Clinical Science

Comparison of infectious complications with synthetic mesh in ventral hernia repair

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Abstract

BACKGROUND: Infection can be a devastating complication associated with prosthetic incisional hernia repair. It is unclear whether the type of mesh used affects the risk of infection.

METHODS: A retrospective review was performed of all patients who underwent elective incisional hernia repair with permanent prosthetic mesh between January 1, 2000, and August 1, 2007.

RESULTS: A total of 176 patients underwent elective incisional hernia repair with mesh. The overall infection rate with the use of goretex (Flagstaff, AZ, USA) was 12 of 86 (14%) and 2 of 90 (2.2%) in cases in which nongoretex material was used ($P<.016$). In the goretex group, infection rates were significantly higher in open versus laparoscopic cases (26.5% vs 5.8%, $P=.030$). Methicillin-resistant Staphylococcus aureus was the most common organism recovered.

CONCLUSIONS: The risk of mesh infection with the use of goretex was found to be higher than with the use of nongoretex mesh. Laparoscopic placement of goretex reduces this risk of infection. No significant differences in recurrence rates were found.

Incisional hernia repair is among the most commonly performed operations. In the past, high recurrence rates (ie, approaching 50%)$^1$ complicated these procedures. Because of this high recurrence rate, prosthetic mesh was developed for hernia repairs. This allowed for a stronger, tension-free repair and over the years dramatically decreased the risk of recurrence.

The use of this new technology introduced new problems. The most challenging and prevalent problem with the use of prosthetic mesh has been infection. The risk of infection in incisional hernia repair appears to be higher than other clean cases, but there is a wide range reported in the literature from 0% to 30%$^2,3$ depending on the type of mesh, technique, and patient population. Infection in the setting of hernia repair with a mesh causes great morbidity and increases the overall cost because of repeat admission to the hospital and costly long-term intravenous antibiotics. In addition, most patients will also require at least 1 more operation for drainage of the infection and many times removal of the mesh. Removal of the mesh leaves the patient with a recurrent and larger hernia than before, with limited options for future successful hernia repair. Because of this morbidity, great attention must be paid to reducing the risk of infection in this patient population.

Over the years, numerous types of prosthetic mesh have been developed to provide greater strength and lower recurrence rates while also decreasing the risk of infection.
and other complications. One of the first materials developed that is still very commonly used is polypropylene. Although it has great strength, it has a propensity to cause dense adhesions to the bowel that can lead to bowel obstructions and fistula formation and make the risk of complications much higher if a future laparotomy is necessary.

In response to this problem, expanded polytetrafluoroethylene (ePTFE or goretex) (Flagstaff, AZ, USA) was developed with purported advantages including decreased adhesion formation and lower hernia recurrence rates. Polyester mesh has also been used. Various arrangements of these materials have been developed in different brand name mesh materials, and more recently composite meshes containing multiple materials have been developed in order to try to gain the advantages of each material combined in 1 implant.

ePTFE has become the most popular type of mesh used in incisional hernia repair today, specifically the Goretex Dualmesh (Flagstaff, AZ, USA). There are only a few studies that have been performed comparing the risk of infections between Goretex Dualmesh and other mesh materials. The objective in this study was to compare the risk of infectious complications and recurrence between goretex and other types of mesh used in elective incisional hernia repair.

Methods

A retrospective review was performed of all patients at a tertiary care veterans affairs medical center who underwent ventral, incisional hernia repair between January 1, 2000, and August 1, 2007. Only patients undergoing elective repair with a permanent prosthetic mesh were included in our dataset. Any patients with an incarcerated hernia, concomitant bowel operation, or other urgent surgery were excluded. Patients in whom a biologic or absorbable mesh was used were also excluded.

All patients received preoperative prophylactic antibiotics with cephalosporin, clindamycin, or vancomycin. The type of mesh used was at the discretion of the attending surgeon. When goretex was used, it was placed intraperitoneally in an underlay fashion. Polypropylene mesh was used as an onlay, sometimes in conjunction with component separation or as an onlay after primary repair. When the Prolene Hernia System (Ethicon, Somerville, NJ USA) was used, there was an element of both underlay and onlay. Polyester meshes were all placed intraperitoneally in an underlay fashion through a laparoscopic approach. SCIP (Surgical Care Improvement Project) criteria were not implemented until later during the study period and would be the same for all groups in the study; therefore, this should not affect the data analysis.

Patient data were collected including demographics, comorbidities, procedure performed, type of mesh used, complications, and microbiology results. Mesh infection was defined as an infection that required a procedure such as incision and drainage; all cases in this study required mesh removal. More minor infections such as cellulitis that could be treated with antibiotics alone were not included in the mesh infection group. Outcomes of infection and recurrence were evaluated, and multiple subgroups were compared including goretex versus non-goretex, laparoscopic versus open, and primary versus recurrent hernia repairs. The Student t test and chi-square analysis were used for statistical analyses, and P < .05 was considered significant. Approval from the Baylor College of Medicine Institutional Review Board was obtained before beginning the study.

Results

A total of 176 patients met the inclusion criteria. Eighty-six had repair with goretex (4 with Goretex Dualmesh and 82 with Goretex Dualmesh Plus), and 90 had repair with other types of mesh, largely polypropylene (Fig. 1). One hundred nine (61.9%) had an open approach, and 67 (38.1%) had laparoscopic repair. One hundred forty-one (80.1%) were primary hernias, and 35 (19.9%) were recurrent hernias.

The average age of the patient population was 57.4 years, and the population was predominantly male (91.5%). The ethnic distribution consisted of 141 whites (80.1%), 17 blacks (9.7%), 17 Hispanic (9.7%), and 1 Asian (0.6%). Twenty-five percent were diabetic, 70.5% had hypertension, 19.9% had known coronary artery disease, 3.4% had known congestive heart failure, and 13.5% had chronic obstructive pulmonary disease. The mean body mass index was 31.4. Most of the patients were currently or had a history of using tobacco and alcohol (ie, 72.9% and 70.5%, respectively). Comparisons of the goretex and non-goretex groups were performed for these demographics and comorbidities and are listed in Table 1. The only statistically significant difference was among the number of Hispanic and white patients in the groups (P = .025 and .009).

The overall infection rate in all elective incisional hernia repairs with prosthetic mesh was 8% (14/176). The median time to infection was 49 days with a range from 3 to 1,046 days. All patients with a mesh infection required removal of the mesh. A significant difference was seen in the rate of infection between the goretex group and the non-goretex group (14% [12/86] vs 2.2% [2/90], P = .016). When an open surgical approach was used, there was a significant difference in infection rates between goretex and non-goretex (26.5% [9/34] vs 2.7% [2/75], P = .001). There was a trend toward a higher infection rate in the laparoscopic goretex group when compared with the laparoscopic nongoretex group; however, it was not statistically significant. Within the goretex group, there was a significantly lower infection rate in the laparoscopic group compared with the open group (3/52 [5.8%] vs 9/34 [26.5%], P = .030). There was no difference seen in the infection rate between repairs of primary and recurrent hernias, but there was a trend toward a higher infection rate in the patients undergoing repair of recurrent hernias. Fig. 2 shows a summary of the infection rates in each subgroup with P values noted for statistically significant differences.

Microbiology data were collected on all patients (Fig. 3). Overall, gram-positive organisms were found in
78.6%, and gram-negative organisms were found in 21.4%. Two of the 14 patients had polymicrobial infections. Methicillin-resistant *Staphylococcus aureus* (MRSA) was the most common single organism, which was found in 35.7%. The second and third most common were *Staphylococcus epidermidis*, which was found in 21.4%, and methicillin-sensitive *S. aureus*, which was found in 14.3%.

The median follow-up time was 58 months. The overall recurrence rate was 9.1% (16/176). There was a trend toward lower recurrence rates with goretex when compared with nongoretex (4.7% [4/86] vs 13.3% [12/90], *P* = .135). A laparoscopic approach showed a trend toward a lower recurrence rate when compared with the open approach (3% [2/67] vs 12.8% [14/109], *P* = .087). There were no significant differences found in recurrence when comparing the type of mesh or the approach used. Fig. 4 shows a summary of recurrence rates for all subgroups.

Although mesh infection and hernia recurrence were the major complications, other procedure and non–procedure-related complications were seen. Other procedure-related complications included cellulites, seroma, hematoma, stitch abscess, enterotomy, and a hole in the mesh. Non–procedure-related complications included acute renal failure, atrial fibrillation, a bleeding gastric ulcer, ileus, small bowel obstructions, pneumonia, sepsis, and 1 death. There was no significant difference in the incidence of these complications between the goretex and the nongoretex groups (Table 2).

### Table 1 Patient demographics and comorbidities

<table>
<thead>
<tr>
<th></th>
<th>Goretex (n = 86)</th>
<th>Nongoretex (n = 90)</th>
<th><em>P</em> value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>56.5</td>
<td>58.3</td>
<td>.216</td>
</tr>
<tr>
<td>Sex (%)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Male</td>
<td>79 (91.9)</td>
<td>82 (91.1)</td>
<td>.984</td>
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<tr>
<td>Female</td>
<td>7 (8.1)</td>
<td>8 (8.9)</td>
<td>.984</td>
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<tr>
<td>Race (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>5 (5.8)</td>
<td>12 (13.3)</td>
<td>.240</td>
</tr>
<tr>
<td>Hispanic</td>
<td>3 (3.5)</td>
<td>14 (15.6)</td>
<td>.025*</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (1.2)</td>
<td>0 (0)</td>
<td>.591</td>
</tr>
<tr>
<td>White</td>
<td>77 (89.5)</td>
<td>64 (71.1)</td>
<td>.009*</td>
</tr>
<tr>
<td>Diabetes</td>
<td>18 (20.9)</td>
<td>26 (28.9)</td>
<td>.476</td>
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<tr>
<td>Hypertension</td>
<td>59 (68.6)</td>
<td>65 (72.2)</td>
<td>.871</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>19 (22.1)</td>
<td>16 (17.8)</td>
<td>.773</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>3 (3.5%)</td>
<td>3 (3.3%)</td>
<td>.998</td>
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<tr>
<td>COPD</td>
<td>10 (11.6%)</td>
<td>12 (13.3%)</td>
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<td>Smoking</td>
<td>67 (77.9%)</td>
<td>61 (67.8%)</td>
<td>.321</td>
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<tr>
<td>Alcohol use</td>
<td>62 (72.1%)</td>
<td>62 (68.9%)</td>
<td>.897</td>
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<tr>
<td>Body mass index</td>
<td>31.8</td>
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<td>ASA</td>
<td>2.7</td>
<td>2.7</td>
<td>.811</td>
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<td>Albumin</td>
<td>3.7</td>
<td>3.7</td>
<td>.887</td>
</tr>
</tbody>
</table>

ASA = American Society of Anesthesiologists; COPD = chronic obstructive pulmonary disease.

* *P* < .05

**Comments**

Although the use of prosthetic mesh materials in incisional hernia repair has dramatically decreased the risk of recurrence, surgeons must now deal with the difficult problem of infection. In reviewing adverse events reported to the Food and Drug Administration for hernia repairs with mesh, Robinson et al found that infection was the most common, accounting for 42% of all adverse events reported. Houck et al proposed that incisional hernia repairs should not even be considered clean cases because of the higher infection risk. In a retrospective review of 995 clean cases, they found the infection rate to be 16% in incisional hernia repairs versus 1.5% in all other clean cases.

The literature reports a very wide range of infection rates for incisional hernia repair from 0% to 30%. Infection in the setting of hernia repair with a mesh causes great...
morbidity and cost to the patient including long-term antibiotics, multiple further operations, and a recurrent hernia with limited future options for repair. It is because of this great morbidity that everything must be done to prevent infection in these patients. This includes the use of evidence-based practices such as the SCIP criteria including maintaining perioperative normothermia, the appropriate prophylactic antibiotics given within 1 hour of incision, appropriate hair removal methods, and the discontinuation of antibiotics within 24 hours postoperatively.

There have been several reports in the literature of low recurrence rates and low infection rates with the use of ePTFE (6–12) touting it to be an ideal material for use in incisional hernia repair; however, we noted an increased number of infections with this material in our series. Overall, we found that our infection rate (8%) was within the range of those commonly reported in the literature. In contrast, there was a significantly higher risk of infection with goretex when compared with other mesh materials (14% vs 2.2%). This increase in the infection rate seemed to be amplified when an open surgical approach was used and diminished with a laparoscopic approach. With an open approach, the infection rate with goretex was 26.5% versus 2.7% with a nongoretex mesh ($P = .001$). In the laparoscopic group with goretex, the infection rate was reduced to 5.8%, and although there was still a trend toward a higher infection rate in the goretex group, there was no statistically significant difference. Table 1 shows that the goretex and nongoretex groups were well matched with no significant difference in multiple demographic factors and comorbidities including age, body mass index, smoking, diabetes mellitus, and others. The only difference found between the 2 groups was a slightly higher percentage of Hispanic patients in the nongoretex group and a slightly higher number of whites in the goretex group.

The study period spanned from 2000 to 2007. In 2005, the Surgical Infection Prevention guidelines were implemented in our practice, which was then followed by the SCIP guidelines in August 2006. Guidelines with respect to the timing of antibiotics, the proper prophylactic antibiotic, and the timely discontinuation of this antibiotic within 24 hours were made mandatory beginning in 2006. Therefore, the SCIP criteria were not applied for the majority of patients in this study because it had not yet been implemented. However, this was the case for all subgroups in this study; therefore, any observed difference would still be valid.

A few other studies have shown a high rate of infection (38.9% to 66.7%) with goretex.5,13 These studies had relatively small numbers and involved repair of “giant” hernias, so they were likely at a higher risk of complications. Our study group is composed of a much larger group with a mix of general surgery patients and has a statistically similar group of nongoretex patients who have a much lower infection rate.

It is unclear why the infection rate seen in the goretex group was higher than the nongoretex group in our study.
Previous investigations have noted that it may be the structure of the mesh that accounts for ePTFE being more susceptible to infections. The ability of the immune system to clear microbes is mostly reliant on the activity of polymorphonuclear leukocytes, which measure 10 to 15 μm in diameter. ePTFE mesh has a microporous surface that has very small spaces that are less than 10 μm in size and allow bacteria (1 μm) to colonize these areas while blocking the entrance of polymorphonuclear leukocytes. This may promote infections and harbor chronic colonization. This may explain the pathophysiology of chronic infections and late presentations that can be seen with goretex.

To reduce the risk of colonization at the time of implantation, some mesh materials have been impregnated or coated with antibiotics. One of the most popular is the Goretex Dualmesh Plus, which is coated with silver and chlorhexidine. This coating has been shown in ex vivo studies to reduce bacterial adherence when inoculated with MRSA in comparison with other mesh materials, including the plain Goretex Dualmesh. Given findings such as these, most institutions have switched over to using Dualmesh Plus. Of our 86 cases performed with goretex, 82 were with Goretex Dualmesh Plus. Despite this, our data still showed a higher infection rate. The ex vivo study’s findings may not carry over to clinical practice because of the issues discussed in the previous paragraph relating to mesh structure and/or other unknown factors.

The reduction in infection risk in incisional hernia repair with the use of laparoscopy has been documented in the literature with reported infection rates being 0% to 3%. Our dataset confirms this finding with a trend toward lower infection rates in the overall laparoscopic versus open comparison (4.5% vs 10.1%) and a significant difference in the goretex only group of laparoscopic versus open (5.8% vs 26.5%). This is likely because of a reduction in exposure to skin flora and contamination from handling the mesh during placement. Whenever possible, a laparoscopic approach should be used in the repair of incisional hernias.

The majority of our infections (65%) involved gram-positive organisms, and 37% grew MRSA as the predominant pathogen in incisional hernia mesh infections. Given these findings, any patient who presents with an infection after an incisional hernia repair with mesh should be placed on an antibiotic with activity against MRSA and gram-positives. Many of the patients undergoing incisional hernia repair have risk factors for colonization with MRSA. Newer tools such as bedside PCR (Polymerase Chain Reaction) for MRSA screening can be performed before surgery, and consideration should be given to using an antibiotic with activity against MRSA for perioperative prophylaxis in patients with positive results.

On the other hand, it must be noted that our dataset showed that 7% of our infections were caused by gram-negative organisms and 14% were polymicrobial. Given this significant number, patients who present with mesh infection should be placed on an antibiotic with good gram-negative coverage in addition to the gram-positive coverage already suggested.

The high rate of hernia recurrence was what prompted the development and use of prosthetic mesh in incisional hernia repair. Now the literature shows a recurrence rate after repair with mesh to be between 2% and 19%. Studies show a reduction in recurrence with a laparoscopic
approach. Our data showed trends toward a decrease in recurrence with laparoscopic repair versus open repair (3% vs 12.8%) and with the use of goretex mesh versus nongoretex (4.7% vs 13.3%). None of our subgroup comparisons showed a significant difference in the recurrence rate. In our dataset, patients who developed infections all required the removal of their mesh. This almost always results in a recurrent hernia. In our analysis, these patients were not counted in the recurrence group; however, a separate analysis was completed including this group, and there was no statistical difference in recurrence found between goretex and nongoretex. From the standpoint of the risk of recurrence, the mesh materials appear to be similar; therefore, the other complications should be focused on to help decide which material to use.

Conclusions

Infection has become one of the most prevalent and challenging complications in incisional hernia repair with mesh. Our study shows that both goretex and other materials yield a similar risk of recurrence and are viable options for use in incisional hernia repair. However, the risk of mesh infection was found to be much higher with the use of goretex. This was especially true if an open approach was used. Laparoscopic repair yielded a much more acceptable risk of infection when using goretex and should be used whenever possible. In our series, the majority of infections were caused by MRSA. Perioperative prophylaxis with an anti-MRSA antibiotic should be considered, especially in patients at high risk for colonization.

References