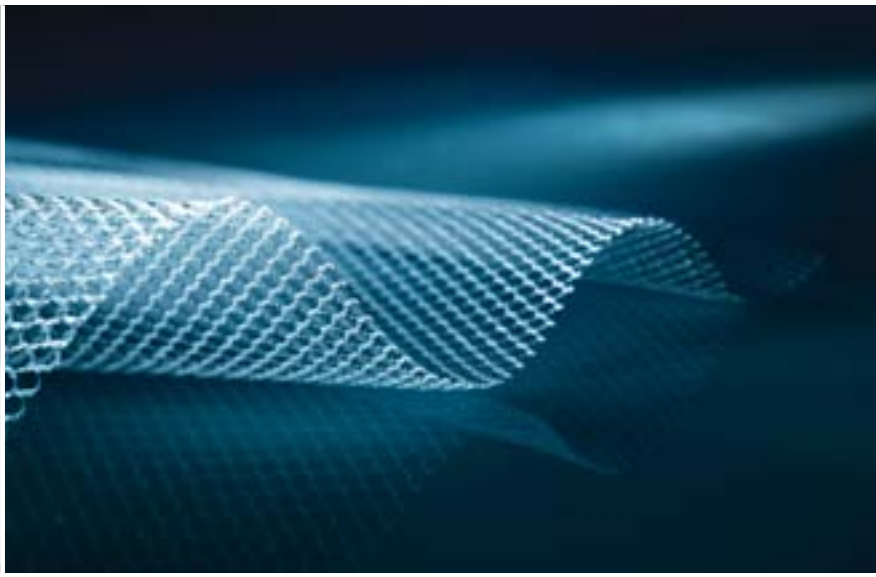
Clinical Evidence

For Optilene® Mesh Elastic – a mesh for inguinal hernia repair



Meshes

B BRAUN
SHARING EXPERTISE

Content

Rationale

An incisional hernia is a complication which can occur after every abdominal surgery, when the abdominal cavity is opened[1 – 5]. In case the sutured wound closure will not lead to a safe healing of the abdominal wall a herniation in the abdominal wall can result in which bowel may protrude[1 – 4].
The risk of an incisional hernia is correlated to the location of the previous operation. The most common origin of an incisional hernia is after a median laparotomy[6].

There are several potential risk factors which may have an influence on the occurrence of incisional hernias like wound healing disorders, wound infections, adipositas, chronic bronchitis, COPD or diabetes mellitus [1 – 5, 7-15].
Incisional hernia should be surgically treated, since sooner or later they may become symptomatic, may cause complications (e. g. Ileus) and tend to increase in size and subsequently cause discomfort.

Currently, the abdominal wall is usually reinforced by implanting meshes[16-17]. The manifold available meshes differ from each other in their material, in the textile and surface structure and in the tissue reaction and absorption. Evaluation of different meshes used for incisional hernia repair is of special interest due to the fact that different meshes do have different biocompatibility behaviour and complication behaviour. Suture repair of incisional hernia resulted in recurrence rates of 12 % to 54 %[8-23], while mesh repair resulted in recurrence rates of 2 % to 36 %[20-31].

Several trials have been performed for the search of the optimal mesh material[32-37] and of the ideal technique for incisional hernia repair[38,39]. There are numerous trials in the literature which compared different mesh materials for hernioplasty[36, 37, 40-42], others analysed the use of suture versus mesh[22, 23, 26, 29, 41, 43-48], or the onlay versus the sublay technique to repair incisional hernias[39, 43, 46, 49] (Table1 - 3). A few surgeons also investigate if the deveplopment of incisional hernia can be prevented in high risk patient (obesity, abdominal aortic aneurym) by the use of a prosthetic mesh after primary median laparotomy[50-56] (Table 4).

Currently most surgeons favour light-weight, large pore size, elastic, monofilament polypropylene meshes in the sublay position for reinforcement of the abdominal wall after herniation [36, 40,42].

Optilene® Mesh Elastic is a pure polypropylene, large pore size, light-weight mesh and it is nonabsorbable. It shows an overall elasticity and adapts to the movements of the abdominal wall perfectly. The Optilene® Mesh Elastic is a commercially available medical product.

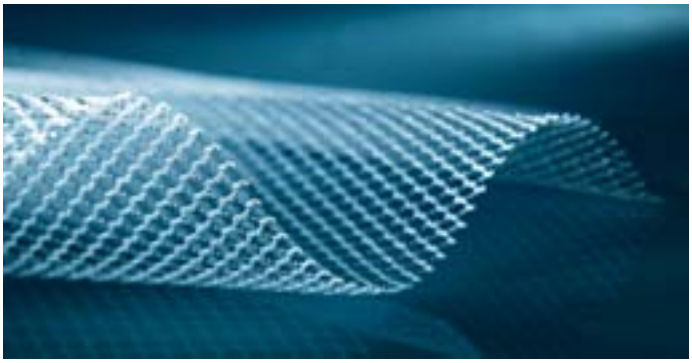


Figure 1: Optilene® Mesh Elastic

Optilene® Mesh Elastic is a sterilized mesh implant for re-inforcement of connective tissue structures. It is constructed from monofilament polypropylene which has been knitted to a thin and elastic shape-stable mesh with a pore size of 3 – 4 mm and a thickness of 0.55 mm.
After implantation the Optilene® Mesh Elastic adapts to the longitudinal and latitudinal expansions taking place in the connective tissue. The large pore structure supports the tissue ingrowth and the formation of an elastic scar tissue. Due to the all around elasticity, it supports the physiological function of the abdominal wall.
Optilene® Mesh Elastic does not possess any independent pharmacological properties. The polypropylene mesh is biostable and is not degraded in the body.

Rationale

Optilene® Mesh Elastic is intended to be used for prosthetic herniaplasty, for the reconstruction of the chest wall and for reinforcement of facial tissue if a non-inforcement material is required. It may not be implanted in contaminated and infected areas[57] and in children during the growth phase. Direct contact between Optilene® Mesh Elastic and the viscera (intestines etc.) must be avoided to prevent adhesion. Non-absorbable suture material and atraumatic round-bodied needles should be used together with Optilene® Mesh Elastic.

Like all non-absorbable meshes, implantation of Optilene® Mesh Elastic can be associated with a limited period of local irritation in the area of the wound; a transient foreign body reaction can occasionally take the form of an inflammatory reaction.

The incorporation of the Optilene® Mesh Elastic has been analysed by **Pascual et al. [59]**. They showed an excellent incorporation of Optilene® Mesh Elastic in the host tissue. Higher Collagen I and III levels were noted for large pore size meshes (Optilene® Mesh Elastic). Furthermore the biomechanical resistance values for Optilene® Mesh Elastic were significantly higher than those recorded for the other tested meshes.
The authors conclude, that meshes with a pore size larger than 3 cm^2 lead to genetic overexpression of collagen type I and III; that light-weight meshes with larger pore sizes induce more collagen type III deposition and its faster conversion to collagen type I and that the light-weight mesh Optilene® Mesh Elastic exhibits improved tensile strength 14 days after implantation over the small pore sized light-weight meshes.

Bellon et al. [60] analysed the functional and morphologic properties of light-weight (Optilene® Mesh Elastic) and heavy-weight meshes in an animal model. They indicate that polypropylene light-weight and polypropylene heavy-weight prostheses show similar tissue integration within host tissue; light-weight meshes exhibit similar tensile strengths to heavy-weight meshes; and that light-weight meshes could offer several benefits when used to repair tissue defects in that tissue elasticity is preserved and less foreign material is implanted in the recipient.

Indication:
- Incisional hernia
- Inguinal hernia
- Reconstruction of the chest wall

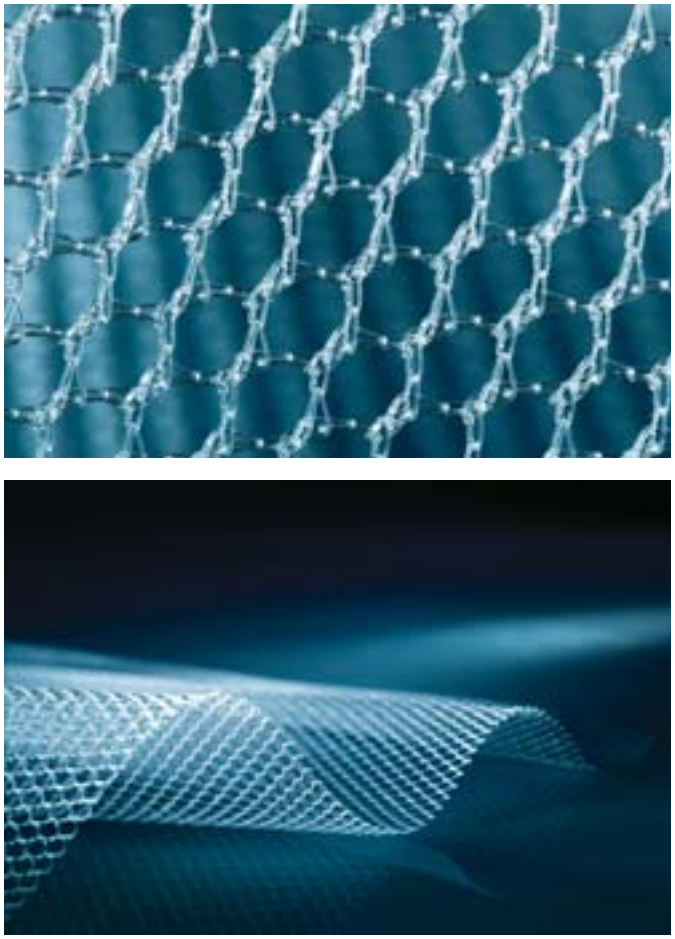


Figure 2: Elastic lightweight and large pore mesh: Optilene® Mesh Elastic

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Suture versus mesh for incisional hernia repair

Randomized Controlled Trial

The objective of the study conducted by **Burger et al. (31)** in 2004 was to determine the best treatment for incisional hernia, regarding recurrence, complications, discomfort, cosmetic result and patient satisfaction. Between 1992 and 1998 they performed a multi-center trial in which 181 eligible patients with primary or first-time recurrent midline incisional hernia were randomly assigned to suture or mesh repair. In 2003 follow-up was updated.

During suture repair, the edges of the fascia were approximated in the midline with a continuous polypropylene suture material. In patients assigned to mesh repair a polypropylene mesh was tailored to the defect so that at least 2 cm of the mesh overlapped the fascia and the mesh was sutured in sublay position with a continuous polypropylene suture material. In 2003 patients were asked to complete a questionnaire. Patient were asked whether they had suffered a recurrence, scar pain, abdominal pain, mesh infection, incarcerated hernia, small bowel obstruction or enterocutaneous fistula.

They were also asked:

- if they had undergone a hernia repair since the last visit
- to score pain in a Visual Analogue Scale
- to rate the cosmetic appearance of their abdomen
- to state whether they were ashamed of the appearance of the abdomen
- if they were satisfied with the result of the operation

The abdomen was examined for hernia recurrence which was defined as any fascial defect that was palpable or detected by ultrasound examination and was located within 7 cm of the site of hernia repair.

Ninety-seven patients were assigned to suture repair and 84 patients to mesh repair. The median follow-up of patients with recurrence was 75 months for the suture group and 81 months for the mesh group. The 10 years cumulative rate of recurrence was 65 % for suture repair and 32 % for prosthetic repair ($p < 0.001$). In a univariate analysis surgery for abdominal aortic aneurysm ($p < 0.01$) and infection ($p = 0.02$) were identified as risk factors for recurrence. Long term follow-up was obtained from 126 patients. In these patients the median follow-up was 97 months for suture repair and 98 months for mesh repair. In the mesh group 17 % suffered a hernia related complication compared with 8 % in the suture repair group.
In the suture group 23 patients (35 %) went through a revision after a recurrence of an incisional hernia repair, while 7 (12 %) of the mesh repair patients underwent a consecutive hernia repair ($p = 0.003$). Patients in the suture group had experienced significantly more scar pain and abdominal pain in comparison to the patients in the mesh group. The rating for the cosmetic appearance was equal in both groups. In the suture group 64 % were satisfied, while in the mesh repair group 77 % were satisfied.

This study provided evidence that in long-term mesh repair of incisional hernia is superior to suture repair. Mesh repair results in lower recurrence rates and less discomfort in the long term, while mesh repair is not associated with an increased incidence of complications. They concluded that to reduce the morbidity and the costs associated with incisional hernia repair and to prevent patients from undergoing pointless surgery, suture repair of incisional hernia should be completely abandoned.

To define the indications for the use of mesh materials, **Luijendijk et al (22)** undertook a randomized multi-center trial of patients with a midline abdominal incisional hernias.

In total 200 patients were assigned to suture repair or mesh repair. Approximation of the fascia edges was performed by using polypropylene suture material. In patients undergoing mesh repair the dorsal side of the fascia adjacent to the hernia was freed from the underlying tissue by at least 4 cm. A polypropylene mesh was tailored to the defect so that at least 2 to 4 cm of the mesh overlapped the edges of the fascia and the mesh was sutured to the back of the abdominal wall 2 to 4 cm from the edge of the defect with a continuous polypropylene suture material. The patients were evaluated by examination at 1, 6, 12, 18, 24, and 36 months after surgery. Recurrence rates and potential risk factors for incisional hernia were analyzed. Suture repair, infection, prostatism and history of surgery for abdominal aortic aneurysm were all identified as independent risk factors for recurrence. Mesh repair was found to result in a 57 % lower rate of recurrence than suture repair. The difference in rates of recurrence between the suture repair group and the mesh repair group was not affected by the size of the hernia.

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The frequency of pain one month after surgery was similar in the two treatment groups. The pain usually disappeared after the first month.
The authors showed that in patients with incisional hernias, retrofascial preperitoneal repair with polypropylene mesh is superior to suture repair with regard to the recurrence of hernia even in patients with small defects.

The study performed by **Korenkov and colleagues (23)** in 2002 was a three armed trial comparing suture repair, mesh repair and autodermal herniaplasty for incisional hernia repair. The aim was to evaluate recurrence and complication rates as well as subjective outcomes and quality of life.

In total 160 patients were included and randomized to one of the three different techniques for hernia repair. The method for suture repair was the Mayo fascia duplication. For mesh repair a polypropylene mesh was implanted as a suprafascial onlay after direct suturing of the fascia with non-absorbable suture material. The mesh was sized so that it overlapped by 6 cm in all directions. The autodermal technique used a skin graft from the hernia region.
After removal of epidermis and the fat, the cutis mesh was implanted in an overlay technique. The primary outcome measure was hernia recurrence. Follow-up examinations took place 3, 6, 12 and 24 months after the operation, or when any patient had a complaint. Complications served as a secondary outcome measure. Other outcome measure included return to usual activities of daily life, pain and stiffness of the abdominal wall.

Return to normal work was similar in all groups. Pain intensity at 6 weeks follow-up was significantly different between the groups. Significant pain was 2.9 times more likely after polypropylene mesh repair than after suture or autodermal repair. The rate of infectious complications was lower after suture repair than after both other repairs. After 9 months there were 4 recurrences in the suture group and 4 in the autodermal graft group whereas three recurrences were present in the mesh group The authors concluded that suture repair was safe for small incisional hernias. Both the autodermal and alloplastic hernia repair yielded comparably low recurrence rates, but led to a higher rate of wound infections.

CONCLUSION: Mesh repair is superior in incisional hernia repair than suture repair. Because mesh repair results in a lower recurrence rate, and is not associated with increased wound complication compared to suture repair [22, 23, 26, 29, 31, 43, 44, 45, 46, 48]**.**

Creating a tension free repair with prosthetic material lowers the recurrence of incisional hernias to 0 – 10 %. Suture repair of incisional hernia should be abandoned[31]**.**

Table 1:
Studies comparing suture versus mesh (polyproplylene) for incisional hernia repair

Author	No. Patients	Recurrence rate	No. Recurrence	P-Value	Follow-up	Wound-infection
Israelsson et al. 2006	Suture: 349 Mesh: 509	Suture: 29.1 % Onlay: 7.3 % Sublay: 19.3 %	51 33 9	ND	ND	9.6 % 8.1 %
Al-Salamah et al. 2006	Suture: 72 Mesh: 51	Suture: 20.8 % Mesh: 5.8 %	15 3	p = 0.04	mean 37 months	5.5 % 3.9 %
Sauerland et al. 2005	Suture: 305 Mesh: 79	Suture: 18 % Mesh: 5 %	55 4	p = 0.02	5 years	9 % 2 %
Burger et al. 2004	Suture: 84 Mesh: 97	Suture: 63 % Mesh: 32 %	54 27	p = 0.001	10 years	0 % 1.6 %
Langer et al. 2003	Suture: 241 Mesh: 180	Suture: 37 % Mesh: 15 %	89 27	p = 0.001	10 years	3 % 9 %
Flum et al. 2003	Suture: 5351 Mesh: 5361	Suture 24.1 % higher than Mesh		p = 0.001	5 years	
Korenkov et al. 2002	Suture: 33 Mesh: 39	Suture: 12 % Mesh: 7 %	4 3	p = 0.68	14 months	0 % 10 %
Clark et al. 2001	Suture: 13 Mesh: 8	Suture: 38 % Mesh: 25 %	5 2	ND	25 months 13 months	5.5 % 3.9 %
Luijendijk et al. 2000	Suture: 97 Mesh: 84	Suture: 46 % Mesh: 23 %	39 17	p = 0.005	3 years	ND ND
Schumpelick et al. 1996	Suture: 190 Mesh: 82	Suture: 33 % Mesh: 7 %	63 6	ND	64 months	3.7 % 3.2 %
Liakakos et al. 1994	Suture: 53 Mesh: 49	Suture: 25 % Mesh: 8 %	13 4	ND	90 months	5.6 % 4 %

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Onlay versus sublay technique for incisional hernia repair

Retrospective comparative studies

The aim of the study performed by **Israelsson et al. 2006 (43)** was to investigate the methods of incisional hernia repair that were employed in Sweden during the year 2002 and the subsequent rates of wound infection and incisional hernia recurrence.

In January 2004 all surgical departments in Sweden were asked to participate in a survery by answering a questionnaire concerning incisional hernia repairs performed at their department during 2002. Perioperative data including the method of incisional hernia repair were registered. Postoperative complications and data on follow-up for detection of incisional hernia recurrence in 12 months or more after repair were asked for.

From the questionnaire a total of 869 incisional hernia repairs were reported from 40 hospitals. A suture repair was performed in 349 incisional hernias, a mesh repair was used in 516 incisional hernias. The mesh was placed by using the onlay technique in 281 cases, the sublay in 228 cases and the inlay technique was performed in 4 incisional hernias. Wound infections occurred in 33 (9.6 %) patients with suture repair and in 39 with mesh repair (8.1 %). The rate of incisional hernia recurrence correlated with the method of repair. The highest recurrence rate was reported with suture repair (29.1 %), the lowest with a sublay mesh repair (9.7 %), recurrence rate with the onlay technique was 19.3 %. A higher incidence of recurrence was reported when the abdominal wall defect was greater than 3 cm together with the suture repair (27 % vs 35 %) or onlay mesh repair (10 vs 23 %). With sublay mesh repair the recurrence rate did not correlate with the size of the defect (5 % vs 6 %).

The authors concluded that this information is essential in helping the future surgeon to select methods when operating in the described region. This study also illustrated that there is definitely room for improvement incisional hernia surgery and this study has initiated the instigation of a national incisional hernia register.

In 2004 **Kingsnorth et al. (39)** asked the question which technique should be used for open mesh repair because there were no comparative studies which indicated under which circumstances the different techniques give the best result and the lowest recurrence rates. He performed a retrospective analysis of 52 incisional hernia repairs in patients with significant loss of domain. Sublay repair was applied in 33 patients, onlay in 16 patients, one patient received inlay repair and two patients the Ramirez abdominoplasty. Length of follow up was between 6 months and 6 years. The meshes used to repair the hernias were sized to allow 6 - 8 cm of excess prosthesis in all directions from the abdominal defect and sutured to underlying fasical structures with a continuous peripheral suture and interrupted central sutures of non-absorbable material spaced not more than 1 - 2 cm apart. Polypropylene mesh was the preferred prosthetic material.

Complications related to the wound recorded in this study were haematomas, wound infection, seroma and hernia recurrence. Sixteen patients experienced postoperative complications (34.6 %). Some patients with seroma or haematoma progressed to an infectious complication and therefore a number of patients had more than one complication. There were 5 haematomas, 11 seromas, 8 infections and two patients developed fistulas. In the sublay group there were 10 patients who suffered complications (30.3 %) and in the onlay group 5 patients were affected (31.2 %). One patient who developed a fistula received an inlay repair. There were 3 recurrences which equates to a recurrence rate of 6 %: in the onlay group, there were 2 recurrences and in the sublay there was one recurrence.

The authors concluded that both sublay and onlay mesh techniques gave good results for repair of complex insicional hernias with a significant loss of domain. The sublay technique was mandatory where there is a suprapubic component to the hernia in order to achieve this fixation within the pelvis. Because the onlay technique is technically more simple, its use is recommended in the upper abdomen where secure peripheral and central fixation is required to minimise seroma formation. They also indicated that the size of the prosthesis used to repair insicional hernias is very important, it should be cover any residual defect plus an additional 6 - 8 cm in all directions from the margins of the hernia and suture intervals should be no more than 2 cm to ensure adequate fixation.

Langer et al. (46) performed in 2003 a comparative retrospective study of 432 incisional hernia evaluating the outcome following mesh repair by using different techniques.
In total 432 incisional hernias operations on 348 patients were analysed: 11 autodermic hernioplasties, 241 Mayo pro-

cedures and 180 mesh repairs over a 25 year time period. The meshes were placed by using the sublay in 155, onlay in 14, inlay in 6, intraperitoneal in 3 and the sandwich technique in 2 patients. In most cases a polypropylene mesh was used. The mean follow-up was 9.7 ± 8.8 years.

The rate of major complications following mesh repair was 9 % in contrast to 3 % after the Mayo procedure (p = 0.091). The sublay technique revealed less complications compared with the onlay procedure (p = 0.016). The total recurrence rate following the overlapping Mayo repair was 37 % in contrast to 15 % after mesh implantation (p = 0.001), with a significant superiority of the sublay technique over the inlay and the onlay technique (p = 0.043). The inlay technique showed the highest recurrence rate 70 % versus 14 % after sublay and onlay repair. After mesh repair 86 % of the patient were better satisfied with the results after polypropylene mesh repair compared with other mesh materials. Mesh size was the only significant factor concerning quality of life following mesh implantation. The complication rate was determined significantly by the patients risk factors, size of hernias, surgical technique, and the surgeons experience, whereas the rate of recurrences was significantly influenced by the parameter obesity, size of hernia, and surgical experience.

The authors concluded that only the mesh repair revealed acceptable recurrence rates with high patient comfort. The sublay technique is superior to the onlay technique concerning the complication rate, whereas the autodermic hernioplasty and the inlay technique are obsolete.
The material of choice is polypropylene. The most important prognostic factor following mesh repair is the surgeon`s experience.
To determined whether the type of prosthetic material and technique of placement influenced long-term complications after repair of incisional hernias, **Leber et al. (49)** conducted a retrospective study .

Two hundred patients undergoing open mesh repair of abdominal incisional hernias with prosthetic material were included in this study. Four types of prosthetic material were used, polypropylene, polyester, polytetrafluorethylene or double filamented meshes and placed either as an onlay, underlay and sandwich technique. The main outcome of this study was the incidence of recurrence and complications.

Long term complication occurred in 54 patients (27 %). Most of these were related to a high recurrence rate of 16.8 %. The median time to long-term complication was 0.5 years for infection, 1.5 years for small bowel obstruction, 1.7 years for recurrence and 3.3 years for enterocutaneous fistula. The polyester mesh was associated with the highest rates for all types of major complications. The polyester mesh had a significant higher incidence of fistula formation (16 % vs 0 % - 2 %), a greater number of infections (16 % vs 0 - 6 %), and more recurrent hernias (34 % vs 10 - 14 %) than the other materials used. The additional mean length of stay to treat these complications was also significantly longer (30 vs 3 - 7 days) when polyester mesh was used.
The technique of repair was not significantly related to long-term complications. The underlay and the sandwich technique were all variations of subfascial placement of mesh. Although the incidence of fistulae was higher in the subfascial group 5.2 % vs 2.6 % for the onlay group the power to detect a statistical significance between these groups was low. The theoretical mechanical advantage of subfascial mesh in reducing the recurrence rate was not demonstrated in this study. The recurrence rate with subfascial placement of mesh was actually higher (19.5 %) than for the onlay technique (14.8 %). This study clearly showed that the incidence of complications from polyester mesh is markedly higher than for other mesh material. There is no advantage to its use (as seen by its higher recurrence rate), and it has an unacceptable high incidence of infection, small bowel obstruction, and enterocutaneous fistula formation. Because these complication can be devastating to the patient and lead to significant additional hospital days for their management, the authors recommended discontinuing the use of polyester mesh in incisional hernia repair.

CONCLUSION:

The sublay technique is superior to the onlay technique concerning the complication rate, whereas autodermic hernioplasty and inlay technique are obsolete [38, 43, 46].

The mesh should cover the defect plus additional 5 cm in all directions from the margin of the hernia, to achieve a sufficient reinforcement of the abdominal wall[37, 39, 41,42].

Material of choice should be polypropylene, because the complication rate with polyester mesh is much higher[38, 46, 49].

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Table 2:
Comparative Studies: Onlay versus Sublay technique

Author	Year	Patients	Technique	Recurrence (%)	No. Recurrence	P-Value	Follow-up
Langer et al.	2003	180	Sublay: 155 Onlay: 14 Inlay: 6	14 % 14 % 70 %	21 2 4	Sublay vs Onlay p = 0.043 Sublay vs Inlay p = 0.043	9.7 years ± 8.8 years
Leber et al.	1998	200	Sublay: 44 Onlay: 118	19.5 % 14.8 %	9 18		6.7 years
Israelsson et al.	2006	433	Sublay: 228 Onlay: 281	7.3 % 19.3 %	9 33		1 year
Kingsnorth et al.	2004	49	Sublay: 33 Onlay: 16	3 % 12.5 %	1 2		6 months- 6 years

Light-weight versus heavy-weight mesh for incisional hernia repair Randomized Controlled Trials (RCT)

To evaluate the potential of light-weight composite mesh a prospective randomized multi-center trial was undertaken by **Conze et al in 2005 (42)** in patients undergoing incisional hernia repair.

Patients were randomized to receive a light-weight composite mesh or a standard polypropylene or a standard polyester mesh. A total of 165 patients (83 lightweight mesh, 82 standard mesh: 34 polyester and 48 polypropylene meshes) were included in the study. The mesh was implanted by usinag the sublay technique. Patients attended for clinical follow-up at 21 days, 4, 12 and 24 months after surgery. At each visit a SF-36 and daily questionnaire was completed. Complications and recurrence rates were recorded.

There were no differences in the SF-36 physical function score and daily activities between the two groups between 21 days and 24 months. Postoperative complication rate was similar between the different mesh types. There were 28 seromas in the composite mesh group and 24 seromas in the standard mesh group. Five patients had a postoperative haematoma that required surgery (four with the composite mesh and 1 with the standard mesh). Chronic wound pain was recorded only at 12 and 24 months. Three patients with composite mesh were affected at 24 months and five with standard mesh. Overall 20 recurrent hernias were identified during the follow-up: 14 (17 %) in the composite mesh group and six (7 %) in the standard mesh group.

The use of a composite mesh for incisional hernia repair had similar outcomes to a standard polypropylene mesh with the exception that the composite mesh showed a trend to increased hernia recurrence.

Schumpelick et al. 1999 (37) compared in their study the results after implantation of either a light-weight mesh or a common heavy-weight mesh consisting of polypropylene. Indicators for clinical suitability were the rate and the volume of seroma, physical capability, abdominal compliance, and the histologically analyzed tissue reaction of samples removed on the occasion of revision operation.
The meshes were implanted by using the sublay technique. Sixty five patients were included in the study, 33 patients received a heavy-weight mesh and 32 patients received a light-weight mesh. These two groups were compared with 81 patients who obtained a heavy-weight, small pore size polypropylene mesh. The patients were examined 6 weeks after surgery and the abdominal wall was examined by ultrasound, the follow-up was 4 - 22 months.

No statistically significant difference was in seen in the rate of wound infection, bleeding and recurrence between the three mesh groups. In contrast to that, a significant difference was obtained for the rate and the volume of seromas ($p < 0.05$) in the heavy-weight, small pore size mesh group. A seroma was seen in 35 % of patient receiving a heavy-weight, small pore size mesh, whereas only 19 % of patients in the light-weight, large pore size mesh group and 22 % in the group of heavy-weight, larger pore size group developed a seroma. The volume of the seroma was 113 ± 142 ml for the heavy-weight, small pore size mesh, 33 ± 32 ml for the heavy-weight, larger pore size mesh and 28 ± 17 ml for the light-weight, large pore size mesh. The use of a light-weight, large pore size mesh decreased the inflammation and scar reaction in comparison to the use of the other two meshes. This mesh also showed a decrease in patients complaints, less restriction of abdominal wall mobility and improved abdominal wall compliance.

Retrospective Comparative Studies

This retrospective analysis of **Conze et al. 2007** (41) focussed on the recurrence in relation to location, material of previous mesh repair and the surgical procedure to resolve the problem.

Overall 77 patients underwent revision operations for recurrences after previous mesh repair. Their records were analyzed with regard to the previously applied technique, the type of prosthesis and the interval to the index operation.

The time interval from the first operation to the revision ranged from 1 to 128 months (mean 22 ± 22 months). Forty-one patients developed a recurrent hernia subsequent to a previous median laparotomy, whereas 36 showed a horizontal incision. In 31 patients the previous mesh repairs was performed with a small pore, heavy-weight polypropylene mesh. Thirty-eight patients had received a large pore size, light-weight polypropylene mesh. In seven patients the abdominal wall had been repaired with an expanded polytetrafluoroethylene prosthesis and only one patient received a polyester mesh at the previous operation. In the medial hernia group primary mesh repair was perform in 24

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sublay, 12 onlay, 4 inlay procedures. In the horizontal hernia group, previous incisional hernia repair was achieved by 22 sublay, 10 onlay, 2 inlay and 2 IPOM procedures.

After median and horizontal incision the location of recurrent hernia was independent of the previous mesh position, whether it has been placed in a sublay or onlay position. After heavy-weight small pore size polypropylene mesh repair an equal distribution of fascia defects to all sides but never a recurrence through a mesh was recognized. After light-weight, large pore size polypropylene mesh repair significantly more recurrences were found at the upper border of the mesh compared to the small size mesh group (63 % vs 29 %). Instead patients of the small size group showed more recurrent hernias at the lateral side of the mesh (48 %) usually combined with a extensive shrinkage.

They concluded that the type of revision has to consider the position and the material of the previous mesh. In their clinical recurrences, heavy-weight polypropylene meshes were mostly treated with mesh exchange and use of a light-weight mesh. Light-weight polypropylene meshes could be treated by extension with as second mesh. They also showed that deficient mesh repair are more evidently related to technical problems in contrast to suture repair.

The objectives of the study perform by **Schmidbauer and collegues 2005 (40)** was to determine early and the long-term course of patients who underwent open sublay hernia repair using heavy-weight versus light-weight polypropylene meshes.

Sixty-nine patients underwent sublay hernia repair with heavy-weight mesh, 106 patients with light-weight meshes. The outcome of this study was the early and long-term complication rate and chronic pain. The clinical course of all patients was registered during the hospital stay as well as 3 months and at least 12 months after open surgery.

Characteristics of patients showed that the mean hernia size and the number of hernias sized > 100 cm^2 of the light-weight mesh group were significantly higher, whereas the number of hernias with a size < 25 cm^2 and ratio of recurrent hernia as well as the length of hospital stay were significantly lower compared to the heavy-weight mesh group. In the heavy-weight group early minor complications (17 %) appeared more frequently than in the light-weight mesh group (13 %), but the differences for each symptom were not significant.

In the long-term follow-up (92 months), patients of the heavy-weight mesh group complained significantly more often about chronic recurrent pain (20 %) and stiff abdomen (38 %) compared to the light-weight mesh group (chronic pain 4 % and stiff abdomen 4 %). Moreover, there have been 2 hernia recurrences in each study group without significant differences.

Since the inflammatory reaction depends on the amount and structure of the incorporated material, the authors indicated that large pore size light-weight polypropylene meshes are clearly to be favoured over large-pore size heavy-weight polypropylene meshes, because of a better abdominal wall compliance and less chronic pain. However both types of meshes are convincing due to tensile strength and low recurrence rates in long-term run.

Welty et al. 2001 (36) investigated whether the type of material influenced the clinical and functional outcome of incisional hernia repair. Therefore in this study patients received different mesh types with a distinct amount of polypropylene and of various pore sizes for incisional hernia repair.

All polypropylene meshes were placed in the sublay position. In total 115 heavy-weight, small pore size meshes (hws), 37 heavy-weight, larger pore size meshes (hwl) and 83 light-weight, large pore size meshes (lwl) were implanted. Patients were examined with ultrasound and the different groups were compared for postoperative complication rates and functional parameters of the artificial abdominal wall, follow-up was 24 months after surgery.

Table 3:
Comparative Studies: Light-weight mesh versus heavy-weight mesh

Author	Year	Mesh Type	Technique	Recurrence	Complication	Chronic pain	Seroma	Complaint	Follow-up
Schmidbauer et al.	2005	Polypropylene Hw: 69 Lw: 106	 Sublay Sublay	 3 % 2 % NS	Minor / Major 17 % / 3 % NS 13 % / 2 % NS	 14 % 4 % p<0.05		Stiff abdomen 38 % 4 % p<0.05	 92 months
Conze et al.	2005	Polyester and Polypropylene vs Lw Lw: 83 St: 82	 Sublay Sublay	 17 % 7 % p = 0.052	Haematoma requiring surgery 5 % 1 %	 3.6 % 6 %	 34 % 29 %	No difference in SF-36 No difference in daily questionaire	 24 months
Welty et al.	2001	Polypropylene LwL: 83 Hws: 115 Hwl: 37	 Sublay Sublay Sublay	 3.4 % 9.6 % 2.7 %	Wound infection 3.5 % 11.3 % 5.6 %		 7 % 16 % 1 %	No compliants: 89 % 57 % 81 %	 24 months
Conze et al.	2007	Polypropylene Lw: 38 Hw: 31 PTFE: 7 Polyester: 1	Onlay: 2 Sublay: 46 Inlay: 6 IPOM: 2 Median: 41 Horizontal: 36	Location: Cranial: Lw vs Hw 63 % vs 29 % Lateral: Lw vs Hw 18 % vs 48 %	Re-operation: Hw: 23 exchange, 5 extension Lw: 4 exchange, 28 extension				mean 22 months ± 22
Schumpelick et al.	1999	Polypropylene Lwl: 32 Hws: 81 Hwl: 33	 Sublay Sublay Sublay	 0 % 3 % 5 %	Infection 3.1 % 2.5 % 6.1 %		 19 % 35 % 22 %	No compliants: 94 % 82 % 44 %	 4 months 22 months 6 months

Lwl: light-weight, large pore size, Hwl: heavy-weight large pore size, Hws: heavy-weight small pore size, St: standard, NS: not significant.

A higher rate of wound infections could be detected in the heavy-weight, small pore size mesh group (hws) (11.3 %) in comparison to the heavy-weight, lager pore size mesh (hwl) group (5.6 %) and to the light-weight, large pore size mesh (lwl) group (3.5 %). Seroma were more frequently present in the hwl (14 %) and the lwl group (8 %) than in the hwl group (3 %). Recurrence of hernia developed in 9.6 % of patients in the hws group, 3.4 % in the lwl group and in 2.7 % in the hwl group. Many of the patients with hws meshes complained when involved in daily activities; however most of the patients with the lwl and hwl mesh were capable of doing heavy work with little or no difficulty.

The data support the hypothesis that the use of a highly elastic, light-weight, large pore size mesh is advantageous for abdominal wall function.

CONCLUSION:

The use of a light-weight, large pore size polypropylene mesh should be favoured, because it decreases the rate of inflammation, scar reaction, the rate and volume of seromas and causes less chronic pain[32, 33,36, 37, 40].

Clinical Evidence

Mesh fixation with fibrin glue versus suture

Randomized controlled trial (RCT)

The aim of the study performed by **Lobato et al. 2001 (58)** was to analyse the result of the application of fibrin glue between the muscle layers and the subcutaneous tissue after incisional hernia repair with polypropylene mesh. They assessed the role of the fibrin glue in reduction of local complications, hospital stay and postoperative wound care.

Sixty patients with incisional hernia repair were included in this study and were divided into two groups: the first group of 30 cases did not received the fibrin glue; group I and in the second group of 30 patients the fibrin glue was applied in the subcutaneous tissue over the mesh. The sublay technique was used for all incisional hernia repair.

Postoperative morbidity was 46.6 % in group I and 20 % in group II. In terms of local morbidity, there was a significant difference in the presence of wound infection (20 % group I vs 3.3 % group II) and haematomas (20 % group I vs 6.6 % group II) between the two groups. Total morbidity occurred in 53.3 % of the patients in group I and 26.6 % in group II. There was no postoperative mortality. The average hospital stay was 12.6 days in group I and 7.1 days in group II with a statistically significant difference ($p < 0.01$). Two hernia recurrences occurred in group I at 30 and 42 months and one in the group II at 20 months.

The authors concluded that fibrin glue application reduces the incidence of local morbidity by 50 %, reduces the severity of complications, shortens hospital stay by 50 %, and lessens the amount of postoperative wound care needed. This procedure reduces the cost of the surgery, and 80 % of the patients in the fibrin glue group were discharged from the hospital without any complications compared with only 54 % of the patients in the group without fibrin glue.

CONCLUSION:
Fixation of the polypropylene mesh with fibrin glue reduces the incidence of local morbidity by 50 %, lessens the severity of complications, shortens hospital stay by 50 % and lessens the amount of postoperative wound care needed. This procedure also reduces the cost of surgery[58].

Preventive mesh repair in patient with a high risk to develop incisional hernia

Randomized controlled trial

Gutierez et al. (50) performed a study in 2003 to evaluate the usefulness of placement of a supra-aponeurotic polypropylene mesh in the primary closure of laparotomies with a high risk for incisional hernia.

One-hundred patients with a high postoperative risk of developing a post-laparotomy incisional hernia were included in this study. In all cases, closure of the laparotomy was accomplished with continuous one-line suture using non-absorbable monofilament and in alternative 50 patients a polypropylene mesh was placed on the aponeurosis . The mesh was fixed to the aponeurotic surface with separate stitches of resorbable material. The edges of the mesh extended past the line of the incision by 3 cm in all directions. Patients were assessed 3 years after surgery. Examination included abdominal wall palpation to detect the possible existence of incisional hernia. Where results were not conclusive an abdominal CAT was taken.

Twelve patients were disregarded for the purpose of this study. Of the remaining 88 patients, 44 were included in the group with simple closure of the abdominal wall and the other 44 in the group with closure of the abdominal wall using a mesh. Secondary endpoints (haematoma, seroma, infection) in the closure of the abdominal wall, defined as those arising within the first 30 days of the postoperative period, between the two groups were not statistically significant. Three years after surgery, five patients in the simple abdominal closure group showed incisional hernia (11.3 % incidence) while none occurred in the group of patients with abdominal closure with a mesh ($p = 0.002$).

The authors believe that the placement of a supra-aponeurotic polypropylene mesh in the primary closure of the abdominal wall in patients whose general characteristics indicate a substantial risk of incisional hernia is an extremely useful surgical technique, allowing reduction of the high rate of incisional hernia in such patients and the consequent decrease in the associated morbidity and mortality rates.

Jeekel and colleagues will perform a randomized controlled trial (Prima-Trial) to investigate if the use of a preventive polypropylene mesh after primary laparotomy in high risk patients may reduce the incidence of incisional hernias.

In this study 460 high risk patients (obesity, abdominal aortic aneurysm) will be included. These patients will be randomized into three groups. In one-hundred patients the midline fascia will be closed by using an long-term absorbable suture material (group 1) in the continuous suture technique. In 180 patients a polypropylene mesh will be placed in sublay position and the fixation of the mesh will be performed by using fibrin glue (group 2). In group 3 another 180 patient will received a preventive polypropylene mesh in onlay position and the mesh is fixed by using fibrin glue. The patients will be examined 1, 3, 12 and 24 months after surgery and the outcome of this study is the recurrence of incisonal hernia, postoperative complications, quality of life and cost effectiveness.

CONCLUSION:
Use of prosthetic polypropylene mesh in the primary closure of laparotomies in patients with a high risk of incisional hernia is useful to decrease the rate of incisional hernia[50–56].

Table 4:
Comparative studies: Prevention of incisional hernia with the use of a prosthetic mesh

Author	Year	Patients	Mesh type	Recurrence	Follow-up
Gutierrez et al.	2003	50 Mesh 50 No Mesh	Polypropylene	0 5	36 months
Strzelczyk et al.	2002	12 Mesh 48 No Mesh	Polypropylene	0 9	12 months
Jänes et al.	2004	27 Mesh 27 No Mesh	Polypropylene	0 8	12 months
Jänes et al.	2004	27 Mesh 27 No Mesh	Polypropylene	1 13	24 months

Key Messages

- Optilene® Mesh Elastic is made of monofilament polypropylene.
- Optilene® Mesh Elstic is a light-weight, large pore size mesh with multidirectional elasticity.
- Due to its multidirectional elasticity Optilene Mesh Elastic adapts to all movements taking place in the abdominal wall.
- Optilene® Mesh Elastic is ideal for incisional hernia repair.
- Optilene® Mesh Elastic shows excellent handling and highest patient convenience.
- The polypropylene mesh shows a good durability, pliability, a high tensile strength and good ingrowth of fibroblasts into the mesh[16, 34, 35, 59].
- In the case of infection the polypropylene mesh can be generally be treated adequately with drainage and with antibiotics without the need of removal[35].
- Mesh repair is superior in incisional hernia repair than suture repair. Because mesh repair results in a lower recurrence rate, and is not associated with increased wound complication compared to suture repair [22, 23, 26, 29, 31, 43, 44, 45, 46, 48].
- Creating a tension free repair with prosthetic material lowers the recurrence of incisional hernias to 0 - 10 %. Suture repair of incisional hernia should be abandoned[31].
- The sublay technique is superior to the onlay technique concerning the complication rate, whereas autodermic hernioplasty and inlay technique are obsolete[38, 43, 46].
- The mesh should cover the defect plus additional 5 cm in all directions from the margin of the hernia, to achieve a sufficient reinforcement of the abdominal wall[37, 39, 41,42].
- Material of choice should be polypropylene, because the complication rate with polyester mesh is much higher[38, 46, 49].
- The use of a light-weight, large pore size polypropylene mesh should be favoured, because it decreases the rate of inflammation, scar reaction, the rate and volume of seromas and causes less chronic pain[32, 33, 36, 37, 40].
- Fixation of the polypropylene mesh with fibrin glue reduces the incidence of local morbidity by 50 %, lessens the severity of complications, shortens hospital stay by 50 % and lessens the amount of postoperative wound care needed. This procedure also reduces the cost of surgery[58].
- Use of prosthetic polypropylene mesh in the primary closure of laparotomies in patients with a high risk of incisional hernia is useful to decrease the rate of incisional hernia[50-56].

Abstracts

Ann Surg. 2004 Oct; 240 (4): 578-83; discussion 583-5.

Long-term follow-up of a randomized controlled trial of suture versus mesh repair of incisional hernia.

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OBJECTIVE: The objective of this study was to determine the best treatment of incisional hernia, taking into account recurrence, complications, discomfort, cosmetic result, and patient satisfaction.

BACKGROUND: Long-term results of incisional hernia repair are lacking. Retrospective studies and the midterm results of this study indicate that mesh repair is superior to suture repair. However, many surgeons are still performing suture repair.

METHODS: Between 1992 and 1998, a multicenter trial was performed, in which 181 eligible patients with a primary or first-time recurrent midline incisional hernia were randomly assigned to suture or mesh repair. In 2003, follow-up was updated.

RESULTS: Median follow-up was 75 months for suture repair and 81 months for mesh repair patients. The 10-year cumulative rate of recurrence was 63 % for suture repair and 32 % for mesh repair ($P < 0.001$). Abdominal aneurysm ($P = 0.01$) and wound infection ($P = 0.02$) were identified as independent risk factors for recurrence. In patients with small incisional hernias, the recurrence rates were 67 % after suture repair and 17 % after mesh repair ($P = 0.003$). One hundred twenty-six patients completed long-term follow-up (median follow-up 98 months). In the mesh repair group, 17 % suffered a complication, compared with 8 % in the suture repair group ($P = 0.17$). Abdominal pain was more frequent in suture repair patients ($P = 0.01$), but there was no difference in scar pain, cosmetic result, and patient satisfaction.

CONCLUSIONS: Mesh repair results in a lower recurrence rate and less abdominal pain and does not result in more complications than suture repair. Suture repair of incisional hernia should be abandoned.

Abstracts

N Engl J Med. 2000 Aug 10; 343 (6): 392-8.

A comparison of suture repair with mesh repair for incisional hernia.

Luijendijk RW, Hop WC, van den Tol MP, de Lange DC, Braaksma MM, IJzermans JN, Boelhouwer RU, de Vries BC, Salu MK, Wereldsma JC, Bruijninckx CM, Jeekel J.

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BACKGROUND: Incisional hernia is an important complication of abdominal surgery. Procedures for the repair of these hernias with sutures and with mesh have been reported, but there is no consensus about which type of procedure is best.

METHODS: Between March 1992 and February 1998, we performed a multicenter trial in which we randomly assigned to suture repair or mesh repair 200 patients who were scheduled to undergo repair of a primary hernia or a first recurrence of hernia at the site of a vertical midline incision of the abdomen of less than 6cm in length or width. The patients were followed up by physical examination at 1, 6, 12, 18, 24, and 36 months. Recurrence rates and potential risk factors for recurrent incisional hernia were analyzed with the use of life-table methods.

RESULTS: Among the 154 patients with primary hernias and the 27 patients with first-time recurrent hernias who were eligible for the study, 56 had recurrences during the follow-up period. The three-year cumulative rates of recurrence among patients who had suture repair and those who had mesh repair were 43 percent and 24 percent, respectively, with repair of a primary hernia (P = 0.02; difference, 19 percentage points; 95 percent confidence interval, 3 to 35 percentage points). The recurrence rates were 58 percent and 20 percent with repair of a first recurrence of hernia (P = 0.10; difference, 38 percentage points; 95 percent confidence interval, 1 to 78 percentage points). The risk factors for recurrence were suture repair, infection, rostatism (in men), and previous surgery for abdominal aortic aneurysm. The size of the hernia did not affect the rate of recurrence.

CONCLUSIONS: Among patients with midline abdominal incisional hernias, mesh repair is superior to suture repair with regard to the recurrence of hernia, regardless of the size of the hernia.

Br J Surg. 2002 Jan; 89 (1): 50-6.

Randomized clinical trial of suture repair, polypropylene mesh or autodermal hernioplasty for incisional hernia.

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BACKGROUND: Since conventional suture repair for incisional hernia is associated with high recurrence rates, alloplastic and autoplastic prosthetic techniques have been suggested.

METHODS: In a randomized trial, 160 patients with simple or complex hernias underwent either suture repair, autodermal skin graft or onlay polypropylene mesh repair. Suture repair was not done in complex hernias. This report concerns a planned interim analysis.

RESULTS: At mean follow-up of 16 months, there were 17 hernia recurrences that were distributed similarly between the surgical techniques. There were fewer infectious complications after suture repair (three of 33 patients) than after skin graft or mesh repair (seven of 39 and five of 28 for simple hernias; seven of 31 and ten of 29 respectively for complex hernias) (P not significant). The severity of infections after polypropylene mesh implantation prompted the trial committee to discontinue the study. No differences were noted in duration of stay in hospital and quality of life. However, pain was significantly more frequent after polypropylene mesh repair (pooled risk ratio 2.9 and 1.8 at 6 weeks and 1 year respectively).

CONCLUSION: Suture repair was safe for small incisional hernias. Both autoplastic and alloplastic hernia repair yielded comparably low recurrence rates, but led to a high rate of wound infection.

Hernia. 2006 Jun; 10 (3): 258-61. Epub 2006 Mar 23.

Incisional hernia repair in Sweden 2002.

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Incisional hernia is a common problem after abdominal surgery. The complication and recurrence rates following the different repair techniques are a matter of great concern. Our aim was to study the results of incisional hernia repair in Sweden. A questionnaire was sent to all surgical departments in Sweden requesting data concerning incisional hernia repair performed during the year 2002. Eight hundred and sixty-nine incisional hernia repairs were reported from 40 hospitals. Specialist surgeons performed the repair in 782 (83.8 %) patients. The incisional hernia was a recurrence in 148 (17.0 %) patients. Thirty-three per cent of the hernias were subsequent to transverse, subcostal or muscle-splitting incisions or laparoscopic procedures. Suture repair was performed in 349 (40.2 %) hernias. Onlay mesh repair was more common than a sublay technique. The rate of wound infection was 9.6 % after suture repair and 8.1 % after mesh repair. The recurrence rate was 29.1 % with suture repair, 19.3 % with onlay mesh repair, and 7.3 % with sublay mesh repair. This survey revealed that there is room for improvement regarding the incisional hernia surgery in Sweden. Suture repair, with its unacceptable results, is common and mesh techniques employed may not be optimal.
This study has led to the instigation of a national incisional hernia register.

Abstracts

Ann R Coll Surg Engl. 2004 Sep; 86 (5): 363-6.

Open mesh repair of incisional hernias with significant loss of domain.

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BACKGROUND: Incisional hernias develop in up to 13 % of laparotomy incisions: the most difficult to repair are complex, multiply recurrent hernias with significant loss of domain (> 15 - 20 % of the abdominal contents).

METHODS: Retrospective analysis by standard proforma of a series of 52 patients operated on at a single institution between 1996 and 2002. All patients received pre-operative CT and anaesthetic assessment. Patients with significant tissue loss were assessed by a plastic surgeon. Cardiorespiratory status was optimised and trophic skin ulcers treated before operation.

RESULTS: Sublay repair was applied in 33 patients, onlay in 16 patients, one patient received inlay repair and two patients the Ramirez abdominoplasty. Additional procedures of stoma closure, muscle flap or abdominoplasty were carried out in 7 patients. Complications occurred in 18 (34.6 %) patients, 5 of whom required further surgery for haematoma, infection or fistulisation. One patient died from pulmonary embolism after postoperative complications. Three recurrences were apparent after follow-up of 6 months to 6 years.

CONCLUSIONS: Complex incisional hernias are a challenging surgical problem. Careful patient selection and surgical technique with a team involving anaesthetists and plastic surgeons is required. Post-operative management may require facilities in HDU and ITU. Clinical trials are required to identify techniques and materials which give the best results.

Chirurg. 2003 Jul; 74 (7): 638-45.

Twenty-five years of experience in incisional hernia surgery. A comparative retrospective study of 432 incisional hernia repairs

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INTRODUCTION: Incisional hernia surgery in Germany is changing from conventional techniques to mesh implantation. The relevance of different factors such as surgical technique, mesh material, and patient-related parameters concerning the outcome following mesh repair is still under debate.

METHODS: In a comparative retrospective study of 432 incisional hernia operations on 348 patients we analyzed 11 autodermic hernioplasties, 241 Mayo procedures, and 180 mesh repairs over a 25-year time period. In addition to the quality of life following mesh implantation, the prognostic relevance of demographic, pre- and intraoperative parameters, surgical technique, mesh material, and the surgeon's experience were subjected to both univariate and multivariate analysis.

RESULTS: With a mean follow-up of 9.7 +/- 8.8 years, the rate of major complications following mesh repair was 9 % in contrast to 3 % after the Mayo procedure (p = 0.091). The sublay technique revealed less complications compared to the onlay procedure (p = 0.016). The total recurrence rate following the overlapping Mayo repair was 37 % in contrast to 15 % after mesh implantation (p = 0.001), with a significant superiority of the sublay technique over the inlay technique (p = 0.043). The rate of recurrences and complications after autodermic hernioplasty was 72 % and 36 %, respectively. After mesh repair, 86 % of the patients were better satisfied

with the results after Marlex mesh compared to GoreTex (p = 0.016). Mesh size was the only significant prognostic factor concerning quality of life following mesh implantation. The complication rate was determined significantly by the patients' risk factors, size of hernia, surgical technique, and the surgeon's experience, whereas the rate of recurrences was significantly influenced by the parameters obesity (BMI > 25), size of hernia, and surgical experience. The recurrence rate decreased significantly with the surgeon's experience: a minimum of 16 mesh repairs led to a recurrence rate of less than 10 %.

CONCLUSIONS: Only the mesh repair revealed acceptable recurrence rates with high patient comfort. The sublay technique is superior to onlay concerning the complication rate, whereas the autodermic hernioplasty and inlay techniques are obsolete. The material of choice is polypropylene. The most important prognostic factor following mesh repair is the surgeon's experience.

Chirurg. 2001 Aug; 72 (8): 953-7.

Standardized sublay technique in polypropylene mesh repair of incisional hernia. A prospective clinical study

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INTRODUCTION: With the introduction of meshes to support hernia repairs the recurrence rates were reduced from 50 % to less than 10 %. Special complications such as scar plates with restriction of the mobility of the abdominal wall, pain and fistula formation are described.

METHODS: In a prospective study trial 38 patients with incisional hernia were treated with Marlex mesh repair in the standard sublay technique.

RESULTS: Within a mean follow-up period of 3 years most of the patients were free from pain and very satisfied. Two recurrences (5.2 %) occurred and 2 hematomas (5.2 %) had to be removed surgically.

CONCLUSIONS: Using a standard operation technique with the mesh in sublay position good clinical results can be achieved compared to published findings. To our surprise we found two central recurrences through the mesh.

Abstracts

Arch Surg. 1998 Apr; 133 (4): 378-82.

Comment in: Arch Surg. 1998 Nov; 133 (11): 1254-5. Arch Surg. 1998 Oct; 133 (10): 1137. Arch Surg. 1998 Oct; 133 (10): 1137. Arch Surg. 2000 Feb; 135 (2): 238.

Long-term complications associated with prosthetic repair of incisional hernias.

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OBJECTIVE: To determine whether the type of prosthetic material and technique of placement influenced long-term complications after repair of incisional hernias.

DESIGN: Retrospective cohort analytic study.

SETTING: University-affiliated hospital.

PATIENTS: Two hundred patients undergoing open repair of abdominal incisional hernias with prosthetic material between 1985 and 1994.

INTERVENTIONS: Four types of prosthetic material were used and placed either as an onlay, underlay, sandwich, or finger interdigitation technique. The materials were monofilamented polypropylene mesh (Marlex, Davol Inc, Cranston, RI), double-filamented mesh (Prolene, Ethicon Inc, Somerville, NJ), expanded polytetrafluroethylene patch (Gore-Tex, WL Gore & Associates, Phoenix, Ariz) or multifilamented polyester mesh (Mersilene, Ethicon Inc).

MAIN OUTCOME MEASURES: The incidence of recurrence and complications such as enterocutaneous fistula, bowel obstruction, and infection with each type of material and technique of repair were compared with univariate and multi-variate analysis.

RESULTS: On univariate analysis, multifilamented polyester mesh had a significantly higher mean number of complications per patient (4.7 vs 1.4 - 2.3; $P < .002$), a higher incidence of fistula formation (16 % vs 0 % - 2 %; $P < .001$), a greater number of infections (16 % vs 0 % - 6 %; $P < .05$), and more recurrent hernias (34 % vs 10 % - 14 %; $P < .05$) than the other materials used. The additional mean length of stay to treat compli cations was also significantly longer (30 vs 3 - 7 days; $P < .001$) when polyester mesh was used. The deleterious effect of polyester mesh on long-term complications was confirmed on multiple logistic regression ($P = .002$). The technique of placement had no influence on outcome.

CONCLUSION: Polyester mesh should no longer be used for incisional hernia repair.

Br J Surg. 2005 Dec; 92 (12): 1488-93.

Comment in: Br J Surg. 2006 Mar; 93(3): 376; author reply 376.

Randomized clinical trial comparing lightweight composite mesh with polyester or polypropylene mesh for incisional hernia repair.

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BACKGROUND: Polymer mesh has been used to repair incisional hernias with lower recurrence rates than suture repair. A new generation of mesh has been developed with reduced polypropylene mass and increased pore size. The aim of this study was to compare standard mesh with new lightweight mesh in patients undergoing incisional hernia repair.

METHODS: Patients were randomized to receive lightweight composite mesh, or standard polyester or polypropylene mesh. Outcomes were evaluated at 21 days, 4, 12 and 24 months from patient responses to the Short Form 36 (SF-36) and daily activity questionnaires. Complications and recurrence rates were recorded.

RESULTS: A total of 165 patients were included in an intention-to-treat analysis (83 lightweight mesh, 82 standard mesh). Postoperative complication rates were similar. The overall hernia recurrence rate was 17 per cent with the lightweight mesh versus 7 per cent with the standard mesh (P = 0.052). There were no differences in SF-36 physical function scores or daily activities between 21 days and 24 months after surgery.

CONCLUSION: The use of the lightweight composite mesh for incisional hernia repair had similar outcomes to polypropylene or polyester mesh with the exception of a non-significant trend towards increased hernia recurrence. The latter may be related to technical factors with regard to the specific placement and fixation requirements of lightweight composite mesh.

Abstracts

Chirurg. 1999 Apr; 70 (4): 422-30.

Minimized polypropylene mesh for preperitoneal net plasty (PNP) of incisional hernias

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Repair of incisional hernias requires the extensive implantation of alloplastic materials. The extent of the scar tissue is markedly regulated by the amount and structure of the incorporated material and is responsible for the increased rate of local wound complications. Correspondingly, minimization of the alloplastic implants should be favorable. In a randomized, prospective clinical study, the early results were compared after implantation of either a minimized, low-weight (26.8 g/m^2) mesh with a pore size of 5 mm or a common, heavy-weight (90.2 g/m^2 polypropylene) mesh with a pore size of 0.8 mm. Indicators for clinical suitability were the rate and volume of seroma, subjective paraesthesia, physical capability, abdominal wall compliance, and the histologically analyzed tissue reaction of samples removed on the occasion of revision operations. As result, the optimized, low-weight mesh showed a remarkable decrease in the rate of seroma, patient complaints, less restriction of abdominal wall mobility, and improved abdominal wall compliance as verified by 3D stereography. These clinical findings corresponded to a pronounced decrease in inflammation and scar reaction, indicating improved incorporation of the alloplastic material. No other major complications except for one recurrence have been found.

Langenbecks Arch Surg. 2007 Jul; 392 (4): 453-7. Epub 2006 Sep 2.

Incisional hernia: challenge of re-operations after mesh repair.

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BACKGROUND AND AIMS: The widespread use of meshes for the repair of incisional hernia is currently followed by an increasing number of re-operations. The incidence of incisional hernia recurrence after mesh repair varies between 3 and 32 %. The problem of mesh failure and options for another surgical intervention seem rather unattended.

METHODS: We present our experience of 77 re-operations after previous mesh repair that were performed between 1995 and 2004 out of a total of 1.070 operations for incisional hernia. The retrospective analysis focused on recurrence in relation to location, material of the previous mesh repair and the surgical procedure to resolve the problem.

RESULTS: The locations of the preceding meshes were epifascial as onlays (n = 23), retromuscular as sublays (n = 46), within the defect as inlays (n=6) or intraperitoneally (n = 2). The direction of the incision was vertical medial (n = 41) or horizontal crossing the linea semilunaris (n = 36). Recurrences after median incisional hernia mesh repair mainly occurred at the cranial border of the mesh subxiphoidal. Except for two patients, all recurrences manifested at the margin of the enclosed mesh.

CONCLUSIONS: Re-operation after previous mesh repair is a surgical challenge. The type of revision procedure has to consider the position and material of the previous mesh. In our clinic recurrences, heavyweight polypropylene meshes were mostly treated with mesh exchange and lightweight polypropylene meshes could be treated by extension with a second mesh. In contrast to suture techniques, deficient mesh repairs are more evidently related to technical problems.

Eur J Med Res. 2005 Jun 22; 10 (6): 247-53.

Heavy-weight versus low-weight polypropylene meshes for open sublay mesh repair of incisional hernia.

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BACKGROUND: The introduction of retromuscular, preperitoneal sublay technique using polypropylene (PP) meshes had significantly decreased the recurrence rates after open incisional hernia repair. Nevertheless, recent data of single institutions reported about non-acceptable high hernia recurrences. The objective of this study was to determine early complications and the long-term course of patients who underwent open sublay hernia repair using heavy-weight versus low-weight PP meshes.

METHODS: Between January 1996 and December 1997, all consecutive patients received large pore-sized, monofilament heavy-weight PP meshes (Prolene); from January 1998 to December 2001, only large pore-sized, low-weight PP meshes (Vypro) composed of multifilaments were used. The clinical course of all patients was registered during the hospital stay as well as 3 months and at least 12 months after surgery.

RESULTS: Sixty-nine patients (mean age 56 +/- 13 years) underwent sublay hernia repair with heavy-weight PP meshes, 106 patients (mean age 60 +/- 14 years) with low-weight PP meshes. No significant differences were determined concerning age, gender, BMI, ASA score, hernia size 25 - 99 cm^2 and number of primary midline incisions. In contrast, mean hernia size and number of hernia size > or = 100 cm^2 were significantly higher, whereas number of hernia size < 25 cm^2, ratio of recurrent hernia and length of hospital stay were lower in the low-weight PP mesh group. Minor complications (17 %) appeared more frequently in the heavy-weight than in the low-weight PP mesh group (13 %). One patient each with major bleeding required re-operation in both groups. One patient with lethal pulmonary

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embolism in the heavy-weight PP mesh group and one patient with unrecognised enterotomy and re-operation in the low-weight PP mesh group were registered. In the long-term run (mean follow-up 92 +/- 20 months), patients of the heavy-weight PP mesh group complained significantly more frequently about chronic pain and "stiff abdomen" than those of the low-weight PP mesh group (46 +/- 14 months). Two hernia recurrences occurred in each study group. Two of them were found after midline hernia repair at the edge of the mesh, the remainder were detected after lateral hernia repair.

CONCLUSION: Large pore-sized low-weight PP meshes composed of multifilaments are clearly to be favoured over large pore-sized, monofilament heavy-weight PP meshes because of better abdominal wall compliance and less chronic pain. However, both types of meshes are convincing due to high tensile strength and low recurrence rates in the long-term run.

Hernia. 2001 Sep; 5 (3): 142-7.

Functional impairment and complaints following incisional hernia repair with different polypropylene meshes.

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The influence of mesh material on the clinical outcome of hernia repair has often been neglected, although recent studies have clearly demonstrated the importance of mesh properties for integration in the abdominal wall. Of particular significance are the amount of mesh material and the pore size. In the following study, patients received different mesh types with distinct amounts of polypropylene and of various pore sizes for incisional hernia repair. We investigated whether the type of material influenced the clinical and functional outcomes. Between 1991 and 1999, 235 patients received polypropylene meshes in a sublay position for incisional hernia repair: 115 patients were implanted with a Marlex heavy-weight mesh (Mhw mesh), 37 patients with an Atrium heavy-weight mesh (Ahw mesh) and 83 with a Vypro low-weight mesh (Vlw mesh). The study protocol included ultrasound examination and 3D-stereography in all patients, with a total follow-up of 24 +/- 13 months (Mhw-mesh), 11 +/- 8 months (Ahw-mesh) and 8 +/- 7 months (Vlw-mesh). Our findings demonstrate that the side effects of mesh implantation, comprising paraesthesia and restriction of abdominal wall mobility, were significantly affected by the type of material implanted. Three-dimensional stereographic examinations were well in accordance with our clinical findings. Our data support the hypothesis that the use of low-weight large-pore meshes is advantageous for abdominal wall function.

Int Surg. 2001 Oct-Dec; 86 (4): 240-5.

Tissucol application in dermolipectomy and incisional hernia repair.

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Biological adhesives have a lot of applications in surgical procedures. Here we present a prospective study with the aim of analyzing results of the application of Tissucol between the muscle layers and subcutaneous tissue after incisional hernia repair with polypropylene mesh and associated dermolipectomy. We assess clinical and technical parameters, local morbidity, and hospital stay. Fifty-six patients were divided into two groups. Patients with whom we used fibrin glue were older, with more obesity ($P < 0.005$) with associated diseases, and their incisional hernias were larger and more complicated to repair. Patients in the Tissucol group developed less local morbidity (hematomas or abscesses; $P < 0.01$), had a shorter mean hospital stay ($P < 0.01$), and required less wound care. The use of Tissucol improves the results of surgical repair of large abdominal incisional hernias repaired by mesh placement and dermolipectomy, and it decreases global morbidity and hospital stay are reduced.

Hernia. 2003 Sep; 7 (3): 134-6. Epub 2003 Apr 3.

Comment in: Hernia. 2004 Aug; 8 (3): 288; author reply 289. Primary closure of laparotomies with high risk of incisional hernia using prosthetic material: analysis of usefulness.

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Incisional hernia continues to be a serious postoperative complication in abdominal surgery. We present a prospective randomised study to evaluate the usefulness of placement of a supra-aponeurotic polypropylene mesh in the primary closure of laparotomies with a high risk of incisional hernia. Closure of a vertical laparotomy in 100 patients was accomplished with continuous suture using non-reabsorbable material, with placement of a polypropylene mesh on the aponeurotic surface in 50 patients. Three years after surgery, five patients in the group without the mesh had suffered incisional hernia. No incisional hernia was detected in the group in which closure was made using the mesh ($P = 0.02$). Use of prosthetic material (polypropylene mesh) in the primary closure of laparotomies with a high risk of incisional hernia is useful for reduction of the rate of incisional hernias.

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Surgery. 2008 Sep; 144 (3): 427-35. Epub 2008 Jul 16.

Early tissue incorporation and collagen deposition in lightweight polypropylene meshes: bioassay in an experimental model of ventral hernia.

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BACKGROUND: This study was designed to assess the early host tissue incorporation of several polypropylene lightweight (PP-LW) meshes used to repair abdominal wall defects and to correlate collagen deposition with the biomechanical response shown by PP-LW versus polypropylene heavyweight (PP-HW) meshes.

METHODS: Ventral hernial defects (7 x 5 cm) were created in the anterior abdominal wall of New Zealand rabbits and repaired by fixing PP-LW mesh of different pore sizes or a low porosity HW mesh to the edges of the defect. Rabbits were killed 14 days after implant, and specimens were taken from the central mesh area to examine collagen deposition by light microscopy, real time reverse transcription polymerase chain reaction, immunohistochemistry, and Western blotting. The biomechanical resistance of the biomaterials was also assessed.

RESULTS: All the materials showed excellent incorporation in host tissue. Relative amounts of collagen III mRNA were considerably higher than collagen I mRNA. Higher collagen I and III mRNA levels were noted for pore sizes equal to or greater than 3.45 +/- 0.19 mm^2 (Ultrapro/Optilene Elastic. These two meshes showed significantly higher levels of collagen III than Parietene and Surgipro with smaller pores. Biomechanical resistance values for Optilene were significantly higher than those recorded for Surgipro and Parietene.

CONCLUSIONS: (a) LW meshes of pore size larger than 3 mm^2 induced the genetic overexpression of collagen types I and III; (b) the larger pore-sized LW meshes induced more collagen type III deposition and its faster conversion to collagen I; (c) Optilene, the most porous LW mesh examined, showed the greatest tensile strength 14 days after implant.

J Biomed Mater Res B Appl Biomater. 2008 Oct 6. [Epub ahead of print]

Comparing the behavior of different polypropylene meshes (heavy and lightweight) in an experimental model of ventral hernia repair.

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New generation prosthetic biomaterials for abdominal wall repair have been designed to be less dense, by having larger pores than that of the standard polypropylene meshes, to improve abdominal wall compliance. The aim of the present study was to analyze the functional and morphologic properties of these new meshes. For this purpose, 7 x 5 cm^2 defects were created in the anterior abdominal wall of 36 male New Zealand White rabbits and repaired using different polypropylene meshes: a heavyweight mesh (HW), Surgipro, and two lightweight meshes (LW), Parietene and Optilene. Six animals each implanted with biomaterial were sacrificed on postoperative days 14 and 90. Histological and morphometric analysis, adhesion assessment, and biomechanical resistance tests were performed. Similar behavior was shown by the LW and HW meshes in terms of the adhesions and macrophage response induced. After 14 days, the tensile strength of Optilene was greater than the strengths recorded for the other two biomaterials, probably because of its high elasticity. By 90 days, however, the tensile strengths of the three biomaterials were comparable. In conclusion, despite an initial tensile strength advantage shown by the mesh with larger pores, at 90 days postimplant, tensile strengths were similar. Compared with HW, LW prostheses have the benefit that less foreign material was implanted, preserving the elasticity of the recipient host tissue. (c) 2008

Wiley Periodicals, Inc. J Biomed Mater Res Part B: Appl Biomater, 2008.

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