Hypothesis: A bioabsorbable tissue scaffold of porcine submucosal small intestine extracellular matrix (Surgis Gold [SIS]; Cook Biotech Inc, West Lafayette, Ind) mesh is safe and effective for ventral hernia repair.

Design: Retrospective case series at a university teaching hospital.

Patients: Fifty-three consecutive patients having 8-ply SIS mesh repair of ventral abdominal hernias.

Main Outcome Measures: Early complications, reoperation, hernia recurrence, mesh or wound infection, or reaction. Outcomes reported and compared on an intention-to-treat basis.

Results: Patients were stratified by wound class: clean, clean-contaminated and contaminated, or dirty. Median follow-up was 14 months (range, 2-29 months) during which there were 22 complications (41%), 17 early reoperations (32%), 13 partial dehiscences (21%), 6 mesh reactions (11%), and 9 recurrent hernias (17%). Seven recurrent hernias (78%) in critically ill patients with dirty wounds had the SIS mesh removed owing to infection or reoperation. In patients without SIS mesh removal or debridement, 1 (2.2%) of 44 developed a recurrent hernia at 6 months. Patients with dirty wounds were more likely to need early reoperation \( (P<.001) \), develop a complication \( (P<.01) \), partial wound dehiscence \( (P<.05) \), or recurrent hernia \( (P<.01) \) compared with patients with clean wounds. Critically ill patients were more likely to have hernia recurrence \( (P<.05) \), early reoperation \( (P<.001) \), and postoperative complications \( (P<.05) \).

Conclusions: Eight-ply SIS mesh is safe in clean and clean-contaminated hernia repair with satisfactory short-term outcomes. However, delayed wound infection, repeated operation, and mesh debridement warrant cautious use of SIS mesh in critically ill patients and those with dirty wounds.

Arch Surg. 2005;140:549-562

**THE USE OF PERMANENT PROSTHETIC MESH FOR THE REPAIR OF INCISIONAL VENTRAL HERNIAS**

The use of permanent prosthetic mesh for the repair of incisional ventral hernias has been shown to reduce the overall risk of recurrent hernia compared with primary suture repair. The placement of mesh in the retrorectus or intraperitoneal position has also been shown to result in the lowest reported risk of recurrence following ventral abdominal herniorrhaphy. However, there are short- and long-term problems related to the use of permanent mesh materials for abdominal hernia repair, especially when placed intraperitoneally. These problems include erosion into bowel resulting in fistulas and bowel obstruction; infection of the mesh as a consequence of contamination from simultaneous gastrointestinal tract surgery; contamination of the mesh following early postoperative dehiscence of the incision anterior to the mesh, or chronic erosion of the mesh through the wound and chronic pain due to a foreign body inflammatory reaction.

When a permanent mesh prosthesis becomes colonized with bacteria for any reason, it almost always requires eventual removal with subsequent development of recurrent hernia and the need for an additional operation. Even though the incidence of mesh infection following ventral abdominal herniorrhaphy is usually less than 10%, the clinical consequences of infected intraperitoneal or abdominal wall mesh are dire.

A conservative and commonly practiced approach for repairing infected abdominal wall hernias, especially in critically ill patients has been a staged approach by placing an absorbable mesh prosthesis made from polyglactin or polyglycolic acid followed by a split-thickness skin graft once the wound has granulated. A recurrent hernia will develop after the ab-
sorbable mesh dissolves that can then be repaired at a latter date by one of several operative techniques. These include removal of the skin graft, placement of a permanent prosthesis and closure of the wound, or dermabra-
sion of the skin graft followed by fascial closure using
the components separation technique.\textsuperscript{15} The second hern-
ia operation is as much at risk for becoming infected as
the first. When a secondarily placed mesh implant be-
comes infected, it will need to be removed again and the
patient will most likely be left with an even larger ab-
dominal wall defect resulting in progressive morbidity
and disability. Another staged approach for closing high-
risk ventral abdominal wounds in critically ill patients
involves vacuum-assisted closure (Wound Vac, Vacu-
Assisted Closure Device; KCI International, San Anto-
nio, Tex) therapy.\textsuperscript{10,17} This approach results in success-
ful closure of the fascia in up to 88\% of patients, but it
is associated with evisceration, intestinal fistulization,
and recurrent hernia.\textsuperscript{16,17}

For all of the aforementioned reasons, alternative
means of reconstructing the abdominal wall without the
use of mesh or with a bioabsorbable mesh prosthesis that
is resistant to infection have become increasingly impor-
tant for general surgeons performing abdominal wall re-
construction.\textsuperscript{18-22} This is particularly true for patients with
wound contamination at the time of surgery, or who have
an increased risk for wound dehiscence.\textsuperscript{22,23} The bilat-
eral sliding rectus abdominis myofascial flap, also known
as the components separation technique, became an in-
creasingly popular technique for the closure of contami-
nated ventral incisional hernias over the past de-
cade.\textsuperscript{15,24-26} However, recurrence rates and wound complica-
tions can be high with this approach.\textsuperscript{26} More re-
cently, biomaterials such as cadaveric allografts and het-
erografts of xenogeneic origin have been developed as
acellular, resorbable bioscaffolds for hernia re-
pair.\textsuperscript{18,20,27-31}

The potential advantages of using tissue grafts in place
of synthetic materials for abdominal wall reconstruc-
tion are less inclination toward infection, erosion, ex-
trusion, and rejection.\textsuperscript{30} One such tissue graft that has
recently become available for hernia repair is developed
from a bioabsorbable tissue scaffold of porcine submu-
cosal small intestine extracellular matrix, referred to as
“SIS-ECM mesh” (Surgisis; Cook Surgical, Bloom-
ington, Ind). This material has been found to be effective at
repairing abdominal wall defects in animals\textsuperscript{32,33} and hu-
mans\textsuperscript{18,20,34} and has also been reported to be resistant to
infection.\textsuperscript{35-38}

The current study reports our experience with the use
of a particular SIS mesh product, Surgisis Gold, in 53 con-
secutive patients operated on for ventral abdominal wall
hernias at the University of Illinois Medical Center, Chi-
cago. Based on earlier reports of SIS mesh being safely
used to successfully repair ventral abdominal wall her-
nias in patients with contaminated wounds,\textsuperscript{18,20,34} we hy-
pothesized that the use of Surgisis Gold would be safe
and effective for the repair of abdominal wall hernias as
well as be effective in preventing dehiscence following
closure of contaminated abdominal incisions in high-
risk, critically ill patients.

METHODS

We retrospectively reviewed 53 consecutive patients, in whom Surgisis Gold mesh was used in abdominal wall surgery be-
tween May 2002 and October 2004. The Surgisis Gold mesh
was used in an attempt to repair abdominal wall defects or to
prevent abdominal evisceration following high-risk closure of
the abdomen in critically ill patients undergoing emergency sur-
gery. Main outcome measures were postoperative complica-
tions, need for reoperation owing to all causes, hernia recur-
rence, mesh or wound infection, and mesh reaction. All outcome
measures were based on an intention-to-treat basis; no patient
was excluded from analysis.

Eight-ply Surgisis Gold was used in 52 patients and 4-ply
Surgisis Gold mesh was used as an overlay mesh in 1 patient. For
large defects, several pieces of mesh were sewn together side-
by-side to provide complete coverage of the defect. Ninety-
five percent of the operations were performed by 3 surgeons.
The mesh was rehydrated in an isotonic sodium chloride so-
lution at room temperature for 3 to 10 minutes prior to use. A
monofilament absorbable or polypropylene suture was placed
every 5 cm in the mesh in horizontal mattress fashion and used
to secure the mesh to the abdominal wall in all patients. The
size of the mesh, the approach (laparoscopic vs open repair),
and the mesh position relative to the fascial defect were based
on the clinical situation. All surgeons in this study placed the
mesh using a similar operative technique. All patients re-
cieved a dose of preoperative antibiotic prior to skin incision.
Patients with clinical wound infection or sepsis continued re-
cieving broad-spectrum antibiotic therapy postoperatively; all
other patients did not receive additional postoperative antibi-
otic therapy. The skin was closed in patients with clean and
clean-contaminated cases and closed suction drains were placed
in the subcutaneous position in an effort to obliterate the sub-
cutaneous dead space. Drains were removed when drainage
was less than 25 mL per 8-hour shift. The skin was left open in
16 of 18 patients with dirty wounds and wet-to-dry dressings
were applied for a minimum of 3 to 5 days prior to the use of a wound
c vaccum in some patients. Open wounds were allowed to heal
by secondary intention and in some cases split-thickness skin
grafts were placed after the wound and/or exposed mesh was
granulated.

When SIS mesh became exposed in the retrorectus space
following a partial fascial dehiscence or exposed in its inlaid
position following a partial skin dehiscence, wet-to-dry dress-
ings were placed directly on the mesh for at least 3 to 5 days
prior to using a wound vacuum (see below). In those patients
undergoing partial debridement of infected mesh, pulsed la-
vage with 3 L of a warm saline solution without antibiotics
was used to clean up the infected abdominal wall defect. Adaptic
gauze or a hydrating gel was placed on the mesh when the wound
vacuum system was used as described by others\textsuperscript{39}; the vacuum
sponge was not placed directly on the mesh. On occasion, gentle
sharp debridement was performed to remove nonincorpo-
rated or sloughed superficial, delaminated layers of mesh.

For those patients who underwent removal or partial de-
bridement of the SIS Gold mesh owing to infection or reop-
eration, no effort was made to close the abdomen with an-
other type of Surgisis mesh. Instead, a double layer of polyglactin
or polyglycolic acid mesh was used to close the abdominal wall.

SURGICAL APPROACH

Thirteen patients had a laparoscopic ventral hernia repair, and
40 patients underwent an open repair. Within the open co-
hort group of patients, the mesh was sewn to the surrounding
fascia as an inlay in 2 patients, sewn as an underlay in 41, and
placed as an onlay on a well-granulated vascularized polyglactin mesh in 3 patients.

**LAPAROSCOPIC TECHNIQUE**

Our laparoscopic incisional hernia technique is similar to that described by Heniford et al. Adhesiolysis is performed sharply, and electrocautery and ultrasonic shears are not used in close proximity to the bowel. No effort is made to excise or fulgurate the hernia sac. Once the fascial defect is cleared circumferentially, its dimensions are measured in a cephalad-caudal direction and left-to-right dimension with the pneumoperitoneum reduced to 8 cm of H₂O. A piece of Surgisis mesh is then trimmed such that it will underlay all of the fascial margins by at least 4 cm in all directions. Horizontal mattress sutures of 0 monofilament polyglyconate suture are placed circumferentially around the mesh every 5 cm. The mesh is rolled up and introduced into the abdomen through the 10-mm port site and then unrolled under videoscopic vision. The horizontal mattress sutures are then brought out, full thickness through small incisions placed in the abdominal wall one at a time. Sutures are placed in a manner to prevent wrinkles in the mesh when the pneumoperitoneum is reduced to 8 cm of H₂O. In between the sutures, a laparoscopic stapling device is used to secure the mesh to the abdominal wall with a single line of staples placed at the mesh edge spaced no more than 1 cm apart.

**OPEN TECHNIQUE**

Our technique is similar to that described by others for the placement of intraperitoneal mesh for the repair of open ventral incisional hernia. Adhesiolysis is performed to clear at least 5 cm beyond the fascial edges in all directions. The mesh is placed in the intraperitoneal position as an underlay with at least 4 cm overlap beyond the fascial margins. Sutures are brought through the full thickness of the anterior abdominal wall fascia in a horizontal mattress fashion; sometimes they are brought out full thickness through the entire abdominal wall through small incisions similar to the laparoscopic technique (Figure 1). Additional polyglactin sutures (3 O) were placed every centimeter to secure the mesh to the anterior peritoneum to prevent bowel from herniating between the abdominal wall and mesh. In all instances, the mesh was secured to avoid any wrinkles or redundancy. An effort was always made to close the anterior fascia over the mesh when it was placed as an underlay as described by Stoppa and Hamy et al. In 3 patients this required performing a bilateral fascial release and components separation to obtain closure without tension. Such a closure could not be achieved owing to the size of the hernia defect in 2 patients and the mesh was sewn to the margins of the defect as an inlay graft. Drains were not placed between the mesh and the overlying fascia in patients who had an underlay mesh. The subcutaneous tissues were reapproximated with absorbable sutures and closed suction drains were placed in the subcutaneous space and brought out through separate stab incisions lateral to the skin closure in an effort to eliminate dead space. In patients with clean and those with clean-contaminated wounds, the skin was closed with staples and vertical mattress No. 2 nylon sutures placed every 3 cm.

**PATIENT DEMOGRAPHICS**

The mean age of the patients was 51 years; most were obese (Table 1). The mean body mass index (calculated as weight in kilograms divided by the square of height in meters) was 32. Fourteen patients were critically ill and 13 of these underwent an emergency operation that was performed in an open fashion. Eight patients had peritonitis, 5 had necrotizing fasciitis, and 2 had previously undergone solid organ transplantation and were receiving long-term immunosuppressive drug therapy. Thirteen patients had a bowel resection at the time of abdominal exploration and hernia repair. The mean hernia defect measured 202 cm².

Patients undergoing laparoscopic and open hernia repair had similar medical comorbidities, but the open group had a higher acuity of illness. All laparoscopic hernias were repaired electively, only 2 were clean contaminated, and 11 were clean. Conversely, 14 of 40 open hernia repairs occurred in critically ill patients, and 13 of these were emergent. Patients undergoing open hernia repair had larger hernias than those undergoing laparoscopic repair, and this was reflected by the mean size of mesh required to obtain a 5-cm overlap beyond the fascial margins in all directions: 375 cm² for open hernias and 173 cm² for the laparoscopic cohort.

There were 3 patients who had well-granulated abdominal walls after having previous polyglactin mesh placed. All of these patients had an onlay of SIS mesh that was sewn to the surrounding skin edges with 2 0 polyglactin sutures. The clinical intent in these patients was for the SIS mesh to provide a neo-fascia to the abdominal wall that would hopefully prevent eventual hernia (Figure 2).

Indications for the use of SIS mesh included immediate repair of fascial defects following the removal of infected mesh, delayed hernia repair in patients who had previous mesh infections with chronic staphylococcal infections, hernia repair at the time of bowel resection and/or colostomy-ileostomy take-down, hernia repair with inadvertent enterotomy, bowel incarceratation and/or strangulation, hernia repair with concomitant intestinal anastomosis or cholecystectomy, posterior fascial buttress to prevent postoperative dehiscence in debilitated critically ill patients at risk for evisceration, closure of the abdomen following debridement for necrotizing fasciitis, onlay on granulated absorbable mesh in patients with open abdomens, and surgeon’s choice in 6 clean laparoscopic hernias.

To investigate if contamination or active infection has any effect on the main outcome measures, we placed patients in groups according to their wound class. There were 22 patients with clean wounds, 12 with clean-contaminated wounds, 1 with a contaminated wound, and 18 with dirty wounds. For lack of

![Image](https://via.placeholder.com/150)
and Figure 4); 4 were in patients with clean wounds, of which 1 was operated on laparoscopically (Figure 3). The reaction in the open clean-contaminated case spontaneously presented by wound breakdown and drainage 6 weeks after complete healing of the superficial wound. Another reaction presented as minor drainage 2 weeks after operation (Figure 4). In all cases, it was impossible to clinically distinguish infection from mesh reaction. Aspiration of the fluid around the graft failed to yield any bacteria, and the inflammatory response rapidly abated in all patients in response to the administration of a cylooxygenase-2 inhibitor. There were no recurrent hernias or long-term sequelae in patients who had a mesh reaction. There was no relationship between having a reaction to mesh and wound class or having critical illness.

Partial dehiscence of the wound, either skin or fascia, occurred in 13 patients (21%). Dehiscence was 4 times more common in patients with dirty wounds compared with patients with clean wounds ($P<.05$) but occurred in 9% of those with clean wounds. Six patients (46%) who had dehiscence underwent reoperation for wound debridement and irrigation. No patient developed evisceration or had exposure of the abdominal viscera. There was no case in which the SIS mesh was torn or disrupted from its attachment to the fascia.

Early reoperation was required in 32% of the patients in this series. Table 3 lists the indications for repeat operation. Wound class had a substantial influence on the need for repeat operation ($P<.001$) and was much more frequent in patients with dirty wounds ($P<.001$) but not in patients with clean-contaminated wounds ($P=.13$) compared with patients with clean wounds. Twenty-two patients (41%) sustained 1 or more postoperative complications, and there was a significant effect of wound class on having a complication ($P<.01$). The proportion of patients having a complication was higher in those with a dirty wound ($P<.005$) compared with patients with clean wounds. While 46% of the patients with clean-contaminated wounds had a complication, this was not statistically higher than the proportion of patients with a clean wound (18%) having a complication ($P<.12$) (Table 4).

Six critically ill patients with dirty wounds who had SIS mesh placed behind the abdominal closure developed delayed infection and partial dehiscence of the wound exposing the mesh. These infections manifested themselves no sooner than 4 weeks postoperatively in all patients by spontaneous drainage through the anterior...
fascial closure, despite having an open granulating abdominal wound that was healing by secondary intention (Figure 5). In 3 patients, there was gross purulence between the anterior surface of the mesh and the overlying fascial closure. There was gross purulence in between some of the delaminated layers of the mesh. The superficial delaminated anterior layers of the mesh were partially liquefied and of a slimy, mucous consistency (Figure 5A). Posterior to the superficial delaminated liquefying layers was a well-vascularized fibrous sheet of new tissue that was rapidly cleaned up with pulse irrigation and wet-to-dry dressings (Figure 5B). This layer was subsequently skin grafted in 3 patients with a 100% take in each case. One patient with a skin graft developed a recurrent hernia 6 months later after the underlying fibrous plate disappeared (Figure 6).

Two patients with dirty wounds developed contained abscesses between the mesh and the anterior fascia. A patient with diabetes mellitus developed an abscess following peritonitis from perforated appendicitis and it was successfully drained percutaneously. The other was in a renal transplant patient who was receiving long-term immune suppression following perforated diverticulitis. Percutaneous drainage failed in this patient and this patient required repeat operation and was found to have complete nonincorporation of the mesh which turned into slime (Figure 7A) and had to be completely extirpated (Figure 7B). Patients with partial fascial or skin dehiscence and exposure of the mesh exhibited marked neovascularization of the wound that rapidly contracted and epithelialized (Figure 8).

There were 9 recurrent hernias for an overall incidence of 17% (Table 5). Wound class had a substantial influence on the risk of recurrence ($P < .01$). Seven of 9 recurrences occurred in patients with dirty wounds ($P < .01$). Among these 7, recurrence occurred in 5 patients who had the SIS mesh completely removed and replaced with polyglactin. Two patients who had partial debridement of the delaminated mesh and subsequent split-thickness skin grafts developed recurrent hernia at 6 months. There was 1 recurrence among the patients with clean wounds and this occurred in a patient who underwent a liver transplantation 6 months after laparoscopic SIS mesh placement; this patient was the only one who had a recurrent hernia among the laparoscopic cohort. One recurrent hernia occurred 6 months postoperatively in the single contaminated patient (included in the clean-contaminated category). This patient was one of the patients who developed delayed infection and underwent partial debridement of the mesh 30 days postoperatively and had a split-thickness skin

<table>
<thead>
<tr>
<th>Table 2. Complications</th>
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<tbody>
<tr>
<td>Major complications</td>
</tr>
<tr>
<td>2 Deaths from multiple organ failure</td>
</tr>
<tr>
<td>1 Postoperative intra-abdominal bleeding</td>
</tr>
<tr>
<td>13 Overall infections</td>
</tr>
<tr>
<td>2 Postoperative peritonitis causing liquefaction from gross infection</td>
</tr>
<tr>
<td>4 Reoperations for diffuse infection around mesh and partial debridement</td>
</tr>
<tr>
<td>2 Postoperative subfascial, confined abscesses</td>
</tr>
<tr>
<td>1 Drained percutaneously</td>
</tr>
<tr>
<td>1 Reoperated on in kidney transplant patient</td>
</tr>
<tr>
<td>1 Rapid liquefaction of mesh from infection in a patient who had Surgisis* placed as an onlay graft in the presence of an enterocutaneous fistula, removed at bedside</td>
</tr>
<tr>
<td>1 Intra-abdominal hematoma between mesh and fascia</td>
</tr>
<tr>
<td>4 Partial fascial dehiscences, exposing underlying mesh</td>
</tr>
<tr>
<td>Minor complications</td>
</tr>
<tr>
<td>6 Mesh reactions</td>
</tr>
<tr>
<td>2 Resulted in minor dehiscences</td>
</tr>
<tr>
<td>1 Subcutaneous wound hematoma</td>
</tr>
</tbody>
</table>

*Cook Biotech Inc, West Lafayette, Ind.

Figure 2. Surgisis Gold mesh (Cook Biotech Inc, West Lafayette, Ind) as an onlay graft. A, Abdominal wall reconstruction with polyglactin mesh. B, Granulated mesh 1 month later. Arrow denotes location of an enterocutaneous fistula. C, Surgisis Gold mesh is grafted on top of the granulated polyglactin mesh and then a wound vacuum (Wound VAC, Vacuum-Assisted Closure Device; KCI Inc, San Antonio, Tex) was applied.
graft to the mesh. This patient’s skin-grafted SIS mesh became progressively softer over time until eventually a hernia developed at 6 months. All of the other patients with skin grafts have solid abdominal wall repairs at more than 1 year after surgery. In the absence of infection requiring partial mesh debridement or complete mesh removal during relaparotomy, the incidence of recurrent hernia was 1 of 44 surviving patients.

Critical illness was associated with an increased incidence of hernia recurrence (P < .05) and the need for early repeat operation (P < .001). There was a trend for critical illness to be associated with an increased incidence of complications (P = .06). The effect of critical illness on outcomes is listed in Table 5.

**COMMENT**

There are several situations in which patients with ventral incisional hernia are at increased risk for mesh infection and others in which patients are at high risk for ventral abdominal wound dehiscence. When the latter occurs, the risk of mesh infection is increased. In addition, patients who develop postoperative evisceration have an incidence of subsequent recurrent hernia approaching 70%. For these patients, prevention of evisceration or ventral abdominal dehiscence is important. To avoid the deleterious consequences of mesh extirpation, it would be desirable to place a prosthesis that is unlikely to become infected or one that will not require extirpation should it become exposed in the event of ventral dehiscence. Several biological, tissue-engineered meshes have

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**Table 3. Indications for Repeat Operation**

<table>
<thead>
<tr>
<th>No. of Patients</th>
<th>Indication for Repeat Operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Reexploration for intra-abdominal bleeding, closed with Vicryl mesh</td>
</tr>
<tr>
<td>1</td>
<td>Drainage of intra-abdominal hematoma, abscess posterior to mesh</td>
</tr>
<tr>
<td>4</td>
<td>Drainage of subfascial abscesses and partial debridement of infected mesh</td>
</tr>
<tr>
<td>3</td>
<td>Debridement of superficial abdominal wound dehiscence</td>
</tr>
<tr>
<td>1</td>
<td>Further wound debridement and irrigation for necrotizing fasciitis</td>
</tr>
<tr>
<td>4</td>
<td>Reoperation for diffuse peritonitis, intra-abdominal sepsis, necrotizing fasciitis</td>
</tr>
<tr>
<td>2</td>
<td>Simple wound debridements of exposed Surgisis* mesh</td>
</tr>
<tr>
<td>1</td>
<td>Exploration for biliary leak, wound debridement</td>
</tr>
</tbody>
</table>

*Cook Biotech Inc, West Lafayette, Ind.*
recently been developed with the intent of serving this purpose. Porcine small intestinal submucosa extracellular matrix (SIS-ECM) tissue graft is one such engineered tissue for use in abdominal wall reconstruction.

The consequences of infected permanent mesh prosthesis in a hernia defect and abdominal evisceration in critically ill patients can lead to substantial morbidity, recurrent hernia, and the need for additional surgery. This potential scenario prompted us to explore the use of Surgisis Gold in the repair of ventral abdominal wall defects. Of particular interest to us was whether this particular graft offered an advantage over a staged abdominal repair with absorbable mesh in critically ill patients with grossly contaminated wounds at the time of hernia repair.

Experimental studies in animals have shown that SIS-ECM is capable of supporting tissue regeneration in large fascial defects. Twelve weeks after implantation, fascial defects are filled with a regenerated tissue that grossly and histologically resembles normal fascia and the mesh material is completely replaced. There are many theoretical advantages to using tissue substitutes such as Surgisis mesh for repairing large fascial defects as op-
posed to using an absorbable mesh. These include the prevention of bowel desiccation, providing greater integrity to the abdominal wall, accelerating angiogenesis and wound repair, and providing a biological barrier to bacterial invasion.

Our patients had substantial risks for mesh infection, recurrent hernia, and abdominal evisceration. Most of our patients were obese and had 1 or more medical comorbidities such as chronic obstructive airway disease, coronary artery disease, cirrhosis, and impaired wound healing predictive of ventral hernia recurrence.3,23,42 Many patients had recurrent ventral abdominal wall hernias, and several had multiple previously infected mesh prostheses removed. Twenty-four percent (13/53) were critically ill and required emergency surgery and 58% (31/53) had bacterial contamination at the time of surgery. Based on this risk profile, we thought that the use of Surgisis Gold mesh was justified and potentially advantageous over permanent mesh, based on the reports of Franklin and colleagues18,34 and Ueno et al.20

Extracellular matrices derived from porcine small intestinal submucosa possess antimicrobial activity37 and have been reported to be resistant to bacterial infection due to rapid angiogenesis and integration in host tissues.35,36,38 Based on this experimental evidence, Franklin and colleagues18,34 investigated the use of Surgisis mesh in laparoscopic ventral hernia repair in a contaminated field and reported no early or long-term problems, chronic infections, or recurrent hernias within 2 years of follow up.18,34 Ueno et al20 subsequently reported the use of Surgisis mesh in 20 patients with hernias in the setting of bacterial contamination, 17 of which were ventral incisional hernias. In contrast to the experience of Franklin and colleagues with the laparoscopic approach, Ueno et al observed a complication rate that was far greater when patients underwent an open operation. Ueno et al reported a complication rate of 50% and 8 (47%) of 17 patients developed wound infection and 6 (75%) of the 8 infected patients went on to develop a recurrent hernia.

Our experience with 8-ply Surgisis Gold mesh is similar to that reported by Franklin et al30 and Ueno et al.20 We observed very few problems and only 1 recurrence in 11 clean elective laparoscopic hernia repairs and this was in a liver transplant recipient. Neither of the pa-

tients with clean-contaminated wounds who had a laparoscopic hernia repair have developed evidence of a recurrent hernia with more than 1-year follow up. We observed an incidence of complications, mesh reactions, infection, and hernia recurrence that was similar to that reported by Ueno et al when the Surgisis Gold mesh was used in an open dirty ventral hernia repair. Our incidence of recurrence was reported from an intention-to-treat basis and 7 (78%) of our 9 recurrences occurred
in patients in whom the mesh was removed owing to infection or reoperation. We cannot adequately compare our results with those of Ueno's group since they did not state if they removed the mesh prosthesis when patients were reoperated on for infection. One difference between our practice and that of Ueno et al is that we tend to leave our wounds open in the presence of gross contamination whereas they closed the skin in all of their patients with dirty wounds. All 6 recurrences in the series reported by Ueno et al occurred in patients who had closed-space infections between the skin closure and mesh; no patient without infection developed a recurrence at the time of their report. This observation was similar to ours in that in the absence of infection, we have seen only 1 recurrent hernia, the liver transplant recipient.

In our critically ill patients, infections occurred predominantly between the Surgisis Gold mesh and the overlying fascial closure, even though the superficial wound was left open. In these patients, we observed increased complications and the need to drain the retrorectus space, and to partially debride and even remove the mesh. Several of our infected patients did not present with early postoperative infection but rather presented in a delayed fashion. Three patients had the mesh partially debrided 30 days or more postoperatively. In 1 of the transplant patients there was no incorporation of the mesh material and it was partially autodigested and infected (Figure 7). In 2 other patients, the layers of the mesh delaminated and the superficial layers pealed off of a well-vascularized posterior fibrous layer. With wet-to-dry dressing changes and pulse irrigation the wound rapidly cleaned up and was able to be skin grafted with a 100% take in 4 patients; a recurrent hernia developed in 1 of these patients.

Our experience coupled with the suggestions of Ueno et al showed that the avoidance of a closed space infection adjacent to the SIS material is important for long-term efficacy of Surgisis mesh. It is possible that a closed space infection or secondarily infected seroma anterior to an inlay mesh or that a retrorectus infection anterior to an intra-abdominal underlay mesh could lead to more

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Patients With Critical Illness, %</th>
<th>Patients Without Critical Illness, %</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hernia recurrence</td>
<td>55</td>
<td>20</td>
<td>.05</td>
</tr>
<tr>
<td>Early reoperation</td>
<td>58</td>
<td>11</td>
<td>&gt;.001</td>
</tr>
<tr>
<td>Complication</td>
<td>41</td>
<td>16</td>
<td>.06</td>
</tr>
<tr>
<td>Dehiscence</td>
<td>45</td>
<td>21</td>
<td>.13</td>
</tr>
</tbody>
</table>

* Determined by the Fisher exact test.
rapid degradation and liquefaction of the mesh. Such a sequence could potentially interfere with the ECM-induced wound-remodeling process that usually results in rapid stem cell ingrowth, angiogenesis of the wound, and eventual replacement of the ECM tissue graft. 30,43,44

Subcutaneous infection did not occur in either of the 2 patients who had an inlay mesh and, therefore, we cannot comment on what effect this would have on the mesh integrity or wound remodeling. On the other hand, we did have several subfascial closed-space infections. In several of these patients the mesh was not completely destroyed or liquefied. In fact, the ECM-induced wound remodeling process was already well on its way despite the presence of an infectious process that developed between the mesh and anterior fascia. Another interesting observation was that these infections typically presented much later than traditional wound or intra-abdominal infections, which usually manifest themselves within 10 days to 2 weeks following surgery. Several of our patients had primary superficial wound healing only to present 4 to 6 weeks later with infection around the mesh in the subfascial position. This observation suggests that the mesh became colonized at the time of implantation and that a foreign body reaction or secondary infection of a postoperative seroma prevented normal host defenses from clearing any bacterial contamination that occurred at the time of the mesh implant.

Two of 3 of our patients having a mesh onlay on top of a vascularized granulated abdominal wall had excellent incorporation into the patient and replacement of the mesh by host wound healing that enabled successful skin grafting to be performed. Our attempt at grafting SIS mesh on the vascularized abdominal wall of a third patient with an enterocutaneous fistula failed owing to rapid digestion of the mesh by enteric bacteria that undermined the mesh following the inappropriate application of a wound vacuum (Figure 2). In retrospect, we should not have applied a wound vacuum to the mesh in this patient but rather kept the mesh moist with a petroleum gel or gauze and isolated the fistula to gravity drainage. Our success following the onlay of SIS mesh on a well-vascularized granulated bed in the first 2 patients without fistulas demonstrated that the anterior surface of SIS mesh can be covered with only moist dressings, provided that the posterior surface is adherent to a vascular bed since it appears that the ECM-induced wound-remodeling process occurs when only 1 side of the SIS mesh graft is adherent to vascularized tissue.

It is unclear why there was infection and lack of integration of the mesh in some critically ill patients with dirty wounds and not in others even though the types of wounds and clinical scenarios were similar. One possible explanation is that wound healing in response to ECM tissue grafts differs depending on the nature of the host’s inflammatory response. For example, it has been reported that SIS mesh induces a Th1, inflammatory cytokine response. 45,46 It is further known that a predominant Th1 cytokine response causes local and systemic immune suppression. 47 It is possible that an overwhelming Th1 cytokine response induced by Surgisis mesh impairs local host defense mechanisms to infection and/or interferes with local wound healing mechanisms. Based on this line of reasoning, gross contamination of the wound or an overactivated Th1 cytokine immunological response, commonly seen in patients with critical illness, may increase the risk of infecting Surgisis mesh implants.

Some of our observations suggest that most ECM-remodeling process occurs when the mesh is in contact with vascularized tissue only from the sides and/or deep to the mesh because some patients had a well-developed vascularized fibrous tissue bed posterior to the mesh when the anterior surface of the mesh was exposed and not in contact with any vascularized tissue. Further evidence to support this reasoning is that non-incorporation or liquefaction of the mesh occurred predominantly in patients in whom a seroma, hematoma, or infection developed between the mesh and the peritoneal cavity or anterior parietes, thus preventing juxtaposition of the mesh with any vascularized tissue.

In the absence of proven infection, we observed an inflammatory reaction in 6 (11%) of 53 patients. Inflammation-related morbidity has previously been reported following the implantation of Surgisis tension-free slings in patients for urinary incontinence. 48 Ho et al 48 reported that of 6 of 10 patients treated with 8-ply SIS had severe postoperative inflammatory reactions characterized by induration, erythema, and pain that occurred 10 to 39 days postoperatively at the incision site where the tissue graft was implanted and anchored in the subcutaneous position. Four patients improved with anti-inflammatory medications, one underwent incision and drainage of a sterile abscess and another had spontaneous drainage of an abscess. Our patients experienced an inflammatory reaction to the mesh that was similar but less frequent than that described by Ho et al and in all cases responded promptly to anti-inflammatory medication or drainage. The patients shown in Figure 3 and Figure 4 are examples of such reactions that promptly responded to a cyclooxygenase-2 inhibitor. The cause of this inflammatory response is not well understood but thought not to be an immunological reaction and more likely to be related to latent anaerobic infection (Michael Hiles, PhD, Cook Biotech Inc, written communication, December 4, 2004). This inflammatory response has not been reported when SIS mesh has been used in inguinal hernia repair. 49,50

The lack of complete integration of all layers of 8-ply SIS mesh into an infected wound raises a number of questions. Is there a limit to the number of layers of SIS mesh that can be rapidly integrated and replaced by host tissue especially in the face of infection and an exaggerated Th1 cytokine inflammatory response? If there are redundant layers of SIS in the 8-ply material that are not rapidly incorporated or revascularized, does their presence in the wound interfere with the ECM-induced wound-remodeling process and do they serve as a nidus for infection in the setting of contamination? Our data would suggest that 1 or more of these reasons might explain why delayed mesh reactions and infections spontaneously expressed themselves through a well-healed superficial wound.

Another possible explanation for the different responses observed by Franklin and colleagues, 18,54 Ueno et al, 56 and our group may be related to the route of mesh placement. We, along with Ueno et al, noted very few
problems with Surgisis mesh when it was placed laparoscopically in the intraperitoneal position even when placed in the presence of contamination. Conversely, most major mesh-related complications occurred in patients undergoing open surgery. It is entirely possible that the increased wound complications and mesh infection in open hernia repairs are related to the more intense wound inflammation associated with an incision and closure than is found when compared with a laparoscopic underlay of mesh against the peritoneum. Well-controlled experimental studies in animals or case-matched studies in humans comparing laparoscopic and open ventral hernia repair in the setting of contamination and in patients with similar clinical conditions will be necessary to investigate this hypothesis.

Our experience suggests that 8-ply Surgisis mesh should be used with caution as a means to prevent evisceration in critically ill patients with dirty wounds. We observed a high wound complication rate in this subset of patients and many required repeat operation specifically for wound and mesh-related problems. Based on our experience with this group of patients, we believe that the fascia should not be closed anterior to a wide underlay of 8-ply Surgisis mesh in the setting of gross infection. Instead, we think 1 of 2 alternative approaches should be used. First, if Surgisis mesh is placed to cover a fascial defect in a dirty wound, it should be sewn in as an inlay prosthesis. An inlay graft may be less likely to become grossly infected compared with a wide underlay graft because there is no potential closed space between the mesh and the overlying fascia that can result in a closed-space infection or abscess. The exposed surface of the Surgisis mesh can be treated with a wound vacuum or wet-to-dry dressing and subsequently skin grafted if necessary. Several of our patients with large gaping wounds with exposed Surgisis mesh contracted completely such that a skin graft was unnecessary, though originally planned. Another approach to avoid infection of Surgisis mesh in a dirty field involves placing an absorbable mesh such as polyglactin or polyglycolic acid to close the defect and after this becomes granulated and vascularized, Surgisis mesh can be sewn on top of it as an inlay graft, similar to what was done in 2 of our patients. Once the Surgisis mesh becomes granulated and vascularized, it can be skin grafted. While this process takes longer than directly skin grafting the granulated abdominal wall, the advantage is the potential to avoid a certain recurrent hernia in the future. Should the Surgisis mesh fail to take to the granulated abdominal wall, there is no morbidity to the patient other than the time loss associated with this approach as opposed to directly placing a split-thickness skin graft.

Experimental evidence in animals has shown that the nature and timing of wound healing is altered by Surgisis ECM tissue grafts. Therefore, it is quite possible that the time course and nature of infection in a wound with Surgisis mesh may also differ from traditional postoperative wound infections. Additional study is necessary to better define the mechanisms and natural history of Surgisis mesh placed into grossly contaminated wounds in critically ill patients.

There were financial reasons and reimbursement issues that led us to choose Surgisis Gold mesh over other xenograft or human allograft tissue grafts for the repair of ventral hernia. Acellular cadaveric dermis (AlloDerm; LifeCell, Branchburg, NJ) is a human allograft material used to repair complex and contaminated ventral hernias. However, this product is substantially more expensive than Surgisis Gold mesh on a cost-per-size basis; the purchase cost of Surgisis Gold and AlloDerm for our hospital is $3.40/cm² and $26.00/cm², respectively. Similar to Surgisis mesh implants, there is limited published experience on the use of acellular cadaveric dermis in repairing contaminated ventral abdominal hernias and only short-term follow up. Our hospital is rarely reimbursed for implants and, therefore, the use of expensive tissue grafts contributes a substantial financial loss to our operating room. On this basis, we cannot financially justify the use of human allograft or other xenograft products that are substantially more expensive than Surgisis Gold until there is published data and longer-term follow-up that demonstrate clinical superiority of one product over another. Ideally, prospective randomized or case-matched clinical studies will be carried out in the future to compare the efficacy, safety, and costs of various tissue grafts for the reconstruction of contaminated and high-risk ventral abdominal wall hernias.

CONCLUSIONS

In the absence of infection, 8-ply Surgisis Gold mesh has similar short-term results that are equivalent to permanent prosthetic materials for repairing ventral abdominal wall hernias. However, longer-term follow up is necessary to establish if Surgisis mesh will result in a low incidence of recurrent hernia similar to that achieved with the use of permanent prosthetic mesh. Eight-ply Surgisis mesh can be safely used in clean-contaminated hernia repair in noncritically ill patients and results in satisfactory short-term outcomes. However, complications and recurrent hernia are high in critically ill patients with dirty wounds undergoing attempted repair with 8-ply Surgisis Gold. Our observation that 8-ply Surgisis mesh becomes infected and requires removal or debridement in a high percentage of high-risk patients demands that caution be exercised when this material is used in critically ill patients with dirty wounds.

Accepted for Publication: January 18, 2005.

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Previous Presentation: This paper was presented at the 112th Scientific Sessions of the Western Surgical Association; November 9, 2004; Las Vegas, Nev; and is published after peer review and revision. The discussions that follow this article are based on the originally submitted manuscript and not the revised manuscript.

REFERENCES

DISCUSSION

Jeffrey Landercasper, MD, LaCrosse, Wis: To my knowledge, this is the largest series in the literature of patients with contaminated wounds undergoing hernia repair with a Surgisis mesh. It is an understatement to say that closure of a hernia in an infected field is a difficult problem. Existing repair techniques all have inadequacies. The marginal results obtained with existing techniques are the impetus for evaluation of new meshes and methods. Helton et al presented a retrospective review of 53 patients undergoing ventral hernia repair with porcine-derived intestinal submucosal extracellular matrix. Helton et al report good results in their low-risk patients. In contrast, in the 31 high-risk patients, 8 patients (25%)...
had recurrent hernias, and many patients required debride-ment and extra operations. They report patients who had por-cine mesh turn into porcine slime. They report 8- ply mesh that delaminates with the top layers turning into a “goo” yet some-times with preservation of the lower layers, supporting capil-lary in-growth and granulation tissue. The authors conclude that we should be cautious in the use of this type of mesh in critically ill patients with dirty wounds. I agree. The authors’ study outcomes do not entirely support the study hypothesis in the article that Surgisis mesh is safe and effective. The au-thors realize this and in the article they discuss causes and al-ternative treatment strategies. The strengths of this study are in its detailed individual patient descriptions and in its 100% follow-up.

The weaknesses of the study are that it is retrospective and without control subjects for comparison. It also has consider-able heterogeneity. Some mesh was placed onlay, some inlay, some underlay. Some operations were laparoscopic; some were open. Some mesh was placed after removal of other infected mesh; some mesh was placed on top of other mesh. Some mesh was sewed to the skin. There was a wide variety of host pa-tients and the length of follow-up was short, 14 months. I have 3 questions.

Have you compared outcomes between high-risk patients un-dergoing hernia repair with Surgisis to a similar cohort of pa-tients undergoing hernia repair with other techniques? Your study has contributed to the understanding that Surgisis mesh is dirty wound, but how does it compare with existing methods?

Can you provide us with more information about the ne-cessity of extirpating Surgisis mesh when purulence is pre-sent? Does it always need to be removed? Is debridement of the top delaminated layers sufficient in some patients? It seems to me that placing this biological mesh in a dirty wound seems to initiate a competitive race. The host is racing to provide capillary in-growth thereby providing a healthy microcirculation to augment immunity and to provide fibroblasts for collagen deposition. At the same time, microorganisms are trying to di-gest the graft. Does the type of Gram-negative vs Gram-positive bacteria or fungus make a difference in who wins the race? Do quantitative counts of microorganisms predict out-come or the optimal timing of when placement should occur? Did you measure these factors?

Does Surgisis mesh prevent dehiscence and evisceration in the high-risk patient undergoing abdominal closure? That was one of the stated goals in the article. Where is the data?

Dr Helton: As you can see from the pictures I showed to-day, our results are far from perfect and the problem of repair-ing contaminated ventral hernias persists despite the availabil-ity of these new biologic materials. Your first question is an excellent one and the answer is no, we have not done a careful comparison between the use of this product with alternative methods of closure in a similar cohort of patients undergoing complex ventral hernia repair. Alternative options include a staged approach with absorbable mesh followed by skin graft, a component separation technique, or the use of other acellu-lar biological implants. We have experience with all of these approaches but we did not do a comparison. I think that the use of Surgisis mesh compares favorably to these other tech-niques, the exception being the need for reoperation and de-bride-ment of the infected material is probably less common com-pared with absorbable mesh like Dexon or Vicryl. Recognize that 100% of those patients repaired with the latter will un-dergo at least 2 additional operations; whereas, in the patients that we debrided without completely removing the mesh, only one developed a recurrent hernia. I have personally used the human acellular dermis and porcine dermis in similarly in-fected patients and I have also seen it digested and have had to remove it. Clearly we need prospective, clinical trials compar-ing these new mesh prostheses and I agree it would be won-derful to do a cohort case matched series comparing the bio-logical implants with the typical staged approach or even a component separation–type approach. One of the important observations I think from our experience is that it is not neces-sary to completely remove the mesh when it becomes in-fected, but this depends upon the time at which the infection manifested itself. For example, Surgisis mesh can become liq-uified within 48 hours. Under such circumstances, it should be completely removed, because, like you said, it becomes a slimy goo and it offers no integrity to the abdominal closure. But on the other hand, there were 4 patients that presented as long as a month postoperatively where the mesh had an infec-tion between the anterior rectus and the mesh itself. In those patients when we exposed the mesh and debrided it gently, we found this very healthy vascularized fibrous plate posterior and under those circumstances, the wound was quite solid, and subse-quently readily accepted a skin graft. The type of bacteria colo-nizing the graft does make a difference in the host response to Surgisis. Bacteria that possess collagenases can rapidly digest the material. Recently, I have been told by scientists at Cook Surgical that the presence of anaerobic bacteria is probably respon-sible for the reactions that were seen to meshes even when the wounds have been culture negative. The high incidence of mesh reaction reported in a single publication in the urology literature for urethral slings is probably due to anaerobic bac-teria that colonize in the mesh when it is placed transvagi-nally. There is no way, unfortunately, to identify the type of bacteria in the wound at the time of surgery that would tell us whether or not it is a collagenase producer. Your final question is, did it prevent evisceration and fascial dehiscence. No, it did not prevent fascial dehiscence. We had 6 cases of partial superficial dehiscence but not a single patient had evis-ceration and there was no separation of the mesh from the fascial edges.

James Debord, MD, Peoria, Ill: I think the take home mes-sage from your presentation is not to be too aggressive in de-briding this material when it starts to look a little funky. If you leave it there long enough, there is an inflammatory, cicat-ri-cial reaction underneath that prevents these patients from de-developing a recurrent hernia after you remove the mesh. We know polypropylene mesh tolerates infection better than any of the other permanent biomaterials and now we have polypropyl-ene mesh with a bonded anti-adhesion barrier and I am won-dering if that might be an alternative to prevent the recur-rences that you are seeing?

Dr Helton: Good question. Dr DeBord. I do not have any per-sonal experience with the composite meshes. However, I am not aware of any data in the literature yet that suggests that the combination mesh products offer any protection from becoming colonized by bacteria, but I think appropriate study will tell us that information before long.

Mercil Dayton, MD, Buffalo, NY: Scott, many of us are con-cerned about the cost of these acellular biomaterials. I re-cently used some AlloDerm during the repair of an infected ab-dominal wall defect. A 4 x 16 cm piece is $2,000. Would you ad-dress justifying cost of these materials at a time when fi-nances are tight, reimbursements are low, and payers reluc-tant to pay for any additions to our armamentarium?

Dr Helton: In our hospital, the cost of human acellular dermis is 8 times that of Surgisis and the cost of the porcine dermis is approximately 3 times that of Surgisis. For this reason, when we decide to use one of these materials, we cannot justify the use of a more expensive product until there is evidence to suggest that it is superior to the others. The real issue that needs to be addressed is whether using the least expensive product, Sur-gisis, is more cost-effective than using a staged approach such as absorbable mesh followed by split-thickness skin graft and even-
tual additional operation and component separation. As suggested by Dr Landercasper, I think we have to do a comparison trial to find out the answer to this question.

**John Moore, MD, Denver, Colo:** First of all, I want to congratulate you on helping us understand the application of these new bioprosthetics in our clinical practice. The question I have is in regard to your clean wound cases. Could you clarify for me in regards to why you chose to use this in a clean wound case and would you recommend the use of this in our clean wound cases, uncomplicated ventral hernia repair?

**Dr Helton:** As you know the follow-up is short in all publications using Surgisis as well as in our experience. Our choice to use it in clean wound cases was as an alternative to permanent prosthesis, particularly when placed in the intra-abdominal position with the presumption that there would be less reaction, less risk of adhesion formation to the bowel long-term, less pain from permanent sutures, and the avoidance of erosion long-term and elimination of the risk of long-term infection and risk for recurrent hernia should the mesh become infected.

To date, the short-term outcomes of using Surgisis in ventral or inguinal hernia in clean cases appears to be equivalent to permanent prosthetic meshes with 2 years of follow-up. Since the product’s cost is similar to the cost of dual-sided PTFE [polytetrafluoroethylene] mesh, one could argue to use it in laparoscopic ventral hernia repair.

**Lawrence Danto, MD, Truckee, Calif:** The whole reason for using a prosthesis is to allow for a tension-free repair and, thus, decrease the incidence of recurrence. Why do you bother closing the fascia either above or below the prosthesis?

**Dr Helton:** That is an excellent point and, in fact, one of the recommendations I make in the article following our observation of infectious complications in dirty wound cases is to not close the fascia anterior to the mesh. Our results, at least with almost 2-year follow-up in many patients with exposed Surgisis mesh in whom the wound was left open, appears to be even better than those in whom we did close the fascia. So my recommendation at this point in time, until we have additional information, is not to do a closure anterior to the mesh when we have a dirty wound. Conversely, in patients with clean contaminated or clean wounds, I believe in reapproximating the midline fascia anterior to any mesh even if it requires a bilateral fascial release since the literature demonstrates that this approach results in the lowest long-term recurrence rate.

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**ARCHIVES OF INTERNAL MEDICINE**

Relationship Between Deep Venous Thrombosis and the Postthrombotic Syndrome

Susan R. Kahn, MD, MSc, FRCPC; Jeffrey S. Ginsberg, MD, FRCPC

The postthrombotic syndrome (PTS) is a frequent complication of deep venous thrombosis (DVT). Clinically, PTS is characterized by chronic, persistent pain, swelling, and other signs in the affected limb. Rarely, ulcers may develop. Because of its prevalence, severity, and chronicity, PTS is burdensome and costly. Preventing DVT with the use of effective thromboprophylaxis in high-risk patients and settings and minimizing the risk of ipsilateral DVT recurrence are likely to reduce the risk of development of PTS. Daily use of compression stockings after DVT might reduce the incidence and severity of PTS, but consistent and convincing data about their effectiveness are not available. Future research should focus on standardizing diagnostic criteria for PTS, identifying patients at high risk for PTS, and rigorously evaluating the role of thrombolysis in preventing PTS and of compression stockings in preventing and treating PTS. In addition, novel therapies should be sought and evaluated. (2004;164:17-26)

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