



**Pelvic Organ Prolapse:
Symptoms, causes & treatment options**

Back to everyday life.

Dear Patient,

are you **unable to let out a hearty laugh** because you can't control your bladder? Are you **no longer able to cycle** because it causes lower abdominal pain? Are you **afraid to leave your home** because you feel you need to go to the toilet every few minutes?

This might be because of a weakened or descended pelvic floor. Many women are affected by this kind of pelvic organ prolapse at some point in their lives. A mild prolapse is usually hardly noticeable. However, if the prolapse is more pronounced, or if there is a genital prolapse, due to the protrusion of organs, such as the bladder, uterus or bowels, which causes the vaginal wall to evert outwards, the symptoms are very distinct and can have a great negative impact on the affected person's quality of life.

Important information:

Please be aware that this information is not meant for purposes of self-diagnosis. It is not a substitute for a diagnosis by a physician.

Therefore, please speak to your general practitioner immediately if you suffer from these symptoms, in order to find out what your individual options are. Your general practitioner will certainly be of great assistance to you when it comes to making a decision.

We wish you good health!

Your pfmmmedical team

Contents

We have put together this brochure to inform you about how prolapse occurs, how it can be identified and how it can be treated.

We have divided the information into the following subsections.

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What is the pelvic floor?

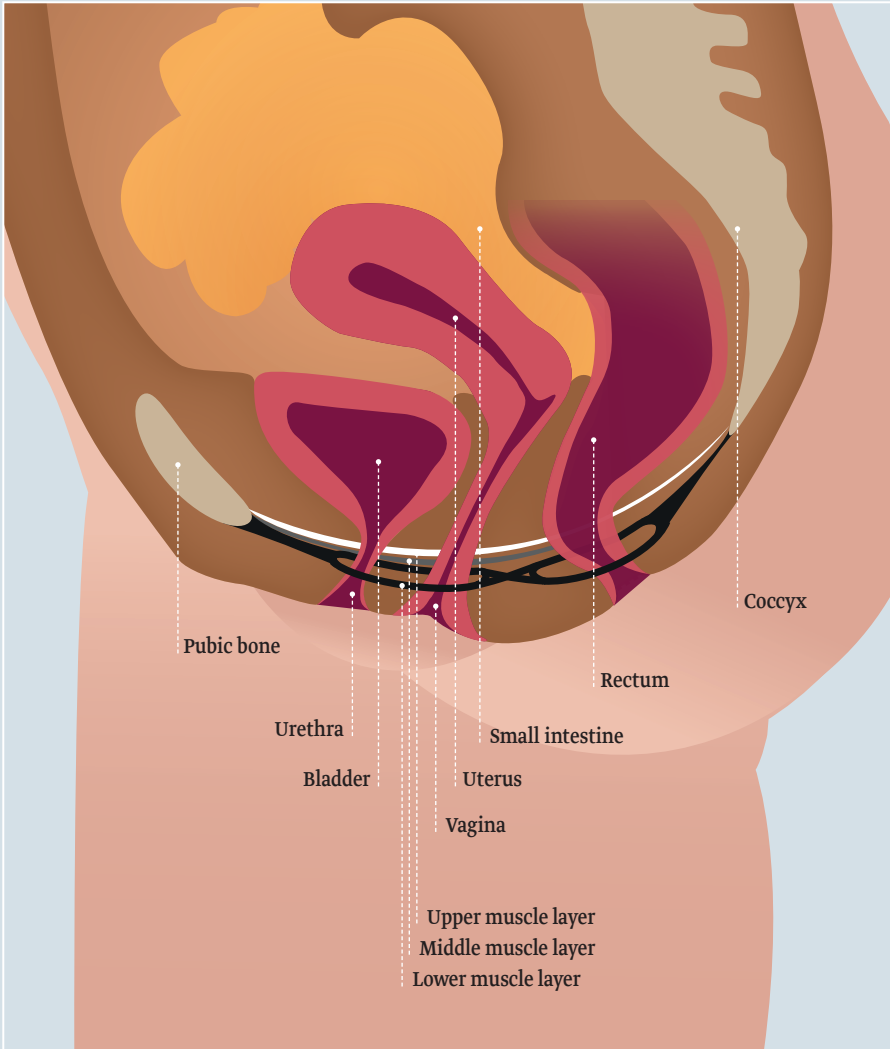
The pelvic floor consists of muscles, ligaments, and connective tissues, that close off the bony pelvic cavity from below. It consists of three layers of muscle: the upper layer spans the entire area of the pelvis and bears the main weight of the organs. It is the most stable layer. The middle layer is at the front of the pelvis, below the bladder, while the lowest layer, which contains the sphincter muscles, is shaped like an eight and encircles the body orifices from front to back.

Women's pelvic floor muscles have an additional opening for the vagina, and it is somewhat different in structure to that of a man, so as to be more stretchable during childbirth. This makes the female pelvic floor more susceptible to problems.

The pelvic floor supports the internal organs and ensures that the sphincters of the bladder and bowel function correctly. In pregnancy, it also stabilises the uterus and the unborn child.

The pelvic floor is supported by the muscles of the abdomen and the back. The muscles of the abdomen help by cushioning any pressure caused by sneezing, coughing or jumping, for example. The back muscles, together with the abdominal muscles, keep the pelvis stable.

A healthy female pelvic floor

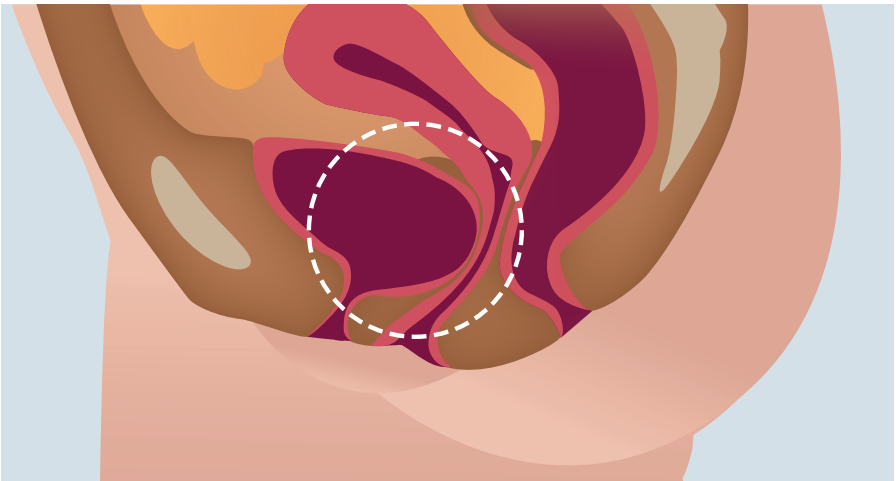


What dysfunctions of the pelvic floor can occur?

Weakened pelvic floor muscles very often result in urinary or faecal incontinence.

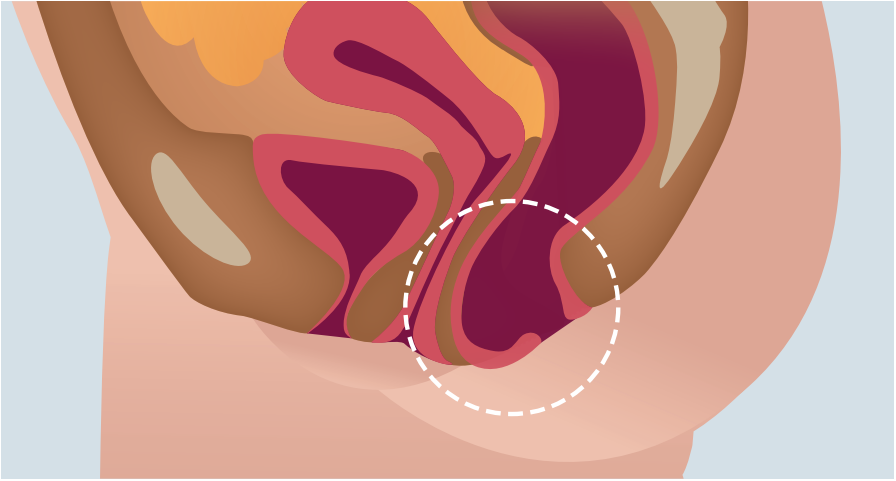
Many women also have to contend with a downward shift of their bladder, uterus or vagina if the muscles of their pelvic floor weaken. Almost half of all women who have given birth to children are affected by this. In the worst cases, it may lead to a prolapse (organ prolapse) in which the bladder, the vagina, the uterus or even the bowel cause eversion of the vaginal wall (towards the outside).

The most common symptoms

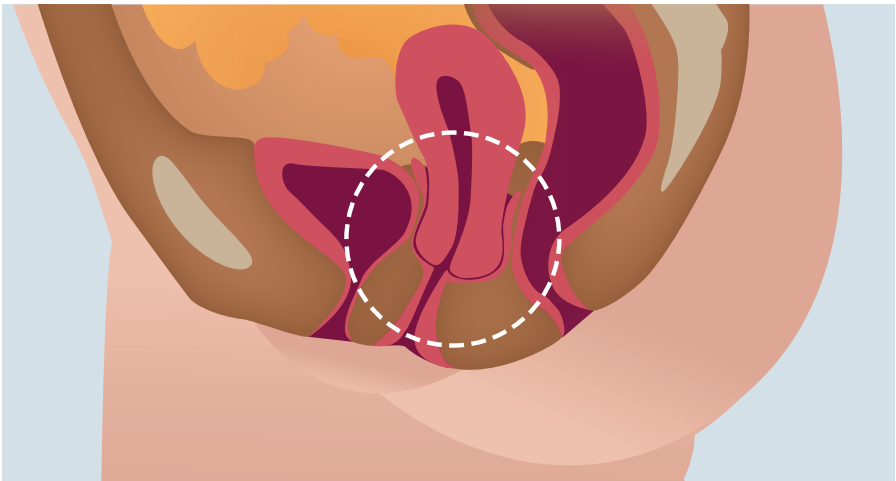


Cystocele (prolapsed bladder)

Bulging or descending of the bladder into the anterior vaginal wall



Rectocele (prolapsed/descended rectum)
Herniation (bulging) of the rectum into the posterior vaginal wall



Uterine prolapse (prolapsed/descended uterus)
Descending of the uterus

Recognition of the symptoms is an important step in the right direction.

What symptoms indicate pelvic organ prolapse?

There are various symptoms that could indicate pelvic organ prolapse. The most common are:

- ▶ **Stress incontinence**
Leakage of urine, for example when coughing, sneezing, laughing or lifting heavy loads
- ▶ **Urge incontinence**
Frequent and very sudden strong and uncontrollable urge to urinate with involuntary loss of urine
- ▶ **Pain when urinating**
- ▶ **Pain during sex**
- ▶ **Problems or pain during bowel movements**

There are many causes of pelvic organ prolapse.

What can cause pelvic organ prolapse?

Weakness of the connective tissue that can lead to pelvic organ prolapse can occur as a result of vaginal birth or genetic predisposition. It can also be age-related, as a result of many years of pressure being placed on the abdominal organs. Heavy physical work, obesity, smoking or chronic constipation also increase the risk of prolapse.

Minimise the risk.**What can be done to prevent pelvic organ prolapse?**

It is not possible to completely prevent pelvic organ prolapse through preventive measures - the muscle tissue can be exercised, but the connective tissue cannot. However, it is possible to reduce the risk through certain patterns of behaviour.

Regular exercising of the pelvic floor muscles, avoiding unnecessary strain and appropriate lifting and carrying techniques reduce the strain and stress on the pelvic floor. In post-menopausal women, targeted vaginal oestrogen administration can have a positive effect on the tissues.

Discuss with your general practitioner, what the best option is for you.**How can pelvic organ prolapse be treated?**

As a first step, a comprehensive diagnostic work-up and accurate indication are crucial for choosing the appropriate treatment. Detailed observation of the individual needs of the patient is also vital - the patient must be questioned in detail (condition and circumstances) and given advice. The appropriate treatment method should always be chosen in close coordination with the patient personally, and with the referring physician.

Conservative treatments

▶ Reduction of risk factors

Such as obesity, smoking or chronic constipation.

▶ Minimally invasive surgery

In the case of stress incontinence, it is possible, in some cases, to implant a ribbon-like synthetic mesh (in both women and men), to support the urethra, thereby restoring continence.

▶ Targeted physiotherapeutic pelvic floor exercises

Targeted pelvic floor exercises - under the instruction of a physiotherapist - can stabilise a descended organ if it has not yet advanced to a prolapse.

▶ Pessaries*

Pessaries can be inserted if it is too early for surgery, or if surgery is not desired or not possible because of the overall health of the patient.

▶ Local oestrogen therapy

Post-menopausal women may benefit from local oestrogen therapy to strengthen the tissues. Vaginal administration of the hormone avoids adverse side effects.

A surgical procedure should only be considered when the conservative therapy options have been exhausted, if the prolapses are very pronounced or if they recur repeatedly.

* Pessaries are rings, cubes or shells made of silicone, that are inserted into the vagina during the day. They help to stabilise the pelvic floor and push the descended organ back into the correct position. There are various pessaries available, which may be either useful or necessary, depending on the diagnosis. Therefore, medical support is essential. Pessary therapy can also help to determine whether existing symptoms can actually be attributed to a prolapse.

Ask your general practitioner to refer you to a specialised competence centre.

Surgical treatment

In order to achieve a high success rate with surgical treatment, the skills and experience of the physician and the right materials are crucial, as is the correct choice of the treatment method. For this reason, it is recommended that the patient receives treatment in one centre of excellence that is specialised in disorders of the pelvic floor.

Diagnosis

The following examinations are usually performed for a detailed diagnosis. They are the basis for the selection of an appropriate surgical method:

▶ **Ultrasound or X-ray examination**

To assess the change in position of the urethra, bladder, vagina, uterus and bowel

▶ **Urodynamic testing**

To evaluate the functioning of the bladder sphincter

▶ **X-ray examination or magnetic resonance imaging**

To check bowel function

▶ **Endoscopic examination**

Of the bladder or rectum

Choose the right surgical procedure.

Choosing the surgical procedure

After the diagnosis, the patient should be informed of all possible surgical procedures, the relevant approaches and the prospects, risks and success prognoses, so that a joint decision can be made.

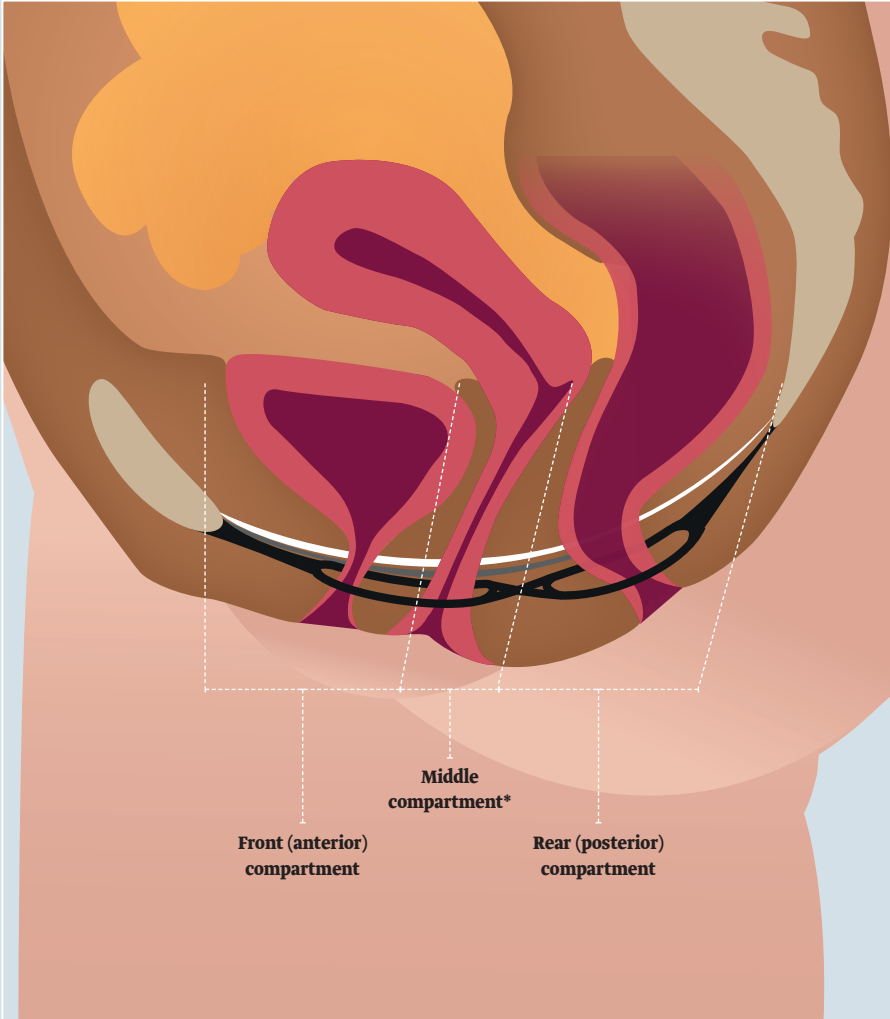
Essentially, a clear distinction can be made between two procedures:

- ▶ **Use of the patient's own tissue to stabilise the organs**
- ▶ **Use of synthetic meshes**

The use of polypropylene meshes has increased in the last few years, in particular in the event of recurring prolapses (relapses) or if maximum stability is desired. Thanks to improvements in material and improved surgical techniques, the use of mesh implants can achieve good anatomical and functional outcomes today.

The surgical procedure is determined by the area in the lower abdomen in which the prolapse has occurred. Here, a distinction is made between prolapses in the anterior compartment (bladder and urethra), middle compartment (vagina and uterus) and posterior compartment (rectum).

Areas of the pelvic floor



*Today, organ-saving surgery is usually performed. However, in the event of a uterine prolapse, it may be better to remove the uterus (hysterectomy). This is usually only considered in women who do not want to have (any more) children.

Anterior compartment

▶ Anterior mesh

During this procedure, a synthetic mesh is inserted between the bladder and the anterior vaginal wall. The mesh is then fixated in the stable structures of the pelvic floor, via the arms of the mesh.

▶ Anterior colporrhaphy/anterior vaginoplasty

This procedure involves the tightening of the anterior vaginal wall with surgical sutures, thereby counteracting the prolapse.

▶ Colposuspension/paravaginal defect repair

This procedure involves lifting the vaginal wall and the neck of the bladder and anchoring them to the front of the pelvis with retention sutures.

Middle compartment

▶ Sacrocolpopexy

In the case of prolapsed organs in the middle compartment, the vagina can be raised again, by stretching a synthetic mesh between the vaginal vault and the sacrum.

▶ Sacrospinal fixation

The vagina is fixed to ligaments in the back of the pelvis by means of retention sutures.

Posterior compartment

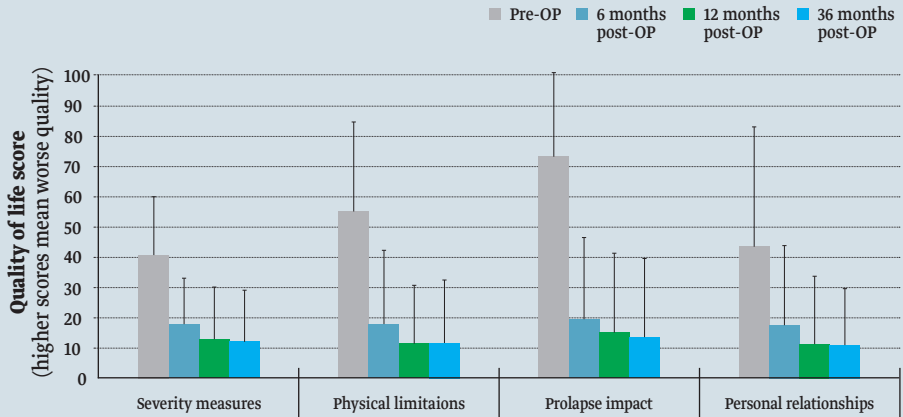
▶ Posterior mesh

During this procedure, a synthetic mesh is inserted between the posterior vaginal wall and the rectum. The mesh is then fixated in the stable structures of the pelvic floor, via the arms of the mesh.

▶ Posterior colporrhaphy / posterior vaginoplasty

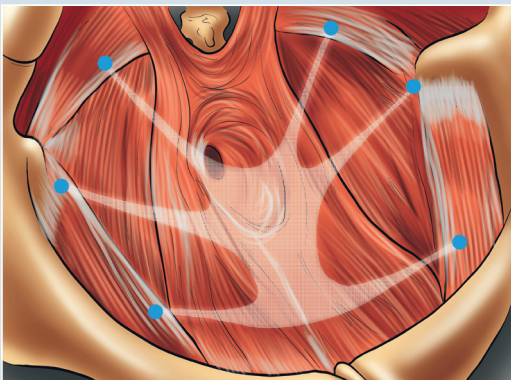
This procedure involves the posterior vaginal wall being tightened with surgical sutures, thereby counteracting the prolapse.

Improvement in quality of life with multi-arm TiLOOP® Total 6 meshes, for use in the anterior compartment (anterior mesh)*



For more information, please visit: www.pfmmedical.com/Studies

Stable 6-arm anchoring with anterior mesh



* pfm medical gmbh, Clinical Investigational Report - Final Report, TiLOOP® Total 6 Study

Patient experiences

“What modern medicine can offer today is great. ... I was finally able to practice the motoric process of walking again.”

Susanne D., 70 years

“It got better every day, and that made me feel better. ... I no longer feel so limited, and I can play with my great-grandchildren and pick them up again. It’s a pleasure now.”

Ute S., 76 years

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