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A Multidisciplinary Pelvic Floor Journal

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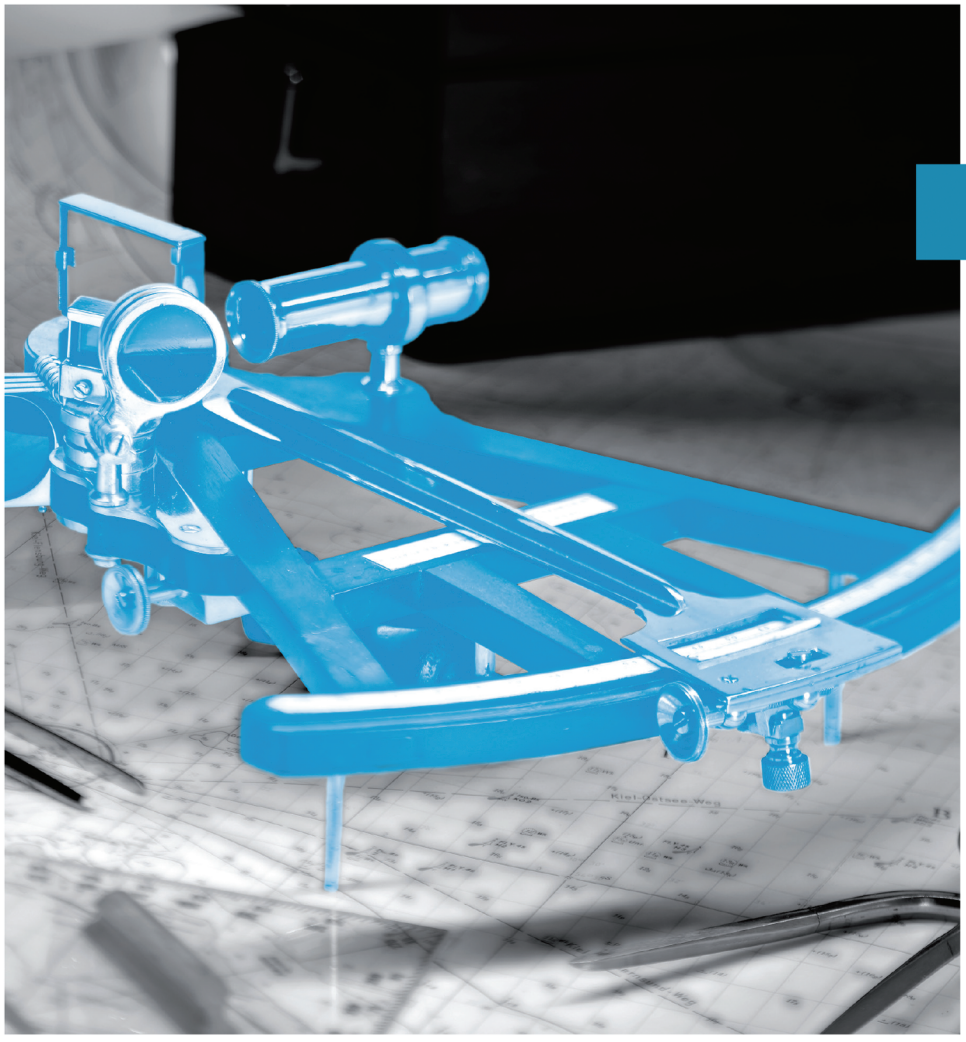

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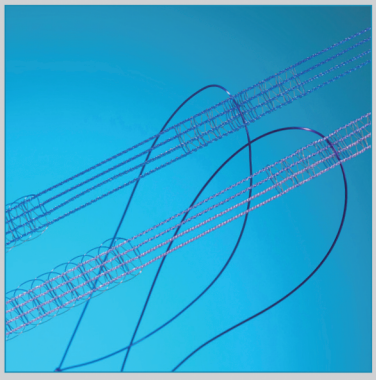

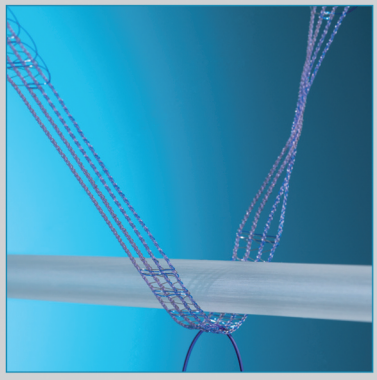

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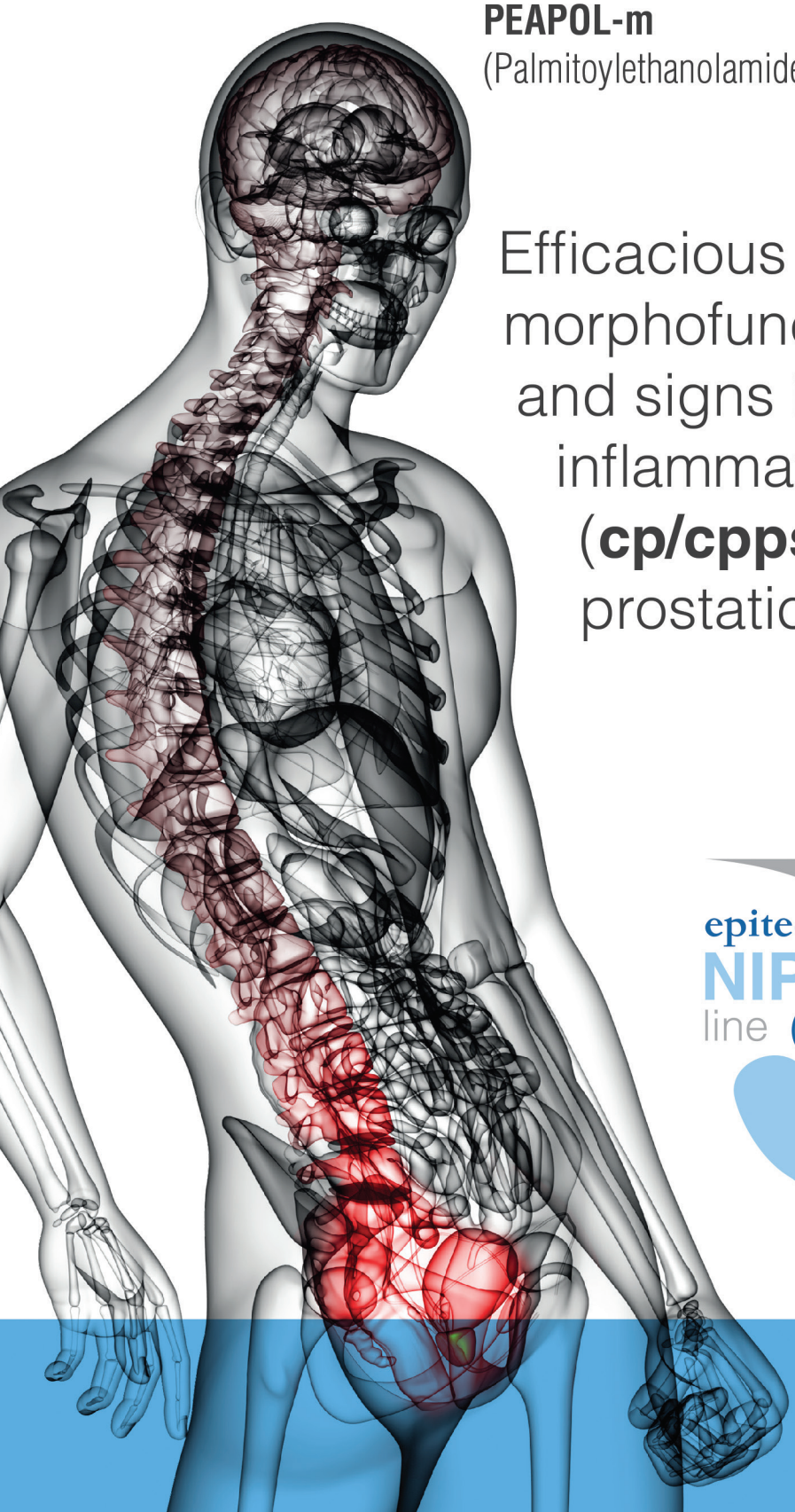

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The Tethered vagina syndrome teaching module

THE EDITORS

With its application to obstetric fistula incontinence, the Tethered vagina syndrome (TVS) has become a very important part of pelvic floor surgery; 3,000,000 women suffer from obstetric fistula in Africa alone. Unfortunately, TVS has received scant attention by the specialist gynaecological or urology journals. TVS was first described by Professors Petros and Ulmsten in their 1990 and 1993 publications of their Integral Theory.[1,2] This included specific examples of the condition, its pathogenesis and how to cure it either with an "I-plasty" or skin graft applied to the anterior vaginal wall. Professor Goeschen expanded the original TVS skin graft treatment proposed by Professor Petros, applying a "skin-on Martius graft" from the labium majus with attached blood supply.[3,4] In this issue, Pelviperineology (PPJ) continues with its teaching modules with a fairly typical case report, comments by invited experts, the outcome of corrective surgery using a skin graft, and a learning module by an acknowledged expert in the field, Professor Klaus Goeschen. The classic symptom of TVS is sudden massive urine loss when the patient gets out of bed in the morning, or getting off a chair. Usually there is little or no stress urinary incontinence. The mechanics of the massive urine loss is explained by the two figures, Figure 1. In the upper figure, the forward arrow depicts a forward-acting muscle, anterior pubococcygeus which closes the distal urethra. The backward acting arrows depict the backward/downward acting muscles levator plate/longitudinal muscle of the anus which close the bladder neck and open it for micturition. Because the muscle forces act in opposite directions, significant elasticity is required in the bladder neck area of the vagina "zone of critical elasticity" (ZCE) so as to allow separate closure actions at bladder neck and distal urethra. Scarring in the ZCE "tethers" the more powerful backward muscles to the weaker

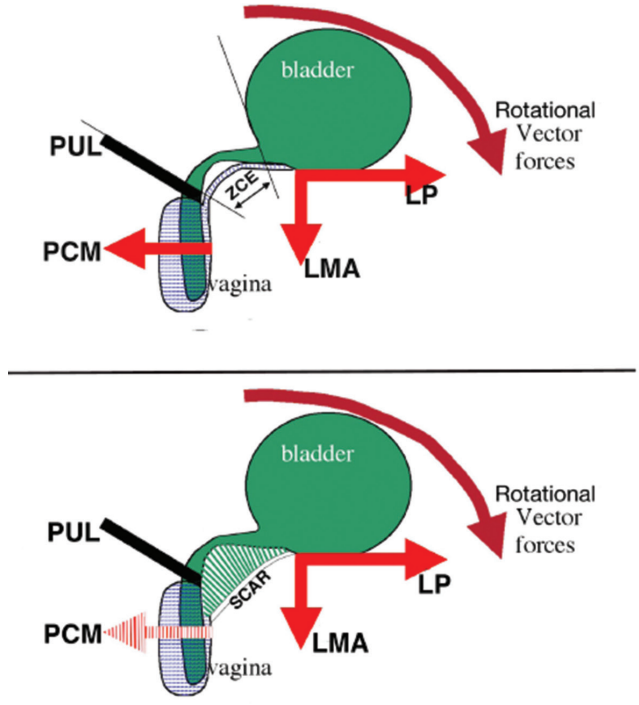

Figure 1. Anatomy and pathogenesis of the Tethered vagina syndrome Normal bladder (*upper figure*) Sagittal view of bladder urethra, and the 3 directional forces which close the distal and proximal urethra the anus. Tethered vagina syndrome (*lower figure*) The scar replaces ZCE and links the opposite muscle forces; PCM is overcome (indicated by broken arrow); urethrovaginal angle is forcibly pulled open.
ZCE: Zone of critical elasticity, PUL: Pubourethral ligament, PCM: Anterior portion of m. pubococcygeus, LP: Levator plate, LMA: conjoint longitudinal muscle of the anus

forward muscle; the bladder outlet is forcibly pulled open much as happens during micturition; urine flows out uncontrollably. In first world countries, TVS is not so common. The

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cause of TVS is always iatrogenic, following scarring from vaginal excision during vaginal repairs or excessive vaginal stretching from bladder neck elevation following a Burch colposuspension or sacrocolpopexy, or scarring from mesh sheets which removed vaginal elasticity from ZCE, Figure 1. The most important application of TVS, however, has been in the treatment of continued massive urine loss after successful fistula closure. Two famous fistula surgeons, Professor Gordon Williams and Dr Andrew Browning applied the TVS concept prophylactically and correctively to the 50% of women with obstetric fistulas who continued to leak urine after fistula closure with dramatic results, using the Singapore flap taken from the groin with attached blood supply.[5-8] The results were immediate and dramatic, with an initial 400% improvement over previous methods. Dr Browning has contributed a short update on his results for the module. The editors of PPJ highly recommend study of this teaching module.

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Vale Catherin Hamlin - a personal homage

PETER PETROS

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Vale Catherin Hamlin
Born: Elinor Catherine Nicholson, January 24, 1924, Sydney, New South Wales, Australia
Died: March 18, 2020, Addis Ababa, Ethiopia

Dr Catherine Hamlin and Reginald Hamlin at the Addis Ababa Fistula Hospital.
Photo courtesy of Fistula Trust, from Internet

Catherine Hamlin was the spiritual mother of 2,000,000 African women who still today suffer from Obstetric Fistula and with her husband Reg, their saviour. In 1974, she and Reg opened their now-famous Hamlin Fistula Hospital and virtually de novo developed techniques to close obstetric fistulas. The Hamlin journey began in the late 1950s. Reg was Superintendent at the Women's Hospital Crown St Sydney, which at the time was the most famous Obstetric Hospital in Australia. Reg was in line to be given a consultant position at the end of his term. However, that did not work out. So, Reg and Catherine applied for a position in Addis Ababa, and the rest is history. The Hamlin hospital has been the inspirational beginning of an ever-expanding network of dedicated organizations and surgeons, who are addressing the devastating problems of obstetric fistula in women worldwide. I worked with Catherine and then the Superintendent of the Hamlin Hospital Professor Gordon Williams in between 2011-12. My introduction to her was serendipitous, even humorous. I was reading Catherine's book "The Hospital by the River". At a certain point in the book, she described how the one remaining

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problem was that even after successful fistula closure, a large percentage of women, perhaps 20-30% continued to lose massive amounts of urine. The condition seemed very similar to the "Tethered vagina syndrome" (TVS) which the late Ulf Ulmsten, and I described for the first time in the 1990 and 1993 iterations of the Integral Theory: anything which destroys anterior vaginal elasticity, for example, over-elevation of vagina by Burch colposuspension, excess excision of vagina or fibrosis from mesh sheets "tethers" the more powerful posterior muscle vectors to the anterior; the posterior urethral wall is pulled open when given the signal to close; the patient loses massive amounts of urine typically on getting out of bed in the morning. The cure is a skin graft to the anterior vaginal wall which works by restoring the vaginal elasticity necessary to transmit the pelvic muscle forces for mechanical urethral closure and opening.[1] *"The humour"*. I wrote to Dr Hamlin suggesting I may have an answer to the problem. I received a curt reply from Dr Williams saying they had lots of offers from doctors to do fistula surgery, but they were not interested in fistula tourism, and with classically understated British irony concluded, *"thank you for your offer, but your assistance will not be required"*. I wrote back to say TVS patients have a scarred anterior vaginal wall, lose very little urine loss on coughing, but massive urine loss on getting out of bed, very little descent on ultrasound on straining, and the solution is a skin graft to the anterior vaginal wall. A few weeks later an email "apology" arrived and a warm invitation from Catherine herself. *"The serendipity"*, the first case was a Sudanese woman who had walked 2000 miles to the Hamlin. Catherine took an intense interest in the case and would question me about it every night when we had dinner together. As things turned out, the operation, urethrolysis and a skin-on Martius graft succeeded, and she was cured. It may have failed, and the cure for this problem, on-going leakage from successful fistula closure may have had a different story. Since 2012, renowned fistula surgeon Andrew Browning has continued to develop this methodology further using a skin-on Singapore Flap graft.[1-3] His results are outstanding, at least 400% superior in the worst cases, Goh class 4. He has used the graft prophylactically, applying a simple principle: if the edges of the dissected vagina do not come together naturally, a skin graft is applied. By her hospital, Catherine was the alpha of fistula treatment for 2,000,000 African women, and serendipitously, by her book, The Omega. Vale Catherine Hamlin, a magnificent human being whose devotion and example has brought the best out in her fellow humans and produced a better world.

ETHICS

Peer-review: Externally peer-reviewed.

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Tethered vagina syndrome

KLAUS GOESCHEN

Medical School of Hannover, Kvinno-Center, Germany

ABSTRACT

The key to understanding the pathogenesis leading to the "Tethered vagina syndrome" and its cure by a skin graft applied to the anterior vaginal wall is to understand the importance of the three oppositely-acting directional forces which close the urethral tube and on relaxation of the forward force, open it for micturition. Any scarring from vaginal excision during "native tissue repair", application of large mesh sheets, or overstretching by a Burch colposuspension effectively "tethers" the more powerful posterior forces to the weaker anterior force; the posterior urethral wall is pulled open exactly as happens during micturition; the patient loses urine uncontrollably typically on getting out of bed in the morning, which is the classical diagnostic symptom.

INTRODUCTION

The "Tethered vagina syndrome (TVS)" is an iatrogenic, but as yet, not well recognised condition. It is caused by scar-induced tightness in the middle zone of the vagina (Figure 1a, b). This syndrome assumes a special position in the concept of the integral theory. Whilst all other bladder symptoms are mainly caused by lax connective tissue, the massive functional problem of the TVS is generated by rigid connective tissue structures.

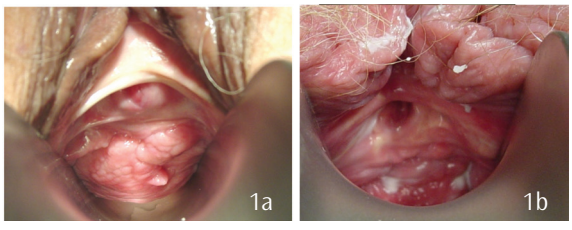

Figure 1a and b. Thick scar tissue in the bladder neck area of vagina; typical for the "tethered vagina syndrome"

The TVS was described by Petros and Ulmsten in 1990, and again in 1993.[1-3] It is not defined as a separate entity by the International Continence Society.[4] This problem is somewhat similar to "motor detrusor instability", and may arise in patients with multiple previous operations in the bladder neck area of vagina. In contrast to that the classical tethered vagina symptom is commencement of uncontrolled urine leakage as soon as the patient's foot touches the floor, indeed, often commencing as the patient rolls over to get out of bed in the morning. The patient does not complain of bed-wetting during the night. The symptoms are caused by loss of elasticity in the bladder neck area of the vagina: the so-called "zone of critical elasticity" (ZCE) (Figure 2). Scar tissue in this area (Figure 3) blocks the physiological opening and closure mechanism, because this mechanism is mainly controlled by the pubo-urethral ligament (PUL) (green arrow in Figure 4a) and not by a so-called sphincter

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in the bladder neck area (black arrow in Figure 4a). Operations in the bladder neck area lead to unphysiological results and functions (Figure 4b, c, Figure 5).

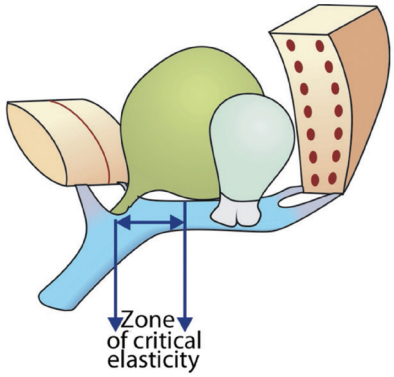


Figure 2. Zone of critical elasticity

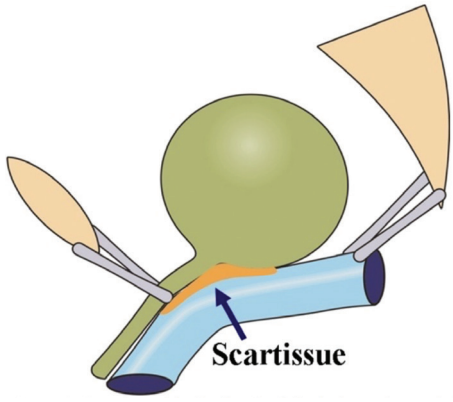


Figure 3. Scar tissue blocks the physiological opening and closure mechanism

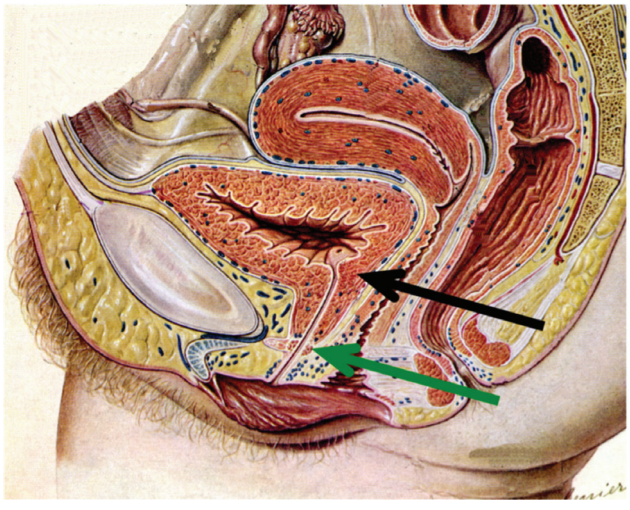


Figure 4a. The opening and closure mechanism are mainly located in the area of the [PUL (green arrow) and not in the sphincter area (black arrow)]
PUL: Pubourethral ligament

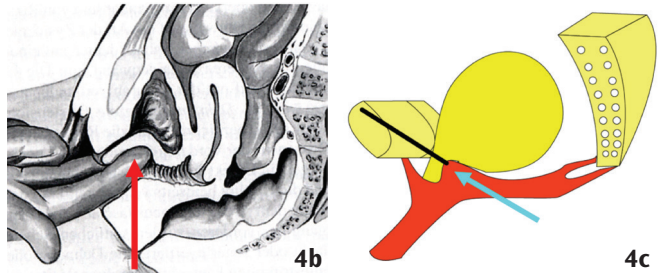


Figure 4b and c. Operations in the bladder neck area lead to the unphysiological results and functions

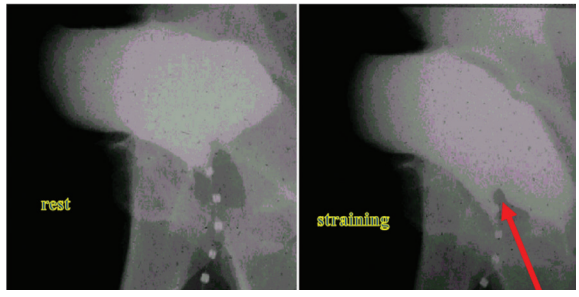


Figure 5. Lateral cystogram after Burch-colposuspension show the unphysiological elevated bladder neck (red arrow) during strain

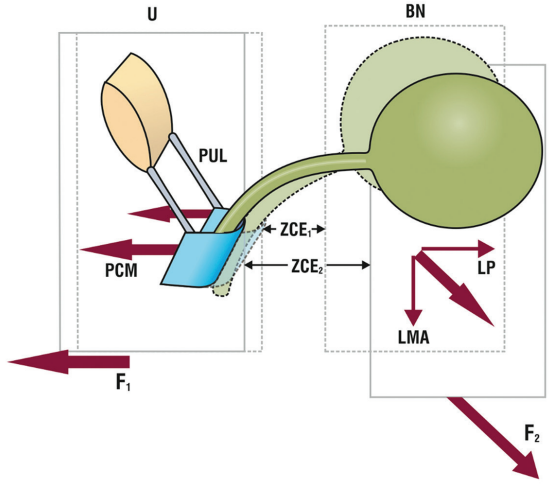


Figure 6. The Zone of critical elasticity (ZCE) ZCE1=ZCE at rest; ZCE2=ZCE during effort or micturition. Adequate vaginal elasticity at ZCE allows the oppositely acting urethral) (U) and bladder neck (BN) closure mechanisms to operate. F1 represents the forward acting vector, which stretches the vaginal hammock forwards to close the distal urethra (urethral closure mechanism). F2 stretches the proximal urethra backwards and downwards against the pubourethral ligament "PUL", to close it (bladder neck closure mechanism). A scar at ZCE "tethers" the oppositely acting muscle vector forces, so that on application of a strong prolonged force, such as occurs on getting up out of bed in the morning, F2 overcomes F1, and the posterior wall of the urethra is pulled open, exactly as occurs during micturition.
PCM: Pubococcygeus; LP: Levator plate; LMA: Longitudinal muscle of the anus. F2 represents the resultant force of the LP/LMA vectors, U: Urethral, BN: Bladder neck, PUL: Pubourethral ligament, ZCE: Zone of critical elasticity

Figure 6 illustrates why elasticity at ZCE is necessary for the separate function of urethral (U) and bladder neck (BN) closure mechanisms. ZCE stretches from mid-urethra to bladder base. Scarring across ZCE "tethers" muscle vectors F1 and F2. Then F2 overcomes F1 to pull open the vaginal hammock on effort, causing uncontrolled urine loss.

SYMPTOMS

Because scar tissue contracts with time, the TVS may present many years after vaginal repair or bladder neck elevation. Patients with exclusively TVS do not wetting the bed and do not suffer from urge. Furthermore, often there is no or only very little stress incontinence. The reason is that cough creates short sharp fast-twitch contractions, and there may be just sufficient elasticity at ZCE to prevent urine leakage on coughing. However, if the vagina just behind the scar is gently stretched backwards by Allis forceps, all the residual elasticity is removed from ZCE, and urine is now lost on coughing. However, isolated tethered vagina symptomatology is rare. In most cases the rigid anterior vaginal wall generates a redistribution of pressure to the posterior vagina resulting in a recto/enterocele. This happened in 96% of our cases (see below chapter: Results). A temporary stiffness in ZCE sometimes occurs after insertion of a sub-urethral sling resulting in de novo urine loss after getting out of bed. In most cases elasticity slowly comes back during the following weeks and month due to decreasing tissue tension in the scar area. This improves the incontinence symptomatology without any treatment. The explanation for urine loss due to scar tissue in ZCE is as follows: Getting out of bed stretches ZCE far more than cough, as the pelvic floor has to contract powerful in order to support all the intra-abdominal organs. Thereby the outflow tract is opened abruptly with the result of massive uncontrolled urine loss as soon as the patient's foot touches the floor. In case of scar tissue in ZCE the bladder neck is porcelain-like and acts like a watering can in the following sense: In supine position bladder fills (Figure 7a). If the patient starts to get up in the sitting position, the levator plate contracts. Scar tissue blocks the effect of the pubococcygeus muscle resulting in an open outflow tract as usual during micturition (Figure 7b). From sitting to vertical position urine leaking starts, whereas in standing position the urine loss is massive (Figure 7c). Reaching the toilet, the bladder is almost empty (Figure 7d).

Vaginal examination

Usually it is no problem to see and feel the scarred bladder neck area whilst speculum and vaginal examination. Nevertheless, it is very important for therapy to clarify whether the scar is responsible for incontinence or not. Stress and urge incontinence require a totally different operation than tethered vagina. As already mentioned above cough and strain do not lead to urine leakage in typical tethered vagina patients. However, if the vagina just behind the scar is gently stretched backwards by Allis forceps, all the residual elasticity is removed from ZCE, and urine is now lost on coughing.

There are three types of tethered vagina patients:

1) Patients after traditional incontinence surgery, such as;

a) Anterior Colporrhaphy,

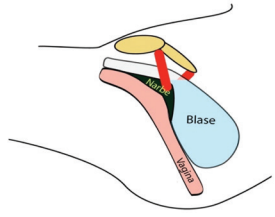


Figure 7a. Bladder fills in supine position

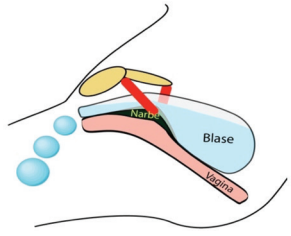


Figure 7b. Getting up: scar prevents urethral closing

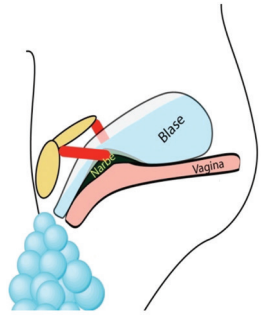


Figure 7c. Foot on the floor: massive urine loss

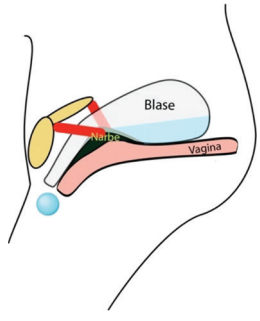


Figure 7d. Reaching the toilet: bladder is almost empty

b) Cystourethropexy according to Marshall-Marchetti-Krantz,

c) Colposuspension described by Burch,

d) Urethral bulking operations with Teflon, Macroplastique etc.

These patients show a very tight anterior vaginal wall with thick scarring (Figure 8) or excessive elevation (Figure 9).

2) Patients after sling procedures with autologous or artificial material, such as;

a) Narik-Palmrich inguino-vaginal sling operation

b) STRATASIS™ Urethral sling

c) Wrong placed sling or mesh crossing the bladder neck area This type of patients show a more restiform, rope shaped scar area (Figure 10), sometimes with protrusion of tape or mesh (Figure 16,17. See below).

3) Patients with vesico-vaginal fistula

In poor countries at least 3 million women have unrepaired vesicovaginal fistulas (Figure 11). 30,000-130,000 new cases develop each year solely in Africa.[5] Success rates of closure for primary surgery range from 73% to 90%.[6] Nevertheless, only 16 to 55% of the patients are continent after closure of the fistula.

Figure 8. Thick scar tissue in the urethral and bladder neck area

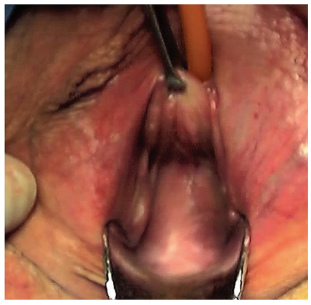


Figure 9. Excessive elevation of bladder neck after eight operations in this area

In nearly all cases the reason for that is scar tissue formation causing the TVS. Petros et al.[7] observed only in two of 95 cases hypermobility in the bladder neck area after fistula repair during ultrasound examination. All other patients demonstrated a rigid zone of critical elasticity.

DIAGNOSTIC

Ultrasound

The typical finding on ultrasound is no significant movement,

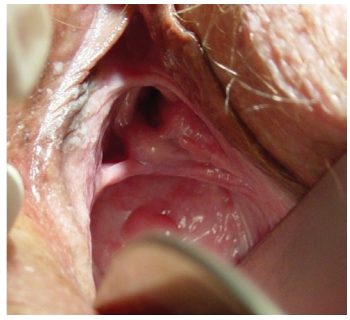


Figure 10. Restiform, rope shaped scar area

funnelling or opening out of bladder neck during straining or squeezing (Figure 12 a, b; Figure 13 a, b).

Urodynamic

Urodynamic usually demonstrates no significant pattern as fluid flow back from the bladder through the rigid urethra like through a “watering can”. One typical urodynamic finding can be a low urethra pressure profile due to rigid tissue (Figure 14).

Therapy

Periurethral application of micro-balloons in the bladder

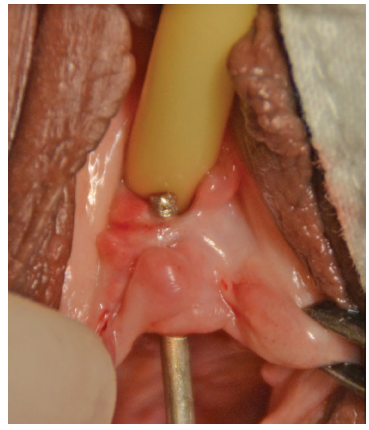


Figure 11. Scar tissue and vesico-vaginal fistula due to three previous bladder neck operations cured by closure of the leak and a Martius skin on flap

neck area definitely does not make sense, as this area is already rigid. This procedure will worsen the situation again. Artificial sphincter implantation is a very expensive and extremely invasive therapy with numerous side effects.

Therefore, our strategy consist of two parts:

1) Removal of all scar tissue and artificial material.

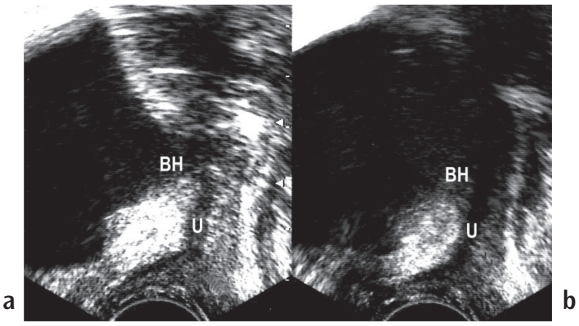


Figure 12 a **and b.** Patient with eight previous operations in the bladder neck area. The BH in rest (left) is extremely elevated up and back through which the posterior wall of the bladder slipped down. During squeezing (right) the bladder neck stays in this position, whereas the posterior wall of the bladder moved in the normal position
BH: Bladder neck, U: Urethra

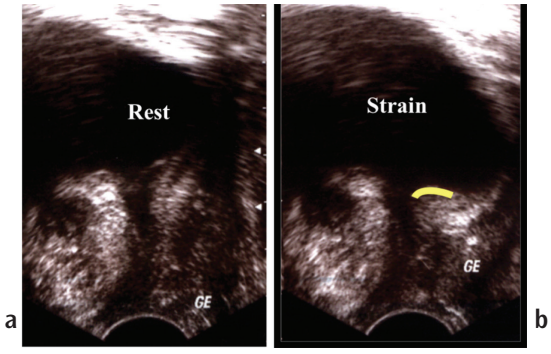


Figure 13 a and b. Patient with three previous bladder neck operations: (**a**) rest, (**b**) no movement of bladder neck area during cough or strai

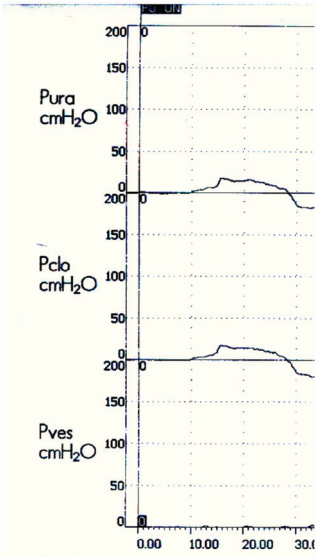


Figure 14. Urethral pressure profile from patient Figure12 with tethered vagina.
Low urethra pressure due to the scar-induced tightness of the urethra

2) Restoration of the elasticity in the neck area of the vagina, the "zone of critical elasticity" (ZCE), so that "F1" and "F2" can act independently of each other (Figure 6).

1) Removal of scar tissue and artificial material

The anatomical basis of our operation resides in the Integral Theory,[8,9] which states that adequate elasticity is required in the bladder neck area of the vagina so as to allow the opposite muscle forces to operate independently of each other (Figure 6). Whatever the technique used to restore elasticity, it is essential to dissect the vagina from the bladder neck and urethra, and then to free all scar tissue and artificial material from urethra, bladder neck (urethro-vesicolysis) and pubic bones (Figure 15 a, b; Figure 16 a, b; Figure 17).

2) Restoration of the elasticity neck area of the vagina, the "zone of critical elasticity" (ZCE)

A simple closure of the incision after scar dissection will create new scar tissue with recurring incontinence. In order to prevent scarring again, healthy tissue has to be brought in the ZCE. Since 1999 we tested the validity of three different operations, all of which aim to restore elasticity in the bladder neck area of the vagina.[10,11]

The I-plasty-operation: (Figure 18) was performed in 13 patients with a co-existing cystocele. I-plasty aims to increase the volume of tissue in the bladder neck area of the vagina, thereby restoring elasticity. To reach this aim a vertical full thickness incision was made from mid-urethra to at least 3-4

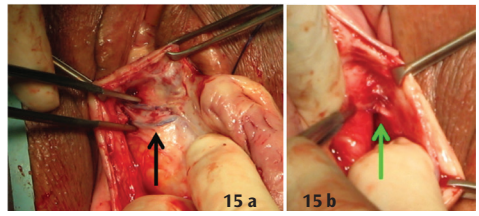


Figure 15. Tethered vagina due to Burch Colposuspension (**a**) (left). Due to Urethro-vesical suspension (Stamey Pereyra) (**b**) (right). The Vagina is dissected from the bladder and proximal urethra. The Burch sutures (black arrow left picture and the Stamey Pereyra suture (green arrow right picture)

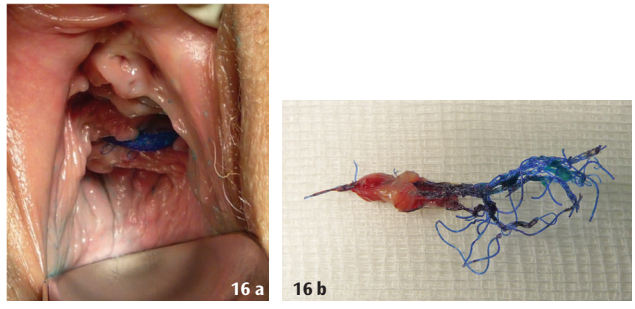
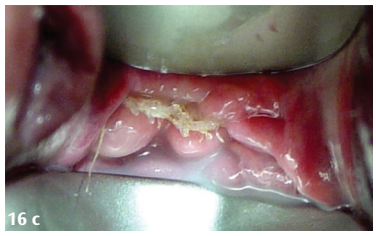


Figure 16 a and b. Patients with tethered vagina syndrome due to sub-urethral sling erosion before (**a,c**) (left) and after (**b,d**) (right) removal



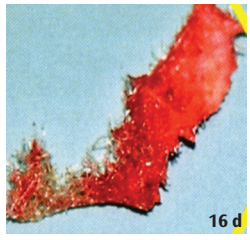


Figure 17 a and b. Tethered vagina due to erosion before **(a)** (left) after **(b)** (right) mesh insertion. Mesh extended from urethra to cervix cm beyond bladder neck. The vaginal skin was dissected off the scar tissue and was extensively mobilised, forwards to the edges of the vaginal hammock, backwards as far possible right down to the hysterectomy scar, and as laterally as possible. The freed tissue was brought into the ZCE and sutured transversely with interrupted sutures.

The skin graft operation: (Figure 19) was performed in 21 Patients. After a full thickness transverse incision in the area of bladder neck the vagina, urethra and bladder neck were freed from the scar tissue. This resulted in opening up of a large gap. Care was taken to effect haemostasis. A full thickness skin graft approximately 6x4 cm was taken from the lower abdominal wall. After removal of underlying-fat the graft was applied to the bladder base using several "quilting sutures". The graft was then trimmed as necessary, and sutured to the adjacent vaginal skin with interrupted 00 Vicryl.

Bulbocavernosus-skin-fat-flap with vessel pedicle (according to Goeschen) or Martius-skin-on-flap (Figure 20 a-f) In 105 patients the large gap after scar dissection was covered with a bulbocavernosus-muscle-fat-skin-flap from the labium majus. A 5x3 cm ellipse of vulval skin was created over the labium majus and transferred with underlying fat and muscle through a tunnel into the dissected area. The tunnel must be sufficiently large to avoid constriction of the vascular pedicle. The graft was attached to the adjacent vaginal skin.

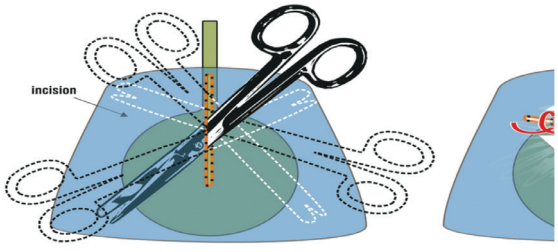


Figure 18. I-plasty operation; A vertical incision is made in the bladder neck area of vagina. The vagina and urethra are extensively mobilized off the adjoining tissues and pelvic sidewall. The incision is sutured horizontally, thus introducing fresh tissue to the site

RESULTS

The cure rates (urine loss <10 gm during 24 hours) were, for I-plasty 3/13 (23%), for the skin graft 11/21 (52%) for the bulbocavernosus-flap and 84/105 (80%). The mean operating time was 62 minutes (range: 41-98 min). Exclusively a tethered vagina repair was performed in five patients, and in 134 cases, a concomitant entero/rectocele repair was necessary at the same time. No serious bleeding was observed. The mean hospital stay was 5 days (range 2-9 days). All patients were mobile at least 4 hours after the operation. Three patients could not pass urine after removal of the catheter one day after the operation and further permanent catheter was

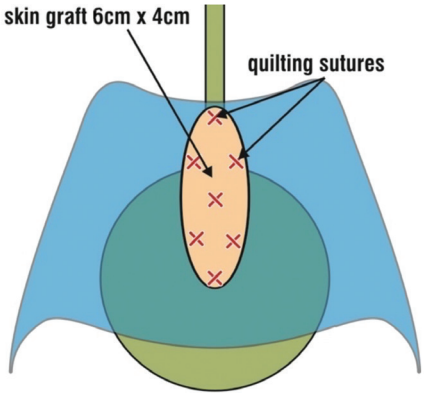


Figure 19. Skin graft to bladder neck area of vagina is attached by quilting sutures

Figure 20 a. 5x3 cm ellipse of vulval skin is marked over the labium majus

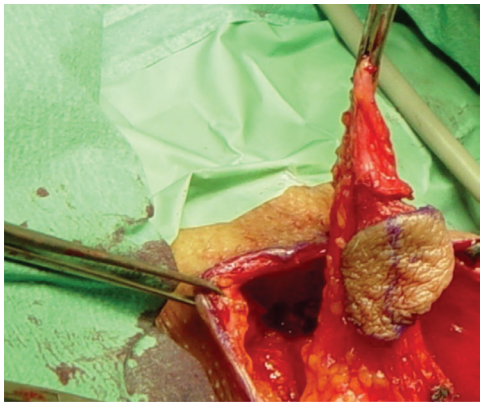


Figure 20 b. Preparation of a bulbocavernosus-muscle-fat-skin-flap with vascular pedicle

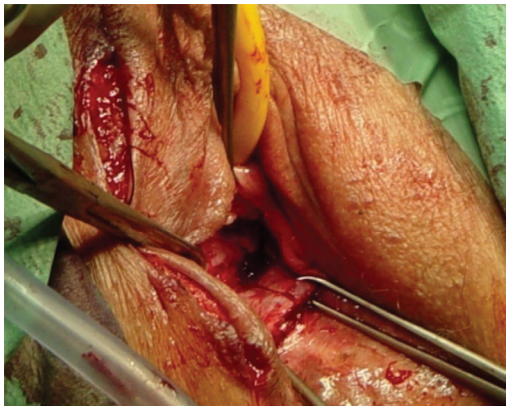


Figure 20 c. Transverse incision at bladder neck. Vagina, urethra and bladder neck are freed from the scar tissue

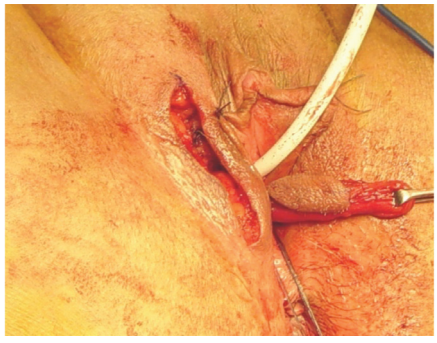


Figure 20 d. The graft is brought through a tunnel in the lateral vaginal sulcus into the dissected area

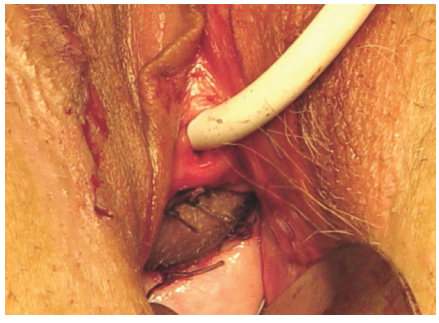


Figure 20 e. The graft is attached to the adjacent vaginal skin

Figure 20 f. Flap after 3 months

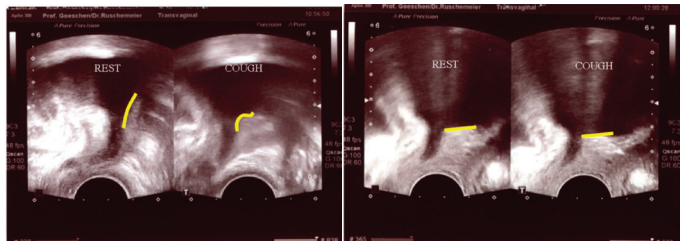


Figure 21 a, b. Ultrasound findings before (left) and after (right) restoration of laxity.
(**a**) Before operation: no movement of bladder neck area during cough or strain
(**b**) After operation: normal movement of the bladder neck area

necessary for another 1 day.

Ultrasound control after bulbocavernosus flap

Ultrasound in successful operated cases shows a normal movement in the bladder neck area and ZCE (Figure 21).

CONCLUSION

Regarding cure of tethered vagina the aim must be to restore the elasticity in the bladder neck area of the vagina, the "zone of critical elasticity" (ZCE), so that "F1" and "F2" can act independently of each other (Figure 6). As a first step, it is essential to dissect the vagina from the bladder neck and urethra, and to free all scar tissue from urethra, bladder neck and pubic bones (urethro-vesicolysis). There must be no scar tissue anchoring the bladder neck to the pelvic sidewall. The second step is to bring fresh tissue to the bladder neck area of the vagina to restore elasticity, and prevent new scar creation in this area. The **I-plasty operation** cures less than one fourth of the patients. Therefore, we decided not to continue with this method in cases where there is obvious tissue deficit. It is still the simplest technique but only indicated if there is no tissue deficit. The I-plasty works very well in patients where the cause is excessive bladder neck elevation, for example, after a Burch colposuspension and with a co-existing cystocoele.

If there is a severe shortage of tissue or a large gap after dissection, this defect has to be covered with a skin graft or a flap. The results with **free skin graft** are much better than with I-plasty, but a cure rate of about 50% is still not convincing. A free graft is problematical because there is no blood supply. Therefore, up to one third may not "take", or the graft may shrink excessively. The **bulbocavernosus-flap operation** is technically more challenging, but brings its own blood supply. This is in our opinion the explanation for the high cure rate. Using this technique, it is very important not to compromise the blood supply of the graft. Therefore the pedicle must be thick enough to prevent too much compression to the vessels in the pedicle, and the space created in the lateral vaginal wall for passage of the graft must be adequate. The explanation for cure of TVS by restoration of elasticity in this area may be explained by reference to a previously described hypothesis,[8,9] (Figure 6): there are separate urethral and bladder neck closure mechanisms. In the former, forward vectors stretch the underlying vagina on each side to close the urethra from behind. In the latter, backward/downward vectors stretch the proximal vagina and bladder base backwards and downwards to close off the bladder neck. Adequate elasticity is required for these separate movements. If fibrosis occurs at this critical point then the opportunity for independent movement is lost and the stronger posterior force overcomes the weaker anterior force. As a result, the urethra is forced open.

ETHICS

Ethics Committee Approval: Since this article is actually a review article for the Pelviperineology as a teaching module; It does not require ethics committee approval.

Peer-review: Externally peer-reviewed.

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Non-conventional haemorrhoid symptoms reported by female patients

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ABSTRACT

Objective: This study was undertaken to assess the importance of several non-conventional symptoms, including perianal hygiene, to female patients undergoing haemorrhoidectomy and to correlate these with the presence of associated skin tags. **Materials and Methods:** A single surgeon retrospective study used a customised questionnaire aimed specifically at female patients undergoing Milligan-Morgan haemorrhoidectomy with excision of significant associated skin tags to assess non-conventional symptoms. Postal surveys were sent to 71 women with 52 replies, three exclusions due to hybrid procedures and 49 patients analysed.

Results: Painful prolapse and bleeding were still the most common reasons for undergoing haemorrhoidectomy but perianal hygiene (the ability to keep the area clean after toileting and during the day) was significant in nearly 60% of patients. Itching (40%), concerns about odour (35%), general discomfort (35%) and embarrassment in case their partner saw the haemorrhoids or skin tags was significant in 27%.

Conclusion: Haemorrhoidectomy with complete removal of the skin tags resulted in statistically significant improvement in the parameters of odour, pruritis, toileting and less interference with the patients sex life. Surprisingly some aspects of continence were improved. The study shows that non-conventional symptoms are important in female patients and may influence the patients perception of the success of the operation. A simple modification of Golighers' classification is proposed to reflect the presence of skin tags and to guide assessment of the success of novel treatments for haemorrhoids in women.

Keywords: Haemorrhoids; treatment; hygiene

INTRODUCTION

Even when there is still debate concerning precise aetiopathogenesis, the symptoms attributed to haemorrhoids tend to correlate with their established classification. Consensus agreement on haemorrhoidal grade is important in deciding about treatment options and in a comparison of management outcomes. In coloproctological practice, there is universal use of the Goligher grades with a traditional separation of internal and external haemorrhoids dependent upon origin above or below the dentate line and where there is either a mucosal or epidermal covering, respectively.[1,2] There is, however, a frequent disparity between the physical symptoms of haemorrhoids and their signs with a bias towards specific surgical managements based more upon their anatomical configuration than upon patient-reported symptoms.[3] All proctologists have seen patients with symptomatic haemorrhoids which do not bleed but where there are significant and persistent complaints such as anal discomfort,

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soiling, leakage and difficulty with perianal hygiene, each of which are not addressed in the standard haemorrhoidal classification system. The acceptance and use of a symptom-led classification would be aimed more at specific symptom improvement rather than at a restoration of normal anatomy. Moreover, these isolated particular symptoms can direct management, influencing clinical outcomes and surgical satisfaction. This short communication reports the use of a customized questionnaire specifically aimed at female patients undergoing Milligan-Morgan haemorrhoidectomy, asking them about a range of non-standard haemorrhoidal symptoms and correlating their outcome with the surgical elimination of anal skin tags.

PATIENTS AND METHODS

The conduct of this retrospective analytical study was approved by the Edith Cowan University Research Ethics Committee (project number: 17024, date: 19 January 2017). Consecutive female patients under the care of one surgeon coming to Milligan-Morgan haemorrhoidectomy for symptomatic haemorrhoids with significant skin tags were included for analysis between June 2013 and December 2017. Patient demographic details (age, marital status and country of birth) were recorded along with the broad indications for surgery and the specific patient-related symptomatic concerns leading to haemorrhoidectomy. Patients returned a pre- and postoperative questionnaire including their principal reasons for undergoing haemorrhoidectomy and broad questions inquiring about the presence of a wet bottom, the use of panty liners, toileting, concerns about odour, perianal irritation and disturbance of sexual function (pain, embarrassment). Symptoms were graded for frequency using a Likert scale of 1-4 where 1= none, 2= > once per month but < once per week; 3= > once per week but < daily and 4= daily. Surgical assessment at 3 postoperative months determined the presence of any mucoanal prolapse during straining and the presence or absence of skin tags. No patient had significant residual skin tags. For the purposes of the study a skin tag was defined as any redundant skin-covered extension of tissue at the anal verge which was of sufficient size that it could be grasped between the forefinger and the thumb and which would be the soft-tissue traditionally grasped with forceps at the commencement of a Milligan-Morgan haemorrhoidectomy.[4] Inquiry about continence status was assessed simply (yes/no) and if present was graded for leakage of solid/ liquid stool or for gas with frequency reported on a Likert scale. In the interests of brevity, and to encourage reply in a survey format, formal continence scoring was not performed. All patients completed the survey at least 12 months after the procedure.

Statistical Analysis

Analysis of data was performed with SPSS Version 25.0 software (Chicago, IL). Categorical data were assessed by a chi-square test where indicated. Comparative data was assessed before and after surgery with the non-parametric Mann-Whitney U or McNemars test depending upon data distribution. P values <0.05 wereconsidered as significant.

RESULTS

Postal surveys were sent to 71 women with 52 replies (73.2% response). Three patients were excluded due to hybrid procedures. The mean age was 55 years (range: 28-77). Table 1a shows how patients rated their symptoms leading into surgery with Table 1b showing the principal single reason for operation. Three-quarters of patients nominated bleeding as very or extremely important in their decision with over half listing painful prolapse or irritation wearing underwear. One-third had major concerns about odour, 40% perianal itching and one-quarter expressed significant concerns about how the appearance of the anus was perceived by their partner. As the single most important reason for surgery half the patients nominated bleeding with 20.4% decisively concerned about perianal hygiene and 12.2% about the appearance of the anus. After an explanation distinguishing haemorrhoidal prolapse from skin tags by asking whether the tissue palpable after defaecation could be reduced or felt like skin that could not be reduced, 44.2% of patients attributed their symptoms to prolapse with 50% to tags and 5.8% unsure. See Tables 1a and b.

Table 2 shows haemorrhoid-related symptoms before and after surgery in those cases (49 patients) where surgical examination showed an absence of postoperative skin tags (as defined).

Table 1a. Patient rating of importance in the indication for haemorrhoidectomy

Symptom	Rated very or extremely important by the patient (%)
Bleeding	75.5
Painful prolapse	57.1
Perianal hygiene	59.1
Irritation from underwear (g string etc.)	16.3
Embarrassment if partner sees	26.6
Concerns about odour	34.6
General discomfort	34.6
Itching	40.4
78% of patients reported multiple symptoms as being important or very important	

Table 1b. Single principal patient related indication for haemorrhoidectomy	
Indication	**Percentage**
Bleeding	57.1
Perianal hygiene	20.4
Appearance	12.2
Other	8.2
Null (patients did not complete the question)	2.1

Table 2. Patient related symptoms before and after Milligan-Morgan Haemorrhoidectomy (Likert scale)

		Before	After	p value
Symptom	**Frequency**	**n/%**	**n/%**	
Wet bottom	Never	26 (53.1)	37 (75.5)	0.075
	Once per month	8 (16.3)	4 (8.2)	
	Once per week	6 (12.2)	5 (10.2)	
	Every day	8 (16.3)	3 (6.1)	
	Null	1 (2.0)	-	
Panty liners	Never	33 (67.3)	41 (83.7)	0.083
	When going out	5 (10.2)	6 (1)	
	< once per week	1 (2)	0	
	Every day	9 (18.4)	2 (4)	
	Null	1 (2)	-	
Odour	Never	26 (53.1)	37 (75.5)	0.001
	Sometimes	15 (30.6)	9 (18.4)	
	Often	3 (6.1)	1 (2.0)	
	Always	5 (10.2)	2 (4.1)	
Itchy bottom	Never	13 (26.5)	31 (63.3)	0.004
	< once per month	16 (32.7)	12 (24.5)	
	Every week	14 (28.6)	6 (12.2)	
	Every day	6 (12.2)	0	
Interfere with sex life	Never	20 (40.8)	37 (75.5)	<0.0001
	Sometimes	18 (36.7)	9 (18.4)	
	Often	3 (6.1)	1 (2.0)	
	Always	6 (12.2)	0	
	Null	2 (4.1)	2 (4.1)	
After stooling	Use a lot of toilet paper	34 (69.4)	15 (30.6)	<0.0001
	Use baby wipes	28 (57.1)	15 (30.6)	0.001
	Shower	21 (42.9)	10 (20.4)	0.003
Afraid to use toilet when out		21 (42.9)	9 (18.4)	0.006
n: Number				

All parameters improved following haemorrhoidectomy with significant reductions in the incidence and frequency of patient perceived odour, perianal itch and disturbance of sexual dysfunction (as broadly defined). Patients also perceived that the basic quality of their toileting was improved after surgery with less use of toilet paper or fear of using unfamiliar toilets. Patients also noted less likelihood of a wet anus or the requirement for panty liners although these parameters of assessment did not reach statistical significance. See Table 2. In broad terms when asked preoperatively about an overall continence history, nine patients (18.4%) admitted to an occasional inability to control their bowels. Table 3 shows the continence status of the patient cohort before and after surgery. On specific questioning regarding any type of loss (solid, liquid or gaseous) prior to surgery 47 (95.9%) respondents were completely continent for solids with two cases reporting occasional solid stool leakage (one < once per week and one < once per month). There were seven patients with leakage of liquid stool (four < once per month, two < once per day and one daily) and eight reporting gaseous loss (one < once monthly, one < once weekly, three < daily but > once per week and three daily). Following surgery there was continence for solid stool, liquid stool and gas in 48 (98%), 47 (96%) and 46 (94%) patients, respectively. One patient reported < weekly solid stool loss, with two cases reporting liquid stool loss (one < weekly and one > weekly but < daily) and three reporting gaseous loss (one < weekly, one < daily but > weekly and one daily; p=0.027). See Table 3.

DISCUSSION

This small, single-surgeon, retrospective study shows that Milligan-Morgan haemorrhoidectomy with excision of skin tags in female patients results in a significant reduction in non-conventional haemorrhoidal symptoms not usually included in haemorrhoidal classifications, most notably concerns about odour, the appearance of the anal area, perianal hygiene and sexual function. Given the increasingly wide range of surgical options for haemorrhoid management, there still remains no standardization concerning the clinical findings following surgery and no validated scoring system yet available for recurrence with most as in our study reliant upon a combination of clinical signs and patient-reported symptoms.[5] In circumstances, however, where non-conventional symptoms are a trigger for surgery, the rigid requirement for registration of patients as recurrence-free when there are no symptoms at all,[6] may not in some cases be appropriate as a measure of surgical success. It is the author's impression that many women coming to surgery for haemorrhoids have symptoms related to skin tags, a feature not represented within the Goligher classification. It

Table 3. Continence status (before and after Milligan-Morgan haemorrhoidectomy)

Continence status	Before (%)	After (%)	p value
Solid stool loss			
Complete continence	47 (95.9%)	48 (98.0%)	
Daily loss	-	-	
< daily but < once weekly	-	1 (2.0%)	
< once per week but > once monthly	1 (2.0%)	-	0.317
< once per month	1 (2.0%)	-	
Liquid stool loss			
Complete continence	42 (86%)	47 (96.0%)	
Daily loss	1 (2.0%)	-	
< daily but < once weekly	2 (4.0%)	1 (2.0%)	
< once per week but > once monthly	-	1 (2.0%)	0.020
< once per month	4 (8.0%)	-	
Gaseous loss			
Complete continence	41 (84.0%)	46 (94.0%)	
Daily loss	3 (6.0%)	1 (2.0%)	
< daily but < once weekly	3 (6.0%)	1 (2.0%)	
< once per week but > once monthly	1 (2.0%)	1 (2.0%)	0.027
< once per month	1 (2.0%)	-	

is proposed that haemorrhoidal skin tags are a prolongation of the perianal skin which has at its apex an internal haemorrhoid and which with prolapse, has a sliding anodermal component resulting in displacement of the dentate line, protrusion of the redundant anal canal at the anal verge and traction on the external skin. These types of skin tags are to be distinguished from those which are the end- or by-product of a painful perianal haematoma.[7] It is accepted that there is no uniform definition of a skin tag although for practical purposes it could include tissue >1.5 cm in length that can readily be grasped between the thumb and the forefinger and which can be locally excised with preservation of the subdermal fascia. The finding that these patients underwent haemorrhoidectomy largely for bleeding and prolapse is expected, but over one-quarter expressed concerns about their partner's reaction to the anal appearance with one-third perceiving their haemorrhoids as a source of odour and a large proportion troubled by the impact their haemorrhoids had on personal perianal hygiene. Success following haemorrhoidal surgery, (however that is performed), is most frequently judged upon an improvement in postoperative bleeding and prolapse, findings which have been confirmed in studies comparing Milligan-Morgan haemorrhoidectomy with a range of stapled haemorrhoidopexies and with Doppler-guided dearterialization/mucopexy procedures.[8-11] Of importance is our finding that success in surgical outcome may be gained by significant postoperative improvements in non-conventional haemorrhoid-related symptoms. In this study, postoperative patients without skin tags were chosen for assessment, with the hypothesis that management of skin tags in advanced haemorrhoids influences outcome and patient satisfaction. If further studies validate that the described symptomatology is attributed to the skin tags and not the haemorrhoids per se then there would be merit in modifying the Goligher classification to include the presence of skin tags resulting in the new grades 3b and 4b. This would assist as an outcome measure following surgery as well as defining the necessity for hybrid procedures which included en passant skin tag excision when either stapled haemorrhoidopexy or dearterialization/mucopexy was used as the definitive surgical treatment. This modification has the virtue of simplicity. The description of an "external component" by Gerjy et al.[12] as none, one or few or circumferential is valid but a skin tag can be associated with grade 3 or grade 4 haemorrhoids and the length of the skin tag also needs to be considered. Currently, the addition of a skin tag excision as part of a stapled haemorrhoidopexy does not appear to significantly impact postoperative pain or convalescence.[5,10] Continence was only broadly assessed in this study with the unexpected finding in small numbers of patients of an improvement in some cases of postoperative continence status. Our patients did not undergo formal continence scoring although there is the possibility that their surgery resulted in an overall improvement of hermetic anal sealing and a diminution in faecal leakage.

There are several limitations to this study. The study reports only a small number of patients and the retrospective nature of the analysis may have introduced bias and the possibility of an alpha error concerning the impact of haemorrhoidectomy on non-conventional symptoms. This study did not control for the possibility that patients with only haemorrhoids could experience similar symptomatology. The impression was, however, that it was the control of larger skin tags in this patient group that improved those symptoms which were "irritative" in nature (perianal itch, underwear irritation and the excessive use of toilet paper for cleansing) and likely also improved sexual functioning. In summary, female patients coming to haemorrhoidectomy are troubled by important non-bleeding, non-prolapse symptomatology which is infrequently asked about or recorded but which can impact surgical success. It is suggested that some of this non-conventional symptomatology is related to an external skin tag component frequently not addressed

in advanced haemorrhoidal grades by surgical alternatives to haemorrhoidectomy such as the stapled haemorrhoidopexy and dearterialization/mucopexy procedures. The presence of skin tags could be incorporated into a modified Goligher classification system in order to decide about the merits of selective separate skin tag excision in hybrid procedures and as a useful outcome measure following a Milligan-Morgan style haemorrhoidectomy.

CONCLUSIONS

Even given the limitations of this retrospective study it is clear that the concept of perianal hygiene is important to female patients and that its control is an important measure of the success of any haemorrhoid treatment.

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ETHICS

Ethics Committee Approval: The conduct of this retrospective analytical study was approved by the Edith Cowan University Research Ethics Committee (project number: 17024, date: 19 January 2017).

Informed consent: Retrospective study.

Peer-reviewed: Externally peer-reviewed.

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Chronic pelvic pain and pelvic organ prolapse: a consequence of upright position?

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ABSTRACT

Objective: The pathogenesis of chronic pelvic pain (CPP) is still incompletely understood. Generally accepted is, that soft tissue structures mutate with age, loose tension and by this can provoke CPP. This raises the question, of whether the bony pelvis underlies comparable age-dependent changes and if so, how this alteration has impact on the static anatomy of the pelvic floor and the suspension and supporting system.
Materials and Methods: In order to answer this question we analysed the biological evolution of human beings and checked the historical literature regarding age-dependent static changes of the bony pelvis.

Results: The vertical spine position is primarily due to an angulation of the lumbar spine against the sacrum causing a lordotic curve. The upright position of human beings forces the sacrum to curve, age dependent more and more. This leads to a descent of the promontorium causing a lifting of the coccyx and the pubic symphysis. This rotation causes a flatter pelvic floor.

Conclusion: The age-dependent, now horizontal positioned pelvic floor provokes an unphysiological stretching on the soft-tissue-pelvic-floor structures causing and boosting a decompensation of the pelvic organ support and suspension system. Overstretched connective tissue, ligaments, nerves and muscles react with pain.

Keywords: Chronic pelvic pain; bony pelvis; upright posture; pelvic organ prolapse; posterior fornix syndrome

INTRODUCTION

In the female organism, the pelvis is an especially vulnerable site for major, often disabling pathology, in particular, pain, bladder and bowel disorders. Dysmenorrhea, uterine fibroids, cycle disorders, immovable retroflexed uterus, endometriosis, inflammation of ovaries or fallopian tubes, ovarian tumour, vaginal or uterine prolapse, are all implicated in the causation of pelvic pain.[1] This explains, why pelvic pain is a common clinical entity among women. Approximately 39% of the female population reports always, often or sometimes having pelvic pain. Fifteen to twenty percent of these women are experienced in having pelvic pain longer than 1 year and 61% of them report, that the cause of their pain is unknown.[2] Due to the numerous possibilities of pelvic pain sources the definition of chronic pelvic pain (CPP) is still incongruent and ambiguous in the literature. An extract and combination of the learned society definitions can be summarised as follows: CPP syndrome (CPPS) as a persistent pain in structures related to the pelvis, in either men or women, is often associated with negative cognitive, behavioural, sexual and emotional consequences, as well as with symptoms and signs related to lower urinary tract, sexual, bowel, pelvic floor or gynaecological dysfunction (European Association of

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Urology).[3,4] CPP is pain in the pelvic area, that lasts for 6 months or longer (American College of Obstetrics and Gyneacologists).[5] The CPPS is the occurrence of CPP, when there is no proven infection or other obvious local pathology, that may account for the pain. It is often associated with negative cognitive, behavioural, sexual or emotional consequences, as well as with symptoms suggestive of lower urinary tract, sexual, bowel or gynaecological dysfunction (International Continence Society).[6,7] Even today numerous CPPS-conditions are still deemed to be of unknown origin, therefore classified as "neurological" or in the German literature as "Pelvipathia vegetativa", "Parametropathia spastica", "Spasmophilia genitalis" "Plexalgia hypogastrica", "pelvic neuralgia" or cervical syndrome".[8] In contrast to this, 1938 Heinrich Martius already stated, that in about 30% of cases, backaches are attributed to organic factors, provoked by damaged suspending or supporting ligaments of the pelvic organs.[9] Unfortunately, Martius's concept has remained largely unknown in the English literature until it was recently rediscovered.[1] Independently from Martius, in 1993 Petros and Ulmsten[10] described CPPS as being caused by lax uterosacral ligaments (USL) as part of the "Posterior Fornix Syndrome", along with other pelvic symptoms, nocturia, urgency, abnormal emptying. They reported a significant cure rate of CPPS and other posterior fornix symptoms following repair of the USL. By this they were able to verify their thesis, that insufficient ligaments can be one important origin of CPPS. Meanwhile numerous publications confirm Martius fundamental ideas and Petros data.[1,11-25] Even if more and more explanations for the cause of CPPS arise, the pathogenesis of CPPS is still incompletely understood. Generally accepted is, that soft tissue structures mutate with age, loose tension and by this can provoke pelvic pain.[1] This raises the question, of whether the bony pelvis underlies comparable age-dependent changes and if so, how this alteration has impact on the static anatomy of the pelvic floor and the suspension and supporting system.

MATERIALS AND METHODS

In order to find further important explanations for pelvic organ prolapse (POP) related pelvic pain we analysed the biological evolution of human beings and checked the historical literature from the static view of the bony pelvis.[26]

Ethics committee approval and informed consent is not necessary, because no patients involved in the study.

RESULTS

Over the long course of biological evolution the human pelvic spine, interestingly, underwent only minimal erections for the necessity of upright walk. However, this apparent little anatomical alteration allowed the human beings to change their movement from quadrupeds to bipeds, unfortunately followed by new orthostatic and pelvic floor problems. The vertical spine position is primarily due to an angulation of the lumbar spine against the sacrum causing a lordotic curve (Figure 1). The pronounced lordosis and the promontorium provide quasi "the selling purchase" for the upright position.

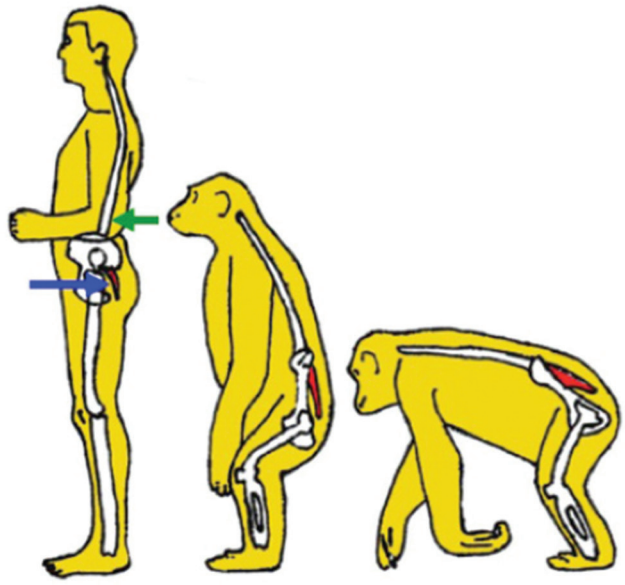

Figure 1. Change of the pelvic spine and sacrum formation from monkey to homo sapiens during biological evolution: for upright position the sacrum has to move backwards (blue arrow), the promontorium and the lumbar spine forwards (green arrow) resulting in a lordotic shape

In 1930 Heinrich Martius has already dealt with the subject pelvic spine und prolapse induced pelvic pain. He pointed out, that in women the promontorium - the base for the trunk weight - is not that strong as in men. On behalf of birth process women have to renounce on greater static strength. Therefore, the frequent sacral and back pains in women are essentially a sex specific gynaecological and orthostatic problem with equal frequency.[27]

Why are anatomical alterations important for prolapse, bladder/rectum problems and pelvic pain formation? Besides deliveries, genetic predisposition, age dependent tissue atrophy, lack of oestrogen, previous operations, there are further crucial important anatomical changes responsible for symptomatic POP in the course of natural progressing life. The biped upright position of human beings forces the sacrum to curve, age dependent, more and more. This leads to a descent of the promontorium causing a lifting of the coccyx and the pubic

symphysis. These for the formation of symptomatic POP and pelvic pain important anatomical alterations were already mentioned in the past, i.e. 1947 by Walter Stoeckel, Director of the gynaecological department of the Charité Berlin 1926-1951. In his textbook he stated, that the distance of the horizontal to the vertical plane (promontorium to upper pubic symphysis rim) consequently decreases from 9-11cm to 4-5 cm over decades (Figure 2). This rotation causes a minor pelvic inclination with a flatter pelvic floor.

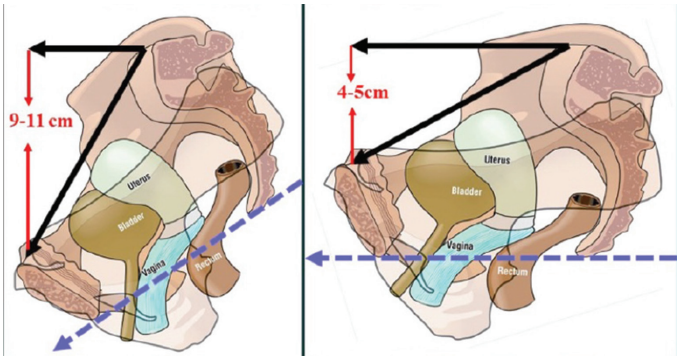

Figure 2. Natural rotation of the female pelvis during life
Left: normal female pelvis in standing position. The distance between horizontal and vertical plane (black arrows) varies between 9 and 11 cm. The direction of the pelvic floor is approximately 45° (blue dotted arrow).
Right: senior female pelvis in standing position. Due to downwards rotation of the bony pelvis the promontorium/sacrum is de- and the pubic symphysis ascended. The distance between horizontal and vertical plane (black arrows) varies only between 4 and 5 cm. The direction of the pelvic floor (blue dotted arrow) is nearly horizontally (90°)

The now much larger opening angle between conjugata anatomica and sacrum plate (Figure 3) provoke an unphysiological stretching of the soft-tissue-pelvic-floor structures causing and boosting a decompensation of the pelvic organ support and suspension system. The static system is coming more and more under pressure. However, if pressure becomes stronger, than overstretched connective tissue, ligaments, nerve fibres of the pelvic plexus and muscles react with pain.[1,28] As the pelvic plexus contains sympathetic (Th12-L2), parasympathetic (S2-S4) and somatic nerves (S2-S4) a large spectrum of different pain qualities and locations can arise, such as pelvic pain, lower abdominal, lower back ache and even pain in the vulva-region. These anatomical changes one has to keep in mind in order to understand the complex range of pelvic pain sources. It gives a very logical important explanation for the hypothesis, that CPPS has mainly an anatomical origin influenced by genetic, gender, birth, age.

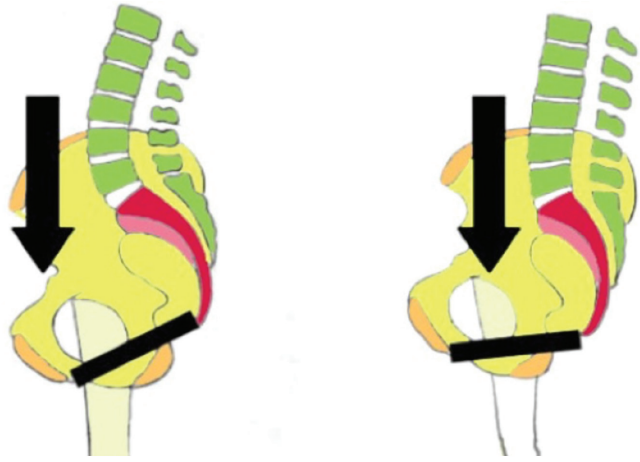

Figure 3. The inclination angle of the pelvis and thus of the pelvic floor determines the acting forces on it. **Left:** Normal position. **Right:** The more the sacrum curves, the more the pelvic floor gets a horizontal shape and comes under pressure

DISCUSSION

The aim of this article is not to list all the numerous already published causes for pelvic pain. It entirely concentrates on the very important, up to now in this context not mentioned explanation for age dependent changes in the bony static and the consequences thereof.

There are four simple mechanical reasons regarding the fact, that pelvic organs leave their normal position causing tension on the supporting and suspending system and pelvic pain: 1) Due to the upright posture of humans the pelvic organs are exposed to the effects of gravity. Therefore, the pelvic organs are pre-destinated to fall down. 2) The biped upright position of humans forces the sacrum to curve, age dependent, more and more. This leads to a descent of the promontorium causing a lifting of the coccyx and the pubic symphysis. 3) The inclination angle of the pelvis and thus of the pelvic floor is getting flat with age. The more the pelvic floor curves horizontally, the more the suspension system comes under pressure and can give way. 4) The fixation of the genital organs has to be so flexible that the tremendous change of uterine position during pregnancy and birth is possible. The pelvic floor has two functions: Firstly to obturate the abdominal cavity downwards and secondly to assure an exit for the intraabdominal organs. The fact that the outlet tract from bladder, rectum and uterus corresponds to the direction of gravity due to posture requires a particular well coordination of the suspension and support system, especially as this system still has to work properly after deliveries. The content of the small pelvis - uterus, bladder, rectum, intestine and mesenterium - is suspended and supported by muscles, ligaments and fascias. The pelvic floor contains three muscle layers located roof tile shaped one above the other.

The upper layer, the levator ani muscle, consists of three parts: anteriorly: pars pubica, centrally: pars ischiadica, posteriorly: pars coccygea. The levator ani muscle contracts horizontally, back- and forwards against the pubourethral ligaments in front and the USL in the back.

The middle layer is to secure the hiatus genitalis, the pathway for urethra, vagina and anus, consisting of the urogenital diaphragm and the longitudinal muscle of the anus. The external layer anchors the organs consisting of the muscles: ischiocavernosus, bulbocavernosus, transversus perinei superficialis and sphincter anus externus. The levator ani is a dynamic muscle with unique physiological features, that are integral in the maintenance of urinary and faecal continence.[29] The striated muscles of the levator ani differ from most other skeletal muscles in that they; 1. maintain constant tone, except during voiding, defecation, and the Valsalva manoeuvre, 2. have the ability to contract quickly at the time of an acute stress, such as a cough or sneeze, to maintain continence and 3. are able to distend considerably during parturition to allow the passage for the child and then contract after delivery to resume normal function. Despite the importance that the levator ani has for the daily well-being, it is among the most neglected and least understood parts of the human body.[30] Abnormalities in the structure or function of supporting muscles and suspending ligaments can be responsible for the development of POP, sexual dysfunction, CPP, voiding and defecatory dysfunction, and urinary and faecal incontinence. Therefore, from the evolutionary perspective, it is logical, that nature additionally secures the mechanical strength of the muscular pelvic floor with fascias and ligaments in the upright walking human being. For this supplemental support an elastic system of visceral innervated muscle-connective-tissue-plate was created, the so-called lissomuscularfibrous system or endopelvic fascia. This unit is closely connected with skeleton muscle fibres, sealing interstices and is acting as a rubber mat.[1] The so constructed pelvic floor represents the supporting buttress for the pelvic organs. A rupture in this fundament or an insufficiency due to tissue overstretching or connective tissue deficiency will cause a significant disturbance in the interaction of the abdominal muscle capsula formed by the pelvic floor, the abdominal wall and the diaphragm. In case of an instable pelvic floor, pressure from the abdominal wall and diaphragm cannot be captured by a sufficient counter pressure. Intestine and pelvic organs begin unbalanced to slide and get pressed down from forces acting from above. Furthermore, a weakened ligament will cause weakened muscle force, because the whole system is interrelated and ultimately reliant on firm suspensory ligaments. A striated muscle only contracts optimally over a short length. Lengthening the muscle results in a rapid loss of contractile force = Gordons law.[31] This can deteriorate the muscle forces enabling closure and emptying of the bladder and ano/rectum with the consequence of urinary and/or faecal incontinence and/or obstructive emptying of bladder and/or rectum. These dysfunctions frequently coexist in women with POP-induced CPPS.[3,7,9,18,23] Age related asthenia in combination with postpartal distension of the abdominal muscles and childbirth induced damage of the pelvic floor lead consequently to enhanced muscle tension, strain on muscle insertion and suspension ligaments, hanging bellies, pronounced lordosis, high strengthening of the back muscles and lastly to a static-dynamic decompensation.[28] Besides birth traumata, age dependent atrophy, genetic predisposition and previous operations the axis of the pelvic floor plays a major, so far in the literature little noticed key role regarding etiology of symptomatic vaginal and uterine prolapse and pelvic pain. An age-dependent horizontal shaping pelvic floor becomes more and more under pressure from the abdominal organs above and the gravity below. This leads in a high percentage to a decline of pelvic floor followed by a descent of pelvic organs. The unavoidable tension against the suspending ligaments can generate pain in the whole pelvic girdle. This explains, why CPP can be located overall in the pelvic area and why the frequency of pain increases with age.

CONCLUSIONS

The upright position of human beings forces the sacrum to curve, age-dependent. The more the sacrum curves, the more the pelvic floor comes in a horizontal position. The now much larger opening angle of the pelvis provoke an unphysiological stretching of the soft-tissue-pelvic-floor structures causing and boosting a decompensation of the pelvic organ support and suspension system. However, if pressure becomes stronger, than overstretched connective tissue, ligaments, nerves and muscles react with pain.

ETHICS

Ethics Committee Approval: Ethics committee approval is not necessary, because no patients involved in the study.

Informed consent: Informed consent is not necessary, because no patients involved in this study.

Peer-review: Externally peer-reviewed.

Conflict of interest

Klaus Goeschen states that he has no conflict of interest. Bernhard Liedl has received honoraria for lectures and pelvic floor workshops from American Medical Systems and Boston Scientific, honoraria for data collection (Propel study) from American Medical Systems.

Author`s participation in the manuscript

Klaus Goeschen: Project development, data collection, manuscript writing

Bernhard Liedl: Project development, manuscript writing

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Transperineal bilateral sacrospineous colpofixation for the treatment of female genital prolapse – 5-year results

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ABSTRACT

Objective: Female genital prolapse is observed with increasing frequency in the era of large aging populations. Various surgical techniques have been established, varying in performance, difficulty and outcome, specifically complications. In order to optimize both aspects, we have developed a refined transperineal bilateral sacrospineous colpofixation technique (TPBCF) and given a detailed, step-by-step description of the technique.

Materials and Methods: In a study of 162 patients with vaginal prolapse surgical and functional outcomes of TPBCF have been evaluated with 5-year follow-up.

Results: No rectal injury was observed re-intervention for any complications was limited to three erosions with only one requiring resection of 2 cm of tape in the median position followed by successful re-closure. Prolapse correction was found at 5 years to be 61% POPQ 0 and 39% POPQ1.

Conclusion: These results were stable when compared with follow-up data at 6 months postoperatively. The authors conclude, that TPBCF is an efficient minimally invasive technique for the treatment of female genital prolapse with a favourable effect/complication ratio.

Keywords: Transperineal bilateral sacrospineous colpofixation; operative therapy; vaginal sling placement; vaginal vault prolapse, surgery, complications, outcome, 5-year results

INTRODUCTION

Female genital prolapse is a known clinical entity observed increasingly frequently in the era of large aging populations.[1]Historically, treatment options included abdominal surgical interventions such as sacrocolpopexy or fascial slings,[2,3] and operations via the vaginal approach such as the unilateral Amreich-Richter operation with the vaginal apex sutured to the sacral bone after hysterectomy.[4] More recently, extensive reconstructions using prosthetic mesh for the induction of neo-ligaments and neo-fasciae have been advocated,[5] sometimes also in the context of primary surgical interventions in the unpretreated patient.[6] Intravaginal slings (IVS) placed transischiorectally have been proposed by Farnsworth[7] and Petros[8] shown to be promising in a small series of cases. However, rectal injury and erosions were identified as major problems of this technique which led to the abandonment of IVS.[9] A multi-centre series in Austria yielded better results but still described severe complications.[10] A refined

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approach to transperineal bilateral sacrospineous colpofixation (TPBCF) utilizing a standardized 12-step procedure was developed[11]. This investigation is based on this surgical strategy.

MATERIALS AND METHODS

The premanufactured tape used for TPBCF consists of a monofilament microporous braided polypropylene mesh of a weight of 70 g/m^2. It is 1 cm wide and approximately 40 cm of this material are implanted during the operation resulting an approximately 2.8 g of foreign body to remain in the patient. In a prospective study 162 patients were treated by TPBCF at HELIOS Klinikum Aue in an open single centre design. Patients with significant anatomical defects in the median pelvic compartment resulting in various stages of vaginal, utero-vaginal or cervical prolapse were included. Primary and secondary cases were admitted to the trial. There was no patient selection and no other treatment modality for the treatment of prolapse was used for the duration of the study. Vaginal estriol pre-treatment for at least two weeks was mandatory. Surgery was performed by three designated surgeons under general or regional anaesthesia following the published method.[11]Follow-up examinations were performed at 2 weeks, 6th, 12th, 24th and 60th months. after surgery.

Results were recorded according to the POPQ scale, complications and quality of life parameters were assessed. Postoperative variables included length of surgery, blood loss, pain and duration of hospital stay. All postoperative examinations and determinations were performed by a single GYN specialist trained as a pelvic floor surgeon, but not otherwise involved in the trial and in no case surgeon of the participating patients.

At the time that the investigation was performed no separate ethics consent was required for routine observational follow-up studies without additional interventions. Data evaluation consent was given at the time of admission as a standard procedure.

Statistical Analysis

Differences between frequencies were assessed using distribution-free statistics i.e Fisher's exact test for small sample sizes or the Wilcoxon test for differences of medians. Regression analysis was performed to examine the possible correlation of age, body mass index (BMI), parity, menopausal status, American Society of Anaesthesiologists (ASA), blood loss and previous pelvic floor surgery with the quality of the surgical outcome.

RESULTS

The median age of participants was 65.8 years [standard deviation (SD)=10.3] (Table 1). Ninety-three percent were postmenopausal, the median BMI was 28 (SD=4.1) with parity at 2.13 (Table 2, 2a, 2b) (SD=0.98). 8% of the patients were classified as ASA 1, 75% as ASA 2, 17% as ASA 3. (Table 3) 127 patients had undergone surgeries relevant to the pelvic floor before presenting for treatment in this study (Table 4).

TPBCF was performed preserving the uterus or in combination with hysterectomy in 105 women (64.8%), anterior colporrhaphy

Table 1. Age distribution

	n	Median	SD	Spread	Youngest	Oldest
Age	162	65.81	10.34	58	30	88

n: Number, SD: Standard deviation

Table 2. Patient characteristics

	n	Median	SD	Spread	Youngest	Oldest
Height	162	1.611	0.0613	0.3	1.5	1.8
Weight, kg	162	72.78	11.553	63	46	109
BMI	162	28.035	4.1083	23.3	17.7	41
Parity	161	2.13	0.988	6	0	6

n: Number, SD: Standard deviation, BMI: Body mass index

Table 2a. BMI Distribution

BMI	n	Percent
17.5 bis 24.9	36	22.20%
>25	126	77.80%

BMI: Body mass index, n: Number

Table 2b. Parity

Births	n	Prozent
No children	1	0.60%
1-2 children	113	69.80&
1-4 children	45	27.80&
5 or more children	2	1.20%

n: Number

Table 3. ASA status of study patients

	n	Percent	Defiinition
ASA 1	11	6.80%	Healthy patient
ASA 2	122	75.30%	Illness without physical limitations
ASA 3	28	17.30%	Severe illness with physical limitations
ASA 4	0	0	Life-threatening illness

ASA: American Society of Anaesthesiologists

Table 4. Surgical pretreatment before entering the study		
Previous surgery	**n**	**Percent**
Hysterectomy	56	34.60%
Colpopexy	3	1.90%
Anterior colporrhaphy	24	14.80%
Posterior colporrhaphy	20	12.30%
Cervical conisation	2	1.20%
TVT	22	13.60%
TVT: Tension-free vaginal tape, n: Number		

Table 5. Surgical procedure on study		
Surgical procedure	**n**	**Percent**
TPBCF	**162**	**100%**
Hysterectomy	**105**	**64.80%**
Anterior colporrhaphy	**114**	**70.40%**
Posterior colporrhaphy	**46**	**28.40%**
Combined colporrhaphies	**31**	**19.10%**
TVT	**5**	**3.10%**
Other procedures	1	0.06%
TVT: Tension-free vaginal tape, n: Number		

Table 6. Postoperative complaints					
Symptoms	**Postoperative**	**Post 14d**	**Post 6m**	**Post 12m**	**Post 24m**
Dysuria	1	1	2	0	0
Dyspareunia	0	0	1	0	0
Constipation	14	7	2	1	1
Cystitis	6	4	4	1	1

in 114 patients (70.4%) or posterior colporrhaphy in 46 (28.4%) (Table 5).

When only TPBCF was performed (n=6), median operating time was 47 minutes (range: 30-83) and median blood loss was found to be 67 mL (range: 20-200). In combined interventions i.e. together with colporrhaphy, the intervention lasted 82 minutes (range: 40-170). During the course of the hospitalization of 3.07 days (1-6) only 58 patients (35.8%) reported any pain at all with those with pain ranking its intensity at 1.81 (1-6) on a visual analogue scale of 1-10.

No postoperative infections of the surgical field or hematomas in need of re-intervention were observed. Subcutaneous suggillations of the buttocks were present in 13.6% (n=22) and resolved spontaneously without treatment. Postoperative complaints are listed in Table 6. The preoperative POPQ distribution is shown in Figure 1. Ninety-two percent of the patients were found to have a POPQ of 1 or better after 6 months (Figure 2), 88% after 12 months, and all patients presenting for examination after 60 months. Figure 3 shows the POPQ distribution after 24 months. Treatment efficacy during follow-up is shown in Figure 4.

Ninety percent of patients subjectively classified the surgical result as good or very good after 1 year. Only one patient reported new onset of dyspareunia.

After 6 months, three patients presented with erosions (1.9%). Two of those were minimal and resolved without treatment, one patient had a 2 cm median segment of tape resected with subsequent primary wound healing. Sixty-one patients followed the invitation for a follow-up examination after 60 months (38%) with an additional 20 (12%) making themselves available for a telephone interview assessing patient satisfaction and the necessity for interim surgical intervention for recurrent prolapse. Seven patients

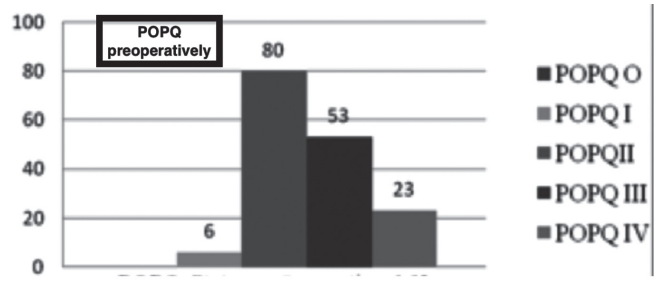

Figure 1. Preoperative POPQ
POPQ: Pelvic Organ prolapse quantifications system

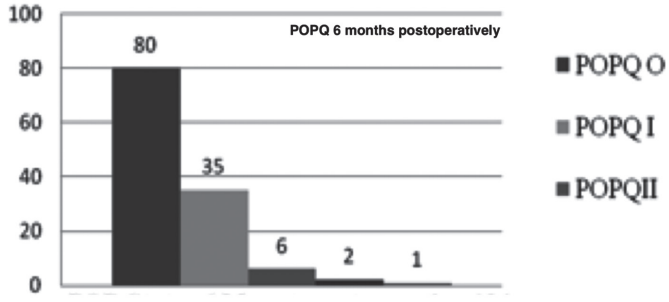

Figure 2. Postoperative POPQ at 6 Months
POPQ: Pelvic Organ prolapse quantifications system

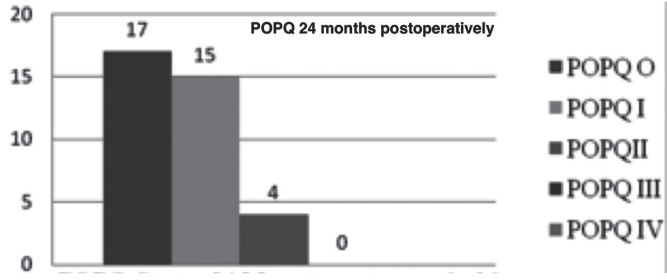

Figure 3. Postoperative POPQ at 24 Months
POPQ: Pelvic Organ prolapse quantifications system

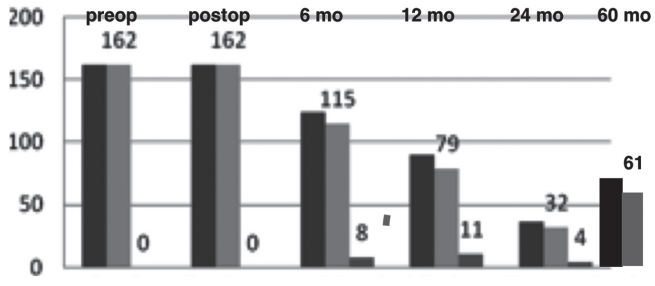

Figure 4. Treatment Success (black and grey bars) determined during follow-up

(4.3%) had died from other causes during the follow-up interval. There was no significant difference in POPQ compared to the result at 6 months ($p>0.2$). At five years 56 patients (92%) were found to have some degree of cystocele with only 13 (21%) newly developed. In those 13 individuals' cystoceles 54% were grade I and 46% grade II.

More pronounced cystoceles grade III (23%) and IV (3%) were only observed in the remaining 43 patients. All of the patients with recurrent anterior defects had been undergoing an anterior colporrhaphy at the time of the TPBCF five years prior. Some degree of rectocele was present in 32 patients (52%). Patient satisfaction was assessed in analogy to German classroom grades ranging from 1 to 6 with 1 being the best. The patients presenting for examination graded their satisfaction with surgical result at five years at 1.6 (range: 1-5), those interviewed by phone at 2.0 (range: 1-6). Seventy-seven percent of all patients assessed at five years ranked their quality of life equal or better than before the surgery.

DISCUSSION

Fascia lata slings and suspension procedures using the round ligaments have been abandoned as have resorbable meshes due to the fact, that the body does not maintain neo-ligaments without continuing stimulation of fibroblasts on site. Sacrocolpopexy with or without prosthetic mesh interposition should be combined with a Burch procedure for optimal results as shown by the studies of the NIH Pelvic Floor Disease Network.[12-14] In sum, this amounts to a significant surgical intervention with laparoscopic techniques adding their own spectrum of possible complications due to their transabdominal nature.

Amreich-Richter results are known for their surgery-induced dyspareunia, deep pelvic pain and secondary urinary continence problems[15] making them unattractive especially for, but not limited to, the younger patient. While having been in clinical use for a long time, systematic studies of this entity are few. Modifications using unilateral or bilateral non-resorbable sutures that serve as fixing strings suspending the vaginal apex at a distance from the sacrum have never been formally evaluated and remain experimental with anecdotal results. Large prosthetic implants as a primary treatment approach for female genital prolapse are meeting with increased scepticism due to their potential for complications. The FDA has recently issued a statement to the effect, that large meshes are contraindicated as primary treatment in such situations.[16] The principal weakness of the present study lies in the possible selection bias induced by the decline in the number of patients following the invitation for re-examination after five years. In a population with a median age of at least 70.8 years at that time and seven patients already deceased this is not entirely surprising. From today's perspective, a formal standardized quality of life assessment tool should have been included.

Strengths of this trial lie in the comparably large number of patients, the long-term follow-up and the meticulously standardized surgical procedure. The complete absence of patient selection and the assessment of study endpoints by a non-involved specialist increase objectivity of the reported outcomes data and their applicability in the routine clinical setting. The TPBCF approach outlined here offers the potential for the generation of an anatomy-analogous support of the vaginal vault or the uterus mimicking the sacrospinous ligaments or creating sacro-vaginal ligaments in its place. The challenge for the surgeon adopting the procedure will be to overcome a possible initial hesitancy when faced with the insertion of the introducer through the perineum, but in our experience the procedure becomes routine quickly. The indication for TPBCF is vaginal vault, vervical or uterine prolapse, it is not designed to correct anterior, posterior or lateral pelvic floor defects.

In this trial, TPBCF has a low complication rate and a very low frequency of erosions at 1.9%. This compares very favourably with FDA-reports of 10% for larger mesh implants and with the 5.4% reported for the IVS apical sling by Farnsworth[7]. This technique was the basis for the development of TPBCF. Our data substantiate the superiority of the standardized TPBCF approach in comparison to the older technique. This fact is further illustrated by less blood loss (67 mL vs 110), shorter operating time (47 vs 60 min) and the total absence of rectal perforations (0 vs 2.2%) in this much larger study population (n=162 vs n= 93). Ninety percent of patients experienced at least a five-year anatomical stability of the apical fixation with Farnsworth[7]. reporting an 87% success rate in short-term follow-up. When compared to FDA reports both studies exhibit a superior risk/hazard ratio with the TPBCF showing the thus far most

advantageous profile. As a minimally invasive approach with the potential for conservation of the uterus or cervix TGBCF would potentially be applicable to all age groups and also the increasingly frequent elderly patient with significant co-morbidities.

CONCLUSION

The sum of the available data indicates, that the anatomy-analogous fixation of the vagina, cervix or uterus by this approach may have to be viewed and judged differently from the experience with larger meshes and may warrant reconsidering the generalized negative position of regulatory authorities towards pelvic floor prosthetic implants in favour of a more differentiated view.

Building on the long-term success of the TPBCF-concept in the treatment of prolapse and on developments in mesh technology and surgical instruments, a bilateral elastic colposuspension has been developed for the same surgical indications utilizing HexaPro monofilament macroporous mesh at a material weight of 21 g/m^2 and I-Stich fixation in the pelvis. The entire implant weighs 0.054 g compared to a regular postal stamp at 0.085 g. The surgical method of Bilateral Sacrospineous Colosuspension has recently been formally described in detail and its evaluation is in progress.[17] The goal of this development is to maintain the high success rate of the TPBCF while further decreasing foreign body load in the organism of the patient and potentially lowering the incidence of complications even further.

DISCLOSURES

The authors report no conflicts of interest.

ETHICS

Ethics Committee Approval: At the time that the investigation was performed no separate ethics consent was required for routine observational follow-up studies without additional interventions.

Informed consent: Informed consent was obtained from the patients.

Peer-review: Externally peer-reviewed.

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Pelviperineology 2020;39(2):65-67

Introduction to the World Federation for Incontinence and Pelvic Problems (WFIPP)

MARY LYNNE VAN POELGEEST-POMFRET

President of World Federation for Incontinence and Pelvic Problems (WFIPP)

Dear Editor,

in this first of what will I hope become a regular feature in the "Pelviperineology" journal, I would like to tell you a little about the WFIPP itself, who we are, etc. and include some information about two of our founder members, namely our Polish and Canadian member organizations. In later issues, I will then be able to tell you what we are currently working on even in these trying and distressing times we are all living in as I write this text. One thing is for sure, our patients and the public at large certainly need an organization and international platform like ours to represent them and to lobby at all levels to make sure their quality of life is at least maintained and at best improved. To achieve this, we work according to a multi-stakeholder approach and make sure we, as an organization, are involved in all the various aspects of healthcare and healthcare policies. It is challenging but certainly over the past few years it has become very apparent that patient engagement, patient centricity and a value-added approach to healthcare are key factors. So who are we? The WFIPP is a federation of national (patient) organizations or institutions that aims to create a global visibility for incontinence and pelvic floor dysfunction, whereby the key objectives are awareness, advocacy and action. The WFIPP aims to create a world where people living with all forms of pelvic floor dysfunction(s) can enjoy a high quality of life, play an active role in society and have access to appropriate treatments. WFIPP's mission and vision is to:

- Be the patient voice
- Be heard and acknowledged in society and by policy-makers both at EU level and internationally
- Be a global umbrella for national (patient) organizations
- Encourage an open public debate and break stigma and taboos (cf. World Continence Week, organized each year by WFIPP and endorsed by the ICS, EAU, IUGA, etc)
- Educate and inform members on the research process, e.g. clinical trials and update members with the latest scientific news and research
- Create a database of patients interested in ongoing or completed clinical trials & participating in new trials
- Formulate new research questions to be addressed by researchers
- Highlight the diversity of topics connected to patient experience, e.g. stigma, pain, psycho/social and economic impact
- Design and participate in surveys (cf the current 2-year project to establish a WFIPP digital web-based platform)
- Identify internal and external stakeholders, their information needs and map information products and communication tools they use
- WFIPP collaborates with relevant stakeholders that share our goals and values such as regulatory bodies, scientific societies (ICS, EAU, IUGA), patient groups and NGOs, industry partners

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And here are some basic facts:

• WFIPP established 2006

• Italian-registered NGO now according to and in compliance with the new Italian legislation redefined as an ODV (Organizzazioni di Volontariato – OdV).

• Currently 10 European and 10 global members (represented therefore in all continents) and growing

• Dedicated elected Executive Council

• July 2017 WFIPP underwent a strategic refocus of the group's aim and direction

Recently also the WFIPP has undergone a complete reshuffle resulting in the name change from WFIP to WFIPP. This is what we have done over the past 3 years following the above-mentioned strategic planning workshop in Brussels in 2017:

• Broadened our aim to cover all areas of pelvic floor dysfunction, not solely incontinence

• Create a dedicated research and communications strategy

Just to illustrate these two aspects, WFIPP is now a Consortium member for a number of Horizon 2020 and IMI projects and is involved in several dedicated research projects, such as the project based on the search for a new diagnostic tool for SUI. Also at a more general engagement level, WFIPP is increasingly being regarded as the major platform for incontinence and related issues So it is evident from the above outline that WFIPP has a crucial role to play as the interface between the scientific community - healthcare professionals, the patient cohort and healthcare institutions at the national and international levels.

In the coming months and future issues, I hope to illustrate just how WFIPP is working to achieve the above goals and also how we are keeping the momentum going during the dire COVID-19 situation. Indeed, it is essential to move forward and to literally keep going with our various plans, of course adjusted when it comes to holding the physical events planned for 2020. So here is the first description of two of our founder members. Their respective CEO's are also WFIPP Executive Council members, namely Jacqueline Cahill who is WFIPP Vice-President and Tomasz Michalek who is WFIPP Treasurer.

UroConti Association (Poland)

The **UroConti Association** was founded in April 2007 as an NGO by patients and for patients with urinary incontinence (UI). Currently, it comprises of over one thousand people covering eight regions and with two sections (bladder and prostate). Regardless of age, anyone affected by incontinence and related conditions can become a member of the Association and actively participate in its activities. The Association has the status of a public benefit organization. There are strong regional branches under the direction of an Association Council formed by the heads of the regional branches and which supervises the Association itself and the Management Board activities.

The main goal of the Association is to work for people affected by the broadly understood UI and pelvic problems to promote knowledge on this topic.

The **UroConti Association** promotes:

- a multidisciplinary approach to the UI,

- comprehensive care,

- the importance of prevention and hygiene in caring for a patient with UI,

- access to a wide range of therapeutic methods.

Activities of the Association:

- organization of cyclical educational lectures and workshops with the participation of health and social care specialists (doctors, nurses,

physiotherapists, dieticians and psychologists),

- organization of regional pelvic floor training groups (more than one thousand hours annually),

- hosting of a nationwide conference on UI once a year (World Continence Week),

- publishing reports and newsletters (e.g. analysing costs of UI treatment from the patient's and healthcare system's point of view)

- activities to broaden access to the latest therapeutic methods.

Some of the Association's successes:

- full reimbursement for SNM,

- changes in the Ministry of Health's drug program for patients with advanced prostate cancer,

- broaden access to reimbursed overactive bladder (OAB) pharmacological treatments

- increasing the monthly limit on reimbursed absorption products
- Silver International Award of the ICS for the best promotion of World Continence Week in 2011.

Challenges for the future:

- introduction of reimbursement of the second line of pharmacological treatment in OAB,

- introduction of reimbursement of SNM for patients with faecal incontinence

www.uroconti.pl

The Canadian Continence Foundation (Canada)

The Canadian Continence Foundation (CCF) is the Canadian patient voice for those living with incontinence. It is the only

national, charity/not-for-profit patient organization addressing their needs. We produce and distribute, "The Source", a detailed urinary and faecal incontinence management guidebook, we offer a telephone and online helpline and numerous other resources for caregivers and those living with incontinence. The Foundation also advocates on behalf of those living with incontinence by lobbying the government for better access to treatment and management of products. The Foundation has published many research papers and surveys across Canada. In addition, CCF was responsible for having incontinence absorbent products and pads listed on the WHO list of 50 essential assistive devices, (APL). CCF has been a WFIPP member since 2009 and its CEO, has been WFIPP's Vice-president since 2010.

CCF's mission is to enhance the quality of life for people experiencing incontinence through education; by helping them, and/or their caregivers, to seek and access cures and treatment options. To this end, the Foundation implements and encourages public and professional education, advocacy and research to advance incontinence treatment and management. Vice-president: World Federation of Incontinence & Pelvic Problems www.canadiancontinence.ca

In the coming months, I hope to tell you more about WFIPP's current activities and our plans for the future.

In the meantime, please do take a look at the WFIPP website at: www.wfip.org.

On behalf of the WFIPP Executive Council, I am very pleased to have this opportunity to share with you just some of the actions and events we are undertaking as an organization to help improve the quality of life of patients and their families.

ETHICS

Peer-review: Externally peer-reviewed.

NOTES

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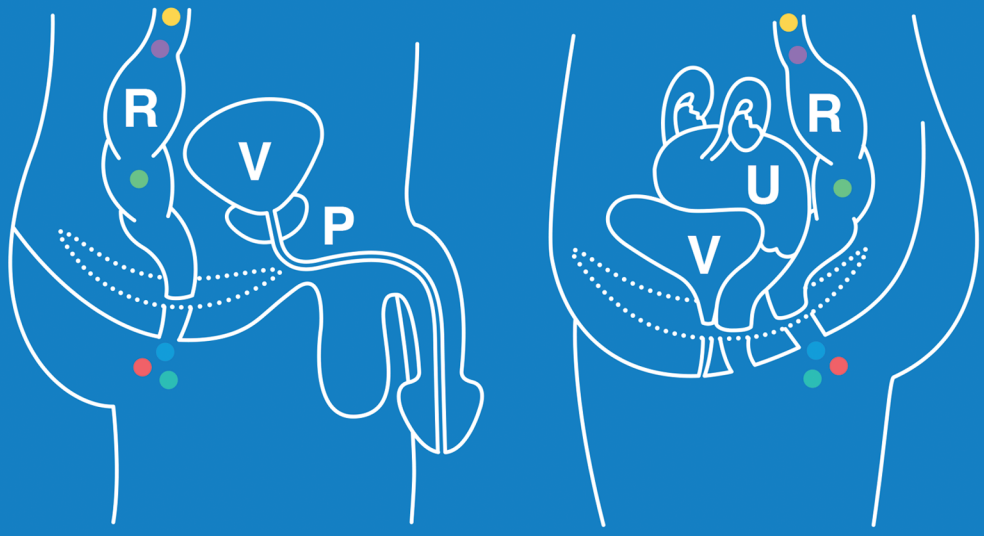
Nutraceuticals and assisting devices
for the care and well-being of the pelvic floor



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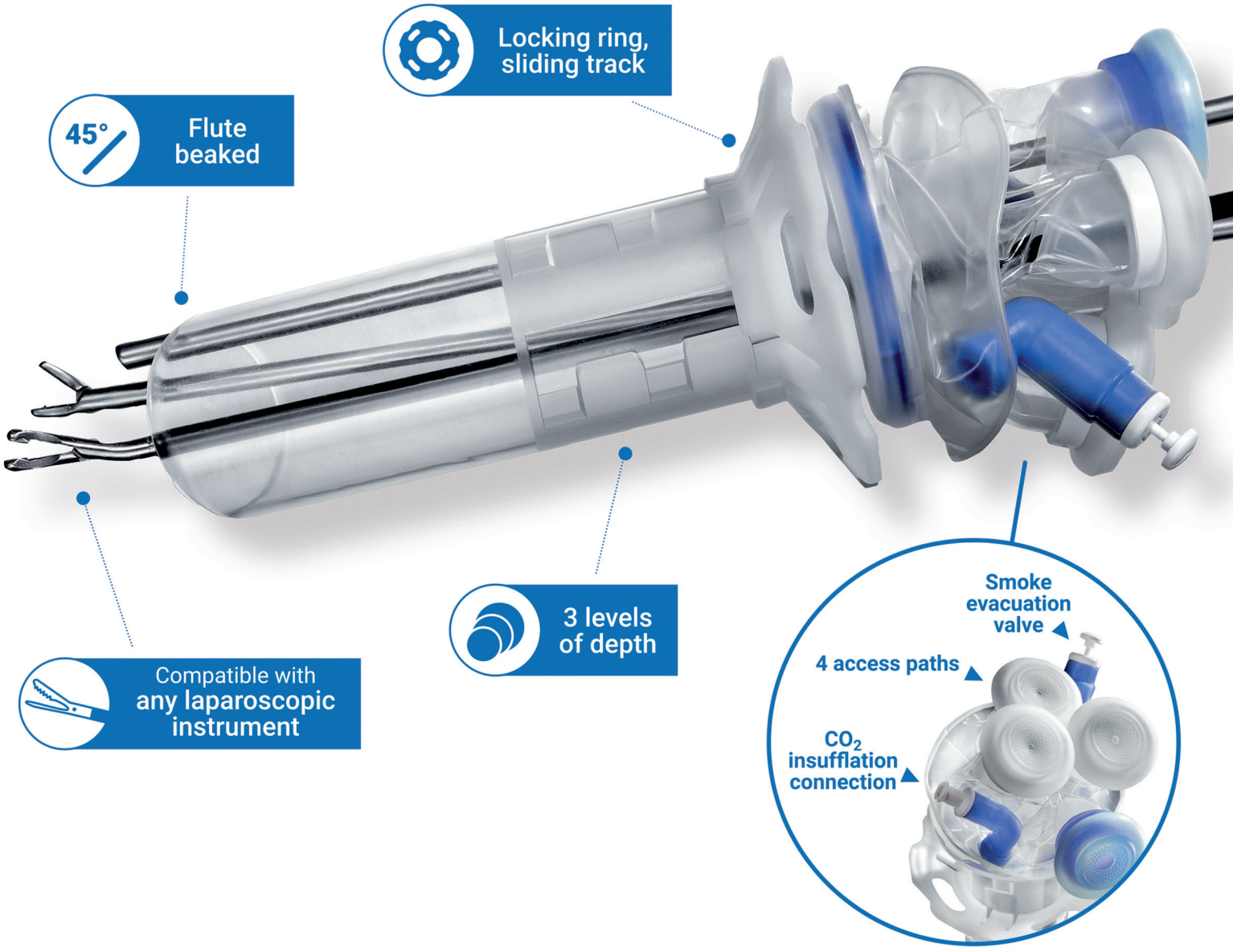

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SAFE
Less than 1% complication rate*

EFFECTIVE
Up to 84% of patients experienced significant improvement*

QUICK RECOVERY
Return to normal activities in a few days

SECCA PATIENTS **84%** experienced significant improvement

Greater Quality of Life

Less than **1%** complications

MEDERI™

Distributore esclusivo:

INNOVA medica SPA