Experimental and Clinical Approaches to Hernia Treatment and Prevention

The research presented in this thesis has been performed at the Department of Surgery of the Erasmus MC, University Medical Center Rotterdam, the Department of Surgery of the Ikazia hospital, Rotterdam and the Department of Surgery of the MCRZ Medical Center, Rotterdam, The Netherlands.

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Für meine Eltern und meine Schwester, mit Liebe
Aan mijn ouders en zus, liefdevol
To my parents and sister, lovingly

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PART 1 - GENERAL INTRODUCTION

“Gewisse Bücher scheinen geschrieben zu sein, nicht damit man daraus lerne, sondern damit man wisse, daß der Verfasser etwas gewußt hat.“

Johann Wolfgang von Goethe

Chapter 1 - Introduction and outline

J.A. Halm

”Any protrusion of any viscus from its proper cavity is denominated a hernia.”

Sir Astley Paston Cooper (1768 -1841)

Introduction

Hernia surgery is one of the earliest forms of surgery altogether. Clinical diagnosis, anatomy and surgical procedures follow each other closely and hernia recurrences present a challenge to all surgeons. Recent developments in the field of herniology encompass biological intervention, technical refinement and prosthetic material advances.

For enhanced understanding the following paragraphs will be used to elaborate on the different types of hernia, their diagnosis, the appropriate treatments and hernia recurrence.

Inguinal hernia

Definition, incidence, anatomy, risk factors and etiology

A groin or inguinal hernia is an abdominal wall defect (perforated or not) with or without evident “bulging” in the inguinal area. The weakness in the abdominal wall of the groin area is anatomically termed the myopectineal orifice of Fruchaud (triangle of Fruchaud). Cranial and medial borders are made up of the conjoined tendon and the rectus muscle respectively. The lateral and caudal border is defined by the iliopsoas muscle and by the superior ramus of the pubic bone. Fruchaud’s triangle is entirely covered by the transversalis fascia. The inferior epigastric vessels originate from the external iliac vessels at the dorsal boundary of the deep inguinal ring and represent the lateral border of Hesselbach’s triangle. The medial border consists of the lateral aspect of the rectus abdominis muscle while the inguinal ligament (Poupart) serves as caudal boundary.

From an anterior point of view the important nerves in the inguinal area include the ilio-hypogastric, the ilio-inguinal and the genital branch of the genitiofemoral nerve. The nerves implicated in the posterior repair (TEP, TAPP & IPOM) are all located in the so-called triangle of pain; an imaginary triangle bounded by the spermatic vessels, the iliopubic tract and the reflected peritoneum. The nerves are the femoral branch of the genitofemoral nerve,

the femoral nerve and its cutaneous branch as well as the lateral femoral cutaneous nerve.
Protrusion of a hernia sac through the transversalis fascia is possible in case of acquired or inborn defects of the fascia.

Inguinal hernia is a common affliction, which is treated surgically in the Netherlands in 32.000 (Figure 1) patients annually (Landelijke LMR-informatie - Verrichtingen, Prismant [1]). In the United States 700.000 inguinal hernia corrections are preformed per annum (Lichtenstein, 1993).

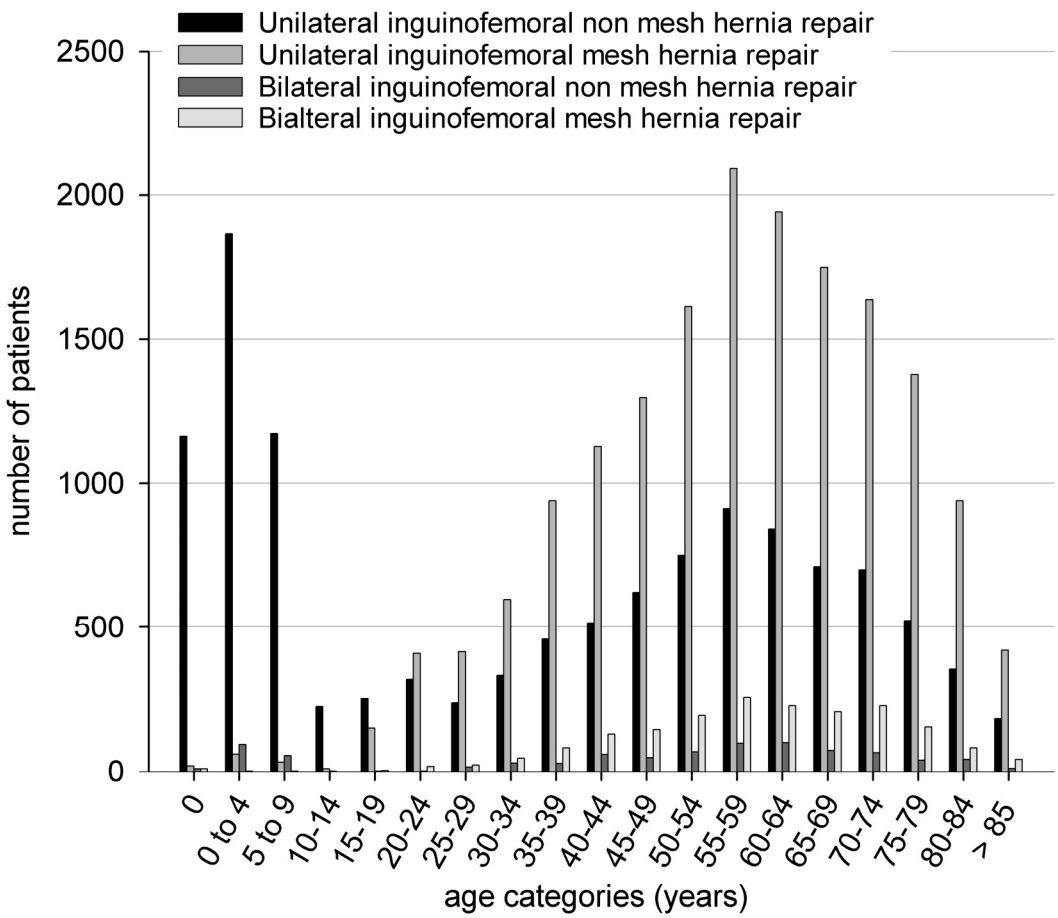

Figure 1. Inguinofemoral hernia repair in the Netherlands 2004

Risk factors that have been implicated in the etiology of inguinal hernias are: smoking [2], disturbed collagen synthesis (through smoking or other causes) [3] and chronic obstructive pulmonary disease (COPD) [4].

In childhood, the indirect hernia begins with incomplete obliteration of the processus vaginalis. During the last trimester the testes, which originate along the urogenital line, descend into the scrotum through the inguinal canal [5]. Failed obliteration of the processus vaginalis results in the so called patent processus vaginalis (PPV); a possible congenital indirect inguinal hernia in children [6].

Clinical signs and diagnosis

Clinically the manifestation of a groin hernia is easily diagnosed as a bulge in the inguinal area above Poupart's ligament accompanied by mild pain and/or discomfort. Patients experience severe pain only in incarcerated and strangulated hernias. Incarceration and strangulation of a groin hernia is rare at about 0.4% [7,8]. Conservative treatment of patients suffering from mildly symptomatic hernias may seem necessary in the light of high incidences of chronic groin pain after surgery [9]. In a recently published randomized trial of watchful waiting versus hernia repair two patients experienced acute hernia incarceration (0.6%). It was concluded that watchful waiting is an acceptable regime for patients suffering from a minimally symptomatic groin hernia [10].

Diagnosis of an inguinal hernia is primarily achieved by a physical examination in an upright position in patients complaining of a "lump" in the groin. The protrusion can usually be reduced manually and provoked by Valsalva's maneuver. A visible impulse in the groin may be seen upon coughing. Differentiating between a medial (direct) and lateral (indirect) hernia through physical examination is not reliable [11,12].

Differential diagnosis of a mass in the inguinal area should include: groin hernia or recurrence, femoral hernia (below inguinal ligament), lymph node (lymphogranuloma inguinale, infection of the lower extremity), aneurysm, varix (saphenous vein), psoas abces and tumor.

Although inguinal hernia is a clinical diagnosis some physicians may feel the need for confirmation. A higher degree of diagnostic certainty may be achieved by utilizing ultrasound, herniography, CT scan or MRI. Herniography and MRI have the highest sensitivity and specificity of all diagnostic modalities. For herniography sensitivity is found to be between 81-100% and

specificity between 92-98% in patients without a palpable swelling [13,14]. MRI has a sensitivity of 94.5% and a specificity of 96.3% in diagnosing inguinal hernia [15]. Ultrasound, with a sensitivity of 85% and a specificity of 93%, is a reasonable alternative in the diagnosis of inguinal hernia in patients presenting with an unknown tumor of the groin [16].

Classification

The traditional classification of inguinal hernia by Halverston and McVay [17] as direct, indirect, combined or femoral has stood the test of time and confused students of surgery since it was used in parallel with medial and lateral as a classification. Nyhus and Schumpelick have described separate classifications for the inguinal hernia. The classification by Lloyd M. Nyhus combines the type of herniation, anatomical aspects of the posterior wall and aspects of the internal ring. The hernia is described from an intra-abdominal point of view. Classifications are: type I (indirect hernia, normal internal ring), types: II (indirect hernia; dilated internal ring), III A (direct hernia; defect posterior wall), III B (Combined hernia; dilated internal ring and defect posterior wall), III C (femoral hernia; normal internal ring, normal posterior wall) and type IV (recurrent hernia; direct, indirect and combined).

The classification by Schumpelick is based on a description of the site of breach (lateral “L”, medial “M” or femoral “F”) combined with a measure of the defect. Grade I herniation takes place through a defect smaller than 1.5 cm, grade II herniation through a defect between 1.5 - 3 cm and grade III defects through a defect larger than 3 cm. Combined pantaloon type herniation is classified as “Mc” [18]. Recently, a combined traditional classification has been introduced by Zollinger explicitly naming fifteen modifiers (reducible, strangulated, incarcerated, sac contents, etc.) for all classification systems.

Hernia classifications			
Hernia	**Nyhus**	**Schumpelick**	**Zollinger Traditional-updated**
Indirect			
Small	Type I (normal size internal ring)	L1 (<1.5 cm)	1
Medium	Type II (enlarged dilated internal ring without impinging direct floor)	L2 (1.5-3 cm)	2
Large	Type IIIB (large dilated internal ring with medial expansion, encroachment of posterior (direct floor) inguinal wall)	L3 (>3 cm)	3
Direct			
Small	Type III A (defect posterior wall; no more than one finger)	M1	4
Medium	Type III A (defect posterior wall)	M2	5
Large	-	M3	6
Combined	Type III B (dilated internal ring and defect posterior wall)	Mc	7
Femoral	IV C (normal internal ring, normal posterior wall)	F	8
Other	-	-	0

Table 1. Hernia Classifications according to Nyhus, Schumpelick and Zollinger

Treatment, outcome and complications

Surgical correction of the inguinal hernia can be achieved by numerous approaches utilizing surgical mesh and equally numerous ways without mesh, the latter being the more traditionally used methods. The surgical mesh may be placed by a minimally invasive or an open technique. Minimally invasive

surgery for the treatment of the groin hernia may be divided into TEP (totally extraperitoneal), TAPP (trans abdominal preperitoneal) and IPOM (intraperitoneal onlay mesh) technique as proposed by Fitzgibbons who conceived the classification [19]. Of all minimally invasive techniques TEP and TAPP repair are the most common. Endo-/laparoscopic inguinal hernia surgery is claimed to reduce postoperative pain and hospital stay and facilitate early return to normal activity [20]. Serious complications of minimally invasive inguinal hernia surgery include vascular damage, nerve injury, bowel obstruction and bladder perforation [21]. The authors of a recently published trial, comparing minimally invasive inguinal hernia surgery to open mesh repair, suggest that the learning curve for TEP and TAPP surgery exceeds 250 procedures. Surgeons having performed more than 250 minimally invasive inguinal hernia repairs had a recurrence rate of 5% compared to 10% in the hands of less experienced surgeons [22].

Current Dutch guidelines for the treatment of groin hernias proposes the open tension free Lichtenstein mesh repair as the golden standard for unilateral groin hernia [23]. Results of the Lichtenstein repair have been studied in detail and recurrence rates are in the range of 0.5 - 5% [22,24]. In our center, one of the early randomised trials comparing open tension free to tissue repair of inguinal hernias yielded a nil percent recurrence rate in mesh repair[25]. In the Netherlands bilateral inguinal hernia corrections are performed in 2809 patients annually, of which 964 take place without surgical mesh and 1853 with surgical mesh. The Dutch hernia guideline advises repair of bilateral inguinal hernia through a totally extraperitoneal approach if the necessary expertise is available. Furthermore the guidelines suggest that totally extraperitoneal inguinal hernia repair in patients with bilateral hernia is more cost effective and leads to faster recovery than anterior mesh surgery (i.e. Lichtenstein) [23].

Retrospective studies on the results of endo-/laparoscopic inguinal hernia repair, including bilateral repair, go back to 1994 when Panton and Panton (Canada) published the first results of a series claiming a nil percent recurrence rate at follow-up (1-12 months) [26]. Recurrence rates reported

range between the aforementioned nil and 4.5% [27]. From the majority of reported studies it does not become clear which fraction of patients (if any) underwent physical examination in order to determine hernia recurrence. Knook et al. performed physical examination in all patients available for follow-up. In their study of bilateral inguinal hernia repair Knook et al. used a single large mesh (30x10 and 30x10/15 cm) to cover bilateral myopectineal orifices as opposed to two single meshes used in unilateral repair [28,29].

The Cochrane review by McCormack et al. lists an remarkable 41 eligible randomised controlled trials of laparoscopic versus open inguinal hernia repair. The Cochrane collaboration concluded that laparoscopic surgery is more time consuming and has a higher risk of rare serious complications. Persisting pain and numbness is less frequent in laparoscopic repair and return to usual activities faster. Recurrence rates were not reduced compared to open mesh inguinal hernia repair [30].

Selection of retro-/prospective studies of endo-/laparoscopic inguinal hernia repair						
Author	**No. patients**	**Types of hernia**	**Technique**	**Follow-up (months)**	**Postoperative Complication (%)**	**Recurrence rate (%)**
Panton [26]	79	P/R/B	TAPP	1-12	10	0
Felix [31]	81	R/B	TEP/TAPP	1-28	-	1
Fitzgibbons [27]	686	P/R/B	IPOM/TEP/TAPP	15	17	4.5
Sandbichler [32]	192	R/B	TAPP	9-31	9	0.5
Vanclooster [33]	976	P/R/B	TEP	6-79	8.4	0.1
Ramshaw [34]	493	P/R/B	TEP/TAPP	?	6.2	1.2
Topal [35]	403	P/R/B	TEP	12	3.6	0.3
Ferzli [36]	400	P/R/B	TEP	38*	4.8	1.7
Knook [28]	98	P/R/B	TEP	32**	10	10.1[$]
Knook [29]	221	P/R	TEP	40*	11.8	6.1[$]

B = bilateral; P = primary; R = recurrent; * mean; ** median; [$] at physical examination

Table 2. Selection of retro-/prospective studies of endo-/laparoscopic inguinal hernia repair

Selection of randomised controlled trials comparing end-laparoscopic inguinal hernia reair with open mesh repair					
Author	**No. patients**	**Technique**	**Follow-up (months)**	**Postoperative Complication (%)**	**Recurrence rate (%)**
Neumayer [22]	989	TEP/TAPP	24	24.6	10.1
	994	Mesh open		19.4	4.9
Wellwood [37]	200	TAPP	3	313 compl.	0
	200	Non-mesh open		396 compl.	0
Dirksen [38]	88	TAPP	24*	0	6
	87	Non-mesh open		5.7	21
Liem [39]	487	TEP	12-24	19.5	3.4
	507	Non-mesh open		20.7	6

* mean

Table 3. Selection of randomised controlled trials comparing endo-/laparoscopic inguinal hernia repair with open mesh repair

Incisional hernia

Definition, incidence, onset, riskfactors and etiology

"Any abdominal wall gap with or without bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging" [40].

Intra-abdominal content such as omentum, intestine and bladder may make up the protrusion, which need not be permanent.

Scar tissue of the skin, the skin and the subcutaneous tissue is never involved in case of an incisional hernia and thus remains intact. The intra-abdominal content is always covered by peritoneum (the hernia sac).

Strictly speaking any "rupture" not contained by the parietal peritoneum is not an incisional hernia but a burst abdomen. Also termed a "Platzbauch" or evisceration, a burst abdomen can occur between the first hours after surgery until four weeks after [41].

With an incidence of 10-20% of all patients developing an incisional hernia after laparotomy the numbers estimated are as follows. In the Netherlands incisional hernia repair is achieved in about 4000 patients per annum [1]. The estimated number of patients suffering from an incisional hernia that do not seek medical attention ranges from 10.000 to 20.000 a year. For the United States of America the number of new incisional hernias presenting each year is estimated to be between 500.000 and 1.000.000 [42]. From the aforementioned numbers it becomes apparent that circa 4% of all patients undergoing a laparotomy will receive operative care for an incisional hernia.

Abdominal wall defects develop due to an early, limited separation of the abdominal wall wound edges and subsequently complicate wound healing [43]. Elevated intra-abdominal pressures (IAP) during for example coughing, sneezing and defecation may facilitate this event. Such events increase the intra abdominal pressures markedly. A continuous positive pressure of 2-20 mmHg, as measured in the abdominal cavity at rest, may increase approximatly sevenfold (150 mmHg) upon coughing and vomiting [44]. The currently accepted normal intra-abdominal pressure is approximately 5 mmHg [45]. IAP increases non-pathologically with BMI [46] and sagital abdominal diameter [47] in the obese. A measured intra abdominal pressure over 12 mmHg over a periode of 4-6 hours is defined as intra abdominal hypertension, pressures over 20 mmHg as abdominal compartment syndrome. In a study

examining abdominal wall perfusion in a porcine model of increased IAP, a significant reduction to 20% of baseline rectus sheath blood flow of was seen at progressively increasing intra-abdominal pressures to a maximum 40 mmHg.

Risk factors for the development of an incisional hernia include the aforementioned increase in IAP. Incisional hernia is significantly more common in patients suffering from diseases that lead to an increase in IAP such as COPD [48] and ileus (through abdominal distention) [49].
Impaired wound healing plays a role in the development of incisional hernia on the basis of diabetes [50] but also through the use of tobacco products [51]. Age [49, 51-53], previous laparotomies [51] and wound infection [49, 52, 53] have been implicated as risk factors in developing an incisional hernia.

Clinical signs and diagnosis

An incisional hernia may present as an irreducible or incarcerated mass. Strangulation followed by ischemia of bowel occurs in about 2% of patients [54,55]. More common however, are esthetic complaints as well as symptoms such as a scar sensitive to touch or an uncomfortable feeling when wearing trousers on the site of the scar. Specific movements and activities may elicit pain and discomfort. Some patients however, experience little to no discomfort/pain and doubts on the indication for incisional hernia repair in these patients remain.
Prolonged increased pressure on the abdominal skin may lead to trophic ulceration, through thrombosis of small vessels [56]. Throphic ulcera are commonly found over the middle and at the apex of the protrusion.
Diagnosis is easily achieved by history taking, inspection and palpation of the surrounding area of a laparotomy scar. The protruding mass may be reduced and the fascial gap appraised. The protruding bulge will be more prominent during Valsalva's maneuver. Should diagnosis be uncertain after inspection and palpation ultrasound imaging may be the diagnostic modality of choice, which if inconclusive may be followed by computed tomography (CT) and magnetic resonance imaging (MRI).

Classification of incisional hernia

A few classifications of incisional hernias have been proposed, the use of which seems to be limited in daily practice. The modified “Chevrel” classification categorizes incisional hernia according to localization in a vertical, transverse, oblique or combined plane. Midline incisional hernia may be divided into above or below umbilicus, midline including umbilicus or paramedian (left/right). Transverse incisional hernias are divided into above or below the umbilicus (left/right) and whether or not crossing the midline. Oblique incisional hernias are classified as being above or below the umbilicus (left/right). Any combination of the localizations mentioned above is possible. Classification according to size divides hernia into either small (<5 cm in width/length), medium (5-10 cm in width/length) or large (>10 cm in width/length). Furthermore hernia classification according to recurrence (primary, 1st, 2nd etc.), reducibility (with or without obstruction) and according to symptoms has been proposed [40].

Modified Chevrel classification of incisional hernia				
Incisional hernia	**Localization**	**Size (length or width)**	**Recurrence**	**Reducibility**
Vertical	Above umbilicus Below umbilicus Including umbilicus Paramedian	Small (< 5 cm) Medium (5-10 cm) Large (> 10 cm)	Primary First Second etc.	With obstruction Without obstruction
Transverse	Above umbilicus Below umbilicus Crossing midline	Small (< 5 cm) Medium (5-10 cm) Large (> 10 cm)	Primary First Second etc.	With obstruction Without obstruction
Oblique	Above umbilicus Below umbilicus	Small (< 5 cm) Medium (5-10 cm) Large (> 10 cm)	Primary First Second etc.	With obstruction Without obstruction
Combined	Combinations of the above are possible	Small (< 5 cm) Medium (5-10 cm) Large (> 10 cm)	Primary First Second etc.	With obstruction Without obstruction

Table 4. Modified Chevrel classification of incisional hernia

Treatment, outcome and complications

Suture incisional hernia repair

Traditionally, after an incisional hernia has been diagnosed, reconstruction of the abdominal wall was achieved through primary closure of the defect. Various techniques such as imbrication (so called Mayo type) repair have been widely used side by side with fascial approximation. The Ramirez components separation technique has been developed to facilitate closure of large defects and to reduce tension on the abdominal wall [57].

Simple suture and the Mayo type repair are prone to high recurrence rates of 25-54% [58-61]. Ramirez components separation is reported to result in a hernia recurrence rate of 32% [62].

Mesh incisional hernia repair

Through mesh repair of the abdominal wall defect surgeons achieved a marked reduction in the observed recurrence rates. Favorable results have been reported by, amongst others, Luijendijk et al. [63]. The randomised controlled trial by Luijendijk (and the long term follow-up by Burger et al.) shows significantly less recurrences in the mesh repair group (32%) when compared to the suture repair group (63%) [63, 64]. Three anatomical positions for mesh repair are possible: onlay, sublay (retromuscular prefascial) and lastly the intraperitoneal position. Onlay positioning of the mesh is associated with both high recurrence rates and high postoperative complications rates such as surgical site/ mesh infections, haematoma and seroma formation and is therefore not recommended [65-67]. Preperitoneal retromuscular positioning of the mesh is considered by many to be the most proper technique because the forces exerted by the intra abdominal pressure holds the prosthesis against the posterior surface of the muscles or the posterior rectus sheath. Retromuscular positioning may result in minor adhesion formation, low recurrence rates and low postoperative complication rates [63-65, 68]. Leaving the peritoneum intact is sometimes impossible making preperitoneal repair more difficult. Dense adhesions, bowel lesions, mesh migration, mesh erosion into associated anatomical structures and enterocutaneous fistula formation are recorded by authors when intraperitoneal grafts are utilized [69-73]. However the latter complication was not associated with intraperitoneal polypropylene mesh placement by Vrijland et al. [74]. Late complications associated with mesh prosthesis, other than previously mentioned, include chronic sinus tract and deep mesh infection [75].

Surgical meshes are produced from synthetic materials such as polyester, polypropylene, expanded polytetrafluoroethylene (ePTFE), polygalactin 910, poliglecapron 25 and polydioxanone, of which the latter three are resorbable. Combinations of materials, for example polypropylene/polygalactin 910, have

been developed to reduce the foreign material load over time. Surgical prosthesis to correct soft tissue defect have also been developed form non-synthetic materials. Examples of such prosthesis are Tutomesh and Surgisis, which are made from bovine pericardium and porcine small intestinal submucosa respectively.

Polypropylene (PPE), ePTFE and composite meshes

Trade name	Produced by	Material(s)	Additional information
Prolene	Johnson & Johnson (Ethicon®)	PPE	Monofilament
Bard Mesh	Davol (Bard®)	PPE	Monofilament
Premilene	B.Braun (Aesculap®)	PPE	Monofilament
ProLite	Atrium Medical Corp.®	PPE	Monofilament
Sepramesh	Genzyme®	PPE Sodium hyaluronate Carboxymethylcellulose	Monofilament
Timesh	GfE Medizintechnik	PPE + titanium coating	Monofilament
Ultrapro	Johnson & Johnson (Ethicon®)	PPE Poliglecapron 25	Monofilament
Dualmesh	W.L. Gore®	ePTFE	N.A.

Poliglecapron 25 = Monocryl, N.A. not applicable

Table 5. Polypropylene (PPE), ePTFE and composite meshes

Composite, polyester and non-synthetic mesh			
Trade name	**Produced by**	**Material(s)**	**Additional information**
Vypro	Johnson & Johnson (Ethicon®)	PPE Polyglactine 910	Multifilament
Vypro II	Johnson & Johnson (Ethicon®)	PPE Polyglactine 910	Multifilament
Ultrapro	Johnson & Johnson (Ethicon®)	PPE Poliglecapron 25	Multifilament
Parietex TECR	Florean (Sofradim®)	Polyester	Multifilament
Parietex Composite	Florean (Sofradim®)	Polyester + collagen-PGG coating	Multifilament
Tutomesh	Tutogen GmBH	Bovine pericardium	N.A.
Surgisis	Cook®	Porcine small intestine submucosa	N.A.

PPE = Polypropylene; PGG = polyethylene glycol-glycerol; Polyglactine 910 = Vicryl
N.A. not applicable

Table 6. Composite, polyester and non-synthetic mesh

Nylon, the trade name for polyamide, was the first purely synthetic fibre, introduced by the DuPont Corporation at the 1939 World's Fair in New York City. Besides the use of nylon as a suture material to replace silk it was also applied as a mesh in inguinal hernia surgery by Aquaviva and Bounet, a practice that they reported in 1944 [76, 77]. The degeneration of polyamide over time finally led to the use of other synthetic materials.

Usher reported repair of incisional and inguinal hernia using a mesh crafted from polypropylene in 1958 [78]. Polypropylene is a thermoplastic polymer that, unlike nylon, does not absorb water. As early as 1962 a survey found that 20% of general surgeons were using Usher's procedure of mesh implantation [79]. Paul Hogan and Robert Banks of Phillips Petroleum (The Netherlands) are

credited as the inventors of the material. Properties attributed to polypropylene are a mild reactivity upon implantation, ingrowth, tensile strength which is retained for indefinite periods of time and a low susceptibility to mesh infection [80]. In the case that a polypropylene mesh does get infected removal is rarely necessary since adequate treatment can be achieved through drainage and the use of antibiotics [58, 81, 82]. However concerns that PPE mesh induces adhesion of viscera when placed intraperitoneally have been reported [75, 83-85]. An increased risk of enterocutaneous fistula could not been confirmed by Vrijland et al. [74].

A further synthetic mesh was crafted from polyester fibers and introduced in hernia surgery by Wolstenholm in 1956 [86]. Polyester, available as a multi- and monofilament, is a condensation polymer obtained from ethylene glycol and terephthalic acid. The first polyester fiber was commercially available in 1941 in Great Britain (first manufactured by Imperial Chemical Industries; ICI). Credits for the discovery of polyethylene terephthalate (polyester) go to two chemists, Rex Whinfield and James Dickson, employed by the small English company "Calico Printer's Association" in Manchester.

The properties of polyester used in hernia repair include flexibility, high tensile strength and high resistance to stretching. Furthermore a sufficient foreign body reaction (fibroblast response) is induced resulting in incorporation in the abdominal wall. Numerous large studies reported favourable results of polyester mesh hernia repair. A single recent report describes an increased incidence of fistula formation, hernia recurrence and postoperative infections after the use of multifilament polyester mesh [75]. Furthermore multifilament polyester was found to degrade in long-term implantation, which may lead to loss of functionality [87].

The development of a polyester and polypropylene mesh coated with a hydrophilic resorbable film (Parietex Composite, Sepramesh) was aimed at a reduction of the risk of adhesion and fistula formation, which was confirmed by Balique et al. in 2005 [88].

A very inert material, ePTFE (expanded polytetrafluoroethylene), was introduced to hernia surgery by Sher et al. [89]. Originally named Teflon by the

DuPont Company, PTFE was discovered accidentally by Roy Plunkett in 1938 (The Fluoropolymers Division Newsletter, Summer 1994). Expanded PTFE has been reported to show evidence of lower rates of adhesion formation than polypropylene [90, 91]. Reports of limited incorporation, resulting in button-hole hernia recurrences, have been published [92]. For the aforementioned reason fixation of ePTFE patches utilizing the so-called “double crown technique” (a double row of sutures) is recommended [92]. Efforts have been made to overcome the aforementioned problem by combining ePTFE with polypropylene and by increasing the pore size of ePTFE for extended tissue incorporation.

Infection of an ePTFE mesh may lead to removal of the prosthesis since drainage and antibiotic therapy is almost never satisfactory as is demonstrated by Petersen et al. in his small retrospective study in which he describes mesh infection of three ePTFE meshes [93].

Choice of incision in incisional hernia prevention

Anatomy ventral abdominal wall

The ventral abdominal wall consists of the rectus abdominis muscle on contralateral sides of the line alba. The origo of the rectus muscle are the 5th, 6th and 7th rib, the insertion is the pubic bone. The rectus muscles are each contained in a fascial layer, the anterior and posterior rectus sheath, which is made up of the aponeurosis (insertion) of the internal, external and transverse muscle. The rectus muscle is horizontally incised by the 3 inscriptiones tendinea. Lateral to the rectus abdominis the abdominal wall is made up of the aforementioned external oblique, the internal oblique and the transverse muscle which extend over the ventral and lateral part of the abdomen (the part not covered by the rectus muscle). The origo of the external oblique muscle runs from the 5th to the 12th rib. The internal oblique originates from the iliac crest. The transverse muscle, with its horizontal fiber direction originates from the previously mentioned iliac crest, the lumbodorsal fascia and the lower six ribs superiorly. The lateral border of the rectus muscle forms the linea semilunaris. At the symphysis pubis the posterior sheath ends in the thin curved margin, the linea semicircularis (Douglasi). Below this level the aponeuroses of all three muscles pass in front of the rectus abdominis and the

fascia transversalis is responsible for the seperation of the rectus from the peritoneum. The pyramidalis muscle (if present) lies anterior to the lower part of the rectus abdominis muscle. It arises from the superior surface of the pubic ramus and inserts at the linea alba.

The vasculature of the muscles of the abdominal wall consists of the superior and inferior deep epigastric vessels as well as transverse segmental branches of the aorta. The superior and inferior deep epigastrics are located in front of the posterior rectus sheath and the rectus muscle and form its blood supply through perforating vessels. The inferior deep epigastric artery branches from the external iliac artery whereas the superior deep epigastric is a terminal branch of the internal thoracic artery. The deep epigastric arteries are anastomosed and thus form the deep epigastric arcade. Saber et al. have mapped the location of the epigastric artery at different levels in 100 patients using computed tomography. At the level of the xiphoid proces the mean distance from the superior epigastric to the midline is found to be 4.41 cm, caudally the distance increases to 5.88 cm at the umbilicus and to 7.47 cm at the level of the pubic symphysis [94]. The transverse segmental arteries supply the transverse muscle, the internal and external oblique and are situated between the transverse and internal oblique. Blood supply, to the relatively avascular linea alba, originates from the perforating vessels of the superior and inferior deep epigastrics.

Innervation of the abdominal wall is achieved through intercostals nerves, the ilioinguinal and the iliohypogastric nerve. The intercostals nerves are ventral branches of thoracic nerves originating from levels Th. 5 through Th. 12 of the spinal cord.

Incisions

First and foremost any incision chosen for access to the abdominal cavity needs to be consistent with Maingot's principles [95]: 1. access to the viscus or the lesion to be treated must be provided 2. extensibility 3. the incision must permit subsequent secure closure. A further demand, although not classically put forward by Maingot, may be the postoperative preservation of function [96]. Further considerations in choosing the incision are the speed of entry,

presence of scars, possibility for hemostasis and a cosmetically pleasing outcome.

Midline incision

Midline incisions incise the skin, subcutaneous tissue, linea alba and the peritoneum vertically. Midline incisions are easily performed, relatively little blood is lost and the incision takes an average of 7 minutes to perform [48, 97, 98]. The exposure achieved through a midline incision encompassing the umbilicus is excellent, and includes access to the retroperitoneum. The upper or lower abdominal midline incisions may be utilized in case the expected pathology is situated in the upper or lower quadrants of the abdomen respectively. Extensions may be made in cranial or caudal direction when deemed necessary. The qualities mentioned above make the midline incision the most ideal for emergency and exploratory surgery.

Paramedian incision

A paramedian rectus incision is possible in two distinctly different ways. Firstly a medial, paramedian incision may be executed by incising the anterior rectus sheath, the rectus muscle and the posterior rectus sheath in proximity to the linea alba and thus gaining access to the abdominal cavity. Secondly the paramedian incision may be performed in a muscle retracting fashion. The anterior rectus sheath is incised; the rectus muscle is retracted laterally bringing the posterior rectus sheath into view, which in turn, may be incised to enter the abdomen through the perioneum. The latter technique spares the epigastric arcade from possible transsection as required during muscle splitting. In general, executing a paramedian incision offers slightly limited access to the contra lateral abdominal quadrants and is somewhat more time consuming, taking about 13 minutes [48, 99].

Transverse incision

Transverse incisions are possible at all levels of the abdomen. Common examples are the Pfannenstiel incision just above the pubic bone and the upper right quadrant transverse incision just below the costal margin. The former is approximately 8-12 cm in length (distance between the superficial

epigastric arteries) and transsects the superfiscial fascia and the fibrous rectus sheath. Further access is achieved by a slightly more cranial, vertical incision of the fascia transversalis, the preperitoneal fat and the peritoneum [100]. Luijendijk has described incisional hernia formation most recently and reported to 2.1% in 243 patients after a follow up between 1.6 and 7.8 years [101]. The latter requires transsection of the oblique and transverse musculature as well as the rectus muscle. The linea alba is incised most commonly when extending the transverse incision across the midline. Dividing the rectus muscle requires ligating the epigastric arcade and poses minor damage to the intercostals nerves and superficial arteries supplying the transverse and oblique musculature [102]. The transverse incision is thus accompanied by more blood loss than the midline incision [103] and takes longer to achieve [98]. Exposure of the abdominal cavity is generally good, although unilateral incisions may leave a view that is somewhat to be desired.

Oblique incision

Two oblique incisions are common: the subcostal incision according to Kocher and the gridiron incision as proposed by McBurney. The former is used in bariatric and biliary surgery and may be extended across or in the midline to increase exposure. The McBurney incision is routine in open surgery of the inflamed vermiform appendix. The technique of the subcostal incision includes transsection of intercostals nerves and segmental arteries as the transverse, oblique and rectus muscle are dissected [44]. The epigastric, arcade described previously, may be spared if the incision is kept approximately 5 cm lateral from the midline during the medio-proximal upward movement [94].

Technically the McBurney incision is not a single oblique incision, rather three muscle splitting incisions in row. The first layer to be split, after medio-caudal incision of the skin, is the external oblique followed by the internal oblique. The last layer, which is split in the direction of the muscle fibers, is the transverse muscle offering view of the peritoneum. Minimal damage is inflicted to the blood supply and nerves that grant vitality to the abdominal wall. Incisional hernia incidence after gridiron incision is reported to range between

0.12% [104] and 15% [105]. Recently Tingsted reported 0.4% hernia incidence in his analysis of 3230 patients after a median follow-up of ten years [106].

Complications: pain, woundinfection and incisional hernia incidence

Armstrong et al., reporting a randomised study comparing midline and transverse incisions in 60 patients, have documented significantly reduced postoperative pain for transverse incisions[107]. Halasz et al. found a reduction in the use of analgesics in patients after an oblique incision when compared to a paramedian approach [108]. A similar result was found by Garcia-Valdecasas comparing oblique to midline incisions [109].

None of the trials performed to date reported a significant difference in surgical site infection rates[110].

Incisional hernia has been studied in randomised trials comparing midline and transverse as well as midline and oblique incisions. Greenall et al. found no significant difference between midline and transverse incision. Incisional hernia was equally distributed in a trial by Garcia-Vadecasas et al. comparing midline and transverse incisions [103,109]. A 14% hernia rate after midline incision was found by Blomstedt et al. compared to 4 % in oblique incisions in a retrospective analysis [111].

Umbilical hernia

Definition, incidence, onset, riskfactors and etiology

Umbilical hernias consist of a protrusion of peritoneum (with or without hernia contents) through an abdominal wall defect in close proximity to the umbilical ring. The hernia may be located superior- or inferiorly but is also found centrally in the umbilicus or located slightly lateral from it.

In 2003, 4518 umbilical hernias (Figure 2) were repaired in the Netherlands (www.prismant.nl) [1]. Adult umbilical hernia is a common surgical affliction mainly encountered in the fifth and sixth decade of life [112, 113].

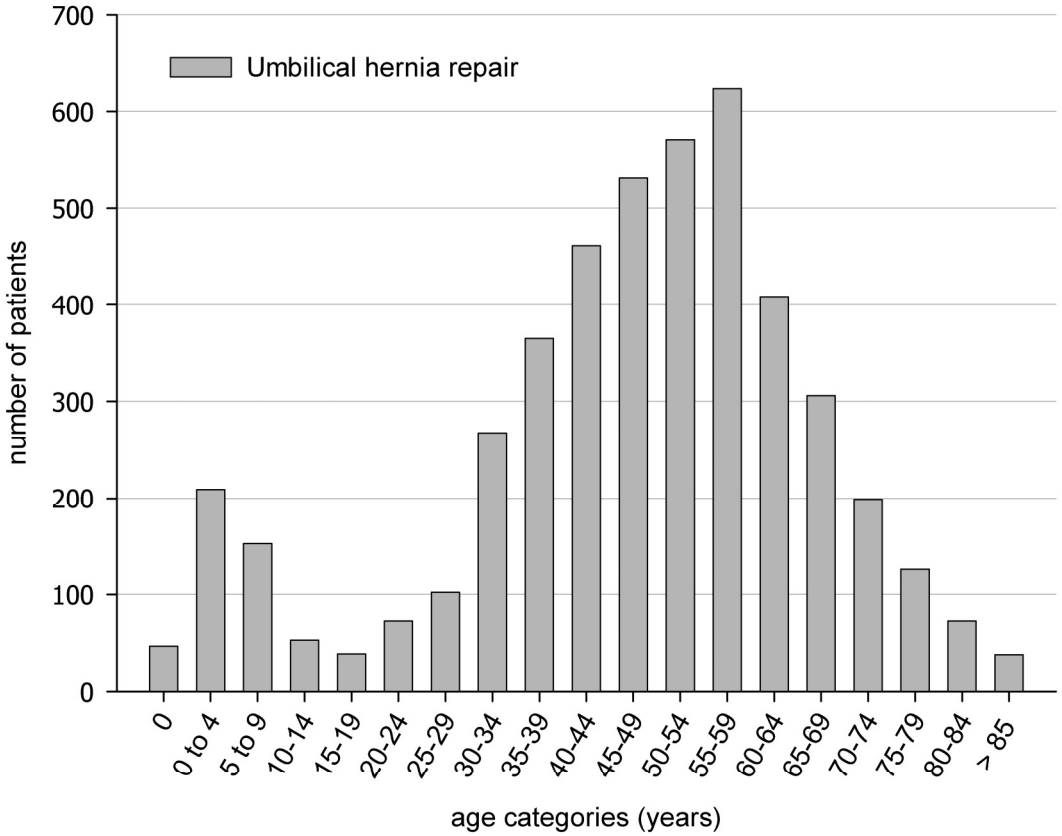

Figure 2. Umbilical hernia repair in the Netherlands in 2004

The adult umbilical hernia does not seem to be the result of a persisting juvenile hernia since only 10% of adults suffering from a umbilical hernia have a history of childhood herniation [114]. The adult hernia is an acquired hernia and represents protrusion through the umbilical canal, probably under influence of increased intra-abdominal pressure [115].

Clinically the patient presents with a protrusion in the umbilical region that is more or less sensitive to touch. A common complaint brought forward is the inability to wear trousers and a belt on top of the hernia as well as having difficulty sitting at a desk (with the umbilical hernia touching the edge).

Anatomy

Important in the embryology of the umbilical defect is the fusion of ectoderm and embryonic mesoderm to form the fascial margin of the umbilical ring. To allow the passage of the umbilical arteries and the umbilical vein to the

umbilical cord, an abdominal wall defect is present from the third week of gestation onwards. After birth, thrombosis of both the arteries and the vein occurs, and thus facilitates contraction of the umbilical ring by cicatrisation. Subsequently, the weakest area of the umbilical ring is the superior aspect of it, the area between the umbilical vein and the cranial margin of the umbilical ring. The relative lack of elastic fibres in the obliterated umbilical vein is held responsible for this weakness. The cranial border of the umbilical ring is the typical site for hernia in the paediatric population, when cicatrisation is impaired or the newly formed scar is subjected to elevated intra abdominal pressures. In adults the anatomical margins of the umbilical canal are the umbilical fascia from posterior, the linea alba from anterior and the medial edges of the rectus sheaths.

Mesh and suture repair of umbilical hernia

For the majority of the symptomatic and asymptomatic adult umbilical hernias, repair is proposed. Surgical repair may be achieved through simple suture repair and the use of mesh.

Despite the frequency of the umbilical hernia repair procedure (Figure 2), disappointingly high recurrence rates, up to 54% after simple suture repair, have been reported [116].

The Mayo technique and its modifications could not stand the test of time: a recurrence rate of 20% and higher is not acceptable for any surgical procedure [115]. Evidence from one retrospective study suggests that the repair of umbilical hernias larger than 3 cm should be performed using prosthetic mesh in order to avoid the high recurrence rates of primary repair of larger hernias. The same study reported an overall recurrence rate of 13% after a suture repair with a mean follow up of 30 months [116].

In the only randomised controlled trial Arroyo and co-workers have used pre-peritoneal mesh for all umbilical defects (using surgeon-fabricated mesh-plugs to close fascial defects smaller than 3 cm) [117]. From this trial it was concluded and heralded that, the use of mesh prosthesis in hernias of all diameters is thought to become the standard in umbilical hernia repair.

A similar technique has been employed by Kurzer et al. to seal umbilical defects smaller than 3 cm's. A mesh cone was inserted and fixed using non-absorbable sutures (2/0 polypropylene) in the four quadrants [118].

Outcome and complications

Recurrence of umbilical hernia is a common problem in the adult population. Recently recurrence rates of 1% have been reported through the use of mesh prosthetics in all size umbilical hernias and pre-peritoneal mesh is thought to become the standard in umbilical hernia repair [117, 119]. Arroyo and colleagues found only minor complications in patients treated with mesh. Furthermore rates of early complications such as seroma, haematoma or wound infection were similar in the two groups [117]. Suture repair is responsible for recurrence rates between 11 and 13% [116, 117]. A factor 10 reduction of recurrence rate through the use of mesh is striking.

Umbilical hernia repair, in patients with ascites, is associated with high morbidity, mortality and recurrence if attempted without prior management of ascites [113, 120, 121]. Hernia size as measured by ultrasound is described as a risk factor for recurrence [116]. Obesity (defined as a BMI over or equal to 30 kg/m2) has been shown to increase the risk of incisional hernia recurrence [59, 122]. A meta-analysis by Sauerland et al. showed that the relative risks (RR) of recurrence in 7 studies investigating the association of obesity and recurrence were heterogeneous (p=0.15) [123]. Until recently obesity was still regarded an indirect risk factor leading to recurrence through a higher rate of wound infection. It remains unclear whether obesity leads to umbilical hernia recurrence through increased abdominal pressure, difficulty in surgery or if it is an indicator for an inherent structural and healing defect. Incarceration of umbilical hernia accounts for 13% of all incarcerated hernias and requires a bowel resection in 20% of cases [124].

Outline

This thesis comprises of several clinical and experimental studies in order to determine ways of preventing incisional hernia as well as recurrence of incisional, inguinal and umbilical hernia.

Chapter 2

In chapter 2 we investigated the literature regarding indications for incisional hernia repair.

Chapter 3

In chapter 3 we explore the possibility of reducing the incidence of incisional hernia. Results of a randomised controlled trial comparing the incidence of incisional hernia between transverse and midline incision are presented.

Chapter 4

In chapter 4 we present the results of a literature review concerning the closure of transverse incisions.

Chapter 5

The incidence of trocar hernia is described in a review of the literature in chapter 5. Suggestions on how to prevent trocar hernias are illustrated.

Chapter 6

In this chapter we investigated arguments, in terms of per-, post- and longterm complications, against intraperitoneal polypropylene mesh hernia repair. In a long-term follow-up study of 66 patients that underwent abdominal surgery after either intra- or preperitoneal mesh incisional hernia repair complications due to mesh were compared between intra- and preperitoneal positioning.

Chapter 7

In chapter 7 we investigated properties of various mesh prosthesis in an experimental animal model. In particular adhesions to mesh, shrinkage and ingrowth were investigated in this experiment.

Chapter 8

In chapter 8, we studied the mechanical properties, in particular persistent deformation, of various meshes in an experimental model of laparoscopic surgery were mesh has been passed through a 10 mm trocar.

Chapter 9

In chapter 9 we studied the effect of mesh on the recurrence and complication rate rate after umbilical hernia repair in a long-term follow-up studie of 131 patients comparing mesh and suture repair.

Chapter 10

In chapter 10 we studied the effect of two different mesh configurations in bilateral totally extraperitoneal inguinal hernia repair. For this purpose a long-term follow-up study was performed in 113 patients in order to determine whether or not mesh configuration is of influence on recurrence rates, postoperative and long-term complications.

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PART 2 - INDICATIONS FOR INCISIONAL HERNIA REPAIR

“Es hört doch jeder nur, was er versteht.”

Johann Wolfgang von Goethe

Chapter 2 - Indications for incisional hernia repair

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Introduction

Incisional hernia is a frequently observed complication after abdominal surgery, with an incidence after midline laparotomy varying between 2 and 20% [1-4]. The incidence of hernia recurrence after incisional hernia repair remains considerable. Burger et al. reported a ten-year cumulative recurrence rate of up to 63% after primary suture repair and 32% after open mesh repair. In Holland alone 100.000 laparotomies are performed annually. This leads to about 4000 incisional hernia repairs a year in the Netherlands, which is only a fraction of the total number of patients suffering from an incisional hernia [5, 6].

Risk factors for incisional hernia and recurrence of incisional hernia are similar, obesity, aortic aneurysm, smoking and wound infection being the major risk factors [5, 7-11]. With the world population becoming more and more obese one might expect an increase in the incidence of incisional hernias, making it a larger burden on patients, healthcare-employees and -healthcare budget [12]. In spite of multiple studies aiming to decrease the risk of primary incisional hernia through alternative incisions and by optimizing closure of the abdomen, the risk remains considerable [6, 10, 13].

During the past decades research focused on how incisional hernias should be repaired, mesh repair clearly being superior to primary suture repair to prevent recurrence [5-14]. Because of these results mesh repair is used more often, 80% of German surgeons now use mesh for incisional hernia repair compared to 15% in 1995 [9]. But, despite the use of mesh, the risk for recurrence can still be remarkably high [5, 8, 9].

The mortality and morbidity associated with incisional hernia repair should not be underestimated. Mortality in elective incisional hernia repair has been reported to be up to 5.3% [15]. Grave complications such as enterocutaneous fistulae and adhesions leading to bowel obstruction and pain can cause a significant decrease in patient condition and quality of life [16, 17]. As of yet unpublished data produced by our research group suggests that after intra-peritoneal mesh placement 20% of patients receive a partial small bowel resection at re-entry surgery because of adhesions. In addition, patients may find the cosmetic result of incisional hernia repair unsatisfactory and can suffer from significant postoperative pain [5]. Recently an interest in minimal invasive incisional hernia surgery has increased [18]. Results of the most recent

large studies still remain unpublished. A meta-analysis and a review of previous studies seem to reveal a lower complication rate with laparoscopic repair, which was still 14% [18, 19].

Because incisional hernia repair is not an operation with a low risk of morbidity and complications, it is very important to perform this procedure with a solid indication. One must consider the risk of morbidity and mortality when choosing for an operation and, equally important; consider the risk of a natural course. Reports defining these indications and describing the natural course of an incisional hernia are not readily available.

Despite the improvements and growing consensus on how incisional hernia should be repaired, little has been published on why and when an incisional hernia should be repaired and whether it is beneficial for the patient to be operated or not. The purpose of this review is to determine the motivations and indications for incisional hernia repair presented in the literature, based on quality of life reports and the risk for complications, morbidity and mortality.

Methods

A database search was performed on Pubmed, Medline and Cochrane with the keywords: incisional, cicatricial, hernia, indication, pain, strangulation, incarceration, cosmetics, adhesions, mortality, pulmonary, ulcer and recurrence. A manual search of the reference lists of identified articles was performed to obtain additional literature.

We set out to identify the various complaints presented by patients, as pain, discomfort or cosmetic appearance when diagnosed with an incisional hernia. Medical reasons to perform an incisional hernia repair were analyzed such as risk for strangulation, pulmonary conditions, skin ulcerations and other pathology caused by incisional hernias.

Complaints and symptoms presented by patients

Several studies have measured patient's satisfaction such as cosmetic result after incisional hernia repair, but little appears to be known about complaints presented by patients before operation [5, 20]. Mudge et al. reported complaints in one third of the patients, although it was not reported what these symptoms were [21]. In the study of Courtney et al., the indication for operation was pain in

78% of the cases, without reporting whether surgical treatment was performed routinely in asymptomatic patients [22]. In a prospective study Pollock et al. reported that 15 of 17 incisional hernias were asymptomatic [23]. Hesselink et al. found 96 incisional hernias in a follow up study after abdominal surgery, 51 having discomfort or pain and 45 being asymptomatic [24]. It is mentioned that large incisional hernias can be the cause of lower back pain. No figures are presented. Patients often mention the negative influence of incisional hernias on everyday activities, like cycling or cleaning, although nothing has been published regarding this topic. Information on cosmetic objectives presented by patients could not be found.

Risk of incarceration or strangulation

The natural course and the risks related to an untreated incisional hernia have not been described in great detail. Strangulation or incarceration was found to be the reason to operate in 6 to14.6% of incisional hernia repairs [1, 2, 22]. The true risk for incarceration or strangulation in the complete population at risk has not been reported.

Respiratory dysfunction

In patients with large incisional hernias with substantial evisceration Rives described pulmonary alterations. Because of the reduction of intra-abdominal pressure and subsequently loss of synergy between abdominal wall and thoracic wall, a paradoxal abdominal breathing pattern may develop with impairment of respiratory function [25, 26]. Figures and measurement of this condition have not been produced. Munegato et al. measured the respiratory function of patients with large incisional hernias before and during operation. Though the measurements showed restrictive and obstructive bronchopneumopathy preoperatively, these were patients suffering from COPD. The authors mainly focused on the impact of closure of the abdomen on the respiratory function [27]. Johnson et al. measured the vital capacity (VC) of the lungs before introduction of pneumoperitoneum for incisional hernia repair and one day postoperative. It showed a reduction of vital capacity (VC), which is normal 1 day after abdominal surgery. Unfortunately the authors

report no further data concerning respiratory function after incisional hernia repair [28].

Abdominal wall fibrosis

Another problem mentioned in the literature involving the natural course of large hernias is the atrophic change of the abdominal muscles [29]. This is the result of loss of the insertion of the oblique and transverse abdominal muscles to the linea alba combined with the evisceration of abdominal contents. The muscles retract, increasing the defect in the abdominal wall and decreasing abdominal capacity. The abdominal wall becomes more rigid, making closure even more difficult. No research has been published describing the histological changes of the abdominal wall in large incisional hernias. The atrophic changes of skeletal muscles due to inactivity are more extensively described [30].

Skin Problems

Large incisional hernias may have its effects on the overlying skin. Due to the constant pressure of the protruding hernia thinning of the skin and capillary thrombosis can occur. A dystrophic ulcer can appear at the apex of the bulge and this condition is mentioned as an indication for surgical repair. These lesions will have to be treated before hernia repair. No figures are published how often this condition occurs [25, 31]. Although a rare event, spontaneous or traumatic rupture of the hernia sac may occur [32-39].

Discussion

It is surprising to see how little has been published about the natural course of a common disorder like incisional hernia and how widely opinions can vary concerning this subject.

The primary reason to perform incisional hernia repair is probably a symptomatic incisional hernia. The symptoms consist of pain and discomfort, but also of cosmetic complaints. Reports on how many patients are having cosmetic complaints or symptoms of pain and discomfort are few and vary considerably. The cosmetic satisfaction after incisional hernia repair varies

likewise and it is unknown how many patients receive an incisional hernia repair because of cosmetical complaints.
In the pursuit of developing the best surgical technique for incisional hernia repair relatively little research has been conducted to elucidate the natural course of incisional hernias. The incidence of the most feared complication of an untreated incisional hernia, strangulation or incarceration of viscera in the hernia orifice is not known. In 6 to 14.6% the reason to operate was acute incarceration and this does not say anything about the incidence in the general incisional hernia population. The incidence may be less than 1%. This figure does not exceed the mortality rate in incisional hernia surgery and hence cannot be regarded as a primary reason to correct an incisional hernia.

Several articles discuss pulmonary problems involved in closure of large incisional hernias, but not if operating has been of any long-term benefit to the pulmonary condition of the patient. Rives claims in his article that large incisional hernias can impair respiratory function, but no measurements have been produced in support of this theory. The effect of a large incisional hernia and its repair on the pre- and post-operative respiratory function remains unknown.

The question is whether or not operating is the best option for every patient with incisional hernia. The article by Mudge et al. suggests that almost two third of the patients remain without any symptoms. It is very plausible that large proportions of patients never seek medical attention or have their condition observed by a G.P.

Is operating on patients with incisional hernias with little or no complaints worth all the risk of postoperative death, infection, recurrence and possible adhesions? Patients with little or no complaints, especially those who are at risk of having a recurrence or postoperative complications, could be monitored at an outpatient clinic or by a general practitioner. The natural course of an incisional hernia should be studied prospectively, which will aid patients and surgeons in their decision on the policy and treatment of incisional hernias.

According to Nyhus there should be an individualisation for all hernia repairs [40]. We recognize that mesh has significantly reduced incisional hernia recurrence, yet we feel that monitoring instead of repairing an asymptomatic incisional hernia should be considered in a large portion of patients.

A prospective study comparing monitoring to repairing an incisional hernia needs to be performed as well as examining the natural course of incisional hernias, both large and small.

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PART 3 - INCISIONAL HERNIA PREVENTION

“A scalpel does not require the authority of force, but it demands of the user the authority of motion.”

John Irving - The Cider House Rules

Chapter 3 - Incisional hernia after upper abdominal surgery: a randomised controlled trial of midline versus transverse incision

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Submitted

Introduction

The rate of incisional hernia after midline incision is commonly underestimated but probably lies between 2 and 20% [1-5].Thus incisional hernia is a major postoperative problem. The treatment of incisional hernia is complicated by high rates of recurrences. Recently, in a randomised controlled trial published by Burger et al., midline incisional hernia repair has been shown to be associated with a 10-year cumulative recurrence rate of 63 and 32 percent for suture and mesh repair respectively [6].

The midline incision is the preferred incision for surgery of the upper abdomen despite evidence that alternatives, such as the lateral paramedian and transverse incision, exist and might reduce the rate of incisional hernia [7]. Various approaches to opening the abdomen have been advocated over time. The choice for a certain incision is dependent on the exposure necessary for the desired procedure to succeed. A midline incision, be it supraumbilical, infraumbilical or both is an approach especially suited for emergency and exploratory surgery because of the quick and generous exposure that can be achieved within a few minutes [8, 9]. The avascular nature of the linea alba minimizes blood loss during this procedure. A supraumbilical transverse incision may be utilized in case exposure of the upper abdomen is desired. During this incision the damage inflicted to the segmental arteries and nerves is previously described as being minimal [10]. Previously only one randomised controlled trial, comparing transverse and true midline incisions, has been published specifically addressing incisional hernia incidence [11].

To determine whether the use of a transverse incision is an alternative to a midline incision for open cholecystectomy in terms of incisional hernia incidence, surgical site infection, postoperative pain and hospital stay, this randomised controlled trial (RCT) was performed. This trial was conducted in an era when laparoscopic cholecystectomy was not yet available. The possibility of low incisional hernia rates after transverse incisions and the fact that little is known about potential advantages, incited us to describe the relevant results of this RCT which has been performed in the past and has only been reported in a Dutch thesis by one of the authors (H.L.). The primary endpoint of this study was the incisional hernia incidence after 12 months of follow-up. Secondary endoints included pain and cosmetic apperance.

Methods

Protocol

Some 150 consecutive female patients were randomly assigned to a midline or transverse incision as an approach for elective cholecystectomy or combined cholecystectomy and cholangiography (with or without consecutive choledochotomy) (75 and 75 patients respectively). Emergency procedures were excluded from participation. Sample size is based on an incisional hernia rate reduction from 20 to 6 percent at a power of 80% and an error-rate of 5%. Obtaining informed consent was conducted in accord with the ethical standards of the Helsinki Declaration of 1975. The investigation reported was performed with informed consent from all patients and followed the guidelines for experimental investigation with human subjects and was approved by the medical ethics committee. An independent statistician prepared closed, tamperproof envelopes containing the random allocation (Figure 1). Patients were randomised for one of the procedures in theater through opening of the envelopes.

Patient-related factors that were recorded were age, body mass and length and date of operation. Operation-related factors that were recorded were the exact nature of the operation, length of the incision, the thickness of the subcutaneous fat, surgeon performing the procedure as well as the duration of the operation (skin-to-skin time). In the immediate postoperative period the use, dose and type of analgesics was recorded and a pain score was administered. The use of analgesics (morphine 7.5 mg intra-muscular injection, 4 hour minimum interval between consecutive injections) was monitored for 48 hours after surgery; the pain score was administered for the first 6 days after surgery.

In patients assigned to surgery through a midline incision the skin was incised from just below the xiphoid proces to just above the umbilicus. The abdominal wall was opened in the midline by incising the linea alba. A Collin type (two bladed) self-retaining retractor was used to maintain exposure. The abdominal wall was closed in one layer using single polygalactin 910 sutures (Vicryl; Ethicon, Amersfoort, The Netherlands). The skin was consequently closed using running monofilament nylon sutures (Ethilon; Ethicon, Amersfoort, The Netherlands).

Patients randomised for a transverse incision received a right-sided unilateral transverse incision between 3 and 4 cm below the costal margin. The rectus muscle was incised. The fibers of the external and internal obliques and the transverse muscles were separated in the direction of their course. Exposure was achieved through use of a manually held single bladed retractor. Closure of the abdominal wall was achieved by closure of the peritoneum and the posterior rectus fascia using a continuous, polygalactin 910 suture (Vicryl; Ethicon, Amersfoort, The Netherlands). The anterior rectus sheath and the fascia of the internal and external transverses were closed using simple interrupted polygalactin 910 sutures (Vicryl; Ethicon, Amersfoort, The Netherlands). Towards the end of both procedures a Redon low vacuum drain catheter was placed which was guided outside the abdominal cavity approximately 5 cm from the incision. The skin was consequently closed using continuous monofilament nylon suture (Ethilon; Ethicon, Amersfoort, The Netherlands). All patients received a dose of 5000 IU of sodium-heparin on the morning of the procedure as thrombosis prophylaxis.

Statistical Analysis

The Pearson χ^2 test was used for comparing percentages. In case of small expected numbers, a Fisher's exact test was performed. Continuous variables were analysed using the Mann-Whitney test. A p-value of 0.05 or less (two-sided) was considered statistically significant. Means and medians are expressed ± standard deviation.

Part of the raw data gathered in this study is not available any longer after having been analysed by the trial statistician (P.S.). The data for the contingency tables were preserved. The results of the analysis have never been published.

Follow-up

Patients returned to the surgical outpatient clinic for evaluation of the cosmetic results of the scar and to evaluate possible complications such as fistula, wound dehiscence and incisional hernia after a minimum of 12 months follow-up. The patient and the surgeon evaluated the cosmetic results independantly

and were asked to rate the scar as un-satisfactory, satisfactory or fine. Furthermore the length and width of the scar was measured.

Results

Study group

Some one hundred and fifty consecutive patients were randomised for participation in this study during an inclusion period from April 1977 until July 1979. Seventy-five patients received a transverse incision and 75 patients a midline incision (Figure 1).

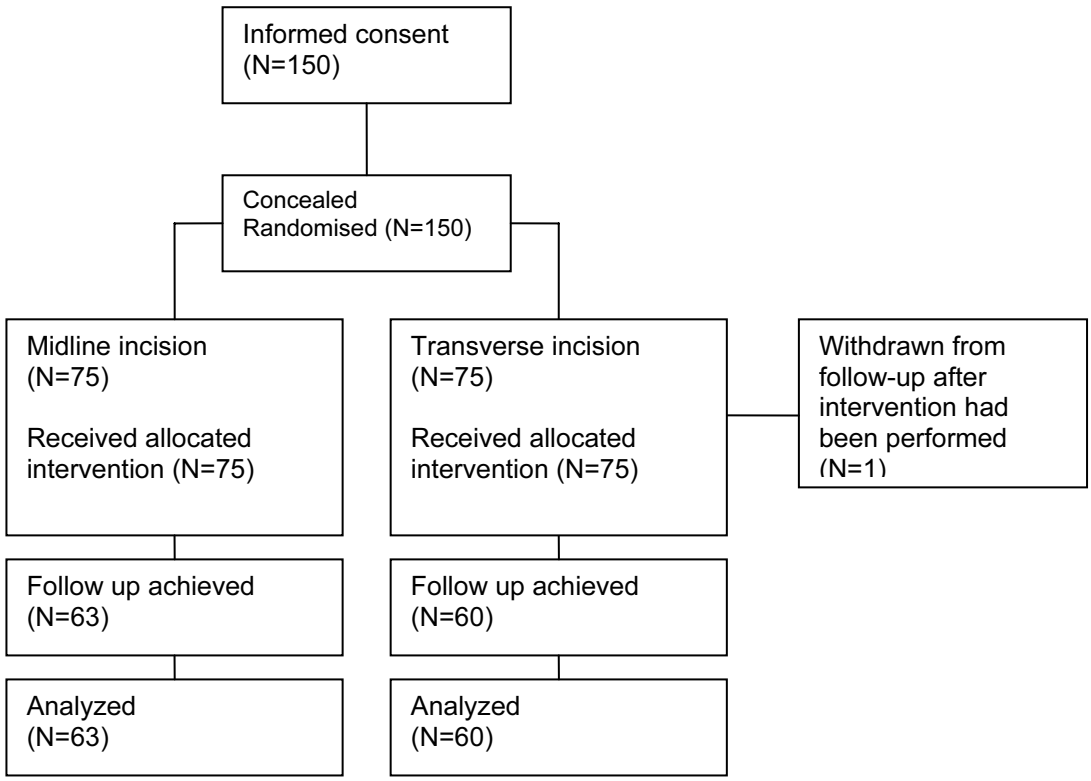

Figure 1. Flow-chart of patient inclusion and follow-up

One patient was withdrawn from further follow-up after developing peritonitis and consequent ARDS not related to the closure of the abdominal wall two days after surgery (transverse incision group).

The patients' average age was 51.9 and 51.4 years for the midline and the transverse incision group respectively. Furthermore no differences were found in body mass and average length between the two groups (Table 1). A

cholecystectomy was performed using a transverse incision in 52 patients and utilizing a midline incision in 52 patients also. Fifteen and sixteen patients respectively underwent a combined cholangiography/cholecystectomy. Further 7 and 6 patients respectively were treated with a cholangiography/cholecystectomy plus additional choledochotomy and the post-exploratory placement of a T-tube.

Variable	Midline Incision (N=75)	Transverse Incision (N=74)
Average age (years) ± sd	51.9 ± 14.8	51.4 ± 13.8
Average weight (kg) ± sd	71.3 ± 14.5	68 ± 14.3
Average length (cm) ± sd	163.5 ± 7.8	164 ± 7.3

Table 1. Baseline characteristics of the patients undergoing surgery, according to study group

Surgeon

Staff surgeons performed 17 percent (13/75) of all procedures performed through a midline incision. The remainder of the procedures through a midline incision was carried out under staff surgeon supervision. Staff surgeons performed fourteen percent of all procedures in the transverse incisions study group (10/74) and supervised the remainder. No statistically significant difference was found between the two randomised groups (p=0.65).

Duration of surgery

No significant difference was noted in the “skin to skin” time (in minutes) for the two different incisions (Table 4). The midline and transverse incision took 56.9 ± 29.3 and 53.2 ± 26.8 minutes respectively (p=0.35). The total duration of the procedures until extubation (in minutes) did not differ between the midline and transverse incision (71.0 ± 30.5 and 67.0 ± 27.3 respectively) (p=0.34).

Variable	Midline incision	Transverse incision	P-value
Length incision (mm) ± sd†	164 ± 28	140 ± 24	<0.0001
Thickness subcutaneous fat (mm) ± sd†	34.5 ± 13.0	30.3 ± 12.4	0.05
Skin to skin time (min) ± sd†	56.9 ± 29.3	53.2 ± 26.8	0.40
Width of scar (mm) ± sd*	8.3 ± 1.4	3.3 ± 1.2	<0.0001

† Measured during surgery in 75 midline and 74 transverse incisions, * measured at follow-up in respectively 63 and 60 midline and transverse incisions.

Table 4. Length of incision, thickness of subcutaneous fat and skin-to-skin time, according to study group

Pain and analgesics

Significantly more patients, having undergone a midline incision, reported pain on day one, two and three postoperatively (p<0.0001, Table 3). In the midline incision group, 28/75 patients required no or only one dose of analgesics, the remainder required two or more doses. Thirty-one patients operated through a transverse incision required nil or only one dose; forty-three patients (the remainder) required two or more. No significant difference in use of analgesics was found between the groups (p=0.69).

Time point after surgery	Midline incision N=75 Patients reporting pain N (%)	Transverse incision N=74 Patients reporting pain N (%)	P-value
3-4 hours	68 (91%)	60 (81%)	0.09
1st day	64 (85%)	39 (53%)	<0.0001
2nd day	57 (76%)	23 (31%)	<0.0001
3rd day	28 (37%)	9 (12%)	<0.0001
4th day	5 (7%)	3 (4%)	0.72
5th day	0 (0%)	1 (1%)	0.50
6th day	0 (0%)	1 (1%)	0.50

Table 3. Post operatively reported pain, according to study group, number of patients reporting pain at time points indicated (percentage), the remainder of patients reported no pain

Complications

Postoperative complications (Table 2) were seen in 16 out of 75 patients (21%) from the midline incision group and in 15% from the transverse incision group (11 patients) (p=0.30). Briefly, one patient in each group developed cardiac complications; eight and six patients respectively developed urinary retention after the midline and transverse incision respectively (p=0.59). Surgical site infections were diagnosed in 7 and 3 patients respectively (p=0.33).

Complication	Midline incision N=75 N (%)	Transverse incision N=75 N (%)	P-value
Cardiac	1 (1)	1 (1)	1
Urinary retention	8 (12)	6 (8)	0.59
ARDS	0	1 (1)	0.50
Surgical site infection	7 (9)	3 (4)	0.33
Hemorrhage	1 (1)	0	0.50
Pneumonia	0	1 (1)	0.50
Total	17 (23)	12 (16)	0.30

Table 2. Rate of complications after surgery, according to study group, number of patients diagnosed with complications (percentage)

Discharge

Forty-five (60%) and forty-two (57%) patients from the patients having undergone a midline or a transverse incision respectively were discharged on day six or seven postoperatively. The remaining patients from each group left hospital care on day 8 or later. The duration of hospital admission did not differ between the two types of incision ($p=0.74$).

Cosmetics

The width and length of all incisions was measured during the follow-up visit (Table 4). The mean width of the scar after a healing of the midline incision was found to be 8.3 ± 1.4 (mm). The mean width of the scar after healing of the transverse incisions was measured to be 3.3 ± 1.2 (mm). This observed difference is significant ($p<0.0001$). The length of the incisions was 140 ± 24 (mm) and 164 ± 28 (mm) for the transverse and the midline incisions respectively. The difference in scar length was found to be significant ($p<0.0001$).

Follow-up

Eighty-one percent of all patients operated through a transverse incision were seen during the follow-up examination (n=60). Of the patients operated through a midline incision 63 out of 75 were seen at the outpatient clinic (84%). The patients that were lost to follow-up could either not be traced or had deceased (Figure 1). The minimum follow-up for evaluation of cosmetic results and hernia incidence was 12 months, the maximum 36 months.

Incisional Hernia

From the patients that had undergone the procedure through a transverse incision, one (1/60; 2%); presented with an incisional hernia as opposed to 9 patients from the midline incision group (9/63; 14%); 95% C.I. 7.5- 25.4%. This difference in hernia incidence is significant (p=0.017). No significant correlation was found between incisional hernia rate and surgical site infection (p=0.07).

Subjective Cosmetics

Patients and surgeons alike were asked to rate the appearance of the scar during the postoperative follow-up outpatient clinic visit. Both the surgeons and the patients found the scar resulting from the transverse incision more cosmetically pleasing (p<0.0001 and p=0.03 respectively, Table 5).

Score	Midline incision (N= 63)		Transverse incision (N=60)	
	Patients N (%)	Surgeons N (%)	Patients N (%)	Surgeons N (%)
Un-satisfactory	6 (10)	25 (40)	2 (3)	6 (10)
Satisfactory	16 (25)	27 (43)	9 (15)	12 (20)
Fine	41 (65)	11 (17)	49 (82)	42 (70)
Total	63	63	60	60

*Difference between type of incision: patients p=0.03; surgeons p<0.0001

Table 5. Number of patients and surgeons rating cosmetics of a scar at follow-up

Discussion

This prospective randomised study of transverse and midline incisions for open cholecystectomy shows that a significant reduction of incisional hernia incidence can be achieved through the use of a transverse incision.

Only one other study reported the incidence of incisional hernia after upper abdominal midline and unilateral transverse incision in a randomised trial. No difference between the two techniques (8 and 6 percent incisional hernia respectively) was found, but the relatively short follow-up of 6 months however may be held accountable for this finding [11]. Three retrospective studies showed rates of incisional hernia of 3.2, 5.4 and 16.5 percent for midline incision and 1.3, 6.7 and 13.4 percent for transverse incision without statistically significant differences [12-14].

The possible reason for the rather high incidence of incisional hernia in the midline incision group (14%) may lie in the use of resorbable 910 polygalactin sutures. Nevertheless the use of the same type of resorbable suture in the closure of the transverse incisions resulted in a 2 percent hernia rate. There is evidence for the importance of proper technique and choice of incision as a means to reduce incisional hernia being more important than the use of suture material [7]. Furthermore, as mentioned above, it is known that the incidence of incisional hernia in case of a midline incision lies between 2-20 percent. From our data the Numbers Needed to Treat (NNT) is calculated to be 8 (95% C.I.: 5-30), the RRR (Relative Risk Reduction) is 88 percent (95% C.I.: 23-100%). Luijendijk et al. have published a hernia rate of 2 percent after Pfannenstiel incisions closed using 910 polygalactin, which is in agreement with our findings in the patients randomised for a transverse incision emphasizing the importance of the incision over the choice of suture material [15].

In our study significantly fewer patients reported pain on day 1, 2 and 3 after transverse incisions, a result that was also described by other authors [16, 17]. Greenall et al. published a contradictory report in which no significant difference in postoperative pain was found between midline and transverse incision [18]. The previously mentioned study however, only analysed 46 out of

572 patients (8%) with regard to pain, which may explain the finding. In the same way Lacy et al. suspended visual analogue pain scoring in a study comparing midline and transverse incision for abdominal aortic surgery. Remarkably the two groups in our study did not differ in terms of postoperative analgesia, a finding that is also reported by Donati et al. and Lindgren et al. [17, 19].

In our study, surgeons as well as patients were significantly more satisfied with the aesthetic appearance after a transverse in comparison with a midline incision. The scars after transverse incisions were found to be significantly shorter and less wide than the midline incisions, which may account for the observed difference. Possibly for the reason that a transverse incision is executed parallel to the prevailing direction of the skin lines on the abdomen and therefore the tension on the wound and consequent scar is low. Cholecystectomy has come a long way since this trial. The introduction and widespread acceptance of laparoscopic technique as treatment of choice has rendered open cholecystectomy an operation for exceptional, perhaps surgically difficult, circumstances. Nowadays the study reported is hardly feasible yet the results are still applicable and very relevant for other surgical procedures in the (upper) abdomen. Knowledge of the favourable results of a transverse incision may aid surgeons in their choice when finding themselves in the unfortunate position of needing conversion to open cholecystectomy.

In conclusion, the investigation whether a transverse incision might be helpful in reducing the incidence of incisional hernia in female patients after open cholecystectomy as this study was performed at a time that laparoscopic surgery was not available for cholecystectomy. The midline incision is a preferred manner to achieve exposure of the abdominal cavity and is considered to be easily performed and quick. Although the midline incision is generally accepted, the incidence of incisional hernias is surprisingly high [1-5]. The choice for a particular incision should not only be based on exposure but also on hernia incidence reduction especially since recurrence rates after hernia repair are reported to be very high. Furthermore the recurrence rate after incisional hernia repair is a disappointing 63 and 32 percent for suture

and mesh repair respectively [6]. In the light of these results incisional hernia prevention is warranted.

In this investigation it is shown that a significant reduction (from 14.5 to 1.7 percent) of incisional hernia incidence was achieved by using a transverse incision. Hence a transverse incision should be considered as the preferred incision in acute and elective surgery of the upper abdomen in which laparoscopic surgery is not an option. Full exposure of two quadrants is feasible through the use of a unilateral transverse incision in for example biliary, bariatric, liver and colonic surgery. The transverse incision should be part of the abdominal surgeon's armamentarium and is a preferable incision to prevent the high incidence of incisional hernia after abdominal surgery.

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Chapter 4 - Closure of transverse incisions

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In press Recurrent Hernia - Prevention and Treatment, Schumpelick & Fitzgibbons Eds.

Incisions

Any incision chosen for access to the abdominal cavity needs to provide access to the viscus or the lesion to be treated. Furthermore an incision needs to provide extensibility and permit subsequent secure closure. A further demand, may be the postoperative preservation of function[1] such as containment of abdominal organs and respiration. Additional considerations in choosing the incision are the speed of entry, presence of scars, possibility for hemostasis and a cosmetically pleasing outcome.

Secure closure must be possible and various suture materials are used in this day and age. Suture materials should ideally: be sufficient to hold parts together; disappear as soon as its work is accomplished; be free of infection; and be non-irritant.

To appreciate the different incisions and problems with closure, thorough knowledge of the anatomy of the abdominal wall is mandatory.

Anatomy ventral abdominal wall

The ventral abdominal wall consists of the rectus abdominis muscle on contralateral sides of the line alba. The origo of the rectus muscle are the 5th, 6th and 7th rib, the insertion is the pubic bone. The rectus muscles are each contained in a fascial layer, the anterior and posterior rectus sheath, which is made up of the aponeurosis (insertion) of the internal, external and transverse muscle. The rectus muscle is horizontally incised by the 3 inscriptiones tendinea. Lateral to the rectus abdominis the abdominal wall is made up of the aforementioned external oblique, the internal oblique and the transverse muscle which extend over the ventral and lateral part of the abdomen (the part not covered by the rectus muscle). The origo of the external oblique muscle runs from the 5th to the 12th rib. The internal oblique originates from the iliac crest. The transverse muscle, with its horizontal fiber direction originates from the previously mentioned iliac crest, the lumbodorsal fascia and the lower six ribs superiorly. The lateral border of the rectus muscle forms the linea semilunaris. At the symphysis pubis the posterior sheath ends in the thin curved margin, the linea semicircularis (Douglasi). Below this level the aponeuroses of all three muscles passes in front of the rectus abdominis and the fascia transversalis is responsible for the seperation of the rectus from the

peritoneum. The pyramidalis muscle (if present) lies anterior to the lower part of the rectus abdominis muscle. It arises from the superior surface of the pubic ramus and inserts at the linea alba.
The vasculature of the muscles of the abdominal wall consists of the superior and inferior deep epigastric vessels as well as transverse segmental branches of the aorta. The superior and inferior deep epigastrics are located in front of the posterior rectus sheath and the rectus muscle and form its blood supply through perforating vessels. The inferior deep epigastric artery branches from the external iliac artery whereas the superior deep epigastric is a branch of the internal thoracic artery. The deep epigastric arteries are anastomosed and thus form the deep epigastric arcade. The transverse segmental arteries supply the transverse muscle, the internal and external oblique and are situated between the transverse and internal oblique. Blood supply, to the relatively avascular linea alba, originates from the perforating vessels of the superior and inferior deep epigastrics.

Innervation of the abdominal wall is achieved through intercostals nerves, the ilioinguinal and the iliohypogastric nerve. The intercostals nerves are ventral branches of thoracic nerves originating from levels Th. 5 through Th. 12 of the spinal cord.

Midline incisions

The midline incision is possibly the most popular incision amongst surgeons today. When investigating alternatives to it, the baseline characteristics need to be described. Midline incisions incise the skin, subcutaneous tissue, linea alba and the peritoneum vertically. Midline incisions are easy, relatively little blood is lost and the incision takes an average of 7 minutes to perform [2-4]. The exposure achieved through a midline incision encompassing the umbilicus is excellent, and includes access to the retroperitoneum. The upper or lower abdominal midline incisions may be utilized in case the expected pathology is situated in the upper or lower quadrants of the abdomen respectively. Extensions may be made in cranial or caudal direction when deemed necessary. The qualities mentioned above make the midline incision the most ideal for emergency and exploratory surgery.

Transverse incision

Transverse incisions are possible at all levels of the abdomen. Common examples are the Pfannenstiel incision just above the pubic bone and the upper right quadrant transverse incision just below the costal margin.

The Pfannenstiel incision is approximately 8-12 cm in length (distance between the superfiscial epigastric arteries) and transsects the superficial fascia and the fibrous rectus sheath. Further access is achieved by a slightly more cranial, vertical incision of the fascia transversalis, the preperitoneal fat and the peritoneum [5]. Luijendijk has described incisional hernia formation in Pfannestiel incisions most recently and came to 2.1% in 243 patients after a follow up between 1.6 and 7.8 years [6].

The upper right quadrant transverse incision requires transsection of the oblique and transverse musculature as well as the rectus muscle. The linea alba is incised most commonly when extending the transverse incision across the midline. Dividing the rectus muscle requires ligating the epigastric arcade yet poses minor damage to the intercostals nerves and superficial arteries supplying the transverse and oblique musculature [7]. The transverse incision is thus accompanied by more blood loss than the midline incision and takes longer to achieve [4, 8]. Exposure of the lesion is generally good, although unilateral incisions may provide a somewhat limited view.

Closure of incisions

Midline closure

Studies describing closure of incisions have been performed focusing on continuous, interrupted, layered closure and various suture materials (absorbable and non-absorbable). A recent meta-analysis reviewed thirteen [9-21] clinically homogeneous randomised controlled trials comparing absorbable, non-absorbable, continuous and interrupted closure of abdominal incisions [22]. Non-absorbable sutures were found to reduce incisional herniae when compared with absorbable sutures. The odds ratio (OR) favoring non-absorbable sutures was 0.68 (95% CI 0.52-0.87) combining data from nine trials [9-12, 15-18, 21]. Neither wound infection nor wound dehiscence was statistically more likely in absorbable sutures. In contrast suture sinuses and wound pain were significantly more frequent in the non-absorbable suture

group with respective odds ratios of 2.18 (95% CI 1.48-3.22) and 2.05 (95% CI 1.52-2.77).

Six trials were identified in the aforementioned meta-analysis comparing interrupted and continuous suture technique disregarding suture type [9, 12, 14, 17, 20, 21]. Continuous sutures compared favorably to interrupted sutures (OR 0.73; 95% CI 0.55-0.99). No statistically differences were found for wound dehiscence and wound infection.

When taking into account the differences in technique (nine trials) continuous non-absorbable suturing outperformed the continuous absorbable suture in incisional hernia prevention (OR 0.61; 95% CI 0.46-0.8) [9-11, 14, 16-18, 21]. No significant differences were found when comparing interrupted absorbable and interrupted non-absorbable closure.

A subgroup analysis revealed that use of slowly absorbable polydioxanone (PDS®) and polyglycolic acid (Dexon®) did not significantly increase the risk for incisional hernia formation compared to polypropylene. Polyglactin (Vicryl®) compared unfavorably with non-absorbable sutures. Previously Wissing et al. have found that nylon has the lowest incidence of incisional hernia yet is unfavorably associated with more wound pain and suture sinuses than polydioxanone sutures [21].

Transverse closure

Randomised studies, not mentioned earlier, specifically describing incisional hernia formation with respect to midline, transverse and oblique incisions are summarized in table 1. Transverse incisions were found to be prone to incisional hernia formation in 3.6 - 40% of patients. Fassiadis et al. used continuous single layered closure with Nylon in the trial reported. The hernia incidence in high-risk patients undergoing abdominal aortic aneurysm surgery was reported to be 40%. In the transverse incisions studied by Fassiadis (using ultrasound) the incisional hernias were found predominatly at the lateral border [23].

Schoetz found the most encouraging results in closure of transverse incisions, 3.6% incisional hernia incidence after continuous closure with polydioxanone.

No studies were found specifically comparing different methods of closure (materials or technique) for the transverse incision.

Author	Year	No. of patients	Incision(s)	Follow-up (months)	Rate of incisional hernia (%)	Technique, suture type, layers (L)	p-value
Blomstedt [24]	1972	30	Transverse	8 - 24	9.5	Various sutures*, 2L	Ns
	RCT	115	Midline		13.9	Various sutures*, 1L	< 0.01
		80	Oblique		3.8	Various sutures*, 2L	
Greenall [8]	1980	235	Transverse	> 6	6.4	Various*, 1L, cont.	Ns
	RCT	234	Midline	> 6	8.1	Various*, 1L, cont.	
Ellis [25]	1984	50	Transverse	< 12	14.0	Nylon, 1L, cont.	Ns
	RCT	46	Paramedian	< 12	17.4	Nylon, 1L, cont.	
Schoetz [26]	1988	28	Transverse	1 - 12	3.6	PDS®, 1L, cont.	Ns
		172	Midline	1 - 12	2.9	PDS®, 1L, cont.	
Lord [27]	1994	126	Transverse	12 - 72	13.5	Nylon, 2L, cont.	Ns
	RCT	109	Midline		16.5	Nylon, 1L, cont.	
Fassiadis [23]	2005	15	Transverse	> 48	40	Nylon, 1L, cont.	<0.01
	RCT	22	Vertical		91	Nylon, 1L, cont.	
Halm	Sub.	60	Transverse	12 - 36	2	Vicryl®, 2L, comb.	p=0.02
	RCT	63	Vertical		14	Vicryl®, 1L, inter.	

RCT = Randomised Controlled Trial; Ns = Not significant; cont. = continuous; inter. = interrupted; comb. = one layer cont. and one layer inter.; L = Layer; * =absorbable/non-absorbable; Sub. = Submitted

Table 1. Randomised controlled trials comparing different incisions

Currently unpublished (submitted) results from a randomised study (n=150) performed at our own institute confirmed the results that transverse incisions (2% incisional hernia) are significantly less likely to develop hernias compared to upper abdominal midline incisions (14% incisional hernia) in the patients seen at follow-up (Table 1). Closure of the transverse incision of the abdominal wall was achieved by closure of the peritoneum and the posterior rectus fascia using a continuous, polyglactin 910 suture (Vicryl®). The anterior rectus sheath and the fascia of the internal and external transverses were closed using simple interrupted polygalactin 910 sutures (Vicryl®).

Complications: pain, woundinfection and burst abdomen

Armstrong et al., reporting a randomised study comparing midline and transverse incisions in 60 patients, have documented significantly reduced postoperative pain for transverse incisions [28], a result that we confirmed in our own (submitted) randomised trial. Halasz et al. found a reduction in the use of analgesics in patients after an oblique incision when compared to a paramedian approach [29]. A similar result was found by Garcia-Valdecasas comparing oblique to midline incisions [30]. The review by Burger et al. concluded that none of the trials performed to date reported a significant difference in surgical site infection rates [31].

Burst abdomen has an incidence between 0 and 2.5% and was found to be more likely after vertical incisions. Pooling of data by Grantcharov and co-workers revealed a significant difference between the incidence of burst abdomen after vertical incision of 1% (46/4480) and after transverse incision of 0.34% (15/4365) [32]. An odds ratio of 2.86 favoring transverse incision 95% CI 1.72 - 4.73 was subsequently calculated (Table 2).

Author	Type of publication	No. of patients	Incision(s)	Rate of burst abdomen (%)	p-value
Greenall [8]	RCT	292	Transverse	0	0.2453
		287	Midline	0.69	
Thompson [33]	Retr.	760	Transverse	0.5	0.004
		603	Midline	2.5	
Halasz [29]	Retr.	3313	Transverse	0.33	0.009
		3590	Midline	0.81	

RCT = Randomised Controlled Trial; Retr. = Retrospective;

Table 2. Studies describing burst abdomen as a complication of different incisions

Randomised Controlled Trial

The POVATI trial (ISRCTN 60734227), as initiated by researchers from Heidelberg, Germany (Prof. Dr. M.W. Büchler), compares the two most common incisions in general surgery, midline and transverse [34].

The trial, which was started in July 2003, proposes abdominal wall closure in a standardized way in both groups: Four Mikulicz clamps are to be placed at the edges of the abdominal fascia and a continuous, all-layer closure technique with two MonoPlus® loops (Aesculap, Tuttlingen, Germany) performed, starting from both ends of the incision with a 4:1 ratio (suture length:wound length). Neither subcutaneous closure nor subcutaneous drainage is proposed. Skin closure is to be achieved with skin clips.

Primary outcome measures are the requirement of analgesics and patient satisfaction. Secondary outcomes are incisional hernia one year postoperative (diagnosed by ultra sound). Burst abdomen, pulmonary infection, and wound infection are secondary endpoints, but are also defined as adverse events.

Closure of the transverse incision: How we do it

Currently, hepaticopancreaticobilliary surgeons of the Erasmus MC propose double-layered closure of transverse incisions reasoning that the cosmetic outcome is more pleasing since, in their experience, the skin inadvertently inverts when single layered closure is employed.

In detail, a USP 0 PDS® loop (Ethicon, Johnson & Johnson Amersfoort) is used to close the posterior fascia in a continuous fashion starting at the lateral border of the incision. Upon reaching the medial border of the incision the same loop, without interruption, is employed to approximate the anterior fascia and the internal and external obliques. A suture length to wound length ratio of 4 to 1 is maintained throughout. Subcutaneous closure is achieved in case the dead space observed is deemed to large in the eyes of the surgeon. For reduction of dead space interrupted Vicryl® (Ethicon, Johnson & Johnson, Amersfoort) sutures are used. Skin closure is achieved by intracutaneous, continuous suturing using Monocryl® 4-0 (Ethicon, Johnson & Johnson, Amersfoort, The Netherlands).

Conclusion

Closure of transverse incisions can be achieved securely using single as well as double-layered closure. Non-absorbable or slowly absorbable sutures seem to be advantageous in the prevention of incisional hernia as is continuous suturing technique. Slowly absorbable sutures seem to reduce the incidence of woundpain and suture sinuses. Further research in the form of randomised controlled trials seems warranted in light of the lack of data on the topic of transverse closure techniques.

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Chapter 5 - Trocar and small incisional hernia

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Trocar hernia

Introduction

Trocar hernia can be defined as the development of a hernia at the cannula insertion site [1]. To this definition Tonouchi and colleagues added the prerequisite that a trocar hernia need not necessarily have a hernia sac (peritoneal covering) [2]. Hernias without a hernia sac are the earliest of trocar hernias by the definition of Tonouchi et al., late onset hernias are defined to be contained in a hernia sac [2]. In 2002 Holzinger and Klaiber remarked that a "herniation" at a trocar site without parietal peritoneum should in fact be regarded as a mini-platzbauch and not as a hernia [3]. Portsite hernias probably occur after the total spectrum of laparoscopic (minimal invasive) surgery.

The first mention of the problem of trocar herniation must be credited to Fear et al. in his large series of laparoscopy for gynecological diagnosis [4]. Erich Mühe performed the first successful minimally invasive cholecystectomy September 12, 1985, although Rosen and Ponsky credit Mouret [5]. Six years passed until the first incisional hernia was described after laparoscopic cholecystectomy. Maio and Ruchman must be credited with the first publication exposing incisional hernia, after laparoscopic cholecystectomy, as a problem of minimally invasive digestive surgery. They were also the first to use imaging in the diagnosis of trocar hernia [6].

Incidence

Investigation of all incisional hernia repairs and the underlying surgery in the Netherlands yielded the following results. A total of 14526 laparoscopic cholecystectomies were performed in 2001. In 2002 a total of 3853 incisional hernia repairs were performed. It was found that 110 hernia repairs were completed after prior laparoscopic cholecystectomy. The percentage of patients that receive treatment for a trocar hernia after laparoscopic cholecystectomy is 0.8 % [7].

Furthermore five hernia repairs were completed after prior laparoscopic appendectomy. A total of 814 laparoscopic appendectomies were performed in 2001, hence 0.61% of patients received treatment for an incisional hernia after laparoscopic appendectomy [7]. The aforesaid numbers are the absolute

minimum found and the fact that asymptomatic patients may not seek medical attention needs to be appreciated.

Two prospective studies reporting on the incidence of trocar hernia find 1.5% and 1.8% [8, 9] respectively. Mayol et al. based his findings on patients after a variety of procedures (range of follow-up: 3-51 months) and Nassar et al. after laparoscopic cholecystectomy (range of follow-up: 2-6 months). The incidence of trocar site hernia, taken from literature reporting the complication rates of laparoscopic cholecystectomy, varies between 0.15% [10] and 7.7 [11] (Table 1).

Recently a study describing complications of laparoscopic fundoplication for gastro esophagal reflux disease reported a trocar site hernia incidence of up to 2.8% [12]. The hernia incidence after transabdominal pre-peritoneal (TAPP) inguinal hernia repair was reported to be 7.7% by Ridings and Evans [11] and found to be more frequent after TAPP inguinal hernia repair than after TEP surgery by Felix et al. in a series of 1087 patients. A total of 6 trocar hernias were found (at median follow-up of 42 months), 5 after TAPP (n=395) and one after converted TEP (n=692, 14 converted to TAPP) [13].

Reference	Study design	No. of patients	Operation(s)	Incidence	Follow-up
Bhoyrul et al.[33]	Randomised; sharp vs. radially expanding (blunt)	244	Cholecystectomy, Hernia, Fundoplication, Colon surgery, Other	0% (sharp) 0% (blunt)	6-18 months
Mayol et al.[8]	Prospective	403	Cholecystectomy, Fundoplication, Colon surgery, Other	1.5%	3-51 months
Nassar et al.[9]	Prospective	870	Cholecystectomy	1.8%	2-6 months
Bowrey et al.[12]	Retrospective	320	Fundoplication	3%	6 weeks-81 months
Azurin et al.[15]	Retrospective	1300	Cholecystectomy	0.77%	Post-operative visit
Ridings et al.[11]	Retrospective (reusable port changed to disposable port)	1700	TAPP	7.7% (reusable pyramidal ports) 3.2% (disposable pyramidal ports)	Not reported
Larson et al. [10]	Retrospective	1983	Cholecystectomy	0.15%	Not reported

Table 1. Selection of large prospective and retrospective studies describing trocar hernia incidence

Trocar size

The use of large diameter trocars and cannulas in minimally invasive surgery is often regarded as a predisposing factor for the development of trocar hernia [14-22]. Theoretically longer incisions, with larger wound surfaces to heal, are at increased risk for wound failure [23]. Based on this theory, small incisions used

during laparoscopy (0.5 cm), should be associated with a concomitant small risk of incisional hernia.

In a survey of the American Association of Gynecologic Laparoscopists regarding the rate of incisional hernia after laparoscopy, Montz and colleagues found that 725 out of 840 (86.3%) trocar site hernias occur in locations in which the diameter of cannula used was at least 10 mm. A herniation rate of 2.7% was observed in case the diameter of the trocar used was less than 8 mm [24]. The previously mentioned prospective studies by Mayol and Nassar found all hernias except one at 10 mm trocar sites. A single hernia was diagnosed in a 5 mm trocar site [8, 9]. Case reports of five patients however have also reported hernias in incisions created by 5 mm trocars after cholecystectomy and fundoplication/Nissen [20, 25-28].

Trocar type

Numerous trocar designs are available to surgeons these days. The most common trocars are the blunt-conical, pyramidal, radially expanding and cutting dilating types (Figure 1).

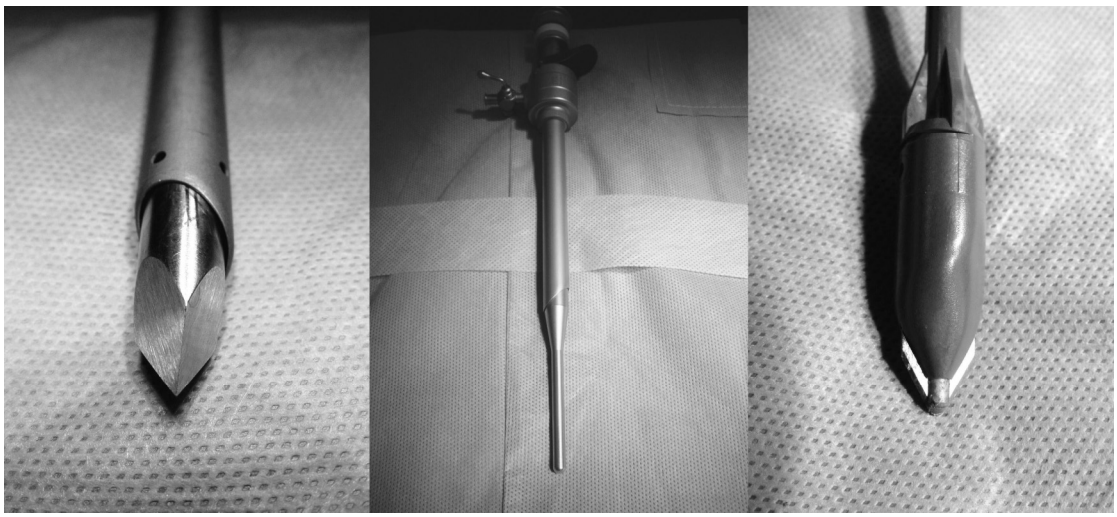

Figure 1. Examples of different trocar designs, pyramidal (left), blunt-conical (middle) and cutting dilating (right)

The trocar-cannula system design has been studied extensively in order to determine the damage inflicted to the abdominal wall during surgery and the

number of incisional complications. Experiments in an animal setting have revealed that pyramidal and cutting-dialating trocars require the least force for introduction, yet that both create significantly larger post-insertion defects than blunt trocars [29, 30].

Clinical research suggests that non-cutting trocars reduce the wound surface and thus the consequent risk of developing trocar hernias. In a study of 70 patients, in which blunt conical (muscle splitting) trocars were used, the post-operative defect was found to range between 6 and 8 mm. Of 180 trocar cannula systems placed, 110 were between 10 and 12 mm (61%). None of the defects were closed and no incisional hernias were diagnosed after a median follow-up of 11 months [31]. Leibl et al. demonstrated a difference in trocar hernia rate when comparing sharp and blunt trocars. Sharp trocars were responsible for incisional hernia in 1.83% while the blunt (conical) trocars were to blame for 0.17% [32]. A randomised controlled trial of 244 patients demonstrated no difference in incisional hernia rates between radially expanding and cutting trocars (Table 1). Hemorrhage however was significantly less present in the group of patients randomised for the radially expanding trocar [33].

Location of entry

Midline sites are the common sites leading to hernia after minimally invasive surgery and umbilical sites are most common [12, 15, 20, 21, 34]. Anatomical considerations are brought forward commenting on the inherent weakness of the paraumbilical region and the use of the largest cannula to facilitate the camera.

From an embryological point of view the umbilical defect is the fusion of ectoderm and embryonic mesoderm to form the fascial margin of the umbilical ring. To allow the passage of the umbilical arteries and the umbilical vein to the umbilical cord, an abdominal wall “defect” is present from the third week of gestation onwards. After birth, thrombosis of both the arteries and the vein occurs, and thus facilitates contraction of the umbilical ring by cicatrisation. Subsequently, the weakest area of the umbilical ring is the superior aspect of it, the area between the umbilical vein and the cranial margin of the umbilical

ring. The relative lack of elastic fibers in the obliterated umbilical vein is held responsible for this weakness cranially. In adults the anatomical margins of the umbilical canal are the umbilical fascia from posterior, the linea alba from anterior and the medial edges of the rectus sheaths.

Azurin and Ahmad hold incidental umbilical hernias responsible for trocar site hernias [14, 15]. The incidence of paraumbilical and umbilical fascial defects is reported to be 12% in 870 patients undergoing laparoscopic cholecystectomy, the majority of the patients being unaware of the defect (83.7%) [9]. Bowrey described all hernias found in the analysis of laparoscopic fundoplication to be at the midline, open Hassan technique, supraumbilical initial port [12]. From questionnaire among the members of the American Association of Gynecologic Laparoscopists, Montz found that 75.7% of all hernias, in which the site was noted (n=152), occurred in the umbilical locale, the remainder in the flank (23.7%) and at a suprapubic site (0.7%) [24, 35].

Retrieval through port-site

Enlargement of umbilical wounds for the retrieval of gallbladders (or other surgical specimens) from the abdomen may be involved in the rate of occurrence of port site hernias [8]. Nassar and colleagues view the enlargement of the midline (umbilical) fascial defect as the most significant risk factor for trocar site hernia and advocate avoiding unnecessary wound extension, if possible [9].

Closure of trocar site defect

In order to prevent trocar hernia authors have advocated closure of all fascial defects after minimally invasive surgery [1, 8, 15, 18, 36-38]. In a study by Kadar closure of the 12 mm trocar sites significantly reduced the incidence of trocar site hernias after major laparoscopic gynecological surgery [39]. The authors promote closure of all extraumbilical fascial defects created by trocars larger than 1 mm and raise the concern that three out of five 12 mm port hernias in their study occurred after closure had been attempted.

Several techniques for the closure of incisions after minimally invasive surgery have been proposed. DiLorenzo and colleagues propose the use of the

Deschamps ligature needle to close defects under direct vision and conclude that the use of the Deschamps needle is straightforward and cost effective [40]. Petrakis et al. describes a technique utilizing a 15 gauge spinal tap needle and a continuous, non-absorbable suture (USP size 0) for the primary closure of fascial defects as well as the placement of mesh [41].

Conclusion

Laparoscopic surgery is faced with an incisional hernia incidence of around 2%. Numerous methods have been studied to reduce the hernia incidence. The use of reduced diameter cannula, novel trocar designs and alternative location of entry are brought forward, few of which have been studied prospectively.

Closures of abdominal defects after laparoscopy are discussed in length in literature. The most commonly suggested factor influencing a surgeon's decision whether or not to close the defect is cannula size. We feel that leaving any fascial defect unclosed is correlated with a higher incidence of trocar site hernia and that more research, taking into account the type of suture used, perhaps even in the form of a randomised controlled trial, is warranted.

Small Incisional Hernia

Introduction

The rate of incisional hernia after midline incision is commonly underestimated but probably lies between 2 and 20% [7, 42-45]. In the Netherlands alone, 100.000 laparotomies and approximately 4000 incisional hernia repairs are preformed annually (data obtained from Prismant) [7]. The "Chevrel" classification divides incisional hernias according to size into either small (<5 cm in width/length), medium (5-10 cm in width/length) or large (>10 cm in width/length) [46]. It is the small hernias that are of interest in this discussion.

Small incisional hernias: subgroup analysis of a RCT

Introduction

In 2000, a randomised controlled, multicenter trial performed by our group indicated that mesh repair of incisional hernia is superior to suture repair [47]. The results which were confirmed by long-term follow-up of the trial in 2004 [48]. A number of authors have previously proposed that there are still indications for suture repair of incisional hernia [49-51]. Upsetting data point out that surgeons are still performing suture repair, in spite of the clinical evidence presented. In 1997, in Germany, 85% of incisional hernias repaired was still performed without mesh[52], while in 1999, in Washington state, 35% of incisional hernias was repaired without the use mesh [53]. In 2002, Dutch surgeons failed to use mesh in 40% of incisional hernia repairs [7]. The argument that small incisional hernias need not be closed using mesh to achieve excellent results is heard often. We performed this subgroup analysis to explore whether or not this argument is valid.

Patients and Method

From the initial randomised study [47, 48], which included 181 patients, a subgroup of 51 patients was identified. Maximum incisional hernia defect in patient selection was defined to be 10 cm^2. Patient demographics previously recorded in our study included: gender, age, smoking history, presence of prostatism, presence of diabetes mellitus, presence of obstipation, Body Mass Index (BMI) and glucocorticoid use.

Statistical analyses

Fractions and continuous variables were compared using Fisher's exact test and the Mann-Whitney U test, respectively. The analysis of cumulative percentage of recurrences over time was performed using Kaplan-Meier curves and comparisons were analyzed by the log rank test. Null hypotheses were tested two-sided and a p-value of 0.05 or less was considered statistical significant. Statistical analyses were performed using Statistical Package for Social Sciences for Windows (SPSS Inc., Chicago, IL., USA). Hernia recurrence was defined as the primary endpoint.

Results

The 51 patients who formed the study group had a median age of 55 years (range: 23-78 years). The median follow-up was 79 and 66 months for suture repair and mesh repair patients respectively. Gender, age, body mass index, smoking habits, as well as obstipation, prostatism and COPD were equally distributed between the groups (Table 2).

The subgroup analysis of 51 patients with small incisional hernias (≤10 cm2) revealed that the 10-year, age adjusted, cumulative recurrence rate was 67% after suture repair, compared with 17% after mesh hernia repair (p=0.0029). The aforementioned results are represented in Figure 2.

Variable*	Suture repair (N=30)	Mesh repair (N=21)
Gender, M:F	1:1.1	1:1.3
Median age, years (range)	67 (25-78)	57 (23-78)
Median BMI [a], kg/m^2 (range)	25.3 (20-41.5)	25.8 (20-41.5)
BMI > 30 kg/m^2 (%)	4/30 (13.3)	3/21 (14.3)
Smoking (%)	5/29 (17.2)	8/20 (40)
Prostatism, no. of males (%)	2/13 (15.4)	1/11 (9.1)
Obstipation (%)	4/29 (13.8)	4/20 (20)
Diabetes (%)	0/29 (0)	2/21 (19)
Steroids (%)	1/29 (3.4)	2/20 (10)
Haematoma (%)	3/30 (10)	1/21 (4.8)
Mean intraoperative area of hernia, cm^2 (sd.)	6.5 (3.2)	5.8 (3.5)
Discomfort (%)	9/21 (42.9)	2/12 (16.7)
Recurrence rate, %	67	17 p=0.0029

* Data were not available for all patients; [a] BMI=Body Mass Index

Table 2. Baseline characteristics and hernia recurrence rate of patients with small incisional hernia (N=51), according to study group

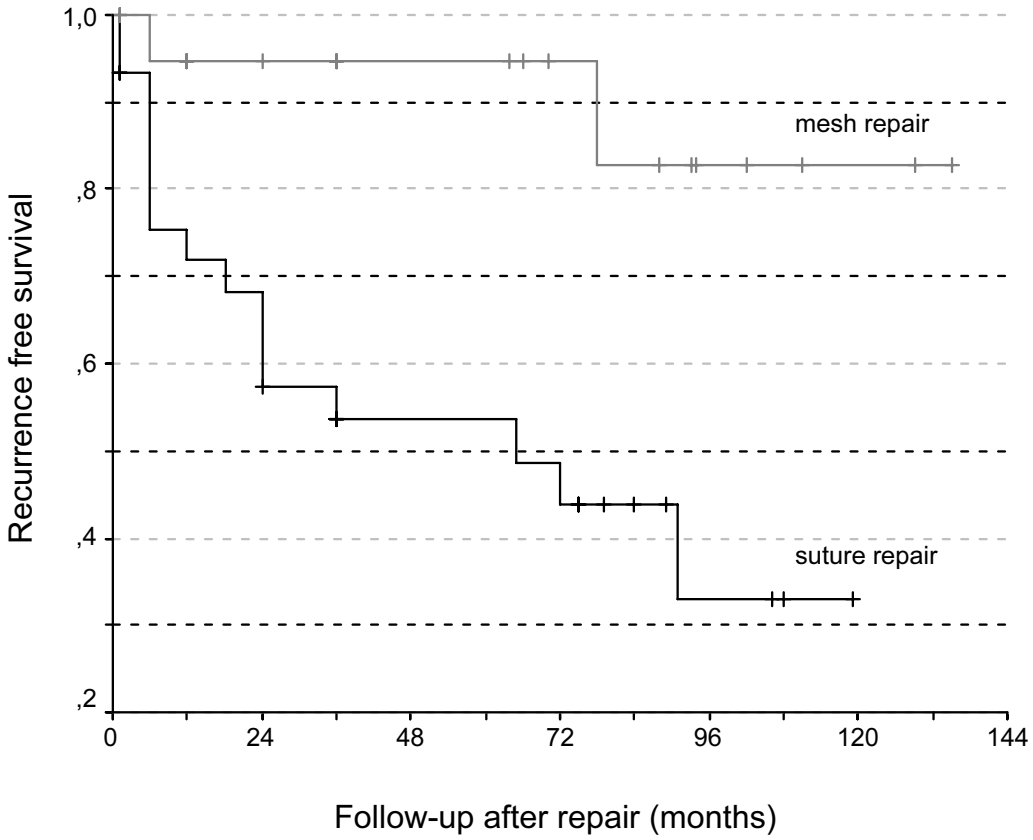

Figure 2. Kaplan-Meier survival curve for recurrence of incisional hernia after repair of a primary or first recurrent small incisional hernia according to study groups. There were significantly fewer recurrences in patients who were assigned to mesh repair (p=0.0029)

From our available data (21 suture and 12 mesh repair patients) scar pain, abdominal pain and discomfort were not significantly associated with either incisional hernia repair method.

Suture and mesh repair patients rated the postoperative cosmetic appearance as 7/10 and 7.5/10 on the VAS respectively (ns). Fourteen out of 21 patients (67%) after suture repair versus 11/12 (92%) after mesh repair were satisfied after surgery (ns). Dissatisfaction was most commonly caused by hernia recurrence.

Discussion

Subgroup analysis of data collected in a RCT comparing suture and mesh incisional hernia repair provides evidence that mesh repair of small incisional hernias is superior to suture repair on the long run.

The current subgroup analysis reveals that the recurrence rate after suture repair of small (≤10 cm^2) incisional hernia increases to an undesirable level ten years after surgery (67%). Although the results of mesh repair are somewhat poor (17% recurrence), a recurrence rate reduction by 75% when not utilizing suture repair is a marked improvement all the same. Naturally all possible complications of mesh repair reported in international literature need to be weighed before the individual patient is treated (as described in Chapter 2)

This study is the only RCT studying recurrence rates after suture and mesh repair of incisional hernia repair. In order to consolidate the data new trials are certainly necessary.

Conclusion

In conclusion, the study published by our group is the first and only to provide prospective long-term follow-up of incisional hernia repair. It proves that mesh repair is superior to suture repair even in the small incisional hernias. Mesh repair results in lower, age adjusted, cumulative recurrence rates without providing significantly more discomfort, abdominal and scar pain or fistula.

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PART 4 - PROPERTIES OF PROSTHETIC MESH

“This is the best thing that ever happened to me since I did my first strangulated hernia.”

Lt. Colonel Henry Braymore Blake, M*A*S*H 4077

Chapter 6 - Intraperitoneal polypropylene mesh hernia repair complicates subsequent abdominal surgery

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In press World Journal of Surgery

Introduction

Incisional hernias occur in 2% to 20% of all patients after abdominal surgery [1-3]. Prosthetic incisional hernia repair (PIHR) has shown to be superior to primary suture repair with recurrence rates of 2% - 36% and 12% - 63% respectively [4-6].

Serious complications have been associated with the use of prosthetic material and depend on the relation of the mesh to the abdominal wall [7, 8]. Three anatomical positions are possible: onlay, sublay (preperitoneal) and the intraperitoneal position. Onlay positioning of the mesh is associated with high recurrence rates and high incidence of postoperative complications such as surgical site and mesh infections, haematoma and seroma formation [7-9]. In sublay positioning the prosthesis is protected from abdominal content by the posterior rectus sheath and the peritoneum or the intact peritoneum alone in case of retrofascial repair. The sublay technique has been reported to result in minor adhesion formations and reduced postoperative complication rates [10]. Intraperitoneal mesh has been used in the past, commonly with interposition of omentum but may also be a result of the inability to close the peritoneum between the bowel and the mesh. Intraperitoneal mesh is described to be associated with dense adhesions, bowel lesions, mesh migration, mesh erosion into associated anatomical structures and enterocutaneous fistula formation [11-15]. The association of fistula with intraperitoneal polypropylene mesh placement however was not found by Vrijland et al. [16].

No reports have been published that specifically address complications of subsequent laparotomies that follow PIHR. A retrospective study was performed to gain insight into complications of subsequent interventions attributable to prosthetic material and in particular to mesh position at PIHR.

Patients and Methods

Study design

Medical records of 335 patients who underwent PIHR in the period from January 1992 to February 2005 at one of our institutions (Medical Center Rijnmond Zuid) were reviewed. Seventy patients who had undergone subsequent laparotomy after PIHR were identified out of these 335 patients. If patients had not received any subsequent abdominal surgery at our institution

a questionnaire was sent to the respective general practitioner to collect information about surgical interventions elsewhere. The response rate of the survey was 82% (n=217) and yielded no patients that had not been identified before. Two patients were excluded because medical records were incomplete at the time of analysis. One patient was excluded because the subsequent laparotomy was performed abroad and data were not available. A single patient having received onlay mesh repair was excluded from analysis (Figure 1).

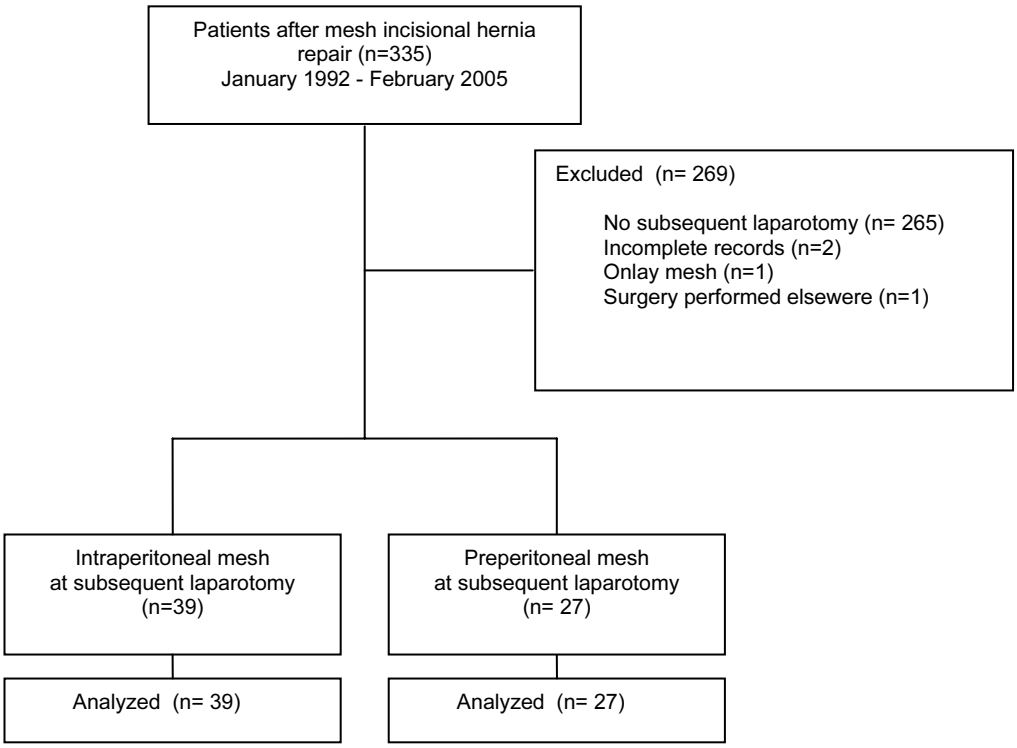

Figure 1. Flow-chart of included patients

Study population

Patient demographics recorded in our study included: gender, age, smoking history, presence of disease responsible for intra abdominal pressure increase and Body Mass Index (BMI). Indication of initial laparotomy, PIHR and subsequent laparotomy was reviewed as well as emergency status, postoperative length of stay/ICU stay and date of death if deceased.

Peroperative complications after subsequent laparotomy reviewed included: transmural bowel lesions, serosa lesions, adhesions and subsequent small bowel resection if necessary, haemorrhage, mesh erosion and mesh migration.

Postoperative complications recorded within the first 30 days after subsequent surgery were classified as seroma, haematoma, surgical site infection (SSI), urinary retention, bowel obstruction and peritonitis. Complications 30 days postoperative were designated late complications and included enterocutaneous fistula and deep mesh infection.

Data analysis

Data were collected in a resident database and statistical analyses were performed using Statistical Package for Social Sciences for Windows (SPSS Inc., Chicago, IL., USA). The study population was divided into two groups according to mesh position, preperitoneal and intraperitoneal respectively. The Pearson χ^2 test and the Student's t-test were used to compare patient demographics and complication rates between the two groups. Null hypotheses were tested two-sided and a p-value of 0.05 or less was considered statistical significant. Statistical analysis of long-term complications of intraperitoneal placement versus preperitoneal positioning was performed using Kaplan-Meier curves and comparisons were analysed by the log rank test.

Results

Study population

Subsequent laparotomies/ laparoscopies were performed in 66 patients. The median age was 61.4 years (range: 25.9 - 83.6 yrs) at the time of the subsequent laparotomy/ laparoscopy. Gender was equally distributed. Median

follow up time was 47 months (range: 1.5 - 150 months). The intraperitoneal and preperitoneal group did not differ significantly concerning patient demographics except for BMI. More patients in the preperitoneal group had a BMI greater than 25 kg/m2 (24/27 vs 26/39, p=0.04).
PIHR with mesh placed intraperitoneally (n=39) was performed by surgeons in 18 cases (46%) and by supervised residents in the remainder. Surgeons performed the preperitoneal PIHR in 16 out of 27 cases (54%). Surgeons performed subsequent interventions (with prosthetic mesh in situ) in 25 of 39 (intraperitoneal mesh) cases (64%) and in 16 of 27 (preperitoneal mesh) cases (59%) respectively (n.s.).

Operative parameters of initial laparotomy

Indications for initial laparotomy prior to PIHR are displayed in table 1. Gastro-intestinal inflammation (25%, N=17/66), urogenital disorder (13%, N=9/66), malignancy (12%, N=8/66) were most common. No difference was found between patients receiving intra- and preperitoneal mesh (Table 1). A midline incision was the main type of incision used in 77% of all initial laparotomies (N=51/66).

Indication	Initial laparotomy		Initial laparotomy in patients with intraperitoneal grafts		Initial laparotomy in patients with preperitoneal grafts	
	(N = 66)		(N = 39)		(N = 27)	
Gastro-intestinal inflammation*	17	(25 %)	10	(26 %)	7	(28 %)
Malignancy	8	(12 %)	4	(10 %)	4	(15 %)
Urogenital disorder	9	(13 %)	4	(10 %)	5	(19 %)
AAA**	6	(9 %)	4	(10 %)	2	(7 %)
Cholecystectomy	6	(9 %)	3	(8 %)	3	(11 %)
Gastric surgery	5	(8 %)	3	(8 %)	2	(7 %)
Umbilical hernia	5	(8 %)	3	(8 %)	2	(7 %)
Bowel obstruction	2	(3 %)	2	(5 %)	0	(0 %)
Other	8	(12 %)	5	(8 %)	3	(11 %)

*Gastro-intestinal inflammation = appendicitis, diverticulitis, pancreatitis with gastric involvement, Crohn's disease, ulcerative colitis; ** Both acute and elective procedures are included

Table 1. Indications for initial laparotomy

Operative parameters of PIHR

Suture based hernia repair prior to PIHR was performed in 13 patients (19%). In case of PIHR (N=66) esthetical concerns and persistent pain complaints were the primary reasons for surgical intervention. In 93% (N=62/66) of all hernia repairs polypropylene mesh prosthesis was utilized. Respectively two polyglactin meshes and two ePTFE meshes were used in the remaining four patients. All PIHR were performed in separat sessions, none of the PIHR were performed after other procedures. Indications for prosthetic incisional hernia repair are shown in table 2.

Indication for incisional hernia repair	Pain complaints	24	(37 %)
	Esthetics	22	(33 %)
	Burst abdomen	6	(9 %)
	Wound dehiscence	5	(8 %)
	Incarceration	2	(3 %)
	Ileus	1	(2 %)
	Other	6	(9 %)

Table 2. Reasons for incisional hernia correction

Operative parameters of all subsequent interventions after PIHR

Hernia recurrence (54%, N=36/66) and complication resolving surgery related to previously performed intervention (24%, N=16/66) represented the two main indications of all subsequent procedures after PIHR (Table 3A).

Indication for subsequent interventions	Intraperitoneal grafts (N = 39)		Preperitoneal grafts (N = 27)		
Hernia recurrence	19	(49 %)	17	(63 %)	n.s. ‡
Complication resolving surgery	11	(28 %)	5	(19%)	n.s. ‡
Cholecystectomy	2	(5 %)	2	(7 %)	n.s. ‡
Urogenital disorder	2	(5 %)	0	(0 %)	n.s. ‡
AAA*	1	(3 %)	0	(0 %)	n.s. ‡
Malignancy	1	(3 %)	2	(7 %)	n.s. ‡
Other	3	(8 %)	1	(4 %)	n.s. ‡

* Abdominal aortic aneurysm, ‡ Fisher's Exact Test

Table 3A. Indication for subsequent interventions

Indication for complication resolving surgery (24%, N=16/66) most commonly consisted of bowel perforation (29%, N=5). Complication resolving surgery was not performed significantly more often in the intraperitoneal mesh group (p=0.4). Subsequent laparotomies were predominantly elective (76%, N=50/66), open, procedures (94%, N=62/66) (Table 3B).

Indication for complication resolving surgery	(N=16)	
Bowel perforation	5	(31 %)
Abscess	3	(19 %)
Fistula	2	(12 %)
Haematoma	2	(12 %)
Ileus	1	(6 %)
Seroma	1	(6 %)
Other	2	(13 %)

Table 3B. Indication for complication resolving surgery

Laparoscopic cholecystectomy was performed twice, once necessitating adhesiolysis and once without any difficulties.

In two patients (3%) with a previously inserted preperitoneal mesh laparoscopic hernia repair was performed. In both cases adhesiolysis was achieved without complications. The resultant abdominal defects were closed using mesh in 59% of patients (n=39/66), most commonly utilizing polypropylene mesh (88%). Polyester and combinations of meshes were both used twice. Polyglactin mesh was used in a single patient. In the rest of patients sutures were used to approximate the remnants of mesh.

Complications of subsequent interventions

The peroperative course of all subsequent interventions was complicated in 38 patients (57%, Table 4). Significantly more peroperative complications were observed with intraperitoneal mesh position (76%, N=30/39) in comparison to the preperitoneal position (29%, N=8/27, $p<0.001$). Specifically adhesions were more frequently present in case of intraperitoneal meshes, respectively 62% (N=24/39) versus 26% (N=7/27).

Adhesiolysis was more challenging if intraperitoneal meshes had been inserted. Subsequent small bowel resections were necessary in 20% of the intraperitoneal group (N=8/39) versus 0% of the preperitoneal mesh group (Table 4).

Complications		Complications in subsequent interventions in patients with intraperitoneal grafts (N = 39)		Complications in subsequent interventions in patients with preperitoneal grafts (N = 27)		p
Per operative	No complications	9	(23 %)	19	(70 %)	<0.001
	Complications	30		8		
	Adhesions	24	(62 %)	7	(26 %)	
	Dense visceral adhesions which required bowel resection	8	(21 %)	0	(0 %)	
Post operative	No complications	20	(51 %)	21	(78 %)	0.04
	Complications	19		6		
(< 30 days)	Surgical site infection	10	(26 %)	1	(4 %)	
	Superficial,	3		1		
	Deep	6		0		
	Mesh removal required	1		0		
	Haematoma/ seroma	1	(3 %)	1	(4 %)	
	Small bowel perforation	3	(8 %)	0	(0 %)	
	Ileus	3	(8 %)	1	(4 %)	
	Urinary retention, UTI	3	(8 %)	1	(4 %)	
	Peritonitis/ sepsis	1	(3 %)	0	(0 %)	
	Pneumonia	3	(8 %)	0	(0 %)	
	Other	9	(23 %)	3	(11 %)	
	Deceased	2	(5 %)	0	(0 %)	
Late (OPD*)	No complications	30	(77 %)	26	(96 %)	0.04
	Complications**	9		1		
(> 30 days)	Enterocutaneous fistula	2	(5 %)	0	(0 %)	
	Deep mesh infection	1	(3 %)	0	(0 %)	
	Other	2	(5 %)	1	(4 %)	

* Outpatient department, ** data missing in 4 cases

Table 4. Complications at subsequent laparotomy related to intra- and preperitoneal mesh

Enterocutaneous fistula developed in two patients of the intraperitoneal group (5%). No difference was observed between the intraperitoneal group and preperitoneal group with respect to late complications after adjustment for follow up period. Two patients in the intraperitoneal group deceased after subsequent laparotomy due to cardio-pulmonary insufficiency.

Mesh related findings

Bowel perforation due to mesh erosion occurred in two patients of the intraperitoneal group (5%) within the first week after surgery. At subsequent laparotomy, mesh fixation was found to be insufficient along one or more sides of the prosthetic material in both patients.

Discussion

This study shows that subsequent re-laparotomies in the presence of previously inserted intraperitoneal meshes for incisional hernia repair can be associated with peroperative complications in 77% of patients.

In our study mesh erosion occurred in two patients (with intraperitoneal) within the first week after surgery. Both developed bowel perforation that required re-laparotomy, which revealed deficiency of the mesh fixation and suture release to be the primary reason for the mesh erosion. To prevent mesh erosion several studies discourage contact between mesh and abdominal organs and omental interposition is recommended [14, 17, 18].

In the literature adhesions were reported to occur in more than 90% patients who underwent a subsequent laparotomy after primary laparotomy [19-21]. The percentage of adhesions found in all subsequent procedures in our study (54%) is probably underestimated because of forgetfulness to report minimal adhesions.

Overall surgical site infections (N=10, 26%) and especially deep surgical site infections (N=6, 15%) were more frequently observed in the intraperitoneal group. In the literature surgical site infection percentages after PIHR with intraperitoneal polypropylene mesh placement are reported in 4.7% [22].

Literature about surgical site infection rates in subsequent laparotomies after PIHR is severly limited. Comparing our results with anything but SSI data from mesh incisional hernia repair is therefore difficult.

Our results revealed that enterocutaneous fistula formation is a complication observed at relaparotmy in patients treated using intraperitoneal meshes however no staistically significant difference was found compared to preperitoneal mesh. In our study two patients developed an enterocutaneous fistula (N=2; 5%) within the first two months after subsequent surgery. Of these, one patient had a history of recurrent fistula formation as a result of Crohn's disease and it is likely that the prosthetic material inserted did not induce the fistula. A retrospective study of 136 elective incisional hernia repairs with polypropylene also described no fistula formation in a 34 months follow-up period [16]. The low percentage of fistula formation is also supported by other studies with follow up periods between 45 months and 144 months [23, 24].

It appeared from our study that subsequent interventions in patients with previously placed intraperitoneal meshes were complicated by adhesions (62%) and necessitated bowel resections in 21 percent of cases (8/39). In contrast surgery after preperitoneal mesh positioning was complicated by adhesions in 26 percent of cases (7/27). No bowel resections were required in patients after previous preperitoneal mesh hernia repair.

Intraperitoneal mesh positioning at incisional hernia repair seems inadvisable if better alternatives are available. However if intraperitoneal mesh positioning is inescapable, like in laparoscopic incisional hernia repair, composite meshes with coating are recommendable, combining minimal adhesion formation and optimal tissue ingrowth [25].

A disadvantage of this study might be the inclusion of complication related interventions after PIHR. Patient related factor and technical aspects might have played a more contributive role in occurrence of complications in comparison to elective subsequent procedures. However, all complication-

related procedures performed were equally divided between the intra and preperitoneal mesh.

Conclusion

This study is the first to specifically describe complications of subsequent surgical interventions attributable to intraperitoneal and preperitoneal mesh grafts. Complications of subsequent interventions after previously inserted intraperitoneal mesh material, are a serious problem. Surgeons should be aware of the risks and possible complications at re-operations associated with mesh prosthesis previously inserted intraperitoneally. Challenging adhesiolysis and the risk for bowel lesions and possibly bowel resections are some of the frequent problems that surgeons may be faced with at subsequent laparotomies if incisional hernia repair was performed with intraperitoneal mesh placement. This peroperative morbidity emphasizes the need for tailored hernia repair.

Enterocutaneous fistulas and mesh erosion are relatively rare and only represent a relative contraindication to the placement of mesh in the intraperitoneal space. This study provides arguments against the use of intraperitoneal polypropylene mesh in terms of complications at subsequent laparotomy. As mentioned previously adhesiolysis complicates 62 percent of re-laparotomies in patients previously treated with intraperitoneal polypropylene mesh. This should be considered when re-entry surgery is required and all subsequent surgery should be performed with the greatest of care and if possible through a part of the abdomen were mesh is not expected. The decision to remove all mesh should be part of a patient tailored approach taking into account degrees of contamination and the chance of succesfull consequent closure of the abdomen.

In conclusion, the percentage of patients that require small bowel resection to gain entrance into an abdomen reinforced with intraperitoneal polypropylene mesh is high (21%) and disturbing.

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Chapter 7 - Evaluation of new prosthetic meshes for ventral hernia repair

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Published Surgical Endoscopy

Introduction

Incisional hernia is a frequent complication of abdominal surgery with an incidence of 2-20% [1-5]. In the United States, 4 to 5 million laparotomies are performed annually [6], which implies that at least 400.000-500.000 incisional hernias develop each year. Incisional hernia repair is performed approximately 200.000 times per year [7]. In the Netherlands, 100.000 laparotomies and 3.900 incisional hernia repairs are performed annually (data obtained from Prismant [8]). These data imply that in both countries, and probably in general, 4% of patients undergoing a laparotomy will undergo subsequent incisional hernia repair.

Incisional hernia repair can be performed either by primary closure, in which case the defect in the abdominal wall is closed by suturing the edges of the defect in the abdominal wall together, or by mesh repair, in which case a prosthetic mesh is implanted. Recent results from a randomised-controlled trial prove that the use of a prosthetic mesh for hernia repair results in a reduction of the hernia recurrence rate [9,10]. In prosthetic mesh hernia repair, direct contact between mesh and abdominal viscera cannot always be avoided. Moreover, direct contact is inherent to laparoscopic hernia repair, which became more popular in recent years, because it may result in a decreased incidence of postoperative complications and a shorter hospital stay [11]. However, contact of abdominal viscera with foreign material, such as prosthetic mesh, may lead to an inflammatory response and adhesion formation [12,13]. Inflammation and adhesion formation can induce chronic pain [14-16], intestinal obstruction [14,17-19], infertility [15,20] and enterocutaneous fistulas [21, 22]. In addition, adhesions can complicate future surgery [23].

Currently, the most commonly used mesh is made of polypropylene. It is relatively inexpensive, easy to handle and well incorporated in the abdominal wall. Polypropylene may however cause significant adhesion formation. New meshes were developed as an alternative for polypropylene. Important developments were the introduction of expanded polytetrafluoroethylene and composite meshes that carry an anti-adhesive barrier on the visceral side of the mesh. However, these meshes did not provide a final solution, because a

reduction of adhesion formation was often associated with a reduction of mesh incorporation or an increase in susceptibility to infection. Recently, new meshes were introduced. Their value has not yet been established.

The purpose of our study was to determine whether four newly introduced meshes are able to combine a decrease in adhesion formation with adequate mesh incorporation, high tensile strength and low susceptibility to infection. Furthermore, we wanted to establish whether the new meshes are an improvement compared to meshes already available. In a rat experimental study, adhesion formation, tensile strength, shrinkage, infection rate and tissue response were studied and compared after 7 and 30 days.

Materials and Methods

Study design

Male Wistar rats were divided into two groups: A and B. Groups A and B were subdivided into eight groups corresponding with the eight meshes that were tested. After the animals were humanely killed (group A after 7 days, group B after 30 days), adhesion formation, mesh incorporation, tensile strength, shrinkage, mesh infection and tissue response were scored and compared. The number of animals needed in each group was established using a power analysis. To be able to establish differences deemed significant, in group A 10 animals were needed per mesh, while in group B 15 animals were needed per mesh. Therefore, group A contained 80 animals, while group B contained 120 animals.

Animals studied

Male inbred rats of the Wistar strain, weighing 300-350 grams, were obtained from Harlan, Zeist, the Netherlands. They were bred under specific pathogen free conditions, kept under standard laboratory conditions (temperature 20-24ºC, relative humidity 50-60%, 12h light/12h dark) and were fed with standard rat chow (Hope farms, Woerden, The Netherlands) and water ad libitum (pH 4.2-4.7). The experiment adhered to the rules of the Dutch Animal Experimentation Act and was approved by the animal experimentation ethics committee (DEC-consult).

Materials

Table 1 presents the materials and the brand names of the eight meshes tested. Monofilament polypropylene 5-0 sutures were used for mesh fixation and closure of the abdominal wall. Multifilament polyglyconate 5-0 sutures were used for closure of the skin.

Material	Brand name	Manufacturer
Polypropylene	Prolene	Ethicon, Inc., Somerville, NJ, USA
Expanded Polytetrafluoroethylene	DualMesh	W.L. Gore & Associates, Inc., Flagstaff, AZ, USA
Polypropylene-Polyglecaprone Composite	Ultrapro	Ethicon inc., Somerville, NJ, USA
Polyester with Collagen-Polyethylene Glycol - Glycerol Coating	Parietex Composite	Sofradim, Trévoux, France
Polypropylene with Carboxymethylcellulose-Sodium Hyaluronate Coating	SepraMesh	Genzyme Biosurgery, Inc., Cambridge, MA, USA
Titanium-Polypropylene Composite	Timesh	GfE Medizintechnik GmbH, Nürnberg, Germany
Bovine Pericardium	TutoMesh	Tutogen Medical GmbH, Neunkirchen a. Br., Germany
Polypropylene-Polydioxanone Composite with Oxidised Cellulose Coating	Proceed	Ethicon, Inc., Somerville, NJ, USA

Table 1. Meshes included in the experiment

Procedure

The experiment was performed under aseptic conditions, using a modification of a validated rat-model, previously described by Alponat and Hooker [24, 25]. At the start of the experiment the animals were anaesthetised using isoflurane/N2/O2 inhalation and buprenorfin analgesia (0.05 mg/kg subcutaneously). The abdomen was shaved and cleaned with alcohol 70%,

after which a midline skin incision of 5 cm was made and skin flaps were raised. Subsequently, the abdominal cavity was opened with a 4 cm midline incision through the linea alba. A sterile mesh, measuring 2.5 x 3.5 cm, was placed in a sublay position (intraperitoneally) and fixated transmuscularly with 6 sutures (polypropylene 5-0). The abdominal wall was closed over the mesh with a running 5-0 polypropylene suture. The skin was closed with a running 5-0 polyglyconate suture.

Measurements

Adhesion formation

After 7 (group A) or 30 days (group B) the animals were anaesthetised and killed by cardiac incision. The ventral abdominal wall was removed through a full thickness incision (including skin) around the mesh. Adhesions were cut and the abdominal wall, including mesh, was removed. Two independent observers assessed adhesion coverage of the surface of the mesh, using a scoring system. A grid was placed over the mesh, dividing it into 24 equal squares, facilitating accurate estimation of adhesion formation. In case of inter-observer variance, the mean was scored.

Incorporation

The edge of the mesh was divided into twenty equal stretches. Mesh incorporation was defined as the percentage of the edge of the mesh that was incorporated in the abdominal wall. Incorporation was scored by two independent observers. In case of inter-observer variance, the mean was scored.

Tensile strength

The tensile strength of the tissue that adhered to and incorporated the mesh was measured on a dynamometer. Half of the mesh was freed from the abdominal wall, while the other half of the mesh remained attached to the abdominal wall. The first half of the mesh, which was freed from tissue, was fixed in a clamp. The abdominal wall lateral to the second half of the mesh, which was still attached to the abdominal wall, was fixed in a second clamp (Figure 1). The mesh was pulled from the abdominal wall at a continuous rate

of 100 mm/min. The maximum force (N) required to release the mesh from the abdominal wall was recorded.

Figure 1. Tensile strength of the tissue that adhered to and incorporated the mesh was measured on a dynamometer

Mesh shrinkage

Mesh shrinkage was defined as the projection of mesh surface and was measured with a calliper by two independent observers. By measuring projection, curling and wrinkling of the mesh were included in addition to actual shrinkage of the mesh. Shrinkage was defined as the relative loss of surface compared to the original size of the mesh (%).

Mesh infection

Mesh infection was defined as the presence of pus or infected seroma at the time of sacrifice. Cultures were taken only when these symptoms of overt infection were present

Tissue response

Of each group, two meshes with adjacent abdominal wall were fixed in 10% neutral buffered formalin. After routine tissue processing, sections were cut and stained with haematoxylin & eosin. Sections were microscopically studied at a 250x magnification. The degree of inflammation was scored using a grading scale. Grade 1 represents mild inflammatory reaction with giant cells, occasional lymphocytes and plasma cells. Grade 2 represents moderate reaction with giant cells and increased numbers of admixed lymphocytes, plasma cells, eosinophils and neutrophils. Grade 3 represents severe inflammatory reactions with micro-abscesses.

Statistical analysis

The incidence of direct bowel adhesions and mesh infection was compared using Fisher's exact test. Comparison of adhesion formation, incorporation, tensile strength and shrinkage was compared using a one-way ANOVA, after a normal distribution and homogeneity were ascertained. A p-value smaller than 0.05 was considered significant. Statistical analysis was performed using SPSS statistical software package (SPSS®, Chicago, Illinois, USA).

Results

During the procedure, one rat in the Prolene group (7 days) and one rat in the Proceed group (30 days) died. The cause of death was probably anaesthesia related. During the postoperative period one rat from the Ultrapro group (30 days) died. Autopsy did not reveal the cause of death.

Adhesions

At seven days, Tutomesh resulted in the smallest percentage of mesh surface covered with adhesions (2.4%). Tutomesh resulted in significantly less adhesion formation than all other meshes, except Parietex Composite (3.9%). Other meshes that showed a decrease in adhesion formation were Sepramesh (25.1%) and Proceed (33.6%). Prolene, Dualmesh, Ultrapro and Timesh showed extensive adhesion formation 7 days postoperatively (Table 2).

At 30 days, Tutomesh showed the least adhesions formation (4.4%). There was no significant difference between Tutomesh, Parietex Composite (11.2%) and Sepramesh (10.4%). Most adhesions were seen in the Prolene group (54.1%). However, there was no significant difference between Prolene, Ultrapro (45.2%), Timesh (44.5%) and Proceed (38.5%) (Table 3).

	Coverage (%)	Prolene	Dual-Mesh	Ultra-pro	Parietex Comp.	Sepra-Mesh	Ti-mesh	Tuto-Mesh	Proceed
Prolene	55,2	-	1	1	<0.001	0.002	1	<0.001	0.081
DualMesh	66,3	1	-	1	<0.001	<0.001	1	<0.001	0.001
Ultrapro	57,9	1	1	-	<0.001	<0.001	1	<0.001	0.019
Parietex Composite	3,9	<0.001	<0.001	<0.001	-	0.094	<0.001	1	0.001
SepraMesh	25,2	0.002	<0.001	<0.001	0.094	-	<0.001	0.049	1
Ti-mesh	60,3	1	1	1	<0.001	<0.001	-	<0.001	0.006
TutoMesh	2,4	<0.001	<0.001	<0.001	1	0.049	<0.001	-	0.001
Proceed	33,6	0.081	0.001	0.019	0.001	1	0.006	0.001	-

Table 2. Adhesion coverage of mesh surface at day 7 (%)

	Coverage (%)	Prolene	Dual-Mesh	Ultra-pro	Parietex Comp.	Sepra-Mesh	Ti-mesh	Tuto-Mesh	Proceed
Prolene	54,1	-	0.009	1	<0.001	<0.001	1	<0.001	0.567
DualMesh	29,3	0.009	-	0.585	0.260	0.160	0.687	0.009	1
Ultrapro	45,2	1	0.585	-	<0.001	<0.001	1	<0.001	1
Parietex Composite	11,2	<0.001	0.260	<0.001	-	1	<0.001	1	0.002
SepraMesh	10,4	<0.001	0.160	<0.001	1	-	<0.001	1	0.001
Ti-mesh	44,5	1	0.687	1	<0.001	<0.001	-	<0.001	1
TutoMesh	4,4	<0.001	0.009	<0.001	1	1	<0.001	-	<0.001
Proceed	38,5	0.567	1	1	0.002	0.001	1	<0.001	-

Table 3. Adhesion coverage of mesh surface at day 30 (%)

Mesh incorporation

At 7 days, the percentage of mesh edge incorporated was highest for Parietex Composite (75%). Dualmesh (29%, $p<0.001$), Timesh (34%, $p<0.001$) and Tutomesh (2%, $p<0.001$) showed significantly less incorporation, while there was no significant difference between Parietex Composite (75%), Prolene (60%), Ultrapro (56%), Sepramesh (54%) and Proceed (49%) (further data not shown). At 30 days, Parietex Composite still showed the most incorporation, although this percentage had decreased to 49.8%. There was no significant difference between Parietex Composite, Prolene, Ultrapro and Sepramesh.

Dualmesh, Timesh, Tutomesh and Proceed showed significantly less incorporation (Table 4).

	Incorporation (%)	Prolene	Dual-Mesh	Ultra-pro	Parietex Comp.	Sepra-Mesh	Ti-mesh	Tuto-Mesh	Proceed
Prolene	34.7	-	1	1	0.354	1	1	<0.001	1
DualMesh	24.3	1	-	1	0.001	0.048	1	0.115	1
Ultrapro	34.7	1	1	-	.423	1	1	<0.001	1
Parietex Composite	49.8	0.354	0.001	0.423	-	1	0.004	<0.001	0.027
SepraMesh	43.3	1	0.048	1	1	-	0.115	<0.001	0.583
Ti-mesh	26	1	1	1	0.004	0.115	-	0.048	1
TutoMesh	7	<0.001	0.115	<0.001	<0.001	<0.001	0.048	-	0.005
Proceed	29.7	1	1	1	0.027	0.583	1	0.005	-

Table 4. Incorporation of mesh edge at 30 days (%)

Tensile strength

At 7 days, the highest tensile strength was seen in the Prolene group (11.7N). However, there were no significant differences between the meshes. At 30 days, Parietex Composite showed the highest tensile strength (14.2N), but there were no significant differences with Prolene (11.9N), Ultrapro (12N), Sepramesh (13.4N), Timesh (10.2N) and Proceed (11.8N). Only Dualmesh (6.2N, $p=0.035$) and Tutomesh (2.8N, $P<0.001$), showed significantly lower tensile strength (further data not shown).

Shrinkage

Ultrapro showed the least loss of mesh surface at 7 days (1.52%). There were few significant differences between most groups: only Dualmesh (45.9%) and Tutomesh (16%) showed significantly more shrinkage than all other meshes. At 30 days, Sepramesh showed the least shrinkage (7%), but this was not significantly different from that in Prolene (11.3%), Ultrapro (11.7%), Parietex Composite 15.3%), Timesh (16.9%) and Proceed (13.1%). Only Tutomesh (44.3%, $p<0.001$) and Dualmesh (44.2%, $p<0.001$) resulted in significantly

more shrinkage than all other meshes (further data and p-values not shown for reasons of conciseness).

Tissue response

Histological evaluation of the meshes showed a grade 1, mild foreign body reaction to almost all meshes with limited numbers of giant cells and lymphocytes present. Only Dualmesh and Parietex Composite elicited grade 2 responses, with numerous giant cells. For Parietex Composite, this reaction was located at the abdominal wall side of the mesh and not at the visceral side.

Infection

Mesh infection was a rare occasion. Only one infection was observed, in a Sepramesh rat (30 days) (NS). Non-infected seromas were found in 4 Proceed animals and 2 Timesh animals.

Discussion

Our study shows that Parietex Composite and Sepramesh currently are the best options for open hernia repair in which contact with abdominal viscera cannot be avoided and for laparoscopic hernia repair. This is evidenced by our results that showed that both meshes resulted in a significant decrease in adhesion formation and increased mesh incorporation and tensile strength. Furthermore, both meshes did not result in increased shrinkage or susceptibility to infection. Two new meshes that were specifically designed for intraperitoneal use and were introduced recently, did not show a decrease in adhesion formation or increased incorporation and tensile strength. Therefore, these two meshes do not seem to provide an improvement to meshes already available.

The most surprising result of the current study is the disappointing performance of several meshes that were specifically designed for intraperitoneal use (Dualmesh, Timesh, Proceed). Several studies reported a decrease in adhesion formation after use of these meshes [26-31]. However, other results are in line with ours [32,33]. Why the performance of Dualmesh and

Timesh compares poorly with that in other reports cannot be concluded from this study. However, the current study was performed using a validated model and the study-size compared well with similar studies. Furthermore, no adverse events were encountered during the experiment.

The ideal design of a mesh that prevents adhesion formation and promotes incorporation and tensile strength probably complies with basic rules. The visceral side of the mesh should be smooth, non-erosive, anti-adhesive and should not be easily susceptible to infection. This visceral barrier should be present for at least one week, because this is the timeframe in which adhesion formation takes place [34]. The ventral side of the mesh should be macroporous, allowing for fibroblast ingrowth, while a foreign body reaction may actually be necessary for incorporation and high tensile strength. Continued severe inflammation on the other hand may actually decrease mesh incorporation and tensile strength [35].

Of those meshes studied, Prolene and Ultrapro meet the fewest requirements. Although the results for both meshes serve as control only in this study, they confirm that intraperitoneal placement of these meshes results in increased adhesion formation. However, neither of both meshes was designed for intraperitoneal use and high tensile strength and extensive tissue incorporation were confirmed. Moreover, mesh shrinkage was negligible and no mesh infection was seen. Dualmesh has been reported to prevent adhesion formation, mainly because of its smooth visceral surface [30]. This could not be confirmed in the current study. We hypothesize that the material e-PTFE results in adhesion formation, despite a non-erosive microporous surface. Furthermore, the macroporous ventral side of the mesh, which is designed to initiate incorporation, did not succeed in doing so. Shrinkage and curling of the mesh were extensive and were probably caused by extensive adhesion formation. The pronounced foreign body reaction to e-PTFE, which has been described previously, may be the cause of both adhesion formation and shrinkage [27, 36]. Parietex Composite's collagen coating and Sepramesh's cellulose-hyaluronate coating appear to be effective adhesion barriers. While these barriers are absorbed within several weeks, both meshes showed

minimal adhesion formation at 30 days post operation. Parietex Composite and Sepramesh also scored well with regard to incorporation and tensile strength, while there was no increased incidence of infection. Timesh was designed specifically for intraperitoneal use, but did not perform well in the current study. Timesh is a composite mesh in which polypropylene is coated with inert titanium. The fact that there was extensive adhesion formation after implantation of Timesh suggests that the inertness of the mesh material is of less importance in adhesion formation than the macrostructure of the mesh. In the case of Timesh, the macrostructure is rough and macroporous. This erosive structure is probably what causes adhesion formation. Tutomesh has an impressive anti-adhesive capability, which is probably caused by both a smooth surface and very mild foreign body reaction. However, these properties result in the near absence of incorporation and low tensile strength. Proceed composite has a smooth surface designed to prevent adhesion formation. However, it is less smooth than that of other composite meshes with anti-adhesive barriers. Furthermore, the barrier applied is oxidized cellulose, which may not prevent mesh adhesions as effectively as anticipated, as was reported previously [37]

All meshes were evaluated after 7 days and after 30 days after implantation. The reason for this dual assessment was the fact that these two time points represent different phases of wound healing. At 7 days, the inflammatory phase has just ended and the proliferative phase has just started. According to Baptista et al, all adhesions have formed now [34]. After 30 days, the proliferative phase has ended and the remodelling phase has started. It is to be expected that neoperitoneum has formed and has covered the prosthetic material. Our results show that in general the number of adhesions decreased at 30 days compared to 7 days. Parietex was an exception. The slight increase in adhesion formation may be caused by the absorption of the cellulose film on the visceral side. This, however, contradicts Baptista's assumption that all adhesions form within seven days. The tensile strength was recorded as a comparative measure and reflects tissue incorporation, tissue response and remodelling of the tissue response. Although the remodelling phase, and therefore collagen formation, has only just begun at

30 days post surgery, a small effect is already discernable, resulting in increased tensile strength at 30 days compared to 7 days. Shrinkage was more pronounced after 30 days compared to 7 days and was probably caused by contraction, inherent to the proliferative wound healing phase.

We conclude that several of the meshes that are currently available perform well with regard to tissue incorporation, tensile strength, mesh shrinkage and mesh infection. Our study identifies two meshes that combine these beneficial properties with decreased adhesion formation. We therefore recommend use of these meshes, either Parietex Composite or Sepramesh, when the mesh is placed in direct contact with the abdominal viscera.

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Chapter 8 - Persistent deformation of meshes used in abdominal wall repair, an experimental study

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Introduction

Repair of inguinal, incisional and umbilical hernias is best achieved through the insertion of prosthetic mesh [1-4]. Surgical meshes used in endoscopic and open hernia repair are available in different synthetic materials such as polyester, polypropylene and composite materials. Furthermore, meshes are produced in different mesh ultra structures of which a knitted structure is the most common. Knitted textiles consist of fibres and are composed entirely of horizontal, parallel courses of these fibres. Courses are joined to each other by interlocking the loops of one course by wrapping the fibre over the bight (loop) of the adjacent course. The direction of the interlocking loops is generally called “wale”. Manufacturers of meshes suggest to have achieved specific properties by altering the knitting pattern. A variety of meshes with characteristics such as thickness, pore size, tensile strength, flexural rigidity and surface texture have been put on the market in recent years. The United States Food and Drug Administration (FDA) has issued a guidance document discussing performance of surgical meshes [5]. Besides biocompatibility, also mechanical properties such as rigidity and deformation are described.

In endoscopic totally extraperitoneal (TEP) inguinal hernia repair the oval or rectangular mesh, measuring up to 15 by 15 cm, is commonly rolled up to fit into a 10 mm trocar, passed into the preperitoneal space and then positioned in such a fashion that the myopectineal orifice of Fruchaud is fully covered [6-8]. Meshes are also utilized in laparoscopic incisional hernia repair were introduction of a mesh through a trocar and subsequent placement is mandatory to achieve the desired repair [9, 10].

It has been suggested that endoscopic totally preperitoneal inguinal hernia repair is associated with a learning curve of 250 procedures [11,12]. The factors causing frustration during, for instance, TEP procedures have been described by Kaaferani et al. Intra-operative frustration levels are based on anatomy, personnel, material and instruments and are found to be a predictor for inguinal hernia recurrence [13]. Taking into account that ultrastructural issues (like textile “memory”) are related to the direction of folding (roling) and unfolding (unroling), part of this frustration could be easily avoided.

The ASTM (American Society for Testing and Materials) has released protocols to determine textile specific properties such as flexural rigidity and wrinkle resistance previously. To date, however, no study has been performed to investigate the degree of persistent deformation of mesh prosthesis after introduction through the cannula as in endoscopic hernia repair procedures. In this study the rate of persistent deformation of various commercially available meshes was assessed experimentally.

Materials and Method

In an experimental setting we quantitatively compared the degree of deformation after folding/rolling of the most common polypropylene, polyester and composite meshes (BardMesh, Prolene, Premilene, TiMesh (16 and 35 gr.), Ultrapro, Vypro, Vypro II, Parietex Composite and Parietex 2D; table 1 and 2).

Trade name	Produced by	Material(s)	Additional information
Prolene	Johnson & Johnson (Ethicon)	PPE	monofilament
Bard Mesh	Davol (Bard)	PPE	monofilament
Premilene	B.Braun (Aesculap)	PPE	monofilament
TiMesh 16 TiMesh 35	GfE Medizintechnik	PPE	monofilament titanium coating
Ultrapro	Johnson & Johnson (Ethicon)	PPE Poliglecapron 25	monofilament

Table 1. Polypropylene meshes (PPE)

Trade name	Produced by	Material(s)	Additional information
Vypro	Johnson & Johnson (Ethicon)	PPE Polyglactine 910	multifilament
Vypro II	Johnson & Johnson (Ethicon)	PPE Polyglactine 910	multifilament
Parietex 2D	Florean (Sofradim)	Polyester	multifilament
Parietex Composite	Florean (Sofradim)	Polyester	multifilament collagen-PGG coating

PPE = Polypropylene, PGG = polyethylene glycol-glycerol, Polyglactine 910 = Vicryl

Table 2. Composite and polyester meshes

All experiments were performed at 37º Celsius, using a heat exchanger which was kept at a constant surface temperature of 37º Celsius utilizing a Proportional Integral Derivative (PID) thermostat (CAL 3300, CAL Controls Ltd. Herts, United Kingdom) and K-type thermocouple. The heat exchanger surface temperature and ambient temperature of the transparent polycarbonate surface (3mm thickness) was additionally monitored using an auxiliary digital thermometer (Siemens Medical Systems Monitor, Erlangen, Germany).

All meshes were kept in a 10 mm trocar for 10 seconds after rolling, to mimic the situation encountered in endo-/laparoscopic hernia surgery prior to introduction into the abdominal cavity or the pneumo-preperitoneum. Consequently one end of the mesh was clamped onto the heat exchanger table and the other released to unfold (Figure 1). The meshes were kept moist through spray application of 0.9% NaCl solution (saline) mist.

To determine the length unfolded, the projection plane of the mesh onto the heat exchanger (P) was used (Figure 1).

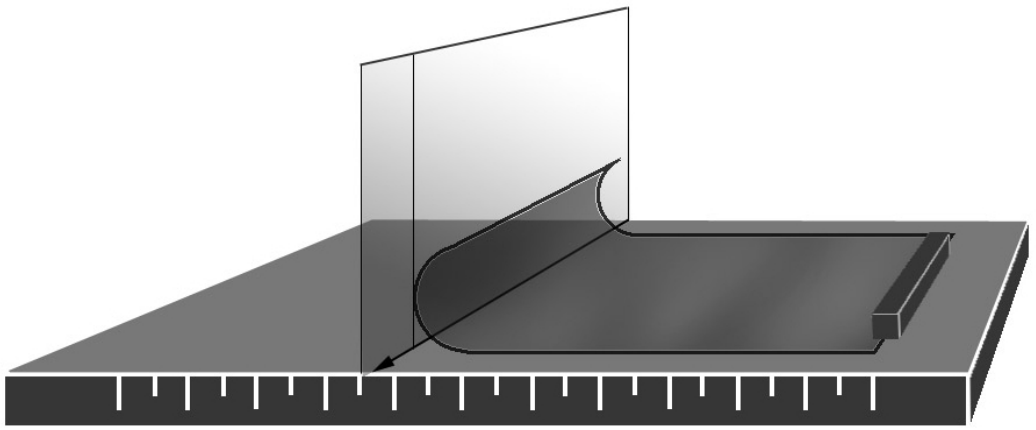

Figure 1. Schematic of experimental setup

The initial length of the mesh measured was defined as (L). Unfolding (U= ($^{P}/_{L}$)*100) was expressed as the percentage of initial mesh length (L) unfolded (P) at various time points. Time points chosen to evaluate unfolding were t=5, 10 and 15 minutes. Persistent deformation (D_p, expressed as percentage) was defined as 100-U and was also evaluated in relation to the direction of folding of the mesh; length or width. As mentioned previously the row of loops in the longitudinal direction is referred to as “wale” whereas the row of knit loops in the width direction is named the “course”. Lengthwise rolling was defined as rolling parallel to the “course” direction whereas rolling in width direction was defined as being perpendicular to the “course” direction (parallel to wale). A total of 12 different mesh samples were tested, each mesh was tested six times per direction.

Data collection and statistical analyses

Data were collected in a database and statistical analyses were performed using Statistical Package for Social Sciences for Windows (SPSS Inc., Chicago, IL., USA).Analysis of variance (ANOVA) was used to compare the mean deformations between the different types of mesh utilizing a Bonferroni post-test. Mean differences between deformation after length and width rolling in one type of mesh were analysed using a two-sided unpaired Student’s t-test. A p-value of 0.05 or less was considered statistically significant.

Results

Three meshes showed significantly lower persistent deformation when “rolled in one direction” was compared with “rolled in the other direction”. Prolene mesh, rolled in length direction, exhibited persistent deformation of 44% of initial mesh length compared to 16.7 % deformation in width direction ($p<0.01$; Table 3).

Trade name	Persistent deformation (D_p) in percent ± sd (Ranking) **Length (cm)**	Persistent deformation (D_p) in percent ± sd (Ranking) **Width (cm)**	Number of samples	p-value student’s t-test
Prolene	44.0 ± 0.89 **(10)**	16.7 ± 0.5 **(10)**	6	<0.01
Bard Mesh	16.3 ± 6.4 **(9)**	7.9 ± 3.9 **(6)**	6	<0.05
Premilene	9.5 ± 5.3 **(6)**	14.2 ± 1.7 **(9)**	6	Ns
TiMesh 16	12.0 ± 2.8 **(8)**	12.7 ± 0.9 **(8)**	6	Ns
TiMesh 35	11.5 ± 3.5 **(7)**	11.3 ± 0.9 **(7)**	6	Ns
Ultrapro	0.8 ± 1.2 **(1)**	0.9 ± 0.05 **(1)**	6	Ns
Vypro	4.0 ± 1.4 **(4)**	4.7 ± 0.9 **(4)**	6	Ns
Vypro II	4.4 ± 2.5 **(5)**	2.1 ± 1.1 **(3)**	6	Ns
Parietex 2D	1.0 ± 0.2 **(2)**	5.3 ± 1.3 **(5)**	6	<0.001
Parietex Composite	1.1 ± 0.2 **(3)**	1.1 ± 0.2 **(2)**	6	Ns

Table 3. Persistent deformation (mean of 6 samples) of polypropylene, composite and polyester meshes; length versus width

The measured deformation of 44% was the overall largest persistent deformation of the meshes under investigation (significantly larger than any other mesh $p<0.01$, the largest deformation in length direction was also found for Prolene (16.7% of initial length) which was significantly larger than all other deformations ($p<0.01$) with the exception of Premilene (14.2% deformation). BardMesh displayed similar properties with deformation in length direction

being significantly greater than in width direction (16.3% and 7.9% respectively; $p<0.05$).

The only non-polypropylene (multifilament polyester) mesh to show signs of different persistent deformation between length and width direction was presented by Parietex 2D mesh with 1% in length and 5.3% in width direction respectively ($p<0.01$; Table 3).

The least mean deformation in width and length direction was found for Ultrapro mesh (0.8% and 0.9% respectively) (Figure 2).

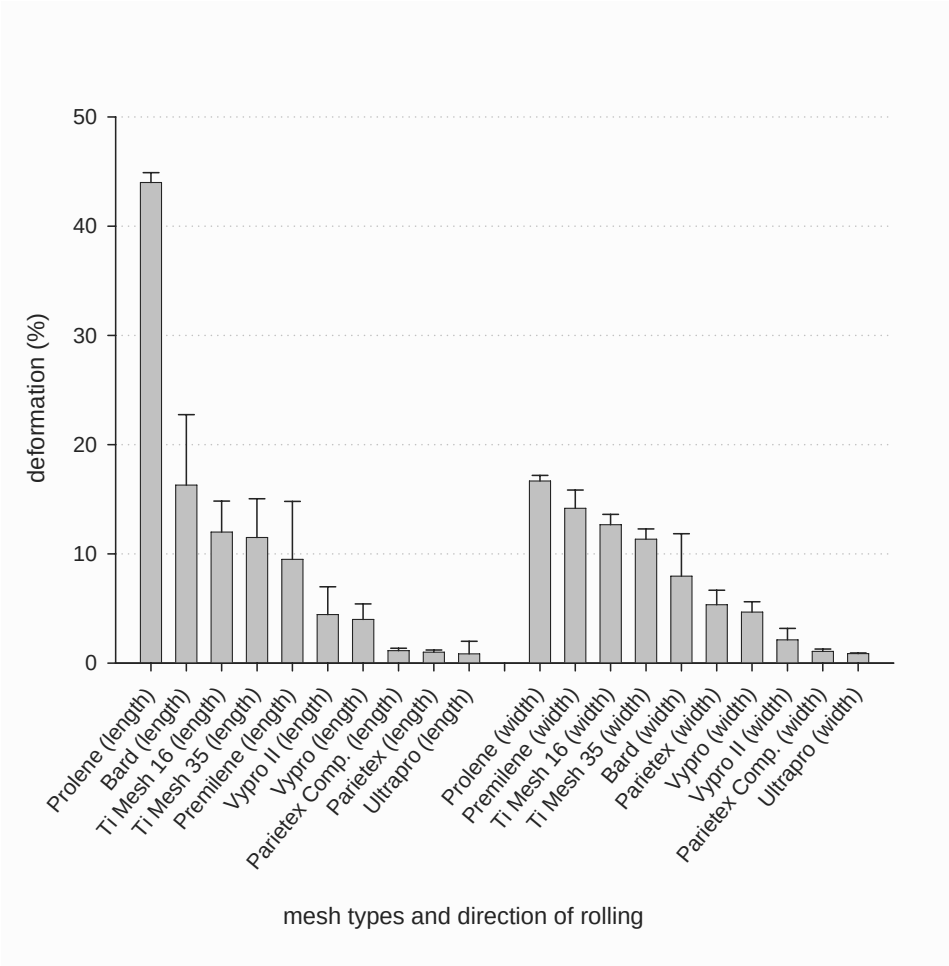

Figure 2. Percentage deformation of meshes (high to low) according to direction of rolling

No statistically significant differences in persistent deformation were found for the different time points evaluated for all meshes (data not shown).

Discussion

Previously studies investigating the properties of surgical mesh prosthesis focused largely on biocompatibility [14-17]. Recently studies have been published dealing with the properties of mesh as a textile rather than prosthesis to be implanted into the abdominal wall. A study by Kes et al. evaluated the degree of protrusion of different meshes when interfaced with biological tissue in a porcine model of abdominal wall repair [18]. Knook et al. in the same porcin model, experimentally investigated the minimum overlap necessary in order to prevent dislodging of the mesh [19]. The earliest investigation of surgical mesh as a textile dates back to 1985 when Chu et al. investigated the properties of Mersilene, Marlex and Teflon mesh [20]. The measurements performed included flexural rigidity and wrinkle resistance, which are both common tests to characterize textiles. The results show that Mersilene as well as Marlex exhibit a marked difference in measured flexural rigidity between wale and course direction. These results are congruent to our results in the way that we have also found a marked difference in persistent deformation for polypropylene and polyester meshes Parietex 2D, Prolene and BardMesh (previously known as Marlex).

Scheidbach et al. assessed the endoscopic handling properties of different meshes through measurement of operative time, amount of CO_2 used and time required for mesh placement in a study of biocompatibility [21]. The finding of this study was that Vypro II was more difficult to handle than Atrium, Parietene and TiMesh 16 requiring 83.6 seconds for mesh placement compared to 53.2 seconds for Atrium mesh.

Parietene and TiMesh were both associated with significantly shorter placement times. This corresponds in part with our observations that TiMesh exhibits a lower persistent deformation compared to Prolene. The observation of Scheidbach and collegues that Vypro II requires significantly longer placement time is not consistent with a low persistent deformation of the mesh in wale and course direction. The placement time of a mesh may be dependent on the rigidity and wrinkle recovery of the textile as well as on the experience of the surgeon.

Intraoperative frustration through difficulty with anatomical landmarks, personel, materials and instruments is described to be a predictor for inguinal hernia recurrence. Frustration levels were found to be strongly related to the occurrence of intra-operative complications. As the principal cause for their frustration surgeons indicated the anatomy of the patient being the reason. As efficient mesh position is dependent on exact identification of the hernia defect, mesh deformation will also hamper visualization of the operation field. The least mentioned source of frustration was technical problems. Further analysis revealed that procedures in which the surgeons were described as being frustrated took significantly longer than procedures in which surgeons remained un-frustrated (30 minutes longer in laparoscopic repair and 18 minutes longer in the open repair) [13].

In an experimental setting the persisting deformation (D_p) of various meshes after simulating introduction into the pre-peritoneal space or abdominal cavity through a 10 mm canula was investigated as a realistic model of mesh behaviour. From the experiment it becomes clear that persistent deformation of meshes is largely dependent on the material (polypropylene or polyester), the fibre (mono- and multifilament) and the direction of rolling (parallel to course or wale).

Conclusion

Until now little consideration has been given to the different mechanical characteristics of different mesh products when choosing mesh prosthesis for hernia repair. Attention to mesh properties and selection of appropriate mesh can simplify the mesh placement procedure in endo- and laparoscopic hernia surgery. Arguably, frustration levels can rise if inguinal hernia repair is accompanied by technical problems, such as persistent deformation of the mesh.

Especially in totally endoscopic preperitoneal inguinal hernia surgery (TEP), in which as a rule the mesh is not fixated by tackers to avoid nerve damage, persistent mesh deformation will negatively alter the intended coverage of the hernia defect with concomitant recurrence.

Furthermore, marking the direction of easiest unfolding is a simple yet effective way to help surgeons optimising laparoscopic surgical procedures, reducing operative time and frustration level.

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PART 5 - MESH USE IN COMMON ABDOMINAL WALL HERNIAS

“There is a computer disease that anybody who works with computers knows about. It's a very serious disease and it interferes completely with the work. The trouble with computers is that you 'play' with them!”

Richard P. Feynman

Chapter 9 - Long-term follow-up after umbilical hernia repair: are there risk factors for recurrence after simple and mesh repair

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Published Hernia

Introduction

Adult umbilical hernia is a common surgical condition mainly encountered in the fifth and sixth decade of life [1, 2]. Ninety percent of all adult umbilical hernias are acquired [3]. For the majority of the symptomatic and asymptomatic umbilical hernias, repair is proposed. Especially so since incarcerated umbilical hernias are reported to be responsible for 13% of all incarcerated hernias and that in one fifth of all incarcerated umbilical hernias a bowel resection is required [4]. Surgical repair may be achieved through double-breasting (Mayo repair) [5], simple suture repair and the use of mesh. Despite the frequency of the umbilical hernia repair procedure, disappointingly high recurrence rates, up to 54% after simple suture repair, have been reported [6]. For the Mayo repair, recurrence rates of up to 40% and 54% have been documented in the literature for umbilical hernias and incisional hernias respectively [7, 8].

More recently recurrence rates of 1% are reported for mesh repair from the first and so far only randomised controlled trial of mesh versus suture repair [9]. From this trial it was concluded and heralded that, the use of a mesh prosthesis in hernias of all diameters is thought to become the standard in umbilical hernia repair [9, 10]. Prior to following the claims laid down in the international literature one should be aware of ones own institutional results. Furthermore risk factors for recurrence and thus indicators for more solid repairs, using mesh for instance, are not unequivocally defined.

Since both mesh and suture techniques are used in our clinic we set out to investigate the respective recurrence rates and associated complications retrospectively.

To this end we reviewed all cases of umbilical hernia repair performed in a teaching Hospital in The Netherlands between January 1998 and December 2002.

Patients and Methods

Study population

Patients were identified from hospital record procedure codes. Case notes, records and operative reports were obtained and the use of prosthetic material, surgeon/resident, surgical site infection, body mass and height as

well as recurrence was recorded at the time of survey. Patients were invited to attend the out patient department for an extra follow-up, history taking and physical examination. Between January 1998 and December 2002 the choice for mesh-assisted or suture hernia repair was left to the surgeon performing or supervising the procedure. Antibiotic prophylaxis was not administered routinely. All meshes were placed in the pre-peritoneal plane. Overlap, fixation and mesh shape were variable. Routine follow-up consisted of a simple outpatient department appointment or as dictated by the postoperative course.

Statistical analysis

Statistical analyses were performed using Statistical Package for Social Sciences for Windows (SPSS Inc., Chicago, Illinois). A Fisher's exact test was performed to compare recurrence rates between mesh and non-mesh repair as well as hernia recurrence in the obese and non-obese population. Means were compared using an unpaired t-test. A p-value of 0.05 (two-sided) was considered the limit of significance in all analysis.

Results

Study population

Over the aforementioned period 131 consecutive patients underwent operative repair of an umbilical hernia. Twenty-eight per cent of the patients were female (n=37). The patients mean age was 57 years (range 21-85 years). All but two patients underwent surgery under general anesthesia (98%). One patient was treated with an emergency procedure for an incarcerated umbilical hernia. Hundred-ten patients (83%) underwent a follow-up physical examination after a median follow-up period of 32 months (range 10-67 months) for this study. A total of twenty-one patients (17%) were lost to follow-up (Table 1A) and the BMI of one patient was lost to follow-up. The average Body Mass Index (BMI) of our population was found to be 27 kg/m^2. All further observations are based on the 110 patients that underwent physical examination by two authors (J.H., J.H.).

A. Patient characteristics	
Total number of patients	131
Male Female ratio	2.5:1
Mean age in years (range)	56.7 (21-85)
Patients lost to follow-up	21 (17%)
Patients followed-up	110 (84%)
Mesh / non-mesh repair	12 / 98
Median follow-up period in months (range)	32 (10-67)
B. Complications	
Superficial incisional surgical site infection	9 (8%)
Discomfort in umbilical region	4 (4%)
Pain in umbilical region (in rest or during exercise)	3 (3%)
C. Recurrence	
Recurrence after mesh repair	0/12 (0%)
Recurrence after simple suture repair	14/98 (14%) p=0.4
Overall recurrence	14/110 (13%)
Patients with BMI >25 kg/m^2 and hernia recurrence [a]	12/67 (18%)
Patients with BMI <25 kg/m^2 no hernia recurrence [a]	2/42 (5%)
Median time to hernia recurrence in months (range)	28 (16-62)
[a] The BMI of one patient was lost to follow-up	

Table 1. Patient characteristics, complications and hernia recurrence

Surgical aspects

In 12 patients (11%) reconstruction of the umbilical defect was achieved through the use of prosthetic mesh implantation. In all instances a flat polypropylene mesh was utilized. The remaining patients (n=98, 89%) underwent hernia repair through fascia adaptation or Mayo reconstruction.

Forty-two of 110 hernia repairs were performed by surgeons; the remainder by surgical residents (62%). The predominant types of incisions were infra- (77%) and supraumbilical (13%). Other types of incisions (longitudinal, umbilical and previous cicatrix) accounted for the remainder (10%). To our

disappointment the diameter of the hernia defect was only noted in 8 percent of all operative notes.

Complications

Nine patients (8%) were found to have developed a superficial incisional surgical site infection. Of these nine patients none had received mesh prosthesis. One patient required incision and drainage of pus. All other patients responded well to appropriate oral antibiotics. Haematoma and seroma have not been noted. A total of 17 patients received a low vacuum drain for the post-operative period (15%). No relationship was found between wound infection and umbilical hernia recurrence. Four patients complained of discomfort in the umbilical region during follow-up (4%). One and two patients (3%) complained of persisting pain in rest or during exercise respectively (Table 1B).

Recurrence

A total of 14 umbilical hernia recurrences were noted (13%) of which 8 were new discoveries during the follow-up physical examination (57%). All recurrences occurred in patients who had undergone suture repair. No statistically significant difference was found between mesh and suture repair (p=0.4). The interval between primary surgery and hernia recurrence ranged between 16 and 62 months with a median of 28 months (Table 1C). Residents and surgeons had both operated half of the patients with an umbilical hernia recurrence respectively (p=0.4). Of 13 patients complaining about protrusion in the umbilical region during this studies follow-up, four were found to have a recurrence (31%). These recurrences were noted during Valsalva's maneuver as a part of extended physical examination in supine and upright position.

The average BMI for patients with (28.4 kg/m^2) or without (26.8 kg/m^2) recurrence did not differ significantly (p=0.6). In the group of patients with a BMI over 25 kg/m^2 (overweight or obese) 12 out of 67 (18%) developed a hernia recurrence compared to 2 out of 42 (5%) in the group of patients with a BMI under 25 kg/m^2 (n.s.).

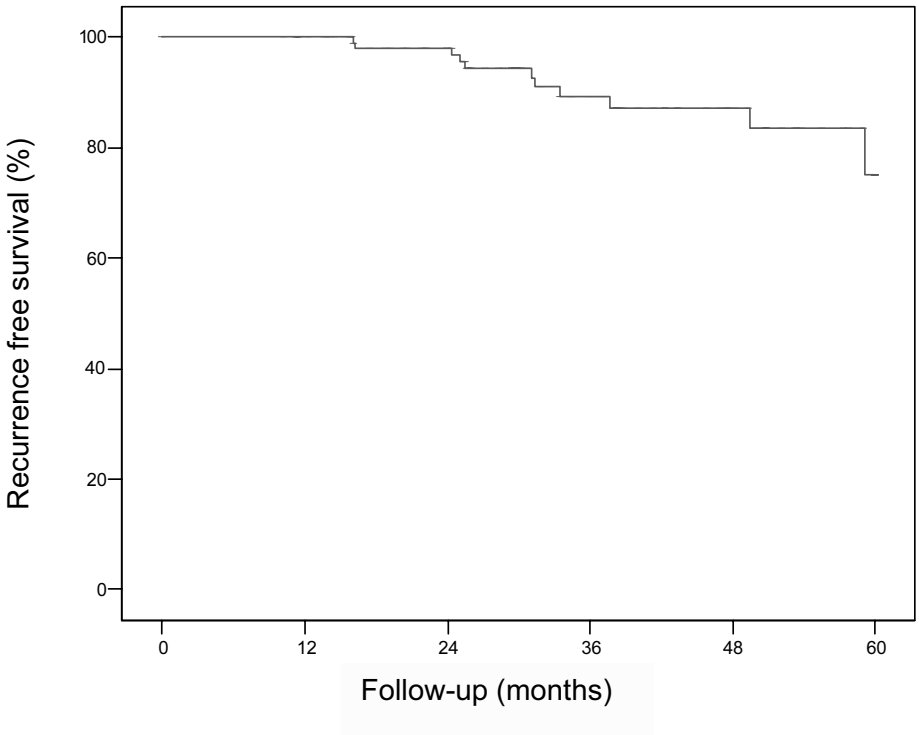

Figure 1. Recurrence free survival

Discussion

In this study we found a favourable overall recurrence rate of 13% in 110 consecutive patients having undergone surgical repair of an umbilical hernia in our clinic, which is specialized in abdominal wall surgery. Prior to this study the outcome of umbilical hernia surgery in our clinic was unknown or limited to the anecdotal “evidence” of senior surgeons.

To our surprise the recurrence rates were favourable and much more so than we had expected. After all, our results approach the results of the randomised controlled trial published by Arroyo and colleagues [9] for suture as well as mesh repair. In addition Schumacher et al. [6] reports an overall recurrence rate of 13% after suture repair in a specialized hernia repair center regardless of BMI or hernia diameter at a median follow-up of 30 months which seems to concur well with our findings.

Previously Bowley and Kingsnorth [11] have published data on 473 adult umbilical hernia repairs (393 suture repairs and 80 (17%) mesh repairs) of which 18 patients (4%) were re-operated for a recurrence (two patients from the mesh repair and 16 patients from the suture repair group). Unfortunately not all patients were invited to visit the outpatient clinic for a follow-up visit, which makes a comparison to our recurrence rates difficult and assessment impossible. Since 8 of the 14 hernia recurrences in our series were diagnosed during the follow-up visit and had gone unnoticed by the patients we feel that follow-up physical examination is of utmost importance when evaluating the results of hernia repair. Recently a ten-year follow up of patients having undergone incisional hernia repair [12] showed a marked increase in hernia recurrence, for mesh and suture repair alike, when compared to data gathered 5 years earlier [13].
The rate of wound infections (8%) found in our series is in accord with the available literature [6, 9, 14-16]. The same holds true for complaints of discomfort (4%) and persisting pain in rest or during exercise (3%) in the umbilical region. In this series we could not establish an association between wound infections and an increased recurrence rate as mentioned in textbooks.

Schumacher et al. [6] have described a significantly increased recurrence rate of 31.8% in obese patients with a BMI over 30 kg/m^2. Of the patients with a BMI > 30 kg/m^2 half were found to also have an abdominal wall defect larger than 3 cm. The mechanism responsible for the dramatically increased recurrence rate seems to be a synergism between an increased intra abdominal pressure as well as the size of the abdominal wall defect. From our data we could not establish a relationship between a BMI over 30 kg/m^2 and an increased recurrence rate but rather an increased recurrence rate from 5 to 18 percent with a BMI > 25kg/m^2. We feel that this finding is not significant because of the limitations of a small sample.

In the light of these results we remain skeptical of the dogma that “every umbilical hernia needs mesh repair”. Mesh repair should perhaps be utilized in all patients suffering from obesity and a concomitant abdominal wall defect of 3 cm or larger, in order to further reduce recurrence rates in umbilical hernia

repair even though by how much is currently unknown. Although the established recurrence rate of 13% leaves room for improvement our results clearly show that not all umbilical hernias require mesh prosthetics. Furthermore one might consider advising on weight reduction prior to surgery. Further research should focus on prospectively establishing risk factors for hernia recurrence after simple and mesh repair to justify the incorporation of surgical mesh prosthetics in patients. Such a multi-center randomised controlled trial has been initiated and launched by the authors.

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Chapter 10 - Totally extraperitoneal repair for bilateral inguinal hernia: does mesh configuration matter?

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Published Surgical Endoscopy

Introduction

Currently it is accepted that inguinal hernias should be corrected using prosthetic materials. Debate is ongoing whether the approach should be posterior (open or endoscopic) or anterior in nature. For a bilateral inguinal hernia there are several advantages of a posterior endoscopic approach. Simultaneous tension-free repair is less expensive, less painful and shortens sick leave compared to sequential unilateral repair or simultaneous anterior repair [1-9]. The Dutch guidelines on hernia repair [10, 11] recommend the endoscopic pre-peritoneal approach for the management of bilateral hernia. In our institution considerable experience exists in the totally extraperitoneal (TEP) hernia repair for simple- and bilateral hernias.

In order to cover both myopectineal orifices of Fruchaud two methods are employed. One using a single prosthetic mesh (SM; 30x10/15 cm) (Figure 1A) with similarity to the anterior preperitoneal approach according to Stoppa [12]. The single mesh prosthesis is placed in such a manner that the central (widest) part rests in the prevesical space of Retzius. The other method consists of two separate prostheses each measuring 10x15 cm (DM; Figure 1B). Upon placement, which is analogous to the unilateral TEP approach, the prostheses are made to overlap in the midline. Choice of approach is based on personal preference. Whether one of the two methods is superior in terms of recurrence rate remains unknown. To answer this question we performed a retrospective evaluation of our results.

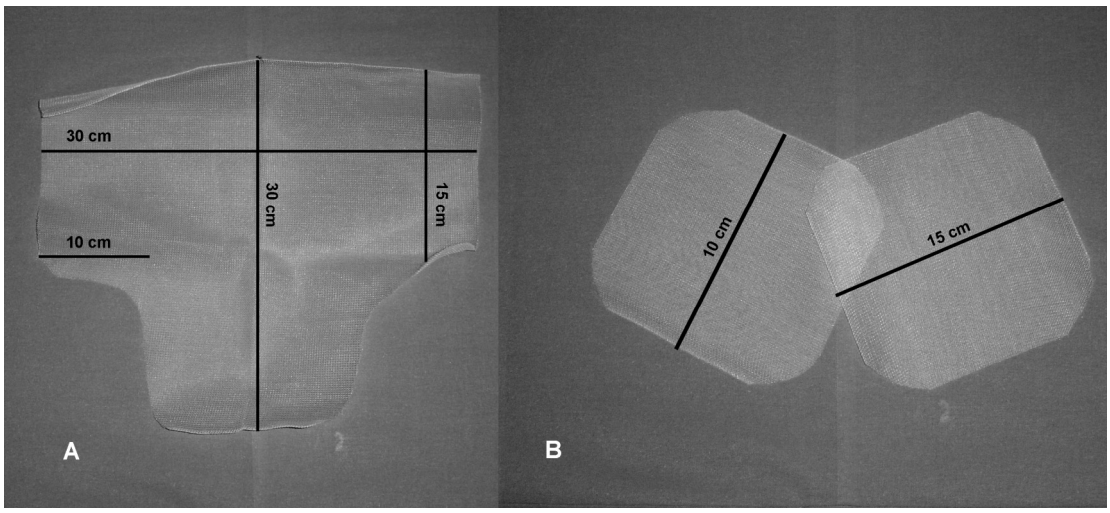

Figure 1. Examples of the two different mesh configurations used. Single mesh on the left (A) and double mesh on the right (B). Mesh dimensions are as indicated.

Materials and Methods

Study group

In this study 113 consecutive cases (four women) of endoscopic preperitoneal bilateral inguinal hernia repair performed in a teaching Hospital in the Netherlands between January 1998 and December 2001 were reviewed. All procedures were performed under general anaesthesia. If preperitoneal explorations had been performed prior to endoscopic approach a bilateral Lichtenstein repair was favoured. All endoscopic preperitoneal hernia repair procedures were performed or supervised by staff surgeons experienced in endoscopic preperitoneal hernia repair (>250 procedures). Two surgeons consistently used a single mesh (SM) whereas two others favoured the double mesh (DM) configuration.

Mesh configuration

In all patients the pneumo-pre-peritoneal space was created using a dissection balloon. Hereafter the space of Bogros was dissected bilaterally and all hernias were subsequently reduced. Prior to introduction, the midline and latero-cranial border of the SM were marked using 4 resorbable sutures and the mesh was rolled up and placed in a cartridge. Introduction of the

cartridge was achieved using an auxiliary 15mm trocar placed contralaterally to the conventional lateral trocar. The double mesh was introduced through the conventionally placed lateral trocar. Besides the mesh configuration the only difference between the DM and SM technique is the use of a fourth (auxillary) trocar for mesh introduction in the latter. Mesh fixation was never used. Antibiotic prophylaxis was not administered routinely. The traditional hernia classification according to Nyhus [13] was performed and registered during the procedures. The left and right groins were treated as being interchangeable for classification purposes only.

Follow-up

Regular follow-up consisted of visits to the outpatient clinic at two and six weeks postoperatively or as dictated by the patients postoperative course. For the purpose of this study patients were identified from hospital record procedure codes. Case notes, records and operative reports were obtained. The use of a single or double mesh, wound infection, pain and recurrence was recorded. Patients were invited to attend the outpatient department for an extra follow-up history taking and physical examination. Two authors (J.H., J.H.) interviewed and examined all patients.

Statistical analysis

A Fisher's exact test was performed to compare recurrence and complication rates between single and double mesh technique. A p-value of 0.05 (two-sided) was considered the limit of significance. Statistical analyses were performed using Statistical Package for Social Sciences for Windows (SPSS Inc., Chicago, Illinois).

Results

Study group

The patients mean age was 60 years (range 33 - 85 years). In 93 patients a primary bilateral inguinal hernia was diagnosed. Consecutively in 20 patients (18%) recurrent hernias were diagnosed (10 bilateral, 10 unilateral). In all but one patient hernia classification according to Nyhus was established during surgery (Table 1). The most common bilateral hernia was the type IIIA (direct

hernia) in both groins accounting for 33% of all patients (37). In 27 out of 113 patients two separate mesh prostheses were implanted (DM, 24%). One patient out of 113 required intraoperative conversion from single mesh to an open pre-peritoneal approach according to Stoppa because of a non-reducible scrotal hernia in the left groin.

Nyhus classification		N (%)
II	II	18 (15.9)
II	III A	11 (9.7)
II	III B	8 (7.1)
II	IV	2 (1.8)
III A	III A	37 (32.7)
III A	III B	8 (7.1)
III A	IV	6 (5.3)
III B	III B	8 (7.1)
III B	IV	2 (1.8)
III C	III C	2 (1.8)
IV	IV	10 (8.8)

Table 1. Intraoperatively determined combinations of hernias according to the Nyhus classification [13] in 113 patients presenting with bilateral groin hernia. Types: II (Indirect hernia), III A (Direct hernia), III B (Combined hernia), III C (Femoral hernia), IV (Hernia recurrence). Left and right hernias were considered interchangeable

Complications

Three patients from the single mesh group reported neuralgia or other pain and 2 patients from the double mesh group (3.5 and 7.4% respectively, n.s.). Of the patients reporting neuralgia or other pain, one patient from the single mesh group was referred to the department of anesthesiology for specialized pain treatment. No mesh infections were encountered. Three patients, all from the single mesh group had a serious complication (Table 2). Briefly, two patients suffered from hemorrhage due to intraoperative damage to epigastric

vessels requiring re-operation. One patient suffered a perforated urinary bladder requiring a Foley catheter for one week. This lesion was noted intraoperatively. Sixteen patients suffered 17 minor complications, which were uniformly distributed across the two groups (Table 3). Of all procedures 90%, was performed by staff surgeons (102/113). The remainder of the procedures was carried out under staff surgeon supervision.

	Single mesh N= 86	Double mesh N= 27
	N (%)	N (%)
Injury to epigastric vessel	2 (2)	-
Bladder perforation	1 (1)	-
Total	3 (3)	-

Table 2. Intraoperative complications of endoscopic preperitoneal bilateral inguinal hernia repair. Differences found are not significant (p=1.00)

	Single mesh N = 86	Double mesh N = 27
	N (%)	N (%)
Pneumonia	1 (1)	-
Urinary tract infection	1 (1)	-
Urinary retention	1 (1)	-
Orchitis	1 (1)	1 (4)
Neuralgia or other pain	3 (3)	2 (7)
Paraesthesia	2 (2)	-
Seroma	3 (3)	1 (4)
Haematoma	2 (2)	-
Recurrence	3 (3)	1 (4)
Total	17 (20)	5 (19)

Table 3. Postoperative complications of TEP bilateral inguinal hernia repair. Differences found are not significant (p=1.00).

Follow-up

The median follow-up at the time of the physical examination was 44 months (range 17- 62 months). 97 out of 113 patients underwent follow-up physical examination (86%), 10 patients were interviewed by telephone (10%) and 5 patients were lost to follow-up (4%).

A recurrence of the inguinal hernia in either groin was diagnosed in 4 patients after 3, 16, 18 and 40 months respectively, three from the single mesh and one from the double mesh group (3.5 and 3.7% respectively, p=1.00). One patient, who was unaware of a hernia recurrence, was diagnosed during the 40 months follow-up physical examination. Re-operation was performed in all cases, employing the transabdominal preperitoneal procedure (TAPP). In all

recurrences the myopectineal orifices of Fruchaud was found uncovered leaving potential medial sites for hernia formation.

Discussion

In a group of 113 patients we found that neither the use of a single mesh nor the use of double mesh is superior in terms of inguinal hernia recurrence rates in endoscopic preperitoneal bilateral hernia repair. This is evidenced by recurrence rates for SM and DM of 3.5% and 3.7% respectively.

Knook et al. have described the use of a large "slipmesh" in endoscopic preperitoneal bilateral hernia repair and found hernia recurrences in 2 out of 81 patients (2.5%) [5]. Our results are comparable especially taking into account that the median follow-up period in our study was 12 months longer, which might explain the slightly higher hernia recurrence rate found. Kald et al. has reported the use of double mesh in endoscopic preperitoneal and TAPP inguinal hernia repair with a hernia recurrence in 2 out of 128 groins (1.6%) [14]. In this study we have calculated recurrence rates per patient and not per groin. Consequently the recurrence rate reported by Kald et al. can be recalculated to a per patient recurrence rate of 3.1%. We feel that a, per patient, hernia recurrence rate is more relevant to the patient and that results are more representative. Our recurrence rates, although slightly higher, are comparable and may be explained by the physical examination that 86% of patients had undergone at follow-up and resulted in the diagnosis of two previously undiscovered recurrences. Patient follow-up including physical examination is essential in assessing the results of inguinal hernia repair since true recurrence rates may be obscured [1, 2, 4]. Since TAPP hernia repair was performed in all patients exhibiting hernia recurrences we can attribute the hernia recurrence to technical shortcomings or mesh migration. In all cases the mesh prosthesis had not been adequately positioned over the myopectineal orifice or migrated hence leaving a possible site for recurrence.

The rate of major complications is low and comparable to other series reporting on bilateral hernia repair [5, 14-16]. No significant difference was found between the two different mesh configurations. The same holds true for minor complications found in the post-operative period, furthermore the rate of minor

complications compares well to reports by other authors [5, 14, 15]. One of the minor complications that deserves extra attention is the occurrence of neuralgia or other pain after endoscopic preperitoneal bilateral hernia repair especially since recent randomised controlled trial data show a rate of 9.8% after endoscopic preperitoneal and TAPP hernia repair (combined data) [17]. The rate of postoperative pain in our series was low 3.5% and 7.4% for single and double mesh respectively. Since the placement of one single mesh prosthesis (SM) involves the use of 4 trocars (as opposed to the three trocars used in DM placement) we were surprised by the higher rate of neuralgia and other pain in the, less invasive, DM group. We are aware that underreporting of neuralgia or other pain may be a problem in this study and possibly the reason for the difference found between the SM and DM group.

The endoscopic preperitoneal inguinal hernia repair is known for its difficulty and the prolonged learning curve [18]. The introduction of the single mesh, as mentioned earlier, is achieved through an extra 15mm diameter trocar during the procedure and constitutes the only significant difference to the placement of double mesh prosthesis.

Conclusion

Previously it has been reported that bilateral inguinal hernia repair has considerable advantages cost wise and in shortening recuperation time over two separate procedures or a bilateral anterior approach [4, 6-9] and is therefore the obvious choice for bilateral inguinal hernia repair. In this paper we demonstrate that endoscopic preperitoneal bilateral hernia repair is a safe and reliable technique in the hands of experienced surgeons and that the rate of hernia recurrence and complications is low and independent of the mesh configuration (single or double).

The choice for either mesh configuration based on personal preference is permissible.

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PART 6 - GENERAL DISCUSSION

“Gegenüber der Fähigkeit, die Arbeit eines einzigen Tages sinnvoll zu ordnen, ist alles andere im Leben ein Kinderspiel.“

Johann Wolfgang von Goethe

Chapter 11 - General Discussion

J. A. Halm

General discussion and conclusion

Inguinal hernia repair is the most frequently performed general surgical procedure in the Netherlands [1], whereas incisional hernia is the most common long-term postoperative complication of abdominal surgery [2, 3]. The economic impact of hernias warrants innovation in order to reduce morbidity, decrease recurrence rates and perhaps prevent incisional hernia from occurring altogether.

Incisional hernia prevention

The commonest of all incisions used in general surgery is the midline incision, which is associated with a high incidence of incisional hernia.

In the study entitled: “Incisional hernia after upper abdominal surgery: a randomised controlled trial of midline versus transverse incision” a significantly lower hernia incidence was observed in transverse compared to midline incision in patients undergoing open cholecystectomy. The transverse incisions were found to be shorter than the midline incisions and esthetically more pleasing. Furthermore patients reported less postoperative pain after cholecystectomy performed through transverse incisions.

The beneficial results of the transverse incision in this study may be explained in part by the favorable direction of the incision parallel to Langer’s lines of cleavage and the division of the highly vascularized abdominal muscles as opposed to the avascular linea alba. Since the incision runs more or less in parallel with the predominant fibre direction of the abdominal wall the incision is not so much cutting as it is muscle splitting.

In contrast the midline incision divides the skin perpendicular to the principal axis of orientation of the subcutaneous connective tissue and divides the avascular linea alba to gain access to the abdominal cavity.

The prevailing muscle fibre direction of the abdominal wall, with the obvious exception of the rectus muscle, is transverse. After transverse incisions, physiological abdominal wall muscle contraction approximates the wound edges rather than separate them, as is the case in midline incisions were the action of the abdominal wall retracts wound edges laterally. This may also be the reason for the more esthetically pleasing resultant scar after transverse incision.

Furthermore, transverse incisions follow the predominant direction of the subcostal nerves, which partially explains the reduction in pain in the postoperative period. Further explanation for reduced post-operative pain may be the reduction in incision length that is achieved by choosing transverse incisions over midline incisions for unilateral exposure of the upper quadrant of the abdominal cavity.

The use of transverse incisions by surgeons is limited. Although beneficial over the midline incision the transverse incision is shunned and the easier and speedy midline incision preferred. The speed and exposure of the midline incision make it ideally suited for exploratory and emergency surgery of the abdomen. In elective surgery an alternative to the midline incision is almost always on hand when less generous exposure is satisfying. The unilateral transverse incision may be extended to cross the midline in order to increase exposure. Incisional hernia incidence of such bilateral transverse incisions is generally not higher than the incidence in midline incisions [4].
Transverse incisions are particularly suitable for bariatric surgery, liver resection, right hemicolectomy and open cholecystectomy with the possibility of reducing hernia incidence in each.
In conclusion, the fact that even for elective surgery of the upper abdomen the transverse incision is only seldomly used, calls for a change in attitude.
Taking steps towards incisional hernia prevention is essential in light of the size of the problem incisional hernia and hernia repair pose. Only the per-operative technique can be changed by surgeons if need be.

Since the introduction of laparoscopic surgery for the removal of the gallbladder, the choice for incision has become somewhat inconsequential. The continued expansion of procedures performed using minimally invasive procedures could further reduce incisional hernia incidence. However even in laparoscopic surgery the defects created by trocars and cannulas can be the site of so-called trocar hernia.

Trocar hernias are relatively uncommon, occurring in the smallest of all surgical incisions. Theoretically, the shorter the incision used the lower the

risk for wound failure [5]. This suggests that incisions for laparoscopic access are at the aforementioned low risk. Laparoscopic surgery is faced with an incisional hernia incidence of around 2%. Luijendijk reported no hernias in 169 patients after Pfannenstiel incision. However if a laparoscopy had also been performed, a significant increase in hernia incidence to 3.5% was found. Luijendijk proposes that the hernias may well be caused by the laparoscopy [6].
Numerous methods have been studied to reduce the hernia incidence. The use of reduced diameter cannula, novel trocar designs and alternative location of entry are brought forward, few of which have been studied prospectively. Closures of abdominal defects after laparoscopy are discussed in length in literature. The most commonly suggested factor influencing a surgeon's decision whether or not to close the defect is cannula size. We feel that leaving any fascia defect unclosed is correlated with a higher incidence of trocar site hernia and that more research, taking into account the type of suture used, perhaps even in the form of a randomised controlled trial, is warranted.

Indication for incisional hernia repair

The precise indication to perform incisional hernia repair remains vague. From a review of the available literature few factors could be identified. It is surprising to see how little has been published about the natural course of a common disorder like incisional hernia and how widely opinions can vary concerning this subject.
The primary reason to perform incisional hernia repair in any patient is probably the symptomatic incisional hernia. Common symptoms include pain and discomfort, but also cosmetic complaints. Reports on how many patients are having cosmetic complaints or symptoms of pain and discomfort are few and vary considerably. The cosmetic satisfaction after incisional hernia repair varies likewise and it is unknown how many patients receive an incisional hernia repair because of esthetical complaints.

The incidence of the most feared complication of any untreated incisional hernia, strangulation or incarceration of viscera in the hernia orifice is not known. In past publications the operation indication was acute incarceration in

6 to 14.6 % [7-9] of patients. Unfortunately this does not reveal anything about the incidence of incarceration in an incisional hernia population. The incidence of strangulation may be less than 1%. This figure does not exceed the mortality rate in incisional hernia surgery and hence cannot be regarded as a primary reason to correct an incisional hernia.

The question is whether or not operating is the best option for every patient suffering from incisional hernia. The publication by Mudge and others suggests that almost two third of the patients remain without any symptoms [3]. It is very plausible that a large proportion of patients never seek medical attention.

According to Nyhus there should be an individualisation for all hernia repairs [10, 11]. We recognize that mesh has significantly reduced incisional hernia recurrence, yet we feel that monitoring instead of repairing an asymptomatic incisional hernia should be considered in a substantial portion of patients.
The natural course of an incisional hernia should be studied prospectively, which will aid patients and surgeons in deciding on the policy and treatment of incisional hernias. A prospective study comparing watchful waiting to incisional hernia repair seems warranted in order to determine the natural course of incisional hernias, both large and small. Such a study is currently being designed at our institute.

Mesh complications in incisional hernia repair

We investigated arguments, in terms of per-, post- and long-term complications, against intraperitoneal polypropylene mesh hernia repair in a study entitled “Intraperitoneal polypropylene mesh hernia repair complicates subsequent abdominal surgery”. In a long-term follow-up study of 66 patients that underwent abdominal surgery after either intra- or preperitoneal mesh incisional hernia repair complications due to mesh were compared between intra- and preperitoneal positioning. Unfavorable results were found in patients re-operated with intraperitoneal mesh in situ leading to bowel resection in 20% of patients. The incidence of enterocutaneous fistula between intra- and preperitoneally placed mesh was not found to differ.

A general fear of intraperitoneal polypropylene mesh, because of enterocutaneous fistula, does not seem to be justified [12]. However, concerns regarding complications of intraperitoneal mesh at a possible reoperation are warranted and justify research into adhesion barrier-surgical mesh.

Evaluation of surgical mesh

The superiority of mesh incisional hernia repair has been well established as a means to reduce hernia recurrence [13, 14]. However, drawbacks to mesh incisional hernia repair exist. Serious complications include enterocutaneous fistula, mesh erosion, bowel obstruction, mesh infection and complications at subsequent abdominal surgery. More commonly, mesh repair has been associated with adhesion formation, abdominal pain and discomfort [13]. Theoretically mesh placed on the viscera puts patients at risk for developing complications. Mesh related complications are attributed to adhesiogenic, erosive or inflammatory properties of mesh materials used.

Mesh related complications might be averted by the introduction of new mesh materials and the use of adhesion barriers. Incorporation of mesh at the tissue-mesh interface and subsequent tensile strength should remain intact in order to prevent hernia recurrence while the inflammatory response and the adhesiogenic properties should be decreased.

Utilizing an experimental model of intraperitoneal incisional hernia repair we set out to characterize the properties of eight meshes. From our experiment it becomes clear that adequate strength of the tissue-mesh interface does not come at the expense of anti-adhesive properties in the case of meshes prepared with protective visceral layers.

The adhesion prevention of the aforementioned meshes is attributable to absorbable barriers that only provoke a mild inflammatory response and prevent contact of the macroporous mesh and viscera during the first weeks of implantation. The macroporous mesh (anti-visceral side) and moderate inflammation appears to be beneficial in the incorporation of the meshes. Of the evaluated meshes two types stand out, offering reduced adhesion formation on one hand as well as incorporation at the tissue-mesh interface on the other. Sepramesh (polypropylene coated with carboxymethylcellulose-sodium hyaluronate) and Parietex Composite (polyester coated with collagen-

polyethylene glycol-glycerol) offer reduced adhesion formation as well as incorporation. A third prosthesis offering minimal adhesiogenic properties is Tutomesh. Tutomesh consists entirely of industrially processed bovine pericardium and, despite the excellent anti-adhesive properties, seems to be less eligible for hernia repair offering only very little incorporation. It is concerning that Dualmesh (as well as Tutomesh) resulted in significantly more shrinkage, over 44% of the initial mesh surface, than all other meshes after 30 days.

Recently introduced meshes for intraperitoneal use, which were not bestowed with an anti-adhesive coating, failed to decrease the adhesion formation and seem to offer no advantages over common polypropylene mesh. The use of anti-adhesive coatings on prosthesis used in abdominal wall surgery will reduce mesh adhesion related complications and may prove beneficial in the future of abdominal wall surgery.

Persistent mesh deformation

The use of prosthetic mesh is an integral part of tension free incisional and inguinal hernia repair both of which have well established laparo- and endoscopic branches. In minimally invasive hernia repair the mesh prosthesis has to be introduced into the pneumo-preperitoneum or the pneumo-pre-peritoneum in order to cover the defect. Manipulating and passing of the mesh through a cannula is the preferred means of introduction. Commonly a 10-mm cannula is used to transfer the roll of mesh.

The behaviour of the mesh upon unrolling is unknown. Persistent deformation may complicate the correct placement in repair and possibly play a role in hernia recurrence. To this extent we investigated common mesh prostheses in order to determine the prosthesis with the least persistent deformation. In order to account for differences introduced by knitting patterns in length and width direction, all meshes were investigated after rolling in both directions.

Persistent deformation is common in meshes made out of polypropylene and largely dependant on the direction of initial rolling.

Persistent deformation is uncommon in polyester based mesh, typically showing deformations of equal magnitude in length and width direction.

To date advices by mesh suppliers on introduction of the prosthesis are lacking. Directions on the rolling of the mesh may lead to unrolling with the least deformation and as such ease the process of mesh introduction and placement. Especially in totally endoscopic pre-peritoneal inguinal hernia repair reduction of manipulation in the penumo-pre-peritoneum may improve safety and outcome.

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Use of mesh in umbilical hernia repair

The randomised controlled trial published by Arroyo and colleagues describing favorable results of mesh repair for umbilical hernia repair is the first publication describing beneficial results for tension free repair for these comparatively small hernias [15]. Since the outcome of umbilical hernia surgery in our clinic was limited to the anecdotal "evidence" of senior surgeons we performed an analysis of our results. In that study we found an overall recurrence rate of 13% in 110 consecutive patients having undergone surgical repair of an umbilical hernia. The recurrence rates were comparable to recurrence rates reported previously. During the follow-up visit at the outpatient clinic (after a median of 32 months) no hernia recurrences were found in the twelve patients treated using mesh.
Since 8 of the 14 hernia recurrences in our series were diagnosed during the follow-up visit and had gone unnoticed by the patients we feel that long-term follow-up physical examination is of utmost importance when evaluating the results of hernia repair.

The rate of wound infections (8%) found in our series is in accord with the available literature. The same holds true for complaints of discomfort (4%) and persisting pain in rest or during exercise (3%) in the umbilical region.

Schumacher et al. [16] have described a significantly increased recurrence rate of 31.8% in obese patients with a BMI over 30 kg/m^2. The mechanism responsible for the dramatically increased recurrence rate seems to be a synergism between an increased intra abdominal pressure as well as the size of the abdominal wall defect. From our data we could not establish a relationship between a BMI over 30 kg/m^2 and an increased recurrence rate but rather an increased recurrence rate from 5 to 18 percent with a BMI > 25kg/m^2. We feel that this finding is not significant because of the limitations of a small sample.

Further research should focus on prospectively establishing risk factors especially for umbilical hernia recurrence after simple and mesh repair to justify the incorporation of surgical mesh prosthesis in patients. The main focus needs to be on hernia orifice size, body mass index and wound infection. Such a multi-center randomised controlled trial has been initiated and launched by the authors.

Use of mesh in inguinal hernia repair

Minimally invasive inguinal hernia surgery has forfeit popularity since the publication of the paper comparing open, tension free repair (Lichtenstein) with laparoscopic and endoscopic (TAPP / TEP) repair [17]. In this randomised controlled trial minimally invasive surgery was found to be responsible for complications as well as hernia recurrences. The authors concluded that minimally invasive inguinal hernia surgery is obsequious to an extensive learning curve.

The inguinal hernia surgery guidance brought forward in the Netherlands suggests that Lichtenstein repair is the repair of choice for unilateral inguinal hernia. This guideline is in part based on a RCT from the Netherlands comparing suture to mesh repair of inguinal hernias [18]. The guidance however leaves room for endoscopic repair for the treatment of bilateral groin hernias

recognizing the benefits of preperitoneal repair combined with advantages of minimally invasive surgery [19].

Similarly the National Institute for Clinical Excellence (NICE) in its guidance concludes that minimally invasive surgery would be the preferred technique for the repair of bilateral hernias (if repaired during the same operation) because of cost saving potential [20].

For a bilateral inguinal hernia there are several advantages to minimally invasive surgery; simultaneous repair is less costly, less painful and shortens sick leave compared to sequential or simultaneous anterior repair [21-24].

Knook et al. have described a totally extraperitoneal giant prosthetic reinforcement of the visceral sac utilizing a single mesh measuring 10/15 x 30 cm. The authors reported a, per patient recurrence rate of 2.5% (2/81) at a median follow-up of 32 months [22].

A subsequent study, performed by our group, was performed evaluating long-term results of patients treated using a single large or two small meshes in TEP inguinal hernia repair. In this study of 113 patients comparing single to double mesh for bilateral inguinal hernia repair low recurrence rates (3.5% and 3.7% respectively) were found while maintaining low morbidity rates.

The totally extraperitoneal repair of bilateral hernias is a safe intervention in hands of trained surgeons regardless whether one or two meshes are used and is rightfully the treatment of choice for patients suffering from bilateral inguinal hernia. Recently a randomised controlled trial, comparing single and double prosthesis in simultaneous bilateral inguinal hernia surgery was published by Ohana et al., largely confirming the results found in our retrospective analysis [25].

Future advances in herniology

Incisional hernia prevention is already possible through the use of incisions other than the midline incision, through proper closure of the abdominal wall [26] and may even be possible through preventive mesh use in patients at risk of developing incisional hernias [27]. It is disconcerting that the implementation of proven hernia prevention methods has not gained wide acceptance in the

surgical community. Instead incisional hernias are taken for granted and incisional hernia repair (a rather elaborate form of symptom relief) is embraced. Unfortunately the results of incisional hernia repair seem to be far from perfect [13]. Further implementation of alternative incisions and use of mesh in incisional hernia repair seems inevitable.

Methods to improve incisional hernia repair may be found in reduction of concomitant atrophy of the lateral abdominal wall, which occurs upon unloading of the transverse and oblique muscles and subsequently reduces abdominal wall compliance. Returning the lateral abdominal wall to its original strength may prove valuable in reducing incisional hernia recurrence rates.

Further improvements may be found in the development of mesh prostheses that mirror the properties of the abdominal wall closely. Possible fields of improvement may include increased mesh elasticity, three-dimensional shape, biological degradability as well as adhesion resistance and may be useful in order to reduce complications and recurrence rates of incisional as well as inguinal hernia repair.

Developing a greater understanding of the role of disturbed wound healing in incisional hernia may prove beneficial in the long run. Franz et al. have successfully attempted incisional hernia prevention through intervention in the wound healing process. In a rat incisional hernia model, utilizing recombinant transforming growth factor- β2 (TGF-β2) and transforming growth factor- β1 (TGF-β1), has lead to a reduced hernia incidence through enhanced macrophage- and fibroblast influx and increased collagen I and III synthesis [28, 29].

To further wound healing research RGTAs® have been developed to mimic the stabilizing properties of glycosaminoglycan molecules on the heparan binding growthfactor receptor of the extra cellular matrix [30]. RGTAs® were found to enhance the neovascularisation in a model of skeletal muscle ischemia [31]. The use of RGTAs® may be beneficial in incisional hernia prevention.

Incisional hernia prevention, through interventions in wound healing and informed choice of incision will prove valuable in the future and inevitably reduce the practice of incisional hernia repair as symptom relief.

Advances in mesh technology may reduce recurrence rates of incisional hernia repair, chronic groin pain and may increase the patient's satisfaction with the outcome.

In general, the patients of the future will benefit from increased interest in tailor made approaches to hernia repair and prevention.

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Beschouwing

De liesbreukcorrectie is de meest uitgevoerde algemeen chirurgische ingreep in Nederland, terwijl de littekenbreuk de complicatie van buikchirurgie is die het vaakst optreed.

Hoofdstuk 1 introduceert het onderwerp van dit proefschrift: herstel van lies-, litteken- en navelbreuken evenals preventie van littekenbreuken.
Achtereenvolgend worden de de lies-, litteken- en navelbreuken besproken, waarbij de aandacht uitgaat naar de definities, incidentie, anatomie, risicofactoren en etiologie.
Alle breuken kenmerken zich door een defect in de buikwand. Hierbij is protrusie van, door buikvlies bedekte, buikinhoud mogelijk.
Bij correctie van de breuken wordt de uitstulpende buikinhoud gereponeerd en het defect in de buikwand gesloten. Deze ingreep kan op meerdere manieren plaatsvinden. De meest gebruikte technieken zijn het hechten van de randen van het defect en het bedekken van het defect met een kunststof mat. De voor- en nadelen van de meest gangbare ingrepen worden besproken.

De littekenbreukcorrectie werd in 2001 in Nederland bijna 4000 maal uitgevoerd. *Hoofdstuk 2* beschrijft de overwegingen, die aan een littekenbreukcorrectie voorafgaan. Hiervoor is in de literatuur gezocht naar publicaties, die de indicatie voor littekenbreukcorrectie beschrijven. De exacte indicatie om littekenbreuk correcties uit te voeren ontbreekt. In eerste instantie lijken symptomen zoals pijn en ongemak de meest voorkomende reden om littekenbreukcorrectie uit te voeren. Voorts lijken esthetische klachten een veel voorkomende reden om tot operatie over te gaan. Hoeveel patiënten naar aanleiding van esthetische klachten worden geopereerd varieert in de gepubliceerde literatuur sterk, evenals de tevredenheid met cosmetiek van de uitkomst

Hoe vaak de meest gevreesde complicatie van de onbehandelde littekenbreuk, incarceratie en strangulatie van darm, voorkomt, is onbekend. Eerdere publicaties spreken van incarceratie als operatie indicatie in 6 tot 14.6

% van de behandelde patiënten. Helaas ontsluieren deze getallen de incidentie van incarceratie niet.
Het gebruik van kunststof matten heeft het recidief na littekenbreukchirurgie drastisch verminderd. Desondanks lijkt een afwachtend beleid bij een aanzienlijk aantal patiënten met een asymptomatische littekenbreuk aan de orde.
Het natuurlijke beloop van de littekenbreuk zou prospectief bestudeerd moeten worden om patiënten en chirurgen te helpen hun besluit te vormen.

In *hoofdstuk 3* wordt de invloed van twee veel gebruikte incisies boven in de buik op het optreden van littekenbreuken onderzocht. In de studie met de titel: “Incisional hernia after upper abdominal surgery: a randomised controlled trial of midline versus transverse incision” werd een significante reductie van littekenbreuken bij de dwarse incisie gezien, vergeleken met de mediane incisie bij patiënten, die een open galblaasverwijdering ondergingen.

De dwarse incisie was korter dan de mediane incisie en het cosmetische resultaat werd, door zowel chirurgen als ook patiënten, beter gevonden. Bovendien gaven patiënten na een dwarse incisie aan minder postoperatieve pijn te ervaren.

Het gunstige effect in de groep van de dwarse incisie met betrekking tot het optreden van recidief, maar ook met betrekking tot pijn kan gedeeltelijk verklaard worden door de gunstige richting van klieven van de spieren waarbij de avasculaire linea alba gespaard blijft en de goed doorbloede spieren worden gescheiden.
De spiervezels van de buikwand, met uitzondering van de rechte buikspieren, verlopen in dwarse richting. Na een dwarse incisie worden de wondranden door de fysiologische contractie van de buikspieren ge-approximeerd. Na een mediane incisie echter veroorzaakt de natuurlijke contractie van de buikspieren juist laterale retractie van de wondranden. De eerder genoemde approximatie van de wondranden lijkt verantwoordelijk te zijn voor de gunstige cosmetische uitkomst. De dwarse incisie volgt verder de richting van de intercostale zenuwen en lijkt, in combinatie met de kortere incisie, voor

exposure van het unilaterale bovenkwadrant van de buikholte geschikt. Desondanks wordt de dwarse incisie door chirurgen slechts sporadisch toegepast.

In *hoofdstuk 4* wordt de invloed van chirurgische techniek bij het sluiten van de transverse incisie op het optreden van littekenbreuken onderzocht. Het blijkt dat er slechts weinig gepubliceerd onderzoek is, dat zich met de beste manier van sluiten van de transverse incisie bezig heeft gehouden. Het sluiten van de transversale incisie dient in een gerandomiseerde klinische studie onderzocht te worden.

In *hoofdstuk 5* wordt de incidentie van de trocarhernia in een literatuuroverzicht onderzocht. De toename van minimaal invasieve chirurgie zal het optreden van littekenbreuken in laparotomielittekens doen afnemen, daarentegen zal het optreden van breuken in de trocarlittekens echter toenemen.

Trocarhernias komen relatief weinig voor en theoretisch zou een kleinere incisie ook het risico op breuken moeten verminderen. Na laparoscopische chirurgie treedt een hernia in een litteken in ongeveer 2% van de patiënten op. Geen enkele hernia werd in 169 patiënten na een Pfannenstiel incisie door Luijendijk gerapporteerd. Indien echter ook laparoscopie was verricht steeg de incidentie tot 3.5%.
Verscheidene methoden zijn onderzocht om de incidentie van trocarhernias te reduceren, onder andere het gebruik van dunnere canules en alternatieve locaties voor introductie van de trocar. Slechts weinig gerandomiseerde studies zijn in verband met deze potentiële verbeteringen gepubliceerd.

Het sluiten van fasciedefecten na laparoscopie wordt uitgebreid behandeld in de literatuur. Het besluit om een trocarincisie te sluiten zou in de meeste gevallen afhankelijk zijn van de diameter van het defect. De gedachte, dat ongesloten defecten op fascie-niveau verantwoordelijk zijn voor hernias is algemeen, maar onderbouwing in de vorm van gerandomiseerde studies is noodzakelijk.

In *hoofdstuk 6* werd een groep patiënten na littekenbreukcorrectie met mat op complicaties bij vervolg-laparotomieën onderzocht. De bedoeling van deze studie was het voorkomen en de aard van complicaties, die kunnen optreden tijdens relaparotomieën, inzichtelijker te maken en te relateren aan de positie van de voorheen geplaatste mat in relatie tot het peritoneum.
Abdominale chirurgie bij patiënten, die eerder een littekenbreukcorrectie met een polypropyleen mat hebben ondergaan, is geassocieerd met meer per- en postoperatieve complicaties, indien de prothese intraperitoneaal was geplaatst.

In *hoofdstuk 7* worden de resultaten besproken van een experimentele studie, waarin acht verschillende soorten van kunststof matten, die voor littekenbreukcorrectie gebruikt worden, vergeleken werden
In het bijzonder bij laparoscopische littekenbreukcorrecties is het soms niet mogelijk om contact tussen de kunststof mat en de buikorganen te voorkomen. Het contact tussen de buikorganen en de mat kan tot ontsteking en beschadiging van het oppervlak van de organen leiden. In zijn ergste vorm kan intestinaal letsel het ontstaan van een enterocutane fistel ten gevolg hebben.
In het experiment werden 200 ratten met één van de acht matten behandeld. De matten werden in de buikholte (intraperitoneaal) gehecht, zodat contact met de buikorganen bestond. De acht onderzochte matten waren Prolene, Dualmesh, Ultrapro, Timesh, Sepramesh, Parietex Composite, Proceed en Tutomesh.
Adhesievorming aan de mat, mat-ingroei, verankering en het krimpen van de mat werd door twee verschillende onderzoekers gemeten.
Zowel Parietex Composite als ook Sepramesh en Tutomesh resulteerden in gereduceerde adhesievorming ten opzichte van de andere matten. Parietex Composite en Sepramesh groeiden bovendien goed in en bleken stevig verankerd.
In conclusie lijken Parietex Composite en Sepramesh goede ingroei en verankering met sterk gerduceerde adhesievorming te combineren en deze lijken dan ook de beste keuze voor littekenbreukcorrecties, waarbij de kunststof mat met de buikinhoud in contact kan komen.

Het gebruik van kunststofmatten is een niet weg te denken onderdeel van de tension-free littekenbreuk- en liesbreukcorrecties in open dan wel minimaal invasieve chirurgie. In minimaal invasive hernia-chirurgie moet de kunststof - mat in het pneumo-preperitoneum of pneumo-pre-peritoneum geïntroduceerd worden om het defect te kunnen bedekken. Het oprollen van de mat en in opgerolde vorm door de canule inbrengen is de meest gebruikte methode van introductie. Het gedrag van de kunststofmat bij ontrollen is onbekend. Blijvende vervorming kan het plaatsen van de mat compliceren en speelt mogelijkerwijs een rol bij het ontstaan van recidief. In een experimentele setting werden de meest gangbare kunststofmatten onderzocht, waarbij alle matten werden opgerold, waarna deze na passeren van de canule konden ontrollen. Alle kunststofmatten werden zowel in lengte als ook in breedte richting onderzocht. De resultaten zijn beschreven in *hoofdstuk 8.*

Blijvende deformatie bleek gebruikelijk in matten vervaardigd van polypropyleen en afhankelijk van de richting van oprollen. In matten gemaakt van polyester bleek blijvende vervorming ongebruikelijk en onafhankelijk van de initiële richting van rollen.
Tot op heden worden kunststofmatten voor litteken- en liesbreukcorrecties niet voorzien van een advies over de richting van oprollen om de vervorming te minimaliseren. Adviezen voor het vervomingsvrij oprollen van matten kan de introductie en het plaatsen van de matten in de endoscopische liesbreukchirurgie vergemakkelijken.

De gerandomiseerde studie van Arroyo was de eerste waarbij een significante reductie van recidieven bij gebruik van mesh ter correctie van navelbreuken beschreven werd. In een studie van 110 patiënten werd een recidief percentage van 13% na navelbreukchirurgie gevonden, waarbij opviel, dat bij die patiënten, bij wie een kunststof mat werd gebruikt, geen recidieven ontstond. De resultaten worden beschreven in *hoofdstuk 9.* Gedurende het follow-up bezoek (mediane follow-up: 32 maanden) werden in de 12 patiënten, die met een mat waren geopereerd, geen recidieven gevonden. Wondinfecties werden in 8% en klachten van ongemak en pijn in respectievelijk 3 en 4% van de patiënten gevonden.

Vervolgonderzoek moet uitwijzen of er risicofactoren (overgewicht, roken, hernia- diameter) bestaan, die herstel met een mat bemoeilijken. In dat verband is een gerandomiseerde studie recent gestart.

De richtlijn liesbreukchirurgie suggereert dat littekenbreukcorrectie volgens Lichtenstein de behandeling van keuze voor de enkelzijdige littekenbreuk is.
De richtlijn laat ruimte voor herstel van bilaterale breuken door middel van de minimaal invasieve totale extraperitoneale techniek (TEP). Op vergelijkbare wijze heeft het “National Institute for Clinical Excellence” (NICE) in zijn richtlijn de minimaal invasive chirurgie als de aangewezen techniek voor de bilaterale breuk beschreven, waarbij een duidelijke kostenbesparing gerealiseerd kan worden.
Een aantal voordelen, verbonden aan de minimaal invasieve bilaterale liesbreukchirurgie, zijn kostenbesparing, minder pijn en sneller herstel.

De door ons uitgevoerde studie heeft de lange termijn resultaten van de TEP onderzocht, waarbij gekeken is of er een verschil in recidiefpercentage dan wel complicaties bestaat tussen één grote mat of twee kleine matten. Hiervoor werden 113 patiënten voor een bezoek aan de polikliniek opgeroepen. De resultaten worden beschreven in *hoofdstuk 10*.
Recidief percentages voor de twee verschillende technieken waren gelijk, waarbij ook de complicaties vergelijkbaar waren.

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Jens

"Another damned, thick square book! Always scribble, scribble, scribble! Eh! Mr. Gibbon?..."
William Henry, Duke of Gloucester (1743-1805) to Edward Gibbon (1737-1794), historian and author of "The History of the Decline and Fall of the Roman Empire"

Curriculum vitae auctoris

De auteur van dit proefschrift werd 16 december 1975 te Bonn (Duitsland), als zoon van Rudolf Halm en Johanna Halm-Leenheer, geboren. In 1995 behaalde hij het diploma “Baccelaureat International” aan het Rijnlands Lyceum te Oegstgeest. In dat zelfde jaar begon hij aan de Katholieke Universiteit te Leuven de studie Geneeskunde welke hij vanaf september 1996 voortzette aan de Erasmus Universteit te Rotterdam.

Ondanks zijn betrokkenheid bij de Rotterdamsche Studenten Sociëteit “Hermes” werd het doctoraalexamen in 2000 behaald. Vervolgens was de auteur gedurende 6 maanden als Research Fellow verbonden aan het “Allogeneic Bone Marrow Transplantation” Laboratorium van het Memorial Sloan-Kettering Cancer Centre te New York (hoofd: dr. M.R.M. van den Brink, dr. H. Varmus).

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