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Complications with pelvic floor repair systems

A literature review

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[redacted]

Table of Content

Introduction

It is estimated that almost half of the women worldwide are affected by some degree of pelvic floor prolapse (1). Especially women in there post-menopausal era are affected by this condition, but also obesity, inheritance, pregnancy and life style factors can play a role. Complications vary from overactive bladder to vaginal pain. These complications can be treated with traditional surgical techniques. There are, however, some drawbacks, such as the long recovery period, and high costs (2). In an attempt to improve outcome of traditional prolapse repair, new surgical techniques like transvaginal or laparoscopic/robotic repair have been developed and used. The prosthetic materials used in pelvic floor repair have evolved from silver meshes as early as 1903, to synthetic materials like polypropylene in 1956 and more recently absorbable products such as polyglactin 910 (3). It is expected that the number of consults for pelvic floor disorder will increase by 45% in the next 30 years, which suggests that there will be an increase in the demand for physicians and surgeons who are trained in management of pelvic organ prolapse (4). These new surgical techniques and materials are not without risks. In 2010, the Dutch Health Care Inspectorate (IGZ) received several complaints from patients who had pelvic floor reconstructive surgery with the pelvic floor repair system PROLIFT of the firm Ethicon. This has led IGZ to decide to start an investigation into the root causes of these complaints, which may be product-related, procedure-related or both. As part of this investigation, IGZ requested the RIVM to perform a literature study on complications of pelvic floor repair systems.

Objective

The aim of this study was to gain information on the use and risks of gynecologic meshes in general and also specifically on the Gynecare PROLIFT Pelvic Floor Repair System[1] from Ethicon.

The following questions had to be answered:

1. Which complications with pelvic floor repair systems are described in scientific literature and after which period following surgery do these complications occur?
2. What is the quality and safety of the 'Gynecare PROLIFT system' compared with similar devices?
3. Were there clinical evaluation available in the literature, before the PROLIFT system was marketed in 2002?

[1] Prolift system Total, Anterior, and posterior Pelvic Floor Repair Systems consist of precut Gynecare Gynemesh*PS, nonabsorbable Prolene soft mesh implants and a set of instruments to facilitate mesh implant placement

Method

The electronic databases Scopus™ (Elsevier BV) and Medline/PubMed (US National Library of Medicine) were used to perform the literature search. Two search strategies were used:

1. General
   The following search strings were used: 'gynecologic mesh', 'gynaecological mesh', 'complications'. Publications in English over the last five years were reviewed.
2. Specific
   For the PROLIFT system, an additional search was performed with the search strings 'gynecare', 'PROLIFT', 'mesh', 'pelvic floor reconstructive surgery', 'Ethicon'. Publications in English over the last twenty years were reviewed.

Articles included were prospective studies and review articles on different types of pelvic floor repair systems, including the PROLIFT system.

Results

The general and specific literature searches in Scopus and PubMed resulted in approximately 200 publications. Seventy-seven articles were selected and downloaded based on their abstract. Eventually this number was reduced to 29 by selecting prospective studies and review articles.

Twenty prospective studies and nine review articles were included. The objectives of these studies varied. In most of the prospective studies the surgical technique including efficacy and safety was evaluated, while in other studies risks of the materials used were identified. In most review articles the aim was to evaluate (long-term) complications of synthetic mesh in pelvic floor reconstructive surgery or to compare the risks and benefits of different surgical techniques. In six articles there was a conflict of interest, i.e. one or more authors were consultant or advisor to Ethicon. In twenty-three article conflict of interest was specified as none or it was not indicated (unknown).

A specific search was performed to investigate whether there were clinical evaluations available in the literature before the PROLIFT system was marketed in 2002.
Only one prospective study was found in which the clinical evaluation of a part of the PROLIFT system, Ethicon Gynemesh, started before 2002. However, this study was not completed before 2002: it ran from 2001 to 2005 (5).

Synthetic meshes

There are several types of synthetic meshes on the market and classification is done by filament number and pore size with tensile strength depending on fiber type, weight-to-area ratio and the weave. There are 4 classes described:

- type I: polypropylene monofilament meshes that are macroporous with pores bigger than 75 µm (e.g. Marlex, Gynemesh™);
- type II: microporous material with pores smaller than 10 µm (e.g. Gore-tex™);
- type III: both macroporous and microporous components (e.g. Teflon™);
- type IV: polypropylene sheets with pore size smaller than 1 µm(e.g. Silastic™).

Mesh types I, II and III have similar high tensile strength (bigger than 50N). Elasticity varies, for instance Marlex, a type I product, is stiffer than several type II products (3). Synthetic meshes are used for suburethral slingplasty procedures for management of stress urinary incontinence, but also for abdominal sacrocolpopexies, augmentation of anterior and posterior vaginal and apical repairs (2, 3, 6).
Gynecare Gynemesh (type I) is used for the PROLIFT system.

Complications, occurrence and period after surgery when complications were observed

From the literature two types of complications were observed, intra-operative and post-operative complications. Intra-operative complications are mainly procedure-related. Examples are bladder injuries, bladder and/or rectal perforations, hemorrhages, occurrence of urinary retention, vaginal laceration, temporary hydronephrosis (swelling of

the kidneys), tapercut (7-15). The occurrence rate of intra-operative complications is less than 6%.

Post-operative complications can be procedure-related and/or product-related.

The top 5 most reported/observed postoperative complications of various types of synthetic mesh products are listed in table 1. The occurrence of complications vary considerably, because reviewed studies have variable methodology, operative techniques of placement, types of meshes and follow-up.

Table 1: TOP 5 most reported/observed postoperative complications of various types of synthetic mesh products

	Prospective studies[a]		**Review articles[b]**	
	Complication	**Occurrence range**	**Complication**	**Occurrence range**
1	Mesh exposure/vaginal erosion	0.7%-19%	Mesh exposure/vaginal erosion	0%-25%
2	Urinary symptoms	2.1%-18.1%	Dyspareunia[c]	2%-69%
3	Recurrent prolapse	3.5%-41%	Urinary symptoms	3%-23%
4	Dyspareunia[c] and urinary tract infection	1%-22.2% and 3.6%-16.9%	Constipation/difficult voiding	4.3%-24%
5	Constipation/ difficult voiding	2.1%-13%	Infection	2.3%-31.5%

a. Complications were observed during follow-up visits between 1 day to a mean period of 3.5 years after surgery.

b. Complications were observed between 8 weeks to a mean period of 3.2 years after surgery.

c. Pain in the pelvic area during or after sexual intercourse.

Mesh exposure/vaginal erosion is the most observed complication. Kaufman et al (2011) identified two types of mesh exposures, namely early and late mesh exposure. Kaufmann and colleagues believed that early mesh exposure was likely to be caused by the procedure itself (e.g. damage to the vaginal tissue, infection, improper closure of the mucosa) and late erosion was likely to be the result from chronic exposure of the tissue due to mechanical stress and long-term interaction of the mesh with the tissue. Age was inversely related to the risk of having late mesh exposure, also late mesh exposure was significantly more common in sexually active patients. It was concluded that young age and sexual activity are risk factors for mesh exposure (16). Another risk factor for mesh exposure was observed by Cundiff et al (2008). In this study the risk for mesh exposure was higher for women who had an ePTFE mesh implant than women who had polyester or polypropylene mesh implants (respectively 19% (4 of 21), 5.3% (16 of 301)). In addition, concurrent hysterectomy and smoking seemed to pose a higher risk factor for the occurrence of mesh exposure. Hysterectomy was also identified as risk factor in several other studies (17, 18).

Improper placement, movement of the mesh material, mesh shrinkage or vaginal anatomy may cause mesh exposure or dyspareunia, complications which are observed frequently. The cause for these problems could be repair technique, mesh material or anatomy of the patient. It is not always clear which one is applicable.
Transvaginally placed mesh for pelvic floor prolapse repair seems to have higher erosion rates and seems to cause more discomfort (18, 19).

In several prospective studies stress urinary incontinence (SUI) symptoms were observed after surgery (8, 20, 21). In the first study (21) de novo stress urinary incontinence was significantly more common after mesh surgery (PROLIFT) (32%) compared to colporraphy (8%). In the second study(20), the effect of the trocar guided transvaginal mesh (PROLIFT) on lower urinary tract symptoms was further investigated. Anterior transvaginal mesh surgery performed in 121 patients was evaluated at baseline (before surgery), and 1 year after surgery. Hundred-nine patients were eligible for analysis.
Before surgery, 52% (57 of the 109) of the patients reported stress urinary incontinence (SUI). Postoperatively, 18 of the 57 patients reported complete resolution of SUI, whereas 32 of the 57 of the patients reported aggravated stress incontinence. Overall results showed an improvement of self-reported obstructive and irritative lower urinary tract symptoms. However, the mesh repair did not result in overall improvement of SUI. Similar results concerning SUI were found in another prospective study, with 261 subjects operated with the PROLIFT system (8).

Although not as frequently observed as mesh erosion, dyspareunia or urinary symptoms, infection was also observed regularly. Factors which influence the development of infections are characteristics of the synthetic mesh material, size of the mesh, type of procedure, and improper placement (2). For instance, microporous synthetic meshes are more likely to become infected (3).

Intra-abdominal pressure may adversely affect the healing of the vaginal repair procedure, leading to recurrent prolapse (10). But also incorrect placement of the mesh can lead to recurrent prolapse. Binding the mesh too tightly to the muscle or too low can result in an increase of constipation and obstructive defecation (7).

For an overview of all post-operative complications see Table 1 and 2 in annex I.

PROLIFT system compared to other gynecological mesh products
The PROLIFT system or parts of the PROLIFT system from Ethicon was evaluated in thirteen prospective studies (5, 8, 10-12, 16, 20-26). In almost all of the prospective studies only the PROLIFT system or parts of the system were evaluated. In only one prospective study parts of the PROLIFT system (e.g. prolene and gynemesh) were compared with other mesh material. The results of this study showed that mesh exposure observed 45-744 days after surgery was higher for women who had ePTFE mesh than the women who had parts of the PROLIFT system implanted (22). In another study, three

operating techniques were compared: transvaginal anterior repair with polypropylene mesh (brand not specified), classic transvaginal anterior repair and internal anterior repair. Follow-up was one year. Complication rate for urinary tract infection, fever and vaginal erosion was higher in the mesh group compared to the classic and internal repair groups. Complications rate for wound infection, overactive bladder (detrusor overactivity) and voiding difficulty were higher in the internal repair group that the other two groups. Overall complications were lowest in the classic repair group.

In several reviews the PROLIFT system or parts of the system were compared with other products (synthetic and biological). Data presented in Table 2 (Annex I) shows that the erosion rate seems higher in some cases when synthetic meshes are used than when biological products are used(6, 27). Furthermore, when a comparison is made between complications observed with different types of synthetic meshes, it appears that the mesh material of the PROLIFT system from Ethicon does not differ from other types of synthetic meshes, considering the occurrence of reported complications (6, 18, 28). However, it must be noted that reviewed studies have variable methodology, operative techniques of placement, types of meshes and follow-up.

Discussion and conclusion

The aim of this study was to gain information on the use and risks of gynecologic meshes in general and also specifically on the Gynecare PROLIFT Pelvic Floor Repair System from Ethicon. Therefore a literature review has been performed. In view of budget and time restraints, this study was limited to publications on prospective clinical investigations and review articles over the last five years, plus a specific search on the PROLIFT system over the last twenty years.

Below, the results are discussed in relation to the questions as mentioned in the objective.

Which complications with pelvic floor repair systems are described in scientific literature, and after which period following surgery do these complications occur?

Most frequently reported complications were: mesh exposure/vaginal erosion, urinary symptoms, recurrent prolapse, dyspareunia, infection, constipation/difficulty voiding. Very large differences in occurrence rates (e.g. 2%-69%) were observed, and also major variations were observed in the period post-operatively when complications were reported (e.g. 1 day to 3.5 years). These large variations were mainly caused by the set-up of the studies reviewed. Methodology, operative techniques of placement, types of meshes and follow-up of the studies were considerably different.

What is the quality and safety of the 'Gynecare PROLIFT system' compared with similar devices?

Due to the lack of prospective studies comparing the PROLIFT system with other products or alternative operating techniques and the major differences in set-up between the various reviewed studies on single products, a comparison between the 'Gynecare PROLIFT system' and similar devices was difficult to make. In some cases results appeared to indicate that the mesh material of the PROLIFT system from Ethicon did not differ from other types of synthetic meshes. However, overall results show that complications occur relatively frequently for all kinds of meshes and show that aspects like repair technique, mesh material or anatomy of the patient, play an important role in the occurrence of complications. This may be a cause for concern in view of the expected increase in the number of consults for pelvic floor disorder, due to the aging population. It also suggests that there is a need for physicians and surgeons who are trained in management of pelvic floor organ prolapse. Systematically organized observational studies on the various alternative treatments would be desirable.

Were there clinical evaluations available in the literature, before the PROLIFT system was marketed in 2002?

A specific search was performed to investigate whether there were prospective clinical evaluations available in the literature before the PROLIFT system was marketed in 2002.

One prospective study was found was found which started in 2001 and ended in 2005, meaning the results were not available before the device was marketed. When interpreting this result, the limitations of this literature review, as described above, should be taken into account. Studies on relevant materials or products, which were not linked to PROLIFT in their publications would not be found in the specific search. Furthermore, data could be available from retrospective studies.

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Annex I

Table 1 Overview post-operative complications in prospective studies

Reference	Conflict of interest	Study population (n)	Product(s)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Chen et al 2010 (29)	None	28	Herniamesh SRL, Turin, Italy	Dragging pain	100%	3 days	Pain disappeared after 1 month
				Recurrent prolapse	3.6%	2 months	
Cundiff et al 2008 (22)	None	322	Woven polyester (Mersilene™ Ethicon) used in 42%, polypropylene (Prolene™ Ethicon) and soft weave polypropylene (Gynemesh™ Ethicon) used in 48%, expended polytrafluroethylene ePTFE used in 6% (Gore™Medical or Trelex™), allograft and xenograft used in rest(Pelvic™CR Bard)	Suture/Mesh exposure	5.3% (group woven polyester and polypropylene) 19% (group ePTFE)	45-744 days	Risk for mesh exposure higher in women who had ePTFE mesh, concurrent hysterectomy, smoking
Carey et al, 2008 (10)	None	95	Gynemesh™ Ethicon	Recurrent prolapse	5.3%	12 months	
				Mesh exposure	4.2%	?	
				Stress urinary incontinence (SUI)	2.1%	?	
				Obstructive voiding	1.1%	?	

Table 1(continued)

Reference	Conflict of interest	Study population (n)	Product(s)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
De Vita, 2008 (23)	None	80	Gynemesh^{TM} Ethicon	Vaginal erosion	3.8%	3-5 weeks	
Ek et al 2010 (21)	Yes	50	PROLIFT^{TM} Ethicon	De novo SUI	32%	2 months	advisors to Gynecare Scandinavia and Ethicon.
Ek et al, 2010 (20)	Yes	121	PROLIFT^{TM} Ethicon	Aggravated stress incontinence	56%	1 year	At basline 52% of the patients reported SUI postoperatively 32% reported complete resolution of SUI. advisors to Gynecare Scandinavia and Ethicon
Elmer et al, 2009 (8)	Yes	232	PROLIFT^{TM} Ethicon	SUI	?	1 year	2% underwent SUI surgery during the follow-up period. Advisor to Gynecare Scandinavia
				Vaginal erosion	11%	1 year	
				Mesh exposure	2.8%	1 year	

Table 1 (continued)

Reference	Conflict of interest	Study population (n)	Product(s)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Granese et al, 2009(7)	None/ Unknown	138	Polypropylene mesh (unspecified), in some cases Vyprol mesh was used)	Nycturia	3.6%	Mean 43 months	Before treatment (BT) 17.4%
				Dysuria	2.9%	Mean 43 months	BT 9.4%
				SIU	7.4%	Mean 43 months	BT 3.6%
				Mixed incontinence	14.5%	Mean 43 months	BT 16.7%
				Pollakiuria	7.2%	Mean 43 months	BT 13%
				Voiding dysfunctions	6.5%	Mean 43 months	BT 15.9%
				Urge incontinence	18.1%	Mean 43 months	BT 10.9%
				De novo urinary incontinence	5.0%	Mean 43 months	BT NA
				Recurrent urinary tract infections	5.1%	Mean 43 months	BT 15.9%
				Constipation	13%	Mean 43 months	BT 7%
				Obstruction defecation	5.8%	Mean 43 months	BT 1.4%
				Urgency (Bowel symptom)	2.2%	Mean 43 months	BT 0
				Pelvic pressure	8.7%	Mean 43 months	BT 66.7%
				False urge to defecate	5.1%	Mean 43 months	BT 50.7%
				Recurrent prolapse	5.0%	7-20 days	
				Mesh exposure	0.7%	1-6 months	
Kato et al 2009 (12)	None/ Unknown	305	Gynemesh™ Ethicon	Mesh exposure	2.3%	6-24 months	
Lucioni et al, 2008 (24)	None/ Unknown	12	Gynecare PROLIFT system	de novo enterocele	8.3%	Within 42 weeks	

Table 1 (continued)

Reference	Conflict of interest	Study population (n)	Product(s)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Jacquetin et al 2010 (11)	Yes	89	PROLIFT™ Ethicon	vesico-vaginal fistula	1.1%	Early post-operative	
				Haematomas	4.5%	Early post-operative	
				Urinary infections	16.9%	6 weeks	
				Recurrent prolapse	3.5%	Within 3 years	
				Mesh exposure	14.4%	Within 3 years	
				Dyspareunia	15.4%	At 3 years	Of the total number of sexually active patients (n = 39) at 3 years 15.4% reported dyspareunia Paid consultant for Ethicon
Kaufman et al, 2011 (16)	None/ Unknown	114	Gynecare PROLIFT	Early mesh exposure	3.5%	Immediate or early	
				Late mesh exposure	8.8%	Within seven months	
				Fever	9.6%	Immediate or early	
				Stress incontinence	6.1%	Within seven months	
				Urge incontinence	4.4%	Within seven months	
				Repair procedure failures	5.3%	Within seven months	
				Dyspareunia	12.3%	Within seven months	

Table 1 (continued)

Reference	Conflict of interest	Study population (n)	Product(s)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Nieminen et al 2010 (30)	None/ Unknown	105	Polypropylene (Parietene Light; Sofradim Co)	Recurrent prolapse	41% (no-mesh group) 13% (mesh group)	Three years after surgery	Comparison study no mesh (97) or mesh (105)
				Novo stress urinary incontinence	5% (no-mesh group) 7% (mesh group)	Three years after surgery	
				Mesh exposure	19%	Three years after surgery	
Rane et al, 2008 (31)	None	70	Perigee transobturator cystocoele repair system	Mesh exposure	7.1%	18-36 months	Funded by the American Medical System only to preceptor surgeons locally and internationally
				Recurrent prolapse	4.28%	18-36 months	
				Urgency	7.1%	18-36 months	
				Urinary incontinence	4.3%	18-36 months	Urinary stress incontinence was reported as cured in 92.7% and worse in 7.3%
Su et al, 2009 (25)	None/ Unknown	65	Self-fashioned Gynemesh	Urinary tract infection	4.6%	One week postoperative	
				Vaginal erosion	6.2%	1- 22 months	

Table 1 (continued)

Reference	Conflict of interest	Study population (n)	Product(s)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
De Tayrac et al, 2010 (13)	Yes	48	Polyform™Boston Scientific	Para-vesical space hematomas	6.3%	At day 6	Consultants for Boston Scientific
				Ureteral kinking	4.2%	At day 1	
				Sciatic pains	4.2%	Median follow-up 8 months	
				Buttock-pain	54.3%	Mean of 8 days (range 2 to 70 days)	
				SUI	14.6%	Median follow-up 8 months	Before treatment 35.4%
				Urge incontinence	25%	Median follow-up 8 months	Before treatment 56.3%
				Defaecatory dysfunction	2.1%	Median follow-up 8 months	Before treatment 12.5%
				Faecal incontinence	6.3%	Median follow-up 8 months	Before treatment 4.2%
				Bulge felt into the vagina	2.1%	Median follow-up 8 months	Before treatment 100%
				Dyspareunia	22.2%	Median follow-up 8 months	Before treatment 4.2%
				Recurrent prolapse	6.5%	Median follow-up 8 months	
				Vaginal erosion	4.2%	Median follow-up 8 months	

Table 1 (continued)

Reference	Conflict of interest	Study population (n)	Product(s)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
De Tayrac et al, 2007 (14)	None/ Unknown	143	Ugytex (Sofradim, Trevoux, France)	Urinary retention and vaginal hematomas	2.1%	Within 30 days	
				Vaginal erosion	6.3%	In 3.5 % of the patients within 3 months the rest after 1 year	
				De novo dyspareunia	12%	after 1 year	
Bai et al, 2007 (32)*	None/ Unknown	138	Polypropylene mesh (n = 28), classic repair (n = 72) and internal repair (n = 38)	Urinary tract infection	7.1%	Within 1 year	1.4% classic repair 0% int. repair
				Wound infection	3.6%	Within 1 year	0% classic repair 13.2% int. repair
				Fever	7.1%	Within 1 year	4.2% classic repair 5.3% int. repair
				Vaginal erosion	3.6%	Within 1 year	1.4% classic repair 0% int. repair
				Detrusor overactivity	7.1%	Within 1 year	4.2% classic repair 7.9% int. repair
				Voiding difficulty	3.6%	Within 1 year	2.8% classic repair 5.3% int. repair

***** Three surgical techniques compared (classic, mesh and internal repair).

Table 1 (continued)

Reference	Conflict of interest	Study population (n)	Product(s)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Granese et al, 2007 (26)	None/ Unknown	177	Prolene mesh (Ethicon)	Persistent SUI	2.3%	Immediate after surgery	SUI did already occur before the surgery.
				Recurrent cystocele due to mesh migration	10%	6 months	At 24 months 11% experienced recurrent prolapse
				Mesh exposure	5%	6 months	
				Dysperneunia	3%	6 months	After 24 months complication dysperneunia was decreased to 1 % due to estrogen therapy
				SIU	5%	6 months	
				De novo urinary incontinence	5% after 24 months 14%	6 months	
Jo et al, 2007 (5)	None/ Unknown	38	Polypropylene mesh (Gynemesh ethicon)	Urinary retention	15.8%	Short after the operation	Symptoms resolved after catheterization, none of the patient had persistent symptoms
				Hematoma	2.6%	Short after the operation	

Table 2 Overview review articles

Reference	Conflict of interest	Products and No. patients (n)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Bako & Dhar, 2009 (2)	None/ Unknown	Polypropylene (e.g. Gynemesh, Atrium, Marlex) (n= 1207)	Mesh exposure	0-25%	17-38.4 months	
			De novo SUI	3-23%	12-24 months	
			Dyspareunia	3-69%	6-24 months	
			Detrusor overactivity	34%	17 months	
			Intractable infection	31.5%	24 months	
			Pelvic abscess	3.2%	17 months	
		Polyester (e.g Mesilene) (n=266)	Sinuses	8.7%	17.1 months	
			Voiding difficulty	4.3%	17.1 months	
			Mesh exposure	4.5%	12 months	
		PTFE (Teflon, Gore-Tex) (n =58)	Mesh exposure	16%	3-19 months	
			Sepsis	2.3%	3-19 months	
		Mix (polyglactin and polypropylene) (n=188)	Mesh exposure	0-12.9%	6-12.5 months	
			Dyspareunia	3-4.5%	6-12.5 months	
			Deep infection	4.5%	12.5 months	
Foon et al 2008 (27)	Yes	Non-absorbable synthetic mesh	Erosion rate	14%	?	2.9% absorbable synthetic mesh and 0.67% biological material Ten prospective studies, 1087 women

Table 2 (continued)

Reference	Conflict of interest	Products and No. patients (n)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Diwadkar et al, 2009 (33)	None/ Unknown	Vaginal mesh kit group (n= 3425)	Mesh exposure or infection	5.8%	Mean follow-up 17.1 ± 13.8 months	0.5% in Traditional repair (n = 7827) and 2.2% in sacral colpopexy (n = 5639)
			Wound complications	0.2%	Mean follow-up 17.1 ± 13.8 months	0.5% in Traditional repair and 1.5% in sacral colpopexy
			Prolapse recurrence	1.3%	Mean follow-up 17.1 ± 13.8 months	3.9% in Traditional repair and 2.3% in sacral colpopexy
			Total reoperation rate	8.5%	Mean follow-up 17.1 ± 13.8 months	5.8% in Traditional repair and 7.1% in sacral colpopexy
Feiner et al, 2009 (28)	None/ Unknown	Apogee (n=525)	Mesh exposure	11%	Mean follow-up 26 ± 15 weeks	
			Dyspareunia	3%	Mean follow-up 26 ± 15 weeks	
		Gynecare PROLIFT (n=1295)	Mesh exposure	7%	Mean follow-up 30 ± 12 weeks	
			Dyspareunia	2%	Mean follow-up 30 ± 12 weeks	
		Posterior Intravaginal Slingplasty (PIVS) (n=655)	Mesh exposure	8%	Mean follow-up 46 ± 36 weeks	
			Dyspareunia	2%	Mean follow-up 46 ± 36 weeks	
		Polypropylene meshes similar to apogee, gynecare PROLIFT and PIVS (n = 178)	Mesh exposure	5%	Mean follow-up 78 ± 47 weeks	
			Dyspareunia	5.5%		

Table 2 (continued)

Reference	Conflict of interest	Products and No. patients (n)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Jakus et al 2008 (3)	None/ Unknown	Mersiline (sling) (n= 136)	Erosion	4%	30 months	Article part of series of continuing education activities.
		Prolene (sling) (n=95)	Erosion	9%	24 months	
		IVS tape (sling) (n=95)	Erosion	9%	24 months	
		Mentor ObTape (sling) (n=67)	Erosion	13.4%	36 months	
		Polypropylene (abdominal sacrocolpopexy) (n= 54)	Graft complications	26%	12 months	
		Fascia lata (abdominal sacrocolpopexy) (n = 46)	Graft complications	15%	?	
		Atrium polypropylene (anterior repair) (n= 64)	Erosion	9%	29 months	
		Prolene (anterior repair) (n= 32)	Erosion	13%	17 months	
			Dyspareunia	20%	17 months	
		Marlex (anterior repair) (n =24)	Erosion	25%	12 months	
		Marlex (anterior repair) (n =142)	Erosion	2%	38 months	
		Polypropylene (anterior repair) (n =103)	Erosion	<1%	16 months	
		Polypropylene (anterior repair) (n =87)	Erosion	8.3%	24 months	
		Polypropylene (anterior repair) (n =40)	Erosion	<1%	16 months	
		Porcine dermis (anterior repair) (n =70)	Wound separation	1.4%	24 months	
		Vicryl-Prolene (posterior repair) (n = 90)	Erosion	7.8%	6 months-1 year	
		Atrium polypropylene (posterior repair) (n = 50)	Erosion	9%	29 months	
		Prolene (posterior repair) (n = 31)	Erosion	6.5%	17 months	
		IVS Tunneler (posterior repair) (n = 34)	Erosion	2.9%	12 months	

Table 2 (continued)

Reference	Conflict of interest	Products and No. patients (n)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
South and Amundsen 2007 (4)	None/ Unknown	Gynecare PROLIFT system (n=55)	Buttock pain	18%	Immediate after surgery. After one week this was 1.8% of the patients	Details were found in the original article Flam, 2007 (15). Fifty percent of the costs of the study of Flam was financed by J&J medical.
			Cystocele	3.6%	8-12 weeks post-operative	
			Same status as before the operation	3.6%	?	
		Gynecare PROLIFT system (n=248)	Visceral injury	Approx. 4.0%	?	
		Gynecare Prolene Soft or Prolene mesh(n=277)	Mesh exposure	12%	8 weeks	Two risk factors for exposure were identified, namely hysterectomy and inverted T-colpotomy (17).
		Gynecare PROLIFT system (n=110)	Mesh exposure	4.7%	8 weeks	
		Ugytex, Sofradim (n= 143)	Mesh exposure	6.3%	8 weeks	
			Novo dyspareunia	12.8%	8 weeks	
Baessler & Maher, 2006 (18)	None/ Unknown	Varies synthetic meshes in varies studies (already mentioned above) (n=?)	Erosion rate	4-25%	?	Transvaginally placed mesh for pelvic organ prolapse repair seems to have higher erosion rates
			Dyspareunia	9-38%	?	
			Shrinkage of the mesh	2.2% (3/138)	?	

Table 2 (continued)

Reference	Conflict of interest	Products and No. patients (n)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Le at al 2007 (6)	None/ Unknown	Mixed fiber (anterior repair) (n= 15)	Novo dyspareunia	20%	23 months	Studies already recorded in the article of Jakus et al, 2008 (3) are excluded.
		Polypropylene (anterior repair) (n =12)	Cystotomt	17%%	20 months	
			Novo dyspareunia	8.3%	20 months	
			Novo urgency	16.7%	20 months	
		Polypropylene (anterior repair) (n =138)	Erosions	9.4%	19 months	
			Dyspareunia	6.5%	19 months	
		Polypropylene (anterior repair) (n =32)	Erosions	13%	17 months	
		Polypropylene (anterior repair) (n =138)	Erosions	8.3%	18 months	
		Polypropylene (Vypro), polyester (anterior repair) (n =30)	Erosions	6.7%	6.7 months	
			Dyspareunia	16.7%	6.7 months	
			Novo urge incontinence	10%	6.7 months	
		Vypro (anterior repair) (n =28)	Urinary retention	7.1%	5 months	
		Polypropylene (anterior repair) (n =98)	Novo SUI	3.1%	?	
			Bladder wall hematoma	1%	? months	
			Novo urge incontinence	3.1%	? months	
		Porcine dermis (anterior repair) (n = 111)	Erosions	13.5%	24 months	
			Ureteral kinking	2.7%	24 months	
		Porcine dermis (anterior repair) (n = 36)	overall	41.7%	18.3 months	
			Graft resorption	2.8%	18.3 months	

Table 2 (continued)

Reference	Conflict of interest	Products and No. patients (n)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Le at al 2007 (6)	None/ Unknown	Porcine dermis (anterior repair) (n = 36)	Granulation tissue	2.8%	18.3 months	
			Urinary tract infection	16.7%	18.3 months	
			Readmission	2.8%	18.3 months	
			Postoperative fever	11.1%	18.3 months	
			Ureteral obstruction	2.8%	18.3 months	
			Hemorrhage	2.8%	18.3 months	
		Porcine dermis (anterior repair) (n = 47)	Bladder injury	2.1%	24.8 months	
			Rectal injury	2.1%	24.8 months	
			De novo SUI	8.5%	24.8 months	
			Pararectal hematoma	2.1%	24.8 months	
			Urethrovaginal fistula	2.1%	24.8 months	
		Mersilene (suburethral slings) (n = 64)	Urge incontinence (anterior group)	8%	22.5 months	
			Urge incontinence (posterior group)	4%	13.6 months	
			SUI	8%	?	

Table 2 (continued)

Reference	Conflict of interest	Products and No. patients (n)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Le at al 2007 (6)	None/ Unknown	Mersilene (suburethral slings) (n = 64)	Sling exposure	1.5%	?	
		Autologous fascia vs cadaveric graft (suburethral slings) (n = 303)	Reoperation (fascia)	3.3%	85.2 months	
			Reoperation (cadaveric)	12.7%	42 months	
		Polypropylene (posterior repair)(n = 43)	Rectovaginal fistula	2.3%	12 months	
			Erosion	2.3%	12 months	
		Polypropylene (posterior repair)(n = 26/25)	Novo dyspareunia	7.7%	22.7 months	
			Difficult defecation	10%	22.7 months	
			Erosion	12%	22.7 months	
		Polypropylene/polygactin 910 (posterior repair)(n = 37)	Erosion	30%	35.7 months	
			Novo dyspareunia	27%	35.7 months	
		Dermis autologous (posterior repair)(n = 15)	Infection	6.7%	31.2 months	
			Novo dyspareunia	20%	31.2 months	
		Biological graft Pelvicol (posterior repair)(n = 32/23)	Difficult defecation	50%	38 months	
		Nylon (vaginal vault suspension) (n = 71)	Erosion	5.6%	1.5-54 months	
		Polypropylene (vaginal vault suspension) (n = 15)	Novo dyspareunia	16.7	34.8 months	

Table 2 (continued)

Reference	Conflict of interest	Products and No. patients (n)	Reported complications	Percentage complications	Period after surgery when complications are reported/follow-up period	remarks
Le at al 2007 (6)	None/ Unknown	Polypropylene (vaginal vault suspension) (n = 50)	Erosion	2%	6 months	
			Unilateral ureteral obstruction	2%	6 months	
		Polygactin and prolene (Vypro) (vaginal vault suspension) (n = 42/33)	Urge incontinence	42.9%	13 months	
			SUI	14.3%	13 months	
			Constipation	24%	13 months	
			Difficult defecation	14%	13 months	
			Novo dyspareunia	4.8%	13 months	
		Prolene PROLIFT (vaginal vault suspension) (n = 110/106)	Erosion	4.7%	3 months	
			Granuloma	2.8%	3 months	
		Polypropylene (Apogee/Perigee) (vaginal vault suspension) (n = 145/120)	Erosion	3%	12 months	
Ridgeway et al, 2008 (34)	None/ Unknown	Low-weight polypropylene (anterior repair) (n = 104)	Erosion	17%	12 months	Studies already recorded in the article of Jakus et al, 2008 (3) and Le et al, 2007 (6) are excluded.
			Increase in SUI	?	12 months	
		Polypropylene (anterior repair) (n = 63)	Erosion	9.1%	37 months	
			Mesh-related pain	5.5%	37 months	