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Mesh Sacrocolpopexy Compared With Native Tissue Vaginal Repair: A Systematic Review and Meta-analysis

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Abstract

Objective—To systematically review outcomes after mesh sacrocolpopexy compared with native tissue vaginal repairs in women with apical prolapse.

Data Sources—We searched MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials, and ClinicalTrials.gov through June 4, 2012.

Methods of Study Selection—For anatomic and functional analyses, we included studies comparing mesh sacrocolpopexy compared with native tissue vaginal repairs with at least 6 months follow-up. The primary outcome was anatomic “success” after surgery. Secondary outcomes were reoperation and symptom outcomes. We included large case series and comparative studies with shorter follow-up to increase power for adverse event analyses.

Tabulation, Integration, and Results—Evidence quality was assessed with the Grades for Recommendation, Assessment, Development and Evaluation system. Meta-analyses were performed when at least three studies reported the same outcome. We included 13 comparative

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studies for anatomic success, reoperation, and symptom outcomes. Moderate-quality evidence supports improved anatomic outcomes after mesh sacrocolpopexy; very low-quality evidence shows no differences in reoperation between sacrocolpopexy and native tissue vaginal repairs. Evidence was insufficient regarding which procedures result in improved bladder or bowel symptoms. Low-quality evidence showed no differences in postoperative sexual function. Adverse event data were compiled and meta-analyzed from 79 studies. When including larger noncomparative studies, ileus or small bowel obstruction (2.7% vs. 0.2%, $p < 0.01$), mesh or suture complications (4.2% vs. 0.4%, $p < 0.01$), and thromboembolic phenomena (0.6% vs. 0.1%, $p = 0.03$) were more common after mesh sacrocolpopexy compared to native tissue vaginal repairs.

Conclusion—When anatomic durability is a priority, we suggest that mesh sacrocolpopexy may be the preferred surgical option. When minimizing adverse events or reoperation is the priority, there is no strong evidence supporting one approach over the other.

Adult women have a 12.6% lifetime risk of undergoing pelvic organ prolapse surgery.(1) Apical prolapse encompasses descent of any apical vaginal structure, including the uterus, cervix, or vaginal cuff after hysterectomy.(2) During surgery, adequate apical support is important for minimizing recurrent prolapse in any area of the vagina.(3, 4) Thus, repair of the vaginal apex is an important component of many prolapse surgeries.

Surgical treatment options for apical prolapse are varied. Vaginal approaches that utilize sutures and a woman's own "native tissue" include McCall's culdoplasty, uterosacral ligament suspension (USLS), sacrospinous ligament fixation (SSLF), and iliococcygeus muscle suspensions.(5) The abdominal sacrocolpopexy (ASC) typically utilizes a synthetic mesh to augment the repair,(6) and minimally-invasive sacrocolpopexy options also exist.(7) In many instances, a permanent mesh may reduce prolapse recurrence but often the potential benefits in durability must be weighed against the potential risks of permanent mesh. Transvaginal mesh procedures have been utilized for apical prolapse but these procedures have decreased in light of reported adverse events and safety concerns raised in the scientific literature.(8, 9) While further data are collected regarding transvaginal mesh, many surgeons have continued using native tissue vaginal repairs or mesh sacrocolpopexy for prolapse repair.

When discussing surgical options with patients, data comparing effectiveness and adverse events is helpful. Although previous large reviews of prolapse surgery exist, they tend to include all types of prolapse surgery (e.g. transvaginal mesh, non-apical prolapse procedures) and focus either on surgical effectiveness or complications.(10, 11) Reviews that include comparative data on both effectiveness and adverse events are lacking. Since surgeons and patients must weigh potential risks and benefits of surgical procedures, we performed a systematic review of native tissue vaginal repairs compared with mesh sacrocolpopexy in women with apical prolapse. We evaluated published anatomic and patient symptom outcomes six months or more after surgery, and any related adverse events.

Sources

The Systematic Review Group of the Society of Gynecologic Surgeons, including gynecologic surgeons and systematic review methodologists, performed a systematic search to identify studies of native tissue vaginal apex repairs compared with mesh sacrocolpopexy for treatment of apical pelvic organ prolapse. We created a working document to define the parameters of our literature search.⁽¹²⁾ We searched MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (clinical trials only), and ClinicalTrials.gov from inception until June 4, 2012. We used the Medical Subject Headings (MeSH) “Pelvic Organ Prolapse”, “Hysterectomy”, as well as title and abstract searches using “cystocele”, “rectocele”, “enterocele”, uterine”, and any combination of “prolapse” with the following: “uterine”, “uterus”, “pelvic”, “vault”, and “apical”. We combined this search with another search of surgical procedures that used the MeSH term “Surgical Mesh” along with title/abstract searches of the following procedures “colpopexy”, “hysteropexy”, “sacrocolpopexy”, “sacrohysteropexy”, “sacrocolpexy”, “sacrospinous”, “uterosacral”, “iliococcygeus”, “McCall’s”, “McCalls”, “paravaginal”, “Manchester-Fothergill”. EMBASE had additional classification categories of “polypropylene” and “biomedical and dental materials” that were exploded and added to our surgical procedures search above. In all databases we limited our searches to English language publications. Reference lists of selected articles and review articles were screened for additional eligible studies, and relevant articles subsequent to our search date, when identified, were included in our review.

Study Selection

Our population included women with any degree of prolapse undergoing surgical treatment for apical prolapse. We included comparative studies (randomized controlled trials [RCT], case-control, or cohort studies) assessing mesh sacrocolpopexy compared with native tissue vaginal apex repairs with a follow-up interval of at least 6 months. The intervention of interest was sacrocolpopexy (including hysteropexy or cervicopexy) with permanent mesh, regardless of the route (abdominal, laparoscopic, robotic). Comparators were any native tissue vaginal repair, including USLS, SSLF, McCall’s culdoplasty, Manchester-Fothergill procedure, and iliococcygeus vaginal suspension. We excluded transvaginal mesh procedures for apical prolapse and any study comparing procedures for non-apical prolapse (i.e., anterior, posterior, or anterior and posterior vaginal compartments). The primary outcome of interest was anatomic “success”, as defined by each study. Secondary outcomes were bladder, bowel, and sexual function, reoperation for any reason (including recurrent prolapse, procedural complications such as mesh erosion, or both), surgical time, hospital stay, and blood loss.

Additional secondary outcomes were proportions and types of adverse events among different surgeries for apical prolapse. Because comparative studies with 6 month or longer follow up intervals may be underpowered to estimate adverse events, we collected adverse event data from case series, and comparative studies with shorter follow up, in addition to the studies meeting inclusion criteria above.

All abstracts were independently screened by two reviewers. Based on abstract review, potential studies were retrieved and re-screened for eligibility. Disagreements were resolved by consensus or the judgment of a third reviewer.

For articles meeting inclusion criteria for our primary analyses (comparative studies of mesh sacrocolpopexy vs. native tissue vaginal repair with at least 6 months follow up), data were extracted using a standardized data extraction form developed and tested by our review group. We collected the following data: 1) study characteristics (year, design, number enrolled and analyzed, length of follow-up); 2) patient characteristics; 3) intervention (type of mesh, intervention, comparator); 4) outcome definitions (anatomic by POP-Q or Baden-Walker, symptoms, and adverse events); 5) study results; and 6) methodological quality items (see below). For each study, data were collected by one reviewer and a second reviewer confirmed the accuracy of data. Discrepancies were resolved by discussion or by referral to a third reviewer.

For our primary analysis, we included comparative studies with at least six months follow-up, regardless of the number of subjects included in the study. For adverse event analyses, we included non-comparative studies and those with shorter durations of follow-up in order to improve our reporting of potential adverse events.(13) However, due to the large number of case series, only the largest series were included for further adverse event analyses. Our group decided by consensus and based on the existing literature, that studies would be reviewed for adverse event data if they included at least 200 subjects with ASC, 150 with laparoscopic sacrocolpopexy (LSC) or SSLF, 100 with vaginal USLS, or 50 with the less commonly reported procedures such as robotic sacrocolpopexy (RSC), McCall's, iliocecocygeous, and the Manchester procedure. Similar to above, adverse events were extracted by two reviewers using a standardized form and discrepancies were resolved by referral to a third reviewer. Adverse events were extracted and reported using criteria and groupings developed by Dindo et al.(14)

We decided *a priori* that meta-analyses would only be performed for outcomes where at least three or more studies had sufficiently similar interventions, study designs, outcome definitions, and duration of follow-up. For analyses of main study outcomes (not adverse events), we conducted DerSimonian & Laird random effects model meta-analyses of odds ratios.(15) For adverse events, we performed random-effects model meta-analyses of the arcsine-transformed proportion of women with the outcome separately for each type of surgery.(16) We also calculated Peto odds ratio meta-analyses for comparative studies with adverse event data, since many studies had no or only a single event for each outcome.(17)

The methodological quality of each study was determined using criteria from a three-category system modified from the Agency for Healthcare Research and Quality.(18) Studies were graded as good (A), fair (B), or poor (C) quality based on the likelihood of bias and the completeness of reporting. The quality of individual outcomes was separately graded within each study, and group consensus was used to determine the level of importance of each outcome, in accordance with the Grades for Recommendation, Assessment, Development and Evaluation (GRADE) system.(19). Data from eligible articles were extracted and used to generate an "evidence profile" by grading the quality of evidence for

each separate outcome. The GRADE process considers the methodological quality, consistency of results across studies, directness of measurement of outcomes, and other factors such as sparseness of evidence to determine an overall quality of evidence. This system categorizes recommendations based on four evidence quality ratings: high (A), moderate (B), low (C), and very low (D).

Results from this review were presented for public comment at the 39th Society of Gynecologic Surgeons Annual Scientific Meeting, held in April 2013. All data are reported in accordance with the PRISMA statement.(20)

Results

The literature search identified 3119 citations. Of these, 34 met criteria for full-text review for our primary analysis and 13 studies were included in the systematic review evaluating anatomic success (Figure 1). These included five RCTs, one prospective and seven retrospective non-randomized comparative (cohort) studies. Of the articles identified in the original search, 633 abstracts reported adverse event data. These abstracts were sorted based on the number of study participants and type of procedure. For each procedure type, the studies with the largest numbers of participants were selected for in depth review of adverse events, resulting in 79 studies undergoing further review. These included the 13 studies above, 5 additional short-term studies comparing mesh sacrocolpopexy to native tissue vaginal repair, and 61 non-comparative studies.

Among the 13 studies included for the primary outcome analyses, there were some variations in procedure types, as described in Table 1. We considered the intervention to be mesh sacrocolpopexy or sacrohysteropexy and comparators were native tissue vaginal apex repairs. The overall quality of evidence is summarized in Table 2. Twelve studies reported on anatomic durability, with moderate evidence quality favoring mesh sacrocolpopexy. Four studies reported on reoperation, with very low-quality evidence showing no difference in reoperation between mesh sacrocolpopexy and native tissue vaginal repairs. For symptom outcomes, postoperative bladder function was assessed in 4 studies and bowel function was assessed in 3 studies. For these outcomes, there is very low-quality evidence with insufficient evidence regarding which procedures result in better outcomes. Postoperative sexual function was assessed in 5 studies; low-quality evidence showed no difference in sexual function between mesh sacrocolpopexy and native tissue vaginal repairs. Surgical times were reported in 5 studies with moderate evidence showing quicker surgical times in native tissue vaginal repairs. Duration of hospital stay and estimated blood loss were reported in 6 studies; very low-quality evidence showed no differences in hospital stays and low-quality evidence showed no differences in blood loss between procedure types. Evidence is further summarized below based on individual outcomes.

All 5 RCTs and 7 of 8 cohort studies reported on post-operative anatomic durability. Within individual studies, surgical failure was most commonly defined as Stage 2 or greater prolapse on pelvic organ prolapse quantification (POP-Q) exam(21–26) or prolapse at/ beyond the hymen.(27–32) Anatomic success was considered to be any prolapse < Stage 2 or above the hymen, as defined and reported by the original study. All RCTs reported post-

operative anatomic data between 1–2.5 years after surgery and therefore we meta-analyzed the outcome of anatomic success. One RCT was published as an abstract only with only a portion of their study participants, and this RCT was not included in the meta-analysis. In RCTs, there was significantly greater likelihood of anatomic “success” with mesh sacrocolpopexy compared to native tissue vaginal repairs [Pooled OR 2.04 (95% CI 1.12 – 3.72)], Figure 2. Three RCTs reported anatomic success by individual compartments (Figure 3).(23, 24, 29) Due to study heterogeneity and variations in study quality, pooled meta-analyses were not performed on outcomes from individual compartments.

The 7 non-randomized comparative studies corroborated these results. In these cohort studies, the follow-up interval ranged from 6 months to 8.3 years. Three cohort studies showed a significantly higher likelihood of anatomic success with sacrocolpopexy.(26, 28, 31) Three cohort studies did not identify significant differences between techniques,(21, 25, 32) but were underpowered. One cohort study showed similar anterior and apical outcomes, but more posterior wall recurrences after LSC compared to SSLF (17% vs. 0, $p < 0.01$). (30) In summary, moderate quality data favors mesh sacrocolpopexy over native tissue vaginal apex repairs in providing anatomic success. This is particularly evident for the anterior and apical compartments.

Three RCTs and 2 cohort studies reported on reoperation (Figure 4).(24, 26, 27, 29, 30) There were differences in outcome reporting and operative techniques that precluded pooling and meta-analysis of data. There were highly inconsistent results from RCTs regarding which technique resulted in fewer reoperations. The highest quality study by Maher et al.(29) showed no significant differences in all-cause reoperation [6/46 (13%) ASC vs. 7/43 (16%) SSLF, $p=0.67$]. The RCT by Benson et al.(27) showed no differences in reoperation for recurrent prolapse. In contrast, the RCT by Roovers et al.(24) showed more reoperations after mesh sacrohysteropexy compared to vaginal hysterectomy with apical suspension. Reoperations for prolapse were performed in 9 subjects in the sacrohysteropexy group and one subject in the vaginal group. The remaining 4 reoperations were for “late complications” that were not further described. This study was unique in that uteri were preserved in the mesh sacrohysteropexy group and removed in the vaginal surgery group..

Data from cohort studies were also inconsistent regarding the procedures resulting in fewer reoperations. In their retrospective cohort study,(30) Marcickiewicz et al. reported more reoperations for recurrent prolapse in those receiving LSC compared to SSLF [15/60 (25%) vs. 4/51 (8%), $p=0.02$], though seven of the 15 LSC recurrences were early in the learning curve. Finally, Thompson et al. reported on all-cause reoperation in their retrospective cohort study.(26) More than 4 years after surgery, 2/72 (3%) of subjects receiving ASC required reoperation (all for mesh removal) compared to 8/24 (33%) receiving USLS who required reoperation (all for recurrent prolapse), ($p=0.002$). In summary, there were inconsistent results across studies resulting in very low–quality evidence showing no difference in reoperation between mesh sacrocolpopexy and native tissue vaginal repair.

Postoperative bladder, bowel, and sexual function were considered to be high importance outcomes. Three RCTs and one cohort study specifically compared postoperative bladder function between ASC and native tissue vaginal apex repairs.(21, 24, 27, 29) Functional

bladder outcomes are difficult to interpret since many studies included concomitant anti-incontinence surgeries but did not control for these in analyses. Ultimately for functional bladder outcomes there is very low-quality evidence and evidence is insufficient regarding which procedures result in better outcomes. Postoperative bowel outcomes were addressed in one RCT and 2 cohort studies.(21, 29, 30) There was very low-quality evidence, which was insufficient to make a determination regarding bowel function after mesh sacrocolpopexy vs. native tissue vaginal repair.

Sexual function was assessed in 3 RCTs, one retrospective and one prospective cohort study. (21, 22, 27, 29, 33) Two RCTs failed to demonstrate significant differences in postoperative dyspareunia between mesh sacrocolpopexy and native tissue vaginal repairs.(27, 29) This was corroborated by a prospective cohort study showing no differences between groups in postoperative sexual function,(33) and a retrospective cohort study showing overall improvements in dyspareunia among both groups.(21) However, one RCT by Lo et al. showed more dyspareunia in those undergoing SSLF compared to ASC.(22) This inconsistency in RCTs resulted in low-quality evidence, suggesting no difference in postoperative sexual function between mesh sacrocolpopexy and native tissue vaginal repairs.

Surgical time, hospital stay, and estimated blood loss were all short-term peri-operative outcomes that were considered only moderately important. For surgical time there was moderate quality evidence from 3 RCTs and 2 cohort studies showing quicker operative times with native tissue vaginal repairs. For hospital stay there was very low-quality evidence from 3 RCTs and 3 cohort studies showing no differences between ASC and native tissue repairs. For blood loss there was low-quality evidence from 2 RCTs and 4 cohort studies also showing no differences between procedure types.

A total of 79 studies were reviewed for adverse events. These were the 13 comparative studies that are reported above, 5 additional short-term studies comparing mesh sacrocolpopexy to native tissue vaginal repair,(34–38) and an additional 61 non-comparative studies with sufficiently large sample sizes of women undergoing ASC, LSC, RSC, SSLF, USLS, McCall's culdoplasty, iliococcygeus suspension, or Manchester procedures. (Appendix) Adverse events were reported inconsistently and the total numbers of subjects who returned for follow-up were not consistently reported. When adverse events were reported we collected the number of instances and the total number of subjects who were followed in the study. Adverse events were categorized based on Dindo classification.(14) For complications that span multiple Dindo categories, we chose to place all instances in one category based on consensus opinion. For example, a mesh extrusion could be treated with local estrogen (Dindo Grade II), excision with local or no anesthesia (Dindo Grade IIIa), or excision under general anesthesia (Dindo Grade IIIb). By consensus, we decided to consider all mesh extrusions or erosions as Dindo Grade IIIa. Similarly, we chose to consider all reoperations (for recurrent prolapse or other reasons) as Dindo Grade IIIb, which requires general anesthesia.

Table 3 summarizes the adverse events reported from 18 total comparative studies. These include the 13 studies included for the primary analyses, as well as 5 additional comparative

studies that reported only on short-term outcomes. Adverse events were categorized and summed separately for the intervention (mesh sacrocolpopexy) and comparator (native tissue vaginal apex repair) groups. A series of meta-analyses were performed on summed adverse events. Summary odds ratios with confidence intervals were calculated for all comparative studies and separately for RCTs only. In comparative studies, adverse events were relatively infrequent with more ileus/small bowel obstructions (SBO) (OR 9.45, 95% CI 3.39 – 26.4), less dyspareunia (OR 0.42, 95% CI 0.25 – 0.72), and more mesh/suture complications (OR 3.26, 95% CI 1.62 – 6.56) after mesh sacrocolpopexy ($p<0.001$ for all).

Since adverse events are relatively infrequent, we further assessed an additional 61 studies with large sample sizes. Once adverse events were categorized, we performed a series of meta-analyses to estimate proportions across all studies, which are summarized in Table 4. In these analyses, ileus/SBO (2.7% vs. 0.2%, $p<0.01$) and mesh or suture complications (4.2% vs. 0.4%, $p<0.01$) remained more common after mesh sacrocolpopexy. Thromboembolic phenomena were also more common after mesh sacrocolpopexy (0.6% vs. 0.1%, $p=0.03$), but no difference in dyspareunia as was found in comparative studies.

Conclusion

Our systematic review identified 5 RCTs and 8 cohort studies comparing medium-term postoperative outcomes between mesh sacrocolpopexy and native tissue vaginal apex repairs. Overall there is moderate-quality evidence supporting improved anatomic durability after mesh sacrocolpopexy. For the critically important outcome of all-cause reoperation, however, the evidence quality is very low and shows no difference between the two surgical approaches. We also systematically reviewed 79 studies noting more adverse events related to ileus or SBO and mesh or suture complications after mesh sacrocolpopexy. Other adverse events were similar between groups.

Our study is strengthened by the inclusion of all studies comparing mesh sacrocolpopexy and vaginal native tissue repair. Because there are only 5 RCTs, we were able to focus on these studies and further evaluate if comparative studies were consistent with results reported in RCTs. We also performed a comprehensive evaluation of adverse events, which is useful since comparative studies are often underpowered to assess infrequent adverse events. The strength of this approach is exemplified by our results for the category of “nerve injury”. In RCTs, it appears that there are higher odds of nerve injury after mesh sacrocolpopexy, but this result comes from only two RCTs where there were no reported events of nerve injury in the vaginal surgery groups. When expanding to include more studies, which essentially increases the sample size, the odds of nerve injury are no longer significantly different between mesh sacrocolpopexy and native tissue vaginal repairs.

We elected to use meta-analyses to provide an evidence-based summary of the literature. However, meta-analyses are limited by variable outcome reporting and the inherent grouping of data that is required to summarize evidence. We recognize that different surgical techniques can result in different outcomes. The majority of the published comparative studies that were included in our review utilized either USLS or SSLF as their “native tissue” repair, and evidence supports the assertion that outcomes are similar with

these two approaches.(39) For mesh sacrocolpopexy, the majority of comparative studies utilized an open abdominal approach, with a small minority using laparoscopic or robotic techniques. Many surgeons have transitioned to minimally invasive techniques of mesh sacrocolpopexy. If minimally invasive approaches were to result in more anatomic recurrences or more reoperations, it is possible that results would differ. Different surgical techniques were certainly considered when we reviewed adverse event data. Though this comprehensive approach provides for a very concise summary of the literature, it may also be considered a limitation. Despite the large body of literature reviewed regarding adverse events, caution must be taken in interpreting these data since there was much heterogeneity.

Based on these results, when anatomic durability is a priority, we suggest that mesh sacrocolpopexy may be the preferred option for surgical reconstruction of vaginal apex prolapse. When minimizing risk is the priority, for example when considering adverse events or reoperation, there is no strong evidence supporting one approach over the other in appropriate surgical candidates.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

1. Wu JM, Matthews CA, Conover MM, Pate V, Jonsson Funk M. Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery. *Obstet Gynecol*. 2014 Jun; 123(6):1201–6. [PubMed: 24807341]
2. Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. *Int Urogynecol J*. 2010 Jan; 21(1):5–26. [PubMed: 19937315]
3. Rooney K, Kenton K, Mueller ER, FitzGerald MP, Brubaker L. Advanced anterior vaginal wall prolapse is highly correlated with apical prolapse. *Am J Obstet Gynecol*. 2006 Dec; 195(6):1837–40. [PubMed: 17132485]
4. Eilber KS, Alperin M, Khan A, Wu N, Pashos CL, Clemens JQ, et al. Outcomes of vaginal prolapse surgery among female Medicare beneficiaries: the role of apical support. *Obstet Gynecol*. 2013 Nov; 122(5):981–7. [PubMed: 24104778]
5. Brubaker, L.; Bump, RC.; Fynes, M. In: Abrams, P.; Cordozo, L.; Koury, S.; Wein, A., editors. *Surgery for pelvic organ prolapse; 3rd International Consultation on Incontinence*; Paris: Health Publication Ltd; 2005.
6. Nygaard IE, McCreery R, Brubaker L, Connolly A, Cundiff G, Weber AM, et al. Abdominal sacrocolpopexy: a comprehensive review. *Obstet Gynecol*. 2004 Oct; 104(4):805–23. [PubMed: 15458906]
7. Lee RK, Motttrie A, Payne CK, Waltregny D. A review of the current status of laparoscopic and robot-assisted sacrocolpopexy for pelvic organ prolapse. *Eur Urol*. 2014 Jun; 65(6):1128–37. [PubMed: 24433811]

8. UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication. [cited 7/7/2014]; Available from: <http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm262435.htm>
9. Clemons JL, Weinstein M, Guess MK, Alperin M, Moalli P, Gregory WT, et al. Impact of the 2011 FDA transvaginal mesh safety update on AUGS members' use of synthetic mesh and biologic grafts in pelvic reconstructive surgery. *Female Pelvic Med Reconstr Surg*. 2013 Jul-Aug;19(4):191–8. [PubMed: 23797515]
10. Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. *Cochrane Database Syst Rev*. 2013; 4:CD004014. [PubMed: 23633316]
11. Diwadkar GB, Barber MD, Feiner B, Maher C, Jelovsek JE. Complication and reoperation rates after apical vaginal prolapse surgical repair: a systematic review. *Obstet Gynecol*. 2009 Feb; 113(2 Pt 1):367–73. [PubMed: 19155908]
12. Counsell C. Formulating questions and locating primary studies for inclusion in systematic reviews. *Annals of internal medicine*. 1997 Sep 1; 127(5):380–7. [PubMed: 9273830]
13. Zorzela L, Golder S, Liu Y, Pilkington K, Hartling L, Joffe A, et al. Quality of reporting in systematic reviews of adverse events: systematic review. *Bmj*. 2014; 348:f7668. [PubMed: 24401468]
14. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Annals of surgery*. 2004 Aug; 240(2):205–13. [PubMed: 15273542]
15. DerSimonian R, Laird N. Meta-analysis in clinical trials. *Control Clin Trials*. 1986 Sep; 7(3):177–88. [PubMed: 3802833]
16. Trikalinos, TA.; Hoaglin, DC.; Schmid, CH. Empirical and Simulation-Based Comparison of Univariate and Multivariate Meta-Analysis for Binary Outcomes. Rockville (MD): 2013.
17. Bradburn MJ, Deeks JJ, Berlin JA, Russell Localio A. Much ado about nothing: a comparison of the performance of meta-analytical methods with rare events. *Statistics in medicine*. 2007 Jan 15; 26(1):53–77. [PubMed: 16596572]
18. Owens DK, Lohr KN, Atkins D, Treadwell JR, Reston JT, Bass EB, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions—agency for healthcare research and quality and the effective health-care program. *Journal of clinical epidemiology*. 2010 May; 63(5):513–23. [PubMed: 19595577]
19. Atkins D, Best D, Briss PA, Eccles M, Falck-Ytter Y, Flottorp S, et al. Grading quality of evidence and strength of recommendations. *Bmj*. 2004 Jun 19; 328(7454):1490. [PubMed: 15205295]
20. Moher D, Liberati A, Tetzlaff J, Altman DG, Group P. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Bmj*. 2009; 339:b2535. [PubMed: 19622551]
21. Bai SW, Kwon HS, Chung DJ. Abdominal high uterosacral colpopexy and abdominal sacral colpopexy with mesh for pelvic organ prolapse. *Int J Gynaecol Obstet*. 2006 Feb; 92(2):147–8. [PubMed: 16325817]
22. Lo TS, Wang AC. Abdominal colposacropexy and sacrospinous ligament suspension for severe uterovaginal prolapse: A comparison. *Journal of Gynecologic Surgery* 1998. 1998; 14(2):59–64.
23. Rondini C, Braun H, Alvarez J, Descouvieres C, Wenzel C, Aros S. Prospective-randomized study comparing high uterosacral vault suspension vs. abdominal sacrocolpopexy for the repair of apical defects and vaginal vault prolapse. *Neurourology and Urodynamics*. 2010 Aug; 29(6):939.
24. Roovers JP, van der Vaart CH, van der Bom JG, van Leeuwen JH, Scholten PC, Heintz AP. A randomised controlled trial comparing abdominal and vaginal prolapse surgery: effects on urogenital function. *BJOG*. 2004 Jan; 111(1):50–6. [PubMed: 14687052]
25. Sze EH, Kohli N, Miklos JR, Roat T, Karram MM. A retrospective comparison of abdominal sacrocolpopexy with Burch colposuspension versus sacrospinous fixation with transvaginal needle suspension for the management of vaginal vault prolapse and coexisting stress incontinence. *Int Urogynecol J Pelvic Floor Dysfunct*. 1999; 10(6):390–3. [PubMed: 10614976]
26. Thompson PK, McCrery RJ, Lotze EC, Santi-Haghepykar H. Vaginal prolapse surgery: Comparing abdominal sacral colpopexy to uterosacral suspension. *Journal of Pelvic Medicine and Surgery*. 2008 Jan-Feb; 14(1):15–22.

27. Benson JT, Lucente V, McClellan E. Vaginal versus abdominal reconstructive surgery for the treatment of pelvic support defects: a prospective randomized study with long-term outcome evaluation. *Am J Obstet Gynecol.* 1996 Dec; 175(6):1418–21. discussion 21–2. [PubMed: 8987919]
28. Hardiman PJ, Drutz HP. Sacrospinous vault suspension and abdominal colposacropepy: success rates and complications. *Am J Obstet Gynecol.* 1996 Sep; 175(3 Pt 1):612–6. [PubMed: 8828423]
29. Maher CF, Qatawneh AM, Dwyer PL, Carey MP, Cornish A, Schluter PJ. Abdominal sacral colpopexy or vaginal sacrospinous colpopexy for vaginal vault prolapse: a prospective randomized study. *Am J Obstet Gynecol.* 2004 Jan; 190(1):20–6. [PubMed: 14749629]
30. Marcickiewicz J, Kjollesdal M, Engh ME, Eklin S, Axen C, Brannstrom M, et al. Vaginal sacrospinous colpopexy and laparoscopic sacral colpopexy for vaginal vault prolapse. *Acta Obstet Gynecol Scand.* 2007; 86(6):733–8. [PubMed: 17520408]
31. Ng CC, Han WH. Comparison of effectiveness of vaginal and abdominal routes in treating severe uterovaginal or vault prolapse. *Singapore Med J.* 2004 Oct; 45(10):475–81. [PubMed: 15455168]
32. Yavagal S, Takacs P, Gallegos LR, Medina CA. Comparison of sacrospinous ligament fixation to abdominal sacrocolpopexy in treatment of severe pelvic organ prolapse. *Journal of Pelvic Medicine and Surgery.* 2010 Sep-Oct;16(5 SUPPL 2):S115.
33. Siddiqui NY, Fulton RG, Kuchibhatla M, Wu JM. Sexual function after vaginal versus non-vaginal prolapse surgery. *Journal of Pelvic Medicine and Surgery.* 2010 Sep-Oct;16(5 SUPPL 2):S74.
34. Bai S, Moon Y, Kwon H, Kim S. A comparison of abdominal sacrocolpopexy with total abdominal hysterectomy and mccall culdoplasty with vaginal hysterectomy in the treatment of uterine prolapse. *Journal of Pelvic Medicine and Surgery.* 2010 Sep-Oct;16(5 SUPPL 2):S123.
35. Imperato E, Aspesi G, Rovetta E, Presti M. Surgical management and prevention of vaginal vault prolapse. *Surg Gynecol Obstet.* 1992 Sep; 175(3):233–7. [PubMed: 1514157]
36. Price N, Jackson SR, Foon R, Moran P. A comparison of vaginal sacrospinous fixation and abdominal sacrocolpopexy for vaginal vault prolapse repair in the UK: An analysis of the british society of urogynaecologists' (BSUG) database. *International Urogynecology Journal and Pelvic Floor Dysfunction.* 2011 Jun; 22(SUPPL 2):S863–S4.
37. Ridgeway B, Barber MD, Walters MD, Paraiso MFR, Jelovsek JE. Perioperative gastrointestinal complications after abdominal and intraperitoneal vaginal surgery for pelvic organ prolapse. *Journal of Gynecologic Surgery.* 2011; 1;27(3):123–7. [PubMed: 21731404]
38. Sanses TV, Shahryarnejad A, Molden S, Hoskey KA, Abbasy S, Patterson D, et al. Anatomic outcomes of vaginal mesh procedure (Prolift) compared with uterosacral ligament suspension and abdominal sacrocolpopexy for pelvic organ prolapse: a Fellows' Pelvic Research Network study. *Am J Obstet Gynecol.* 2009 Nov; 201(5):519 e1–8. [PubMed: 19716533]
39. Barber MD, Brubaker L, Burgio KL, Richter HE, Nygaard I, Weidner AC, et al. Comparison of 2 transvaginal surgical approaches and perioperative behavioral therapy for apical vaginal prolapse: the OPTIMAL randomized trial. *JAMA: the journal of the American Medical Association.* 2014 Mar 12; 311(10):1023–34.

Fig. 1. PRISMA flow diagram depicting study selection process. RCT, randomized controlled trial; AE, adverse event

Fig. 2.

Forest plot depicting meta-analysis results: anatomic success of mesh sacrocolpopexy compared with native tissue vaginal repair, data from randomized trials. Preop, preoperative; OR, odds ratio; CI, confidence interval; RCT, randomized controlled trial; POPQ Ba, extent of anterior wall prolapse based on Pelvic Organ Prolapse Quantification exam; I^2 , percentage of total variation across studies due to heterogeneity; P_{het} , P value for statistical heterogeneity.

Fig. 3.

Forest plot depicting anatomic success of mesh sacrocolpopexy compared with native tissue vaginal repair in trials reporting outcomes by vaginal compartment. Preop, preoperative; OR, odds ratio; CI, confidence interval; RCT, randomized controlled trial; POPQ Ba, extent of anterior wall prolapse based on Pelvic Organ Prolapse Quantification exam.

Fig. 4.

Forest plot depicting data from 3 randomized trials and 2 comparative studies showing reoperation after mesh sacrocolpopexy compared with native tissue vaginal repair. OR, odds ratio; CI, confidence interval; RCT, randomized controlled trial.

Table 1

Summary of studies included in primary outcome analyses

Author	Study Quality	Year	Intervention	Mesh type	Comparator	Suture type	Follow up (months)
Randomized trials							
Maier (30)	A	2004	ASC n=46	Polypropylene	SSLF n=43	ND	6–58
Benson (28)	B	1996	ASC n=38	ND	SSLF n=42	Permanent monofilament	12–66
Roovers (25)	B	2004	Sacrohysteropexy n=41	GoreTex	Hyst + USLS n=41	1-0 Vicryl	12
Lo (23)	C	1998	ASC n=52	Mersilene	SSLF n=66	1-0 Nylon	12–62
Rondini (24)	C	2010	ASC n=42	ND	USLS n=39	ND	18
Prospective Cohort							
Siddiqui (34)	B	2010	ASC + RSC n=25	Polypropylene	USLS n=33	Delayed absorbable	6
Retrospective Cohort							
Bai (22)	C	2006	ASC n=34	Mersilene	USLS n=79	ND	6–12
Hardiman (29)	C	1996	ASC n=80	Polypropylene	SSLF n=125	Monofilament (Permanent & delayed absorbable)	6 – 60
Marciakiewicz (31)	C	2007	LSC n=60	Polypropylene	SSLF n=51	Permanent (braided or monofilament)	33–38
Ng (32)	C	2004	ASC n=113	GoreTex	SSLF n=64	Ethibond	13–18
Sze (26)	C	2010	ASC n=47	ND	SSLF n=54	ND	23–24
Thompson (27)	C	2008	ASC n=72	GoreTex	USLS n=32	Permanent	53–55
Yavagal (33)	C	2010	ASC n=25	ND	SSLF n=25	ND	86–100

Study quality based on the GRADE system. Studies graded as good (A), fair (B), or poor (C) based on likelihood of bias and completeness of reporting

ASC, abdominal sacrocolpopexy; RSC, robotic sacrocolpopexy; LSC, laparoscopic sacrocolpopexy; ND, not described; SSLF, sacrospinous ligament fixation; Hyst, hysterectomy; USLS, uterosacral ligament suspension

Table 2

Evidence Profile: mesh sacrocolpopexy versus native tissue apical repair

Outcome	No. Studies	Comparator	Total N	Methodological Quality	Consistency	Directness	Other considerations	Summary of Findings		
								Evidence Quality	Effect	Outcome Importance
Anatomic success	12 (5 RCT, 7 Cohort)	4 USLS, 8 SSLF	1286	1A, 2B, 9C	C	D	11 ASC, 1 LSC	Moderate	Favor colpopexy	Critical
Reoperation	4 (3 RCT, 1 Cohort)	1 USLS, 3 SSLF	362	1A, 2B, 1C	I	D	3 ASC, 1 LSC	Very Low	No difference	Critical
Bladder function	4 (3 RCT, 1 Cohort)	2 USLS, 2 SSLF	339	1A, 1B, 2C	I	D	ASC only	Very Low	Insufficient evidence	High
Bowel function	3 (1 RCT, 2 Cohort)	1 USLS, 2 SSLF	288	1B, 2C	C	D	2 ASC, 1 LSC	Very low	Insufficient evidence	High
Sexual function	5 (3 RCT, 2 Cohort)	1 USLS, 3 SSLF, 1 both	394	1A, 2B, 2C	I	D	4 ASC, 1 RSC	Low	No difference	High
Surgical Time	5 (3 RCT, 2 Cohort)	2 USLS, 3 SSLF	531	2B, 3C	C	D	4 ASC, 1 LSC	Moderate	Favor native tissue	Moderate
Hospital Stay	6 (3 RCT, 3 Cohort)	3 USLS, 3 SSLF	635	2B, 4C	I	D	5 ASC, 1 LSC	Very Low	No difference	Moderate
Blood Loss	6 (2 RCT, 4 Cohort)	2 USLS, 4 SSLF	632	2B, 4C	I	D	5 ASC, 1 LSC	Low	No difference	Moderate

Methodological quality based on the GRADE system. Studies graded as good (A), fair (B), or poor (C) based on likelihood of bias and completeness of reporting. Evidence quality summarizes the number and type of studies, methodological quality, consistency of data, and directness of outcomes.

RCT, randomized controlled trial; USLS, uterosacral ligament suspension; SSLF, sacrospinous ligament fixation; C, consistent; I, inconsistent; D, direct outcome assessment; ASC, abdominal sacrocolpopexy; LSC, laparoscopic sacrocolpopexy; RSC, robotic sacrocolpopexy

Table 3

Adverse events in comparative studies

Adverse Event	Studies	No. Studies (Excluded*)	Summary OR (95% CI)	Sum Events/Total Mesh Sacrocolpopexy	Sum Events/Total Native Tissue Vaginal Repair
Dindo I					
Ileus/SBO	All	7 (-1)	9.45 (3.39, 26.4)	16/514	2/780
	RCTs	2	9.55 (1.31, 69.4)	4/86	0/108
Nerve injury [†]	All	5	0.61 (0.18, 2.05)	4/514	7/743
	RCTs	2	8.32 (1.15, 60.3)	4/75	0/83
Dyspareunia [‡]	All	5	0.42 (0.25, 0.72)	23/445	46/384
	RCTs	3	0.14 (0.06, 0.33)	1/107	27/106
Dindo II					
Bleed [§]	All	12 (-1)	1.00 (0.63, 1.59)	43/1317	37/1863
	RCTs	3	1.02 (0.20, 5.14)	3/123	3/128
DVT/PE	All	4 (-2)	1.36 (0.14, 13.7)	2/569	1/599
	RCTs	0			
Infection	All	7 (-1)	2.01 (0.91, 4.45)	17/676	9/617
	RCTs	4	1.98 (0.60, 6.55)	7/171	4/193
Dindo IIIa					
Mesh/suture complication	All	7	3.26 (1.62, 6.56)	28/650	6/537
	RCTs	3	7.72 (1.08, 55.2)	4/122	0/131
Dindo IIIb					
Reoperation	All	7	0.76 (0.28, 2.09)	46/615	51/511
	RCTs	4	0.97 (0.33, 2.88)	25/153	29/168
Urinary tract Injury	All	8 (-2)	1.68 (0.79, 3.55)	20/1068	9/1108
	RCTs	3	1.65 (0.28, 9.65)	3/134	2/154
Bowel injury	All	10 (-2)	0.91 (0.35, 2.37)	8/1219	10/1574
	RCTs	3	0.57 (0.06, 5.54)	1/130	2/147
Dindo IVa					
ICU admission [¶]	All	4 (-2)	4.64 (0.42, 50.6)	3/561	0/506

Adverse Event	Studies	No. Studies (Excluded *)	Summary OR (95% CI)	Sum Events/Total Mesh Sacrocolpopexy	Sum Events/Total Native Tissue Vaginal Repair
Dindo V					
RCTs					
0					
Death	All	4 (-3)	0.14 (0.003, 6.97)	0/503	1/582
	RCTs	1	0.14 (0.003, 6.97)	0/47	1/47

* Studies excluded from meta-analysis; no events occurred in either group.

[†] Or neuropathy

[‡] Or sexual dysfunction

[§] Or hematoma or transfusion

// Wound or pelvic/cuff infection

[¶] Cardiovascular or pulmonary event

CI, confidence interval; SBO, small bowel obstruction; DVT, deep venous thrombosis; PE, pulmonary embolism; ICU, intensive care unit

Table 4

Adverse events in comparative and non-comparative studies

Adverse Event	Mesh Sacrocolpopexy				Native Tissue Vaginal Repair			
	Percent (95% CI)*	Range [†] , %	No. Studies	Sum AE/Total	Percent (95% CI)*	Range [†] , %	No. Studies	Sum AE/Total
Dindo I								
Ileus/SBO	2.7 (1.7, 3.9)	0–12	24	131/4168	0.2 (0.1, 0.6) [§]	0–0.50	11	3/1449
Nerve injury ^{//}	1.3 (0, 3.7)	0–8.2	12	96/2601	4.5 (1.8, 8.2)	0–46	16	147/2813
Dyspareunia [¶]	7.3 (3.0, 13)	0–39	15	371/2986	9.9 (5.2, 16)	0–58	17	200/2180
Dindo II								
Bleed ^{**¶}	1.5 (1.0, 2.1)	0–12	34	128/6555	2.9 (1.5, 4.8)	0–20	34	367/7044
DVT/PE	0.6 (0.2, 1.2)	0–2.8	15	46/4579	0.1 (0, 0.3)	0–0.83	15	8/4114
Infection ^{††}	2.2 (1.2, 3.4)	0–7.9	25	114/5119	1.8 (0, 8.3)	0–55	19	558/4743
Dindo IIIa								
Mesh/suture complication	4.2 (3.2, 5.4)	0–18	40	348/7831	0.4 (0, 1.7)	0–7.8	11	13/1169
Dindo IIIb								
Reoperation	5.4 (3.8, 7.1)	0.32–25	31	367/7218	3.7 (2.0, 5.9)	0–33	22	114/3872
Urinary tract injury	1.5 (0.8, 2.3)	0–9.8	34	113/6894	0.6 (0.2, 1.1)	0–3.5	25	46/5111
Bowel injury	0.3 (0.1, 0.6)	0–4.7	31	37/6642	0.6 (0.2, 1.0)	0–3.8	28	47–5744
Dindo IVa								
ICU admission ^{§§}	2.1 (0, 6.3)	0–24	14	281/4233	0.5 (0.1, 1.2)	0–4.5	13	27/3532
Dindo V								
Death	0.2 (0.1, 0.4) [§]	0–2.4	13	6/3343	0.1 (0, 0.4)	0–2.1	14	12/4105

* Summary (meta-analyzed)

[†] Full range across studies[‡] Comparison of studies of mesh sacrocolpopexy versus studies of native tissue vaginal repair, by meta-regression.[§] Exact proportion of sum of events/sum of total across studies (conducted if meta-analyzed estimate <0.1%)^{//} Or neuropathy[¶] Or sexual dysfunction

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Or hematoma or transfusion
Wound or pelvic/cuff infection
Cardiovascular or pulmonary event
CI, confidence interval; SBO, small bowel obstruction; DVT, deep venous thrombosis; PE, pulmonary embolism; ICU, intensive care unit