Hernia
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ORIGINAL ARTICLE

The use of a novel synthetic resorbable scaffold (TIGR Matrix®) in a clinical quality improvement (CQI) effort for abdominal wall reconstruction (AWR)

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Abstract

Purpose The use of hernia mesh is a common practice in abdominal wall reconstruction (AWR) operations. The high cost of biologic mesh has raised questions about the value of its use in AWR. Resorbable synthetic mesh may have the potential benefits of biologic mesh, minimizing the need for removal when infected, at a lower cost.

Methods A hernia program has implemented the principles of clinical quality improvement (CQI) to improve patient outcomes. One process improvement attempt was implemented using a newly available resorbable synthetic scaffold. Long-term follow-up was obtained as a part of the CQI process.

Results A total of 91 patients undergoing AWR were included between 8/11 and 9/15 (49 months). There were 58 female (64%) and 33 male (36%) patients. The average age was 57.2 years (28–80). The average BMI was 34.0 (17.6–53.4). There were 52 patients (57%) with recurrent hernias. Mean hernia defect size was 306.6 cm^2 (24–720) and mean mesh size was 471.7 cm^2 (112–600). Outcomes included a mean length of stay of 7.5 days (0–49), a recurrence rate of 12% (11/91) and a wound complication rate of 27% (25/91). The recurrence rate decreased to 4.5% (3/66) after several improvements, including adopting a transversus abdominus release (TAR) approach, were implemented. There were no mesh-related complications and no mesh removal (partial or total) was required. The mean follow-up length was 42.4 months (0–102).

Conclusion In this group of patients, an attempt at process improvement was implemented using a resorbable synthetic scaffold for AWR. With no mesh-related complications and no mesh removals required, there was an improvement in value due to the decrease in mesh cost and improved outcomes over time. Long-term follow-up demonstrated the durability of the repair.

Keywords Clinical quality improvement · Hernia · Abdominal · Resorbable synthetic scaffold · Hernia recurrence · Abdominal wall reconstruction

Introduction

Open ventral hernia repair using various techniques is one of the most common general surgery procedures performed [1]. A post-operative wound complication, including infection, is one of the most common complications related to this procedure [2]. For large, complex open ventral hernia repairs, biologic meshes have been used commonly over the past decade due to the perceived tolerance to the open environment, including contaminated and/or infected fields. At an extremely high average selling price, there is a concern about the value of using biologic mesh in this setting and if there are potentially less costly alternatives. Here, we describe an effort to improve the value of care by decreasing the use of biologic mesh and using a less costly alternative, a two-polymer synthetic resorbable scaffold, for patients who underwent abdominal wall reconstruction (AWR) in a single-surgeon hernia program. To determine the long-term performance of this mesh, follow-up beyond 3 years was obtained.

This unique synthetic resorbable scaffold is designed with two types of resorbable synthetic copolymers: a faster resorbing copolymer of glycolide, lactide and trimethylene

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carbonate, and a slower resorbing copolymer of lactide and trimethylene carbonate. The faster resorbing copolymer completely resorbs within 4 months and the slower resorbing copolymer maintains strength for at least 6 months and is fully resorbed within 3 years. The resorption of both copolymers occurs through hydrolysis into endogenous metabolites which reenter the metabolic system or are cleared from the body through the kidneys. The intent of the mesh design is to provide strength during the early phase of wound healing and to increase elasticity of the material, as the shorter resorbing copolymer is resorbed, to support more movement during the remodeling phase of wound healing [3].

Demonstrating the value of care is becoming an increasing priority in healthcare. It is obvious that the current trajectory of per capita healthcare spending is not sustainable [4]. Recently, patients are increasingly responsible for healthcare costs and this has put a significant financial strain on many people. In fact, healthcare costs have become the most common contributing factor to personal bankruptcy in the United States [5]. To transform to a sustainable healthcare system, we will need to learn how to better measure the value of care that is provided in the context of whole, definable patient care processes so that value-based continuous quality improvement (CQI) tools can be applied to lower costs and improve outcomes at the same time.

CQI initiatives can potentially be focused on improving the value of patient care in the actual clinical environment. Using the principles of CQI is often more appropriate for developing an understanding of the factors that drive improvements in patient care than are randomized controlled trials that aim to prove or disprove a hypothesis [6]. Specifically, traditional randomized controlled trials may not be appropriate for studying complex dynamic processes, such as patients with ventral/incisional hernias undergoing open abdominal wall reconstruction (AWR), because there are many inherently uncontrollable variables that can influence interpretation of trial results. Rather, systems and data science tools, such as CQI and nonlinear statistical analyses, are increasingly recognized as more appropriate for measuring and improving patient outcomes [6].

Patient care models that attempt to measure and improve patient value have been proposed by the US academic business community [7, 8]. By taking a systems science view of healthcare, patient care can be simplified by designing care around definable patient groups, diseases, and/or problems (patient care processes) [9]. The information generated by these care processes can then be used to continually improve outcomes over time, resulting in improved overall quality, safety, and patient satisfaction, along with decreased costs, resulting in improved value [7, 8]. Rather than trying to prove or disprove a scientific hypothesis, value-based CQI is implemented with the goal of measuring and improving the value of patient care for each process in which these principles are applied.

Lawmakers have recognized the value of CQI initiatives for improving patient care, and thus, the use of CQI, defined as a part of healthcare operations, has been supported since the HIPAA law was implemented in 1996. The principles of CQI were again supported in the Patient Safety and Quality Improvement Act of 2005. In addition, the US Department of Health and Human Services recognizes that there is a distinction between most quality improvement efforts and research involving human subjects that requires IRB approval [10]. CQI focuses on local process improvement and real-world, clinical data and analytics that are interpreted by the care team. In addition, whenever possible, patients and their families are included in the CQI and shared decision-making processes. With the signing of the 21st Century Cures Act into law in 2016, the FDA regulatory process is now mandated to apply principles of complex adaptive methods using real-world data, such as the process of implementing a CQI method for patient care as demonstrated in this project.

Methods

Because CQI was implemented as part of the actual patient care process with the primary intent to improve patient outcomes, this initiative was exempt from Health Insurance Portability and Accountability Act (HIPAA) rules, and the project was not required to go through an institutional review board (IRB) approval process. A meeting with an IRB service was held and it was confirmed that this interpretation of the law as it relates to CQI initiatives was consistent with the interpretation of the IRB service. In addition, this model for patient safety and quality improvement was vetted with the United States government through the Agency for Healthcare Research and Quality (AHRQ). As a part of the CQI process, our hernia team executed a data-sharing agreement with CQInsights (a healthcare data analytics company) to allow for additional data analyses of de-identified data and to obtain access to additional resources that contributed to this CQI initiative. De-identified analysis of data can also be shared with others who could add value to the process of data interpretation and contribute process improvement ideas.

Patients

Patients who presented to our center with an abdominal wall hernia between August 2011 and September 2015 were offered a range of surgical treatment and nonsurgical management choices. The surgical options included an open approach (including AWR) and a laparoscopic approach

(with a variety of mesh choices) for ventral hernia repair. Patients with active infection were not offered a laparoscopic approach due to the concern for increased likelihood of permanent synthetic mesh infection. Patients were provided with a review of current evidence as part of the dynamic care process, and treatment decisions were made as a shared process between patients, their families, and the clinical hernia team, which included the director of patient care management, other patient care specialists, and the surgeon. Patients were encouraged to do their own research, talk with other patients who had undergone similar procedures, and consider alternate options, if desired. Consecutive patients who chose to undergo open AWR (including two patients converted from a laparoscopic to open operation) who had this resorbable synthetic mesh placed were included in this analysis. As a part of our CQI process, we periodically include a meeting with patients and family members, as well as asking each patient in follow-up communications what we can do to make their experience better.

An attempt at process improvement

At a hernia team CQI meeting in 2011, we discussed the cost and outcomes for the use of biologic mesh in AWR. At about that time, a new class of mesh, long-term resorbable synthetic, became available on the United States market. Although short-term resorbable synthetic mesh had been previously available, the results in complex AWR had been limited. With an interest to potentially use a long-term synthetic resorbable scaffold for AWR in place of more expensive biologic mesh, a literature search was performed by our hernia team and there was no compelling data to suggest that using a long-term synthetic resorbable scaffold instead of biologic mesh would increase the likelihood of harm or complications for patients using current AWR techniques. The long-term synthetic resorbable scaffold chosen was a macroporous product with two types of resorbable copolymers. The team reviewed the science behind the product, including a 3-year sheep study. There was the potential that the resorption characteristics of the two polymers were appropriate for the wound healing process. There also seemed to be handling benefits with a slight stretch that could allow for the mesh to lie taut. Because the scaffold is macroporous, it is not placed in contact with bowel. If bowel coverage was not possible, an alternative strategy (no mesh or a microporous product) would be utilized. After these CQI meetings, the first patient to receive the new synthetic resorbable scaffold in our program was in August 2011. During this time period, there were 10 AWR procedures when this mesh was not used, and these patients are not included in this analysis. A microporous resorbable synthetic mesh was used in three cases when bowel coverage was not possible. A permanent synthetic mesh was used in five cases—two for failure to close the fascia and three because of prior open CST during a TAR procedure. In two cases, the patient requested another option—one chose a different resorbable synthetic mesh and one chose no mesh.

CQI process

All patients received care from the diverse group of health professionals on the hernia team. This team has regular CQI meetings, during which the members discussed and documented ideas to improve the patient care process, and outcomes that measure value were presented and discussed. Patient and family member volunteers, surgical residents, medical students, and other general surgeons were invited to participate in some of these CQI meetings to share their perspectives on how the process could be improved. In addition, feedback from former patients and review of the current literature helped the hernia team continue to refine the patient care process and attempt to improve outcomes that result in improved value for the patient.

The major changes implemented after August 2011 included wide resection of the skin, scar and soft tissue of the superficial anterior abdominal wall, including resection of the umbilicus. For a subset of patients, this included a low horizontal incision or an inverse "T" incision; however, most patients received a wide vertical elliptical excision of tissue that resulted in a vertical midline closure. Another technique process improvement that was implemented was the layered closure of the abdominal wall using quilting sutures to help eliminate the need for drains. After a wide resection of the superficial anterior abdominal wall, most patients had a transversus abdominus release (TAR) procedure performed using this long-term synthetic resorbable scaffold placed in the retrorectus position.

Throughout this effort, there were other attempts at process improvement involving the AWR technique. Early in the project, open AWR (external oblique transection with separation from the internal oblique) was the most common technique. For several cases, an endoscopic component separation technique was utilized in an attempt to decrease wound complications. For most patients who underwent surgery after 2012, a TAR approach was performed. The decision to implement the TAR technique was to decrease the potential for wound complications compared with the open CST approach and gain more fascial mobilization compared with the endoscopic CST approach.

A single surgeon (BR) performed all surgical procedures, sometimes with a resident or other attending surgeons assisting. General anesthesia techniques varied based on the preferred techniques of the anesthesiologist who assisted with each procedure. Another attempt at a process improvement was the implementation of a multi-model peri-operative pain management and enhanced recovery program. After this was

implemented, anesthesiologists performed bilateral transversus abdominal plane (TAP) blocks in the preoperative holding area using ultrasound guidance for administration of 266 mg of liposomal bupivacaine (Exparel®). More recently, an additional intraoperative block was added in an attempt to improve the effectiveness of the anesthetic blocks. Opioid analgesics were available to all patients to achieve adequate pain control. The nurse and patient determined the need for opioid use during the length of the hospital stay.

Assessments

Outcome measures included hospital length of stay (LOS), wound complication rate including surgical site infection, hernia recurrence rate, and 30-day re-hospitalization and death rates. Patients were followed from the moment of first symptom or contact until full return to their best possible quality of life. Ongoing contact was maintained with patients for long-term follow-up by the director of patient care management and patient specialists on the hernia team. A follow-up form was used to obtain feedback about patient outcomes to inform the CQI process. The majority of follow-up feedback was obtained through phone calls although some long-term follow-up was obtained through other forms of communication such as in-person clinic visits, emails, texts and medical records from outside physicians and hospitals.

The clinical parameters from the current study were compared to the published values using one-sample *t* tests for the continuous outcomes and chi-square goodness-of-fit tests for the categorical outcomes. All analyses were conducted using SPSS Version 26 (Armonk, NY, USA: IBM Corp.) and statistical significance was assumed at an alpha value of 0.05.

Results

The analysis population included 91 consecutive patients between 8/11 and 9/15 (49 months) who underwent open AWR who had TIGR mesh placed including 66 patients who had TIGR mesh placed who underwent a TAR approach.

Baseline demographic characteristics are summarized in Table 1. There were 58 female (64%) and 33 male (36%) patients. The average age was 57.2 years (28–80). The average BMI was 34.0 (17.6–53.4). There were 52 patients (57%) with a recurrent hernia. Mean hernia defect size was 306.6 cm^2 (24–720) and mean mesh size was 471.7 cm^2 (112–600). Contamination was present in 27/91 (30%) patients. A list of types of contamination is presented in Table 2. Some patients had more than one type of contamination. The mean follow-up was 42.4 months with a range between 0 and 102 months.

Hernia and procedure characteristics are summarized in Table 3. Outcomes included a mean length of stay of 7.5 days (0–49), a recurrence rate of 12% (11/91) and a wound complication rate of 27% (25/91). The recurrence rate for the TAR approach was 4.5% (3/66). There were no hernia recurrences identified after 3 years post-operatively.

Table 2 Contamination: number of patients and types of contamination

Total	27/91 patients (30%)
Active abdominal wound infection	21/91 patients (23%)
Active abdominal mesh infection	11/91 patients (12%)
Bowel stoma	5/91 patients (5%)
Small bowel resection	9/91 patients (10%)
EC fistula resection	5/91 patients (5%)
Colon resection	8/91 patients (7%)
Inadvertent enterotomy	2/91 patients (2%)

Table 1 Patient demographics

Total	91 patients > Prior abdominal surgeries: average = 4.7 (range 0–26)
Follow-up	Average = 42.4 months (range 0–102 months)
Age	Average = 57.2 (range 28–80)
Gender	Female = 58 patients (64%)|male = 33 patients (36%)
BMI	Average = 34.0 (range 17.6–53.4)
Primary Ventral	1 patient (1%)
Primary incisional	38 patients (42%)
Recurrent incisional	52 patients (57%) > Number of prior recurrences: average = 3.4 (range 1–22)
Active wound infection	21 patients (24%)
Loss of domain	34 patients (37%)
Chronic pain	46 patients (51%)
Taking opioids pre-operatively	41 patients (45%)

Table 3 Outcomes

OR time	Average = 217 min (range 74–607)
Length of stay	Average = 7.5 days (range 0–49)
Recurrence	11 patients (12%) > Repair attempted = 9 patients (9%) > Not repaired = 2 patients (2%)
Seroma requiring intervention	3 patients (3%)
Would complications:	Total = 25 patients (27%)
Minor—minimal intervention required	> Minor = 13 patients (14%)
Moderate—outpatient wound care required	> Moderate = 6 patients (7%)
Major—invasive procedure/hospitalization required	> Major = 6 patients (7%)
Mesh removal	0 patients (0%)

There were no mesh-related complications and no mesh removal (partial or total) was required.

Discussion

This CQI effort suggests that this long-term synthetic resorbable scaffold was safely implemented for AWR in a hernia program. These outcomes are also similar to or better than trials that have been published for biologic mesh, other long-term synthetic resorbable products and a hybrid mesh product that includes biologic and synthetic components [11–15]. For example, there were 80 patients in the RICH trial which evaluated the use of Strattice® porcine biologic mesh for open ventral hernia repair including AWR [11]. There recurrence rate was 28% at 24-month follow-up and the rate of infection-related events was 30%.

One difference between all these other studies and the CQI effort presented here is that all other studies included patient inclusion and exclusion criteria, while this CQI effort included all patients, without inclusion or exclusion criteria. Almost a third of the patients in this CQI project had contamination either pre-operatively and/or from opening the GI tract during the operation. To look at this more closely, patient demographics and outcomes were compared with the published results from the Phasix® (a single-polymer resorbable synthetic mesh) trial [12]. Patient demographics and outcomes comparing patients with this two-polymer resorbable synthetic mesh (no exclusion criteria) to the study using the single-polymer resorbable synthetic mesh are in Tables 4 and 5.

There were eight patients who died within 36 months after the AWR procedure. Two patients died within 1-week post-op, one from aspiration and the other from abdominal compartment syndrome and necrotic bowel. Two patients died 1–2 months post-op from sepsis. The other four deaths occurred after discharge from the hospital for a variety of causes. Excluding these eight patients, 73% of patients (61/83) had follow-up contact at 36 months or longer. Some results were more favorable for the two-polymer mesh and some are more favorable for the single-polymer mesh, but overall the results are similar. However, when the exclusion criteria are applied to the single-polymer study patients, 49/91 (54%) patients would have been excluded. The specific exclusion criteria and number of patients removed is shown in Table 6. In comparing the remaining 42 two-polymer mesh patients with a more similar group of patients in the single-polymer mesh trial, there is some improvement in

Table 4 Patient demographics comparison between TIGR with no exclusions and Phasix trial

	TIGR	PHASIX	*p* values
Number of patients	91	121	NA
Follow-up	36 months (67%) Average = 42.4 months (range 0–102)	18 months (79%) Average = less than 18 months	NA
Gender	Female = 58 patients (64%) Male = 33 patients (36%)	Female = 75 patients (62%) Male = 46 patients (38%)	0.79
Age	Average = 57.2 ± 12.40	Average = 54.7 ± 12.0	0.05
BMI	Average = 34.0 ± 8.58	Average = 32.2 ± 4.5	0.05
Primary ventral	1 patient (1%)	17 patients (14%)	< 0.001
Primary incisional	38 patients (42%)	54 patients (45%)	0.69
Recurrent incisional	52 patients (57%)	50 patients (41%)	0.02
Defect size	Average = 306.6 (range 24–720)	Average = 115.7 ± 80.6	< 0.001
Mesh size	Average = 471.7 (range 112–600)	Average = 580.9 ± 216.1	< 0.001

Table 5 Patient outcomes comparison between TIGR with no exclusions and Phasix trial

	TIGR $n=91$	PHASIX $n=121$	p values
OR time	Average = 217 min (range 74–607)	Average = 168 min ± 84	< 0.001
Length of stay	Average = 7.5 days (range 0–49)	Average = 5.3 days ± 5.3	0.013
Recurrence	11 patients (12%)	11 patients (9%)	0.48
Wound infection	9 patients (10%)	11 patients (9%)	0.84
Seroma requiring intervention	3 patients (3%)	7 patients (6%)	0.40
Wound VAC	3 patients (3%)	11 patients (13%)	0.09
Mesh-related adverse event	0 patients (0%)	11 patients (9%)	0.01

Table 6 Exclusion criteria applied for comparison with Phasix trial (18-month follow-up)

Total = 91 patients
19 patients (removed for 4 or more recurrences)
16 patients (removed for active wound infection)
7 patients (removed for active smoking)
3 patients (removed for having a stoma)
2 patients (removed for having an enterotomy)
2 patients (removed for BMI over 50)
Number of patients excluded: 49 (54%)
Remaining number of patients: 42 (46%)

outcomes in the two-polymer mesh group of patients demonstrated in Tables 7 and 8.

The potential for improving value-based outcomes is the primary intent of applying the principles of CQI to real patient care. During the 4 years of this project, there were numerous CQI meetings held by our hernia team to look at outcomes, review analyses of data and get input from many other resources including patient and family members, engineers, data scientists, social workers and other types of physicians such as anesthesiologists. Some of the process improvement ideas that were implemented included: eliminating the use of drains, modifying the abdominal wall incision and closure techniques, applying principles of multi-modal pain management to reduce the reliance on opioids for post-operative pain management,

Table 7 Patient demographics comparison for TIGR, with exclusions, and Phasix trial

	TIGR	PHASIX	p values
Number of patients	42	121	NA
Follow-up	36 months (69%) Average = 41.8 months (range 1–88)	18 months (79%) Average = less than 18 months	NA
Gender	Female = 31 patients (64%) Male = 11 patients (36%)	Female = 75 patients (62%) Male = 46 patients (38%)	0.17
Age	Average = 55.7 ± 13.3	Average = 54.7 ± 12.0	0.63
BMI	Average = 32.6 ± 8.53	Average = 32.2 ± 4.5	0.76
Primary ventral	1 patient (2%)	17 patients (14%)	0.04
Primary incisional	23 patients (55%)	54 patients (45%)	0.26
Recurrent incisional	18 patients (43%)	50 patients (41%)	0.86
Defect size	Average = 276.6 (range 33–646)	Average = 115.7 ± 80.6	< 0.001
Mesh size	Average = 462.4 (range 112–600)	Average = 580.9 ± 216.1	< 0.001

Table 8 Patient outcome comparison between TIGR, with exclusions, and Phasix trial

	TIGR $n=42$	PHASIX $n=121$	p values
OR time	Average = 191 min ± 66.3	Average = 168 min ± 84	0.02
Length of stay	Average = 6.7 days ± 9.6	Average = 5.3 days ± 5.3	0.36
Recurrence	4 patients (9.5%)	11 patients (9%)	0.93
Wound infection	3 patients (7%)	11 patients (9%)	0.70
Seroma requiring intervention	1 patient (2%)	7 patients (6%)	0.38
Wound VAC	0 patients (0%)	11 patients (13%)	0.15
Mesh-related adverse event	0 patients (0%)	11 patients (9%)	0.19

evolving the component separation technique to the TAR approach and implementing the principles of prehabilitation and enhanced recovery concepts including pre-operative weight loss, smoking and opioid cessation, cognitive behavioral therapy (CBT) and early ambulation and oral nutrition in the post-operative period.

The result of some of these attempts at improvement have been published [16–18]. These previously published manuscripts demonstrated improvements that led to lower costs (this two-polymer resorbable synthetic mesh replacing a biologic mesh) and improved outcomes such as less use of opioids for post-op pain (using a multimodal pain management strategy). This analysis specifically focused on the long-term outcomes including recurrence rate to better understand the long-term value of these CQI efforts and to learn from this analysis.

To see the impact of these attempts at improvement, a third comparison is shown between this two-polymer mesh and the single-polymer mesh study in Tables 9 and 10. These 66 two-polymer mesh patients were all consecutive patients, no exclusion criteria, who had the TAR approach as well as many of the other process improvement attempts, such as multi-modal pain management. These improved outcomes reflect the potential power of the CQI method when applied by a small team measuring outcomes and using a variety of analytics and data visualization tools over time.

In reviewing the outcomes of this project in more detail, there were less recurrences after the TAR approach 3/66 (4.5%) than all other types of AWR where the recurrence rate was 8/25 (32%). Although the average follow-up time for the TAR group was shorter than the whole group (37.6 months, range 0–73 months), the mean follow-up time was still more than 3 years. Of the 11 total recurrences, seven had their recurrence repaired laparoscopically, two have had their recurrence repaired open and two patients have chosen to not yet have their recurrent hernia repaired. Most of the recurrences were small and either subxiphoid, suprapubic or lateral. These were repaired laparoscopically. The two recurrences repaired open were large midline bulges with large fascial defects. One recurrence that has not been repaired is a large midline bulge and the other is a small lateral recurrence. All patients with midline bulging were identified as recurrences.

All the recurrent hernias occurred within 3 years of the initial AWR. There have been no recurrences documented after 3 years post-operatively and this includes patients whose follow-up spans three to over 8 years post-operatively. Addressing recurrence rate after any resorbable synthetic or biologic hernia mesh is fully resorbed is a main reason

Table 9 Comparison after quality improvement implemented including transversus abdominus release (TAR) technique with no exclusions

	TIGR and TAR approach	PHASIX	*p* values
Number of patients	66	121	NA
Follow-up	36 months (65%)/18 months (70%) Average = 37.6 months (range 0–73)	18 months (79%) Average = less than 18 months	NA
Gender	Female = 42 patients (64%) Male = 24 patients (36%)	Female = 75 patients (62%) Male = 46 patients (38%)	0.82
Age	Average = 56.3 ± 13.4	Average = 54.7 ± 12.0	0.33
BMI	Average = 33.3 ± 9.1	Average = 32.2 ± 4.5	0.31
Primary ventral	1 patient (1.5%)	17 patients (14%)	0.005
Primary incisional	29 patients (44.0%)	54 patients (45%)	0.93
Recurrent incisional	36 patients (54.5%)	50 patients (41%)	0.08
Defect size	Average = 328.5 (range 70–720)	Average = 115.7 ± 80.6	< 0.001
Mesh size	Average = 512.9 (range 150– 600)	Average = 580.9 ± 216.1	< 0.001

Table 10 Outcomes after quality improvements implemented

	TIGR and TAR approach No exclusions *n* = 66	PHASIX *n* = 121	*p* values
OR time	Average = 230 min ± 100.5	Average = 168 min ± 84	< 0.001
Length of stay	Average = 6.5 days ± 6.4	Average = 5.3 days ± 5.3	0.15
Recurrence	3 patients (4.5%)	11 patients (9%)	0.26
Wound infection	3 patients (4.5%)	11 patients (9%)	0.26
Seroma requiring intervention	1 patient (1.5%)	7 patients (6%)	0.17
Wound VAC	1 patient (1.5%)	11 patients (13%)	0.04
Mesh-related adverse event	0 patients (0%)	11 patients (9%)	0.04

for long-term follow-up. What will happen when the mesh is gone? In the case of this two-polymer mesh, the mesh is fully resorbed within 3 years; so, it is important to follow patients beyond that time period. Because the attempt to contact these patients occurred in 2019, the minimum follow-up for those contacted is over 3 years and up to over 8 years. For those patients who had died or who could not be contacted, their follow-up was documented at the time of last contact with them.

The use of a permanent mesh such as a light or midweight polypropylene mesh is a less costly option and has been used in AWR techniques. However, the risk of wound complications and mesh infection can result in the need for reoperations and mesh removal. This can be a costly complication with significant morbidity for the patient [19]. The durability of the repair and using this two-polymer mesh and the lack of need for mesh removal, even in patients with wound complications, supported the use of this mesh as an option for AWR.

With a greater than 36-month follow-up rate of almost 70% for all patients (and a maximum follow-up of over 8 years), it appears that the remaining abdominal wall integrity is maintained even after this two-polymer mesh is fully resorbed. This is the intent in the design of this two-polymer mesh and improved collagen deposition has been previously shown in a 3-year animal study [3], but this is the first presentation of follow-up beyond 3 years after AWR in real patients. The design of the material also allows for some stretching of the mesh during suture fixation. This was helpful as part of the process improvement to eliminate the use of drains. With the mesh taut, closure of the anterior fascia does not result in mesh buckling which could increase the risk of seroma formation in the retrorectus space.

The wound infection rate was also better after a TAR approach 4/66 (6.1%), compared with earlier AWR techniques which resulted in a wound infection rate of 7/25 (28%). When the outcomes of the patients repaired with the TAR approach using this two-polymer mesh are compared with the outcomes from other published trials of biologic and resorbable synthetic meshes for open ventral hernia repair, the benefits of a CQI process are demonstrated [11–15].

It is challenging to compare results from one patient group to another due to the complex nature of patients with large ventral/incisional hernias and the variability in techniques for AWR, but these results compare favorably with other series of AWR patients reported in the literature, especially when evaluating the more recent group of 66 patients who had the TAR approach. In comparison to biologic mesh, the cost of biologic mesh is typically 3–5 × that of the synthetic resorbable scaffold used in this CQI study. By combining true costs of care with outcomes, we can measure the value of care provided. By measuring the value of care, and working together as a multi-disciplinary team, including patients, we can generate process improvement ideas that will decrease the cost of care while outcomes are improved. This could be an ongoing process for any clinical team and the impact on value-based outcomes could be measured after the implementation of any process improvement idea. This CQI effort is an example of a value-based process improvement method that led to better value for patients who underwent AWR.

A limitation of this analysis is that many patients traveled from other states, so their long-term follow-up did not include clinic visits and CT scans. We also have a mean follow-up of less than 5 years. Another limitation of this analysis, and of CQI in general, is that results of a project in one local environment may not be reproducible in other local environments. Variations between local environments can result in different patient outcomes from the same process improvement intervention. Another limitation is that the observed improvements in outcomes could be related to other factors unrelated to the implemented attempts at process improvement such as operative technique adaptations implemented during the course of this CQI project. However, CQI as a systems and data science tool is a dynamic method that should result in improvement of value over time for any complex patient care process when implemented according to the principles described in this manuscript.

Conclusion

In this group of patients, an attempt at process improvement was implemented using a two-polymer resorbable synthetic scaffold for AWR in place of a variety of biologic meshes. With no mesh-related complications and no mesh removals required, there was an improvement in value due to the decrease in mesh cost and improved outcomes over time. Long-term follow-up demonstrated the durability of the repair with TIGR Matrix for AWR.

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Data availability A de-identified dataset containing the data used in this CQI project is available on request.

Compliance with ethical standards

Conflict of interest RL, MP and EH have no conflict of interest to disclose. BF and BAP are employees of CQInsights which is a healthcare data analytics company that provided data management and analytics for this CQI project. BR provides consulting services and receives consulting fees from WL Gore, Medtronic, Johnson & Johnson, Pacira Pharmaceutical, Anchora, Theator, Novus Scientific, Verb Surgical, Atrium and ConMed. He also has ownership stock in CQInsights.

Ethical approval This data was collected under the approval of our Institutional Review Board. All collected data was done so as an integrated and inherent part of the standard patient care process at our institution, and given that CQI was implemented as part of the actual patient care process, this initiative was exempt from Health Insurance Portability and Accountability Act (HIPAA) rules.

Informed consent None.

Human and animal rights No animals were used in this investigation.

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