1 **Where to for pelvic organ prolapse treatment after the FDA**
2 **pronouncements? a systematic review of the recent**
3 **literature**

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6 **“ Back to the Future ”**

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Abstract:

Introduction: With the publication of the updated FDA communication in 2011 on the use of transvaginal placement of mesh for pelvic organ prolapse (POP) it is appropriate to review now recent studies of good quality on POP to assess the safety and effectiveness of treatment options and determine their place in management.

Methods: A systematic search for studies on the conservative and surgical management of POP published in English literature between January 2002 and October 2012 was performed. Studies included were review articles, randomized controlled trials, prospective and relevant retrospective studies as well as conference abstracts. Selected articles were appraised by the authors regarding clinical relevance

Results: Prospective comparative studies show that vaginal pessaries constitute an effective and safe treatment for POP and should be offered as first treatment of choice in women with symptomatic POP. However a pessary will have to be used for the patients lifetime. Abdominal sacral colpopexy is effective in treating apical prolapse with an acceptable benefit/risk ratio. This procedure should be balanced against the low but non negligible risk of serious complications. The results of native tissue vaginal POP repair are better than previously thought with high patient satisfaction and acceptable re-operation rates. The insertion of mesh at the time of anterior vaginal wall repair reduces the awareness of prolapse as well as the risk of recurrent anterior prolapse. There is no difference in anatomic and subjective outcome when native tissue vaginal repairs are compared with multicompartiment vaginal mesh. Mesh exposure is still a significant problem requiring surgical excision in approximately $\geq 10\%$ of cases. The ideal mesh is not yet found necessitating more basic research into mesh properties and host response. Several studies indicate that greater surgical experience is correlated with less mesh complications. In women with uterovaginal prolapse uterine preservation is a feasible option which women should be offered . Randomized studies with long term follow-up are advisable to establish the place of uterine preservation in POP surgery.

Conclusion: Over the last decade treatment of POP has been dominated by the use of mesh. Conservative treatment is the first option in women with POP. Surgical

55 repair with or without mesh generally result in good short-term objective and
56 functional outcomes. However ,basic research into mesh properties with host
57 response and comparative studies with long term follow-up are urgently needed.

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59 **keywords:** Pelvic organ prolapse (POP) , conservative management of POP , POP
60 repair, vaginal surgery, transvaginal mesh, Uterine preservation.

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Introduction.

The introduction of synthetic implants in transvaginal POP surgery, some 15 years ago, has prompted a much greater interest in the impact of pelvic floor dysfunction in women and the effectiveness of reconstructive vaginal surgery.

With the updated FDA safety communication in July 2011 (1, 2) there is increasing concern regarding this important health issue in women .. POP like stress incontinence is rarely a life threatening condition but is common resulting in 1 in 5 to 10 women having 1 or more operations(3). POP may present with a variety of symptoms which can have a negative impact on women's daily activities and quality of life (QoL). Current treatment options include pelvic floor muscle training, use of pessaries and surgery. During the last few years studies of good quality have shed new light on the management of this challenging health problem. This review focuses on the clinical relevance of the various treatment modalities based on evidence from recent literature.

Methods.

A systematic search for studies on the conservative and surgical management of POP published in English literature between January 2002 and October 2012 was performed. The databases Medline, PubMed and Cochrane database as well as reference lists of relevant articles were searched. Search terms included conservative management of POP, POP repair, vaginal surgery, vaginal mesh, sacrocolpopexy and uterine preservation and POP. Clinical studies on POP treatment reporting objective anatomic and subjective patient determined outcomes using validated questionnaires were assessed: review articles, randomized controlled trials, prospective and relevant retrospective studies and major conference proceedings. Reference to studies published before 2002 is given when deemed necessary. Selected articles were appraised by the authors regarding clinical relevance.

Results

Conservative treatment.

Pelvic floor muscle training: There is now limited evidence indicating a positive, short term effect of pelvic floor muscle training (PFMT) in alleviating prolapse symptoms and severity. Evidence relating to long term effectiveness and cost-effectiveness is lacking.(4)

Mechanical devices: Vaginal pessary is an effective and safe method in the treatment of POP symptoms with high patient satisfaction and low economic cost. It is not clear which women will benefit from pessary treatment, but almost two-thirds of women with symptomatic POP would opt for a vaginal pessary as initial treatment (5). Most studies reported successful fitting trial over 85% with continuation rates ranging from 50 to 80%. Most insertion failures or discontinued use occur within 4 weeks of pessary insertion. (6,7). With proper training and understanding of pessary management the majority of complications such as discomfort, vaginal discharge, foul smell and bleeding can be managed usually with short-term pessary removal(7). Sexual activity is not a contra-indication for pessary treatment. However patients must appreciate that the pessary needs to be worn life-long and will need to be changed and cleaned on a regular basis. In a prospective study using validated ICIQ-VS questionnaire the effectiveness of pessary was compared with surgery in 287 women with symptomatic POP. Of the eligible women 116 opted for pessary and 153 for surgery. After one year data was available: in the pessary group n=80, in the surgery group n=109. There was a significant improvement in vaginal symptoms and quality of life parameters in both treatment arms (8). There was no significant difference between the two treatment groups. Given that surgical correction of POP is associated with complications and recurrence rates, women with symptoms of POP should be counseled and, if desired, given a fitting trial as first treatment of choice. There are no RCT's comparing the effectiveness of pessary treatment with surgical POP repair.

Surgical treatment.

POP can occur in one or more compartments: approximately 70% of patients presenting with POP have two or all 3 vaginal compartments involved(3). Some clinicians believe that if prolapse is present in one compartment, then all 3 should be repaired to prevent further recurrences in the unrepaired site. This however would be at the cost of greater morbidity especially if synthetic mesh is used.

I. Middle or apical compartment:

Utero-vaginal prolapse (UV) and post-hysterectomy vaginal vault prolapse result from laxity of the supportive pelvic fibromuscular tissue that connects the pelvic organs laterally to the pelvic walls: cardinal and uterosacral ligaments and the endopelvic fascia: Delancey's level I support(9). The pelvic organs are also supported by the levator ani muscles which are frequently damaged in childbirth. Until now, no POP surgery targets these supports, thus setting the scene for recurrence. Surgical treatment of UV- or vaginal vault prolapse can be performed either by the abdominal route or by the vaginal route. At

present, the most commonly performed procedures for utero-vaginal and/or vaginal vault prolapse are abdominal sacral colpopexy (ASC)or colpohysteropexy, vaginal hysterectomy (VH) with plication of uterosacral ligaments , vaginal sacrospinous ligament suspension and transvaginal mesh repair (TVM).

• **Abdominal sacrocolpopexy (ASC)** is said to be the gold standard for apical prolapse with an acceptable risk/benefit ratio. The abdominal approach involves apical suspension with a permanent mesh which is – without tension - fixed to the longitudinal ligament of the sacrum . A review of observational studies reported long term success rates of 78% to 100%. Mesh erosion is observed in 2 % to 11% (10 ,11). These data compare well to the results of a large systematic review of the efficacy and safety of using mesh in surgery for uterine and vaginal vault prolapsed, published in 2010 and including all relevant studies from 1980 onwards. Recurrence is reported in the range from 0 to 6 %, persistent prolapse symptoms ranged from 3% to 31% and mesh erosion occurred from 0 to 12 % , median: 4% (12.) The risk of erosion increases when concomitant hysterectomy is performed , when the vagina is opened by accident or when a combined abdominal/vaginal approach is used . In women with uterovaginal prolapse who desire to preserve the uterus abdominal sacro-hysteropexy (ASH)with mesh extending between the back of the uterus and the sacrum is a feasible and effective procedure, which allows restoration of vaginal length and is associated with good functional outcome(13). There is level I evidence that ASC, either by laparotomy or laparoscopy or with the aid of a robotic device , is more effective and durable in correcting anterior and apical anatomy than the vaginal approach using sacrospinous colpopexy (14) or uterosacral vault suspension (15) . ASC is also more effective in maintaining vaginal and lower urinary tract function but is associated with greater peri-operative morbidity and higher economic cost (12,14). Serious complications such as bowel injury , sacral myelitis and severe bleeding are uncommon with an, estimated incidence of 2% (range 0% to 8%),and should always be kept in mind as they can ultimately result in patient death . The higher morbidity is the reason for the continuing popularity of vaginal procedures among patients and gynaecologists

Vaginal approaches include: traditional vaginal hysterectomy (VH) with or without plication of uterosacral ligaments (Mc Call culdoplasty), sacrospinous ligament suspension (SSLs), high uterosacral vault suspension (USL S) and more recently posterior intravaginal slingplasty (PIVS)and transvaginal mesh (TVM). In women with an intact uterus, uterus preserving techniques either by vaginal route or by abdominal route can be considered.

• **Traditional vaginal hysterectomy (VH)**: if there is significant uterine prolapse, in most institutions worldwide, vaginal hysterectomy with or without anterior and/or posterior colporrhaphy , is still the procedure of choice. Vaginal hysterectomy with plication of the utero-sacral ligaments is an efficient treatment for UV prolapse with swift recovery , low rate of complications and good anatomic support at short term follow-up (16). In 2 recent surveys in the UK and in Australia and New Zealand, 82%and 79% of gynaecologists would perform a vaginal hysterectomy with vaginal wall repair for significant uterovaginal prolapse once reproduction was finished (17,18). In many countries , e.g. Taiwan and the Netherlands(19,20), a tendency towards uterine preserving procedures can be observed . At long term follow-up, failure rates of traditional vaginal prolapse repair involving more than one compartment are reported to be high with one literature review having a range of 0 to 60 % (10). However, many of the studies reviewed did not have POP-Q as an objective outcome measure for anatomic success, validated questionnaires were not used to assess functional outcome and there was no proper definition of success or failure given. Approximately 50% of parous women have POP to the hymen (POPQ ≤ 2)and usually are asymptomatic i.e. do not experience vaginal bulge symptoms. Consequently, the clinical relevance of this degree of POP in failure rates is unclear . Clark et al . in their prospective study on conventional POP repair found a re-operation rate of 13% after 5 years (21). Comparable results, i.e. re-operation rates ranging from 10 to 15 %, were reported by other investigators in population-based retrospective or case control studies (22-24). Based on statistics provided by the departments of Obstetrics and Gynecology in Austria Aigmuller et al.(2010) calculated the frequency for post hysterectomy vault prolapse requiring surgical repair between 6% and 8 % (25). These findings indicate that failure rates after traditional native tissue POP repair may be lower than generally estimated. The risk of POP recurrence was strongly associated with the degree of preexisting prolapse or previous POP repair (21-24).

• **Transvaginal mesh repair (TVM)**:

Based on the principles of the use of synthetic mesh in abdominal surgery and after the successful introduction of synthetic vaginal tapes for the treatment of stress incontinence and new anatomic routes for mesh insertion, a group of French urogynecologists started in 2002 a prospective multicenter study on transvaginal POP repair using a tension free polypropylene mesh in patients with stage ≥ 3 vaginal prolapsed (prolifttm) . The preliminary published reports were encouraging and within a relative short period of time many gynecologists decided to introduce this technique or modifications of this technique into

their practice (26). In 2010 B. Jacquetin et al. published their 3 years results (N=90, follow-up: 94%) : objective cure rates 80,5%, patient satisfaction >80%, mesh exposure 14,4% , shrinkage 12,6% and total re-operation rate 13,3% (27). Miller et al.(2011) using the same graft material published their 5 year results in 85 women with a follow-up rate of 77%. Overall anatomic cure rates were 88%, 69% and 67% at 1,3 and 5 years respectively and significant improvement in quality of life was sustained after 5 years. Three serious complications were reported and mesh exposure was observed in 18%(28). Recently ,two prospective multicenter, industry sponsored studies with partially absorbable low weight implants presented their data: Prolift+M with 3 year follow-up and 85% response (29) and Elevate EAA with 2 year follow-up , 87% response (30). Objective anatomic success rates varied between 76% and 96%. The quality of life measures including pelvic symptoms and sexual function improved significantly with high patient satisfaction. Mesh exposure was observed in 14,8 and 5,6% respectively. Looking at all comparative studies of native tissue (NT) and mesh-augmented (MA) POP repair published between 1950 and May 2011, Stanford et al. concluded that the overall success rates for NT and MA repair were very similar when recurrent prolapse is the primary outcome measure particularly when apical support is included (31). At the 37th IUGA Annual meeting the Cochrane review group presented a meta- analysis of all RCT's (N=54) published or presented between 1950 and February 2012 addressing the surgical management of pelvic organ prolapse .The review group concludes that use of mesh or graft inlays at the time of anterior vaginal wall repair reduces the risk of recurrent anterior vaginal wall prolapse. Two trials compared native tissue vaginal repairs to a combination of total , anterior or posterior mesh repairs in women with prolapse involving anterior, posterior and/or apical compartment. The total reoperation rate for prolapse, stress urinary incontinence or mesh complications after the combined mesh repair was 10% as compared to 3.4% after native tissue repair (32). The benefits of TVM must be balanced against mesh related complications requiring surgical intervention (table I). It needs stating that all the list complications other than mesh exposure can also occur with NT repair. However, mesh exposure is a significant problem which may require repeated return to the theatre negating the potential benefits of a stronger repair. Several studies have shown a decreasing rate of mesh complications with increasing surgeon's experience (26, 33,34).This emphasizes the need of further research addressing mesh properties, surgical training and techniques and the impact of vaginal surgery on women's symptoms and quality of life.

• **Abdominal sacrocolpopexy versus Transvaginal mesh (TVM):**

229 Maher et al. performed a prospective RCT comparing laparoscopic sacrocolpopexy (LSC.
 230 N=53) with mesh extending over the anterior and dorsal vaginal wall if deemed necessary
 231 vs. transvaginal mesh (TVM. N=55) .At 2 years follow-up their results showed that LSC
 232 had a higher satisfaction rate and objective success than TVM (77% vs. 43%. P <0.001).
 233 Reoperation rate was higher after vaginal mesh surgery as compared with LSC : 22% vs. 5%.
 234 p=0.06 (35).
 235 Withagen et al. compared prospectively two cohorts of consecutive women with
 236 symptomatic vault prolapse referred to 3 tertiary referral centres. Forty-five women were
 237 included in the LSC group (bone anchor fixation and mesh limited to the apex) and 52 in the
 238 TVM group. The short term failure rate (6 months follow-up) of symptomatic prolapse of
 239 the apical compartment in both groups was 2%. However , when all vaginal sites are
 240 included the failure rate in the LSC cohort was 51% vs. 21% in the TVM cohort (p=0.002).
 241 The high rate of recurrent or *de novo* prolapse after LSC was explained by the fact that
 242 mesh was applied to the apex only without combining LSC with anterior and/or posterior
 243 repair. In the TVM group mesh exposure at 6 months follow-up was 8%. The results of
 244 these 2 studies lead one to conclude that when performing ASC (or LSC) extension of the
 245 mesh down on the anterior or posterior wall is necessary to treat co-existing POP and/or
 246 reduce the risk of recurrence or *de novo* prolapse. (36)
 247 • **Traditional vaginal POP repair vs.TVM in women with recurrent prolapse:**
 248 A large , adequately powered ,multicenter RCT , including 190 women with recurrent pelvic
 249 organ prolapse , compared conventional vaginal repair with mesh reinforced repair (37) .
 250 The follow-up after 12 months was 98%. Anatomic failure(POP-Q stage $\geq$ II) in the treated
 251 compartment was observed in 45,2 % in the conventional group and in 9,6% in the mesh
 252 group (p<0.001; OR:7.7; 95% CI. 3.3-18). Mesh exposure was detected in 16,9% and in 6%
 253 (5 patients) these mesh exposures were excised. Secondary analysis of this RCT revealed
 254 that mesh-reinforced repair in one vaginal compartment is associated with a higher
 255 incidence of *de novo* prolapse in the untreated compartments (47% vs. 17% ; p < 0.001;
 256 OR. 4,3; CI. 1.9-10.0) (38). As a consequence, the overall anatomic failure rate after
 257 conventional repair was 66%, after MA repair 49%. Subjective improvement as evaluated
 258 by validated urogynecologic questionnaires was equal among both groups (Table 2). In
 259 conclusion, mesh-augmented repair in only one compartment may provoke or deteriorate -
 260 latent - prolapse in the untreated compartment. Additional apical support to a mesh-
 261 reinforced anterior repair significantly reduced *de novo* prolapse rate. Adequate apical

support (Level I Delancey) during pelvic reconstructive surgery is essential to reduce the risk of prolapse recurrence or *de novo* prolapse.

• **Uterus preservation in utero-vaginal prolapse :**

Uterine descent is often part of vaginal prolapse. Consequently ,hysterectomy at the time of POP repair is the standard practice in most parts of the world. A Medline search of the literature in the English language (1966 to 2003) pertaining to the role of uterine preservation during pelvic reconstructive surgery found only fourteen articles addressing the surgical repair of uterovaginal prolapse with uterine preservation . The quality of most studies was poor with only small number of patients included, short term follow-up and variable outcome measures used (39).

Dietz et al. (40) presented the results of a literature search on complications, anatomic and functional outcomes and quality of life after vaginal hysterectomy and 3 uterus preserving procedures i.e. modified Manchester-Fothergill (Donald, 1888) , sacrospinous hysteropexy (Richardson, 1989) and posterior intravaginal slingplasty(P. Petros ,2001). Studies published in English language between 1987and 2007 were assessed. All studies included were of a retrospective design and heterogenic with respect to follow-up time, inclusion criteria, definition of recurrent prolapse and methods of data collection. In many patients a combination of 2 or more surgical procedures were performed . There were no randomized controlled trials available for the four surgical techniques. Consequently , proper comparison of the efficacy and safety of these procedures is not possible. Re-operation rates for recurrent prolapse were similar for all techniques ranging from 0-7%. Vaginal hysterectomy and the three uterus preserving techniques were equally effective with regard to apical cure at short term, but long term results and data on functional outcomes are limited. Complication rates for these procedures differed considerably between different studies(41). Based on the currently available limited data uterus preservation at the time of POP repair may be a feasible and safe option with less morbidity and shorter recovery time..

The Modified Manchester Fothergill (MMF)procedure was first described in 1888 by Archibald Donald from Manchester and later modified by Fothergill. The MMF operation consists of transvaginal cervical amputation, colporrhaphy and fixation of the cervical stump to the cardinal ligaments. Subsequent investigators “extended “ the procedure to include culdoplasty with plication of the uterosacral ligaments to prevent post-operative enterocele (42). Earlier publications on MMF are limited by methodological deficiencies and fall short of objective data. In addition , uterine preservation carries the risk of future

uterine pathology including the risk of haematometra . Patients should be advised against any future pregnancy. These considerations led clinicians to abandon this procedure in favor of vaginal hysterectomy (43). Recently, 2 retrospective case control studies compared the effectiveness of the MMF procedure versus vaginal hysterectomy with uterosacral plication (VH). Follow-up was performed using validated questionnaires. The MMF procedure was equally effective as VH in terms of functional outcome and recurrence rates but was associated with shorter operation time and less blood loss (42,44). These reports suggest that MMF is a viable option in women with uterine descent as it restores good apical support, maintains the physiologic vaginal axis and allows for adjustment of vaginal depth. Adequate patient information and routine surveillance measures to assess for uterine pathology over time are mandatory

Sacro-spinous hysteropexy (SSH): Richardson et al. reported in 1989 a case series of 5 women with utero-vaginal prolapse, age range between 24 to 31 years, having a transvaginal sacrospinous hysteropexy (SSH). In this small series no recurrences were observed during a follow-up period of 6 to 24 months. The authors found SSH to be a feasible option for the correction of utero-vaginal prolapse in women who desire to preserve uterine function(45) .

Maher et al. reported on a retrospective non-randomized comparative study on 34 women who had a SSH procedure and 36 who had a vaginal hysterectomy with sacro-spinous vault fixation (VH- group). The groups were comparable with regard to age, parity ,Body Mass Index, prior pelvic surgery history, menopausal status and percentage of grade 2 and 3 vault prolapse. Anatomical and subjective cure rates were similar for both groups (74 % vs. 72 % and 78% vs. 86 % respectively) (44). Subsequent investigators, in non-randomized comparative studies, reported comparable outcomes with regard to uterine and upper vaginal support , complication rate and subjective improvement(47 ,48).

A randomized multicenter trial compared SSH with VH for uterine descent grade 2 to 4. The study was well designed ,but non-blinded and slightly under-powered as only 17% of 409 eligible women consented to participate. At one year follow-up the recurrence rate of apical prolapse in the VH group was considerably lower than in the SSH group (3% vs. 27% respectively). Both procedures were comparable with respect to complication rate , functional outcome and quality of life. A high recurrence was noted in the pre-operative high stage prolapse patients who underwent SSH. Recurrence rates for anterior and/or posterior prolapse were comparable in both groups . Re-operation rates for prolapse after SSH was 11% vs. 7 % after VH (49) .

Feiner et al. (50) performed a prospective study to evaluate the combination of anterior vaginal mesh, sacrospinous hysteropexy and posterior wall plication in 100 women with anterior compartment and uterovaginal prolapse. At 12 months follow-up objective success rate at the anterior compartment was 87% and at all compartments 75%. Subjective success rate was 84%. As the majority of women (70%) present with multicompartiment prolapse this combined procedure seems a logic and reasonable surgical approach with favourable objective anatomic and patient determined outcomes , but long term results are needed.

A retrospective study of 200 women, compared hysterectomy with uterosacral cuff suspension (VH) to hysteropexy with uterosacral suspension (USH). The 2 groups of 100 women each were comparable for degree of prolapse. Follow-up varied between 2.4 months and 10 years. There were 3 recurrences of apical prolapse in each group and 2 ureteric complications in the VH group. One year success rate was 97.8% in the USH group, and 98.6% in the VH group. There were no data on functional outcome or on quality of life (51).

These studies suggest that SSH is a safe and effective alternative to hysterectomy in treating uterovaginal prolapse. SSH is associated with shorter operation time , less bloodloss, shorter hospitalization , earlier recovery and return to daily activities. The concept of prolapse repair with uterine preservation warrants further evaluation . Prospective randomized trials with and without hysterectomy with long term follow-up are needed to clarify this issue. Appropriate candidates should be informed about the ongoing possibility of incurring uterine and cervical pathology and the need for continued routine surveillance to assess for such pathology .

• **Post-hysterectomy vault prolapse:**

Conventional surgical treatment for post-hysterectomy vault prolapse by the vaginal route is accomplished either by sacrospinous ligament suspension(SSLS) , posterior intravaginal slingplasty (PIVS); or by using the uterosacral ligaments with high uterosacral ligament suspension (USLS) or Mc Call /Mayo culdoplasty.

Sacrospinous ligament suspension (SSLS): This procedure was first described by Sederl in 1958 and further developed by Richter in 1967 and is at present the most commonly performed transvaginal procedure for vault prolapse (52,53). Several systematic reviews have evaluated the published literature and show that SSLS is a highly effective therapy for vaginal vault prolapse with low recurrence and complication rates and good patient satisfaction . One concern is the high incidence – ranging from 8% to 30% - of recurrent

cystocele presumably due to posterior orientation and fixation of the upper vagina which predisposes the anterior compartment to excess intra-abdominal pressure leading to a higher incidence of recurrent or *de novo* anterior wall prolapse (54-59). Also, for similar reasons ,there is an increased prevalence of postoperative stress incontinence compared to ASC (14). Reported incidence of post-operative or *de novo* dyspareunia varies but is inconclusive as only few studies used validated questionnaires on sexual function. A recent study reported the objective and subjective outcomes of a combination of anterior transobturator mesh and SSLS in 120 women with severe prolapse (stage III –IV). At 30 months follow-up the overall objective cure was 92% and subjective cure 93%. No stage ≥ 2 recurrences of anterior and apical prolapse were observed. There were data on sexual function. Mesh complications occurred in 8%. (60)

Posterior intravaginal sling plasty: This procedure aims to suspend the vaginal vault in its natural position using a tension free tape that is tunneled through puncture incisions in the buttock around the rectum and vagina and guided with a small apical incision (61). A systematic review of the efficacy and safety of mesh in surgery for uterine or vaginal vault prolapse identified 14 studies on PIVS. The estimates for the efficacy and safety outcomes of this procedure were wide. As a consequence , In January 2009 NICE (UK) recommended that, for all vaginal procedures for vaginal vault repair but sacrocolpopexy , “special arrangements for clinical governance, consent and audit or research” should be used (11).

McCall culdoplasty and High Uterosacral ligament suspension(USLS) : These procedures treat apical prolapse by reattaching the uterosacral ligaments to the vaginal vault. McCall culdoplasty: Hysterectomy with shortening and plication of the distal uterosacral ligaments in the midline is still an effective surgical treatment for the majority of patients.(62)

The uterosacral ligament suspension (USLS) anchors the vaginal apex to the proximal uterosacral ligaments. The procedure keeps the vaginal axis in the midline and allows for adequate vaginal depth. The uterosacral ligaments can be approached intra-peritoneally or extra-peritoneally. The intraperitoneal approach was first described by Miller in 1927 (63). Shull et al. (64) more recently has popularized this approach especially in the USA and described plication of the uterosacral ligaments at 1,5 to 2 cm from the ischial spines to create a bridge of fibromuscular tissue to which the anterior and posterior vaginal wall are attached. In his series of 289 consecutive women optimal anatomic success was observed in 87%, recurrent grade 2 support defect was present in 5% and ureteric injury occurred in 1%. Margulies et al. reviewed all studies on the intra-peritoneal uterosacral ligament suspension

as well as some modifications of this technique and reported comparable objective and subjective patient determined outcomes (65). USLS is associated with increased risk of ureteric injury, reported to occur in 1 to 11% , thus necessitating post-operative cystoscopy . USLS can also performed by an extra-peritoneal approach for posthysterectomy vault prolapse and does not require entry into the peritoneal cavity and has less risk of ureteric injury than intraperitoneal USLS [66]. It can be performed through an anterior or posterior vaginal approach. Two delayed absorbable sutures are placed into each uterosacral-cardinal ligament complex after dissection of the endopelvic fascia from the vaginal mucosa and identification of the remnants of the ligament complex and ischial spines. The ends of the sutures are passed out through the full thickness of the vaginal mucosa at the level of the new vault. A RCT on surgical treatment of post hysterectomy vaginal vault prolapse compared an extraperitoneal transvaginal uterosacral suspension and anterior mesh reinforcement with abdominal sacrocolpopexy . At 14 months follow-up objective cure rates were 70 and 76% for the vaginal and abdominal groups respectively and all subjective scores improved significantly with no differences between the 2 groups (67)

Diwadkar et al. (68) carried out an extensive meta-analysis to compare post-operative complication and re-operation rates after 3 surgical procedures to repair apical vaginal prolapse i.e. abdominal sacrocolpopexy(ASC) , traditional vaginal surgery (SSLS, USLS and McCall) and vaginal mesh kits (TVM and PIVS): Re-operation rates for apical prolapse recurrence were highest in the traditional vaginal surgery group: 3,9 % vs. 2,3% for the sacrocolpopexy and 1,3% for vaginal mesh. However, total reoperation rate was highest in the vaginal mesh group (8,5%) because of a higher rate of complications such as mesh erosion and/or occurrence of prolapse in the untreated compartment. (See Table 3). One can speculate that more recurrences and complications may be diagnosed given the relatively shorter mean follow-up period in the vaginal mesh group. More long term studies and clinical trials that directly compare these surgical techniques are needed to support these findings.

II. Anterior vaginal wall prolapse:

The anterior vaginal wall is the most common site of POP and > 80% of all surgical POP repairs involve the anterior vaginal wall (8). The anterior vaginal wall has the highest potential for recurrent prolapse following traditional native tissue repairs with reported failure rates ranging from 30 to 60% (10,69) . However, variations in surgical techniques—e.g. proper dissection of the pubovesicocervical fascia, site-specific repair, whether or not apical support was included, primary repair or repeat surgery , concomitant SUI surgery –and

differences in definitions of success and/or failure make proper comparisons difficult. Jia et al. (70) published an extensive systematic review on the efficacy and safety of mesh/graft for anterior and posterior repair. Forty-nine studies involving 4569 women were included , median follow-up was 13 months. In anterior repair there was short term evidence that mesh reinforcement significantly reduced objective recurrence rates: non-absorbable synthetic mesh : cure rate 91.8%, for absorbable synthetic mesh: 76,9% and for biological graft :82.1% whereas for traditional anterior colporrhaphy the objective cure rate was 71.2%. These findings compare well to the data published in a recent review by Stanford et al. (31). Modern definitions of success include a composite of anatomic outcome and subjective patient-oriented success. During the last few years a number of adequately powered RCT's using objective and validated subjective outcome measures have compared traditional anterior colporrhaphy with trocar guided transvaginal mesh repair or mesh interpositioning (71-78). All studies show a comparable and significantly better, short-term anatomical success rates in the transvaginal mesh group as compared with traditional anterior colporrhaphy: 61-91% for transvaginal mesh vs.35-72% for traditional repair. (Table IV).The great variation in anatomic outcomes , after traditional vaginal wall repair as well as after mesh augmented repair , also reflects our – lack of- knowledge about the pathophysiology of this condition . “Not all cystoceles are alike” : Delancey (79). Damage to the pelvic floor muscles (levator ani) results in enlargement of the urogenital hiatus thus paving the path for the intra-abdominal pressure to push the anterior vaginal wall downward (80, 81). If on the other hand the cardinal and uterosacral ligaments are defective, the uterus or vaginal vault will eventually descend leading to uterovaginal or vault prolapse. In most women with anterior compartment prolapse(60-70%) both etiological factors co-exist. Mesh insertion - with or without the use of a trocar guide - resulted in higher rates of adverse events including mesh exposure (exposure: 4 to 19 %, reoperation: 3-6%), bladder perforation, buttock pain and *de novo* prolapse of the untreated compartment. In spite of the improved anatomical outcome the re-operation rate after anterior vaginal wall repair was higher in the mesh group than for native tissue repair: 9% vs. 5% (81). Functional outcomes and subjective improvement were similar between the groups(32, 74-78,81).

One study using validated questionnaires addressed the effects of vaginal prolapse surgery on sexuality in women with and without mesh-augmented repair and observed clinically relevant improvement of sexual functioning after traditional colporrhaphy . This improvement was not observed in the mesh group. (82)

In a prospective study using POPQ measurements and validated symptom and quality of life questionnaires on 70 women with symptomatic anterior vaginal wall prolapse who underwent traditional anterior colporrhaphy under local anesthesia in an out-patient setting with 5 years follow-up Greisen et al. reported that 78% of the women were relieved from their symptoms: 11% were re-operated and another 11% still experienced bulge symptoms(83). These outcomes compare well to data from other studies on traditional anterior colporrhaphy. (81 , 84).

Recently the results of a new technique for anterior and vaginal vault prolapse using a lightweight (24 g/m²) soft Type I mesh, so-called second generation mesh kits , were published . The mesh is inserted through a single incision and anchored bilaterally with self-fixating tips to the obturator internus muscle and sacrospinous ligament. At 13 months follow-up the authors reported excellent results without major complications and “low “ mesh extrusion rate (85). Mourtialon et al. (86) compared in a prospective multicenter study, including 230 women with symptomatic anterior vaginal wall prolapse, the anatomic outcome of 3 different surgical techniques of mesh placement (Ugytextm): retropubic, with two to four arms in the obturator foramen or fixation to the arcus tendineus. The overall objective success rate after 3 years for cystocele repair was 88%. However the retropubic placement was significantly less effective than the 2 other routes of insertion: 69% vs. 90,1 and 96,6% respectively. Mesh erosion was present in 13,2% and its incidence appears highly correlated with surgeon’s experience. These studies lead one to conclude that use of mesh has a role in anterior and vaginal vault wall repair but much study still needs to be done to determine the ideal material and the optimal way to place it.

III. Posterior vaginal wall prolapse:

Posterior vaginal wall defects are present in 18 - 40% of parous asymptomatic women. Rectoceles are the most common posterior wall defect and often occur in combination with other vaginal wall defects. Rectocele is caused by fascial weakness in the posterior compartment secondary to divarication of the levator muscles resulting in the rectum protruding into the lower vagina or perineum. This frequently results in bowel symptoms or difficult defecation often necessitating the patient to use manual pressure on the lower vagina or perineum to defecate. Enterocoele is where there is a significant herniation of the pouch of Douglas into the vagina. A transvaginal posterior colporrhaphy and site specific repair are the traditional surgical treatment for rectocele and enterocoele and generally result in good anatomic cure rates ranging from 85 to 95% and significant improvement in

bowel symptoms, quality of life and sexual function (87,88). The addition of synthetic or biologic graft does not improve anatomic outcome but may give rise to mesh associated complications: exposure, infection and dyspareunia(10,70, 89). Compared with transanal repair posterior colporrhaphy is more effective at reducing recurrence of posterior vaginal wall prolapse whereas symptomatic relief is similar(90). Posterior compartment prolapse is often associated with loss of apical support necessitating a combined procedure with apical repair:Asc, SSLS or USLS. A recent prospective ,multicenter study describes the insertion of a lightweight synthetic mesh via a single posterior midline incision to restore apical support and correct posterior wall defect. At 12 months objective posterior and apical cure rates were good : 92% and 89% respectively ,with improved functional outcomes and high patient satisfaction. Mesh extrusion rate was 6.5% (91).

Conclusions: POP is a common condition affecting about 30 to 50% of parous women in the western world. Only a minority, 10% to 15% experience symptoms: the feeling and/or seeing vaginal bulging being the most significant symptom (92). POP is almost never a life threatening condition. Consequentlyconservative treatment modalities should be discussed with the patient, before deciding to operate.

Traditional native tissue repair has been associated with high re-operation rates . Many papers refer to the epidemiologic study by Olsen et al. (1997)(8). However , revision of this paper using different success criteria by the same authors, as well as follow-up studies from other institutes clearly show that native tissue repair have better success rates than previously thought. The number of conventional procedures for POP repair is limited but almost every clinic has its own specific modifications of a certain technique. In addition ,concomitant procedures e.g. hysterectomy may be performed. The wide variety in surgical techniques may partly explain the wide variety in surgical outcomes and compels for standardization of the surgical intervention. The concept of POP repair with uterus preservation (ASH, MMF and SSH) warrants further evaluation. During the last decade a large number of studies , using different meshes and different surgical techniques , have been published and many gynecologists have eagerly embraced this new technique focusing on anatomic success as primary outcome measure. The FDA has acknowledged this issue and published an updated safety communication warning clinicians about serious complications associated with mesh augmented POP repair (2). In 2012 the Cochrane review on surgical management of pelvic organ prolapse concludes: " The Use of mesh at the time of anterior vaginal wall repair reduces the risk of recurrence of anterior vaginal prolapse . There is no difference in anatomic and subjective outcome when native tissue

534 vaginal repairs are compared to multicompartiment transvaginal mesh repair” (32). Mesh
535 repair is associated with a considerable risk of mesh exposure and de novo prolapse of the
536 untreated compartment resulting in a higher reoperation rate in the mesh group. The risk of
537 mesh complications is less if vaginal mesh surgery is performed by experienced
538 urogynecologic surgeons. Mesh insertion may have a role in reconstructive pelvic surgery in
539 woman at high risk of failure but basic research into mesh properties and host response,
540 improving surgical skills and accreditation, standardizing surgical techniques , proper patient
541 selection and redefining surgical outcome are urgently needed. So,it is: “ back to the future
542 “.
543

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810 **Table I** : Safety of mesh in POP repair. Mean percentages and range of adverse events as
811 reported in literature (adapted from FDA and ACOG 2011 (1,2))

812

813

814 Peri-operative risks:

815 Organ perforation: 2,6%

816 Bleeding (haematoma): 3.8%

817

818 Long term risks:

819 Mesh exposure: 5-19% (mean: 10,3% , 56% surgical excision)

820 Vaginal scarring (tightening): 8-11%

821 Dyspareunia: 4,4-7,7%

822 Infection: 1.6-7,3%

823 Pain: 1.0-9.8%

824 Re-surgery : 5.5-8.5%

825 Urinary problems: 4.7-10.2%

826

827 **Table II:** Trocar guided mesh vs. conventional vaginal repair in recurrent prolapse (

828 Withagen et al. (37, 38)

829

830

831 **RCT. N=194. Follow-Up. 1 year**

832 **Response : 98% Conventional repair: n=97 Mesh augmented repair:**

833 **n=93**

834 Anat. Failure de novo POP

835 **Conv. Repair:** 45% 17%

836 **Mesh repair:** 9.6% 47%

837 Overall failure patient satisfaction

838 **Conv. Repair:** 66% 80%

839 **Mesh repair:** 49% 81%

840 **Mesh exposure:** 16.9%

841

842 **Table III:** complication and re-operation rates after vaginal and abdominal prolapse repair
843 Diwadkar et al . (68)

844

845

846 **Traditional repair :** 48 studies. N=7827 F-U: 2-3 years

847 • Mean complication rate: 15.3%

848 • Re-operation for POP : 3.9%

849 ➤ Total re-operation: 5.8%

850

851 **Abdominal sacrocolpopexy:** 52 studies. N=5639 F-U: 26 ms.

852 • Mean complication rate: 17.1%

853 • Re-operation for POP : 2.3%

854 ➤ Total reoperation: 7.1%

855

856 **Vaginal mesh repair :** 24 studies. N=3425 F.U: 17 ms

857 •Mean complication rate: 14.5%

858 •Re-operation POP : 1.3%

859 ➤ Total re-operation: 8.5%

860

861 **Table IV:** RCT's comparing traditional anterior colporrhaphy vs. mesh augmented anterior
 862 colporrhaphy: follow-up, anatomic cure rates and mesh exposure

863

864	RCT's.		Trad. Ant. Colp.		Mesh Ant. Colp.	
865	<u>Authors:</u>	<u>F.U.</u>	<u>Anatom. Cure</u>		<u>anatom.cure</u>	<u>Mesh exp.</u>
866	Nguyen et al. (71)	1yr.	N=38	55%	N=37 87%	5%
867	Sivaslioglu et al.(72)	1 yr.	N=42	72%	N=43 91%	6.9%
868	Carey et al. (73)	1 yr.	N=61	66%	N=63 81%	5.6%
869	Nieminen et al. (74)	3 yrs.	N=97	59%	N=105 87%	19%
870	Vollebregt et al. (75)	1yr.	N=58	41%	N=56 91%	4%
871	Altman et al. (76)	1yr.	N=189	35%	N=200 61%	3.2%
872	Menefee et al.(77)	2yrs	N=24	42%	N=28 82%	14%
873	Sokol et al. (78)	1yr	N=33	30%	N=32 41%	15.6%

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