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Research Article

Minimizing Retained Foreign Body in Hernia Repair Using a Novel Technique: Reinforced Biologic Augmented Repair (ReBAR)

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Abstract

With the digital age in healthcare upon us, patients are more aware, educated, and concerned about their surgical options for hernia repair. As a result of exposure to the growing litigious environment surrounding synthetic mesh products, patients are demanding hernia repairs with minimal or no foreign body. In response to these pressures, we have developed a novel technique known as the Reinforced Biologic Augmented Repair (ReBAR) which incorporates the data proven principles of: (1) tissue defect closure and (2) primary repair reinforcement, while minimizing the amount of foreign body material exposure long-term.

A cohort of 619 (1.2% recurrence) patients representing a variety of hernia types and using multiple methods underwent repair using the ReBAR technique: 259 Robotic Inguinal: TAPP (1.2% recurrence), 47 Open Inguinal (4.3%), 59 Robotic Ventral: TAPP (1.7%), 32 Stapled Single Incision Retrorectus (0%), 54 Open Abdominal Wall Reconstructions: TAR/ACS (1.8%), 48 Open Ventral: Onlay (2.0%), 95 Open Ventral: Preperitoneal (0%), 2 Open Ventral: Bridged (0%), 2 eTEP Ventral (0%), and 21 Open Umbilical hernia repairs.

Increasing consumer demand for alternatives to traditional synthetic mesh repairs has driven the development of the ReBAR technique. Outcomes to this point are equivalent or better using the ReBAR technique as compared to classical methodology, however further study will be required to determine if long-term outcomes are superior to traditional techniques. The easily adoptable ReBAR technique satisfies the patient-centered care goals of today's healthcare and may drive enhanced overall value of hernia care delivery.

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Keywords: Hernia surgery; Hernia mesh; Hernia repair; Shared decision making; No mesh hernia repair; ReBAR; Reinforced biologic.

Introduction

Awareness of the increasing litigation relating to permanent synthetic mesh use for hernia repair has become pervasive amongst patients seeking consultation. Over the past several years, prospective patients have been inundated with marketing from law firms soliciting patients that may have had an adverse outcome because of a mesh complication. Since 2016, approximately 288,000 hernia mesh litigation advertisements were aired on televisions across the United States (AdvaMed). More recently, the focus of these marketing efforts has shifted online by way of organic / paid search optimization as well as targeted Pay-Per-Click advertisements on search engines, websites, and social media platforms. As a result, patients researching hernia symptoms and treatment options on the web are likely to encounter results that highlight mesh-related lawsuits and the associated complications. The impact of these pervasive marketing campaigns has subsequently generated inherent bias in a subset of patients prior to office consultation with their surgeon.

In the U.S., approximately 800,000 inguinal and 350,000 ventral hernia procedures are performed annually [1,2]. Hernia repair surgery can range from simple to very complex and can be performed with open surgical techniques or, more recently, minimally invasive laparoscopic/robotic techniques. The choice of technique is dependent on hernia type, size, location, wound status, patient co-morbidities, and prior surgeries. Past studies demonstrate mesh-based hernia repairs lead to less recurrence as compared to non-mesh or suture repairs and this work is driving surgeons to perform most hernia repairs today with the use of a mesh material regardless of technique for repair [3]. Despite the data demonstrating decreased recurrence rates with synthetic mesh, concern over infection and complications led to the introduction of the biologic meshes to decrease infection-related surgical complications [4]. However, a duality exists among biologic and synthetic mesh in that while biologic mesh offers superior performance in contaminated fields, recurrence rates have been shown to be inferior to that of synthetic mesh repair. A 2016 systematic review by Heurta et al. showed a recurrence rate ranging from 0 to 80% using biologic mesh. Due to their high cost and the complex nature of patients and procedures utilizing biologics, the published recurrence rates may suffer from selection bias. Nevertheless, over the past decade there has been a pendulum shift back and forth between synthetic and biologic repair techniques partially based on outcomes and partially driven by increased expense of biologics being driven out of hospital systems to maximize DRG profit margins [5].

The increasing popularity of minimally invasive approaches over the past decade has taught us that placement of synthetic mesh alone may not be the best answer for all repairs as recent studies demonstrate mesh alone without defect closure results in higher

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seroma and recurrence rates than when combined with defect closure [6]. In addition, 5-year follow-up outcomes after synthetic mesh and non-mesh repairs from the Danish Patient Registry demonstrate a 5.6% cumulative incidence of complications (i.e. bowel obstruction, bowel perforation, bleeding, chronic surgical site infections, late intra-abdominal abscess, enterocutaneous fistula, seroma, hematoma, nonhealing wound, and diagnostic surgery due to pain) with mesh as compared to 0.8% in non-mesh repairs resulting in a seven times higher incidence rate in the mesh group [7].

These findings for both biologic and synthetic mesh repair, combined with the recent litigation environment surrounding permanent synthetic meshes, has once again resulted in motivating surgeons to re-evaluate the best technique for repair along with the implants used for reinforcement. In our practice, we sought to leverage the advantages of both biologic and synthetic mesh options while mitigating the inherent risks of each in a combined technique. A brief review of the literature found a study performed by Rosen et al. in 2014 that suggested that reinforcing a biologic with synthetic suture material could potentially mitigate bulging associated with unmodified biologics [8]. As a result, we elected to design and offer a repair combining the data supported principles of (1) suture closure of the defect and (2) reinforcement of the primary repair (Figure 1). Instead of using traditional synthetic or biologic mesh materials individually, we chose to use a permanent reinforced biologic material (OviTex® Reinforced Tissue Matrix, TELA Bio, Inc.) to produce a more natural repair while maintaining data-driven principles. The repair leverages the surgeon's existing tissue repair strategies with the goal of defect closure and augments traditional techniques using the reinforced biologic material to create what we have labeled the Reinforced Biologic Augmented Repair (ReBAR) technique. Here we describe the various techniques and versions of ReBAR that we have performed since 2015 in this single surgeon practice along with the associated clinical results.

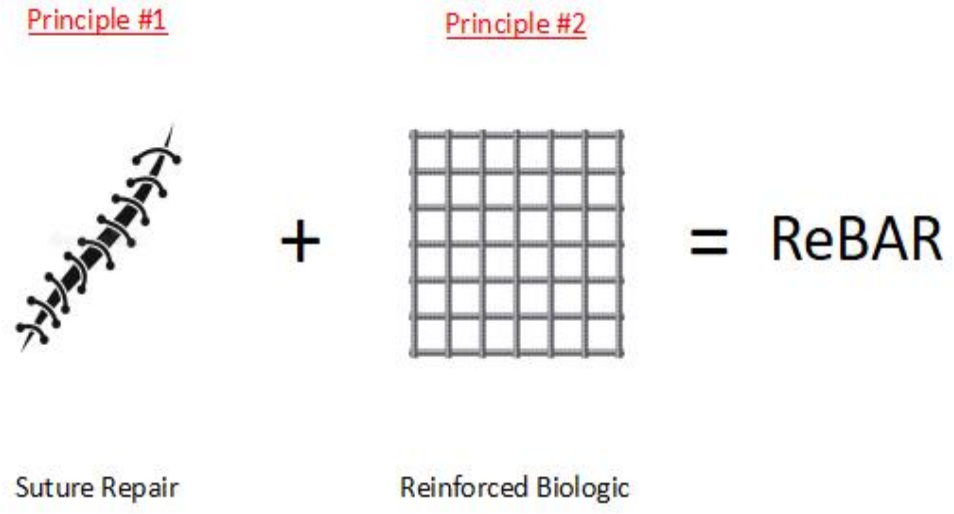

Figure 1: Defining two Principles of a Reinforced Biologic Augmented Repair (ReBAR).

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Methods

All patients undergoing ReBAR from June 2015 to January 2021 were selected for this retrospective quality improvement review. Patient follow-up was conducted through the HIPAA compliant KlaraTM (www.klara.com) direct messaging application. Over time, patients received multiple prompts to self-report any complications. Hernia recurrence, surgical site occurrence (SSO), and surgical site infection (SSI) were specific outcomes selected for review. The basic techniques described here were used in each case.

Robotic TAPP Inguinal Hernia ReBAR Technique

All patients undergoing robotic inguinal hernia ReBAR technique underwent standard TAPP dissection to completely expose the myopectineal orifice. Any indirect, direct, or femoral hernia is reduced. Based on principle 1 of the ReBAR technique the defect is primarily closed with a 2-0 V-LocTM (Medtronic) suture. A proprietary, sterilizable, and reusable template (TELA Bio, Inc.) is used to cut a 10x20cm OviTex Core (permanent) to improve anatomical conformity of the implant. The device is then hydrated, rolled, and passed down an 8mm robotic trocar. The reinforced biologic is carefully positioned to cover the entire myopectineal orifice, anchored at Cooper's ligament medially with a 2-0 permanent V-Loc suture, unrolled bottom to top, and then secured laterally to the abdominal wall using a 2-0 permanent V-Loc suture. The preperitoneal pocket is then closed, the robot undocked, and skin closed based on surgeon's preference.

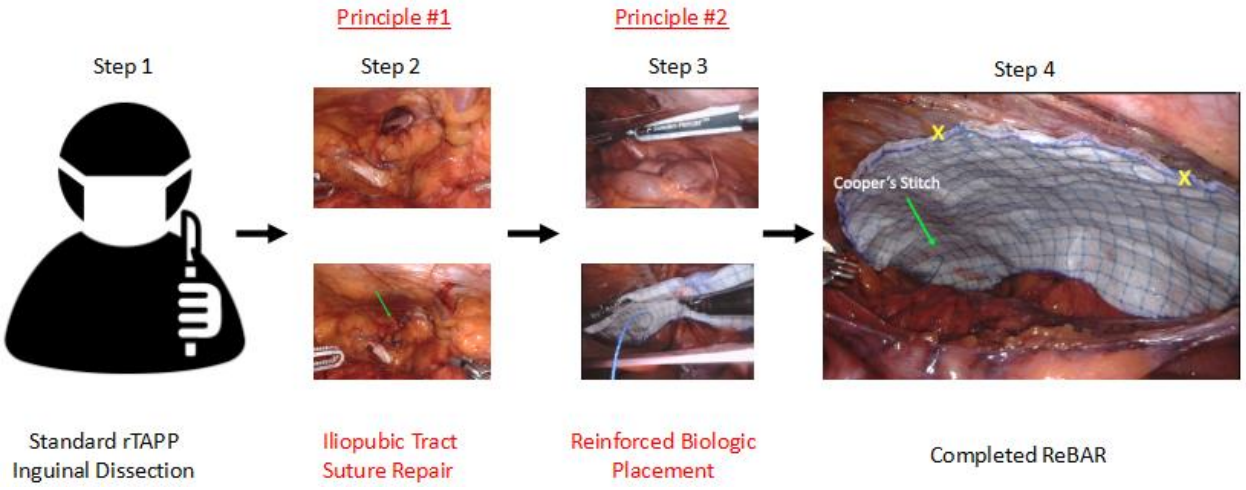

Figure 2: Steps of Robotic TAPP Inguinal ReBAR Technique.

Open Inguinal Hernia ReBAR Technique

The open inguinal hernia ReBAR technique repair combines components of the non-mesh tissue repair of surgeon choice (Shouldice, Bassini, etc.) and augmentation using a reinforced biologic to uphold the principals of repair. When placing the reinforced biologic, we utilize a notch repair with lateralization of the cord to the pelvic brim in contrast to the classic Lichtenstein where we wrap the cord structures in a

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keyhole fashion with mesh. The result is that the repair of the floor of the canal and augmentation with the reinforced biologic creates a Sugarbaker effect within the inguinal canal akin to parastomal hernia repairs. In this series the technique performed was a Shouldice repair using 0 Prolene® (Ethicon) suture followed by placement of a 6x10cm OviTex Core (permanent), notched reinforcement using a running 0 Prolene suture along the shelving edge and subsequently suturing the mesh down circumferentially. The external oblique and Scarpa's fascia were then closed using a running 2-0 PDS® (Ethicon) suture. The skin was run closed using 4-0 Vicryl® (Ethicon) sutures and skin glue.

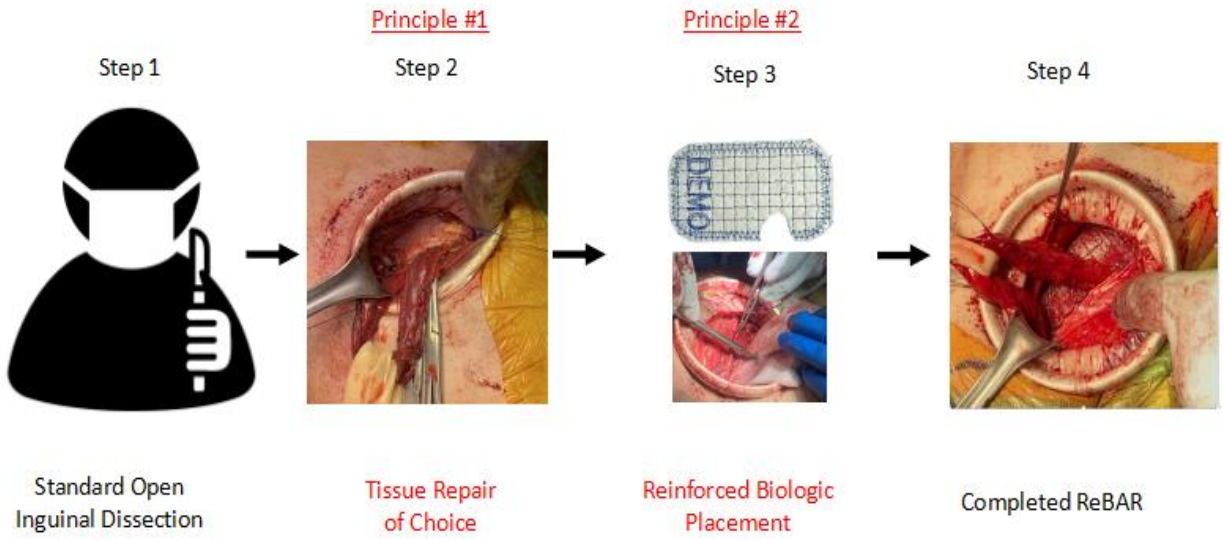

Figure 3: Steps of Open Inguinal ReBAR Technique.

Robotic TAPP Ventral/Incisional Hernia ReBAR Technique

The robotic TAPP Ventral / Incisional Hernia ReBAR technique combines a suture closure of the ventral defect, as well as any diastasis recti greater than 2cm with reinforced biologic augmentation. The surgeon begins by gaining access to the abdominal cavity, docking the robot, and performing a standard TAPP ventral hernia dissection as per their normal technique. After complete reduction of the hernia(s) the diastasis is assessed for plication needs. At this point the hernia defects are closed using a permanent 0 V-Loc suture after placement of several 0 V-Loc absorbable sutures to begin the plication and take the tension off the hernia sites prior to closing the defects with the 0 permanent V-Loc using a serial tension offloading technique through serial tightening. After completion of the hernia defect closure and first layer of plication, a second layer of plication is performed using a 2-0 Stratafix™ (Ethicon) suture. Subsequently, an OviTex LPR 12x 18cm reinforced biologic is trimmed to size, hydrated, rolled with proline side out, and passed down the 8mm DaVinci Trocar. The OviTex reinforced biologic, which has been cut to fit the entire pocket, is then anchored with a single stitch along the far wall and unrolled to completely fill the pre-

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peritoneal pocket. After satisfactory placement, the peritoneal flap is closed using a running 3-0 V-Loc in standard fashion at surgeon discretion to complete the repair.

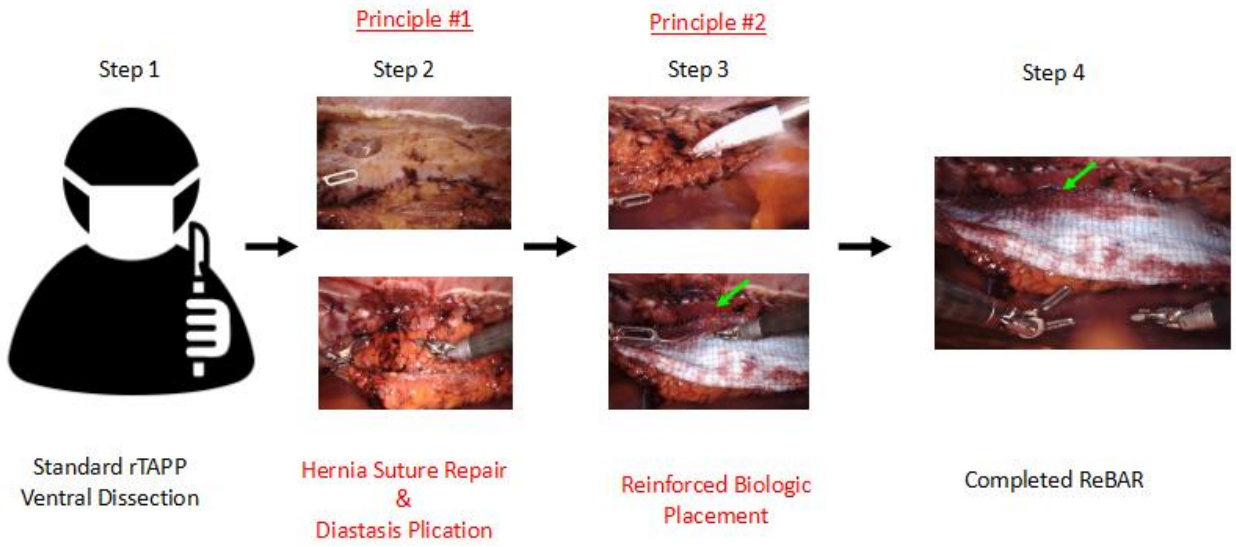

Figure 4: Steps of Robotic TAPP Ventral/Incisional ReBAR Technique.

Open Stapled Single Incision Retrorectus Ventral/Incisional Hernia ReBAR Technique

The open staple Single Incision Retrorectus (sSIRR) ventral/incisional hernia ReBAR technique combines the closure of ventral/incisional defects and diastasis recti using an Signia™ (Medtronic) articulating, laparoscopic powered stapler with reinforced biologic augmentation through a single open incision. The repair begins by making a small 3-4cm incision above the hernia defect and dissecting the subcutaneous tissue to reveal the defect and the anterior rectus fascia. A wound retractor is then placed to allow for visualization and retraction of the subcutaneous tissues. The hernia is then reduced, the pre-peritoneal space is dissected in the cephalad direction, and any holes in the peritoneum are closed using a 3-0 PDS suture. The anterior or posterior rectus sheath are then opened using cautery in the cephalad direction. Once open the posterior rectus space is dissected bluntly and with cautery to create a tunnel on either side. At this point the articulating, laparoscopic powered Signia™ stapler (Medtronic) with 60mm Black reload is inserted into each posterior rectus space and closed with care as not to include peritoneal contents in the jaws. After 20 seconds of tissue compression the stapler is fired. This will create an inferior and superior staple line closure of the midline defect and simultaneously plicate any diastasis recti. This process is repeated cephalad and caudad until the dissection is complete as desired. If necessary, a component separation can be added usually through the same incision. At this point the residual posterior sheath is closed using a running 2-0 PDS II suture. After complete closure, the retrorectus space is irrigated and hemostasis confirmed. At this point two 18" 0 V-Loc sutures are placed at the

apex of the staple lines in either direction. The length and width of the desired reinforcement is then measured and the 20x20cm OviTex Core (permanent) reinforced biologic is turned on a diamond to get a 27cm length and trimmed to fit the entire posterior rectus space. The reinforced biologic is then placed by cabling it into position in the cephalad direction followed by the caudad direction using the previously placed o V-Loc sutures. A this point a single hubless 15 Fr Jackson-Pratt® (Cardinal Health™) drain is placed in the posterior rectus space and the anterior fascia is closed using the o PDS suture. The wound is then closed in layers at the surgeon's discretion.

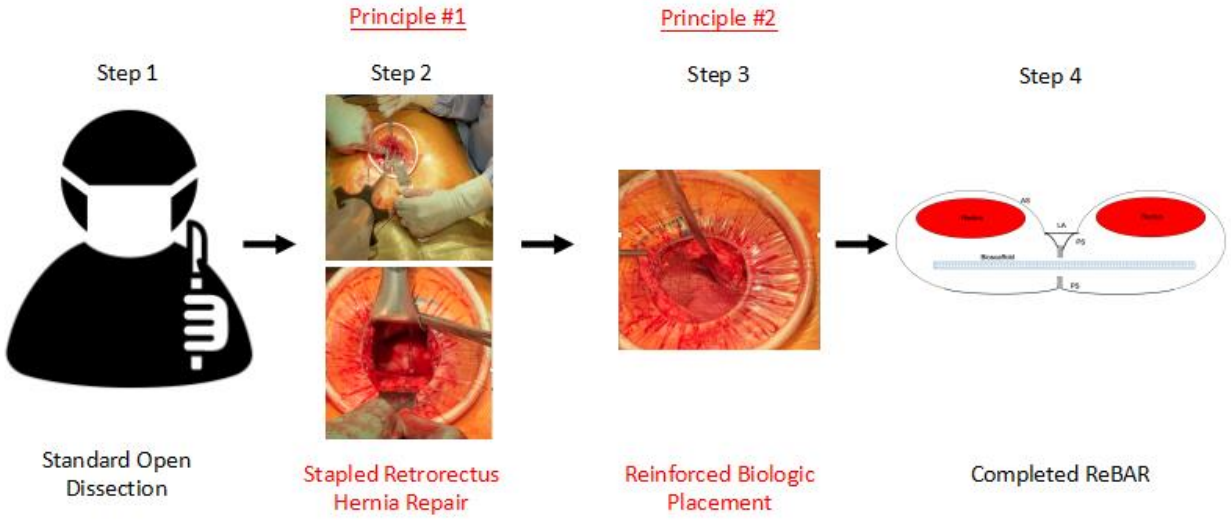

Figure 5: Steps of Stapled Single Incision Retrorectus Vental/incisional ReBAR Technique.

Open Abdominal Wall Reconstruction ReBAR Technique

The open abdominal wall reconstruction ReBAR technique combines the closure of large ventral/incisional defects and diastasis recti requiring component separation of surgeon choice with reinforced biologic augmentation. In our series this utilized a midline incision followed by a transversus abdominis release (TAR) component separation. All defects were closed and a 20x20cm OviTex Core (permanent) reinforced biologic was placed on a diamond. Closure of the midline was performed using running o looped PDS suture followed by a second plication line using o Stratafix. Wound management is at surgeon discretion.

Open Onlay Ventral/Incisional Hernia ReBAR Technique

The open onlay ventral/incisional ReBAR technique combines midline defect closure with diastasis plication through either a midline incision or bikini line panniculectomy incision with a reinforced biologic only to support the closure. The dissection begins with the incision of choice. Flaps are raised and the hernia(s) reduced. At this point all hernia defects are closed using a running o Looped PDS suture. A second plication layer is then performed the alleviate

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any associated diastasis recti using a 0 Stratafix running suture. At this point the 20x20cm OviTex Core (permanent) reinforced biologic is brought to the field, trimmed, hydrated and sewn into the onlay position using a progressive tension manner. The reinforced biologic is anchored cephalad and caudad using 0 V-Loc sutures. The cephalad 0 V-Loc is then run down the lateral border of the reinforced biologic to anchor it 4 cm lateral from the midline closure and plication. At this point the suture is run back up on the same side of the midline closure approximately 2cm medial to the lateral suture line to create a progressive tension pattern. At this point the caudad suture is run up 2cm lateral to the midline closure on the opposite side of the midline and then back down the edge of the reinforced biologic to create the two rows of progressive tension sutures on the opposite side. At this point a 15 blade is used to pie-crust the OviTex reinforced biologic onlay and enhance drainage. The flaps are then sewn down using progressive tension sutures to the reinforced biologic to eliminate dead space. A drain is placed anterior to the mesh in the subcutaneous tissue. The wound is closed and managed at the surgeon's discretion.

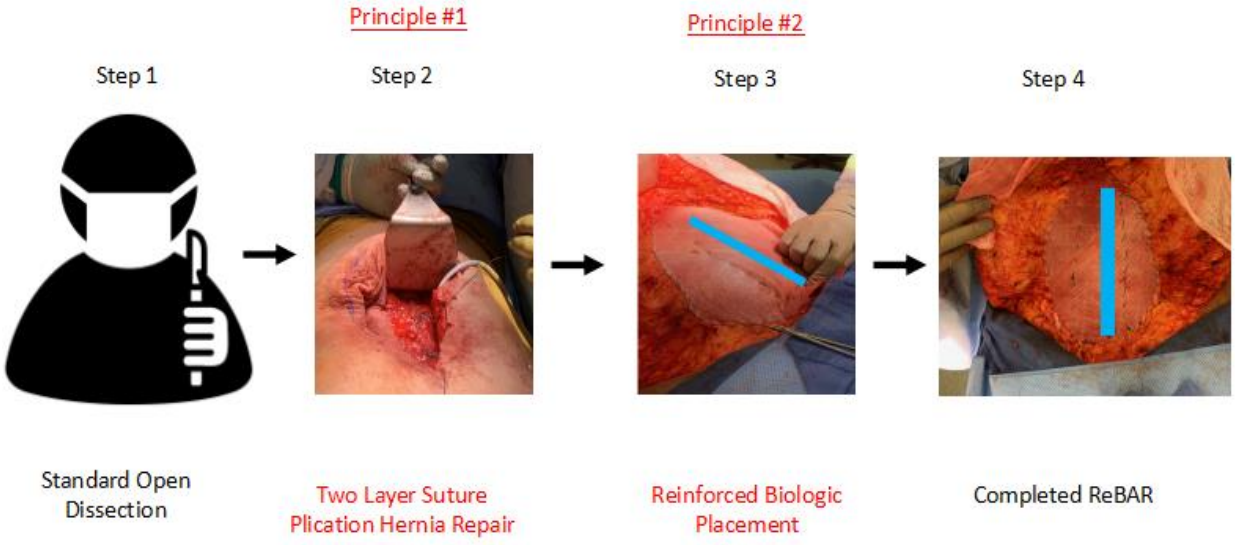

Figure 6: Onlay Ventral/Incisional ReBAR Technique.

Results

From January 2018 to April 2021, 619 implants for the ReBAR technique were identified (data summarized in Table 1). There were 259 (41.8 %) patients who underwent the Robotic Inguinal: TAPP ReBAR. Of these, 3 (1.2%) recurrences were identified with a range of follow-up from 34 to 1092 days and 1 SSO was identified as a seroma that resolved without intervention. In the Open Inguinal ReBAR cohort, there were 47 patients, 2 of which underwent bilateral repair. There were 2 recurrences (4.3%) with a range of follow-up of 41 to 1089 days and 2 SSOs were identified in this group (no intervention except local wound care). There were 59 patients who underwent Robotic Ventral: TAPP ReBAR. Of these, 1 (1.7%) recurrence was identified with a range of follow-up of 32 to 662 days. No

SSOs were identified in this group. The recurrence in this group represented the sole explant in this series when we performed revision of the repair. The Stapled Single Incision Retrorectus ReBAR cohort included 32 patients and no recurrences with a range of follow-up from to 467 to 974 days. There was 1 SSI in this cohort requiring drain placement. In the Open AWR: TAR/ACS ReBAR cohort there were 54 patients. There was 1 recurrence (1.8%) located at a parastomal location with a range of follow-up from 95 to 1155 days. There were six (6) SSOs identified in this group with 4 SSIs (all treated with local wound care and antibiotics, no explants). There were 48 patients who underwent the Open Ventral: Onlay ReBAR with 1 (2.0%) recurrence with a follow-up range of 36 to 774 days. This group had 2 SSOs and 1 SSI (treated with local wound care, antibiotics, and no explants). No recurrences were identified to date in 95 patients underwent Open Ventral: Preperitoneal ReBAR (follow-up range 99 to 1184 days), 2 patients who underwent Open Ventral: Bridged repair (follow-up range 61 to 610 days and both developed SSOs treated with local wound care), and 2 patients who underwent eTEP Ventral ReBAR (follow-up range 139 to 665 days). The final cohort of 21 patients underwent Open Umbilical ReBAR with zero recurrences to date, a range of follow up of 621 to 1764 days, and no SSOs. The total number of recurrences for all patients undergoing ReBAR to date in our series is 8 (1.3%).

Procedure (ReBAR)	Number of Cases	Number of Recurrences	% Recurrences
Total Implants	**619**	**8**	**1.2**
Robotic Inguinal:TAPP	259	3	1.2
Open Inguinal	47	2	4.3
Robotic Ventral:TAPP	59	1	1.7
Stapled Single Incision Retrorectus	32	0	0
Open AWR:TAR/ACS	54	1	1.8
Open Ventral:Onlay	48	1	2
Open Ventral:Preperitoneal	95	0	0
Open Ventral:Bridged	2	0	0
eTEP Ventral	2	0	0
Open Umbilical	21	0	0

Table 1: Statistical distribution of demographic data of all subjects included in this study, in terms of frequency and percentage.

Discussion

Given the increasing emphasis on shared decision making by patients, increasing access to healthcare resources online, and increased litigation surrounding traditional repair techniques, there is a growing need for a hernia repair procedure that addresses both patient concerns and medical benefit. As a result, there has been a resurgence of non-mesh related techniques such as the Shouldice hernia repair. However, this is a prime example of how patient research online can be misleading since most patients believe

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and refer to the tissue repairs as "non-mesh" repairs despite the fact that procedures such as the Shouldice repair utilize 32–34 gauge steel wire or Prolene permanent suture resulting in significant retained foreign body that may even rival some available mesh products on the market. Despite this fact, many patients are choosing the open inguinal "no mesh" repairs over the minimally invasive repairs that have been shown to have less complications and faster recovery but traditionally require mesh reinforcement. In fact, when we measured the retained foreign body for an open "no mesh" Shouldice repair, a classic minimally invasive synthetic mesh repair, and the robotic TAPP inguinal ReBAR technique (Figure 4), we found that the robotic ReBAR technique with OviTex Core (permanent) and our template has less retained foreign body (0.13 grams) as compared to the "no mesh" Shouldice repair (0.20 grams) and the classic synthetic mesh MIS repair (0.97 grams). Hence, we can conclude that the robotic ReBAR repair can provide the advantages of an MIS repair without the use of classic synthetic mesh and result in less retained foreign body than "no mesh" open techniques while providing outcomes for durability that are not significantly different based on our early follow-up.

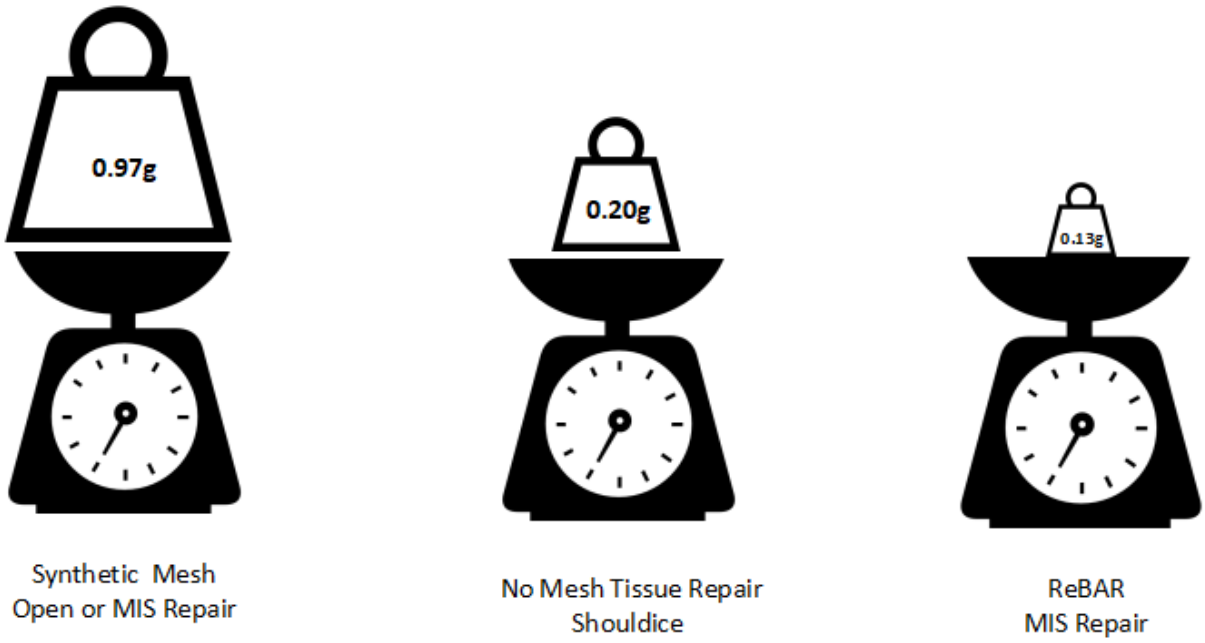

Figure 7: Retained Foreign Body Weight by Repair Type/Material Weight.

The outcomes in this single surgeon series suggest that by following the defining ReBAR technique principles of defect closure and reinforced biologic augmentation, we can provide both safe and durable results while addressing patient fears and desires. In doing so, we can safely offer a shared decision-making model of care delivery to our patients and confidently offer a more natural hernia repair using the ReBAR technique in our practices. The fact that surgeons can leverage pre-existing training with tissue repair

combined with reinforced biologic augmentation makes the ReBAR technique easily adoptable and scalable across a wide variety of practice patterns. By using the ReBAR principles as a guide, surgeons can offer patients a durable repair with minimal permanent foreign body footprint and meet growing patient desires to avoid traditional synthetic mesh. Our ReBAR technique addresses the full spectrum of hernia types, uses all available techniques, is easily adapted into a surgeon's practice leveraging existing skillsets, and enhances patient satisfaction. Our excellent early outcomes show this to be a reliable and durable technique in comparison to classic synthetic mesh repairs without the associated complications. As litigation increases and employed surgeons/hospital systems are faced with increasing responsibility for mesh-related complications as a result of corporate cost-cutting efforts through bulk purchasing of the cheapest materials possible, the ReBAR technique could provide a clear alternative to classic hernia repair methodology and, despite slightly higher upfront costs, may provide improved overall value to patients and the healthcare system. Furthermore, the ReBAR technique and reinforced biologic would provide a more natural hernia repair compared to classic hernia methodology and mesh. Further studies of our ReBAR technique long term outcomes are warranted.

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