controversial topics in surgery

Mesh repairs in hiatal surgery

Hiatal hernia repair is noted to have a considerable failure rate. Using clips placed on the crural repair and on the fundoplication limbs we have noted a 20% failure rate 6 months following standard laparoscopic fundoplication – albeit the anatomical failure rate has a low correlation with symptomatic failure. Hashemi *et al.* (*J Am Coll Surg* 2000; **190**: 553–61) radiologically demonstrated a 29% recurrence rate (42% in those repaired laparoscopically) in type III hiatal hernia. Ketly and Falk oppose the wide-spread use of mesh hiatoplasty citing complications such as fibrotic stenosis and mesh erosion into the oesophagus, sometimes necessitating oesophagectomy. They compare the success of mesh hiatoplasty with that of mesh

repair of parastomal hernia. Smith argues in favour of mesh repair on account of the tension of sutured hiatoplasty on the thin, attenuated and widened crural pillars observed in large hiatal defects. With increasing use of the more biologically compatible meshes now available, this technique will gain in popularity in an attempt to reduce the anatomical recurrence rate of sutured hiatoplasty.

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The case against mesh repairs in hiatal surgery

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Repair of hiatus hernias has evolved over recent years, and is now almost universally performed by the laparoscopic approach. There has been an increasing vogue for using prosthetic material to reinforce the repair in large hiatus hernia, particularly since the recurrence rate following this type of surgery is high, and recurrent hiatal herniation accounts for up to 70% of re-operations for failed antireflux surgery.^{1,2} There is, however, a lack of hard data to back up this practice, and the use of prosthesis remains developmental.

The rationale for using prosthetic reinforcement

An enlarged hiatus is traditionally closed with interrupted large-gauge sutures (primary closure; simple cruroplasty).^{3,4} However, any closure method is prone to disruption since the diaphragm is under repetitive stress due to the mechanics of respiration. The driving force for the use of prosthetic mesh placement is the reported recurrence rate

in large hiatus hernia in the range of 5–30%.^{1,2} It is widely recognised that the closure of large fascial defects elsewhere in the body (*e.g.* inguinal or ventral hernia) under similar mechanical stresses has been performed using prosthetic patches with excellent results.⁵ However, the use of mesh is associated with an intense scarring response; although this is, in part, the rationale for its use, it can also cause problems, particularly when the site where it is used is considered.

The techniques used for hiatal repair vary in the studies reported, with some using primary closure of the crura followed by prosthetic onlay, whereas others are encircling the entire hiatus with a ‘slit’ cut in the mesh for the oesophagus (similar to an inguinal hernia repair).⁶ It is presumed the mesh in this situation functions as a buttress, protecting the cruroplasty sutures from the intra-abdominal forces. A laparoscopic hiatus hernia ‘tension-free’ repair with prosthetic has been described, in which the defect is left open

and the prosthetic bridges the gap. This has also been modified using a relaxing incision in the diaphragm to the right of the hiatus, which is patched following repair of the crura. The theoretical advantages and disadvantages of the above procedures may be argued, but there is no evidence to demonstrate the superiority of any of these techniques.

Complications of prosthetic material

Various complications have been reported with the use of prosthetic material following hiatal hernia repair. These include inflammation, stricturing, bleeding and visceral erosion of the prosthesis. The most significant of these is erosion of the prosthetic material into the oesophagus, as well as complications related to severe adhesions and fibrotic strictures. This can be dependent upon the type of prosthetic material used; indeed, polypropylene mesh has been recognised as being responsible for erosion into hollow viscera when placed elsewhere within the body.⁷ Teflon pledgets, despite supposedly being biologically inert, have been shown to erode into the oesophagus and stomach after fundoplication, requiring re-operation.^{8,9} It has, therefore, been argued that more inert substances are more appropriate, including PTFE and newer 'biomaterials' (e.g. porcine acellular tissue graft, Surgisis®; Cook Biotech Inc., West Lafayette, IN, USA). Nylon meshes have been reported as eroding into the oesophagus, necessitating re-operation and, almost invariably, resection of the effected segment, requiring oesophagectomy.^{6,9,10}

Although these reports could be dismissed as being anecdotal, there are further negative experiences associated with another prosthetic implant – namely the silastic Angelchik prosthesis which was used at the hiatus for the treatment of reflux disease.¹¹ This was associated with a large complication rate, and had to be removed in almost half of the patients in whom it was inserted. Its most dangerous complication was visceral erosion, and it caused bowel obstruction after extrusion into the lumen of the stomach, or was passed per rectum. It would seem that placement of any type of mesh prosthesis against a hollow organ is much more likely to cause complications than in incisional or inguinal hernia repair.

Discussion

The decision as to the advisability of a mesh repair hinges upon the rate of recurrence and complications in the longer term, compared with the recurrence rate and complications of primary repair alone. In the literature, an improvement is noted in the results of incisional and inguinal hernia repair as prosthetic utilisation became more common; thus, the extension of prosthetic use to include the large hernia of the oesophageal hiatus initially seems logical. However, the

presence of a hollow organ changes the paradigm. A better analogy may be that of repair of parastomal hernia, which is associated with high rates of morbidity, mortality and recurrence (in up to two-thirds of patients having simple fascial repair). However, mesh repair is still associated with a recurrence rate of up to 40%,¹² and re-operation for complications is frequent (25–30%) – similar to those reported in hiatal hernia surgery.

It could be argued that since recurrence occurs in approximately 10–30% of patients who undergo primary repair of large hiatus hernias without prosthetic mesh, the use of mesh placement at the hiatus of every large defect to reduce the likelihood of recurrence would not be necessary in 70–90% of patients. These patients are thus put at risk of mesh-related complications unnecessarily. However, the data required (and lacking presently) are the complication rates from repair of hernias with and without mesh, over a long period of time. Of the studies performed to date, there is rarely long-term follow-up (the mean follow-up is at best 5 years). The majority of symptomatic problems will occur after this period of time; indeed, erosion of prosthetic material into the oesophagus has been reported over 9 years following the original surgery.⁹ More importantly, it is the impact upon quality of life that treatment of the complications incurs that may be the deciding factor. Even assuming a low rate of complications of mesh repair, the morbidity and mortality associated with oesophagectomy (even in the best hands) is significant, and we would argue has a far greater impact on quality of life for these patients than a laparoscopic revision of hiatus hernia repair. This may be compounded by the elderly nature of this population at the time of primary surgery, who may be 10 or 15 years older at the time of revision and unable to tolerate revisional surgery.

We would argue that whilst there have been some promising early results with the use of prosthetic material, the long-term outcomes remain unknown. It may be that, when long-term data are available, we will find that the implications of complications are much higher than currently thought. Albeit the risk of prosthesis-related complications appears to be infrequent (ranging from 2–20%⁶), when one considers the potential need for major radical surgery in the event of complications, this is not a valid reason for performing routine mesh placement in the repair of hiatus hernias, and cannot justify the wide-spread adoption of what remains an unproven technique. A more appropriate policy, therefore, may be to consider mesh hiatoplasty in the select group of patients who have a recurrence following primary repair as the risk of complications can be better justified.

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The case for mesh repairs in hiatal surgery

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The use of fascial prostheses, or mesh, to repair the oesophageal hiatus has provoked discussion among upper gastrointestinal surgeons. Opinion is generally divided:

1. Those favouring the use of mesh argue that primary hiatal repair failure occurs at sufficient frequency that prosthetic reinforcement should be considered in order to minimise the risk of symptomatic hernia recurrence and subsequent difficult and potentially unsuccessful re-operative surgery.
2. Those opposing the use of mesh cite the risk of erosion and infection, both which may have catastrophic consequences, as sufficient reason to avoid its use.

It is this author's opinion that large hiatal defects associated with para-oesophageal herniation of the gastric fundus pose a different surgical challenge than small hiatal defects typically found in patients with gastro-oesophageal reflux disease. Patients with large defects are often elderly with intercurrent medical problems which may increase the risk of repair failure. The crural pillars may be attenuated and apposition for repair may only be possible under tension, particularly when the hiatal aperture is markedly dilated. On the other hand, hiatoplasty, when performed in conjunction with fundoplication for gastro-oesophageal reflux disease, usually involves the closure of a mildly dilated hiatal aperture with one or two sutures. Patients tend to be younger than those with large defects and have more robust hiatal pillars. In this article, the case for the use of mesh in each of the above two clinical situations will be discussed.

The repair of large hiatal defects associated with para-oesophageal herniation of the stomach has long provided a challenge for surgeons. Reduction of hernia contents, which may include the entire stomach, greater omentum and other viscera may be difficult, particularly if performed in the acute setting. A durable hiatal repair in many cases would seem difficult to obtain as hiatoplasty involves the apposition of often attenuated crural pillars. Indeed, the primary repair of large hiatal defects is anathema to the principles of hernia repair. The margins of the oesophageal hiatus consist of parallel fibres of striated muscle which are drawn together, often under tension intra-operatively, sutured and then subjected to the increases in intra-abdominal pressure associated with respiratory movement, coughing and straining.

It is generally accepted that repair of hiatal defects is associated with a high recurrence rate although there is little good quality data in the literature regarding failure rates of laparoscopic or open repair. The repair of large symptomatic recurrent hernias is technically challenging, often unable to be performed laparoscopically and results in an inferior symptomatic outcome.¹

The long-standing perception among the surgical community that the primary repair of large hiatal defects has a high failure rate has resulted in the use of a number of graft materials. In the first half of last century, autologous fascia lata² was used in an attempt to prevent recurrence. Later, prosthetic materials such as tantalum,³ polyvinyl formaldehyde sponge (Ivalon),⁴ and non-expanded polytetrafluoro-

roethylene (PTFE)⁵ were employed prior to the introduction of modern biomaterials currently in use.

The enthusiasm for prosthetic repair among some authors is reflected in 1989 by Condon's comments:

Prosthesis reinforcement is needed in every instance. The reason is that, without prosthetic reinforcement, the constant suction effect of each respiratory cycle leads to eventual breakdown of the diaphragmatic hernia repair; recurrence rates approach 50%. In fact, the reputation among physicians is so bad that many do not refer patients with intrathoracic stomachs for indicated repairs because the expectation that the hernia will only recur. Prosthesis-reinforced hiatal hernia repair enhances the chances of success and markedly reduces the incidence of recurrence.

Robert E Condon⁶

An oft-quoted series followed,⁷ consisting 44 patients undergoing open primary repair reinforced with polypropylene. No recurrences were recorded, although radiological or endoscopic assessment of the repair was carried out in less than a third of patients. Symptomatic follow-up intervals ranged from 2 months to 15 years. Asymptomatic erosion of mesh into the gastric fundus was noted in one patient who underwent oesophago-gastrectomy for adenocarcinoma. This series from Carlson, Condon and others exemplifies the difficulty in drawing meaningful conclusions from the vast majority of publications dealing with the repair of large hiatal defects, namely, there is a preponderance of case series with non-standardised follow-up and little in the way of objective evaluation of repair durability or presence or mesh-related complications with routine postoperative barium studies and endoscopy.

In a recently published review of prosthetic hiatal repair for large defects and in laparoscopic antireflux surgery, the authors state: 'In general, hiatal reinforcement with the use of prosthetic meshes has proven to be a safe and effective procedure to prevent postoperative hiatal hernia recurrence'. The authors may well be correct and in this author's opinion they probably are; however, close reading of the series cited in their review confirms the shortcomings as described above. An exception to this is the randomised controlled trial published by Frantzides *et al.*⁸ who randomised 72 patients with large hiatal defects to a primary repair with or without expanded PTFE prosthesis augmentation. Radiological follow-up was undertaken to a median of 2.5 years (range, 6 months to 6 years). There were no recurrences in the prosthesis group and eight symptomatic recurrences in 36 patients in the primary repair group (22%). The results of this series provide the most compelling evidence for the use of prostheses in the repair of large hiatal defects.

Prosthetic meshes have been employed in a variety of configurations including a true tension-free repair where

mesh is placed across the defect without any attempt at primary closure, circumferential placement where a circular defect is created in the mesh to allow the passage of the oesophagus, and posterior onlay reinforcement of primary repair. The most widely used fascial prosthesis currently are expanded PTFE, polypropylene, small intestine submucosa and composite prostheses.⁹

Regardless of the specifics of mesh configuration or type, its use necessarily results in placement of the prosthesis in close proximity to the oesophagus and proximal stomach. The risk of prosthetic erosion is a strong factor in the reluctance of surgeons to embark upon a prosthetic repair. Published reports of complications are infrequent although it seems likely that these may go unreported. Intraluminal erosion has been reported with both PTFE¹⁰ and polypropylene prostheses.⁷ Stricture due to fibrosis has been reported with polypropylene.¹¹ Inadequate fixation of the prosthesis is likely to predispose it to migration and erosion. Laparoscopic screws may not provide sufficient diaphragmatic purchase particularly when used to fix non-porous materials such as ePTFE.

The use of a prosthetic repair has been shown to be superior than primary closure in one well-designed randomised trial. Further randomised evaluation would be valuable. It is our current practice to randomise patients with large hiatal defects into one of three study arms: (i) primary suture repair; (ii) posterior reinforcement with soft titanium/polypropylene mesh; or (iii) posterior reinforcement with porcine submucosa. Our current standard treatment for patients not enrolled is posterior repair reinforced with titanium/polypropylene mesh. Endoscopy and barium study is performed at 2 years' postoperatively.

Hiatal repair failure following surgery for gastro-oesophageal reflux disease probably occurs less frequently than repair failure following hiato-plasty for large defects. The use of mesh in the treatment of small defects has not been examined to the same extent, therefore, as for large hernias. Granderath and colleagues¹² have championed the use of polypropylene mesh to augment hiato-plasty for some time and have published a randomised trial demonstrating significantly less instances of repair failure following the use of mesh. Over a quarter of patients undergoing fundoplication and hiatal repair without mesh were shown to have intrathoracic wrap migration at short-term follow-up. This rate of repair failure may seem a little high to some surgeons. Currently, our practice is to perform a primary crural closure with heavy polyester sutures for patients undergoing fundoplication.

Despite a paucity of confirmatory data in the literature, it is reasonable to assume that performing a primary repair for large hiatal defects is inadequate. The lessons learned regarding the folly of primary repair of large fascial defects in the context of incisional and inguinal hernia are likely to

apply. Prospective, comparative evaluation of various prostheses is required if we are to improve the results of surgery for an often debilitating condition that, to date, has been inadequately addressed by surgery. Conceptually, the role of mesh to repair smaller defects would seem less obvious; however, again, only prospective comparative evaluation will provide meaningful answers.

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