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ORIGINAL ARTICLE

Ventral herniorrhaphy: experience with two different biosynthetic mesh materials, Surgisis and Alloderm

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Abstract
Objective The aim of this study was to compare the efficacy and the complications associated with the use of two new bioactive meshes, Surgisis Gold 8-ply mesh, a product obtained by the processing of porcine small intestine sub-mucosa (Cook Surgical, Bloomington, IN, USA), and Alloderm, processed cadaveric human acellular dermis (Life Cell Corporation, Branchburg, NJ, USA), for ventral herniorrhaphy.
Background Ventral hernia repair in potentially contaminated or potentially infected fields limit the use of synthetic mesh products. In this scenario, biosynthetic mesh products that are absorbed and/or replaced with the body's own tissue reduce the incidence of post-operative chronic wound complications (Franklin et al. in Hernia 8(3):186–189, 2004; Franklin et al. in Hernia 6(4):171–174, 2002; Hirsch in J Am Coll Surg 198(2):324–328, 2004; Holton et al. in J Long Term Eff Med Implants 15(5):547–558, 2005; Buinewicz and Rosen in Ann Plast Surg 52(2):188–194, 2004). Rapid revascularization, repopulation, and remodeling of the matrix occur on contact with the patient's own tissue. Only limited, and mostly preliminary data, is available on the use of these types of mesh and concerning the potential complications associated with the use of these types of meshes. We publish our experience with the use of these mesh products, along with their associated complications. Furthermore, we have also provided suggestions for improvements in the mesh designs.
Methods Between June 2002 and March 2005, 74 patients underwent ventral hernia repair using biosynthetic or natural tissue mesh. The first 41 procedures were performed using Surgisis Gold 8-ply mesh formed from porcine small intestine sub-mucosa, and the remaining 33 patients had ventral hernia repair with Alloderm. The patients had their first follow-up 7–10 days after discharge from the hospital. They were again seen at 6 weeks, or, if needed, earlier, and, thereafter, as needed. Patients who reported any complications to the office were followed up immediately within 1–2 days. Any signs of wound infection, diastasis, hernia recurrence, changes in bowel habits, and seroma formation were evaluated.
Results Non-perforated Surgisis mesh resulted in significant seroma formation in 10/11 patients. The seroma complication was reduced, but not eliminated, with the use of the perforated Surgisis mesh (3/30 patients). Explanted material revealed separated layers of un-incorporated middle layers of the 8-ply Surgisis mesh. Three of the patients had the mesh placed in a contaminated field with no resultant sequela, and there were no hernia recurrences. Patients also had a significant degree of discomfort and pain during the immediate post-operative period. The use of the Alloderm mesh resulted in eight hernia recurrences. Fifteen of the Alloderm patients (15/33) developed a diastasis or bulging at the repair site. Seroma formation was only a problem in two patients.
Conclusions Seroma formation was a major problem with the non-perforated Surgisis mesh repair, as was the post-operative pain. On the other hand, post-operative diastasis and hernia recurrence were a major problem with the Alloderm mesh. Further design improvements are required in both forms of these new

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mesh products. Surgeons should be aware of these potential complications prior to the selection of either of these products and the patient should be informed and educated accordingly.

Keywords Herniorrhaphy · Surgisis · Alloderm · Seroma · Diastasis

Introduction

Ventral herniorrhaphy is one of the most common operations performed in the US. The use of mesh in hernia repair is ubiquitous. The use of mesh to reduce tension and bridge gaps is often necessary to reduce the risk of recurrence. In general, mesh repair is considered to be superior to the suture repair with regard to the recurrence of hernia, and regardless of the size of the hernia according to some literature [1, 2]. While some authors believe that mesh repair results in a lower recurrence rate and less abdominal pain, and does not result in more complications than suture repair, others believe that the mesh repair leads to a high rate of wound infection [3, 4]. Furthermore, the presence of open bowel and morbidly obese patients are at a higher risk of the complications [5, 6]. Although different techniques have been described in the literature with claims of reducing some complications, most have not been proven to be without limitations [7, 8].

There are a number of different types of mesh available for ventral hernia repair. The choice of mesh to be used is usually more a matter of preference than science. The majority of the available mesh products are synthetic and, in general, they serve their purpose well. Ventral hernia repair in potentially contaminated or potentially infected fields, however, limits the use of synthetic mesh products. In this scenario, biosynthetic mesh that is absorbed and replaced with the body's own tissue should, at least theoretically, reduce the incidence of post-operative chronic wound complications.

We report our experience with the use of two types of biosynthetic mesh materials: Surgisis Gold 8-ply mesh, a product obtained by the processing of porcine small intestine sub-mucosa (Cook Surgical, Bloomington, IN, USA), and Alloderm, processed cadaveric human acellular dermis (Life Cell Corporation, Branchburg, NJ, USA).

Background

Surgisis mesh is derived from a natural biomaterial harvested from porcine small intestine mucosa (SIS). The three-dimensional, extra-cellular matrix (ECM) comprises of collagen and non-collagenous proteins and biomolecules, including glycosaminoglycans, proteoglycans, and glycoproteins (Fig. 1). Material is then vacuum-dried and sterilized. When implanted, host tissue cells and blood vessels readily infiltrate the graft. Connective and epithelial tissue growth and differentiation, as well as deposition and maturation of the host ECM components, occur. Finally, tissue remodeling takes place and the graft and the host tissue become indistinguishable. Porcine extracellular matrix does elicit an immune response that is, however, predominately Th2-like, which is consistent with a remodeling reaction rather than rejection [9].

SIS mesh has, in the past, been successfully used for the repair of inguinal and paraesophageal hernias, as well as for the treatment of entero-cutaneous fistulas and bile duct repairs [10–13]. The mesh also appears to be a safe new prosthetic material for ventral hernia repairs in contaminated or potentially contaminated fields [14, 15].

Alloderm mesh is an acellular matrix derived from the donated cadaveric human skin. It provides a complex, three-dimensional array of proteins that interact with each other and with the host cells. These proteins include networks of collagen, elastin, hyaluronan, and proteoglycans. Rapid revascularization, repopulation, and remodeling of the matrix occur on contact with the patient's own tissue. As a result, the mesh gets completely incorporated into the host fascial tissue. Acellular human dermis is capable of significant revascularization of its compact collagen composition in the early postoperative period. In thicker geometries, however,

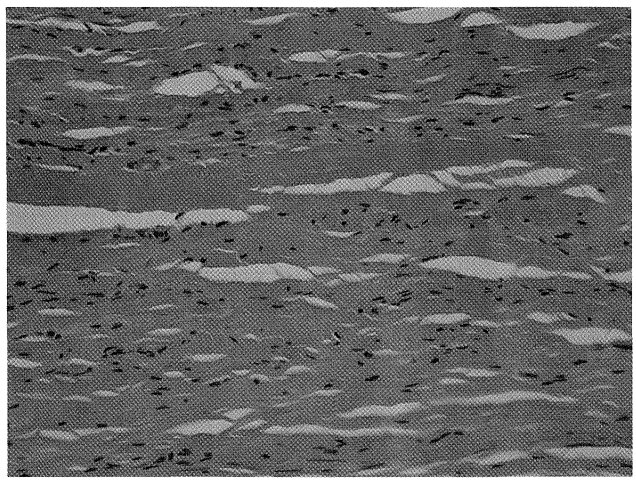

Fig. 1 Surgisis Gold (H & E stain 400×) extracellular matrix (ECM) shows the histologic appearance of mature layered collagen. However, at the molecular level, the ECM is comprised of collagen and non-collagenous proteins and structural biomolecules

the rate and completeness of vessel in-growth are predictably slower [16, 17]. This material has been shown to become revascularized in both animal and human subjects. Once repopulated with a vascular network, this graft material is, theoretically, capable of clearing bacteria, a property not found in prosthetic graft materials. Unlike autologous materials such as fascial grafts and muscle flaps, an acellular dermal matrix can be used without subjecting the patient to additional morbidity in the form of donor site complications [18].

Human acellular dermis has been used for the treatment of recurrent hernias [19], dural repairs [20], and various ophthalmic and facial reconstructive procedures [21]. In addition, the alloderm mesh has also been shown to be safe and more efficacious for ventral hernia repairs performed in the contaminated or infected fields, including salvage laparotomies for sepsis [18, 22, 23].

Since both of the above-mentioned meshes involve revascularization, the scaffold retains the ability to resist against infections. Furthermore, there is no synthetic material to be colonized. Thus, various studies have advocated their use in the cases of ventral hernia repair in contaminated environments. However, most of the studies remain preliminary and have shed little light on other potential complications associated with the use of the above-mentioned mesh products.

Methods

Between June 2002 and March 2005, 74 patients underwent ventral hernia repair using biosynthetic or natural tissue mesh. The first 41 procedures were performed using Surgisis Gold, a prosthetic 8-ply mesh formed from porcine small intestine sub-mucosa (Cook Surgical, Bloomington, IN, USA). The first 11 patients had the non-perforated Surgisis mesh, whereas the latter 30 patients had the perforated Surgisis mesh. The mesh was prepped, prior to implantation, as per the manufacturer's recommendations. The mesh was sutured using a running # 2 Prolene or # 2 Polydioxanone (PDS) suture as an overlay, interposition, or underlay patch (Table 1). The decision to use the underlay, overlay, or interposition technique was primarily based on the technical feasibility for the particular case. Some of the factors included for consideration were: the distance and the tension between the fascial edges and, thus, the feasibility of the direct approximation; the quality of the available fascia; the flap surface created above and below the fascia; the presence of any contamination and the intra-abdominal adhesions near the edges of the fascia. Three patients had the mesh placed in a grossly contaminated field.

The remaining 33 patients had ventral hernia repair with Alloderm, human acellular dermis (Life Cell Corporation, Branchburg, NJ, USA). In 11 cases, two or more pieces of the mesh had to be sewn together for the repair of larger defects, due to the unavailability of the larger size mesh. The mesh was sewn together and secured to the fascia using running # 2 Prolene suture.

Patients had their first follow-up 7–10 days after discharge from the hospital. They were again seen at 6 weeks, or, if needed, earlier, and, thereafter, as needed. Patients were followed up sooner if there was any concern from the patients' communication or during the scheduled visit of any infection, recurrence, swelling or seroma formation, fever, change in bowel habits, pain, nausea or vomiting, and changes in skin appearance. Patients who reported any complications to the office were followed up immediately within 1–2 days. Once again, any signs of wound infection, diastasis and hernia recurrence, changes in bowel habits, or seroma formation were evaluated. All patients were then contacted again in May 2005 for the purpose of this study. We were able to contact 100% of our patients involved. The mean follow-up for the patients in the Surgisis group is approximately 29 months,

Table 1 Surgical outcome and complications

Type		Placement	*N*	Explanation	Seroma	Recurrence	Diastasis
Surgisis (*N* = 41)	Original	Sub-fascial	1	0	3	0	0
		Sub-cutaneous	7	3	5		
		Interposition	3	2	2		
		Total	11	5	10		
	Perforated	Sub-fascial	14	1	3	0	0
		Sub-cutaneous	8	1	3		
		Interposition	8	1	1		
		Total	30	3	7		
Alloderm (*N* = 33)		Sub-fascial	4	0	0	1	3
		Sub-cutaneous	10		1	0	4
		Interposition	19		1	7	8
		Total	33		2	8	15

whereas the mean follow-up for the Alloderm group is near 18 months. The discrepancy simply highlights the late use of the Alloderm in our study. However, it is important to note that only one complication of diastasis in the Alloderm group was noticed at 14 month post-operative, and all other complications reported in this study were evident within the first 12 months. No new complications were picked on the late interviews in May 2005.

The same surgeon and the assistant surgeon in a single institution performed all of the operations. This data was collected prospectively. The specifics of each mesh, known complications, and options were discussed with the patients at great length prior to the operation.

Results

Our first experience was with the use of the non-perforated Surgisis mesh, which resulted in significant seroma formation in 10/11 (91%) patients (Fig. 2). The presenting complaints of these patients were abdominal distension, pain, and low-grade fever. Their laboratory studies identified normal or near-normal white count with normal indices. These complications were significant enough to prompt us to contact the manufacturer for possible unforeseen immunologic reaction. The reported incidence of seroma formation with the use of synthetic mesh is reported to be between 5% and 13% [3, 4, 24].

The seroma complication was significantly reduced, but not eliminated, with the use of the perforated Surgisis mesh in 7/30 patients (23%). After numerous ultrasound-guided drainages of seromas, eight patients had their wound re-explored under general anesthesia within 6 months of their original operation. All eight patients went on to heal completely with no further problem, without any hernia recurrence. Five of the eight non-perforated meshes were explanted (Fig. 3). In all of these explantations, the hernia repair was found to be intact. In fact, there were no hernia recurrences in any of the patients that had repair with Surgisis.

In all the cases where Surgisis mesh was explanted, the material was analyzed histologically. Photomicrograph identified the incorporation of all of the outer layers of the 8-ply mesh. However, explanted material revealed separated layers of un-incorporated middle layers of the 8-ply Surgisis mesh (Fig. 4). The outer layers of the mesh pieces explanted showed complete incorporation in the native host tissue (Fig. 5). Three of the patients had the mesh placed in a contaminated field with no resultant sequela. In one case, Gram+

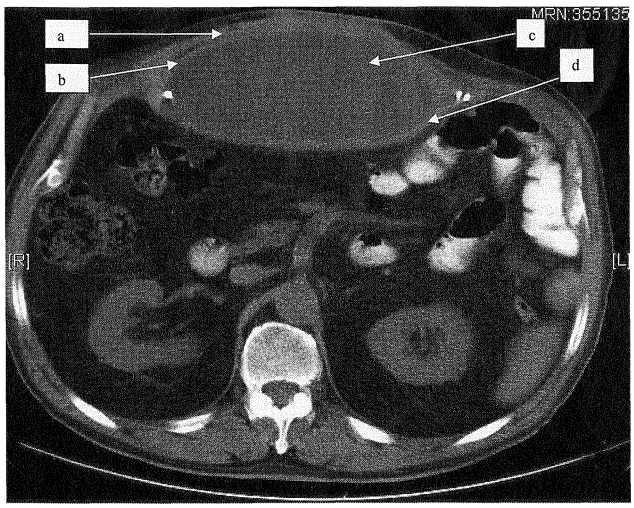

Fig. 2 Sub facial placement of Surgisis Gold perforated mesh. This computed tomography (CT) scan clearly demonstrated the incorporation of the outer layers of the mesh. The un-incorporated inner layers of the mesh result in the seroma formation. *a* Fascia. *b* Superficial layer of Surgisis mesh in contact with peritoneum. *c* Inner layers of the fascia seroma. *d* Deep layer of the Surgisis mesh in contact with omentum

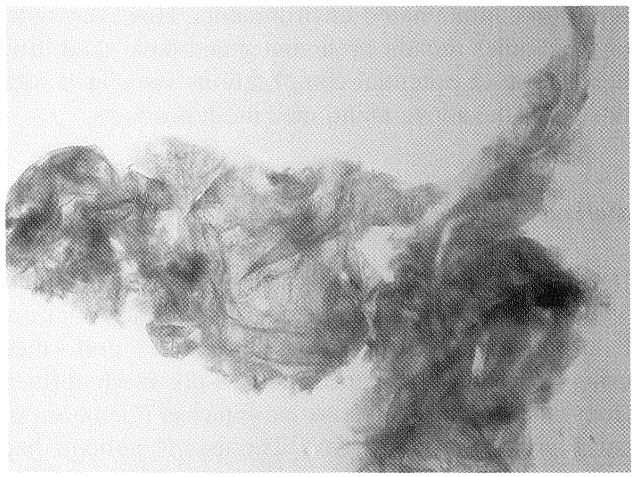

Fig. 3 Photograph of explanted Surgisis mesh material (back lit)

cocci, *Staphylococcus aureus*, was grown from the cultures, although in this patient, other clinical or gross pathological signs of any infection were absent.

Patients with the Surgisis mesh, whether non-perforated or perforated, also had a significant degree of discomfort and pain during the immediate post-operative period, especially those that had significant seroma formation post-operatively. This post-operative morbidity discouraged us from using Surgisis mesh any further and, instead, Alloderm was selected for the future hernia repairs.

Patients who had Alloderm mesh placed presented with different problems. One of the difficulties with the

Fig. 4 H & E stain (100×) explanted Surgisis mesh, remnant of Surgisis, showing inner layers that remain unincorporated into the native tissue. There is evidence of vascularization (angiogenesis) and an acute and chronic inflammatory reaction

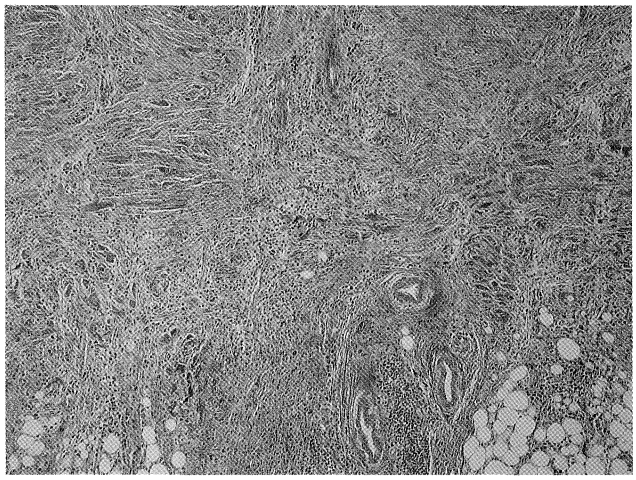

Fig. 5 Trichrome stain (40×) photomicrograph of the explanted Surgisis mesh. Surgisis mesh/native tissue interface showing incorporation of mesh into host tissue with tissue remodeling

Alloderm mesh was its poor handling during suturing. There appears to have been a number of tears at the seams and the edges where the fascia was secured to the mesh or to each other. This could be explained based on the understanding of the way that the mesh is harvested. The dermatome harvest of the cadaveric skin results in thin borders at the edges, which is where the perimeter suturing fails. The use of the Alloderm mesh resulted in eight hernia recurrences. The recurrences occurred between 10 and 90 days from the time of the original operation. On re-operation for the repair of the recurrent hernias, incomplete incorporation of the mesh with native tissue was noted. All of the hernia recurrences were located either at the mesh-to-fascia or the mesh-to-mesh seam. Fifteen of the Alloderm patients (15/33, 45%) developed a diastasis. Eight patients had hernia recurrence (8/33, 24%). Seroma formation was only a problem in two (6%) patients. This incidence of seroma formation, as mentioned above, is same as the incidence of seroma formation after ventral herniorrhaphy with synthetic mesh.

Discussion

Both mesh products seem to validate the use of biosynthetic mesh in potentially contaminated fields. Of note, there were no problems with post-operative infections. Seroma formation was a major problem with the non-perforated Surgisis mesh repair, as was the post-operative pain. Once the perforated Surgisis mesh was available, the latter was used for the hernia repairs. Both of the above-mentioned issues appeared to be somewhat better, although not eliminated with the introduction of the perforated mesh and they still cause significant morbidity. It appears that the seroma formation is caused by the slow and delayed incorporation of the inner layers of the Surgisis 8-ply mesh. This observation is based on the fact that for one of the explanted meshes, there was incorporation of the outer layers of the mesh that had the tissue contact, yet, the inner layers were separated from the rest of the mesh. This problem could possibly be resolved by either less condensed manufacturing of the 8-ply mesh, or by creating tissue in-growth channels within the mesh. Other solutions may include a composite mesh where fewer layers of Surgisis are incorporating other material.

Although, theoretically, these meshes should show better cellular and vascular growth with the overlay or underlay techniques, the incidence of complications or the recurrences failed to show any such trend. We believe that, since the growth in the matrix primarily starts at the edges, these bioactive meshes can be used as inter-position grafts as well.

Although no clear histological evidence was available for acute inflammation at the mesh site, we believe that the low-grade fever and the post-operative pain that patients experienced does indicate the activation of the inflammatory cytokines, resulting in pain and fever.

Possible causes for a higher recurrence rate with the Alloderm mesh may be related to the fact that pieces need to be sewn together to bridge larger defects. In addition, suture tears at the edges and seams were more easily created in the Alloderm mesh than in the Surgisis mesh. Post-operative diastasis was a major problem with the Alloderm mesh. This may be secondary to inherent stretching of the mesh skin. The manufacturer indicates that there may be as much as a 50%

increase in the size of the implanted mesh. This characteristic may limit its utility. Since, in the early stages of the healing, before the stretch is set in, there are significant strain forces at the thinnest portion of the mesh, that is, the edges anastamosing mesh-to-fascia or mesh-to-mesh. This problem may be addressed by the changes in harvesting methods, which would allow larger mesh sizes without the thinning of their edges.

In summary, both of the above-mentioned bioactive mesh products have been shown in the previous literature to be advantageous in their use in the infected or contaminated field. The recurrence rates for the ventral hernias are comparable to or better than compared to the synthetic meshes, with Surgisis mesh being more reliable in that respect. Both mesh products do have their failures in terms of the post-operative morbidity mainly related to the pain, seromas, or diastasis. Explantations were related to the above-mentioned morbidities only and, in our study, were only necessary in the Surgisis group. Understanding the histology of the tissue and the changes in the microstructure over time in these meshes may be the key to further improvements in these meshes.

Conclusion

The use of natural tissue mesh in potentially contaminated fields reduces the incidence of post-operative infections. Seroma formation was a major problem with the non-perforated Surgisis mesh repair, as was the post-operative pain. Both of these issues appeared to be somewhat better, although not eliminated with the introduction of the perforated mesh. On the other hand, post-operative diastasis was a major problem with the Alloderm mesh.

Further design improvements are required in both forms of these new meshes to reduce the post-operative seromas and discomfort from the Surgisis mesh and the avoidance of diastasis problems, as well as the recurrences from the Alloderm mesh. Surgeons should be aware of these potential complications prior to the selection of any of these products. Patients' inherent risks of developing any of these complications should be considered and the patient should be informed and educated accordingly.

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