# National Institute for Health and Care Excellence

# IP311/3 - Sacrocolpopexy using mesh for vaginal vault prolapse repair
# Consultation Comments Table

**IPAC date: 12 January 2017**

| Com. no. | Consultee name and organisation | Sec. no. | Comments | Response<br>Please respond to all comments |
|---|---|---|---|---|
| 1 | Consultee 1<br>NHS professional | N/A | Sacrocolpopexy is a procedure where you attach piece of mesh, you can add FRONT as well so it will be a piece of mesh attached to front, top and back of the vagina.<br>Also Alternative methods Sacrospinous fixation, which is a vaginal approach less co morbidities compare to open abdominal SCP.(can be added) | Thank you for your comment.<br><br>The IPAC has decided to change the lay description of the procedure to “This is achieved by attaching a piece of mesh, usually from the top and occasionally the front and back of the vagina, to the longitudinal ligament or above the sacral promontory.”<br><br>The section on current treatments is intended to provide a brief summary of some of the treatment options and is not intended to be a definitive list of all the surgical techniques used to repair vaginal vault prolapse. |
| 2 | Consultee 2<br>Retired Healthcare Professional. | | No line numbers provided<br>Generally an excellent, and overdue update.<br>Only 2 minor and one major issue commented below: | Thank you for your comment. |
| 3 | Consultee 2<br>Retired Healthcare Professional. | Page 1, Box 1, Line 1 | It is wrong to describe the vaginal vault as a specific structure; why not simply say 'The vaginal vault is the name given to the top of the vaginal canal after surgery to remove the womb and cervix.' | Thank you for your comment.<br><br>The Committee considered this comment but decided not to change the guidance. |

| | | | | |
|---|---|---|---|---|
| 4 | Consultee 2<br>Retired Healthcare Professional. | Page 5, paragraph 4.2, Line 1. | I appreciate the need for standard formatting, but the repeated use of the phrase 'In the systematic review and meta-analysis of 5,954 women from 56 RCTs,' paragraph after paragraph is rather tiresome. Would a single reference not be easier? | Thank you for your comment.<br><br>Current NICE style requires the efficacy and safety section to be presented in this way. |
| 5 | Consultee 2<br>Retired Healthcare Professional. | Page 9, paragraph 5.3 | Erosion is recognised to be more of an issue when SCP is carried out concurrently with hysterectomy (hence IPG284, and your current update). It would not be my personal experience that SCP without hysterectomy (or intentional or inadvertent vaginotomy at operation) carries much risk of erosion. I note that you describe one study comparing RASC with supracervical and total hysterectomy; this should surely be included in the guidance on SCP with hysterectomy rather than here. Are the experts/committee confident that other papers reviewed in this guidance DO NOT include women having hysterectomy? If the guidance is to be hardened, with greater emphasis on safety than previously, it is vital that SCP+hyst and SCP-hyst are separated completely. | Thank you for your comment.<br><br>The paragraph reporting mesh erosion rates after RASC with supracervical or total hysterectomy is one of the multiple conclusions of a systematic review used to formulate this guidance.<br><br>Some of the papers do also report patients with concomitant hysterectomy as well as those with prior hysterectomy. In drawing the conclusions that it did, the committee recognized there was some overlap between the papers reviewed for the update of this procedure with those being reviewed for “sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse” (IPG284) which is also being updated. |

| | | | | |
|---|---|---|---|---|
| 6 | Consultee 3<br>NHS Professional | | I perform laparoscopic sacrohysteropexy since 2011 and so far I have done more than a hundred cases with minimal/no major complications. According to the advice for the need to use/search new material in this procedure by SCEHNIR in 2015 I have successfully started to do the laparoscopic sacrohysteropexy with [redacted] (by [redacted] company-Germany). There are several data both in Europe and in UK about the superiority of this new type of mesh. The biggest Study to my knowledge is by Prof. Ian Deprest from University of Leuven - Belgium of 180 cases with excellent results. I have performed about 30 cases of laparoscopic sacrohysteropexy with [redacted] myself. | Thank you for your comment.<br><br>The guidance under consultation if for sacrocolpopexy using mesh to repair vaginal vault prolapse in women previously treated by hysterectomy. Sacrohysteropexy is the subject of a separate IP guidance (IPG282). |
| 7 | Consultee 3<br>NHS Professional | | I have use [redacted] for pectopexy only to suspend the prolapse of the uterus or cervix (after subtotal hysterectomy). The laparoscopic pectopexy has been mentioned on several occasions during international conferences (ESGE 2014, 2015, 2016) by lead laparoscopic urogynaecologists in Europe (Prof Botoroshfili, Prof. Wattiez and others) and has been awarded a gold medal for innovation. I feel that there is a need to mention this option as there are RCTs to support pectopexy as well as it is a more and more popular alternative to sacrohysteropexy. | Thank you for your comment.<br><br>Sacrohysteropexy is the subject of a separate IP guidance (IPG282).<br><br>The IP programme does not assess comparative efficacy and safety with other interventions. |
| 8 | Consultee 3<br>NHS Professional | | One more benefit which is worth to mention is no risk if discitis which is a major complication related to sacrohysteropexy (especially with metal tacks). I hope you will be able to consider my comments in your final report to make it more comprehensive and up to date. | Thank you for your comment.<br><br>Sacrohysteropexy is the subject of a separate IP guidance (IPG282). |

| | | | | |
|---|---|---|---|---|
| 9 | Consultee 4<br>NHS Professional | 3.1 | The mesh to attached to the level of S2 to the longitudinal ligaments not to the promontory | Thank you for your comment.<br><br>The procedure description is intended to provide a brief summary of the procedure and not be a comprehensive description of the surgical technique. |
| 10 | Consultee 4<br>NHS Professional | 3.2 | Using the Polyvinylidene Fluoride (PVDF) mesh | Thank you for your comment.<br><br>Section 3.2 points out that "Several different types of meshes or grafts have been used for this procedure, including synthetic meshes, allografts and xenografts. Different types of mesh may have different safety profiles". |
| 11 | Consultee 5<br>NHS Professional | 1.4 | Regarding item 1.4 of the draft recommendations, we are very much in favour of establishing and maintaining a national registry on sacrocolpopexy using mesh materials. There is a marked difference between the number of meshes actually used in surgery and peer-reviewed publication of the results of these operations. A well-maintained registry can contribute to rapid detection of non-reportable complications and therefore would be in the interest of the patients as well as the manufactures. In light of the upcoming changes to the MDR, compilation of post-market clinical data is an integral part of monitoring a product's safety and efficacy. | Thank you for your comments. Consultee agrees with the draft recommendations in section 1.4 of the document. |

| | | | | |
|---|---|---|---|---|
| 12 | Consultee 5<br>NHS Professional | | Regarding items 2.2 and 3.1 of the draft recommendations, we would like to point out that we agree that there are "a number of different surgical procedures available for repairing vaginal vault prolapse". Since its inception by Lane in 1962, sacrocolpopexy has evolved considerably. However, recent improvements to sacrocolpopexy, seems to have been overlooked current draft. | Thank you for your comments.<br><br>The list of alternative treatments in section 2 is not intended to be definitive.<br><br>Section 3 is intended to provide a brief summary of the procedure only. |

| | | | | |
|---|---|---|---|---|
| 13 | Consultee 5<br>NHS Professional | | The first aspect concerns the graft material used. While the draft rightly notes "that different materials are used in this procedure" (6.4), we feel that in particular the search strategy cited in the accompanying document overemphasises older materials such as polypropylene (PP). This is evidenced by the explicit use of the search term "polypropylene" as well as several brand names of products that use PP (e.g. [redacted], [redacted]). | Thank you for comments.<br><br>The search strategy was primarily designed to capture the published literature on patients having sacrocolpopexy using mesh for vaginal vault prolapse repair. Comparative efficacy is not within the remit of the Interventional Procedures programme. NICE specifically encourages the collection and publication of data on this technique which was recommended for standard arrangements by the committee. In line with its published procedures NICE will consider updating its guidance on Sacrocolpopexy using mesh for vaginal vault prolapse repair if new evidence emerges to suggest the procedure is not efficacious or safe. |

| | | | | |
|---|---|---|---|---|
| 14 | Consultee 5<br>NHS Professional | | Currently, there are three polymers in use for the construction of surgical textiles. Polyester polymers are usually spun into multifilament. Polypropylene is a cheap polymer which has been used as a monofilament for surgical sutures for decades. However, polypropylene shows a degree of rigidity and surface cracking after implantation into tissues as it degrades. This leads to an enhanced inflammatory reaction when compared to the properties of other materials such as polyvinylidenfluoride (PVDF). | Thank you for your comment.<br><br>Evidence on the use of PVDF arises manly from animal and in vivo studies which cannot be considered by the committee. Human trials have limited sample size and follow-up times. |
| 15 | Consultee 5<br>NHS Professional | | Furthermore, Laroche et al. have shown that the stability of PP decreases by up to 40% over 7 years compared to less than 10% for PVDF. An analysis of 100 explants by ClavÃ© et al. demonstrated that polypropylene is not as inert as previously thought. There is also evidence that biocompatibility of all synthetic polymers can be improved by coating. However, it was shown that uncoated PVDF shows better biocompatibility than any of the coated PP meshes. PVDF has already been used successfully for years in cardiac and ophthalmic surgery, whereas its use for surgical textiles started in early 2000. We had been using PVDF meshes since July 2013. To date we have only one case of mesh erosion (< 3mm) vaginally out of over 200 procedures. Whilst there is published evidence of PP use in prolapse surgery, PVDF being a late entry into the arena of pelvic floor surgery should not be discounted. | Thank you for your comment.<br><br>Evidence on the use of PVDF arises manly from animal and in vivo studies which cannot be considered by the committee. Human trials have limited sample size and follow-up times. |

| | | | | |
|---|---|---|---|---|
| 16 | Consultee 5<br>NHS Professional | | A further aspect concerns the posterior point of attachment of the mesh material. In traditional sacrocolpopexy as originally devised by Lane et al., the posterior part of the mesh is attached to the sacral promontory. However, soon afterwards there were modifications of the attachment point in order to restore a more physiological vaginal axis by attachment at the level of S1-S2, or S3-S4. The points of attachment have since further evolved to include bilateral fixation at the S1-level 5,,,, or bilateral attachment to the iliopectineal ligaments.7 These methods of attachment show improved efficacy or safety profiles, e.g. due to a less complicated operating field or a more natural vaginal axis. Again, we have been using the bilateral attachment method since July 2013, without major complications. We feel the outlined procedure is too narrow in scope. | Thank you for your comment.<br><br>The list of current treatments and alternatives is not intended to be definitive. |

| | | | | |
|---|---|---|---|---|
| 17 | Consultee 5<br>NHS Professional | | References<br>Klink, CD et al. "Comparison of long-term biocompability of PVDF and PP meshes", Journal of investigative surgery 2011, 24(6), 292-299.<br><br>Laroche G et.al. "Polyvinylidene Fluoride Monofilament Sutures: Can They be Used Safely for Long-Term Anastomoses in the Thoracic Aorta?" Artificial Organs19/11: 1190â€“9; Â©Blackwell Science, Inc., Boston (12/1995).<br><br>ClavÃ©, Arnaud, Hannah Yahi, Jean- Claude Hammou, Suzelei Montanari, Pierre Gounon, und Henri ClavÃ©. "Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants". International Urogynecology Journal 21, Nr. 3 (2010): 261â€“70. | Studies that do not contain clinical information on efficacy and safety outcomes (for example, narrative review articles, animal studies or studies reporting on physiological outcomes) are not included in the overview, and are therefore not considered by the Committee.<br><br>Studies that do not contain clinical information on efficacy and safety outcomes (for example, narrative review articles, animal studies or studies reporting on physiological outcomes) are not included in the overview, and are therefore not considered by the Committee.<br><br>Studies that do not contain clinical information on efficacy and safety outcomes (for example, narrative review articles, animal studies or studies reporting on physiological outcomes) are not included in the overview, and are therefore not considered by the Committee. |

| | | | | |
|---|---|---|---|---|
| | | | Gerullis et al â€žIDEAL in Meshes for Prolapse, Urinary Incontinence, and Hernia Repairâ€œ. Surgical Innovation, 2013. doi:10.1177/1553350612472987. | Studies that do not contain clinical information on efficacy and safety outcomes (for example, narrative review articles, animal studies or studies reporting on physiological outcomes) are not included in the overview, and are therefore not considered by the Committee. |
| | | | Joukhadar et al â€žA Novel Operative Procedure for Pelvic Organ Prolapse Utilizing a MRI-Visible Mesh Implant. Safety and Outcome of Modified Laparoscopic Bilateral Sacropexy.â€œ Biomed Res Int. 2015; 2015:860784. | This study was included in appendix A. |
| | | | Conze, Joachim et al. â€žNew Polymer for Intra-Abdominal Meshes--PVDF Copolymerâ€œ. Journal of Biomedical Materials Research. Part B, Applied Biomaterials 87, Nr. 2 (November 2008): 321â€“28. | Studies that do not contain clinical information on efficacy and safety outcomes (for example, narrative review articles, animal studies or studies reporting on physiological outcomes) are not included in the overview, and are therefore not considered by the Committee. |

| | | | | |
|---|---|---|---|---|
| | | | NoÃ©, KG, Schiermeier, S, Alkatout, I, Anapolski, M "Laparoscopic Pectopexy: A Prospective, Randomized, Comparative Clinical Trial of Standard Laparoscopic Sacral Colpocervicopexy with the New Laparoscopic Pectopexyâ€"Postoperative Results and Intermediate-Term Follow-Up in a Pilot Study" Journal of Endourology 2015, 29(2), 210. | Paper captured in the update literature search. A large percentage of patients undergoes concomitant hysterectomy. |
| | | | Lane FE. Repair of posthysterectomy vaginal-vault prolapse. Obstet Gynecol 1962; 20:72â€“7. | Studies that do not contain clinical information on efficacy and safety outcomes (for example, narrative review articles, animal studies or studies reporting on physiological outcomes) are not included in the overview, and are therefore not considered by the Committee. |
| | | | Sutton GP, Addison WA, Livengood CH 3rd, Hammond CB. Life-threatening hemorrhage complicating sacral colpopexy. Am J Obstet Gynecol 1981; 140:836 â€“7. | This study was included in appendix A. |
| | | | Birnbaum SJ. Rational therapy for the prolapsed vagina. Am J Obstet Gynecol 1973; 115:411â€“9. | Studies that do not contain clinical information on efficacy and safety outcomes (for example, narrative review articles, animal studies or studies reporting on physiological outcomes) are not included in the overview, |

| | | | | |
|---|---|---|---|---|
| | | | | and are therefore not considered by the Committee |
| | | | Rajskekhar, S; Mukhopadhyay, S; Morris, E "Early safety and efficacy outcomes of a novel technique of sacrocolpopexy for the treatment of apical prolapse" International Journal of Gynecology and Obstetrics 135 (2016) 182â€“186. | This study was included in appendix A. |
| | | | JÃ¤ger, W.; Ludwig, S.; Stumm, M.; Mallmann, P. "Standardized bilateral mesh supported uterosacral ligament replacement â€“cervico-sacropexy (CESA) and vagino-sacropexy (VASA) operations for female genital prolapse" Pelviperineology 2015; 35: 17-21. | This paper reports the outcomes of women treated by cervico-sacropexy and vagino-sacropexy with no direct comparison to sacrocolpopexy. Therefore this paper has not been considered by the committee when producing guidance on Sacrocolpopexy using mesh for vaginal vault prolapse repair. The Interventional Procedures Programme does not consider comparative effectiveness with other techniques. |
| | | | Ludwig, S.; Stumm, M.; JÃ¤ger, W. "Surgical Replacement of the Uterosacral- and Pubourethral-Ligaments as | This paper reports the outcomes of women with mixed or stress urinary incontinence treated by |

| | | | | |
|---|---|---|---|---|
| | | | Treatment for Urgency Urinary Incontinence" Austin J Womens Health. 2016; 3(1): 1019. | cervico-sacropexy or vagino-sacropexy with no direct comparison to sacrocolpopexy. The Interventional Procedures Programme does not consider comparative effectiveness with other techniques. |
| 18 | Consultee 6<br>Company , Boston Scientific | | We support the draft recommendations proposed by NICE following their review of the available evidence and would like to thank them for the opportunity to comment during this consultation. | Thank you for your comment. |