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### Update of laparoscopic incisional hernia repair

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# Update of laparoscopic incisional hernia repair

## *Reparación de la hernia incisional por laparoscopia: actualización*

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### Abstract

The repair of incisional hernias with the laparoscopic technique has continued to evolve since its inception in 1991. An analysis of the current literature has revealed that hernias as large as 1,600cm<sup>2</sup> have been successfully repaired with this method. The average size appears to lie in the 105cm<sup>2</sup> range, however. There are several choices of biomaterials that are available today. These differ in the type of synthetic product or the combination of products that are used to manufacture them. Others incorporate an absorbable component. The goal of all is to prevent adhesion formation. The fixation devices that can be used are also varied. The use of trans-fascial sutures in addition to a metal fixation device remains controversial but most place these sutures.

The results of laparoscopic incisional hernia repair are described. The conversion rate of these procedures is an impressive 2.4% with an enterotomy rate of 1.8%. These results affirm the low risk of this operation. The recurrence rate of 4.2% confirms the permanence of the repair. This procedure may become the standard of care in the near future.

**Key words:** Laparoscopy, incision, hernioplasty, prosthetic biomaterial.

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### Resumen

La plastía de hernias incisionales con la técnica laparoscópica ha continuado evolucionando desde su concepción en 1991. El análisis de la literatura actual revela que pueden repararse con éxito hernias hasta de 1,600 cm<sup>2</sup> mediante esta técnica. Sin embargo, el tamaño promedio se encuentra en el rango de 105 cm<sup>2</sup>. Hoy en día existen diversas opciones de biomateriales disponibles. Éstos difieren en el tipo de producto sintético o la combinación de productos empleados en su manufactura. Otros incorporan un componente absorbible. La meta de todos estos materiales es evitar la formación de adherencias. Los dispositivos empleados para su fijación también varían. El uso de suturas trans-fascias junto con un dispositivo metálico de fijación sigue siendo controversial, aunque la mayoría de los cirujanos coloca estas suturas. Se describen los resultados de la hernioplastia incisional laparoscópica. La tasa de conversión de estos procedimientos es de un impresionante 2.4% con una tasa de enterotomías del 1.8%. Estos resultados reafirman el bajo riesgo de esta operación. La tasa de recurrencia del 4.2% confirma asimismo la permanencia de la plastía. Este procedimiento podría convertirse en el estándar de atención en un futuro cercano.

**Palabras clave:** Laparoscopia, incisión, hernioplastia, biomaterial protésico.

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### Introduction

There are many well-known and accepted methods to surgically treat the hernias that develop following incisions of the anterior abdominal wall. The permanence of the repair of incisional hernias has been difficult because of the high frequency of failure with the traditional open repair methods. This has been reported as

high as 52% for the primary sutured repair and 25% with the utilization of a prosthetic biomaterial.<sup>1-4</sup> With the introduction of the laparoscopic technique for this hernioplasty, it was hoped that an improvement in the recurrence rates, as well as the complication rates, would be achieved.<sup>5</sup> The increasing growth of this methodology across the world would indicate that these

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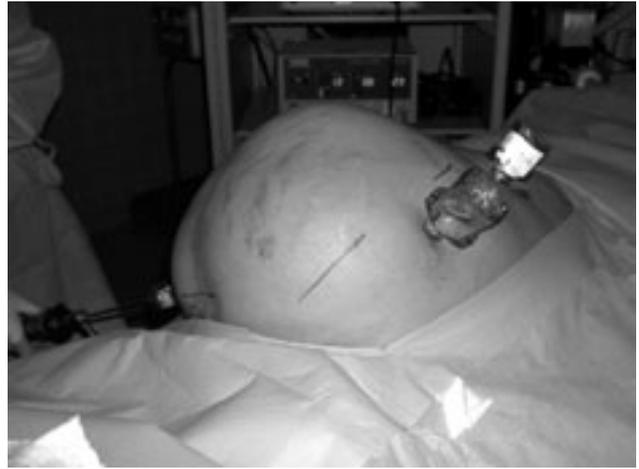
goals might be appreciated. There are many publications in the literature that appear to prove that the complication and recurrence rates are markedly lower with the laparoscopic methodology. This article will provide a short review of the literature of the current methods of the minimally invasive approach to incisional and ventral hernia.

### Technique

While, like most surgical procedures, there are numerous variations of the exact methodology that is used by any one surgeon, there are several common steps that are followed by all. This would include the entry into the abdominal cavity by any of a variety of methods, based upon the surgeon's preference and the prior abdominal procedures that the patient may have had. One may elect to enter the abdominal cavity with the use of a Veress needle, an open entry (Hasson) or the use of an optical trocar that allows the view of the layers of the abdominal wall to be seen as they are penetrated. The choice of the trocar sizes that follow will be influenced by the sizes of the laparoscope and the instruments that are used to perform the operation. I, typically, will use only 5mm trocars.

Once the appropriate number of trocars, generally 3-4, has been introduced into the abdomen, the next and most tedious portion of the operation commences. The lysis of the adhesions within the abdomen will be done with or without the use of an energy source such as the electrocautery or an ultrasonic scalpel. This will be dictated by the proximity of the bowel. No energy should be applied adjacent to any structure that might incur an injury. Perforation of the intestine, even if recognized, remains the most lethal risk of laparoscopic hernioplasty.<sup>6</sup>

Once the hernia defect or defects are revealed, the surgeon must assess the dimensions of them. There are many alternatives in which to accurately determine the size of the fascial defects. For some, this is marked by the passage of spinal needles into the abdomen. For others, such as this author, simple marks on the exterior surface of the skin will denote the location of the cranio-caudal and lateral extent of the hernia orifices (**Figure 1**). The actual measurement of these marks can be grossly inaccurate if the abdomen is fully insufflated when the measurement is taken. This will be caused by the extreme increase in the size of the abdominal wall because of the insufflation pressure. Because of this, the carbon dioxide must be released prior to this measurement to reveal the true size of the fascial defect. This difference in the appearance of the abdomen will sometimes be surprising (**Figure 2**). The cranio-caudal and lateral measurements will then be made, to which six centimeters will be added to both directions. This will then provide for a minimum of a three-centimeter overlap of the fascial edges of the hernia by the prosthetic biomaterial. This minimum overlap is the consensus of opinion by most laparoscopic surgeons, although some prefer a 4-5cm overlap.<sup>7</sup> I tend to use the larger dimensions if the hernia is very large, the patient is morbidly obese or if the hernia is multiply



**Fig. 1.** Marks on the exterior surface on the skin to denote the location the extent of the hernia.



**Fig. 2.** Inaccurate mark when the abdomen is fully insufflated.

recurrent. The prosthetic size that most closely approaches this measurement will be the one that is selected for implantation. Generally this will be the next larger measurement. For instance, if the defect measures 10 x 15cm, the additional three centimeters will become 13 x 18cm. The available patch size closest to that dimension is the 15 x 19 cm product, which should be chosen. On only a few occasions will any portion of the biomaterial require trimming. This can occur near the costal margin or in patients with very small abdominal cavity dimensions laterally. Additionally, most surgeons prefer to place a prosthesis of sufficient size so that the entire incision will be covered by the biomaterial even if the hernia is smaller than the length of the incision. This will prevent the future development of a hernia in the uncovered portion of the original incision.

The choice of biomaterial varies greatly even within a single institution. There are a variety of products that are

commercially available which attempt to prevent the contact of the intestinal contents with the synthetic biomaterial so that the development of adhesions is diminished or prevented. The proven risk of fistula formation with direct contact of the bowel to polypropylene or polyester has caused most surgeons to avoid these biomaterials.<sup>8</sup> My product of choice is the DualMesh<sup>®</sup> Plus (W. L. Gore and Associates, Flagstaff, AZ, USA) because of the anti-adhesive properties, the antimicrobial agents that are impregnated within it and the brown color that is imparted because of these agents.

Finally, the prosthesis is introduced after it is tightly rolled and brought in via a trocar site. It will then be fixed to the abdominal wall by any one of several metal fixation devices and/or transfascial sutures. This latter point is one that has been associated with a large degree of disagreement as to the true need of the addition of these sutures. Those that use them argue that the recurrence rate is too high without them. Those that do not use them disagree and further state that the postoperative pain in these patients is lessened by the omission of their use.

### Biomaterials

The biomaterials that are available to repair these hernias laparoscopically have undergone many changes over the last several years. In fact, there are new products that have either been recently introduced or are in the developmental stages. All seek to achieve two goals, rapid and permanent in-growth into the prosthesis and diminution of the risk of intestinal adhesions. These synthetic products can be divided into that of a single material or those of two or more composite materials (**Table I**). The composite types may or may not include an absorbable component. The majority of these can be used either for the laparoscopic repair or the open method based upon the choice of the surgeon.

The expanded polytetrafluoroethylene (ePTFE) biomaterials have the longest history in the use for this hernia repair. The original description of the procedure used an early generation of the ePTFE product.<sup>5</sup> The current product is one-millimeter thick and has different surfaces on either side of the sheet. One surface has a smooth surface in which the interstices of the ePTFE measure three microns, while the other side has interstices of approximately 22 microns. Additionally, the surface of this side has ridges that resemble corduroy fabric. This is meant to facilitate in-growth of collagen to ensure firm fixation, which has been confirmed in the laboratory.<sup>9</sup> The DualMesh with holes is 1.5mm thick and has evenly spaced holes throughout the product. The antimicrobial agents silver and chlorhexidine have been incorporated into these biomaterials to become the 'Plus' product line. Dulex has a sandpaper appearance on one surface and a smooth surface on the other. This ePTFE differs from that of the DualMesh in that it has a laminated structure rather than the pores that transverse within the product.

All of the Composix prostheses have ePTFE and PPM but differ in the number and attachment of them

together. The original Composix has two layers of Bard mesh that are heat sealed together with a thin layer of ePTFE, while the Composix has a single layer of Bard mesh and a slightly thicker ePTFE layer that is sewn to it. The Composix Kugel is similar to this but adds a ring of polyester to stiffen the prosthesis in an effort to ease its manipulation within the abdominal cavity.

Parietene and Parietex both incorporate hydrophilic collagen into the weave of the biomaterial. The latter is absorbed by the fourteenth postoperative day. It is meant to inhibit the contact of the intestine to the polypropylene (PPM) or polyester (POL) respectively, thereby minimizing the risk of adhesions. Proceed has four components. The PPM is the Prolene Soft mesh that is commercially available from Ethicon, Inc. On either side of it, a thin film of PDS has been laminated onto the PPM to stiffen the mesh. On one surface, oxidized regenerated cellulose (ORC) is attached to create a 'tissue-separating' mesh in that the ORC will separate the PPM from the underlying intestine to minimize tissue attachment. The PDS and ORC will be absorbed to leave only the PPM. Sepramesh IP should not be confused with the older (and no longer available) Sepramesh. The newer biomaterial is constructed of PPM with incorporation of bioresorbable polyglycolic fibers and a layer of hyaluronic acid with carboxymethylcellulose. The latter is meant to protect the viscera.

The clinical experience with all of these products varies from country to country. The DualMesh has gained the largest global experience but the Composix products are increasing in use. Surgeons should base the choice of any of these products on the available clinical and research data.

### Fixation methods

Fixation of all of these biomaterials is required until sufficient in-growth has made the collagen impregnation sufficiently strong to ensure repair of the fascial defect. While there is controversy of the need for suture fixation, there is agreement that the use of a metal fixation device is vital. There are actually five devices that are currently available; all are different in some way.

The original methods were those of titanium staples. There have been many variations of the shape, size and articulations of the devices themselves. Currently, the most commonly available staplers are those of the Ethicon EMS and the AutoSuture Universal stapler. These are not used extensively because both require the use of a trocar larger than 5 mm. An additional unique fixation device that differs from all of the others is that of the Sofradim Pariefix. This is the only fixation device that utilizes an absorbable product to fixate the mesh. It has a distinctive 'T' shape appliance that is delivered via a 10 mm instrument.

The more commonly used fixation methods are those of the 5 mm products. The Protack delivers a helical titanium coil that is screwed into the mesh and the fascia. While there is a large experience with this product, there are a few adverse reactions that have been reported, such as fistulization or herniation as a direct

**Table I.**  
**Synthetic prosthetic biomaterials available for laparoscopic incisional hernia repair.**

Type of Biomaterial	Product Name	Manufacturer
ePTFE	DualMesh	WLGore & Associates, Flagstaff, AZ, USA
ePTFE	DualMesh Plus	WLGore & Associates, Flagstaff, AZ, USA
ePTFE	DualMesh with holes	WLGore & Associates, Flagstaff, AZ, USA
ePTFE	DualMesh Plus with holes	WLGore & Associates, Flagstaff, AZ, USA
ePTFE	Dulex	CRBard, Cranston, NJ, USA
PPM(2) + ePTFE	Composix	CRBard, Cranston, NJ, USA
PPM + ePTFE	Composix EX	CRBard, Cranston, NJ, USA
PPM + ePTFE + POL ring	Composix Kugel	CRBard, Cranston, NJ, USA
PPM + Collagen	Parietene	Sofradim Int., Villefranche-sur-Saône, France
POL + Collagen	Parietex	Sofradim Int., Villefranche-sur-Saône, France
PPM + PDS(2) + ORC	Proceed	Ethicon Inc., Somerville, NJ, USA
PPM + PGA+HA+CMC	Sepramesh-IP	Genzyme Corp., Cambridge, MA, USA
CMC – carboxymethylcellulose		
ePTFE – expanded polytetrafluoroethylene		
HA – hyaluronic acid		
ORC – oxidized regenerated cellulose		
PDS – polydioxanone		
PGA – polyglycolic acid		
POL - polyester		
PPM – Polypropylene		

result of the product.<sup>10,11</sup> The Salute stainless steel construct differs from all of the other fixation products in that this is not a preformed device. This is the only reusable instrument that utilizes a spool of wire that delivers the construct at the site of fixation as the instrument is fired. The spools that deliver the coils are available to deliver either 20 or 50 constructs. The latest addition is that of the EndoAnchor which is also unique in that the closure of the firing mechanism does not release the fixation device but instead causes a large needle to exit the end of the instrument. Within it is the nitinol anchor that is deployed when the handle is released.

## Results

We have had a keen interest in this procedure since our first trials in its utility in 1991. While we continue to closely monitor the results of our patients, we have published our results in our first and second hundred patients.<sup>12,13</sup> We have modified our technique based upon the results that we have observed in the follow-up of these patients. Initially, the use of transfascial sutures was not considered important. However, in the first group, the recurrence rate was 13% without the use of them whereas none were noted in the patients in which these were used. Additionally we noted that the fascial overlap required to perform an adequate operation must be at least 3cm. Subsequent to the change in the technique that incorporated these important tenets, the recurrence rate dropped to 2% in those patients that did not involve a true technical error. The second series of patients incurred two individuals that developed infections that involved the patch, which required explantation of it, resulting in re-herniation. Two other recurr-

es were noted but one occurred along the incision that was not covered by the original patch. The other resulted from intraoperative clamping of a transfascial suture that caused it to fracture allowing the patch to pull off of the fascia shortly after the operation. Modification of our technique to encompass these factors and the use of the antimicrobically impregnated DualMesh has virtually eliminated any recurrences or immediate postoperative infections.

The most common postoperative complication remains that of a seroma. This will be seen in almost all patients but will be clinically significant in only approximately 8% of them. Aspiration is rarely needed but will be required if the patient experiences significant pain or a poor cosmetic result. Persistent pain at a suture site has been noted in about 1.5% of the patients.<sup>13,29</sup> More often than not, this pain may be controlled by a trial of anti-inflammatory agents but may require treatment for several weeks. The injection of bupivacaine at the site of the painful suture location will very frequently eliminate the pain and should probably be attempted at the onset of the complaints once the immediate postoperative period of pain has subsided. If this fails, operative extraction of the offending suture will be required but this is a very infrequent occurrence. The key is prevention by not tying the sutures so tightly during the procedure such that the suture knot will be drawn into the subfascial space over time. (**Table II**).

The long-term follow-up of our patients has confirmed that there are three critical considerations in this procedure. First, the use of a biomaterial that has sufficient in-growth to allow permanent fixation and minimizes adhesion formation is paramount. Second, the overlap of the fascia must be at least 3cm for all patients but

should be 4-5cm if the hernias are recurrent or if the patient is morbidly obese. Finally, the use of staples or tacks alone is insufficient to ensure adequate fixation of the patch and prevention of recurrence. Transfascial sutures must be placed no more than 5cm apart along the entire periphery of the patch to ensure sufficient attachment to the anterior abdominal wall. Because some studies contradict this statement, the use of these sutures is controversial.

There have been numerous studies that have reported experiences of this procedure, many have few patients and included those operations that were performed in the early experience of the surgeons. A literature review has produced the series in **table III**, all of which have an experience of greater than 50 cases. Authors that have published more than one paper on their series are only shown with the latest update of that data.

From these series, a total experience of 3,434 patients has been reported. As shown, 82% of these patients underwent a repair with the single ePTFE product from W. L. Gore and Associates. This represents a very favorable record with this prosthesis. The majority of authors included the use of transfascial sutures as a method of fixation of the patch. A careful review of these papers does not clearly identify an absolute need of suture fixation. However, none of these papers included a prospective trial with and without the use of the sutures. My own bias remains that the use of the additional sutures seems prudent. Since our early experience, newer biomaterials and better fixation devices may negate the need of the sutures, which seem to predispose to more postoperative pain. However, firm clinical evidence is lacking at this time. It is uncontested that a minimum follow-up of 36 months is required to accurately assess the recurrence rate of hernias. Therefore, the series that do not meet this criterion cannot be assumed to be the final outcome. My recent extensive review of the literature to define the need for sutures did not affirm an advantage or disadvantage of transfascial sutures.<sup>14</sup> A prospective randomized trial investigating the use of transfascial sutures in this operation is ongoing and will, hopefully, answer this question definitively.

The noted complications of seroma and infection are quite low. There is a larger incidence of seroma formation but the low number reported is related to the varying clinical definition of this complication. It is generally agreed that this is insignificant if the patient is asymptomatic or if no intervention is required. Infections are very low, as expected. If this develops, the ePTFE patch will generally require excision.

**Table III** itemized the number of patients and other measurements. The operative time is comparable to that of the open procedure, as is the overall defect size. From the ranges of defect sizes that are reported in these series, very large hernias have been proven to be repairable with the laparoscopic methodology. The conversion rate of 2.4% is very low considering the fact that many of these patients had numerous prior procedures, including a hernia repair with PPM. Sever-

al of these series converted to open because of an observed enterotomy. The important number in these data is the fact that an average of 1.8% of these cases will be complicated by an enterotomy. The majority will be observed and the appropriate repair will be performed. However, if unrecognized, this injury can result in death.<sup>6</sup>

The gold standard of comparison with this operation is that of the recurrence rate. In these reports, this represented a very low rate of 4.2%. Most of these series included the early experience of the authors; therefore, this figure is even more impressive compared to the known rate of recurrence in the open prosthetic repair of 10-25%. There is a large variation from 1-16% in these reports but this reflects the early experience of the authors. Given the length of follow-up of many of these publications, one should assume that this may represent the accepted rate of failure of this procedure in experienced hands.

### Discussion

There are many aspects of this technique that could be discussed but this would be beyond the scope of this article. Suffice to say that this is an acceptable method to repair the complex problem of incisional herniation. The technical skills to successfully complete this operation can be learned by most laparoscopic surgeons. In fact, its use is increasing and I believe that this procedure will become the standard of care in the not too distant future.

There has not been an extensive discussion in the literature regarding case selection of the patients that present with hernias that may be amenable to this technique. The majority of surgeons in the series above did not perform any additional operative procedures during the hernioplasty. However, several authors, including myself, will perform cholecystectomy or additional hernia repairs if indicated. Only a few of the authors have performed intestinal resection during the repair of the hernia that included the placement of a prosthetic biomaterial. Incarceration is not a contraindication to this technique.<sup>13</sup>

Hernia defect size should be considered carefully, especially early in one's experience. In our own series, the average size of the defects that were repaired was 111cm<sup>2</sup> but ranged from 2.25-600cm<sup>2</sup>. Currently, the only patients that are not offered this procedure by our group are those that have obvious loss of domain that will prohibit the introduction of the trocars lateral to the fascial edges of the hernia or if an infection is present. These are repaired with an open technique that incorporates relaxing incisions, the component separation technique, or one that mimics the laparoscopic approach described. We have also repaired a few of them with the use of a prosthesis that incorporates a tissue-separating layer of absorbable material but our results have not been favorable with this prosthetic biomaterial.

While the dimensions used in this decision process are not specifically addressed in the quoted articles, there are several that included the measurements of the defects that were treated. The sizes of these herni-

**Table II.**  
**Published results of laparoscopic ventral hernia repair postoperative findings.**

Reference	Seroma rate (%)	Infection rate (%)	Recurrence rate (%)	Prosthesis Used	Transfascial sutures	Average follow-up (months)
Toy <sup>14</sup>	16	3	4	ePTFE	+ (4)	8
Kyzer <sup>15</sup>	-	2	2	ePTFE	+ (4)	12
Roth <sup>16</sup>	4	4	9	ePTFE, PPM	+	-
Chowbey <sup>17</sup>	18	2	1	PPM	-	35
Birgisson <sup>18</sup>	5	4	2	ePTFE	+	10
Bageacu <sup>19</sup>	16	3	16	ePTFE	+	49
Ben-Haim <sup>20</sup>	11	1	2	ePTFE	+	19
Berger <sup>21</sup>	92.7	0	2.7	ePTFE	-	-
Aura <sup>22</sup>	14.1	0	7	ePTFE	+ (4)	37
Gillian <sup>23</sup>	-	0	1.0	ePTFE + PPM	-	-
Eid <sup>24</sup>	3.8	0	5	ePTFE	+/-	34
Chelala <sup>25</sup>	5	0	0.8	Polyester + collagen	+	10
Carbajo <sup>26</sup>	11.8	0	4.4	ePTFE	-	44
LeBlanc <sup>27</sup>	7.5	2	6.5	ePTFE	+	36
Heniford <sup>28</sup>	2.6	0.7	4.7	ePTFE	+	20.2
Bower <sup>29</sup>	1.0	2.0	2.0	ePTFE	+	6.5
Sánchez <sup>30</sup>	9	0	3.5	ePTFE	-	18
Franklin <sup>31</sup>	3.1	0.3	2.9	PPM, collagen	+	47.1
Frantzides <sup>32</sup>	0	0	1.4	ePTFE	-	24
Average	13	1.9	4.2			25.8

**Table III.**  
**Published results of laparoscopic ventral hernia repair perioperative findings.**

Reference	Patients (n)	Hernia Size (cm <sup>2</sup> )	Operating time (min)	Conversion rate (%)	Enterotomy rate (%)
Toy <sup>15</sup>	144	98	120	-	1.4
Kyzer <sup>16</sup>	53	-	89	4	3.6
Roth <sup>17</sup>	75	101	105	3	2.7
Chowbey <sup>18</sup>	202	-	50	0	0
Birgisson <sup>19</sup>	64	119.2	130	0	3.1
Bageacu <sup>20</sup>	159	-	89	14	1.9
Ben-Haim <sup>21</sup>	100	89	114	3	6
Berger <sup>22</sup>	150	89.5	87.5	0	2.0
Aura <sup>23</sup>	86	26.5	110.3	1.2	0
Gillian <sup>24</sup>	100	-	-	0	3.0
Eid <sup>25</sup>	79	103	110	1.25	2.5
Chelala <sup>26</sup>	120	-	75	0	0
Carbajo <sup>27</sup>	270	145	85	0.3	1.1
LeBlanc <sup>28</sup>	200	111	83.5	3.5	0
Heniford <sup>29</sup>	850	118	120	3.6	1.5
Bower <sup>30</sup>	100	124.4	-	1.0	0
Sánchez <sup>31</sup>	90	69	101	5.8	3.3
Franklin <sup>32</sup>	384	-	68	2.9	1.3
Frantzides <sup>33</sup>	208	173	126	0	1.0
Average	181	105.1	97.8	2.4	1.8

as ranged from 2.25-1600cm<sup>2</sup>, with an average size range of 40.6-150cm<sup>2</sup>. The average size, as shown in **table III** is 105.1cm<sup>2</sup>. The success of these authors lends credence to the general applicability of this operation. It is apparent, however, that this use of this methodology does not restore the normal anatomy with the pre-requisite normal physiological function. While this has caused many surgeons to criticize this technique, no series published thus far has experienced any adverse pulmonary outcome because of the lack of the reconstruction of the linea alba. Further study in this area is still warranted, however.

A point that has not been adequately addressed in the literature is the preferred management of the hernia defect once a recognized enterotomy occurs. I recently reviewed the available studies that have experienced this event.<sup>6</sup> Based upon that study, it was shown that 85% of the enterotomies are recognized. In the majority of cases the hernia was repaired as planned with the use of a prosthetic biomaterial (usually antimicrobially impregnated ePTFE). There were no adverse outcomes related to the hernia repair in any patient. It could be inferred, then, that if there is no or minimal contamination with the bowel injury that the hernia should be repaired concomitantly. However, antibiotics should probably be continued for seven days prophylactically. The experience of the surgeon and the definitive risk of infection should be considered carefully in any patient in whom this situation presents.

## Conclusion

The future of incisional hernia repair is evolving today. There are some authors that have successfully repaired these complex hernias using robotic devices.<sup>33</sup> This may or may not prove beneficial in the further study of these methods. Of more importance is the continuing development of newer prosthetic biomaterials. The ideal product has yet to be achieved in the clinical setting as all have some aspect of imperfection or acceptance by the surgical community. Ultimately, I believe the answer may lie in the production of genetically re-engineered collagen from the patient's own fascia that will be enhanced and strong enough to be used for the repair of fascial defects. This may provide the best results for our patients.

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