This consensus document is the result of a workshop held in Eichstätt, Germany, on 23-24 June 2016. The participants were surgeons who have performed a total of 500 bilateral cervico-/vaginosacropexies with the aim of reconstructing pelvic floor defects since 2011.

The surgical technique on which the focus lies here, CESA/VASA, is a modified version of the standard sacrocolpopexy technique. The uterosacral ligaments (USL) are reinforced on both sides with a narrow, biocompatible ligament replacement made of PVDF (polyvinylidene fluoride, a synthetic "yarn", monofilament).

Compared with the unilateral technique, this method takes the length, axis, elasticity and mobility of the vagina into consideration: Bilateral fixation at the height of the S2 sacral vertebra ensures stable and physiological positioning of the organ; a tension-free, standardised surgical technique guarantees the mobility of the reconstructed uterosacral ligaments.

In many cases, it is also possible to treat concomitant urge urinary incontinence at the same time.

This consensus document focuses on the method via a laparoscopic access.

<table>
<thead>
<tr>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendations for reconstruction</td>
</tr>
<tr>
<td>Advantages of bilateral CESA/VASA</td>
</tr>
<tr>
<td>Indication</td>
</tr>
<tr>
<td>Choice of mesh implant</td>
</tr>
<tr>
<td>Patient briefing</td>
</tr>
<tr>
<td>Preoperative diagnostics</td>
</tr>
<tr>
<td>· With patient lying</td>
</tr>
<tr>
<td>· With patient standing</td>
</tr>
<tr>
<td>· Further preoperative examinations</td>
</tr>
<tr>
<td>Laparoscopic operation</td>
</tr>
<tr>
<td>· Endoscope trocar</td>
</tr>
<tr>
<td>· Position of additional trocars</td>
</tr>
<tr>
<td>· Number of additional trocars</td>
</tr>
<tr>
<td>· Requirements on instruments</td>
</tr>
<tr>
<td>· Additional instruments</td>
</tr>
<tr>
<td>Surgical technique</td>
</tr>
<tr>
<td>· Tunnelling of uterosacral ligaments</td>
</tr>
<tr>
<td>· Presacral preparation</td>
</tr>
<tr>
<td>· Caudal fixation of implant</td>
</tr>
<tr>
<td>· Insertion of implant arms</td>
</tr>
<tr>
<td>· Fixation of implant arms</td>
</tr>
<tr>
<td>· Procedure if residual cystocele encountered intraoperatively</td>
</tr>
<tr>
<td>Postoperative tips</td>
</tr>
<tr>
<td>Possible postoperative complications</td>
</tr>
<tr>
<td>· Late infection</td>
</tr>
<tr>
<td>· Vaginal/visceral exposure and wound shrinkage</td>
</tr>
<tr>
<td>· Neurogenic pain</td>
</tr>
<tr>
<td>· Defecation</td>
</tr>
<tr>
<td>Relative and absolute contraindications</td>
</tr>
<tr>
<td>Documentation</td>
</tr>
<tr>
<td>Conclusion</td>
</tr>
<tr>
<td>References</td>
</tr>
<tr>
<td>Moderator of the workshop group</td>
</tr>
<tr>
<td>Author</td>
</tr>
<tr>
<td>Workshop participants</td>
</tr>
</tbody>
</table>
Advantages of bilateral CESA/VASA

The bilateral cervico-/vaginosacropexy (CESA/VASA) boasts the following advantages:

- Anatomical reconstruction of the pelvic floor
- Functional reconstruction of the pelvic floor
- Tension-free reconstruction of the pelvic floor
- Reconstruction using a standardised technique
- Short surgery
- Short period of convalescence (shorter stay in hospital)
- Low, mesh-related complication rate thanks to PVDF implant and ligament replacement (PVDF = polyvinylidene fluoride)

Indication

The incidence of pelvic organ prolapse is as high as 50% in women who have previously given birth (Nygaard et al, 2008). It is normally the apical support which deteriorates (Delancey et al, 2002). In fact, women with advanced prolapse always require adequate support of the apex of the vagina (Shull, 1999).

Indication for laparoscopic, bilateral cervico-sacropexy (CESA) or vaginosacropexy (VASA):

Prolapse of the uterus or vagina with participation of the central compartment with or without concomitant urge/mixed urinary incontinence.

Choice of the mesh implant

The FDA made reference to MESH complications in POP surgery in 2008. Thanks to innovations in MESH technology, PVDF mesh implants now demonstrate excellent biocompatibility. Further positive features include:

- Low bridging in the central fixation area (vagina/cervix): Polypropylene (PP) implants must have a pore diameter of at least 1 mm in all directions – including under tension (!) (because of the lower granuloma thickness, just 0.6 mm is sufficient in the case of PVDF) – for the pores to remain open. This is the only way to ensure that autochthonous physiological tissue can grow through a pore (A).
- Low inflammation: PVDF induces only low inflammatory and fibrotic foreign body reactions. (B)
- Low bacterial adherence: PVDF displays low bacterial adherence, which reduces the risk of postoperative infection. (C)
- High biostability: Long-term implant trials over seven years show: PVDF loses just 7.5% of its tensile strength compared to 46.6% for conventional polypropylene. (D)
- Optimal follow-up checks: PVDF implants are visible on conventional MRI scans, allowing excellent postoperative follow-up checks.

No overstretching or wearing out: The foundations for surgical success are sufficient stability, an adapted ductility and high dimensional stability even when subjected to tension. Above all, the ligament replacement must not overstretch or wear out! The PVDF material satisfies these requirements.

Patient briefing

Brief your patient on the procedure and possible consequences comprehensively and in good time. Use a standardised patient information sheet for this purpose. Patient information brochures, models and videos are also helpful in demonstrating the procedure. You can find corresponding information materials and patient information sheets at: www.cesa-vasa.de.

The briefing should be held at least 24 hours before the operation (and be well documented). The briefing must be well structured so as to allow the patient to make an informed decision.

Additionally you should include as much of your own experiences as possible, concerning the success of interventions and associated complications:

- Explain to the patient that the bilateral sacro-colpopexy is a modified version of the unilateral technique used to date and that there are as of date no long-term results from prospective, randomised trials available.
- Address the effects that the surgery will have on the patient’s sexual activity as well as her bladder and bowel function.
- Discuss and explain both non-surgical and surgical alternatives (including alternatives to implants).
· Explain prior to the surgery that a further, sequential operation and an anterior colporrhaphy or a stress incontinence operation (usually in the form of a TVT tape) may be necessary.

Preoperative diagnostics

The medical history is taken using a standardised questionnaire and via evaluation of a micturition protocol (to exclude a neurogenic or medication-related bladder disorder). This is followed by a gynaecological exam to assess the prolapse – firstly with the patient laying and then with her standing. If possible, the exam should be performed with a full bladder (cf. Dr. Jäger’s surgical guide).

With patient lying

The gynaecological exam is always performed with a Sim’s speculum. The first step is to push or lift the cervix or vaginal stump upwards in a horizontal direction using the rear blade. This should allow determination of whether there is truly a cystocele present. In almost all cases, it is merely a consequence of the prolapse of the cervix or the vaginal stump. The same procedure with the rear blade shows the same for the rectocele.

With the patient standing

Examining the patient on her feet is also prudent, as the true extent of a prolapse can often not be appreciated fully when the patient is lying down. However, gynaecological exams in a standing position take some time, as the organs do not descend immediately, but rather only after being subjected to a certain load. As such, it is advisable to have the patient stand and cough for a while.

Preoperative examinations

In addition to the examinations already mentioned, a gynaecological ultrasound and introitus sonography for evaluation of the pelvic floor and determination of the residual urine are also obligatory. It is essential to be able to rule out a urinary tract infection, colpitis and pre-existing urinary obstructions. Remove any IUDs prior to the surgery. If the medical history and clinical findings are decisive, performance of a urodynamic examination is optional.

Laparoscopic operation

Endoscope trocar

We recommend the use of a 30° laparoscope, as this allows optimal visualization of the presacral structures and following of the tunnels for the implant arms. (The surgeon is of course free to select an endoscope with a different angle if preferred.)

Position of the additional trocars

Insert the implant arms through the rudimentary uterosacral ligament. The preparation should be performed atraumatically and in such a way that the neural structures are protected – this depends decisively on the positioning of the additional trocars. There are two possibilities for tunnelling under the uterosacral ligaments:

· Tunnelling from cranial to caudal: In this scenario, a trocar is positioned in the upper abdomen.

The lifting, pushing and depression of the vagina shows when the patient feels the urge to urinate and when not. The urge is often less intense when the speculum is pointing towards the S2. Important: The point of the urge can only be pinpointed accurately with the patient standing (for example with a small swab).
• Tunnelling from caudal to cranial: In this scenario, it is important to pay attention to far caudal and medial suprasymphysary positioning of the trocars. The trocars should be positioned no more than two finger widths above the symphysis. The instrument used to create the tunnel should be introduced from the contralateral trocar side.

Number of additional trocars
The technique is usually performed with three additional trocars; the surgeon is free to select their diameter as preferred.
The third additional trocar is positioned in the right abdomen when preparing from caudal to cranial.
This results in the corresponding instrument interfering less with the other suprasymphysarily introduced trocars.

Requirements for the instruments
The surgery is generally performed with standard instruments. However, it is also possible to use curved instruments. The instruments are selected based on the surgeon’s experiences and personal preferences.
The peritoneum can be tunnelled atraumatically with a conically tapered preparation instrument (e.g., Manhes forceps).
If the suprasymphysary trocars are placed sufficiently deep, the instrument does not need to be curved for the caudal-cranial preparation.

Additional instruments
Cervicosacropexy: In this technique, the uterus (if present), is repositioned to cranial by means of laparoscopic traction or a Portio adapter inserted vaginally. Stay sutures can also be practical for keeping the colon, adnexa and bladder out of the operating field.
Vaginosacropexy: In this technique, a rectal manipulator/dilator is inserted vaginally. The vaginal movement of the manipulator makes it easier to locate the vaginal apex and the correct points for suture fixation of the implant.

Surgical technique
Tunnelling of the uterosacral ligaments
Before the implant is fixed to the cervix, it is advisable to tunnel the uterosacral ligaments and prepare the presacral space at the height of S2. Performing this step now avoids the risk of the implant or the implant arms impeding vision during this preparation.
The tunnelling of the uterosacral ligaments starts close to the implant margin and continues directly under the peritoneum under visual control. This prevents incorrect positioning of the implant arms (too far lateral or caudal).
Increasing tissue resistance is indicative of an unsuitable preparation layer.
An atraumatic grasping instrument with a lock can be used to apply tension to the pelvic floor peritoneum from caudal during the tunnelling. This tensioning facilitates the atraumatic preparation of the tunnel.

Presacral preparation
The peritoneum is opened cranially of S2. Opening of the retroperitoneal space is followed by gas dissection, which facilitates the preparation. In order to prevent tissue and nerve damage, the preparation is performed exclusively by spreading the tissue carefully.
The hypogastric nerve can be visualized and protected.
There are two typical sources of errors with regard to determination of the vertical entry point into the presacral peritoneum:
• Preparation is more difficult if it is performed too far to caudal. Due to the dorsal orientation of the course of the sacrum, there is a risk of missing the required S2 position.
• Vascular anomalies are encountered time and time again in the pelvic cavity. Atraumatic preparation helps to identify peculiarities. If the aortic bifurcation is located high, the point of entry into the peritoneum may also be too high. The result is preparation which starts too far cranial - atraumatic preparation is then practically impossible.
There are also two typical sources of error with regard to determination of the lateral point of entry into the presacral peritoneum:
• If the entry is too far lateral, there is a risk of injuring a ureter.
• If the entry is too far medial, the fat of the mesosigmoid and the vessels it contains render preparation more difficult.
Especially on the left side, this is decisive for the success of the operation. If the peritoneum is opened laterally of the fat shining through the peritoneum there, there is no preparation through the mesosigmoid. The mesosigmoid can be tensioned to medial and held in place.
The left hypogastric vein is often visualized during this preparation. The preparation is performed atraumatically
medially of this structure and continued through spaces that open easily. Palpation of the sacrum with a probe can be helpful for the preparation. Minor bleeding usually stops on its own or can be stemmed through the application of pressure.

**Caudal fixation of the implant**

**Cervicosacropexy:**
The body of the uterus is removed above the insertion of the uterosacral ligaments at the cervix.

When using the CESA technique, the implant should be positioned centrally above the cervical channel free of wrinkles. It is then fixed in place with four separate, interrupted sutures, one in each quadrant of the cervix stump. This is done using a multifilament, braided, non-absorbable 2/0 suture made of polyester. The sutures are placed deeply and securely. Incorrect positioning of the implant laterally or vertically has negative consequences: It alters the direction of tension.

**Vaginosacropexy:**
The fixation is performed at the apex of the vagina with the help of a rectal manipulator. The apex of the vagina must be clearly identified: Its correct localisation is decisive for the success of the operation.

Following classic, vaginal hysterectomy, the apex can be identified by the outlet of the round ligaments and the adnexa. The bladder is only dissected minimally from the apex of the vagina. The fixation is also performed with four non-absorbable interrupted sutures and the implant should also be positioned here without any wrinkles.

**Insertion of implant arms**
Once the implant has been fixed caudally: Insert the implant arms (composed of narrow, high-strength PVDF filaments) through the prepared tunnels.

Peritoneal closure at the apex of the vagina or above the cervix is obligatory before the implant arms are fixated. Following the operation, the entire implant should lie outside the peritoneum.

**Fixation of implant arms**
The implant arms are fixed in position with interrupted sutures or titanium spiral clips.

The dorsal divisions of the sacral spinal nerves exit the back of the sacrum through the posterior sacral foramina; towards the pelvis, the corresponding ventral divisions exit the anterior sacral foramina. When working with titanium spiral clips it is essential to avoid incorrect positioning in the anterior sacral foramina. Palpation with an instrument and vertical insertion of the spiral clips under exertion of slight pressure can guarantee their correct position. Closure of the peritoneum in front of S2 is optional.

**Procedure if residual cystocele encountered intraoperatively**
The success of the operation is checked by introducing a speculum. But what should you do if the anatomical findings do not reveal satisfactory reconstruction of the anterior wall of the vagina following the bilateral technique?

There are two possible courses of action:

- On the one hand, you can wait and see how the patient responds: This allows you to decide after a period of time whether subsequent correction is still necessary.
- On the other hand, an intraoperative cystoscopy or sonography can be performed for diagnostic differentiation: If a pulsion cystocele is still evident, some surgeons view this as an indication for simultaneous anterior colporrhaphy.
Postoperative tips

Perform thrombosis prophylaxis in accordance with the applicable guidelines.
As is also the case for other minimally invasive procedures, it is important to initiate mobilisation and a gradual return to normal oral feeding as soon as possible. Pain management is no different from that for any other minimally invasive, gynaecological procedures. The usual minor postoperative pain is well addressed with NSAIDs. For example: 400-800 mg ibuprofen three times per day, plus 40mg omeprazole once per day. The urinary catheter inserted intraoperatively can usually be removed on the day after the operation. The micturition on the same day should be documented and the residual urine checked with sonography.

In cases of confirmed vaginal atrophy, postoperative vaginal oestrogenisation is advisable. We recommend examining the patient with a speculum and performing a vaginal sonography and a renal sonography before the patient is released from hospital. These confirm the success of the surgery. The patient can return to her normal daily activities immediately. However, she should also allow her body to rest for 8-12 weeks so as to give the implant time to heal in place. During this time, we recommend avoiding vaginal intercourse. A diet which is high in fibre and roughage for normal to soft stools is also advisable. Follow-up examinations: The patient’s gynaecologist should perform a routine check-up four weeks after the surgery; the surgeon should perform follow-up examinations after 3 and 12 months respectively. It is recommended to perform a normal gynaecological examination and a sonography at these visits. A special urogynaecological examination is required if the patient is still incontinent following the surgery. The patient should contact the surgeon in case of suspected complications.

Possible postoperative complications

Late infection
Infections following implantation of PVDF implant structures are very rare. As such, we are unable to make any special recommendations. As a general rule: Postoperative infections should be managed in accordance with the corresponding principles of foreign body surgery.

Vaginal/visceral exposure and wound shrinkage
Vaginal or visceral exposure of the implant: It is not normally an indication of an infection. It is also unlikely to be due to biomechanical interactions. Wound or implant shrinkage: Can occur if the tissue lying directly next to an implant structure retracts. Thanks to the good biocompatibility of PVDF, these complications have only occurred in isolated cases to date. As such, we are unable to make any special recommendations. Should these complications nevertheless develop: Proceed in accordance with the recommendations for problems with PP mesh implants.

Neurogenic pain
If the patients experiences pelvic pain radiating down into the leg: The cause could be incorrect presacral fixation affecting the sacral nerves in the anterior sacral foramina. A four-week course of treatment with carbamazepine is recommendable. In the cases documented to date, this left the patients completely free from complaints.

Defecation
Defecation disorders are possible if the procedure is not conducted correctly. Consequently, particular attention should be paid to tension-free insertion and correct positioning of the implant lateral on the sacrum at the height of S2.

Relative and absolute contraindications

Contraindications:
There are relatively few contraindications. The procedure should not be performed if the patient presents with a vaginal infection, urinary tract infection or vaginal erosion. Outlet problems (e.g., soiling, anal incontinence and intussusception): These problems should be clarified interdisciplinarily and coloproctologically before the surgery.

Pelvic radiation:
Sufficient experience is not yet available.
Desire for children:
In North America in particular, there are users who perform the procedure and preserve the uterus completely. There is still no valid consensus available on the extent to which this procedure can be performed if the patient still desires children.

Dyspareunia:
Was not discussed at the workshop.

However:
It is not currently possible to rule out dyspareunia in the long term. As such, the patient briefing should reference this factor explicitly, as is the case for all other prolapse procedures too.
The vaginal wall is not surgically altered when the CESA/VASA procedure is employed alone.
The apex of the vagina is suspended without tension. For this reason, the procedure is also suitable for patients under 50 years of age.

Documentation
Implant passports should be used.

Conclusion
A surgeon’s experiences and learning curve are of enormous importance, particularly when attempting new and modified surgical techniques. The available literature is still limited, as is to be expected – the indications, technical refinements and results have still only been discussed to a small extent. As such, it is all the more important to share experiences at an early stage and make them available to all users.

These procedures have now been performed more than 5,000 times around the world. Experiences have been collected in Germany with both the open surgery and the laparoscopic procedures. There are a number of specialist workshops on offer at different locations. For example, a national training centre has been established in Norwich, UK.

An increasing number of experienced surgeons in many countries are focusing on the laparoscopic performance of the procedure. This overview displays the possibilities of the laparoscopic procedure.

References
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