
Low Pressure with Standard Insufflation			
Dx Laparoscopy	7	2	9
TEP* inguinal	4	0	4
Subtotal	11	2	13
Low Pressure with AirSeal® Mode			
TAPP** inguinal	9	14	23 (1 hidden hernia)
TEP* inguinal	2	3	5
Lap Ventral	9 (one patient LOA – no mesh placed)	11	20
Lap mesh removal for chronic pain (revisions)			
Inguinal	5	8	13
Ventral	1	0	1
Lap neurectomy	1	0	1
Subtotal	27	36	63
Total	38	38	76

* Totally Extraperitoneal
** Transabdominal Preperitoneal

Table 1: Total use of the AirSeal System for laparoscopic procedures performed in our hernia program between 9/11/14 and 5/22/15.

There were a total of 106 patients who underwent laparoscopic ventral/incisional hernia repair between 4/9/12 and 5/8/15. Two major process improvement attempts were instituted during this time. A TAP block was begun after the 50th case and the AirSeal® System was implemented after the 87th case. Since that time, there have been 19* patients who have had laparoscopic ventral/incisional hernia repair with mesh with the AirSeal® System. Figures 3a-f show the outcomes across these patient groups:



Figures 3a-f: Outcomes for laparoscopic ventral/incisional hernia repair including the impact of two process improvement attempts: instituting a pre-operative TAP block after the 50th case and using the AirSeal® System in AirSeal® Mode at low pressure (8-10 mmHg) after the 87th case (cases 1-87 were performed with standard insufflator set at an intra-abdominal pressure of 15 mmHg). Metrics evaluated include: a) PACU Time, b) Percent of Patients w/ No Pain in PACU, c) PACU Morphine Equivalents, d) Total Morphine Equivalents, e) Percent Outpatient, f) Length of Stay.

LEGEND:

S15: Standard Insufflation at 15 mmHg
ALP: AirSeal Mode at 8-10 mmHg

● 2-sided t-test
▲ 2-sided Fisher's exact test

* One patient of 20 was excluded from analysis because only adhesiolysis was performed and no mesh was placed.

The results demonstrated that patients experienced a quicker recovery and that there was less use of opioid pain medications. In particular, combining a TAP block with the AirSeal System resulted in over 60% of patients waking up in PACU and having little or no pain (based on no use of opioid pain medication during the time in PACU). Also, there was a 49% decrease in PACU time, a 64% decrease in length of stay, a 68% decrease in PACU opioid use (based on morphine equivalents) and a 82% decrease in opioid use for the total hospital stay (based on morphine equivalents).

To document value, we collected procedural costs. We have collected real costs from 30 ventral hernia patients (not included in the initial 106 patient study) and determined what factors correlate with lower costs of care and higher hospital margins. To demonstrate this, two figures below show scatter graphs of these 30 patients with trend lines included.

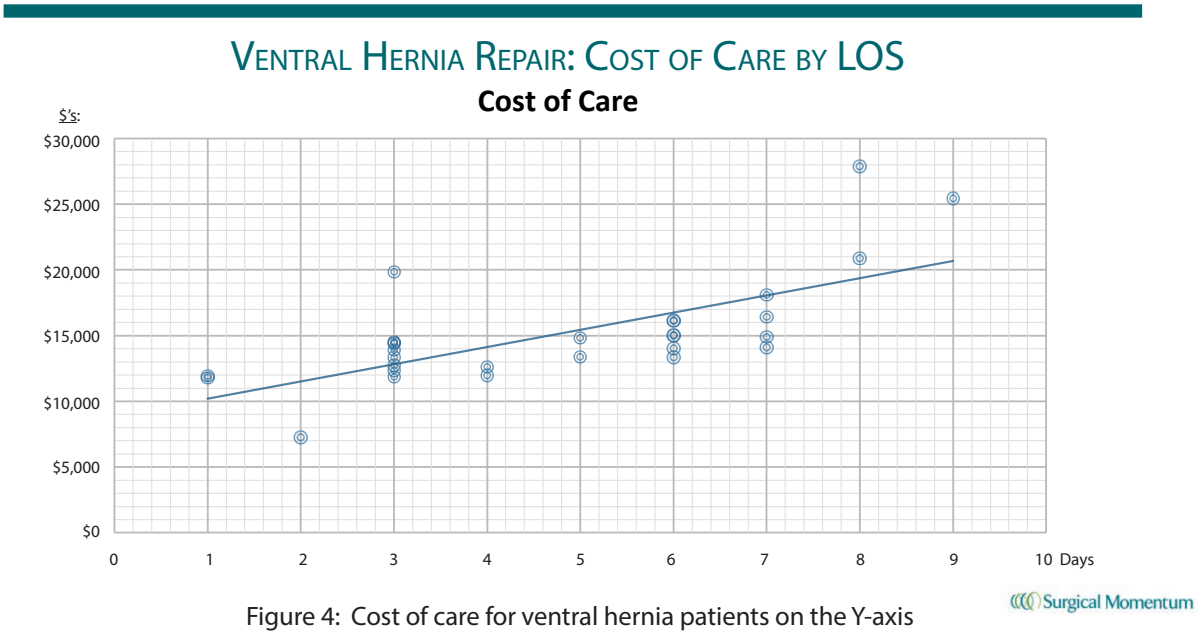


Figure 4: Cost of care for ventral hernia patients on the Y-axis and length of hospital stay on the X-axis.

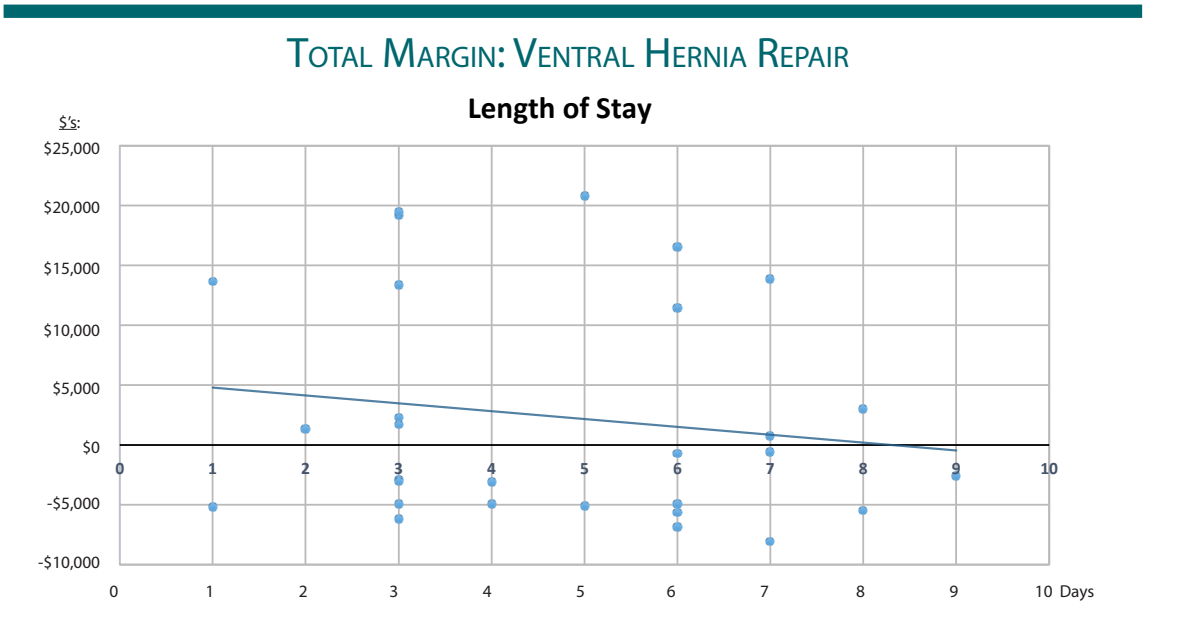


Figure 5: Hospital margin plotted on the Y-axis and length of hospital stay on the X-axis.

We documented that decreasing the hospital length of stay significantly reduced costs for ventral hernia patients. The implementation of process improvements that decrease length of stay and decrease costs had a positive impact on the hospital margin in this group of patients.

Overall, the process improvements performed during the course of the project contributed to improved clinical outcomes and improved value for the patient as well as for the hospital.

Discussion

The clinical incidence of CO_2 embolus during laparoscopic surgery is relatively low, between 0 and 0.062% based on several publications [7]. However, the rate of CO_2 embolus during laparoscopy when evaluated with an intraoperative trans-esophageal echocardiogram (TEE) is between 6 – 100% [7]. The mortality of a clinically significant CO_2 embolus is 29% and it is not known what the implications might be for the high rate of sub-clinical CO_2 emboli [8]. Due to the risk associated with a clinically significant CO_2 embolus and lack of predictably, there is a strong desire to reduce risk through active management of contributing factors. Risks for CO_2 emboli may include the insufflation pressure setting and insufflation rate, injury to a blood vessel or solid organ, and the position of the patient- a Trendelenburg (head down) position may prevent or minimize serious complications by preventing gas bubble accumulation in the brain. If a CO_2 embolus is suspected, the abdominal cavity should be deflated and the procedure should be halted while the anesthesia team assesses for cardiopulmonary and neurologic sequelae. Once the patient is stable, a decision should be made to continue or abort the operation. Because neurologic sequelae cannot be assessed completely while under anesthesia, postponing the procedure may be appropriate in many cases. In the case of the patient who had a CO_2 embolus during a laparoscopic ventral hernia repair in our hernia program, respiratory compromise was identified by the anesthesia team about 30 seconds after insufflation was initiated through a 10 mm blunt right subcostal access site at the anterior axillary line. It is presumed that a small liver laceration occurred and allowed for initial insufflation gas to enter the hepatic vasculature. The insufflation pressure was set at 15 mmHg using a standard insufflation system and the flow rate was on the highest setting. The CO_2 was immediately evacuated from the abdominal cavity and the operation was halted until the anesthesia team was able to address the situation. Additional ventilator support was begun and a TEE revealed gas bubbles in the cardiovascular system. The operation was aborted and the patient was monitored overnight in the ICU and was discharged home the next day without pulmonary, cardiac or neurologic sequelae.

Our hernia team has been functioning for several years in a patient-centered, small team model utilizing the principles of clinical quality improvement (CQI) to measure outcomes and implement process improvement ideas. One of the tools in CQI is to look for anomalies (both positive and negative) in an attempt to learn from them. In this case, the CO_2 embolus was a negative anomaly during a laparoscopic ventral hernia repair procedure. The hernia team did a literature search and brought ideas to one of the monthly CQI meetings to discuss ideas for process improvement. There were simple observations such as the fact that the surgeon usually enters the abdomen in a left subcostal location therefore moving to the less common (right) side may have been a contributing factor. Also, the insufflation rate was on high early during the initial insufflation and a slower insufflation rate could have been used. The research on insufflation pressure and the pressure variation was also reviewed and it was found that a significant amount of literature is published in support of a lower insufflation pressure. Also, with new insufflation technology, it is now possible to control intra-abdominal pressure constantly in real time, rather than intermittently as is the case in standard insufflation technologies. This relatively new technology was thought to be a potential idea for process improvement for our patients who undergo laparoscopic ventral hernia repair. Potential improved value could come from a lower likelihood of rare complications

from CO_2 embolus, from less visceral pain with a lower pressure and more stable pneumoperitoneum. There was also a potential benefit of better smoke evacuation from the operative field. There was an ostensible increase in equipment cost, but this would be measured as a part of the outcomes evaluation after this process improvement was implemented. The hospital Technology Assessment Procedure committee agreed to allow this technology to be assessed within the context of this CQI project and a presentation of value-based outcomes was made to the committee after approximately nine months of data collection. Interestingly, as a byproduct of our hernia program using this technology, other surgeons tried it on their cases and several have adopted it as a part of their laparoscopic techniques.

CQI is a tool used to attempt to improve the value of a complex process. For a simple process, it is relatively easy to identify optimal improvements. However, when a process is complex (such as any patient care process in healthcare), there is a need to measure outcomes that define value for that specific process and small teams are ideal for interpreting the outcomes and analyses and to propose potential process improvement ideas. Over time, as more data is accumulated, these small teams will be able to implement predictive algorithms to improve outcomes. These tools are based on complex systems science which provides a more complete understanding of our complex and ever changing biologic world. Until now, much of healthcare improvement attempts were based on reductionist science principles where the focus was on the parts of a process, rather than the whole process. By focusing only on parts, there is a limited opportunity to understand how to improve the outcomes for the whole process. For example, we had previously implemented a process improvement for our hernia patients that included a Transversus Abdominus Plane (TAP) block with a long acting local anesthetic in an attempt to minimize pain and speed recovery for patients who underwent laparoscopic ventral hernia repair. After implementation, we did see a decrease in length of stay as well as a decrease in post-operative opioid use for pain control. But when we added the AirSeal® System, which facilitated low-pressure pneumoperitoneum, we saw an even greater improvement in positive outcomes. It did appear that the whole was greater than the sum of the parts. Taken alone, TAP block and low pressure pneumoperitoneum would each likely have some positive impact on outcomes as has been demonstrated in literature published using traditional research methods. But, evaluated together in a CQI model, the improvement in outcomes appears to be greater than if they were evaluated separately and the improvements were added together.

In general, these process improvement attempts involved a patient-centered attempt to improve value. Using this low impact strategy, the negative impact of surgery on a patient can be minimized. Post-operative somatic pain can be minimized with a multi-modal pain management strategy including TAP blocks with long acting local anesthetic. Visceral pain can be minimized with a complementary strategy using a low pressure and more stable insufflation technology. When patients experience less pain, they can get up and walk more easily and more frequently, they can potentially breathe deeper and minimize the use of opioids for post-operative pain management. In fact, after implementing the AirSeal technology, over 60% of patients took no opioid medications in the PACU and no laparoscopic ventral hernia repair patient has yet experienced shoulder pain in the post-operative period. Minimizing the use of opioids will likely also minimize nausea and other opioid related complications during recovery. This is a part of the growing effort to look at pre-operative patient optimization physically and emotionally, peri-operative multi-modal pain management and post-operative enhanced recovery pathways to improve value for the patient and the entire system.

To truly provide the greatest positive impact on value, true costs of care must be measured. To date, we have evaluated the cost of care for 30 complex ventral hernia patients. Obtaining accurate cost data has been the greatest challenge in our attempt to measure value. By looking at actual cost data, correlations can be made to determine the impact of various factors such as length of stay on outcomes such as cost and hospital margin. In this series of 30 ventral hernia patients, costs could be cut approximately

in half if a hospital stay is 1 or 2 days versus 5-7 days. The hospital margin is neutral at a hospital stay of approximately one week, but is net positive $5,000 if the hospital stay is less than 3 days. Although costs and hospital net margin should not be goals in isolation, costs should be a part of the value measurement for all patient care processes and hospital margin, as well as physician reimbursement, should also be measured to ensure financial sustainability for the hospital and physician. Costs are a critical part of any process value measurement. Other measures that contribute to a measurement of value include quality measures pertinent to each specific patient care process and the satisfaction, or experience, of the patient and family as they go through the care process.

One caveat of CQI is that each local environment has its own combination of local variables, such as specific surgeon skills and experience, and therefore outcomes from a specific process improvement implemented in one local environment may not be the same when implemented in another, different local environment.

The table below represents the study's findings excluding 1 outlier patient in the TAP Block Only group that had a 1,434 minute PACU stay.

EXCLUDING OUTLIER PATIENT IN S15 W/ TAP BLOCK GROUP			
	S15 no TAP Block	**S15 w/ TAP Block**	**ALP w/ TAP Block**
LOS	4.4	3.2	1.6
PACU Time	163.5	128.6	83.4
PACU MEQ	11.2	9.5	3.6
% Patients w/ No Pain in PACU	20.0%	11.0%	63.0%
Total MEQ	161.0	88.3	29.1
% Outpatient	2.0%	11.0%	37.0%

Table 2.

Summary

Using complex systems science tools such as CQI will become increasingly important as healthcare complexity increases in part due to an increasing pace of change. Measuring the value of care provided by hospitals and physicians for definable patient care processes will not only differentiate them from others that do not adopt these tools, but will also be necessary to demonstrate the value of the care provided for payers. Value-based process improvements can potentially positively impact patient safety and outcomes to allow for ongoing improvement of value for the patient and the system. In the current study, the AirSeal® System resulted in significant patient outcome improvements and will likely result is significant cost savings.

About Surgical Momentum:

Surgical Momentum (www.surgicalmomentuminc.com), based in Daytona Beach, FL, with offices in Atlanta, GA, is a healthcare data analytics company that utilizes clinical quality improvement (CQI) research as a foundation; providing expertise in applying the principles of CQI research to real patient care.

Dr Bruce Ramshaw is Chairman and CMO of Surgical Momentum. Bruce is also co-director of Advanced Hernia Solutions, a clinical hernia program. He is Chairman of the General Surgery Residency program at Halifax Health and is past President of the Americas Hernia Society. On October 1st, 2015 Bruce will become Chair of the Department of Surgery at The University of Tennessee Graduate School of Medicine.

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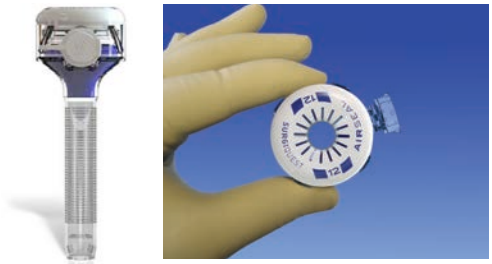
About the AirSeal® System

The AirSeal® System is the world's only integrated access system for laparoscopic and robotic surgery. By completely redesigning each individual component of the system (insufflator, trocar, tubing), SurgiQuest has been able to optimize the way the components work together to provide:

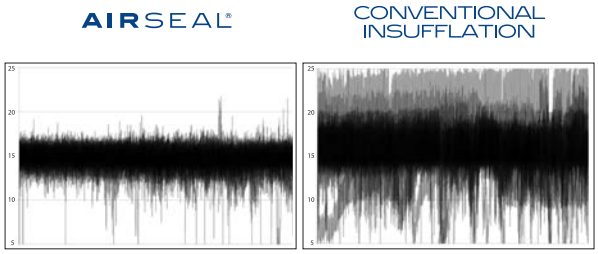
- Unequaled stability of pneumoperitoneum
- Automatic and continuous smoke evacuation
- Valve-free access to the abdominal cavity
- The ability to routinely perform laparoscopicand robotic procedures at lower intra-abdominal pressure

The AirSeal® Intelligent Flow System (iFS) represents a compelling approach for operative care in the abdominal cavity management by combining insufflation, real-time pressure sensing, and integrated smoke evacuation to provide a clear and uninterrupted working space, even when there are significant leaks or aggressive suction is used.



The AirSeal Access Port offers significant advantages over conventional trocar design. Instead of using valves and seals to maintain pneumoperitoneum, the AirSeal Access Port is valve-free, creating a revolutionary, pressure-based, invisible gas barrier that enables both "friction-free" instrument/prosthetic passage and intact specimen removal.

The AirSeal® Tri-Lumen Filtered Tube Set (FTS) provides 3-channel "communication" with the abdominal cavity, delivering carbon dioxide for pneumoperitoneum and invisible gas barrier operation, smoke evacuation through a 0.01 micron filter, and intra-abdominal pressure sensing in real-time.



Because the AirSeal System provides superior stability of pneumoperitoneum, surgeons are able to perform laparoscopic procedures routinely at lower intra-abdominal pressure which has been proven to reduce post-operative shoulder pain, medication use, and length of stay.

Finally, multiple studies have demonstrated reductions in operative time ranging from 12-15%, freeing up operating rooms and OR personnel for improved efficiency.