Prof. Dr. Wolfram Jäger

CESA / VASA

A Standardized Surgical Technique for Treatment of Female Urge Urinary Incontinence (UUI) and Pelvic Organ Prolaps (POP)
for Claudius, Julius and Amadeus

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FOREWORD

Female urge urinary incontinence is probably one of the biggest health problems in the elderly. The exact number of affected women is difficult to quantify because many hide their illness. Knowing that initially there is almost always an attempt to deal with this by using pads, then by calculating the sales numbers of such products we can, according to conservative estimates, assume that every third elderly woman suffers from incontinence – a problem that often limits the quality of life of those affected so considerably that many hardly ever leave their house.

While stress incontinence is considered curable, thus far there has been no effective treatment for urge urinary incontinence. It was incurable. Through the development of a new surgical technique this has changed. With the CESA/VASA methods the urge urinary incontinence of a woman can be treated effectively for the first time. Previous studies show that three out of four women can be cured.

In this book more than just the details of the individual steps of the procedure are clearly explained. Among other things, attention is also paid to the selection of suitable patients as well as the medical history and diagnostic areas. Furthermore, it is shown how much the successful application of the method depends on detailed surgery and especially the materials used.

Not least, in terms of the women concerned, we should work to see to it that CESA/VASA surgery is used by selected experts worldwide. Since the correction of the pubourethral ligament (PUL) can also be standardized and the pelvic size of women is the same worldwide, it is possible to perform the identical procedure worldwide and thus to achieve standardization. In this way, we can achieve the goal of getting a crucial step closer to being able to provide a 100% cure for urge urinary incontinence in a few years.

Prof. Dr. Wolfram Jäger
DEVELOPMENT OF
SURGICAL PROCEDURES

CONTEXT

Stress urinary incontinence is defined as loss of urine with increased abdominal pressure. The hypothetical pathogenesis is from damage to the pubourethral ligaments (PUL) under the urethra, which with the strongest pressure can no longer provide resistance for the bladder filled with urine and lets urine through. As a result, the treatment consists of replacement of the PUL. The use of different tension-free slings was tried in the past. The surgical technique was widely used at first, and as the Swedish gynecologist Ulmsten changed the position of the band from the „neck“ to the „knee“ of the urethra, the correct materials and mainly the appropriate surgical instruments were developed. Initially called IVS (intravaginal sling) by Ulmsten, the method gained worldwide fame as TVT. Millions of women have been treated with it worldwide, with a success rate (continence after surgery) of almost 80%.

In contrast to stress urinary incontinence, urge urinary incontinence is defined as a compulsion to urinate frequently or not being able to hold urine properly any longer. This subsumes a wide range of forms – from very frequent trips to the toilet to the complete inability to hold the urine. The pathogenesis of urge urinary incontinence has thus far not been satisfactorily resolved. Problems involving innervation of the muscles of the bladder that ultimately give it autonomy are assumed. Studies involving more than 1000 participants have tested various drug therapies to treat the suspected neurological cause of the disease, which however have not been shown to be more effective than the placebo.

As early as the 1990s, both de Lancy as well as Petros hypothesized that urge urinary incontinence if based on an anatomical defect in the posterior pelvic floor area or is associated with such. Some years ago we managed to prove this connection. It was the simple observation that women who had daytime incontinence problems could sleep at night relatively undisturbed, which led us to
the solution. We accepted urge urinary incontinence as a position-dependent phenomenon and therefore hypothetically assumed that the problem does not lie in the neural system.

TREATMENT OF URGE URINARY INCONTINENCE – THE TURNING POINT

As early as the mid-1990s we made the observation that some patients, following a procedure for the treatment of recurrent carcinoma of the cervix (CORT) reported that they no longer suffered from urge urinary incontinence (this occurred after the primary radical Wertheim operation). In the CORT operation afterloading probes, among others, were placed in the pelvic wall and the small pelvis was completely covered with vicryl mesh to prevent the small intestines from being able to fall into the planned radiation field. Since at that time the focus was primarily on the oncological results, initially no further clinical consequences were drawn from them. The observations provided however the first clues for a possible turning point with regard to the treatment of urge urinary incontinence.

The assumption of the operation method of Egger for treatment of Descensus genitalis however did produce the impetus for further development of surgical treatment of urge urinary incontinence. In this abdominal-vaginal surgery polypropylene mesh or slings were sutured bilaterally in the paravaginal and pararectal areas between the levators in the introitus area and the sacral vertebrae. Then, the vagina and rectum were fixed. Because this procedure was presented as a surgical approach for the treatment of prolapse conditions in the female pelvis and the normal surgical procedures often lead to recurrence, we initially used it for the treatment of vaginal stump decensus. Many of the affected patients complained before the procedure of urge urinary incontinence and reported post-surgery that there was a significant improvement. However, it was reported as very unpleasant and in addition with cohabitation as bothersome due to the scarring of the vaginal wall due to the implanted bands to the right and left of the vagina.
The partial failure of the surgery for one patient showed surprising results in terms of the further development of the technology. In this case, shortly before the end of the procedure, the sutures in the levator area were torn. Due to the anesthesiological situation the correction was not possible. It was surprising that the patient directly after the surgery and even months later no longer showed any urge urinary incontinence symptoms. For us, this was the reason to believe that the vaginal stage is dispensable in the treatment of urge urinary incontinence. We developed the technique further and as a result also use it for prolapse of the uterus. We named the operation VA(gino)Re(cto)Sa(cropexy) according to the anatomical structures to which the ligaments are fixed.

**DOCUMENTATION OF THE METHOD**

During the operation all steps and clinical effects as well as supposedly small modifications (e.g. horizontal vs. vertical stich direction, strength of the knots, sharpness of the needle) are documented. The clinical observation of patients with descensus and urge urinary incontinence make it clear which steps are vital. The fact that a patient was immediately again incontinent if one of the slings broke showed that in each case two slings (one each left and right of the rectum) were needed. These observations as well as studies on rhesus monkeys let to the working hypothesis that urge urinary incontinence can only be cured if the uterosacral ligaments (USL) are replaced. The claim of the most naturally possible replacement gave way to the observation that the USL could no longer be depicted in affected patients, but only the peritoneal folds, which themselves do not tighten. As a result, alloplastic slings had to be implanted. Attempts to anchor the slings stably to the musculature were made on corpses, but failed. Therefore, it was necessary to find ways to fix the implants in the area of the bony structures. The fixation on the promotorium – a typical location in gynecology – seemed the simplest localization, but it did not show the desired success with respect to the symptoms of urge urinary incontinence. This was fixed only by the implantation in the periosteum before S2/S3 – a typical location in urology. Further investigations were made on corpses to determine the correct length, width, tension as well as course of the slings in the small pelvis. This
resulted in the need for different sling lengths when suturing to the cervical or vaginal stump. Further shown was an influence on the clinical results due to a difference in the right and left sling lengths as well as the pulling directions of the implants.

Further changes were made to surgical procedure defined after these preliminary investigations, which were based on the analysis of the postoperative course. Originally, up to 75% of the patient who underwent the surgery left the clinic cured. Because to date it has been assumed that according to the „Integral Theory“ of Petros both the uterosacral ligaments (USL) as well as the pubourethral ligaments (PUL) must be replaced in all cases a TOT was also put in place. For organizational reasons, the procedure was amended in subsequent years where initially a VA(RE)SA or CERESA (Cervico Recto Sacropexy) was performed and the TOT insertion was performed three months post OP. However, it could be observed that the urge urinary incontinence was already successfully treated without TOT in 40% of all cases.

SEARCHING FOR THE RIGHT MATERIALS

Of the first 160 patients who underwent CE(RE)SA including TOT or VA(RE)SA including TOT 32 (=20%) developed a recurrence of urge urinary incontinence. A total of 28 women examined with laparoscopy showed the cause to be suture- and one- or two-sided sling tears (5 patients), shrunken or overstretched slings as well as strong adhesions (23 patients).

These results could indicate that the problems lie not in the method, but rather in the materials used. Due to the stiffness of the common polypropylene slings and the frequently occurring adhesions, the first slings used were replaced mainly by hernia implants cut by the surgeons themselves. In addition to strong adhesions, which among other things in the course of the peritoneal fold impair the function of the USL and in part fully enclose the ureter, these materials often also showed contraction (shortening of the slings) or overstretching (lengthening of the slings). With the use of polyester slings, due to this „sagging“ there
was loss of primary tensions and 'fluttering' occurred during the recurrence operations. With polytetrafluoroethylene strong and long-term ingrowth could not be provided either on the periosteum before S2/S3 or on the vaginal stump.

Based on these findings, it was clear that a successful and standardized technique is only possible with the help of an implant developed especially for these new methods. In 2011, therefore, joint product development began with the company FEG Textiltechnik, which already has developed and distributes the high performance plastic polyvinylidene fluoride (PVDF). Within the scope of this development four structures were specially adapted for the application of each of the CESA and CERESA as well as VASA and VARESA techniques. These implants allow us to now standardize the procedures further and to ensure high reproducibility.

Prior to October 2012, 50 women with mixed incontinence had surgery using the PVDF material. 17 patients were continent without TOT implantation and 33 patients also had the TOT implanted. In total, 41 patients were able to be cured. In the remaining nine, still no satisfactory improvement was achieved in the previous post examinations.

CURRENT STATE AND PERSPECTIVES

At this time, we are surveying approximately 700 patients who were treated with the CESA, CERESA, VASA and VARESA methods. With a previous total cure rate of more than 75%,7 in the course of development we have gained the knowledge and not least with the optimized implants as well as the highly standardized OP methodology we are confident that the widespread disease of urge urinary incontinence will be close to 100% curable in the foreseeable future.
First steps in this direction are the ongoing URGE I and URGE II studies comparing the new methods of the current standard of care.
As already stated above, we were able to prove a few years ago that the female urge urinary incontinence is probably based on an anatomical defect in the posterior pelvic floor or associated with such a defect. As described, it was a simple observation, which brought us closer to solving the problem: For many patients the existing incontinence problems are more pronounced during the daytime. The same women can sleep through the night relatively undisturbed for several hours at a stretch. Thus, the urge urinary incontinence appears to be a position-dependent problem.

The (first) trials in women, who remained awake at night and slept during the daytime, showed that this is not a daytime problem, but that this can actually be caused by the upright position of the upper body.

**BENEFITS OF STANDARDIZATION**

A detailed anamnesis can give first information about structures in the pelvis being affected. Recommended here is the use of a standardized patient questionnaire, which will evaluate important parameters for the therapy.

According to our research, internationally up to 21 different questionnaires have been tested and recommended for the classification of incontinence. Since the answers to questions, in the absence of therapeutic options, could lead however to differences in treatment, the questionnaires served only to assess the smallest effects that were achieved through medication, for example.

In light of further studies with the goal of worldwide compatibility of the CESA/VASA surgical procedure, the collection of different parameters is sensible and useful not just during the initial interview (before surgery), but also upon discharge from the hospital as well as at other follow-ups.
Based on the many years of experience with 700 patients, a medical history form was developed. This was offered at **www.cesa-vasa.com** in a neutral form to download.

**Intact pelvic floor anatomy**

**Greatly stretched PUL: hypothetical situation with stress incontinence**

**Anterior avulsion and posterior defect (strain). Complying with the urge to urinate is no longer possible.**

**The PUL and USL no longer function. The patient is no longer able to contain the urine and is „always wet“.**

**city – in spite of an empty bladder – results in a neuro-related pulse of the frequent urge to urinate.**
CENTRAL PARAMETERS OF THE MEDICAL HISTORY

**Urine loss**
Urine loss during stress (e.g. coughing, sneezing, sports) is indicative of a pubourethral ligament (PUL) defect. If there is urine loss when coughing with an empty or only slightly full bladder, this corresponds to an intact uterosacral ligament (USL), since there the vagina is still suspended horizontally. Urine loss when coughing with a full bladder, however, is an indication of a no longer intact, but also not completely defective PUL. Confirmed in this case, however, is a defect of the uterosacral ligament (USL), which causes the bladder under intraabdominal pressure and with coughing to drop down into the vagina.

For patients with whom there is urine loss while lying down, there is usually a very complex injury to the pelvic floor. This usually indicates the additional implant of a TOT here after VASA or CESA.

**Bladder emptying**
Information on whether the bladder is completely emptied after voiding is provided by most patients with the addition of „I think so“. Often it is reported that subsequently after a voiding, they suddenly (may) have to void again. To date it is not clear what this symptom is based on.

**Holding the urine**
The question that is very important for the patients is how long can the urine be held with the urge to urinate, since daily life will be set up around this. Can a toilet be easily and quickly reached, or is there another behavior possible if this is or is not fully the case (e.g. cinema, theater, etc.). Each woman can evaluate the following situation and she gives the doctor important information with regard to the choice of therapy. „Imagine that you have bought a blouse in a store and want to go to checkout. On the way there you feel that you need to go to the toilet. At the checkout you see two customers waiting. What do you do?“ If there are no problems, the patient will answer that she will line up at the checkout. If the answer is that she would prefer to go to the toilet first, then experience shows that she cannot hold her urine for very long, estimated at more than 3 minutes, but seldom longer than 10 minutes. Women who report that
they immediately start looking for the toilet when they first get the urge to urinate can, according to experience, hold the urine for less than 3 minutes.

These experiences elicited by questioning provide important differentiations in comparison with the „always wet“ women who find it impossible to hold the urine flow – even for just a short time. For them a correction to all the ligaments is almost always necessary.

**Incontinence since Youth**

Incontinence as connective tissue weakness – or as its consequence – may not be accepted in young women. For this reason, it is important that patients who have indicated that they have already suffered from bladder infections or incontinence from a young age be questioned very carefully and sensitively. Experience shows that such complaints are often the result of childhood abuse or painful experiences in youth. These women should first be presented to a psychosomatic specialist. The special problems of the patient should be detailed in advance to these specialists since the competent treatment of such issues is thus far reserved for a few experts.
GYNECOLOGICAL EXAMINATION

The gynecological examination should always be performed with a split speculum. Initially, the cervical or the vaginal stump should be moved in a horizontal direction upwards with the rear blade. This should show whether there really is a cystocele. In almost all cases, this is only the result of the descensus of the uterus or the vaginal stump, which is clean when lifting it with the speculum. An identical approach with the rear blade shows the same for the rectocele. Anterior and posterior colporraphies are rarely indicated.

The lifting, moving and pressing down of the vagina indicates if the patient feels the urge to urinate or note. The direction of the speculum should be promptly recorded or a sketch may be drawn. Often, it can be determined that the feeling of urgency decreases when the speculum is in the direction of S2. It must be considered that this study applies only to the horizontal position. Only when standing can the feeling of urgency be localized. This is possible with a small swab.

Therefore, during diagnostics supplementing the examination usually performed while lying down with an examination while standing is indispensable. This is mainly because a descensus cannot be determined or cannot be determined with any certainty while the patient is in a horizontal position.

In practice, the examination is started with the patient lying down and the chair is then moved into the starting position. The patient is then asked to stand up with the investigator leaving the index finger in the vagina the entire time. The gynecological examination while the patient is standing requires some time, since the organs do not settle immediately, but only after some force. Therefore, it is advisable to have the patient stand a little longer and to cough. If possible, the patient should be examined with a full bladder. It is therefore advisable to allow the patient to wear a single use pad since there is often (un)expected discharge of urine.
NOCTURIA

Patients with urge urinary incontinence usually have no problems at night (while lying down). Going to the toilet two times a night is considered normal. Any nocturnal visits to the toilet more than twice is significant and should be considered another problem and a urination log should be kept to measure the amount of urine excreted. The patients shall receive the appropriate form to document the times and the amount of urine excreted. This is also available for download at www.cesa-vasa.com.

Respective quantities under 100 ml are often assumed to indicate the presence of multiple adhesions from previous surgeries in the abdominal cavity, which affect the resting position of the bladder and these pulls and thus create the impression of a „full“ bladder. If larger amounts are excreted, other disorders should be excluded through differential diagnosis.

Tipp:
The expression „diaper“ is very negative to most patients and should not be used by the practitioner. The patient will, if necessary, mention the use of diapers.
HOW DO I TELL MY PATIENT?

Dealing with patients who suffer from incontinence requires a considerable degree of sensitivity. Naturally and quite understandably most women are uncomfortable with their problem and it takes a great effort to overcome this. Just going to see a specialist about the problem suggests a considerable amount of psychological stress.

Therefore, it is first important to convey to the patient that she is by no means alone with her problem and that she shares it with millions of other women and that the doctors who specialize in the treatment of incontinence are confronted by this every day. Reducing the level of shame is the first step in building a relationship of trust between the doctor and patient.

ANATOMICAL STRUCTURES SIMPLY EXPLAINED

It is not easy to explain to a patient about her incontinence problem because she usually does not have the anatomical knowledge. Therefore, it is important to find metaphors to succeed in explaining the problem in layman’s terms. The bridge analogy has proven useful in these cases.
Thus, the anatomical structures are represented as a bridge. Here, the bony structures pubis and ischium serve as the „pillars of the bridge“. The „roadway“ (vagina) hangs on the ropes (front: pubourethral ligaments (PUL), rear: uterosacral ligaments (USL). If both ropes are intact, the bridge is fully functional. If a rope is loose however, the roadway becomes slack. The bridge (bladder) can no longer meet its function. If a rope is lying on the ground, there is no longer any control over the bladder and the woman loses urine at any opportunity.

The clinical symptoms are usually the result of broken ropes – front, rear or in both places. Thus, in order for the function of the bridge to be fully restored, they must be replaced.

UNDERSTANDABLE EXPLANATION OF THE SURGICAL PROCEDURE

Of course, to explain the operation as well as to obtain consent the patient receives a special information sheet prior to the surgery, which explains the method and the possible risks, complications and consequences. Regardless, it is advisable to explain to the patient already during the examination the basic principles of the operation and thus not least to also reduce the fear of the procedure. According to the bridge analogy, one explains that with reduced tension strength of the holding ligaments of the internal organs („the ropes sag“), the goal of the operation is to bring the organs back into their former positions. It doesn’t work to simply streamline the original ligaments („ropes“). Instead, you have to replace these in order to restore the correct anatomical conditions (or – to stay with the metaphor – the structure of the bridge). This goal can be clearly illustrated by using a simplified anatomical drawing.
It is also important to point out that both the rear and front ligaments must be replaced in about two out of three cases. Time and again the desire is expressed to do this in the procedure. Such an approach however is not recommended for about one third of all patients who undergo this operation as this would, on the other hand, somewhat worsen the chances for a cure in these cases. This leads one to suspect that the reasons for this can be found in tissue swelling in the course of the operation.

The sheet for clear explanation of the problem as well as the consent form for the surgery are now available for download at www.cesa-vasa.com.

*Middle Defect* and Repair of the Pubourethral Ligaments (PUL) as well as the Uterosacral Ligaments (USL)
Anterior Defect and Repair of the Pubourethral Ligaments (PUL)

Posterior Defect and Repair of the Uterosacral Ligaments (USL)
REQUIREMENTS FOR THE IMPLANT

ANALYSIS OF REQUIREMENTS

The following requirements for the implant are defined based on previous experience with different materials and the results of the studies carried out:

- The implants used must be made of one piece to achieve high reproducibility and standardization of the surgical procedure. The time-consuming and error-prone intraoperative confection must be transferred to implant manufacturing.

- The shape and dimensions of the implants must be matched to the requirements of the respective procedure. This requires at least four different structures for the procedures of CESA and CERESA and VASA and VARESA.

- On the one hand, the fixation of the implants on the periosteum and the vaginal or cervical stump must ensure solid and sustainable ingrowth with finite tissue and on the other hand, the mobility of the reconstructed uterosacral ligaments must be preserved. Firm adhesions in the ligament area jeopardize long-term healing success.

- Visceral adhesions to the implant as well as material contraction due to wound contraction, which results from a pronounced foreign body reaction, must be avoided through the selection of the appropriate materials.

- Sufficient stability, customized stretching capability and high dimensional stability area prerequisites for the long-term success of the operation. In particular, the overstretching or sagging of the ligament insertion due to stress must be avoided.

- To reduce the operating time, the implant design must allow an easy intraoperative handling.

- The possibility of a non-invasive follow-up is desirable.

Basically, these requirements can only be realized through the selection and construction of the appropriate material and structural properties.
MATERIAL PARAMETERS

Polyvinylidene fluoride (PVDF) is used as a material of choice for all structures. The excellent biocompatibility of the PVDF results, when compared to conventional polypropylenes (PP), in a less inflammatory and fibrotic foreign body reaction. In particular, the minimal necessary required thread distance is reduced to avoid bridging and the formation of a rigid scar plate, going from a thread distance of 1 mm with polypropylenes to only 0.6 mm in comparison. As a result of the material properties of PVDF and decreased wound contraction due to a lower inflammatory reaction, there is significantly lower shrinkage of the implants in comparison to conventional structures. This unique material characteristic even allows the intraperitoneal use of PVDF implants and thus direct contact between the mesh and intestines.

In addition, the biostability of the PVDF, as compared to other materials, is significantly higher. So the strength of the PVDF in long-term implantation attempts over seven years is only reduced by 7.5%, while conventional PP loses more than 46.6% of its strength. This mainly enables the long-term realization of constant dynamometric properties such as strength and stretching and recovery capabilities. Due to its material composition, PVDF also shows a reduced bacterial adherence in comparison to conventional implant materials. In this way both the risk of a direct postoperative infection as well as the long-term formation of a biofilm, which may lead to infection even years after surgery, are reduced.

In general, the conventional materials in mesh surgery cannot be depicted by imaging techniques such as x-rays or MRI. Visualization by modern ultrasound devices is greatly limited in the target area of the new methods by the maximum depth representation of the available devices. Here, a highly innovative innovation of special PVDF thread offers a new solution. By adding minimal amounts of iron oxide microparticles during the melt spinning process in thread manufacturing, it is possible to map the new implant in the patient with conventional MRI sequences.
STRUCTURAL PARAMETERS

In addition to these parameters – determined primarily by the material – the structural parameters of the textile construction are of the utmost importance for the quality of the implant. Here too, some general requirements can be defined from the biomaterial research and the clinical application. This includes in the first place the effective porosity, the only parameter that demonstrably influences the quality of the growing tissue and the resulting foreign body reaction. Sufficient strength, application-oriented stretching and recovery capability, high dimensional stability and functional handling are the parameters used in the textile construction. This is only possible through the close interaction of all the departments involved. And in this lies the big advantage for FEG Textiltechnik in its nearly 100% vertical range of manufacturing. From yarn production to the ready-made implant, all the manufacturing steps take place at Aachen.
IMPLEMENTATION

The insertion aid ensures a secure grip with a curved clamp or a TOT-needle (page 50) and enables easy passage through the preperitoneal space. The atraumatic edges and the special transition between the insertion aid and the implant facilitate insertion into the tunnel and avoid tearing of the peritoneum. The stitch marks on the right and left sides are matched to the anatomical dimensions of the CE(RE)SA or VA(RE)SA. In addition, it is ensured by the marks that the identical ligament length is restored on the left and right sides and a high reproducibility is guaranteed. The large-pored structure allows easy threading of the suture ends. At the same time the textile construction ensures the safe anchoring of the load bearing structure. The excess insertion aid can be cut off 5 mm behind the stitch marks after fixation.

In case of a rectopexy during CERESA or VARESA there is a special fixation area, which allows easy and secure fixation of the mesorectum. The large-pored textile structure ensures fast and solid ingrowth of the mesorectum after the absorption of the suture materials. With the CESA or VASA implants this area is significantly shorter due to material reduction.

The reconstruction or augmentation of the uterosacral ligaments is performed using a tiny narrow sling structure, which is created from high strength PVDF filaments. The connection of these load-bearing structures with each other in the shape of a large-pored web structure facilitates the intraoperative handling and prevents twisting or dislocation of individual filaments. The large-pored structure avoids the formation of a scar strand and the encapsulation of the ligament replacement. This special textile construction allows the long-term and constant mobility of the newly formed ligaments. Due to the material and structural properties the defined elasticity and excellent recovery capacity remain for the long term. In addition, the sagging or stretching of the ligaments is prevented.

In the transition to the fixation surface on the vaginal stump or the cervical ring there is a special torsion and bend protection that prevents high shear stresses or bending forces from occurring due to the 3-dimensional position of the implant at this point.
The open-pore centre patch for the fixation of the vaginal- or cervical stump ensures a fast ingrowth of the terminal tissue and thus the long-lasting and solid anchoring of the implant. The high porosity of this area and the excellent biocompatibility of the PVDF minimize the foreign body and inflammatory reaction and avoid the formation of a painful scar plate and excessive shrinkage of the implant. The dimensions of the fixation surface are matched to the appropriate site of the CESA or VASA operation and can be cut, as needed, to the individual patient situation. The textile construction prevents the further tearing or fraying of the structure.

The entire implant is made of one piece. This avoids joining points, which necessarily represent a weak spot with respect to strength and structural integrity at the transitions between the various functional elements. In particular, the load-bearing elements consist of continuous structures and offer maximum security and long-term preservation of function.

Another advantage is the use of MRI-visible PVDF threads. This offers the possibility, in the event of recurrence or a post-operative complication, to plan a treatment concept with non-invasive procedures or to be able to narrow down the cause of the failure, without exposing patients to further surgical stresses.
The intervals for the follow-up of the patient after surgery and discharge from the hospital can vary in individual cases and also depend on factors such as medical history, general condition, individual constitution, etc. Four examination intervals have proven successful in studies.

2 Weeks Post Surgery
Among other things, here a general examination of the abdominal incision is performed as well as an ultrasound to check the correct position of the implant.

4 Weeks Post Surgery
The focus here is on a check of the incontinence symptoms (urinary frequency and urge) and the patient’s general condition.

8 Weeks Post Surgery
If adhesions have formed as a result of surgery, possible changes in the operation results are gathered and documented.

12 Weeks Post Surgery
At this follow-up appointment there can be a reaction to the results of the previous examination. With an unsatisfactory result, a TOT 8/4 or with deterioration of the previously restored continence, an adhesiolysis, should be discussed. Should a second operation become necessary, the corresponding clarification should be performed and a date for the operation should be agreed upon.

All appointments should include a continence check. Using the medical history sheet the various parameters (urine loss, urination, number of visits to the toilet during the day/at night, etc.) should be queried and documented accordingly.

If such close monitoring is not possible for various reasons, the follow-up examinations, however, must be performed after 2 and 12 weeks.
The CE(RE)SA and VA(RE)SA operations are divided into five or six (with additional rectopexy) steps. Each step takes about 20 minutes.

- **Step 1:** Opening of the abdominal cavity
- **Step 2:** Removal of the uterus (not required in VA(RE)SA)
- **Step 3:** Fixation to the cervix or the vaginal stump
- **Step 4:** Fixation to the sacrum
- **Step 5:** Rectopexy (optional)
- **Step 6:** Closure of the abdominal cavity
The Cervico (Recto) Sacropexy is used in patients in which only a part of the uterus was removed.

**Operation Equipment**

**INSTRUMENTS:**
Additional extra-long instruments:
Dissecting scissors at least 260 mm, fine dissecting forceps at least 300 mm, intestinal holding forceps at least 155 mm, artery forceps at least 130 mm, surgical forceps at least 305 mm, atraumatic forceps at least 300 mm, lung holding forceps at least 230 mm, 2 x vaginal speculum at least 180 x 40 mm, 2 x vaginal speculum at least 130 x 25 mm, medium long curved needle holders (approximately 240 mm, 260 mm and 300 mm)

**IMPLANTS:**
DynaMesh®-CESA or CERESA

**SUTURE MATERIALS:** (other brands see page 70)
**Skin suture:** 3/0 Monosyn or 2/0 Premilene
**Subcutaneous:** 2/0 Novosyn HR37
With transverse incision laparotomy: Fascia (Aponeurosis externus): 1 Novosyn HR37
Parietal Peritoneum: 0 Novosyn HR 37
With longitudinal incision laparotomy: Loop suture 1 Monoplus HRT 48
Removal of the uterus: 1 Novosyn HR 37
Fixation of the mesh to the sacrum: 4 x 2 PremiCron HR 26ss
Fixation of the mesh to the cervix: 4 x 2 PremiCron HR 27s
Fixation of the mesorectum: 4/0 Mono Plus HR 26, 70 cm
Peritonealization of the cervical stump: 2/0 Mono Plus HR 26s, 70 cm
Peritonealization in the area of the sacrum: 3/0 Novosyn HR 26, 90 cm
The abdominal incision should provide enough space so that depth can be reached (incision width = fist width, approximately 8 cm).

The abdominal cavity is opened with a transverse incision approximately 2 cm above the pubic symphysis.
Step 2: Supracervical Removal of the Uterus

Normal site after opening of the abdominal cavity

Grasp the uterus with a clamp
By pulling the uterus up you can identify the approach of the uterosacral ligaments in the cervix ("Archway").

Just above the "Archway" mark the removal site for the uterus.
Step 2: Supravascular Removal of the Uterus

Macro view of the removal site

Removal of the right parametrium. The right ureter is drawn back.
Right-side removal of the uterus. Remove diagonally because the cervix lies mostly on somewhat of a slant.
Step 3: Fixation of the DynaMesh® Ligament Reconstruction to the Cervix

Site after supracervical removal of the uterus. A stay suture is attached to the middle of the cervical stump so that this can be fixed during the next steps.

Placement of non-absorbable sutures with a strength of 2/0 in all quadrants of the cervical stump. The sutures are set deeply and tightly.
Step 3: Fixation of the DynaMesh® Ligament Reconstruction to the Cervix

The sutures should be threaded through the centre patch so that it can be placed on the cervix free of folds.

Placement of the centre patch downwards onto the cervical stump.
Fixed centre patch. Do not make the sutures so tight that they cut through the cervix ("air knots"). Then cut the protruding edges.
Step 4a: Fixation of the DynaMesh® Ligament Reconstruction to Sacrum (right side)

Depiction of the right uterosacral ligament by shifting and lifting the rectum.

Incision of the dorsal fixation site over the 2nd sacral vertebra
Step 4a: Fixation of the DynaMesh® Ligament Reconstruction to Sacrum (right side)

The posterior sutures are set. Horizontal insertion direction. Caution: Do not suture the nerve, do not stab too deep (venous plexus).

Grasp the departure of the right uterosacral ligament
Incise the uterosacral ligament at the departure of the cervix

Preparation of the channel with a lung clamp or alternatively with DynaMesh® instrument IVT01 (Page 50)
Step 4a: Fixation of the DynaMesh® Ligament Reconstruction to Sacrum (right side)

The insertion aid is applied to the instrument.

The insertion aid is pulled extraperitoneally with the instrument into the hole over the 2nd sacral vertebra (S2).
Step 4a: Fixation of the DynaMesh® Ligament Reconstruction to Sacrum (right side)

The insertion aid is grasped with the forceps and tightened. The ligament reconstruction is pulled through the channel to the outside.
Step 4a: Fixation of the DynaMesh® Ligament Reconstruction to Sacrum (right side)

The ligament reconstruction is pulled-through. The stitch marking site of the ligament lies over the fixation site.

The predefined threads are pulled through the stitch marking. The insertion aid is cut 5 mm behind the stitch marking.
Step 4a: Fixation of the DynaMesh® Ligament Reconstruction to Sacrum (right side)

Fixation of the implant with the predefined threads before S2

The defect is closed.
The procedure is more difficult on this side because the rectum lies right in front of the fixation site of the ligament reconstruction. Here: Depiction of the left uterosacral ligament by tightening the cervix and moving the rectum aside with the swab.

Preparation of the suture attachment site before S2 on the left.
Step 4b: Fixation of the DynaMesh® Ligament Reconstruction to Sacrum (left side)

The first suture is already set.

Grasp the departure of the left uterosacral ligament and make an incision the same as on the right side.
Step 4b: Fixation of the DynaMesh® Ligament Reconstruction to Sacrum (left side)

Pull the ligament reconstruction through the same as on the right side

The predefined threads are pulled through the stich marking. The insertion aid is cut 5 mm behind the stich marking.
Step 4b: Fixation of the DynaMesh® Ligament Reconstruction to Sacrum (left side)

Sutures are knotted.

Peritoneal closure over S2 on the left
Step 4b: Fixation of the DynaMesh® Ligament Reconstruction to Sacrum (left side)

Closure of the peritoneum over the cervix

Closure of the lateral peritoneal defects
Step 4b: Fixation of the DynaMesh® Ligament Reconstruction to Sacrum (left side)

Final complete peritonealisation

Preparation of the channel with DynaMesh® instrument IVT01 as an alternative to the lung clamp
Step 5: Rectopexy (optional)

The rectopexy is an option in the context of the surgery and can or should be performed with the appropriate indication. It is performed during Step 4a (right side) as well as during Step 4b (left side).

Here the rectopexy patch of the DynaMesh® implant is already fixed to the sacrum.
At first a long-term absorbable suture is placed through the rectopexy patch. The mesorectum is pierced firmly with the needle and the needle is brought out again through the hole in the lateral end of the rectopexy patch. The sutures are loosely knotted and the recopexy patch is fixed to the mesorectum.

The sutures are loosely knotted and the Implant is fixed at the mesorectum.
The procedure is ended with the closure of the abdominal cavity in the classical manner.
The Vagino (Recto) Sacropexy is used in patients who have had a hysterectomy. The surgical technique, with few exceptions, is similar to CE(RE)SA.

### Operation Equipment

**INSTRUMENTS:**

Normal equipment for a laparotomy:

Additional extra-long instruments:
- Dissecting scissors at least 260 mm, fine dissecting forceps at least 300 mm, intestinal holding forceps at least 155 mm, artery forceps at least 130 mm, surgical forceps at least 305 mm, atraumatic forceps at least 300 mm, lung holding forceps at least 230 mm, 2 x vaginal speculum at least 180 x 40 mm, 2 x vaginal speculum at least 130 x 25 mm, medium long curve needle holders (approximately 240 mm, 260 mm and 300 mm), vaginal phantom

**IMPLANTS:**

DynaMesh®-VASA or VARESA

**SUTURE MATERIALS:** (other brands see page 70)

**Skin suture:** 3/0 Monosyn or 2/0 Premilene

**Subcutaneous:** 2/0 Novosyn HR37

With transverse incision laparotomy: Fascia (Aponeurosis externus): 1 Novosyn HR37

Parietal Peritoneum: 0 Novosyn HR 37

With longitudinal incision laparotomy: Loop suture 1 Mono Plus HRT 48

Fixation of the mesh to the sacrum: 4 x 2 PremiCron HR 26ss

Fixation of the mesh to the vaginal stump: 4 x 2 PremiCron HR 37s

Peritonealization of the vaginal stump: 2/0 Mono Plus HR 26s, 70 cm

Fixation of the mesorectum: 4/0 Mono Plus HR 26, 70 cm

Peritonealization in the area of the sacrum: 3/0 Novosyn HR 26, 90 cm
The abdominal incision should provide enough space so that depth can be reached (incision width = fist width, approximately 8 cm).

The abdominal cavity is opened with a transverse incision approximately 2 cm above the pubic symphysis.
NOT APPLICABLE DURING VA(RE)SA
So that the vaginal stump can be depicted, at the start of Step 3, vaginal phantom is inserted into the vagina and pushed strongly forwards in a cranial direction.

The end of the vagina must be clearly located. This is most successful when the departure of the round ligament and the adnexa are identified. These are usually set directly at the vaginal stump. Situation: Ligamentum Rotundum left.
Site with the vaginal phantom shoved upwards. Subsequently, the bladder is somewhat dissected from the vagina.

Freely dissected vaginal stump
Step 3: Fixation of the DynaMesh® Ligament Reconstruction to the Vaginal Stump

Now similar to the CE(RE)SA the 4 stay sutures can be placed in a rectangle. Here the first suture is attached to the vaginal stump. Important: Take care not to pierce the vaginal lumen.

All 4 sutures are placed in the vaginal stump.
The centre patch of the implant will now be placed and fixed on the vaginal stump. The sutures are loosely knotted.
Step 4a: Fixation of the DynaMesh® Ligament Reconstruction to Sacrum (right side)

From Step 4 the procedure continues analogous to CE(RE)SA.
See photos C 6 to C 29

Step 4a: Fixation of the DynaMesh® Ligament Reconstruction to Sacrum (left side)

Analogous to CE(RE)SA
See photos C 30 to C 40

Step 5: Rectopexy (optional)

Analogous to CE(RE)SA
See photos C 41 to C 43

Step 6: Closure of the Abdominal Cavity

Analogous to CE(RE)SA
See photo C 44
TOT 8/4

In comparison to normal TOT/TVT procedures TOT 8/4 has special features. These allow the procedure to be performed worldwide according to a uniform standard and make the results comparable internationally.

Operation Equipment

The usual Operation Equipment is expanded to include blue solution as well as HEGAR 8 and HEGAR 4 pins.

The first deviation in TOT 8/4: blue solution is injected into the bladder via a single use catheter after emptying of the urinary bladder. In this way, any possible injuries to the organ during the procedure are immediately visible.
In a TOT/TVT procedure the usual methods are continued. Initially, the DynaMesh®-SISdirect soft sling (ligament reconstruction) is pulled in on both sides.

Then the patency of the urethra is checked with a single use catheter. Repeated insertion and withdrawal showed whether a roughness can be palpated in the urethra. If this is the case, then a part of the sling is positioned too close to the urethra. It must be removed and re-positioned.
Before tightening the Dyna Mesh®-SISdirect soft sling a HEGAR 8 pin (arrow) is initially inserted into the urethra. This prevents the urethra from being pulled together with tightening of the implant.

In addition, a HEGAR 4 pin (arrow) is held between the implant and the urethra.
Then the DynaMesh®-SISdirect soft sling is pulled tight. The HEGAR pins ensure that an 8 mm large urethra diameter is maintained and also that the distance from the implant to the urethra is always 4 mm. In this way, the same tension is always achieved in the suburethral sling.
The following two patient progress reports are representative of the over 700 women who have thus far had the surgery and been cured of their urge urinary incontinence. And this sample clearly shows how much the incontinence problem impairs lives and how much better quality of life a CESA/VASA operation can give those women affected by it.

Helga N., 73 years old, married, 3 children

After her last two difficult births Helga N. suffers from mild bladder weakness. With the onset of menopause, there was a dramatic deterioration. Permanent urine loss has resulted in the patient no longer participating in sports, activities and trips. An almost complete withdrawal from social life has taken place, which is perceived as isolation, especially as she can no longer keep step with the still active partner.

At the christening of her youngest grandchild, there was a key moment. During the celebratory lunch Ms. N. had to get up in order to change her pad whereby a granddaughter was heard to say in the silence: „Look, grandmother is dripping.“ Helga N. left the gathering deeply depressed and embarrassed.

Helga N.’s daughter has only now learned of her mother’s bladder weakness and contacted the Department of Urogynecology and Pelvic Floor Surgery of the Cologne University Women’s Clinic. Here Mrs. N. had successful surgery in April 2012. According to her own statement, since then she has been able to do all the things that were previously not possible. These include, among other things, travelling, participating in cultural events and also visiting the playground with her grandchildren. Helga N. assesses the situation after her surgery as „being given the gift of life again“. 
Gertrud K., 78 years old, widowed

Ms. K. reports that since the onset of menopause she has frequently had to go to the toilet. Her husband, even though he had to constantly wait outside the ladies' room, was very understanding.

Some time after her husband's death in 2002 she made a new acquaintance, but out of shame over her permanent loss of urine she withdrew from the relationship, which still makes her unhappy today. Ms. K. had endured many treatment methods, including invasive ones. In addition to pelvic floor exercises she had a TVT applied and then removed and medications did not produce the desired result. In desperation, Ms. K. had Botox injections, which initially actually alleviated the symptoms. After the third series however she had to catheterize herself since independent urination was no longer possible.

Just when she had almost given up the hope of living a carefree life, she saw by chance a TV report about the successful surgical treatment of female urinary incontinence by CESA/VASA at the Department of Urogynecology and Pelvic Floor Surgery of the Cologne University Women's Clinic and she made an appointment at the office. In August 2012, Mrs. K. underwent the procedure. Since then she is continent and can once again participate with her circle of friends in an active life. She feels particularly positive that she can now leave the house carefree and not have to make sure she limits the amount she drinks. She feels "completely comfortable“ and regrets that she did not learn about this opportunity much sooner.
CONCLUSION

Although female urge urinary incontinence was previously regarded as incurable, the CESA/VASA surgical method is recognized as a clear turning point in the field of therapy of this „widespread illness.“ Within the framework of the so-called URGE I and URGE II studies a review and verification is underway of the previously documented results. In cooperation with Prof. Dr. Stephen Jeffery, Director of the Department of Urogynecology and Pelvic Floor Surgery of the University of Cape Town (Groote Schuur Hospital) the operations are being compared with the existing standard procedures for the treatment of urge urinary incontinence.

As described, the technique has now been standardized and shows – partly in combination with TOT 8/4 – a cure in approximately three out of four women who have undergone the procedure. Through international comparability made possible by standardization there exists the chance to identify through more carefully planned studies the previous „failures“ of the method and to further increase the cure rate. Sooner or later almost 100% of all women could be treated successfully.

The goal should be to make incontinence in women history by the year 2020. Admittedly, against the background of previous results with a combination of a technique performed worldwide under the same standard and the development of the most optimally appropriate implants this ambitious claim is no longer unrealistic.

Let`s make incontinence history!


4 de Lancy JOL: Structural support of the urethra as it relates to stress urinary incontinence: the hammock hypothesis. Am J obstetric Gynecol 1994;170:1713-1723


8 Klosterhalfen, B. (2010) Institute of Pathology Düren, Foreign Body Reaction


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MONOSYN = monofilament suture, medium term absorbable
Premilene = monofilament suture, Polyester, non absorbable
PremiCron = multifilament suture, Polyester, braided, non absorbable
MonoPlus = monofilament suture, long term absorbable
NovoSyn = multifilament suture, braided, covered suture, medium term absorbable

- For fixation of the sacrum: 4 x multifilament suture, polyester, braided, non absorbable with the thickness of USP 2, HR 26 ss (ss = super strong)

- For fixation of the cervix: 4 x multifilament suture, polyester, braided, non absorbable with the thickness of USP 2, HR 37 s (s = strong)

- For fixation of the vaginal stump: 4 x multifilament suture, Polyester, braided, non absorbable with the thickness of USP 2, HR 37 s

- For fixation of mesorectum: 2 x monofilament suture, long term absorbable, with the thickness of USP 4/0, HR 26, 70 cm