

Use of vaginal mesh for pelvic organ prolapse repair: a literature review

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Received: 15 July 2011 / Accepted: 30 August 2011 / Published online: 9 September 2011
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Abstract The use of mesh for pelvic organ prolapse repair through the vaginal route has increased during this last decade. The objective is to improve anatomical results (sacropexy with mesh seeming better than traditional surgery) and keep still the advantage of vaginal route. Numbers of cohort series and randomized control trials have been recently published. These works increase our knowledge of advantages and risks of mesh. It has been shown that the use of mesh to treat cystocele through vaginal route improves anatomical results when compared to traditional surgery. The rate of complications, especially de novo dyspareunia, remains equivalent between the two techniques.

Keywords Pelvic organ prolapse · Gynaecologic surgical procedure · Vaginal surgery · Female · Mesh · Review

Background

Recommendations and reviews were recently published in the USA and in France about the surgical treatment of pelvic organ prolapse (POP) in women. In 2010, a Cochrane review gathered all randomized studies published until February 2009 [1]. Authors concluded that prosthetic

reinforcement when treating cystocele by vaginal route seems to lessen the risk of anatomic recurrence, but better satisfaction, better quality of life and decrease of re-interventions could not be demonstrated. There were not enough data to prove the impact of mesh when treating prolapse in the posterior compartment through the vaginal route [1].

Mucowski warned surgeons on the increased number of patients complaining after treatment of POP with prosthetic reinforcement mesh [2]. Over 1,000 undesirable effects were reported between 2005 and 2010 to the US Food and Drug Administration (FDA). A report listed the most frequent due to the technique (vaginal erosion, infection, pelvic pain, urinary problems and recurrence of prolapse). The FDA also encouraged surgeons to declare all adverse effects they could consider linked to the mesh, even those that come under a non-mandatory declaration. Finally, to improve (1) knowledge of surgeons about the possible complications of this procedure and (2) informed counselling provided to concerned women, the International Urogynecological Association and the International Continence Society recently proposed a classification of the complications related directly to the insertion of prostheses in this indication [3].

Since then, several randomized trials and many cohorts were published. Our aim is to collect and analyze them all.

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Method

A computerized bibliographic enquiry on Pubmed used the keywords: "pelvic organ prolapse", "mesh", "graft", "vaginal surgery", with limits: "randomized control trial" and "clinical trial". We added to the review of Savary [4] all randomized trials published in English or French until

December 2010. To study the adverse effects, we also included prospective or retrospective works. We excluded fundamental studies (using or not animals) and anatomic studies. All included articles were analyzed by two reviewers.

For each randomized study, data were collected on a standardized file which noted: the objectives of the study (main and secondary) with their criteria of judgement (standardized scales), the approval of an ethical committee and the written consent of the patients, the length of inclusion, the calculation of the number of included patients, inclusion and exclusion criteria, the blind definition, the method of randomization, the anatomic level treated, the material used and surgical technique, the method used to homogenize the techniques, surgeons and centres, the statistical method used, the number of patients included and lost to follow-up, the duration of the study and follow-up, the anatomic and functional results, the complications and adverse effects and the conclusions of the authors.

In other studies, we used similar reading files without the items specific to randomized studies.

Findings

Sixteen randomized trials matching our inclusion criteria were published: one in 2006 [5], two in 2007 [6, 7], four in 2008 [8–11], four in 2009 [12–15] and five in 2010 [16–20]. We added two publications of Nieminen, reporting long-term results of the randomized trial initially written by Hiltunen in 2007 [6, 21, 22]. Table 1 sums up for each study the number of patients included, the anatomic level involved, the surgical technique and mesh used and the main and secondary criteria of evaluation. The work of Allahdin was dismissed because of the lack of precision about the conception and the description of surgery [8].

Thirteen of these randomized trials mainly compared traditional surgery and use of mesh on anatomic results [5–7, 10–14, 17–20, 22]. Twelve studied non-absorbable synthetic (NAS) polypropylene implants [6, 8–12, 14, 16, 19–22] and six absorbable biomesh (AB) [5, 7, 13, 15, 17, 18]. Anatomic results are summed up in Table 2.

Improvement of symptoms and quality of life were the main objectives of two studies: Nieminen in 2008 (polypropylene NAS mesh versus colporrhaphy) and Guerette in 2009 (bovine pericardium graft versus colporrhaphy) [13, 21]. They were secondary objectives in the other 15 studies. Among studied symptoms, nine authors took interest in the impact of the mesh reinforcement on sexuality. Nieminen used an original questionnaire as no validated one existed in a Finnish translation. Authors studied not only sexuality but also symptoms and quality of life [21]. For Guerette,

sexuality was the main objective: they used the validated questionnaire “Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire” (PISQ-12) [13], also used by Nguyen [10]. Some authors only reported existence or not of a sexual activity and/or pre- and post-surgical dyspareunia. Functional results are summed up in Table 3.

Since December 2010, six randomized studies have been published [23–28]: two studies comparing the anatomical outcomes after 12 months between conventional vaginal prolapse surgery and polypropylene mesh insertion (respectively, $n=189$ versus $n=200$ and $n=97$ versus $n=93$) [23, 28], one study comparing the improvement of symptoms and quality of life 2 years after a 2×2 factorial design first described by Allahdin (Vicryl mesh $n=32$ or not $n=34$ and PDS $n=33$ or Vicryl suture $n=33$) [8, 25], one study comparing the anatomical outcomes after 36 months between sacrospinous ligament fixation (SSLF, $n=8$) and posterior intravaginal slingplasty (IVS, $n=14$) for uterovaginal or vaginal vault prolapse [24], one study comparing the anatomical outcomes after 24 months between laparoscopic sacropexy ($n=53$) and vaginal mesh (Prolift Kit, $n=55$) for the treatment of post hysterectomy vault prolapse [26], and one study comparing the sexual function at 12 months after either a vaginal surgical repair with native tissue or a trocar-guided mesh insertion in patients with recurrent POP [27]. The work of Madhuvrata was also dismissed because of the lack of precision about the conception, the description of surgery and the complication rates for different groups (no mesh versus mesh).

For Maher, the rate of anatomic success (all compartments, state 0 or 1) is significantly higher after sacropexy (77% versus 43%) with a higher rate of re-intervention in the Prolift group (79% versus 87%). But the number of symptomatic prolapse is similar [26]. Altman and Withagen showed a number of anatomic failures (state 2 or higher) observed after a tension-free vaginal mesh insertion significantly less important than after a conventional vaginal repair after 12 months (respectively, 65.5% versus 39.2% and 45.2 versus 9.6%) [23, 28]. Heinonen showed a similar rate of anatomic recurrence between the two apical support operations (21% in the IVS group and 13% in the SSLF group) with only one symptomatic patient in each group and no re-intervention [24]. Surgery is significantly shorter for vaginal route when comparing with laparoscopic sacropexy [26], but longer when comparing with conventional vaginal repair [23]. All these studies showed an improvement of quality of life and symptoms of POP in both groups, most often with no significant difference between the two surgical techniques [23, 26–28]. Complications in these recent randomized studies are described in the paragraphs below.

Finally, during the study period, we collected 108 non-randomized trial (NRT) which studied the surgical treat-

Table 1 Randomized trials summary

Trial	Number	Level of prolapse	Graft type and technique compared	Main objective(s)/Criterion(a) Secondary objective(s)/Criterion(a)
Hiltunen 2007 [6]	202	ANT	Polypropylene mesh fixed by 4 lateral arms NAS (Parietene®) versus Colporrhaphy	Anatomic results/POP-Q<2 at 2 et 12 months POP symptoms improvement, per and post-surgical complications, and postvoidal urine residual volume at 2 and 12 months/non-validated questionnaire, clinical examination
Allahdin 2008 [8]	66	–	1° Polyglactin mesh AS versus Colporrhaphy 2° Polydioxone suture AS versus Polyglactin suture AS	QoL and POP symptoms improvement / POPPY (Bugge et al. 2005)
Nguyen 2008 [10]	76	ANT	Polypropylene mesh fixed by 4 lateral arms NAS (IntePro® + Perigee System®) versus Colporrhaphy	Anatomic results/POP-Q<2 at 1 year (intermediate analysis) Sexual functional results and QoL improvement/validated questionnaire
Nieminen 2008 [21]	202	ANT	Polypropylene mesh fixed by 4 lateral arms NAS (Parietene®) versus Colporrhaphy	POP symptoms improvement and sexual functional results/non-validated questionnaire
Sivasliolgu 2008 [11]	90	ANT	Polypropylene mesh fixed by 4 lateral arms NAS (Parietene®) versus Colporrhaphy	Anatomic results/POP-Q: Ba<-1 at 1 year QoL improvement, dyspareunia, cicatrisation and complications/validated questionnaire, clinical examination
Carey 2009 [12]	139	ANT + POST	Free Polypropylene mesh NAS (Gynemesh®) versus Colporrhaphy	Anatomic results/POP-Q<2 at 12 years POP symptoms, QoL and satisfaction improvement/validated questionnaire
Lunardelli 2009 [14]	32	ANT	Polypropylene mesh fixed by 4 lateral arms NAS (Nazca TC®) versus Site-specific surgical anterior vaginal prolapse repair: reinsertion of the pubocervical fascia into the tendinous arch	Anatomic results/POP-QI with a difference of Ba point of 1 cm between the 2 groups
Ek 2010 [16]	50	ANT	Polypropylene mesh fixed by 4 lateral arms NAS (Prolift®) versus Colporrhaphy	Urodynamic examination/MUCP<40 cmH2O
Iglesia 2010 [19]	65	ANT + / - POST	Hysterectomy and: Polypropylene mesh NAS anterior or total (Prolift®) versus Uterosacral ligament suspension as Schull described or Sacrospinofixation of vaginal dome as Richter described	Anatomic results/POP-Q<2 at 3 and 12 months POP symptoms and QoL improvement, complications/validated questionnaire, clinical examination
Nieminen 2010 [22]	202	ANT	Polypropylene mesh fixed by 4 lateral arms NAS (Parietene®) versus Colporrhaphy	Anatomic results/POP-Q<2 at 3 years POP symptoms improvement and complications/non-validated questionnaire, clinical examination
Meschia 2007 [7]	206	ANT	Porcine skin collagen implant with lateral fixation AB (Pelvicol®) versus Plication of the pubocervical fascia	Anatomic results / POP-Q<2 at 3, 6 and 12 months, then once a year Complications/clinical examination at 3, 6 and 12 months, then once a year
Guerette 2009 [13]	94	ANT	Bovine pericardium collagen matrix implant with 2×2 lateral fixation AB versus Colporrhaphy	Anatomic results, POP symptoms improvement, sexual functional results, cicatrisation and complications/validated questionnaire, clinical examination, POP-Q at 3, 6, 12 and 24 months
Natale 2009 [15]	190	ANT	Porcine skin collagen implant AB (Pelvicol®) versus Polypropylene mesh NAS (Gynemesh®)	Incidence of erosions/decrease of 15% POP symptoms and QoL improvement, sexual functional results/validated questionnaire
Feldner 2010 [17]	56	ANT	Porcine collagen implant (submucosa of small intestine) with 3×2 lateral fixation AB versus Colporrhaphy	Anatomic results / POP-Q<2 (Ba point) at 1 year POP symptoms and QoL improvement, complications/validated questionnaire, clinical examination

Table 1 (continued)

Trial	Number	Level of prolapse	Graft type and technique compared	Main objective(s)/Criterion(a) Secondary objective(s)/Criterion(a)
Hviid 2010 [18]	61	ANT	Porcine skin collagen implant with lateral fixation AB (Pelvicol®) versus Plication of the fascia + colpectomy	Anatomic results/POP-Q: Ba<-1 at 1 year QoL improvement/validated questionnaire
De Tayrac 2008 [9]	49	MOY	Polypropylene mesh with lateral fixation NAS (IVS®) versus Sacrospinofixation	Pain the first day post-surgery/VAS Operating time, pre- and post-surgical complications, length of stay, satisfaction, QoL improvement, sexual activity, anatomic results, erosion, surgical procedure facility
Paraiso 2006 [5]	106	POST	Porcine skin implant with central and lateral fixation (Fortagen®) versus Plication of the fascia or Site-specific surgical repair	Anatomic results/POP-Q: Bp<or=-2 at 1 year POP symptoms and QoL improvement, sexual functional results/validated questionnaire
Lopes 2010 [20]	32	POST	Hysterectomy and: Polypropylene mesh fixed by 4 lateral arms NAS (Nazca TC®) versus Sacrospinofixation +/- pubocervical fascia repair if indicated	Anatomic results/POP-Q and POP-Q-I at 1 year POP symptoms and QoL improvement, complications/validated questionnaire, clinical examination

POP pelvic organ prolapse, QoL quality of life, AS absorbable and synthetic, NAS non-absorbable and synthetic, AB absorbable and biologic, MUCP maximum urethral closure pression

ment of POP with reinforcement mesh, mainly NAS meshes (92/108 studies). Complications are described in Tables 4 and 5. It seemed important to distinguish complications due to the dissection or the suspension of the mesh through trans-obturator or trans-levator and the complications due to the mesh itself (vaginal exposition, mesh shrinkage, dyspareunia, infection...).

Bleeding

In randomized studies, there was no significant difference between the two techniques (traditional surgery or using graft) when comparing “average blood loss” (596 patients in seven studies) [5, 7, 13, 14, 18–20] or “important blood loss” (446 patients in four studies) [6, 9, 12, 17]. A superior blood loss in the group with prosthetic reinforcement was found by Hiltunen and Altman [6, 23]. Heinonen reported one transfusion in the IVS group [24]. Sixty-seven non-randomized studies reported their per-surgical bleeding or post surgical haematomas. However, definition of bleeding varied from one study to another: most often the subjective impression of the surgeon, sometimes a more precise quantification (>200, 300, 400, 500 or 1,000 ml), or the need of blood transfusion. Other causes of bleeding have been reported as a vascular lesion in concomitant surgery (such as a hysterectomy) [29]. The precise time of onset of important bleeding due to the mesh set up (opening of pararectal or paravesical fossa, passage through trans-obturator or trans-levator) was never reported. No death due to

haemorrhage occurred in these series. Post-surgical haematomas were seen in 2.15% out of 6,034 patients (41 NRT). Their localization and their management were different according to the teams (vaginal mesh, surgical draining, simple clinical monitoring...) and not always explained. Only three studies reported infection of haematoma (three cases out of 368 patients, 0.8%); all were seen after using a NAS mesh [30–32]. In the recent randomized studies published, Heinonen reported one haematoma in the IVS group [24], Withagen observed significantly more haematomas in the group with mesh reinforcement [28], and Altman found no difference between the two groups (mesh versus not) [23].

Visceral injury

Non-randomized studies showed, respectively, 1.94%, 1.6% and 1.55% of bladder, urethral or ureteral injuries, while in randomized studies, these complications were reported, respectively, in three studies for bladder injury (meaning four patients out of 160) [6, 9, 19], one study for urethral injury (one patient out of 29) [17] and one study for ureteral injury (one patient out of 31) [5]. No rectal injury was reported in randomized studies, versus 0.58% out of 5,877 patients in cohorts (47 NRT). Two non-randomized studies have mentioned vaginal perforations (4.35% of 99 patients) [33, 34]. Randomized studies showed no difference with or without mesh reinforcement regarding to these complications, and recently Altman confirmed this result [23].

Table 2 Anatomic results (graft surgery versus traditional surgery)

Trial	Number	Number of patients studied (graft surgery versus traditional surgery)	Results (graft surgery versus traditional surgery)
Hiltunen ^a 2007 [6]	202	2 months: 201 (104 versus 97) 12 months: 200 (104 versus 96)	One-year recurrence rate in favour of graft reinforcement (7% versus 38%)
Nguyen ^a 2008 [10]	76	75 (37 versus 38)	One-year recurrence rate in favour of graft reinforcement (11% versus 45%)
Sivaslioglu ^a 2008 [11]	90	85 (43 versus 42)	One-year recurrence rate in favour of graft reinforcement (9% versus 28%) POP-Q difference for points Aa, Ba and C in favour of graft reinforcement
Carey ^a 2009 [12]	139	124 (63 versus 61)	No significant POP-Q difference <2 at 1 year (81% versus 65.6%)
Lunardelli 2009 [14]	32	32 (16 versus 16)	POP-Q difference for points Aa and Ba in favour of graft reinforcement (mean follow-up=8.5 months)
Iglesia 2010 [19]	65	65 (32 versus 33)	No significant difference for recurrence rate with mean follow-up=9.7 months (59% versus 72%) Point Ba higher in the group with graft reinforcement
Nieminen 2010 [22]	202	182 (97 versus 85)	Two-year recurrence rate in favour of graft reinforcement (12% versus 41%)
Meschia 2007 [7]	206	201 (98 versus 103)	One-year recurrence rate in favour of graft reinforcement for point Ba (7% versus 19%) No significant difference for recurrence rate on the posterior wall
Guerette 2009 [13]	94	1 year: 72 (35 versus 37) 2 years: 44 (17 versus 27)	No significant difference for recurrence rate (15% versus 22% after 1 year, 23.5% versus 37% after 2 years)
Feldner 2010 [17]	56	56 (29 versus 27)	One-year recurrence rate in favour of graft reinforcement (13.8% versus 40.7%) POP-Q difference for point Ba in favour of graft reinforcement
Hviid 2010 [18]	61	3 months: 50 (27 versus 23) 12 months: 54 (28 versus 26)	No significant difference for recurrence rate after 3 and 12 months (15% versus 7%)
Paraiso 2006 [5]	106	81 (26 graft reinforcements versus 27 plication of the fascia versus 28 site-specific surgical repair)	One-year recurrence rate (meaning Bp point >-2) higher and earlier in the group with graft reinforcement (46% versus 22% versus 14%) No significant difference for recurrence rate between these 3 groups if recurrence is defined by Bp >0
Lopes 2010 [20]	32	30 (14 versus 16)	No significant difference for recurrence rate after 12 months whatever level treated
De Tayrac ^b 2008 [9]	49	45 (21 versus 24)	No significant difference for recurrence rate whatever level treated (anterior 4.8% versus 25%, apex 4.8% versus 0%, posterior 0% versus 4.2%) with mean follow-up=16.8 months
Natale ^b 2009 [15]	190	190 (96 Gynemesh [®] versus 94 Pelvicol [®])	No significant difference for recurrence rate after 24 months (28.1% versus 43.6%)

^a From these trials: number of patients with 1-year follow-up: 247 anterior graft reinforcement NRS versus 236 anterior traditional surgery. Mean recurrence rate after 1 year: with graft reinforcement surgery=11.5%, without graft reinforcement surgery=36.35%

^b In this study, anatomic results are secondary criteria

Mesh exposition

The rate of graft exposition, whatever its type (NAS or AB) was 7.6% on average. In randomized studies, it was higher with NAS meshes (most studies): 44 patients out of 398 in nine trials [6, 9–12, 14, 15, 19, 20]. But it varied largely, from 0% to 35.7% of cases [13, 17, 20]. Mean frequency of exposition was lower for AB meshes (<1%), excepted in one study [35]. In the majority of randomized trials, mesh expositions were treated with local excision (most often

under local anaesthesia) and/or vaginal oestrogen cream [6, 9–12, 14, 15, 20, 28]. A total removal of the mesh in this indication is exceptional. Milani showed that mesh exposure was independently associated with deterioration in sexual function [27].

Infection

Three randomized studies did not show a significant increase of local infection on surgical site [6] or urinary

Table 3 Functional results (graft surgery versus traditional surgery)

Trial	Number	Number of patients studied (graft surgery versus traditional surgery)	Results (graft surgery versus traditional surgery)
Nieminen ^a 2008 [21]	202	182 (97 versus 85)	Score for vaginal bulge significantly lower in the mesh group 2 years after surgery Scores for sexual function did not differ between the groups at baseline and 2 years after surgery Score for dyspareunia significantly lower in the mesh group Higher rate of patient reported their vagina to be too loose for intercourse in the mesh group
Guerette ^a 2009 [13]	94	1 year: 72 (35 versus 37) 2 years: 59 (26 versus 33)	Better UDI-6 score after surgery in both groups Scores for sexual function did not differ between the groups at baseline and after surgery Better rate of dyspareunia and PISQ-12 score after surgery in both groups
Hiltunen 2007 [6]	202	2 months: 201 (104 versus 97) 12 months: 200 (104 versus 96)	Majority of the symptoms resolved after surgery in both groups Symptomatic recurrence higher in mesh group 12 months after surgery (4% versus 15%) Stress urinary incontinence reported more frequently in the mesh group 12 months after surgery (23% versus 10%)
Nguyen 2008 [10]	76	75 (37 versus 38)	Better PFDI-20 and PFIQ-7 scores after surgery in both groups Lower POPDI-6 and UDI-6 scores, and higher CRADI-8 score in the mesh group Sexual function, PISQ-12 score and rate of dyspareunia did not differ between the groups at baseline and after surgery
Sivasliolgu 2008 [11]	90	85 (43 versus 42)	Better P-QOL score after surgery in both groups
Carey 2009 [12]	139	124 (63 versus 61)	Worsening PSI-QOL, SUDI, SIIQ and CCCS scores after surgery in both groups Rate of dyspareunia did not differ between the groups at baseline and after surgery
Lunardelli 2009 [14]	32	32 (16 versus 16)	Similar rate of de novo stress urinary incontinence between the groups after surgery (6.25%)
Ek 2010 [16]	50	47 (22 versus 25)	Higher rate of de novo stress urinary incontinence in mesh group after surgery (32% versus 8%) Lower MUCP in mesh group after surgery in overweight women Lower MUCP in mesh group after surgery in 65-years old or older patients
Iglesia 2010 [19]	65	65 (32 versus 33)	Better scores about symptoms, quality of life and dyspareunia after surgery in both groups
Nieminen 2010 [22]	202	182 (97 versus 85)	All symptoms of prolapse resolved after surgery in both groups Sexual function did not differ between the groups at baseline and 2 years after surgery
Meschia 2007 [7]	206	201 (98 versus 103)	Improvement of symptoms of prolapse after surgery in both groups
Natale 2009 [15]	190	190 (96 Gynemesh [®] versus 94 Pelvicol [®])	Improvement of quality of life after surgery in Gynemesh [®] group in the domains: prolapse impact, social limitations, emotions, and severity measures. Improvement of quality of life after surgery in Pelvicol [®] group in all domains with the exclusion of physical limitations Comparing the postoperative quality of life in both groups: better impact of Pelvicol [®] in the domains: social limitations and emotions Better PISQ-12 score after surgery in Pelvicol [®] group Comparing the postoperative sexuality in both groups: better impact of Pelvicol [®]
Feldner 2010 [17]	56	56 (29 versus 27)	Better P-QOL score after surgery in both groups
Hviid 2010 [18]	61	3 months: 50 (27 versus 23) 12 months: 54 (28 versus 26)	Better P-QOL score after surgery in both groups

Table 3 (continued)

Trial	Number	Number of patients studied (graft surgery versus traditional surgery)	Results (graft surgery versus traditional surgery)
De Tayrac 2008 [9]	49	45 (21 versus 24)	Lower pain and buttock pain in IVS® group the first day after surgery No difference of “mean VAS” and “rate of patients with VAS>5” in both groups after long term follow-up (4.8 versus 12.5%) No difference of rate of patients “satisfy” and “very satisfy” in both groups after long term follow-up (85.7% versus 79.2%) Better UDI, POPDI, CRADI, UIQ, CRAIQ and POPIQ score after surgery in both groups Absence of improvement of PISQ-12 score after surgery in both groups
Paraiso 2006 [5]	106	81 (26 graft reinforcements versus 27 plication of the fascia versus 28 site-specific surgical repair)	Better PFDI-20 and PFIQ-7 scores after surgery in all groups Better quality of life after surgery in all groups Better PISQ-12 scores after surgery in all groups Absence of lower rate of dyspareunia after surgery in all groups
Lopes 2010 [20]	32	30 (14 versus 16)	Better quality of life (KHQ) 1 year after traditional surgery but without statistically significant difference

PISQ-12 Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, *UDI-6* Urogenital Distress Inventory Questionnaire, *PFDI-20* Pelvic Floor Distress Inventory-Short Form Questionnaire, *PFIQ-7* Pelvic Floor Impact Questionnaire-Short Form Questionnaire, *POPDI-6* Pelvic Organ Prolapse Distress Inventory Questionnaire, *CRADI-8* Colorectal–Anal Distress Inventory Questionnaire, *P-QOL* Prolapse Quality Of Life Questionnaire, *MUCP* maximum urethral closure, *KHQ* King’s Health Questionnaire

^a In these studies, functional results and sexuality are the main criteria

infection [10, 17] in one or other technique. Paraiso was the only one to report a pelvic abscess after surgery [5]. In 11 non-randomized studies (623 patients), nine of which using NAS meshes, no post-surgical infection was detected [33, 36–45]. Six studies with NAS meshes reported post-surgical hyperthermia, meaning 3.15% out of 755 cases [46–51]. Other frequent infections were

urinary, low or high (13 studies, 1,899 patients, mean frequency 5.8%), and infection of the surgical site (nine studies, 1,287 patients, mean frequency 2%). These complications were mainly seen with NAS grafts (28 out of 32 studies). Deep infection (abscess, cellulites) or generalized infections were reported in 14 cases, four times of which with a prosthesis IVS.

Table 4 Pre- and post-surgery complications in mesh groups

	Randomized trials	Non randomized trials
Major bleeding	5.3% 8 patients out of 152 in 4 trials (1.6% to 13.8%) [9, 12, 17, 18]	1.23% (0–3.6) 29 trials <i>n</i> =4164
Blood transfusion	3.1% 2 patients out of 63 in 2 trials (2.7% to 3.1%) [5, 19]	2.05% (0–25) 24 trials <i>n</i> =3379
Haematoma	3% 4 patients out of 131 in 2 trials (3.8% to 9.5%) [5, 7]	2.15% (0–8.3) 41 trials <i>n</i> =6034
Bladder injury	2.5% 4 patients out of 160 in 3 trials (0% to 9.6%) [6, 9, 19]	1.94% (0–8.3) 51 trials <i>n</i> =6827
Ureteral injury	1 patients out of 31 in 1 trials [5]	1.55% 2 trials <i>n</i> =359
Urethral injury	1 patients out of 29 in 1 trials [17]	1.6% 1 trial <i>n</i> =123
Vaginal injury	0	4.35% (1.6–5.5) 2 trials <i>n</i> =99
<i>NAS</i> non-absorbable and synthetic, <i>AS</i> absorbable and synthetic	Rectal injury 0	0.58% 47 trials <i>n</i> =5877

Table 5 Pre- and post-surgery complications in mesh groups

Graft type	Randomized trials				Non randomized trials			
	All	NAS meshes	Biologic meshes	All	NAS meshes	AS meshes	Mixed meshes	Biologic meshes
Mesh Exposition	6.1% 45 patients out of 733 in 13 trials (0% to 35.7%)	11% 44 patients out of 398 in 9 trials (5% to 35.7%) [6, 9–12, 14, 15, 19, 20]	0.34% 1 patient out of 298 in 5 trials (0% to 3.6%) [7, 13, 15, 17, 18]	7.7% (0–34.1) 98 trials n=10076	7.9% (0–34.1) 84 trials n=8747	6.4% (0–12.9) 2 trials n=173	7.9% (0–30) 8 trials n=786	5.5% (0–16.7) 4 trials n=370
De novo urinary incontinence	6.3% 26 patients out of 415 in 8 trials (0% to 40%)	7.8% 25 patients out of 319 in 7 trials (0% to 40%) [6, 9, 11, 14–16, 20]	1 patient out of 96 in 1 trial [15]	7% (0–24%) 26 trials n=3078	6.6% (0%–24%) 24 trials n=2941	0 0	5.6% 1 trial n=36	16.8% 1 trial n=101
De novo Dyspareunia	5.3% 9 patients out of 170 in 4 trials (0% to 27.8%)	6.7% 9 patients out of 135 in 3 trials (4.6% to 27.8%) [10–12]	None out of 35 patients in 1 trial [13]	9.2% (0–69) 42 trials n=3444	9.2% (0–69) 35 trials n=3008	3% 1 trial n=90	14.9% (4.5–27) 3 trials n=115	4.9% (0.9–10) 3 trials n=231

NAS non-absorbable and synthetic, AS absorbable and synthetic

Pain

Mesh shrinkage was reported in 6.8% of cases but none in randomized studies. Frequency was higher with NAS prosthesis (7.9%). Chronic pelvic pain was observed in 5.6% of patients with mesh. In randomized studies, three chronic pains were described, all in the prosthetic reinforcement group: in the buttock (Lopes, two cases out of 14 patients) [20] or in the leg (Nguyen one case out of 37 patients) [10]. Altman and Withagen did not find a significant difference between both groups for this postoperative symptom [23, 28].

Most studies did not specify the type of dyspareunia (de novo or not) or the rate of sexually active patients before and after surgery. Mean rate of dyspareunia in non-randomized studies is 9.2%. In the majority of randomized studies, the rate of postoperative dyspareunia does not differ significantly with or without graft (nine patients out of 170 in four trials) [10–13, 26, 28].

General complications

Less frequently, these are reported in Table 6. Two studies on AB meshes compared the rate of general complications between the two groups: Guerette did not find any significant difference [13], and Feldner found a higher rate in the group with prosthetic reinforcement [17]. Among non-randomized studies, three authors claimed absence of post-surgical complications (for 186 treated patients) [43, 52–54].

De novo stress urinary incontinence

Concerning stress urinary incontinence (SUI), there is a great disparity in definition and assessment between studies: the rates varied from 0% to 24%. Some authors only included patients without SUI before surgery. Distinction between SUI and urgenturia was not systematic. Five randomized studies evaluated the post-surgical rate of SUI, but only Ek and Altman showed a higher frequency of de novo SUI after prosthetic reinforcement [16, 23]. When de novo SUI is clearly defined, it was reported in 26 cases out of 415 patients in eight trials [6, 9, 11, 14–16, 20].

Discussion

Number of studies

This literature review shows that many studies have been recently published on cure of prolapse with mesh inserted through the vaginal route. The number of controlled randomized trials and the use of standard questionnaires

Table 6 Long-term complications in non randomized trials

Graft type	All kind of meshes	NAS meshes	Biologic meshes
Chronic pain (buttock, groin, perinea)	5.6% (0–24.4) 25 trials <i>n</i> =3307	5.8% (0–24.4) 24 trials <i>n</i> =3206	0.9% 1 trial <i>n</i> =101
Vesicovaginal or rectovaginal fistula	1.5% (0.3–5) 9 trials <i>n</i> =1576	1.6% (0.3–5) 8 trials <i>n</i> =1475	0.9% 1 trial <i>n</i> =101
Shrinkage	6.8% (1.3–17) 6 trials <i>n</i> =1530	7.9% (1.3–17) 5 trials <i>n</i> =1398	1.5 1 trial <i>n</i> =132
Vaginal adhesion	3.1% (0.9–6.9%) 5 trials <i>n</i> =835	3.1% (0.9–6.9%) 5 trials <i>n</i> =835	0
Granuloma	4.7% (0.8–13) 5 trials <i>n</i> =533	4.7% (0.8–13) 5 trials <i>n</i> =533	0
Leukorrhoea	5.6% (0–4) 4 trials <i>n</i> =447	5.6% (0–4) 4 trials <i>n</i> =447	0

show the will of real objective evaluation of these techniques. Few surgical techniques have undergone such an assessment, both on anatomic and functional results. But some questionnaires seem unsuited to the specificity of prolapse surgery: for example, they are not very pertinent on sexuality and dyspareunia. Works actually try to adapt them more precisely. Moreover, surgical standards are not always respected: hysterectomy is systematic for Iglesia, though it is classically a risk factor for mesh exposition [19]. Lopes also inserts the synthetic mesh between vagina and fascia, which is not recommended and could explain the rate of vaginal mesh exposition in this study: 35% [20].

Anatomic results

For the treatment of cystocele, five randomized trials on the seven published show that the risk of anatomic recurrence is reduced with NAS mesh. The global rate of relapse at 1 year is estimated around 37% after traditional surgery (87 patients out of 237) and at 11% with NAS mesh (27 patients out of 247) [6, 10–12]. We must remain careful: our review does not represent a meta-analysis, and many biases may exist. But NAS meshes seem to bring an anatomic benefit when treating cystocele. One of these studies demonstrates after a 3-year follow-up the anatomic benefit of NAS meshes (12% of recurrence after 104 grafts versus 41% after 96 traditional surgery) [22]. Carey did not find any benefit with a sub-vesical mesh, but in his surgical description, it was the only observation where prosthesis was left free without any suspension [12]. This technical variation seems to be important: in all other studies, sub-vesical mesh is suspended by its four arms. Carey changed his technique, using a vaginal support device after intervention and during 1 month [55]. Clinical results are not yet enough to conclude, and no comparative study has been published. The second trial showing no benefit of NAS prostheses was stopped after an unacceptable rate of

meshes expositions (five patients out of 32, 15%) [19]. Hysterectomy was also systematic during the cure of cystocele. The high number of failures at 1 year (59% and 72%), the concomitant hysterectomy and also the surgeon skills were questioned [56].

Two studies tried to assess the benefit of treating rectocele with a trans-vaginal mesh [5, 20]. For Paraiso, anatomic failures were more important with a biological prosthesis [5]. Lopes did not either find any anatomic benefit in this indication with a synthetic graft [20]. Pre-rectal mesh cannot be recommended with the actual data. But it seems surprising that a prosthetic surgery more efficient than traditional surgery in the anterior compartment might not be equally in the posterior one. We might need to collect a more important number of cases to show its benefit. Lopes also did not calculate the number of subjects enquired to include.

Treatment of apex is one of the actual discussions in 2011. Suspension to the sacrospinous ligament (SSL) seems the reference technique for the vaginal route. When the four arms of a sub-vesical prosthesis are bound to the tendinous arch of pelvic fascia, apex remains free. Classically SSL is reached by colpotomy and rectal dissection. When there is no rectocele, anterior route by paravesical fossa may be tempted. Prolapse of apex and bladder will be cured in the same surgical time. The sub-vesical prosthesis having several arms: two will be bound to the SSL. Traditional techniques of fixing cannot be used. Two recent systems seem interesting: harpoon or threading (Capiro™). De Tairac published a series of 48 patients whose sub-vesical prostheses were fixed with Capiro™ to the SSL by anterior route and also to the tendinous arch of pelvic fascia [57]. The rate of anatomic success was 96% for cystocele and 98% for apex after 8 months follow-up. The cure of apical prolapse cannot only be realised by a sub-vesical obturating prosthesis. Suspension to SSL must be completed by a Richter's traditional method, a posterior prosthesis or an

anterior one with anterior access of SSL. No technique seems better than the other.

Infracoccygeal sacropexy is described in several publications. The rate of mesh exposition was high, probably due to the multifilament grafts used. Data are scarce, and compilation and analysis of results are difficult as studied populations are heterogeneous (with or without hysterectomy) [58].

Question of moderate and long-term recurrence has recently find answers in several cohorts with longer follow-up. In 2010, Jacquetin showed a stability of anatomic results in the cohort TVM with a three-level surgery after 3 years follow-up [59]. Letouzey reports a rate of failures growing from 11% at 3 years to 24% after 5 years follow-up, in the treated compartment (cystocele) [34]. But in the technical surgery description, authors let the graft free, without suspension. An anatomic failure does not always mean re-intervention: in the TVM cohort, re-intervention for anatomic failure was 3% at 3 years. And Letouzey reports no re-intervention for anatomic failure at 5 years. In January 2011, Maher demonstrates better anatomic results of sacropexy compared to Prolift kit without any difference in functional terms. The rate of anatomic failures after Prolift seems very important (57%) at 2 years, largely more than literature data and also the rate of re-interventions (22% for all indications, 5% for pelvic organ prolapse) at 2 years. Such major discrepancies compared to the general results questions the specific skills of the particular teams using this vaginal route [26].

Use of AB meshes does not seem useful: two randomized studies on four published did not show a reduced rate of recurrence when compared to traditional surgery [13, 18].

Functional results

They were evaluated most often by standardized and validated questionnaires. Seven randomized studies evaluated the treatment of cystocele by meshes. Improvement of urinary symptoms is significant but is equivalent without prosthetic reinforcement. The contradiction between anatomic and functional results leads to question the modalities of evaluation and the criteria used. How can it be explained that symptom scores do get better after traditional surgery though anatomic relapse will reach 37%?

De novo urinary incontinence is found in 11% of women after prosthetic surgery and 7% after traditional surgery. Only considering sub-vesical NAS prostheses, the rate is 16% versus 8.5% in the surgery without mesh. It is difficult to conclude as indications to treat urinary incontinence vary largely from one study to another. Management of urinary symptoms remains a complex chapter we will not open here.

In the two studies of Paraiso and Lopes about vaginal surgery with graft reinforcement in posterior prolapse,

functional results were identical when comparing results with or without mesh [5, 20].

Complications

The main complication of prosthetic surgery by vaginal route is mesh exposition. Frequency varies largely from 0% to 35.7% [13, 17, 20]. Our increasing knowledge of this particular risk leads to a standardization of surgical technique: no systematic hysterectomy, no inverted-T colpotomy when dissecting cystocele, infiltration, dissection and positioning of the mesh while keeping the fascia on the vaginal wall, absence of colectomy, meticulous check-up so there is no transfixion of prosthetic arms in lateral vaginal cul-de-sac. Surgical experience is also linked to the complication rate, with a learning curve evoked by Dwyer [60]. Moreover, management of this complication seems simple enough for most authors. It should not be considered as a major complication.

Infection has become exceptional with the use of polypropylene.

The most dreaded problem is the mesh shrinkage, sometimes with pain and dyspareunia. Its definition is not clear, and the frequency is difficult to evaluate. In cohort studies, the rate of dyspareunia could not be homogenized: the pre- and post-surgical sexual activity figures and inclusion criteria vary (some teams only suggest mesh surgery at time of relapse). There may be sometimes association to other surgery (colectomy, myorrhaphy...). Letouzey finds no de novo dyspareunia at 5 years, but the rate is 9% (3/33) in the TVM series [34, 59]. Randomized studies on sexuality and dyspareunia show no significant difference between vaginal surgery with mesh and traditional surgery [5, 9, 10, 12, 13, 21, 22]. De novo dyspareunia reaches 10% in average. This rate seems superior than after sacropexy but data vary largely with this technique: Handa reports 14.5% after sacropexy by laparotomy [61]. There may be improvement of pre-surgical dyspareunia after vaginal prosthetic surgery [13, 21, 59, 62]. In a prospective cohort on 96 patients who underwent placing of a mesh by vaginal route, Hoda found a significant increasing of sexuality with a 2-year follow-up [63]. He signals a transient deterioration during the first 3 months after surgery, which might correspond to healing. But the questionnaires used are not suitable for the evaluation of dyspareunia and sexuality in the post-operative period.

New trends

To reduce surgical risk and post-surgical pain after the trans-obturator or trans-levator passage of the arms, it might be changed for suspension to the tendinous arch of pelvic fascia and also SSL by harpoon, Capiro™ suture capture device, clip or vaginal device. These techniques are being

evaluated. Suspension of a posterior prosthesis by harpoon (Elevate™) has been reviewed in 139 patients [64]. Authors report one rectal injury during dissection, two haematomas and two buttock pains. On 48 suspensions with Capio™, de Tayrac reports: one bladder injury during dissection, two embedded needles, three paravesical haematomas, two ureteral kinking, two major sciatic neuralgias and 54% of patients had buttock pain during around 8 days (2 to 70 days) [57]. Carey suggests a post-surgical intra-vaginal device but has complications due to dissection: one rectal injury and one paravesical haematoma needing re-intervention [55]. In a multicentre study with the same technique ($n=136$), authors also report two bladder injuries [62]. Intra-vaginal device was lost six times; two devices had to be taken away for infection and two for discomfort. Premature ablation of the device may generate more anatomic failures.

Severe complications were seen with trocars, but they remain exceptional [65]. The complication rate in studies with or without trocars does not seem very different: they most often happened during dissection. Some are specific of the techniques without trocar (kinking, sciatic neuralgia) with no benefit on post-surgical pain. These are preliminary studies and more important series are needed to conclude. Special care must be given to tension when positioning the mesh: when excessive, it becomes a contributing factor to chronic pain, shrinkage, rectal compression [66]. Surgeons must be especially careful when they use a graft without tension adjustment device.

The weight of the non-absorbable material and the elasticity of the mesh seem to favour prosthetic shrinkage. Prostheses used in prolapse surgery stem from hernia surgery and their mechanic properties may be unsuited to vaginal tissues. No author reported anatomic relapse due to the “breaking” of the prosthesis: they may be too robust and rigid. We might wait for meshes specifically developed for genital prolapse. Semi-absorbable mesh with a special knitting and different transversal and longitudinal elasticity was used and published after 1 year of experimentation [31]. Authors report 2% of de novo dyspareunia but cure of pre-surgical dyspareunia in 76% of cases and 4% of de novo pelvic pains. These results may seem encouraging though there are 22% of anatomic failures in the treated compartment with only 1-year follow-up. Long-term survey is necessary to be sure the benefit for pain is not obtained to the detriment of anatomic results.

Conclusion

Literature is every day growing, and the use of mesh by vaginal route is now coming to maturity with certain indications and middle-term data. Compared to traditional

vaginal surgery, use of a non-absorbable synthetic sub-vesical mesh to treat cystocele gives an anatomic benefit. All skilled surgeons have identical functional results and rate of complications, when technical surgical rules are respected. New techniques might give further improvements, but we have yet no sufficient data to conclude. Meshes specifically designed for vaginal surgery might allow even more ameliorations. Comparison with sacropexy by skilled teams (knowing both techniques) might also be interesting.

Declaration of interest Dr. Lucot Jean-Philippe: teaching sessions with Prolift® (Johnson & Johnson), IPSEN and Endofast® (IBI)

Pr. Cosson Michel: teaching sessions with Prolift® (Johnson & Johnson), IPSEN, funding for fundamental research Ethicon®, patents in progress with Ethicon®, Cousin Biotech®

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