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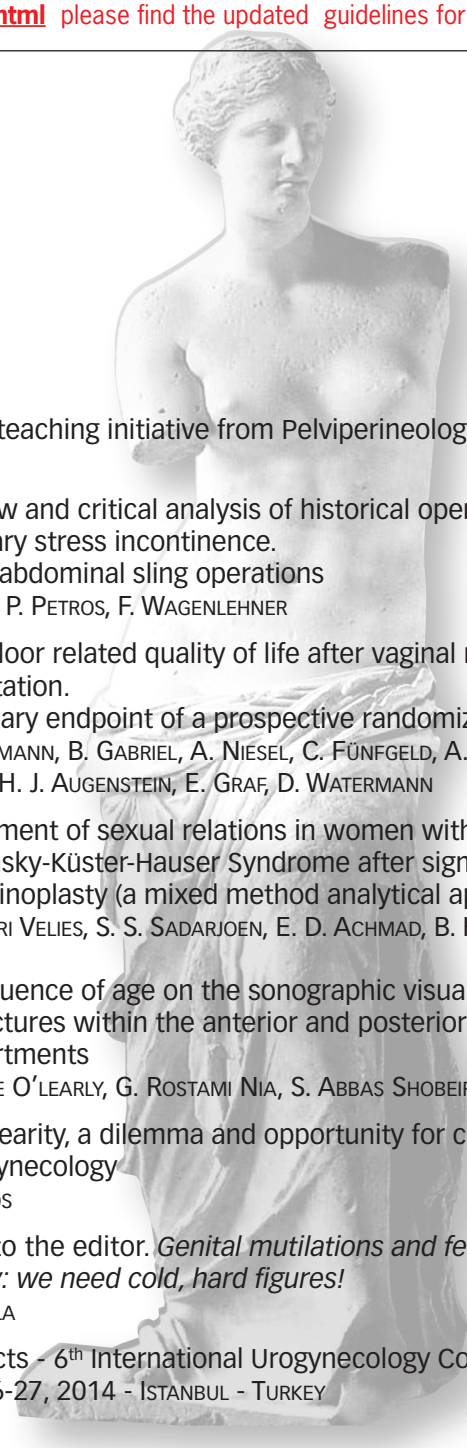

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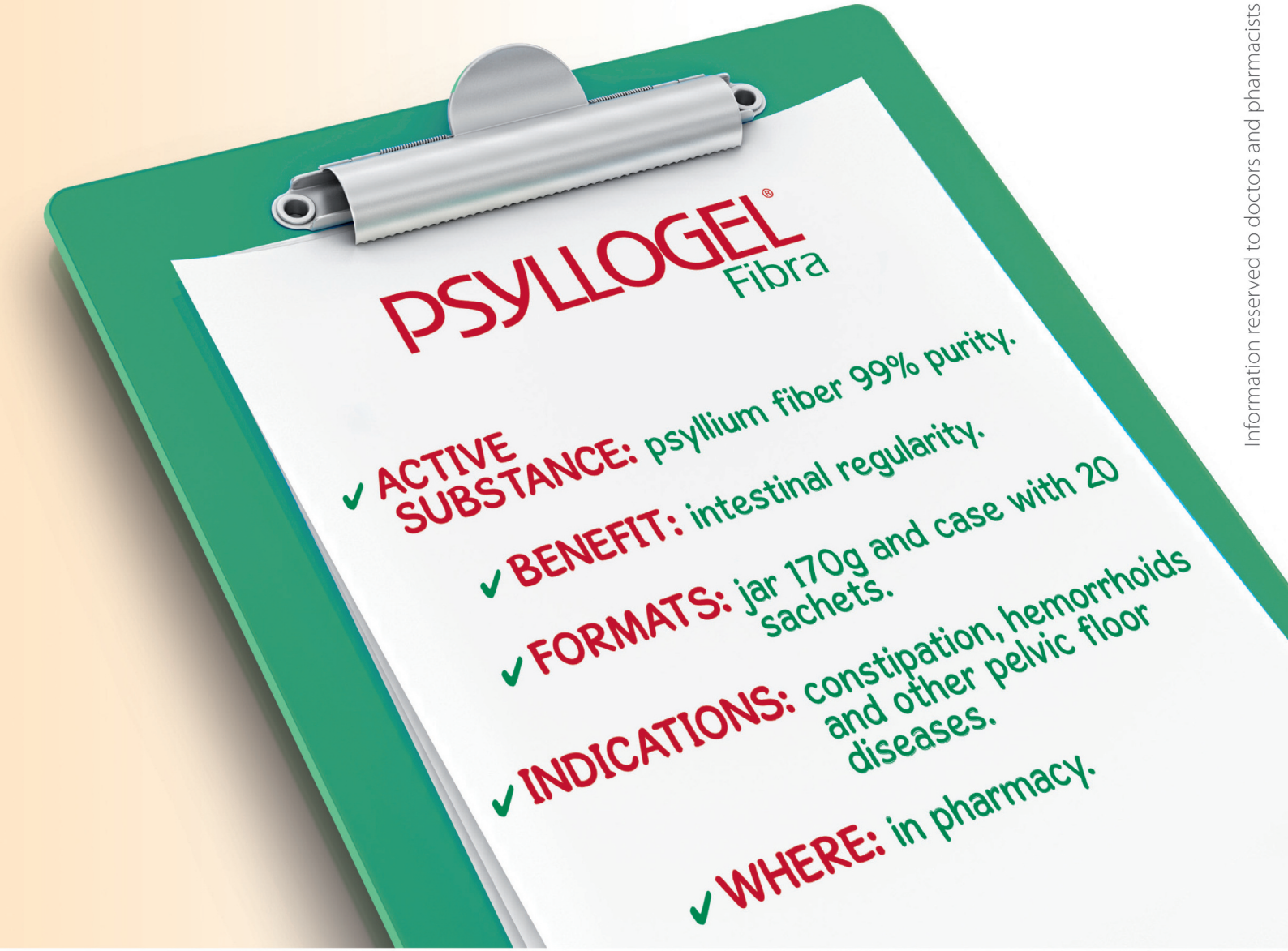

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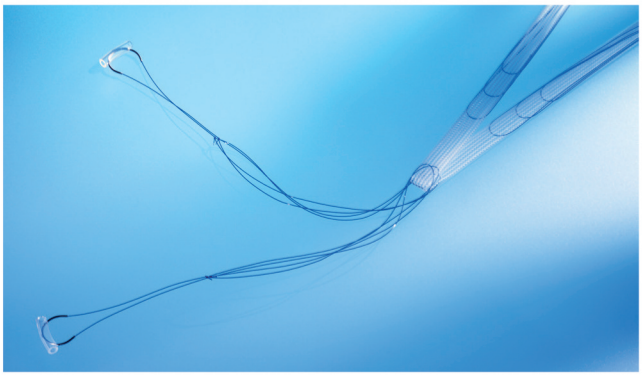
A.M.I. TOA / TVA System
for Female Stress Urinary Incontinence

Q.: Who needs an adjustable sling?



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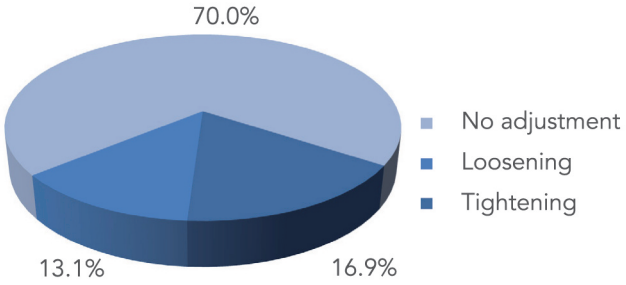
A.: About 30% of patients.

% of patients requiring adjustment



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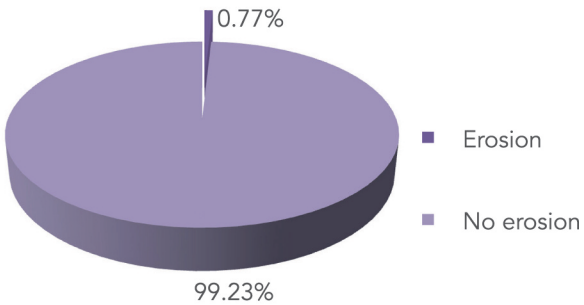

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Editorial

A new teaching initiative from Pelviperineology

A section on management of difficult pelvic floor problems by application of the Integral System

Many patients present with symptoms, stress or urge urinary incontinence, nocturia, frequency, voiding dysfunction, chronic pelvic pain, bowel evacuation problems and fecal incontinence. Surgeons who use the International Continence Society's urodynamic paradigm consider surgery contraindicated with all these symptoms except *genuine stress incontinence (GSI)*. The Integral Theory System (ITS) views all these symptoms as secondary manifestations of a laxity in the pelvic suspensory ligaments and therefore surgically curable.

Since its inception Pelviperineology has led the world in publishing scientific articles based on the ITS. We'll continue our dedication to bringing the ITS to the notice of the scientific community in a practical way, by introducing a section dedicated to solving difficult pelvic floor clinical problems through application of the ITS, a unique diagnostic system which diagnoses laxity in specific pelvic ligament and therefore symptoms and prolapse causation.[1] Such an anatomical paradigm becomes ever more relevant as cysto-colpo-defecography, anorectal manometry and electromyography, based on anatomical variations and visceral and somatic muscles functions, as well as the urodynamic paradigm based on bladder pressure measurements, seem to be invalid as predictors of surgical success or failure.[2,3] The ITS provides a minimally invasive alternative to issues raised by the FDA as regards the use of mesh for repair of POP. Morphologic and functional pelvic floor tests and paradigms were nevertheless seminal events in pelvic floor science, as they were the first scientific approach to the problem of urinary and fecal incontinence and retention.

The urodynamic test was a product of the International Continence Society (ICS) in the 1970s to evaluate bladder and bowel incontinence problems. The ICS drew attention to the problem of incontinence and created a forum where these problems could be practically and scientifically addressed. The initial problems ICS faced in these endeavours were that urine leakage had seemingly multiple causations with a wide individual variability in symptoms, and that surgery needed to be done with caution, as it did not work on many patients. Expert standardization committees were set up to create a common language and definitions such as *urge* or *stress incontinence*, etc. The next problem was objective diagnosis of *detrusor instability* (DI),[4] and since the ICS system was based on the concept that urodynamic findings were *objective* and therefore *reliable* and unstable bladder symptoms were said to be unreliable, not surgically curable and required drug therapy, the outcome of this was the concept that only patients with GSI were surgically curable, and patients with mixed incontinence, stress and urge, frequency, nocturia should not be operated on if urodynamics demonstrated DI, now known as *overactive bladder* (OAB).[6] It seems that with the passage of time the urodynamic paradigm, now almost 40 years old, began to falter. In 2006 the Cochrane collaboration[2] found that urodynamics had no predictive value and this was more recently substantiated by a major article by Nager et al. in NEJM.[3]

In the *colorectal field* anorectal manometry, also based on pressure measurements, has been overestimated in the past, and similarly has little predictive value. Both manometry and evacuation proctography retain a definite but limited place in investigating pelvirectal disorders.[7] Their contribution to the diagnosis of *anismus* and to the work-up of patients with *fecal incontinence* is also limited,[8] nor do they provide sufficient grounds for the diagnosis of *slow transit constipation* or *obstructed defecation*.[9] Clinician must be thoughtful and prudent when considering the numerous investigations commonly applied in anorectal and colonic disorders.[10] There is not a story for the anorectal function through well structured international scientific societies as for bladder studies. A passive acceptance of fecal incontinence as a fatal event of the elderly, and a lack of financial interest in low cost laxatives by the industry and therefore a lack of support to research and to sponsorship has not favored a significant progress in this field.

The ITS is an entirely anatomical management system based on a validated questionnaire[1] and a three zone diagnostic flowchart indicating the site of damage/laxity of the four suspensory ligaments and perineal body and therefore the site to be enforced in a site specific way with polypropylene tapes. There is an increasing body of data demonstrating that reinforcing with minisling these structures is sufficient to cure not only cystocele, rectocele and uterine/apical prolapse but also bladder and bowel symptom dysfunction and many instances of chronic pelvic pain.[11-13] In the new section *Management of difficult pelvic floor problems* the ITS will be applied to solve cases that cannot be addressed by the common laboratory paradigms. A full account of this system with case reports is available online from a previous publication.[14]

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Review

A review and critical analysis of historical operations for cure of urinary stress incontinence. Part 2- abdominal sling operations

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Abstract: Aim: To critically analyse the anatomical basis of historical abdominal sling operations for the cure of urinary stress incontinence (USI). *Methods:* Historical abdominal sling operations for cure of USI were critically analyzed as regards their modus operandi from an anatomical perspective using a 15 point system: 1. Minimally Invasiveness. 2. Ease of Performance. 3. Built-in Safety of the procedure. 4. Short term complications. 5. Long term complications. 6. Applicability to obese patients and those with poor tissues. 7. Applicability to patients with previous operations for stress incontinence. 8. Blood loss. 9. Length of operation. 10. Early discharge from hospital. 11. Urinary Retention. 12. Long-term Continence. 13. Early resumption of normal activities. 14. Anatomical damage. 15. Physiological mode of action of the operation. *Results:* A critical analysis is given for abdominal slings using both natural tissues such as rectus abdominis sheath, or plastic inserts. Benefits and complications such as post-operative pain and urinary retention are detailed. *Conclusions:* The main obstacle to abdominal slings becoming day-care operations revolve around the obstruction of urination by the positioning of the sling at bladder neck. This prevents the funneling required to reduce intraurethral resistance to urine flow, potentially causing obstructed micturition. Excess pressure on the overlying stretch receptors may cause de novo urgency. Finally, the large incisions required to access the operation site may cause organ damage, hemorrhage and thrombosis.

INTRODUCTION

In 1983, Ingelman-Sundberg,[1] stated that there were >100 surgical operations described for the cure of stress incontinence. We can reasonably conclude that no one operation fully addresses the problems and complications associated with surgical cure of this condition. We have previously reviewed historical vaginal operations. In the following sections, an analysis is made of abdominal sling procedures.

Evaluation with reference to a 15 point table is made. The most common variants of these operations are described. It will be assumed that the same limitations of the category of sling operations applies to a greater or lesser extent also to the variations. Criticism will be based on logical analysis with reference to known anatomy, physiology etc, or on references in the literature. Important papers will be quoted in detail. An attempt will be made to evaluate each operation as to its modus operandi, referring specifically to the hypothesis.

Suggested criteria needing to be filled by the ideal operation

(1) Minimally Invasiveness.

(2) Ease of Performance.

This allows the operation to be performed by less skilful surgeons. It also reduces the operating time and the potential complication rate.

(3) Built-in Safety of the procedure.

In a methodological sense, the operation must have an inbuilt safety margin, if possible to avoid penetrating the various adjacent organs and to diagnose any perforations occurring. As part of this process, one should bear in mind the complicating presence of scar tissue from previous operations, and the fact that anatomical variations, especially of the ureters, not infrequently occur.

(4) Short term complications.

There are complications associated with general anaesthesia, the presence of intercurrent disease (often a problem due to the high incidence of incontinence in the aged), thrombosis, haemorrhage, lung complications, and infection, especially as the operation is conducted in an area inhabited by the bladder, urethra, ureters and the blood vessels of the vesical plexus.

(5) Long term complications.

Retention of urine is dealt with separately, but complications such as enterocoele formation and dyspareunia, pain at the site of artificial fibre insertion in the rectus sheath, herniation through the rectus sheath in, for example, Aldridge sling operations. Each operation has its specific complications. These complications will be attributed to the anatomical distortions associated with bladder neck elevation procedures.

(6) Applicability to obese patients and those with poor tissues.

All suprapubic operations are difficult in obese patients, the open operations being particularly so. In the elderly patient, the diabetic, the obese with poor tissues where the integrity of the operation hangs on the suturing of tissue to either bone or ligament there is a risk of the suture tearing out of the tissue, usually the vagina.

(7) Applicability to patients with previous operations for stress incontinence.

Previous operations tend to form fibrosis and even if the urethra is freed from the fibrotic tissue.

(8) Blood loss.

There are very few reports in the literature which measure the amount of blood loss. The importance of blood loss relates to an accompanying increased incidence of thrombosis, infection, risks from transfusion and, of course, greater morbidity and increased length of stay in hospital. As an indication of the importance of this parameter, Stanton et al[2] recorded an average blood loss in the Burch operation of 377ml, rising to an aggregate of 858ml with hysterectomy.

(9) Length of operation.

This parameter partly impinges on 1), 2), 4), 6) and 8) above, and there is also wide variation here, depending on the patient and the surgeon. Certain operations, however, are inherently more complicated than others. For example, there is much more involved in an Aldridge sling or a Zacharin operation than there is in a Burch or Marshall-Marchetti operation.

(10) Early discharge from hospital.

Over and above the economic factor of saving the cost of hospital days, an operation which allows early discharge almost certainly is a far more efficient, less traumatic and more desirable operation.

(11) Urinary Retention.

"The most vexing problem has been incomplete voiding", Hodgkinson,[3] referring to the complications of retropubic urethropexy. This needs to be stated as a specific complication. It is very discomforting to the patient, adds considerably to the cost of the operation and greatly predisposes to urinary tract infection.

(12) Long-term Continence.

All operations have an increasing failure rate with time, Spencer.[4] Very few series have properly defined objective criteria for assessment of post-operative results, Spencer.[4] Thus this parameter has to be carefully examined. Many operations have very good short term results which, unfortunately, are not borne out when the patient is reassessed after two years.

(13) Early resumption of normal activities such as housework, intercourse, sport. The operation can be painful and may require up to two weeks lying in bed with an indwelling catheter.

These are some of the most serious obstacles to young women with families undertaking a vaginal repair operation.

(14) Anatomical damage.

It is important to avoid any damage which could hinder a successive operation should the primary operation fail. Specifically, fibrosis to the urethra and bladder neck must be avoided in the methodology of all operations, Tanagho.[5] This, of course, is not always possible, but certain operations do appear to be less likely to cause this problem, especially if large segments of vagina are excised.

(15) Physiological mode of action of the operation.

The central criterion here will be whether there is anatomical distortion following operation, on the traditional basis that function follows restoration of normal anatomy.

The historical development of the sling procedure.

In 1907 Giordano used a part of a double gracilis muscle transposed beneath the bladder neck to give support and cure incontinence in a 7yr old patient with spina bifida.[1]

In 1910 Goebell[6] described an operation in which he dissected free the pyramidalis muscle from the anterior abdominal wall, brought it down posterior to the symphysis, through the Cave of Retzius, to form a sling beneath the urethra near the bladder neck. He reported two successful cases in which no other type of procedure would have been feasible, and continence was established. An obvious shortcoming of this technique was the inconsistency, or even congenital absence, of the pyramidalis muscles.

In 1914 Frangenheim[7] utilized what portion of the pyramidalis muscles were present, but with an attached strip of the anterior abdominal fascia. He performed an operation on a male. The strap was dissected as one continuous strip and slung underneath the urethra as a loop and reattached to itself at its origin.

In 1917 Stoeckel[8] combined the use of pyramidalis muscle and the strip of fascia from the anterior abdominal aponeurosis, making the operation virtually independent from pyramidalis muscle. The superior end of the fascia was split, passed retropubically and plicated beneath the urethra with the appropriate tension. He reported success in two difficult cases, one with previous successful repair of a vesicovaginal fistula and the other with a large cystourethrocoele. The operation subsequently became known as the Goebell Frangenheim Stoeckel technique.

In 1919 Solms[9]) used the distal ends of the round ligaments. Thompson[10] used bilateral fascial strips from the rectus muscle .

In 1932 Norman Miller[11] modified the technique of what was now called the Goebell/Frangenheim/Stoeckel operation, by bringing the developed musculofascial sling of the pyramidalis and anterior abdominal aponeurosis anterior to the symphysis and beneath the urethra. His rationale was to try and avoid the haemorrhage often encountered in the retropubic space, especially from the perivesical plexus of veins. Unfortunately, he encountered similarly troublesome bleeding at the region of the clitoris. As well, he had difficulty in achieving the proper angle of support necessary at the region of the posterior third of the urethra.

Price (1933) again modified the procedure and obtained a cure of urinary incontinence in a young girl who had no bladder sphincter control because of congenital deformity of the lower spinal cord, sacrum and coccyx.[12] He used a sling of fascia lata, diverted it below the urethra as a sling and attached it to the other rectus muscle fascia. This was a more logical modification, as the attachment to the rectus muscle fascia was able to achieve a constant and equivalent tension underneath the urethra.

In 1942 Aldridge[13] made transverse abdominal incision on both sides, dissected out strips of abdominal aponeurosis approximately 1cm wide, parallel to Cooper's ligament. The medial ends were left attached and the distal ends were brought down, either lateral to the rectus muscle valleys or actually passed through them beneath the urethra and sutured together in the midline with silk. This operation had two problems:

(1) there was no way to adjust the post-operative tension below the urethra, so that a fair amount of guesswork was involved in how much looseness to leave to take up the slack when the patient stood up;

(2) a defect was left in the anterior abdominal wall on both sides, which predisposed to hernia formation.

In 1948 Millen & Read[14] again modified Aldridge's technique, by dissecting two long strips, leaving them attached at the lateral ends, pulling them underneath the urethra and attaching them both to the opposite abdominal wall. This operation had the singular disadvantage of having to be performed blind in the suburethral area.

In 1949 Shaw[15] devised a sling which consisted of passing autogenous fascia beneath the urethra. He fastened the free end to holes drilled in the pubic symphysis. He reported 35 successful operations out of 51 cases. One patient died.

Barns (1950), used the uterine ends of the round ligaments to form a sling in 6 patients with “good results”.[16]

Ball & Hoffman (1963) did a combined approach with retropubic and vaginal approach, consisting of plicating the bladder.[17] Narik and Palmrich (1962) used strips of external/muscle fascia.[18] Havlicek (1972) used a lyophilised dural sling. Beck and Lai (1982) used a fascia lata sling .[19] Poliak et al (1984) used tendon from palmaris longus muscle (6 patients only) .[20]

Other (plastic) sling techniques: Bracht (1956) , performed a nylon sling;[21] Anselmino (1952), used a Perlon sling);[22] Zoedler (1961), used a nylon sling.[23]

Aldridge sling operation - (1957)

McLaren (1968) reported that the major post-operative complication was delay in micturition.[24,25] Transection of the urethra was reported. Initial success rate was 87%, falling to 71% in periods of up to 16 years. Patterns of micturition were altered, as 16 out of 48 patients had to stoop to allow the bladder to empty completely.

McLaren also quotes a case whereby a sling operation made the patient continent when she was upright but if she bent down, e.g. when gardening, then urine escaped involuntarily.

Comment

The fact that 16 out of 48 patients had to stoop to allow the bladder to empty completely implies that a secondary sphincteric action, stretching upwards of the sling by the rectus abdominis may be part of the mode of action of the Aldridge sling operation. This is not, of course, under neurogenic control.

Similarly, Beck and Lai (1982), in reviewing 88 cases[26] noted a principal complication of delayed voiding times (average successful voiding time 40.7 days). They felt that the cause was one of detrusor muscle hypotonia, usually associated with previous severe incontinence, interference with funnelling of the bladder neck, which is necessary for voiding, and excessive urethral kinking at the sling site when the patient strained to void. Detrusor overactivity, some of it appearing for the first time, was considered to be a major cause of operative failure. Other complications were DVT, pulmonary atelectasis, total inability to void, and wound infection. Cure rate was 88.6%. They considered that the modus operandi of the operation is the provision of support to the bladder base and urethra, replacing the poor tissues which prevented this pressure equalization in the first place.

Parker et al (1979) use a variation in their technique.[27] They dissected away the pubocervical fascia of the anterior vaginal wall, sutured it over the bladder and urethra and then placed a fascia lata strap connecting up to the anterior abdominal wall. Their mean average time for urination was 12 days and they felt that the mechanism of action was to lift up the bladder neck during all Valsalva manoeuvres. They agree with Ridley (1966) that the chief error of a sling operation is placing too much tension on the sling, and that there is a problem in trying to have an objective means of measuring sufficient tension in the anaesthesised patient, because "we do not feel that intra-operative urethral pressure profiles with the patient anaesthesised and recumbent, or mechanical determination of tension on the sling under the same conditions, can be directly related to forces generated by the conscious patient in the upright position".[28] McGuire (1976). Intra-operative pressure determination is, however, an essential part of McGuire's Technique, (1976).[29]

Williams/Telinde operation

Mersilene ribbon 5mm in width was used by Williams and TeLinde (1962). They have reported a series of 12 cases but ultimately it was abandoned because of a propensity to transect the urethra. Two out of the twelve cases were reported as having either a suprapubic sinus or abscess sinus. Other complications were retention, standing in order to be able to void. The cure rate was nevertheless high, with nine cases cured and one improved out of twelve).[30]

Marlex sling operation - Morgan (1985)

A total of 281 patients mostly with multiple failed operations had a suburethral Marlex Sling inserted.[31] Cure rate: 77.4%. Complications: 7% had sloughing of their urethra. Five per cent had difficulty emptying their bladder; 5% had a new incidence of urgency and frequency; 3% had large haematomas. Other complications included stone formation, late transection of urethra, (1 & 3 years), and, of course, the intra-operative risk of bladder and urethra perforations. The authors suggest that in spite of its complications, this operation may be an acceptable alternative to urinary diversion. Morgan states that no slings have been rejected or removed. This does not accord with the experience of Barton (1989). Slings were removed in 3/37 patients. Skipper (1977) reported 1/30 removals.[32]

Drutz et al (1990): Sixty five women had operations, ulceration of the anterior vaginal wall was present in 4 patients, 1 patient died, success rate with urge incontinence was 75% and stress incontinence 95.3%, residual urine increased from 89mls to 129mls post-operatively.[33] There was a reduction in peak flow. No comment was made as to the number of hospitalization days or as to urinary retention.

Polytetrafluoroethylene suburethral sling procedure (PTFE)

This was performed for the first time and reported by Horbach, Blanco, Ostergard et al in 1988 (34). The material used is a non-absorbable polytetrafluoroethylene which is designed for use as a prosthetic material. The inert, porous microstructure of polytetrafluoroethylene, according to the authors, facilitates tissue incorporation without excessive foreign body reaction, and apparently allows treatment of an infection without graft removal. The authors reported a series of 17 patients with genuine stress incontinence and low urethral closure pressures, documented by urodynamic testing. Patients with a primary diagnosis of genuine stress incontinence and resting maximum urethral closure pressures of 20cm of water or less in the sitting position at maximum cystometric capacity were eligible for this sling operation.

Operative technique was similar to the Marlex sling. The graft was trimmed to 20cm x 1.5cm except for a 3cm x 2.5cm elliptical portion in the centre of the graft. The graft was sutured to the fascia overlying the urethrovesical junction and proximal urethra with two interrupted polytetrafluoroethylene sutures. The tension on the graft was adjusted to create a -5 degree Q Tip angle with the horizontal. Out of the 13 patients who had post-operative evaluation, 3 patients had no history of anti-incontinence procedures. Three others had had an endoscopic suspension procedure. i.e. at least 6 out of the 13 had not had any operation which could have implicated the urethra. Average hospital stay was 6.2 days and the average suprapubic catheter duration was 29.2 days. Two patients required intermittent self-catheterisation. One patient developed a wound seroma after her hospital stay. Despite initial healing, the patient suddenly developed an abdominal sinus tract. Surgical re-exploration showed the tract involved the graft, which was no longer under tension and was therefore removed. Functional urethral length increased from 1.6 to 2.1 cm post-operatively and the maximum urethral closure pressure was found to increase from 11.4 to 36.1 cm. Objective cure was seen in 11 of 13 patients.

PTFE sling

Summitt et al (1992) Results: Ten out of 48 patients required intermittent self catheterization. Six continuing beyond three months, six needed to be removed due to erosion or sinus formation, 62 developed at least one urinary tract infection, 29% demonstrated post-operative bladder instability which half were of new onset. The sling material used was PTFE, i.e. a type of Teflon (35).

Silastic sling

Korda et al (1990) performed this operation for indications which included previous failed bladder neck elevation procedures (13 patients), chronic obstructive airways disease (22 patients) and inability to elevate the vagina (32 patients). Eighty one per cent of patients were cured, 6 patients required self-catheterization and 9% of patients had voiding difficulties twelve months after the procedure. Two patients developed sinus tract, post-operative urinary retention was

common (9 to 99 days). Sixteen patients required release of the sling to establish voiding (36).

Critical analysis

In principle, the above operations are similar to the Marlex Sling operation. It is very hard to justify a sling operation on patients who have had no previous procedure performed, especially as 15%-20% of the patients subsequently need self-catheterization.

The reporting of a seroma post-operatively contrasts with the claim earlier that polytetrafluoroethylene is an inert material. Huland et al (1984)[37] reported a 10% incidence of fistulae with a mean recurrence time of 15.3 months using a No. 3 monofilament polyamide suture material. Whereas the sinus formation in the experimental animals in this thesis is at least partly attributed to the dogs' hypersensitivity to braided suture material, the presence of a sinus shows that there is no such thing as an inert suture material. There will always be an instance or an individual where a reaction will occur, Tanagho (1980).[38] The fact that the graft was no longer under tension when it was removed is interesting. Almost certainly there was a fibrous tissue reaction around the graft and it has been found in the 2nd author's experimental animal work that the tape lies loosely within the created sinus tunnel.[39] In this case, almost certainly the reaction at the suturing to the rectus sheath would have allowed loosening of the tape.

A urethra with low closure pressure has virtually no resistance to leakage in the presence of defective closure mechanisms. Therefore a sling should constrict the bladder neck on effort. McGuire and Lytton attributed low maximal urethral pressures to a fibrotic urethra. In Horbach's series, 11 out of the 13 patients had a hypermobile urethra, suggesting that there was no fibrosis and rigidity. Therefore, it appears, on first glance, that a more dangerous operation was performed for inappropriate indications. The fact that the patient was under general anaesthesia meant that the anterior abdominal wall muscles were relaxed. On waking up and standing up then there would be further elevation of the UV junction due to contraction of the pelvic floor. Chassar Moir, in performing the Aldridge sling operation, used to leave enough space for a small finger to fit in, presumably to allow for this factor, William Garrett (personal communication) (1968). It is well known that the urethra is shortened in stress incontinence and one would expect an increase in functional urethral length, purely from the elevation of the urethra, by the sling. The upward force provided by the abdominal wall tension pulling on the posterior urethral wall by means of a 3cm x 2.5cm hammock per se could increase the intraurethral pressure by decreasing the area below the periurethral striated muscle,[39] according to the formula, pressure = force/area .

Absorbable polyglactin mesh for retropubic sling operations in female urinary stress incontinence - Fianu (1983).

Absorbable polyglactin instead of synthetic materials resulted in no tissue rejection in 21 patients observed 4-14 months. Cure was noted in 20 /21 patients.[40]

Porcine dermis bladder sling[41] - Jarvis (1985)

The operative success rate was 78% over a 21 month period. Complications such as postoperative detrusor instability (14%) and urinary retention were in line with other sling operations. Suprapubic cellulitis/weeping usually in the absence of bacterial growth was a feature of this operation.

Critical analysis

A major problem noted repeatedly in this survey is tissue rejection. Use of an absorbable mesh appears prima facie to provide the answer to this problem. However it has been demonstrated earlier (Bailey 1972)[42] that only plastic creates a permanent scar. Other irritants of a temporary nature (e.g. turpentine, carrageenan) are absorbed over a period of 6 to 12 months. In contrast the porcine dermis sling had a 50% tissue reaction, in spite of having been enzymatically cleaned and depilated. It is possible that this was an allergic type reaction. Nevertheless, the Lyodura sling (a human sling made from dura mater) has very few problems with rejection (1985).[43] Interspecies homology of collagens from the same tissue may be 85% to 95%, Peacock (1984). The difference may involve one amino acid base pair in the DNA molecule. The conclusion reached , is that the porcine dermis sling is not homologous, and therefore provokes a tissue rejection.

FIFTEEN POINT ASSESSMENT OF SLING OPERATIONS

(1) Invasiveness.

An abdominal sling is a highly invasive operation.

(2) Ease of performance.

The combination of atrophic tissues, scarring, and the inherent difficulties encountered by operating in a confined space populated by blood vessels ureters bladder and urethra all contained within a few square centimetres ensures that all sling operations require a considerable amount of skill.

(3) Built in safety.

It is not possible to structure these operations to incorporate such a factor. They are by their very nature the most traumatic, and the most uncontrollable in terms of long term complications such as urinary retention, transection, etc. Also, these operations required the most surgical skill and judgment. Nevertheless the sling operations using the patient's own fascia, e.g. in the Aldridge operation do have an in-built advantage over the other operations such as the Williams/Te Linde Mersilene ribbon operation. There is always some "give" in the sling. i.e., the lack of rigidity of the fascia gives the operation an in-built protection factor.

(4) Short term complications.

These may be severe, and include damage to bladder, urethra, ureters, perivesical veins (haemorrhage), infection.

(5) Long term complications.

A wound seroma occurred requiring operative removal of implants, fistulae, urethral stones, transection of urethra, herniation (fascial slings), pain in the scar region.

There is no indication given as to the more subtle complications found with sling operations, such as the quality of micturition, as patients often have to bend over to micturate.

Micturition may come in little drips, often with a squirting action from the bladder. The stream can be cut off midway and often has to be restarted.

(6) Applicability to the obese and patients with poor tissues.

These operations, by their very nature are technically difficult operations and also weaken the muscles and fascia of the anterior abdominal wall. If the tissues tore at the site of the artificial tape's attachment to the rectus sheath early in the post-operative period then operative failure is always possible. This is, in fact, highly likely as the shearing force would be quite considerable in an obese patient with poor tissues.

(7) Applicability for patients with previous incontinence.

The results of all the operations indicate that this is an operation of last resort McGuire however, advocates its use in patients with low urethral pressures. Dissecting the urethra and the provision of a constricting sling, would have a use in patients with a fibrotic urethra where all other means of

control of the incontinence had failed, and where urethral constriction is the necessary mechanism of action.

(8) Blood loss.

The average blood loss of 153ml recorded by Horbach, an excellent figure, was the only recording of blood loss for sling operations that I could find in the literature. In selected patients the blood loss may be considerable during sling operation. On this criterion this operation should be inferior to say the Stamey operation.

(9) Length of operation.

Generally, the authors do not state, length of operations, but even with two teams operating above and below, an hour would be a minimum time. Iosif reported times of 1-2 hours for the Zoedler and Lyodura sling operations. Fowler (1986)[44] reported operating times of 1-3 hours for Marshall Marchetti and Stamey procedures. If correct, however, then we would be looking at up to 4 hours for some sling procedures such as the Aldridge sling, especially in obese patients.

(10) Hospital stay.

As this operation is the most traumatic, with also very high rates of urinary retention, hospital stay is potentially the longest. There are very few references to hospital stay in the literature.

(11) Long term urinary retention.

Requiring self catheterization is a very serious and significant problem with this operation. Horbach (1988) reported 15%, Korda (1990) reported 10%.

(12) The success rate.

This varies between 61% and 94%. It is usually very close to 90% in most series. Hohenfellner and Petri (1980)[45] state that the success rate depends on patient selection and indication. Incontinence from detrusor contraction is not, however, usually included as a cause of failure. i.e. Stress incontinence is often the parameter assessed.

(13) Early resumption of normal activities.

This operation is the most traumatic, with very high rates of urinary retention. Return to work may take a long time.

(14) Anatomical damage. By its very nature this procedure is the most surgically traumatic. Uncontrolled scar formation is a principal complication with any surgical procedure, Peacock (1984).[46] Indeed, the fibrotic urethra is considered to be an indication for this operation according to McGuire.[29] Morgan is more explicit. He states that prior to insertion of his Marlex sling, the anterior scar in the Cave of Retzius, and the posterior vaginal scar must be released.

(15) Restoration of normal anatomy.

The anatomy is not actually restored in these operations. Morgan[31] states that the process of elevation per se may cause enterocoele, as in other bladder neck elevation operations. The physiology of return to urinary continence in these operations is still not properly understood. McGuire found an increase in intraurethral pressure post-operatively. Henriksson and Ulmsten (1978)[47] did not. Both studies found increased cough transmission profile. Almost all authors (Morgan, McGuire, Stanton, Beck, to name but a few), report uninhibited detrusor contractions after this procedure. There is no consensus concerning the modus operandi of the sling procedure. Kinking of urethra is considered a primary mode of action, Beck et al (1982). McGuire demonstrated a drop in urethral closure pressure prior to the onset of a detrusor contraction, indicating that the sling was not a significant cause of obstruction "unless the patient attempted to void entirely by straining". Stanton considers that elevation of the proximal urethra to an intra-abdominal position, plus support of the posterior urethra allowing better pressure transmission are also significant factors. Wheeless et al (1977)[48] believe that the sling elevates the urethra slightly on increased intra-abdominal pressure, and also that the intraurethral pressure is raised by elevation of the posterior urethral wall. According to the Integral Theory,[39] the sling provides an anchoring point for the proximal and distal urethral closure mechanisms.

Critical analysis

The mode of action of the sling operation as quoted by various authors is that the sling elevates the bladder neck. This may not be strictly correct. It is inconceivable that the fascia lata sling would elevate the urethra precisely at the point where it passes underneath it. Almost certainly fibrous tissue formation results, so that the whole anterior vaginal wall is probably lifted up, although by virtue of the indentation made by the sling, constriction would be applied at the point where it passes under the urethra if the suture was too tight. No detailed studies have been made as to the other modes of action of this operation. It is quite likely that the considerable amount of haemorrhage that is provoked will lead to adhesions, probably between the vagina and the pubic symphysis. As well, there is no mention made as to whether or not the actual sling remains viable. It is highly likely that a necrosis will occur, and an alternative blood supply will form. McGuire's (1976) exclusion of obstruction by referring to a premicturition drop in urethral pressure does not make sense if, as seems likely, the drop may be reflexly induced , and if other factors e.g., either smooth or striated muscle contraction are involved as components of urethral pressure. The very high rate of unstable detrusor reported after these operations has been simply ignored by all authors. No explanation is attempted. The intra-abdominal pressure equalization theory cannot in any way explain this phenomenon. Wheeless et al (1977) believe that the sling elevates the urethra slightly on increased intraabdominal pressure, and also that the intraurethral pressure is raised by elevation of the posterior urethral wall. The authors conclude on a strong doubtful note, however, in questioning that if the foregoing were all true, how can cure of congenital defects such as total bladder exstrophy occur with this operation? The alternative explanation, Petros and Ulmsten (1990), is that the levator plate pulls back the vagina and bladder neck and then kinks the urethra at the bladder neck by contraction of the longitudinal muscle of the anus. The sling, therefore, provides a fulcrum point for such "kinking". However, the position of the sling at bladder neck prevents the active funneling required to open out the urethra, a pre-requisite for the exponential fall in intraurethral resistance which allows nomal micturition.[39] Post-operative urgency associated with bladder neck slings is explained as being caused by upward pressure of sling on the nerve endings of urethra and bladder neck.[39]

CONCLUSIONS

The main obstacle to abdominal slings becoming day-care operations revolve around the obstruction of urination by the positioning of the sling at bladder neck. This prevents the funneling required to reduce intraurethral resistance to urine flow, potentially causing obstructed micturition. Excess pressure on the overlying stretch receptors may cause de novo urgency. Finally, the large incisions required to access the operation site may cause organ damage, hemorrhage and thrombosis.

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Original article

Pelvic floor related quality of life after vaginal mesh implantation. Secondary endpoint of a prospective randomized trial

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Abstract: Objective: To evaluate the impact of mesh implantation and the type of mesh used on pelvic floor related quality of life (QoL). Mesh implantation is commonly used for prolapse repair, but mesh exposure and chronic pain are risks. *Material and methods:* Pre- and postoperative QoL was evaluated as secondary endpoint of a prospectively randomized multicenter open-label trial; primary endpoint was the difference of exposure rates between a nonabsorbable and a partially absorbable mesh. QoL was evaluated after 3, 12, and 36 months using a validated pelvic floor questionnaire, together with visual analogue scales on pelvic floor pain and satisfaction with surgery and compared to baseline by paired t-tests. Mean scores within treatment groups at 36 months were compared adjusting for baseline values in a linear regression model. *Results:* Between 2007 and 2008, 200 patients with cystocele ≥ stage 2 were centrally randomized to the nonabsorbable (n=102) or the partially absorbable (n=98) mesh. QoL improved significantly after 3 months, remaining constant: mean±SD 8.3±3.2 preoperatively (n=193) to 3.9±2.9 (3 months, n=188), 3.6±2.5 (12 months, n=186), 3.8±2.7 (36 months, n=181). Change from baseline was significant ($p \leq 0.002$). There were no relevant differences among study arms; at 36 months, QoL improved by 0.6 points more for the partially absorbable (n=85) than for the nonabsorbable mesh (n=84; 95%, CI: -0.2 to 1.4). *Conclusions:* We demonstrate a clinically relevant improvement of pelvic floor related QoL together with improved pelvic floor pain and high satisfaction after 3 years, with an equal improvement in both study arms.

Key words: Quality of life; Pelvic organ prolapse; Sexuality; Polypropylene mesh; Pelvic floor pain.

Abbreviations: POP pelvic organ prolapse, QoL Quality of life, PP nonabsorbable mesh, PA partially absorbable mesh, FDA US Food & Drug Administration, ICS International Continence Society.

INTRODUCTION

Pelvic organ prolapse (POP) is a health condition that virtually never affects patients´ life expectancy but has a significant impact on the quality of life of women. Almost one third of women suffer from POP during their lifetime, and the lifetime risk for POP and incontinence surgery at the age of 80 is approximately 11%.[1,2] Quality of life is reduced because women feel ashamed or due to impaired bladder and bowel function. Women may refrain from sexual intercourse because they are afraid that POP could worsen or because they do not want to present themselves to their partner in this condition.[3] Considering that many POP patients are active women with many more years of life expectancy they need an operation that a) produces long-lasting results and b) does not impair their quality of life.

There are several techniques of native tissue repair for anterior vaginal wall prolapse, colporrhaphy being the most frequently used. For this procedure a recurrence rate of up to 40% is known.[4] Classical surgery techniques have been partially replaced by vaginal mesh repair due to better anatomical outcomes.[5] Unfortunately, there are few randomized trials directly comparing native tissue repair with vaginal mesh implantation.[6] However, only recently the ongoing discussion of risks of mesh repair has been renewed after the second warning of the US Food & Drug Administration (FDA).[7] A well-considered reply to the FDA warning has been authored by Murphy et al. on behalf of the Pelvic Surgeons Network.[8] In 2013 another update on the Cochrane analysis on mesh repair was published. This update emphasizes the need for more data on quality of life after mesh repair, as the anatomic results are superior compared to native tissue repair.[5]

With the increasing number of patients treated using vaginal meshes, new postoperative problems have emerged. While native tissue repair also has specific problems, mesh implantation is under discussion for the risk of mesh exposure, dyspareunia and chronic pelvic pain. Mesh exposure is the most common problem and the risks have not been completely understood. Both simultaneous hysterectomy and younger age seem to play an important role.[9] Dyspareunia and chronic pelvic pain are difficult problems, because often the exact cause is unknown and treatment may be difficult. Pain may be due to shrinking of the mesh or compression of pudendal nerves or scarring. Possible treatments are partial excision of the mesh, pelvic floor exercises or infiltration with local anesthetics.[10,11]

In order to evaluate the long-term subjective and objective outcome of vaginal mesh repair this prospectively randomized study was initiated (PARETO-trial, German Clinical Trials Register DRKS00004566). Patients were randomized either for a nonabsorbable or a partially absorbable mesh. The primary endpoint was the effect of the type of mesh used on the mesh exposure rate; as secondary endpoints the effect of POP repair on quality of life and whether the type of mesh used made any difference were tested. The hypothesis was that the lighter mesh would cause less mesh exposures compared to the nonabsorbable meshes. Furthermore, less pain was expected after implantation the partially absorbable mesh. Whether there would be a difference regarding QoL between the treatment groups could not be forecast.

MATERIAL AND METHODS

Patient randomization, the mesh, surgical technique

After approval of the local ethics committee, 200 patients were included in this two-arm prospective open-label study. Surgery was performed in one of six urogynecologic centers in Germany between 2007 and 2008. All patients eligible had a cystocele stage 2 or above in combination with a lateral defect and risk factors for POP (e.g. obesity, constipation). The exclusion criteria were as follows: age <18 yrs, imcompleted family planning, allergy to polypropylene, previous malignancy of the urinary tract, genital organs or rectosigmoid, previous mesh implantation, missing informed consent, life expectancy <3 yrs or patients who could not ensure follow-up visits over 3 years. The prolapse was classified according to the International Continence Society (ICS) definition.[12]

After informed consent, patients were randomized for either a nonabsorbable prolypropylene mesh (PP group) or a partially absorbable mesh of the same size and shape (PA group) (Seratom®, Serag Wiessner, Germany). The threads of the partially absorbable mesh are made of polypropylene filaments with an absorbable coating of polyglycolic acid and caprolactone. Following absorption after approx. 120 days, a light and soft mesh remains. Patient characteristics, the exact features of the mesh and the surgical technique, which was identical in both groups, have been described before.[13] For treatment concealment, block randomization with a 1:1 allocation ratio and variable block size, stratified for center, was performed by the study's main office. There was no blinding to group assignment. For reasons of practicability and feasibility a sample size of 100 patients per group was chosen, as mesh exposure rates vary from 2% up to 25%.[4, 14-15]

Primary and secondary outcomes

The primary end point of the study was to evaluate mesh exposure rates at 12 months after surgery. As secondary endpoints, risk factors for mesh exposure, the influence of the mesh used on POP recurrence and, as reported here, the effect on pelvic floor related quality of life were evaluated.

Quality of life data

For evaluation of pelvic floor related quality of life the German version of a validated pelvic floor function questionnaire was used.[16, 17] It was completed by the patients on paper before the operation and at follow-up visits. Patients unable to come for follow-up were contacted by mail and asked to fill out the questionnaire in order to achieve a low drop out rate.

This questionnaire comprises 15 questions on bladder and 12 questions on bowel function, 9 on sexual activity and 5 on prolapse sensation. The four resulting scores of each domain range from 0 to 10, with 0 representing no problems and 10 representing high dysfunction. Furthermore, a summary score including bladder and bowel function and prolapse symptoms, ranging from 0 to 30, can be calculated. In accordance with the recommendation of the questionnaire´s author the sexual function score was not included in the total score, as approximately one half of the study population was not sexually active. Regarding clinical relevance, an improvement of the subdomains was considered significant if change from baseline was >1, regarding the total score >2-3 points.[17]

Visual analogue scales

Apart from the validated questionnaire, patients filled out a visual analogue scale regarding satisfaction with the operation (range 0 to 10; 0 meaning no satisfaction, 10 highest satisfaction) and pelvic floor related pain (range 0 to 10; 0 meaning no pain, 10 corresponding to strong pain).

Follow-up visits

Follow-up was scheduled at 3, 12 and 36 months at the operating hospital. Apart from quality of life data, mesh exposure rates and other clinical data (further surgeries etc.) were obtained. Mean follow-up time of the study population was 3.3, 13.7 and 39.1 months.

Statistical analysis

Distributions of score values at follow-up time points were compared to baseline by paired t-tests. Mean scores within treatment groups at 36 months were compared adjusting for baseline values in a linear regression model. Satisfaction with surgery and pelvic floor pain were compared between treatment groups in a cumulative logit model. The model for pelvic floor pain was adjusted for baseline pain measurements. Throughout, complete case analyses were performed, and two-sided p-values <5% were considered statistically significant. SPSS version 19 and SAS version 9.2 were used for statistical calculations.

RESULTS

Patient characteristics and follow-up

From 02/2007 to 07/2008, 200 women with POP were included in the study. Patient characteristics of the two treatment groups regarding surgery and medical history were similar.[13] Follow-up was performed between April 2007 and December 2011. 198 patients were treated according to the study protocol, with 101 patients in the PP group and 97 in the PA group. In 120 patients, additional sacrospinous suspension was performed in view of a central defect, using arms 5 and 6 of the mesh.

Quality of life data could be obtained from 196, 188, 186, and 181 patients at baseline and after three, twelve and 36 months of follow-up. There were various reasons for missing follow-up mainly that women were too sick or too old to come to the hospital or that the contact address had changed. The CONSORT-PRO flowchart is shown in fig. 1.

Quality of life data: Questionnaire

Preoperative QoL scores were compared to values at 3, 12 and 36 months of follow-up. The overall score including bladder, bowel and prolapse sensation improved significantly: the mean score ±SD was 8.3±3.2 preoperatively (n=193), 3.9±2.9 after 3 months (n=188), 3.6±2.5 after 12 months (n=186) and 3.8±2.7 after 36 months (n=181). Change from baseline was of a clinically relevant order of magnitude and also statistically significant at all three time points (mean improvement 4.6±3.5, p <0.001 at 3 months (n=180); 4.7±3.5, p= 0.001 at 12 months (179); 4.8±3.7, p= 0.002 at 36 months (n=170). This improvement was mainly due to the subdomain covering prolapse sensation.

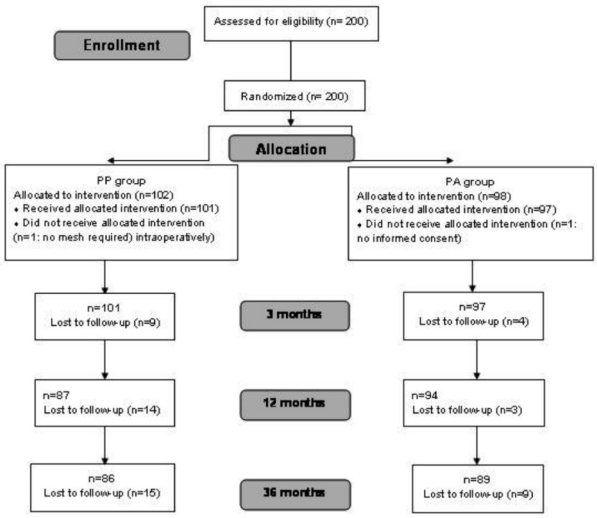

Figure 1. - CONSORT-PRO statement.

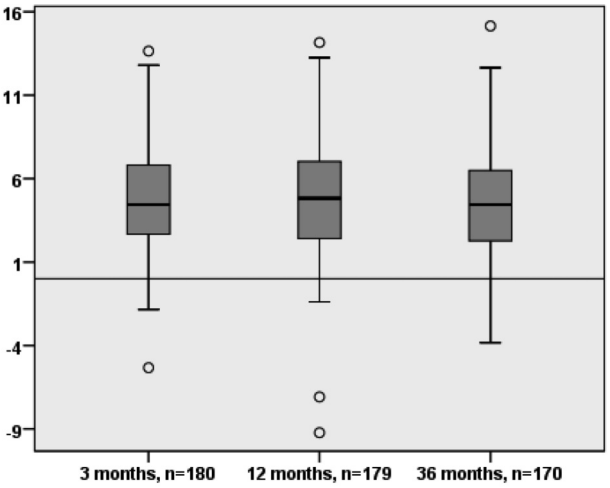

Figure 2a. - Total score change (bladder, bowel, prolapse).

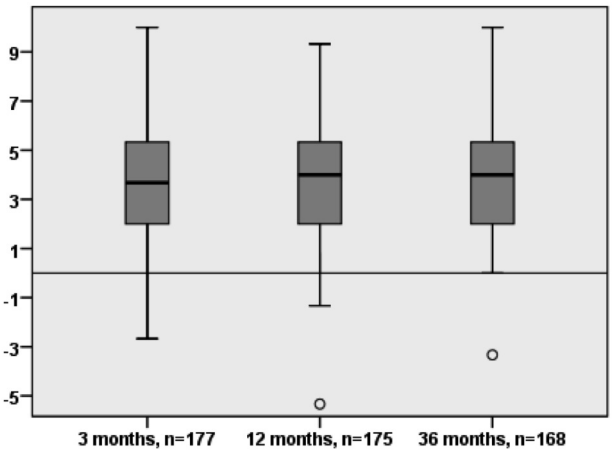

Figure 2b. - Prolapse score change.

Sexual function did improve, however not significantly (mean score 1.9±1.6 preoperatively (n=93) vs. 0.9±1.3 after 3 months (n=78), 1.1±1.4 after 12 months (n=91) and 1.1±1.6 after 36 months (n=74). Looking at the mean age of our patients being 67 years (range 35-88 yrs), only part of them were sexually active: 47.7% (93/195, missing n=3) preoperatively vs. 42% (76/181, missing n=17) at 3 months, 50.6% (89/176, missing n=22) at 12 months and

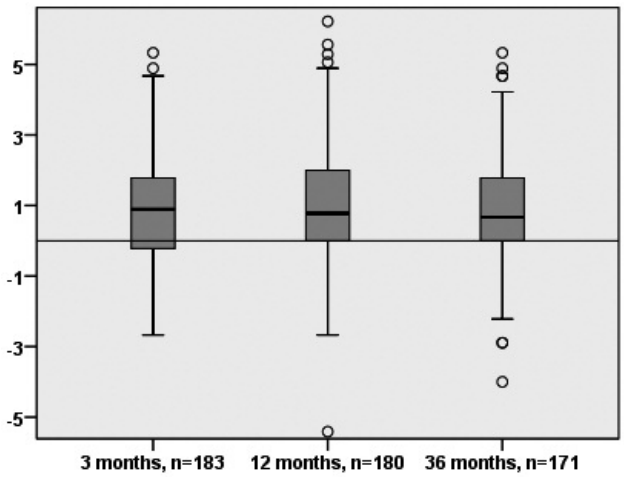

Figure 2c. - Bladder score change.

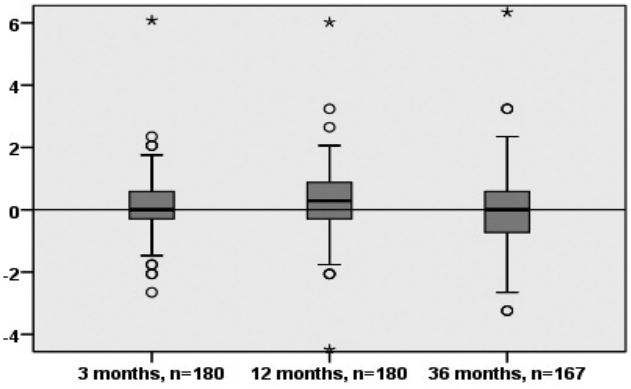

Figure 2d. - Bowel score change.

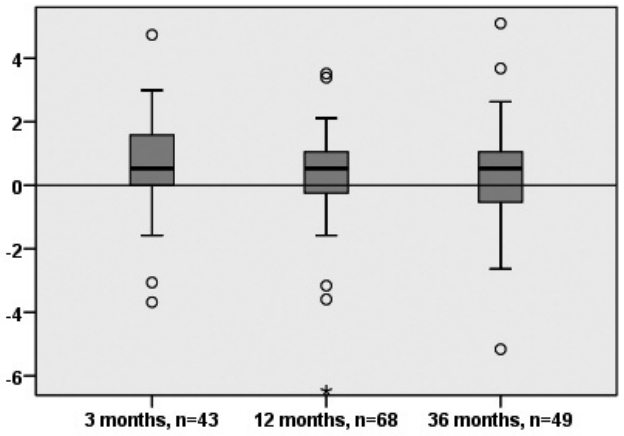

Figure 2e. - Sexuality score change (within the sexually active).

43% (74/172, missing n=26) at 36 months. Among the sexually inactive women, the main reason was "missing partner" or "sickness of partner" (60% (63/105) preoperatively vs. 61.3% (57/93) after 36 months). Only 49 patients answered the questions on sexual activity both at baseline and at 36 months. For details, see Figures 2 a-e. Bowel function did not show a relevant change after surgery (1.6±1.2 preoperatively (n=193) vs. 1.6±1.2 at 3 months (n=188), 1.4±1.2 at 12 months (n=184) and 1.7±1.3 after 3 years (n=174). Also in patients who had a simultaneous posterior repair by colporrhaphy or using mesh, the bowel function score did not change relevantly (n=93, data not shown).

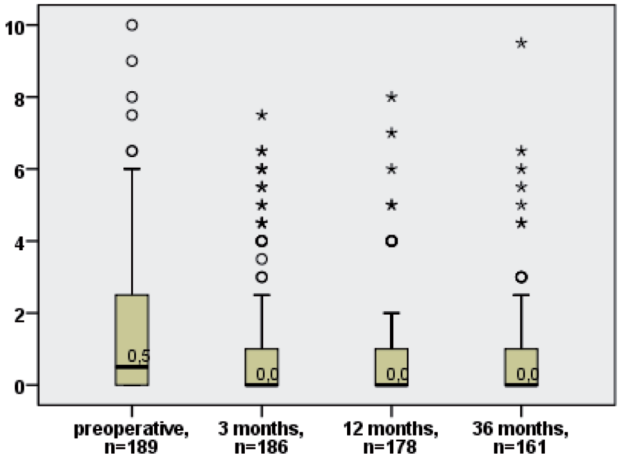

Figure 3a. - Pelvic floor related pain (0= no pain, 10= strong pain).

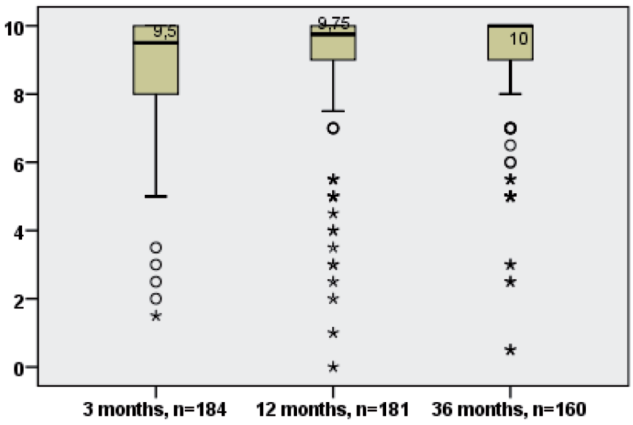

Figure 3b. - Satisfaction with the operation (0= not satisfied, 10= very satisfied).

Visual analogue scales

Preoperatively, the mean score of pelvic floor related pain was 1.5±2.1 (n=189) on a scale ranging from 0 to 10 (10 meaning strong pain). This was improved after 3 months to 1.1±2.0 (n=186), to 0.9±2.0 after 12 months (n=178) and after 36 months to 0.7±1.5 (n=161); see figure 3. Change from baseline was statistically significant at all three follow-up visits ($p< 0.05$, data not shown).

Satisfaction with the operation on a scale ranging from 0 to 10 (10 meaning very satisfied) was very high at all three time points (8.7±2.0 at 3 months (n=184), 8.7±2.2 at 12 months (n=181) and 8.7±2.2 after 3 years (n=160), (Figure 3).

Influence of mesh type on QoL data after 3 years

Apart from the primary outcome of mesh exposure rates,[13] the influence of randomized mesh type used on pelvic floor related QoL after 3 years was evaluated. All quality of life data were compared between the two study groups (Table 1). Changes from baseline of the QoL total score and subscores were similar in both study arms. Clinically relevant differences between them could be excluded for all scales, based on confidence intervals for the treatment effects (Table 1). Similarly, the visual analogue scale regarding pain showed comparable results in both arms, and also satisfaction with the operation was at the same level. However, the confidence intervals for the effect of treatment on pain and satisfaction with the

TABLE 1. – Difference in QoL data among nonabsorbable (PP) and partially absorbable (PA) mesh.

Score (range: best to worst)	**Baseline scores**		**Change from baseline (baseline-month 36) unadjusted means**		**Difference adjusted for baseline**	**95% CI**	**p-value**
	PP	**PA**	**PP**	**PA**	**PA - PP[1]**		
Total score (0 to 30) n	8.6 99	8.1 92	4.3 84	4.4 85	0.6	-0.16 to 1.4	0.1220
Bladder (0 to 10) n	3.0 100	2.4 96	0.7 83	0.8 86	0.4	-0.02 to 0.79	0.0624
Prolapse (0 to 10) n	3.9 99	3.7 92	3.8 84	3.7 84	0.1	-0.15 to 0.31	0.4880
Bowel (0 to 10) n	1.5 100	1.6 93	-0.2 84	0.0 85	0.2	-0.18 to 0.50	0.3432
Sexuality (0 to 10) n	2.3 43	1.6 50	0.6 20	0.2 29	0.0	-0.80 to 0.88	0.9297
Visual analogue scales (range: best to worst)			**Change from baseline (baseline-month 36) medians [unadjusted means]**		**Odd ratio for greater pain (>1 pt.), adjusted for baseline, PA vs. PP[2)]**		
	PP	**PA**	**PP**	**PA**	**PA - PP[1]**		
Pain (0 to 10) n	1.7 95	1.3 94	0 [0.8] 73	0 [0.9] 73	0.98	0.54 to 1.79	0.9469
			Month 36, medians		**Odd ratio for greater satisfaction PA vs. PP[3)]**		
Satisfaction (10 to 0) n	n.a.	n.a.	10 76	10 84	1.1	0.63 to 2.04	0.6729

[1)] A value above 0 favours PA; [2)] A value below 1 favours PA; [3)] A value above 1 favours PA
PA, nonabsorbable polypropylene mesh; PP, partially absorbable mesh; CI, confidence interval

operation were too wide to exclude a potential difference of clinically relevant magnitude (Table 1).

DISCUSSION

It has become clear in recent years that POP needs to be seen and treated in all its complexity, taking into account all effects it has on affected women's quality of life. In this prospectively randomized trial on 200 women, a positive course of patients´ quality of life after vaginal mesh implantation could be demonstrated. All patients underwent surgery mainly for cystoceles. As expected, bladder function and prolapse sensation improved after the operation. Furthermore, sexual function improved, however not at a statistically significant level. Bowel function did not show a relevant change. This is also true for patients with additional surgery for posterior compartment prolapse.

Overall, pelvic floor related quality of life improved significantly. These effects could already be seen at 3 months´ follow-up, but remained constant after 3 years. In the comparison of the two meshes, the absorbable -meshes showed a negligible benefit compared to the non-absorbable meshes for the four domains and for the total score. Since all confidence intervals exclude clinically irrelevant differences, we conclude that both treatments worked equally well with respect to pelvic floor related QoL (Table 1). To our knowledge, there are no other prospectively randomized studies on the quality of life after mesh implantation with a similarly long follow-up.

Furthermore, the effect of the partially absorbable mesh on patients' pain was under investigation, as one could assume that a lighter mesh causes less pain. At all three follow-up intervals we observed less pelvic floor related pain in the group which had received the lightweight mesh, but the difference in change from baseline was not statistically significant between the treatment groups. The lower pain score may be due to the special features of the partially absorbable mesh, supplying good support without rendering the tissue too firm to yield. On the other hand, the mesh must not be too thin as this could cause more recurrent prolapse.[13]

As for the risks of vaginal mesh implantation, the two most relevant risks are mesh exposure and chronic pelvic pain. According to the most recent Cochrane data, the risk of mesh exposure is 11.4% on average, with surgical interventions being necessary in 6.8%.[5] In the majority of cases, mesh exposure causes minor or no problems for the patients even in long term follow-up and can mostly be handled by local estrogen application or partial excision of the mesh.[18] An adequate patient selection and profound surgical training is important for successful mesh-based repair.[19]

Chronic pelvic pain originating from the operation is something that surgeons using vaginal meshes dread. An operation causing chronic pain is a severe problem. Therefore, the reasons of chronic pelvic pain after mesh implantation need to be studied further on in order to improve surgical techniques and also to identify patients who are at special risk. In this trial, we compared pre- and postoperative pain. Interestingly, the change from baseline in pelvic floor related pain was statistically significant, with improvement after the operation.

In order to evaluate patients' satisfaction with the operation, a visual analogue scale on this topic was included in the questionnaire. Patients' satisfaction was very high and consistently remained at this level. Patients with mesh exposure did not have a higher pain score than those patients with complete wound healing. Amrute et al. could also show high patient satisfaction after mesh augmented surgery.[20]

As a limitation of the study, we cannot draw any conclusion whether the improvement in QoL is comparable to patients treated with native tissue repair. This has been investigated in a trial by Nieminen et al., showing better relief of bulge symptoms after mesh implantation compared to native tissue repair.[21] Furthermore, not all our patients were available for follow-up, especially after 3 years.

In summary, in this multicenter, prospective and randomized study we describe a relevant improvement of QoL in patients after mesh augmented POP surgery. After a follow-up time of three years, no difference between treatment groups was observed. Patients' satisfaction was very high over the course of time. Pelvic floor related pain decreased significantly after surgery compared to preoperative data. Being conscious of the risks of mesh surgery, we hereby present data emphasizing good quality of life after mesh augmented POP repair.

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Original article

Assessment of sexual relations in women with Mayer-Rokitansky-Küster-Hauser Syndrome after sigmoid neovaginoplasty (a mixed method analytical approach)

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Abstract: Objective: To evaluate sexual satisfaction and distress scale score of women with MRKH syndrome after sigmoid neovaginoplasty, and how it affects marriage life. *Method:* A mixed method study, using The Sexual Satisfaction Scale for Women (SSS-W) as the quantitative method, continued by focused interview as the qualitative method, on eight women with MRKH and sixteen normal women. The research was held in Hasan Sadikin hospital. Result: Quantitative method results with t test shows the mean score of sexual satisfaction and distress scale corresponding to the equivalent score of normal women, measured by contentment, communication, compatibility, relationship and personal distress factors with p value: 0.083, 0.496, 0.056, 0.971 and 0.266 respectively. Qualitative method shows analysis of seven themes which are described under the following headings: sexual relations, partner's reaction to women with MRKH, relationships with partners, patients' concerns, motivations to have operation, family support, and self esteem as female. Participants who underwent neovaginoplasty were able to engage successfully in sexual intercourse. Partners of our patients could accept the MRKH condition and were satisfied with the neovagina. Participants have good relationship with partner. Participants' current concern related to the inability of bear children. Motivations to have operation were to have better sexual relations. Family support is very important. Positive self-esteem, including self-confidence, was related to a successful treatment outcome. *Conclusion:* Sigmoid neovaginoplasty is an effective technique to improve sexual relationship and help to alleviate distress of women with MRKH.

Key words: Distress; Mayer-Rokitansky-Küster-Hauser syndrome; Mixed Method analytical approach; Sexual relations.

INTRODUCTION

Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome is one of many Disorders of Sex Development (DSD), characterized by a normal female phenotype with congenital aplasia of the uterus and the upper part (2/3) of the vagina with functional ovaries, normal development of secondary sexual characteristics and a normal 46, XX karyotype.[1-3]

A woman's sense of well-being and quality of life are impacted by the condition.4 The incidence of MRKH syndrome has been estimated as 1 in 4500 female births, but need special attention due to the impact on patient's life.[2]

The management of MRKH falls into two categories: the need to anatomically manage the anomaly so that women could engage more easily in sexual intercourse and the need to help women cope with the psychological impact of the condition.[4] The ideal surgical technique for neovaginoplasty is the one that can provide the patient with a vaginal vault of sufficient size, adequate introitus and an acceptable cosmetic external appearance.[5] Many methods of vaginal reconstruction were reported, including the non operative (Frank procedure) and operative technique (including McIndoe and Sigmoid neovaginoplasty), but the chosen method needs to be tailored to the individual needs, motivation of the patient and the options available.[6]

Since 1990-2009, the urogynecology subdivision of Obstetrics and Gynecology Department in Hasan Sadikin Hospital Bandung are using McIndoe procedure which involves insertion of a mold covered with split thickness skin or amnion graft into the created neovaginal space followed by postoperative vaginal dilation.[7] High percentage of vaginal stenosis was reported after 1 year. Moreover, this modality requires long term vaginal dilatation and stenting by a vaginal mold which affects the patient`s psychological condition.[5]

Since 2009 we have started using sigmoid for vaginal replacement. The use of isolated bowel segments has been shown to provide excellent results, circumventing the need for regular dilatation. Long term evaluation shows minimal complications and low risk of stenosis.[8] The sigmoid neovagina shows a good anatomic result, but it's also important to evaluate how it affects patient's sexual relations.

Treatment of MRKH syndrome, poses challenges that go far beyond physical concerns. Additionally, it has been recommended that a shift in emphasis takes place from the physical aspects of DSD to how individuals adjust to the conditions. Consensus Statement on the Management of Intersex Disorders suggested that more attention be focused on the psychological aspects of DSD.[1]

Genital surgery on one side, is typically presented as an obvious solution, but on the other hand, genital surgery can itself be stigmatizing and shaming.[9] The centrality of surgical correction in care delivery may have inadvertently sidelined the development of quality care that targets psychological adaptation, and more commitment from service providers will be needed to make this a primary focus in clinical management. Shame and fear of repercussions may continue to render personal communications about DSD too challenging for some individuals. So perhaps the most important collaboration between professional and user communities, ultimately, is a long-term social project to improve public understanding of DSD.[10]

Although the outcomes of surgical treatments to create a new vagina have been reported, there have been few reports addressing the psychological impact of the condition and quality of life (QoL) outcomes. There was no previous research aimed to evaluate the result of sigmoid neovaginoplasty in Hasan Sadikin Hospital. The aim of this study is to evaluate patient's sexual relations after sigmoid neovaginoplasty and how it affects marriage life.

Quantitative research is not an appropriate paradigm for psychotherapy research. Qualitative research or clinical observation should be the evidence source.[11] This study supports the consensus statement that psychological issues as well as medical aspects must be addressed in order to provide optimal care, using qualitative-quantitative method.

SUBJECTS AND METHODS

Subjects

This study included women with MRKH syndrome who underwent sigmoid neovaginoplasty as their surgical treatment from 2009 to 2012. All women with current partners were offered to participate in the study together. Subjects chosen for focused interview by stratified purposive sampling.

Normal women were chosen from the outpatient gynecological clinics of Hasan Sadikin Hospital, which had primary infertility, and have matched qualities of the control group. The ratio between MRKH patients and normal women was 1:2.

Methods

This is a mixed method study using explanatory sequential design. The primary method chosen as the quantitative method was The Sexual Satisfaction Scale for Women (SSS-W) questionnaire to measure patients' sexual relations, followed by focused interview as the qualitative method.

The quantitative method was cross sectional, whilst the qualitative method was descriptive ethnographic.

The study was approved by the Committee on the Ethics of Human Research.

The Sexual Satisfaction Scale for Women (SSS-W)[12]

The SSS-W was developed to provide a comprehensive measure of sexual satisfaction and sexual distress that would benefit researchers and clinicians interested in further understanding what constitutes sexual satisfaction in women and how it relates to levels of sexual functioning. The SSS-W is a brief, 30-item measure of sexual satisfaction and sexual distress, composed of five domains supported by factor analyses: contentment, communication, compatibility, relational concern, and personal concern.

Quantitative data analysis

All statistical analysis was performed using SPSS version 18.0 (SPSS Inc, Chicago, IL). Questionnaires were assessed using published standardized scoring systems. Comparison of mean score from questionnaires between MRKH patients and control group were analyzed using t test on the normally distributed data.

Statistical significance test results are determined based on the value of $p < 0.05$.

Qualitative data analysis

Each interview was analyzed using a number of steps, which starts with coding, categorization, defining themes, and interpretation. The validity of this study is not compromised despite the small sample size because of the different assumptions which underlie the philosophy of qualitative inquiry. The validity of a qualitative study should not be judged with reference to sample size and selection or statistical power, but rather in terms of the applicability of the concepts for describing similar experiences in other situations.

RESULTS

From 2009 to 2012, there were 15 potential samples of participants diagnosed with MRKH syndrome from outpatient gynecological clinics of Hasan Sadikin Hospital, who underwent sigmoid neovaginoplasty. Potential participants were contacted directly by the researcher. One patient did not have contactable address. Three patients declined to participate. Three patients were abandoned by their husbands after the surgery; only 1 of the women was willing to be interviewed. Eight patients indicated they were interested in participating.

Informal telephone contact was carried out with all interested participants who were encouraged to ask any questions about the study, following which they and their partner were asked to come to Hasan Sadikin Hospital for the research participation. They were asked to give written confirmation if they wished to take part and so eight MRKH patients and sixteen normal women agreed to fill in the questionnaires.

Quantitative result

Table 1 shows that our MRKH patients have a matched characteristic with the control group.

Figure 1 shows that both groups have equal mean sexual satisfaction score, with p value for contentment, communication, and compatibility was 0.083, 0.49, and 0.056 respectively.

Figure 2 show that both groups have equal mean distress scale score, with p value for relational concern and personal concern was 0.971 and 0.266 respectively.

TABLE 1. – Characteristics of MRKH patients after sigmoid neovaginoplasty and control group.

Characteristics	MRKH		Control		p*) value
	n	%	N	%	
1) Total subject	8	100	16	100	
2) Age (years)					
< 25	2	25	2	12.5	0.682
25-34	3	37.5	8	50	
> 35	3	37.5	6	37.5	
3) Occupations					
Not working	4	50	9	56.3	1.0
Working	4	50	7	43.8	
4) Education					
Low	5	62.5	6	37.5	2.727
Middle	0	0	4	25	
High	3	37.5	6	37.5	
5) Family income					
< min. rate	4	50	6	37.5	0.673
≥ min. rate	4	50	10	62.5	

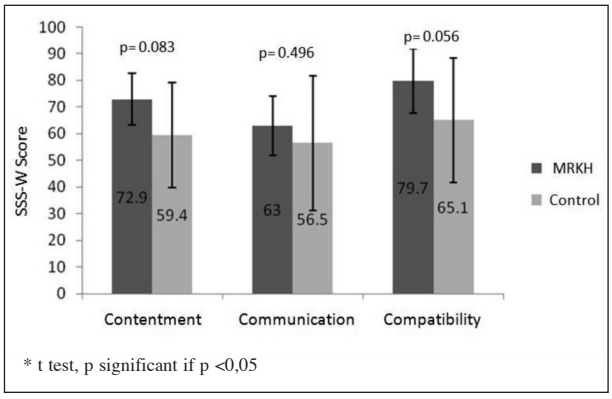

Figure 1. - Comparisons of Sexual Satisfaction mean score between MRKH patients after sigmoid neovaginoplasty and control group.

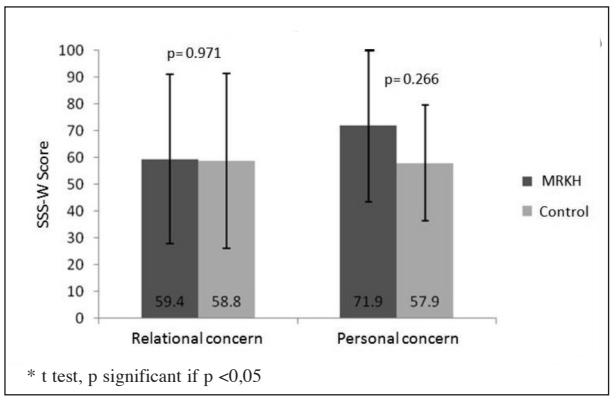

Figure 2. - Comparisons of distress scale mean score between MRKH patients after sigmoid neovaginoplasty and control group.

Qualitative result

Five patients and three with their partners were chosen for focused interview. Seven themes emerged from the analyses which were: sexual relations, partner's reaction to women with MRKH, relationships with partners, patients' current concerns, motivation to have operation, family support, and self esteem as female.

1. Sexual relations

Participants and partners complained difficulties to engage penile-vaginal intercourse due to short vagina.

"After we were married, we found it difficult to engage a sexual intercourse. Then we went to a doctor and were told that I didn't have a vagina" (patient E)

They admitted better sexual relations after patients underwent sigmoid neovaginoplasty due to longer neovagina.

"After the operation, we had a better sexual relations. and it's not painful anymore, for both of us" (patient A)

2. Partner's reaction to women with MRKH

Partners show different reactions to patient's MRKH condition. They feel disappointed by the inability to have normal sexual relations and infertility, but generally accepted the condition. They gave support for patients to have operation.

"Well I think it's normal to feel disappointed, especially when I realized I couldn't have children with her. But I'm grateful enough to have children from my previous wife so I tried to accept her for what she is.." (husband A)

One patient was abandoned after she was diagnosed MRKH actually never got any support from her husband.

"I didn't know my condition before we were married. After I was diagnosed MRKH and suggested to have operation, my husband didn't agree.." (patient F)

3. Relationships with partners

Partners support patients to have a better life, thus the decision to have operation was a result of their discussion. Most of the participants have a good communication with their partners especially related to difficulties in sexual relations and how to deal with it.

"We actually often discuss about our difficulties in engaging sexual intercourse.. He encouraged me to consult to a doctor and supported me when I had to underwent surgery.." (patient A)

Divorced patient admitted to have a poor relationship with her husband since they were married, before she was diagnosed MRKH.

"We never had any communications in our marriage. Maybe because our marriage were arranged by our parents.. We were divorced two.. three months after the operation.. I think the reason of our separation was the arrangement of our marriage." (patient F)

4. Patients' current concerns

Patients' most concerns related to their inability to bear children because they consider it's very important in their marriage life.

"I actually expected to have children... just like a normal woman... I wish I could menstruate... and pregnant… " (patient E)

The other concern was the possibility of being cheated by their partner due to their condition.

"Of course I was afraid of being cheated. I only have an artificial vagina... what if he's not satisfy enough? so I'm grateful enough he's still loyal to me until now..." (Patient D)

Our divorced participant lost her self confidence after being abandoned by her husband and still afraid to get involved in a new relationship.

"Now… I just try to live my life... but if anyone ask me whether I want to have a new husband or not, I must say that I'm not confident enough..." (Patient F)

5. Motivations to have operation

Their motivation to have operation is to improve their sexual relations, also to please their partner.

"I was afraid to have the operation. But I tried not to think about it because I really wanted to please my husband… I feel guilty because of my flaw.." (Patient B)

6. Family support

Patients suggested that family support is very important to help patients to cope with their condition.

"Family support is very important to me… they really helped me to get through everything..." (Patient C)

7. Self esteem as female

Participants felt devastated when they found out about their MRKH condition. Their inability to engage sexual relations before surgery, inability to menstruate and to bear children made them feel incomplete as a woman.

"I didn't feel sad when I knew I didn't have vagina... but I was very disappointed and devastated when I realized I also didn't have a womb which means I won't be able to get pregnant... I always think a complete woman is those who can get pregnant... to have children... so I felt really sad... so incomplete.." (Patient E)

They also feel ashamed, disappointed and felt sorry for their partner because feel not normal.

"I'm so disappointed... so sad... I'm angry but don't know what to do... I feel sorry for my husband to have a flaw wife..." (Patient A)

DISCUSSION

Although the outcomes of surgical and non-surgical treatments to create a new vagina have been reported, there have been few reports addressing the psychological impact of the condition and quality of life (QoL) outcomes.

The aim of creating a neovagina is to enable satisfactory sexual activity and thus to achieve a physical and psychological equilibrium.[13] The results of this study show no significant differences between sexual relations of MRKH patients and normal women (Figure 1).

Sexual relations measured by sexual satisfaction score of SSS-W are highly affected by good sexual communication. Effective communication between partners could con-

tribute to sexual satisfaction by facilitating closeness and intimacy, and by informing partners about sexual desires and preferences that, in turn, could lead to enhanced arousal and orgasm.[12]

Mean score of contentment domain from SSS-W questionnaire in MRKH patients are relatively higher than normal women, as suggested by the literature; probably because of higher communication and compatibility mean score. This supported by the result of interview that patients and their partner could have a frank discussion about their sexual difficulties, before and after surgery. This suggested good communication and relationship between patients and their partner that could enhance their sexual relations after neovaginoplasty.

Participants stated that they had a better sexual intercourse after neovaginoplasty, as suggested by a study that a longer vagina could improve sexual satisfaction.[14] Many studies suggested MRKH syndrome patients could have a normal sexual function after neovaginoplasty. Sexual satisfaction is an important component of sexual function assessment. Psychological adjustment plus anatomical remediation are aimed in this improvement. Considering each domain mean score, women with MRKH syndrome treated by sigmoid neovaginoplasty could be considered ''normal'' in terms of global sexual satisfaction.[4,13,15]

There was a statistically significant correlation between sexual satisfaction and relationship satisfaction and between sexual satisfaction and commitment. There was a significant positive correlation between commitment and the pro-relationship sexual behaviours. Commitment was most highly correlated with emotional bond, followed by motivation to satisfy partner, and disclosure. The three pro-relationship sexual behaviour scales were also correlated with one another. These results indicate that women who reported being more committed in their relationship also reported an increased use of the three pro-relationship sexual behaviors.[16]

The result of this study shows that our patients have a strong commitment which proofed in marriage, motivation to satisfy partner as the reason to have surgery, and disclosure about their sexual difficulties, could improve their sexual relations after sigmoid neovaginoplasty.

Patients' distress concerning their sexual difficulties was measure by distress scale in SSS-W questionnaire. Those who answered questions number 19-30 are patients who admit difficulties in their sexual relations. Figure 2 shows no significant difference between MRKH patients compared to normal women. All of our MRKH patients admitted their sexual difficulties but no longer as their concern after surgery.

Interview result shows that patients' concern related to their artificial vagina was admitted by the patients, but not as important as the inability to bear children. They were worried to be abandoned because they could not give children to their partners more than sexual intercourse difficulties.

MRKH gives a significant and lasting negative psychological impact on women with this condition, with levels of psychological distress being high and self-esteem impaired even after successful creation of a neovagina.17

Our patients stated in the interview about how MRKH affected their self esteem as female. They found it difficult to engage in sexual intercourse before surgery, unable to menstruate, and unable to carry a pregnancy. These challenges compromised their emotional well-being and no longer feeling complete.

Neovaginoplasty have been proven to improve sexual relations, but the infertility remains a problem. Our patients stated having jealous feelings towards women who could have children but found it hard to accept these difficult feelings as part of themselves, as suggested in a qualitative study that this condition led patients to a sense of isolation and an accompanying sense of insecurity about their own self worth.[18]

This study also discuss about partner's reactions to the MRKH condition. They felt sorry for the patients and disappointed due to the desire to have a perfect wife. They described positive and reassuring reactions to the neovagina. Several other studies suggested that partners were satisfied with the neovagina and that partners experienced no negative reactions.[4]

Good relationship and strong support from their partner could affect patients' self confidence and help patients to cope with their condition. Our patient lost her confidence and found it difficult to continue her life after being abandoned by her husband. Luckily she had supportive family that helped her to deal with her condition. All participants stated that family support is very important.

This entire area of research is limited by the rarity of case also the paucity of studies that focus on psychological more than the clinical aspect only. In addition, this is a cross sectional study that focused only to the conditions after surgery, therefore in the future, it's better to also study the condition before surgery and the differences.

CONCLUSIONS

Our experience shows that sigmoid neovaginoplasty is an effective technique to improve sexual relationship and help to alleviate distress of women with MRKH, although infertility remains the hardest aspects of the condition to accept. Physicians can further assist patients by being very thoughtful and deliberate in the manner that they reveal the diagnosis of MRKH. Frank discussion about how MRKH affects the physical aspects of sexual intercourse as well as acknowledging its impact on a patient's psychological well-being will be important. Physicians can also provide information about the condition and provide referrals to support groups.

Further investigations about the psychological impact and quality of life will assist healthcare professionals in improving medical and psychological care for women with MRKH.

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Original article

The influence of age on the sonographic visualization of structures within the anterior and posterior pelvic floor compartments

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Abstract: The aim of study was to evaluate the inter-observer reliability in assessing anterior and posterior pelvic floor compartments in nulliparous women using 3-dimensional endovaginal ultrasound, and to evaluate the association of age with the visualization or measurement of these structures. 3D EVUS images were obtained in community-dwelling nulliparous women ages 21-80. Two observers independently read all images, looking anteriorly for the vesical trigone (VT), trigonal ring (TR), trigonal plate (TP), striated urogenital sphincter (SUG), compressor urethra (CU), longitudinal and circular smooth muscle (LCM); posterior structures included the superficial external anal sphincter (EAS-sq), main external anal sphincter (EAS-m), internal anal sphincter (IAS), and rectovaginal septum (RVS). Urethral, RVS, and anal sphincter measurements were recorded. Inter-observer reliability was determined with Cohen's kappa. Spearman's rank correlation was used to evaluate the association between these measurements and age. Ultrasound images of 77 volunteers, including anterior and posterior compartment 3D volumes (total of 154), were analyzed for this study. The median measurements were: urethral length 3.68 cm (range 1.67, 6.84), IAS length 2.60 cm (range 1.74, 4.12), IAS width 0.32 cm (range 0.17, 0.63), RVS length 3.02 cm (range 2.15, 3.98), anorectal angle 157° (range 142, 168). Inter-observer agreement for the visualization of structures was substantial to almost perfect. There was no correlation between age and variations in urethral length, IAS length or width, RVS length or anorectal angle. 3D EVUS can reliably identify anterior and posterior compartment structures. Age is not associated with the visualization or measurement of these structures.

Key words: Age; 3D EVUS; Anterior and posterior compartment.

INTRODUCTION

Pelvic floor disorders represent an important part of women's healthcare throughout the world. POP, voiding disorders, and defecatory dysfunction are estimated to affect millions of women worldwide. 41% of women aged 50-79 have some degree of POP[1, 2] resulting in an estimated annual cost of more than $1 billion dollars per year in the United States alone.[3] It is estimated that the number of American women with at least one pelvic floor disorder will exceed 40 million by 2050. Despite the high prevalence and financial burden of these disorders, they continue to be poorly understood. A major contributor to our poor understanding of these disorders is our inability to reliably and accurately characterize key pelvic floor structures in women using conventional techniques.

Currently, MRI is the primary means of imaging many of the structures of the female pelvic floor. As such, MRI has revealed both anterior and posterior compartment anatomy in great detail, and correlative studies using MRI in patients with and without incontinence, and pelvic organ prolapse have shown a number of structural abnormalities.[5-10] However, MRI has a number of limitations that limit its use on a broad scale. 3D Transperineal ultrasound techniques have been widely used to evaluate pelvic floor dysfunction and have been shown to be reliable and valid for detecting abnormalities.[11, 12] 3D endovaginal ultrasound (3D EVUS) imaging of the pelvic floor has emerged as a promising technology for use in patient evaluation. The ease of use and availability of 3D EVUS currently makes it feasible to screen large numbers of subjects with minimal cost. 3D EVUS techniques have been demonstrated to visualize with great detail and reliability the structures of the pelvic floor in young nulliparous women.[13]

While 3D EVUS has been shown to be useful in the evaluation of a "normal" young female pelvic floor, no studies to date have established its use in an older population. Age is a well-established risk factor for the development of most pelvic floor disorders.[1, 14-18] Although it has not consistently been associated with clinical evidence of deterioration in pelvic organ support, urethral support, or levator function,[17] age-related changes in histologic aspects of support structures, such as muscle and collagen composition are well documented.[19-21] It is not known if changes related to age will have an effect on the appearance of pelvic floor anatomy in nulliparous subjects.

In this study, we aim to assess anterior and posterior compartment pelvic floor anatomy in a community-based cohort of nulliparous women with 3D EVUS. The main goals of this study are to assess for inter-observer reliability in measuring these structures, and to determine the effect of age in the visualization of these structures.

METHODS

This study was approved by the Institutional Review Board at the University of Oklahoma Health Sciences Center. Informed consent was obtained by all participants. It is a sub-analysis of a study aimed at assessing age-related changes of the levator ani in nulliparous women using 3D EVUS. Imaging of the anterior and posterior compartments was obtained at the time of the primary study using the BK Medical Ultrafocus (Peabody, MA) and an 8848 12 MHz transducer by one of the authors (LHQ). The transducer is the size of an average index finger and rotates on a timed mechanical arm at a constant speed in a standardized way to obtain reproducible data cubes. For each patient, a length of 6 cm was scanned every 0.25 degrees for a total of 180 degrees starting at the 0300 position and ending at 0900 position with 720 cumulative radial scans from which 3D rendered cube of each compartment was calculated.

All ultrasounds were performed in the office setting, with the patient in dorsal lithotomy position, with hips flexed and abducted. No preparation was required and the patient was recommended to have a comfortable volume of urine in the bladder. No rectal or vaginal contrast was used. To avoid excessive pressure on surrounding structures that might distort the anatomy, the probe was inserted into the vagina in a neutral position. It has been shown that an endovaginal probe does not have an adverse effect on anatomy compared to

transperineal ultrasound.[22] The 3D cube for each compartment was digitally catalogued for future analysis.

Two observers (DW and GR) independently evaluated all images of the anterior compartment structures and confirmed the visibility of the following structures in the anterior compartment: vesical trigone (VT), trigonal ring (TR), trigonal plate (TP), striated urogenital sphincter (SUG), compressor urethra (CU), and the longitudinal and circular smooth muscle (LCM) (Figure 1 a/b). Several investigators are working to show correlation of these structures with clinical symptoms.[20, 21] The same two observers evaluated the posterior compartment 3D data cubes (Figure 2 a/b). Posterior structures visualized included the superficial external anal sphincter (EAS-sq), main external anal sphincter (EAS-m), internal anal sphincter (IAS), and the rectovaginal septum (RVS). Structures were rated as "seen" or "not seen". Urethral length, RVS length, and internal and external anal sphincter measurements were recorded.

Ultrasound protocol

In reviewed images, we used the mid-sagittal view for our measurements.

Anterior Compartment: The trigonal ring was seen as a mixed echoic structure around the urethral opening to the bladder, the vesical trigone was seen as a hypoechoic structure in the inferior border of the bladder, and the trigonal plate was identified as a hypoechoic line that continued from the vesical trigone to the mid-urethra. Longitudinal and circular muscles were seen as an olive-shaped density encompassing the mid-urethra. The striated urogenital sphincter was a hyperechoic stripe anterior to the longitudinal and circular layer. The compressor urethra and the urethrovaginal sphincter complex were seen at the distal 1/3 of the urethra. The length of the urethra was defined as the distance from the opening into the bladder to the opening at the external urethral meatus. If a structure was architecturally unidentifiable, it was coded as a defect.

Posterior compartment: In the mid-sagittal view, the rectovaginal septum was seen as a hypoechoic line that superficially starts from external anal sphincter and continues cephalad; this length was measured as the RVS length. The external anal sphincter was seen as two parts - the superficial part and he main part, both as hypoechoic structures starting at the same level of the perineal body and continuing to the rectovaginal septum. The internal anal sphincter was a hyperechoic structure starting at the level of main part of external anal sphincter and the length was measured from the beginning to the end part that narrows and is finished. The anorectal angle in the midsagittal plane was measured as the angle between the axis of rectum with the axis of anal canal.

Statistical Analysis

Statistical analyses were performed using SAS v9.2 (SAS Institute, Cary, NC). Summary statistics were calculated for the patient population. Spearman's rank correlation (rs) was used to evaluate the association between urethral and anal sphincter measurements and age. Logistic regression was used to evaluate the association between age and the visualization of anterior or posterior compartment structures. Two-sided p-values of < 0.05 were considered significant. Exact agreement was calculated as the total number of each structure identified by both readers and dividing it by the total number of cases. Inter-observer reliability was determined with Cohen's kappa statistics. Landis

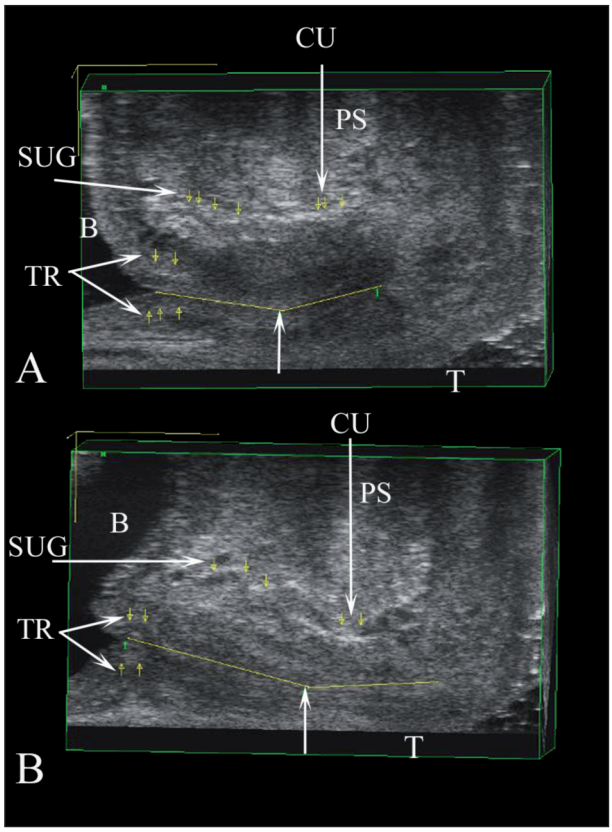

Figure 1. - 3D EVUS image of the anterior compartment in A) 27 year old nulliparous woman, and B) 64 year old nulliparous woman.
B: Bladder, CU: Compressor Urethra, PS: Pubic Symphysis, SUG: Striated urogenital sphincter, TR: Trigonal ring, U: Urethra.

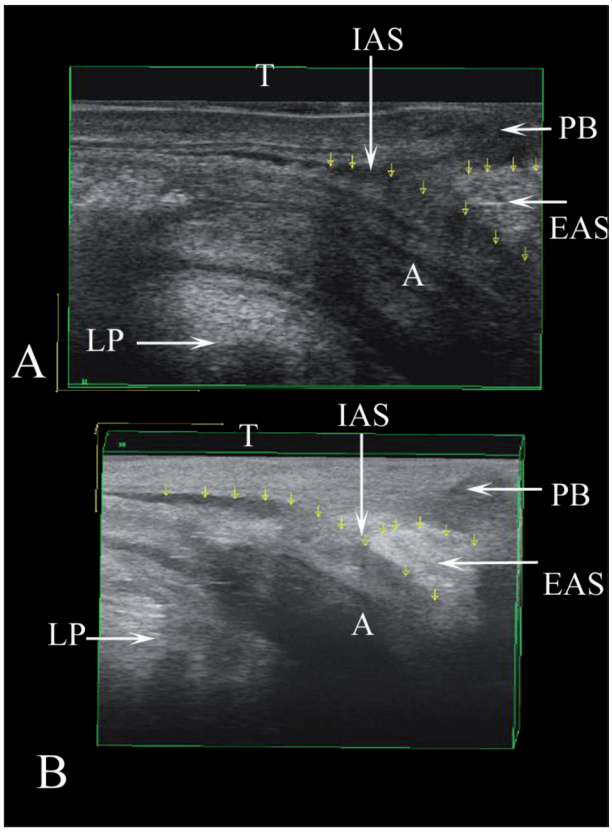

Figure 2. - 3D EVUS image of the posterior compartment in A) 27 year old nulliparous woman, and B) 64 year old nulliparous woman.
A: Anus, EAS: External Anal Sphincter, IAS: Internal Anal Sphincter, LP: Levator Plate, PB: Perineal Body.

and Koch's benchmarks for the evaluation of observed Kappa values were used: 0.81-1.00 was considered almost perfect agreement, 0.61-0.80 substantial agreement, 0.41-0.60 moderate agreement, 0.21-0.40 fair agreement, 0.01-0.20 slight agreement, and 0.00 poor agreement.[23]

RESULTS

Eighty participants were enrolled in the primary study and included in this sub analysis. The ultrasound images of 3 participants were excluded due to corruption of the image files. The median age of the participants was 47 (range 22, 70). The average body mass index (BMI) was 28.3 (± 7.2 SD). The majority of the participants were Caucasian (81.25%). Demographic information is shown in Table 1. Thirty percent of the participants were postmenopausal, and 10% were on hormone replacement therapy (HRT), with only one participant having evidence of vaginal atrophy on examination. 52.5% considered themselves healthy; hypertension was the most common medical comorbidity (17.5%). 35% of participants reported having a prior abdominopelvic surgery, with hysterectomy being the most common (12.5%). None of patients had surgeries for urinary incontinence, pelvic organ prolapse or anal incontinence.

The median urethral length was 3.68 cm (range 1.67, 6.84). The median IAS length was 2.60 cm (range 1.74, 4.12) and width was 0.32 cm (range 0.17, 0.63). The median RVS length was 3.02 cm (range 2.15, 3.98). When evaluating the association between age and each measurement, none of the individual measurements showed a significant correlation with advancing age. When grouping age by decade, there continued to be no correlation between age and the measurement of any structure (Table 2). Additionally, no association was found between age or age group and the visualization of any structure in the anterior or posterior compartment (Table 3). Menopausal status was evaluated as part of the logistic regression model but was excluded due to non-significance in the model.

Table 4 shows the percent agreement for the visualization of each structure (seen/not seen). Cohen's kappa demonstrated almost perfect agreement for the visualization of VT, TP, RVS, IAS, and EAS-m. Substantial agreement was noted for the visualization of TR, LCM, SUG, CU, and EAS-sq (Table 4).

Table 1. – Characteristics of the study population.

Variable	Summary Statistic
Age (median, range)	47 (22, 70)
Race (n, %)	
Caucasian	65 (81.25)
African American	10 (12.5)
Native American	3 (3.75)
Asian	1 (1.25)
Hispanic	1 (1.25)
BMI (kg/m2) (mean, SD)	28.3 ± 7.2
Menopausal Status (n, %)	
Pre-	56 (70)
Post-	24 (30)
Use of HRT (n, %)	
Yes	8 (33)
No	16 (66)
Vaginal atrophy (n, %)	
Yes	1 (1.25)
No	70 (98.75)
Current Tobacco Use (n, %)	8 (10)
Medical Co morbidities (n, %)	
None	42 (52.5)
Hypertension	14 (17.5)
Diabetes	3 (3.75)
Steroid use	1 (1.25)
Autoimmune disease	1 (1.25)
No response	19 (23.75)

Table 2. – Spearman's rank correlation for age with the measurement of anterior and posterior compartment structures.

Structure	Measurement (median, range)*	rs (p-value)**
Urethral length	3.68 (1.67, 6.38)	0.05 (0.69
RVS	3.02 (2.15, 3.98)	-0.18 (0.12)
IAS length	2.60 (1.74, 4.12)	-0.15 (0.26)
IAS width	0.32 (0.17, 0.63)	-0.001 (0.99)
ARA	157.00 (142.00, 168.00)	-0.07 (0.57)

Table 3. – Association between age and the visualization of anterior and posterior compartment structures.

Structure	OR (95% CI)
Anterior compartment	
TP	0.959 (0.923, 0.997)
TR	0.959 (0.923, 0.995)
VT	0.978 (0.940, 1.017)
SUG	1.099 (0.967, 1.248)
LCM	1.099 (0.967, 1.248)
CU	0.997 (0.954, 1.042)
Posterior compartment	
RVS	0.966 (0.929, 1.005)
IAS	0.962 (0.919, 1.006)
EAS-m	0.959 (0.915, 1.005)
EAS-sq	0.963 (0.927, 1.001)

DISCUSSION

In order for 3D EVUS to become a suitable option for imaging the female pelvic floor, its use must be validated in the patient population that it will be clinically useful for. However, due to the novel nature of this technology, it is important to first prove its ability to identify normal key structures in clinically normal patients. We have previously shown that 3D EVUS can reliably provide a detailed anatomic depiction of the anterior and posterior pelvic floor compartments in young, asymptomatic, nulliparous women by correlating the rendered images with histologic specimens.[13] However, a limitation of that study was the generalizability of our findings to a broader population, given

Table 4. – Inter-observer analysis of the visualization of key structures within the anterior and posterior compartments.

Structure	Agreement (n, %)	k	95% CI	p-value
VT	70/75 (93.33)	0.806	0.643, 0.969	<0.0001
TR	67/77 (87.01)	0.696	0.537, 0.854	<0.0001
TP	73/75 (97.33)	0.937	0.852, 1.000	<0.0001
LCM	76/77 (98.70)	0.794	0.400, 1.000	0.0010
SUG	76/77 (98.70)	0.794	0.400, 1.000	0.0010
CU	72/77 (93.51)	0.724	0.496, 0.953	<0.0001
RVS	70/74 (94.59)	0.854	0.716, 0.992	<0.0001
IAS	74/75 (98.67)	0.957	0.874, 1.000	<0.0001
EAS-sq	67/75 (89.33)	0.718	0.536, 0.901	<0.0001
EAS-m	72/75 (94.67)	0.878	0.743, 1.000	<0.0001

that many patients seeking care for pelvic floor disorders are neither young, nulliparous, nor asymptomatic.

The incidence and prevalence of pelvic floor disorders is known to increase with age.[19] There is evidence suggesting that pelvic organ support, urethral function, and levator function are not affected by age.[17] Quiroz et al. showed that age had no significant effect on the visualization of levator ani muscles by 3D EVUS in nulliparous women.[24] Using transperineal ultrasound, Dietz et al. showed that age seems to have a limited effect on contractility and distensibility of the pelvic floor muscle. The small effect of aging results in reduced contraction strength and increased hiatal diameter.[25] Our group has published on the association between the visualization of anterior compartment structures by 3D EVUS and urinary incontinence symptoms;[26] however, to our knowledge, the influence of age on the visualization of anterior and posterior compartment structures seen on 3D EVUS has not been previously studied . Several age-related changes in pelvic floor tissues, such as muscle atrophy and collagen degradation have been noted in several studies.[19-21] With such structural changes, it is possible that the ability to visualize pelvic floor structures changes with age, thus affecting the usefulness of 3D EVUS in an older population. In the current study, we demonstrated that age was not related to urethral, rectovaginal septum, or anal sphincter measurements. In this study, the ability to visualize important structures in the anterior and posterior pelvic floor compartments was not affected by increasing age, and there is good agreement between observers when viewing 3D EVUS images across all age groups.

This study does have some limitations that must be acknowledged. Since the majority of our patients were Caucasian, our findings may not apply to other ethnic groups. Additionally, these findings have limited generalizability because, as previously mentioned, the majority of patients in whom 3D EVUS would be indicated are parous and have symptoms of pelvic floor disorders. However, the aim of this study was not to evaluate the use of 3D EVUS in symptomatic patients. Rather, it is the next step in establishing the reliable visibility of pelvic floor structures of interest using this novel technology, as a baseline for future studies in a more generalizable urogynecologic patient population.

We acknowledge that this technology is still in the early stages of development. Age alone did not significantly impact the visualization of anterior and posterior compartment structures. Future studies are needed to address the clinical implications of 3D EVUS in the clinical assessment of women with symptomatic pelvic floor disorders.

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INVITED COMMENT. The modern transperineal sonography of the pelvic floor

High-resolution three-dimensional endovaginal ultrasound (3D-EVUS) has recently come into the clinical practice to evaluate the complex anatomy of the female pelvic floor including the bladder base, urethral and paraurethral structures (anteriorly) and anal sphincter complex, rectovaginal septum and postanal space (posteriorly). Compared to 3D- transperineal ultrasound (TPUS), in face of the disadvantage of not allowing a dynamic evaluation[1] of the pelvic floor under the effect of useful provocative maneuvers (i.e., Valsalva and Kegel maneuvers), 3D- EVUS avoids the adverse effect of excessive variability when accurately measuring distances, areas, angles and volumes in any plane. Common to both techniques, a series of advanced post-processing techniques including digital enhancing of individual voxels for better representation of transparency (volume render mode), selection and display on the screen of the brightest value found along the ultrasound beam (maximum intensity projection) and marking and/or subtraction from the neighbor anatomy of selected volume voxels (sculpting) can also been applied for better interpretation of the pertinent anatomy[2]. Although not adding new relevant information to knowledge, the elegant study by White et al. confirms that 3D-EVUS is a highly reproducible diagnostic tool[3] for the measurements of the most common biometric indices used in the clinical practice and, even more important, that ageing has no (adverse) effect on the visualization of pelvic floor structures, thus indicating that the technique is feasible for becoming the baseline investigation in the general female population. Moreover, given the good-to-excellent interobserver and interdisciplinary reproducibility of the technique demonstrated by Santoro et al. with the exception of the anorectal angle (ARA) measurement[4], 3D-EVUS seems ideal as an objective site-specific diagnostic tool for describing, quantitating, and staging pelvic support defects in women, ultimately enhancing both clinical and academic communication among urologists, gynecologists, coloproctologists and radiologists. This is a primary issue in Perineology, as confirmed by the fact that, although patients may present with symptoms which involve only one compartment, a multicompartment defect is usually revealed at imaging[5], highlighting the role of a simple, cheap and tolerable tool, such as 3D-TVUS, for assessing the presence of associated defects and the severity of singular abnormalities so as to reach a more accurate diagnosis than during physical examination alone, regardless of the specialization of the examiner. Further improvement with the technique may be anticipated when considering the possibility of simultaneous capturing and subsequent merging of images obtained during the assessment of urethral vascularity[6] based on selected Doppler parameters such as velocity (V), resistive index (RI) and pulsatility index (PI), for better comprehension of urinary continence mechanism. Unfortunately, the application of similar principles to the investigation of the posterior compartment has received little attention in the literature. Conversely, using 3D- TVUS to depict the cushioning effect of blood vessel within the anal submucosa (Figure 1) can disclose new interesting scenaries for the diagnosis and treatment of the hemorrhoidal disease, one of the most common clinical problem in proctology. Finally, a space for implementation of comparative studies that apply 3D - TVUS and magnetic resonance (MR) imaging using an endovaginal coil does exist and is highly desirable. In fact, while 3D-ultrasonography can be considered an unsurpassed technique for visualizing and measuring the most important structures of lower urinary tract anatomy, such as the vesical trigone, trigonal ring, striated urogenital sphincter, compressor urethra and longitudinal or circular smooth muscle, as shown in the present article, it is worth mentioning that MRI using an endovaginal coil has even been reported by Kim JK et al.[7] to allow discrimination between continent and incontinent subjects on the basis of a score of the risk of stress urinary incontinence (scale of 0-5). All of this taking into account established MR diagnostic criteria, including the degree of asymmetry of the puborectalis muscle, and frequency of distortion in the periurethral, paraurethral and pubourethral ligaments, which are not visible at sonography. Hopefully, data obtained using both methods of investigation (fusion imaging) will help physicians in the future reaching a more accurate diagnosis and treatment.

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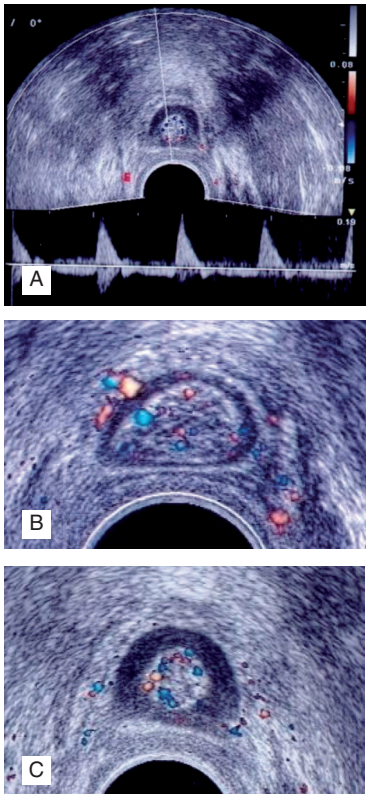

Figure 1. – Analysis of flow parameters (A) from a region of interest of the anal canal by biplane endovaginal probe in a case on normal vascular pattern (B) and one with 2nd degree hemorrhoidal varices (C): note the shift of the flow from the submucosal space toward the intersphincteric space (arrow).

Original article

Non-linearity, a dilemma and opportunity for clinical research in urogynecology

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Abstract: The female pelvic floor contains the most complex interconnected nonlinear controlled system of muscles and ligaments in the body. *The dilemma*. Much of the research in urogynecology today is reductionist, never ending classifications attempting to fit complex issues into simplistic reductionist boxes. Examples are the POPQ system, urodynamics, replacing symptoms with numbers, "scores". Use of simple language is suggested to report results and application of Occam's Razor to distinguish relevance of rival systems. *The opportunity*. Complexity and Chaos are the key to understanding the variance inherent in pelvic floor function and are a rich direction for future research. The importance of 'criticality' in speedily changing the bladder phase from 'closed' to 'open' is described as are the non-linear mechanisms driving this system, an external striated muscle mechanism acting against suspensory ligaments, and the internal resistance to urine flow which is proportional to the 5th power of the change in urethral radius by this mechanism. The impossibility of pre-operatively determining the initial conditions as a guide to therapy is discussed and how this can be bypassed by repairing the ultimate cause of the dysfunction, damaged ligaments, with tensioned slings. Repairing the ligaments works by reversing the non-linear cascade of events consequent upon inability of the musculoelastic control mechanisms to 'grip' on the loose ligaments. A simple research protocol for reversing these complex cascades is detailed, by supporting various suspensory ligaments.

Key words: Urogynecology; Complexity; Chaos; Pelvic floor; Non-linear mechanisms.

GLOSSARY

Chaos is the generation of complicated, aperiodic, seemingly random behaviour from the iteration of a simple rule. In urogynecology it applies especially to the feedback systems inherent in control of continence, the micturition and defecation reflexes.

Complexity is the generation of rich, collective dynamical behaviour from simple interactions between large numbers of subunits.

Criticality. A system is critical if its state changes dramatically given some small input. A good example is the almost instantaneous activation of bladder/urethral closure and micturition.

Dynamical system – a set of interacting and interrelated elements that can change in time. The pelvic floor is a classical example, with all structures, muscles, nerves, connective tissues, blood vessels acting co-ordinatedly to achieve organ support, opening and closure.

Integral Theory (IT). States that POP and pelvic floor symptoms mainly derive from laxity in the vagina or its supporting ligaments because of altered collagen/elastin.

Integral Theory System (ITS) or Integral System. A management system based on IT which diagnoses and treats lax vagina/ligaments using squatting based exercises or small strips of tape accurately applied to damaged ligaments.

Linear system is simple and predictive. It is the sum of its parts. 1+1 always = 2.

Nonlinear system: a nonlinear system in contrast to a linear system, is a system in which the output is not directly proportional to the input. Non-linear systems dominate the pelvic floor.

QOL Quality of life.

Reductionism is the practice of simplifying a complex idea to the point of minimizing, obscuring, or distorting it. Examples are new terminologies such as POPQ, urodynamics, some classifications, symptom scores, really, any artificial structure imposed on a Natural system.

VAS Visual analogue scale.

THE DILEMMA

Pelvic floor function is non-linear and therefore constantly variable. Marcus Aurelius, the Roman emperor and stoic philosopher described the holistic non-linear character of Nature thus [1]: "constantly regard the universe as one living being, having one substance and one soul; and observe how all things have reference to one perception, the perception of this one living being; and how all things act with one movement; and how all things are the cooperating causes of all things which exist; observe too the continuous spinning of the thread and the contexture of the web.[1] This quote beautifully encapsulates the modern science of Complexity,[2] that Nature works in an interconnected, holistic and non–linear way: every part of a system affects every other part, with the sum being greater than the parts. Though the pelvic floor contains the most complex interconnected system of muscles and ligaments in the body, very little has been written about the non–linear control mechanisms of these dynamical systems and how they impact on clinical and research urogynecology. Yet much of the research in urogynecology today is reductionist, never ending classifications attempting to fit complex issues into simplistic reductionist boxes. Such reductionism cannot encompass the wide variance seen in clinical conditions and symptoms, even within the same patient (Figure 1).

Karl Popper, discussing the problems of artificial model languages, stated: "thus the method of constructing artificial model languages is incapable of tackling the problems of the growth of our knowledge"; and "It is a result of their poverty that they yield only the most crude and the most misleading model of the growth of knowledge - the model of an accumulating heap of observation statements".[3]

Two such examples are the POPQ system[4] and the predictive value of urodynamics.[5] Replacing symptoms with numbers, "scores", is another example of an "artificial model language".[4] Reporting the change in the total number of episodes of frequency, urge incontinence,

nocturia in a cohort[6] using standard ICS definitions is much easier to understand than a set of numbers. Furthermore symptoms are experienced differently by different patients and the QOL varies considerably even within the same patient (Figure 1). This is the dilemma. Classifications have to be productive and helpful in patient management. Non-productive classifications serve only to burden clinical practice and research.

Occam's Razor - A tool to resolve the dilemma

Occam or Ockham, a14th century English philosopher stated that a simpler solution was more likely to be the most valid, and simpler theories are preferable to more complex ones because they are better testable and falsifiable. In urogynecology this could mean that we should use the halfway system instead of POPQ; the sign of USI instead of urodynamics; reporting the change in the total number of frequency, urge incontinence, nocturia episodes in a cohort instead of a set of numbers.

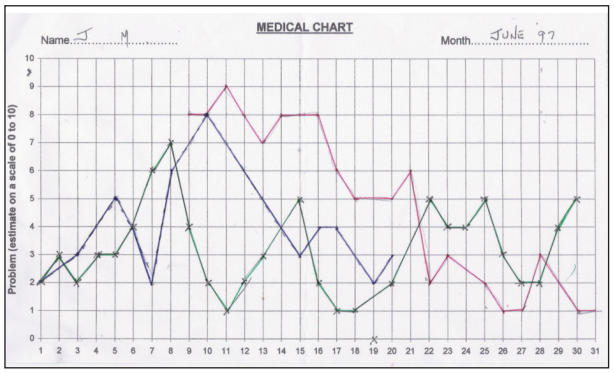

Figure 1. - This graph was constructed from a QOL which used a VAS score recorded on a daily basis by a patient who had urinary incontinence. The non-linearity of the VAS scores displayed question the validity of "Pelvic Floor Scores" and "validations" as performed today. Different colours denote different months. Looking at the top (red) graph, there would be an enormous difference in score depending on whether the assessment was on Day 11, or Day 26.

THE OPPORTUNITY

Complexity and **Chaos** are the key to understanding the variance inherent in pelvic floor function and are a rich direction for future research. Complex and chaotic systems are nonlinear and sensitive to initial conditions. A system is 'critical' if its phase state changes dramatically with some small input.[2] The bladder has two phases, open and closed. The bladder is always "en garde", ready to instantly open (evacuate) or close (continence) depending on circumstance. Criticality is important for rapid phase change. What makes a rapid phase transition possible is

1. The external striated muscle vectors, arrows (Figure 2) which can rapidly open or close the urethral tube.
2. The exponential relationship (5th power) between the radius and the resistance to urine flow[7] which exponentially accelerates 1.

For example, a sudden halving of the urethral diameter 'D' by vector closure (Figure 2) increases resistance by a factor of 32. Doubling 'D', by the vectors stretching the urethra posteriorly enables micturition by reducing resistance to flow by a factor of 32.[7] It is this mechanism which gives instant commencement of urination and instant stoppage of flow.

Continence. Effort such as coughing activates the fast-twitch forward vectors to contract against the suspensory ligaments. This small change in initial conditions sets forth a cascade of events in associated subsystems, muscles (arrows), stretch receptors, suspensory ligaments and all their components, collagen, elastin, nerves, blood vessels. The effect is to exponentially narrow the urethra for closure.

Emptying At a critical point, the hydrostatic pressure of the urine stimulates the bladder base stretch receptors to set off a different cascade of events in the same subsystems to swing the system into open phase, micturition. The posterior urethral wall is stretched open by the vectors (Figure 2) exponentially decreasing the internal resistance; the bladder contracts and empties.

Urgency & Frequency. Any loose ligament will prevent the vectors from stretching the vaginal membrane sufficiently to support the bladder base stretch receptors. Depending on their sensitivity, they may fire off at a low bladder volume to cause urgency and frequency and at night, nocturia. The control of urgency is consistent with a classic chaotic feedback mechanism.[8] This mechanism adequately explains the instability curve of urodynamics and bladder stability in the normal patient during filling; a low compliance bladder is consistent with a partly activated but controlled micturition reflex.[8]

How to address non-linearity in clinical situations?

From a Complexity perspective, the exponential nature of the control system makes it difficult for any system to predict an outcome, as it requires the initial state of the system to be described with perfect accuracy, a nearly impossible task.[2] So any pre-operative test (e.g., urodynamics) is doomed to fail as a predictor. The ITS bypasses this problem by repairing the ultimate cause of the dysfunction cascade, damaged ligaments, with "micro' tensioned slings.[9]

New research directions

The ligament concept of function and dysfunction provides many opportunities for research. It can be tested without surgery by examining a patient with a full bladder. Upward pressure on one side of the urethra

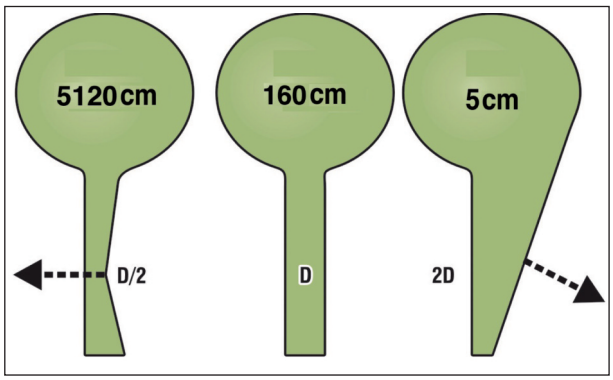

Figure 2. - The non-linear relationship of urethral resistance to continence and micturition (for non-laminar flow). Resting closed (middle figure). 160cm H2O is a nominal pressure for leakage at diameter D. For closure (continence) (left figure). If the forward vector can close the diameter to D/2, resistance to flow increases by the 5th power. The head of pressure required for leakage increases to 5120cm H2O (The inverse of ½: 2x2x2x2x2=32). For opening (micturition) (right figure) If the backward vectors can open the diameter to 2D, resistance to flow decreases by the 5th power. The head of pressure required for leakage decreases to 5cm H2O.

immediately behind the symphysis will control USI and often urgency. A large tampon in the posterior fornix will support the posterior ligaments and often diminish urgency, pelvic pain and nocturia.[9] Gentle digital support of the vagina just anterior to the cervix may diminish urge symptoms and may alter DO (detrusor overactivity).[8] Performed under urodynamic or ultrasound control, these 'simulated operations' would constitute a most original research project. They work by reversing the non-linear cascade of events consequent upon disturbance of the musculoelastic control mechanisms.[8,10,11]

CONCLUSIONS

Non-linearity and chaotically influenced feedback mechanisms are fundamental to Nature. They are the key to understanding the complexity of pelvic floor anatomy and function, day to day symptom variation in an individual patient. They help us make sense of anomalous and varied experimental results, and even to appreciate how the randomness of initial experimental results may influence a whole new direction in surgery in a positive or negative way.

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Letter to the Editor

Genital mutilations and female intimate surgery: we need cold, hard figures!

Dear Editor,

after reading Dr. Varol's article,[1] I couldn't help thinking of one of the most notable contradictions of our time: in one part of the world female intimate surgery and medicine are required and performed for aesthetic and functional purposes, thus aiming at improving health and quality of life for women; conversely, in many countries and regions around the world, women are subjected to several forms of genital mutilation and this practice prevents them – since early in their adolescence – from having a serene, agreeable and satisfactory life.

It would seem as though the world has gone crazy and has become more and more unpredictable. Therefore, I often look for data and numbers I can really rely on. Cold, hard figures: that is what we need!

However, searching the Internet, you will mmediately notice that plastic surgery-related statistics, particularly the ones dealing with female intimate surgery with "aesthetic purpose" are very often provided and presented by media; in most cases they do not provide findings coming from rigorously conducted scientific studies.[2]

On the other hand, in the few scientific publications that have been published, instead of numbers, I often find sentences with meanings similar to the following one: "A preliminary discussion around 'normality' and a psychotherapy should be tried in order to not treat a dysmorphobia by surgery".[3]

The "Western" scientific world increasingly aims at meeting the social demand for a medicine focused on a longer life and a better health; the search for mini-invasive techniques in female intimate surgery is now a reality that fulfills two key requirements, the aesthetic one and the functional one.

Unfortunately, there is also another attitude – shared not only by media – that considers the intimate surgery and medicine as a taboo, as a science with a poor or doubtful ethical value; in my opinion this attitude is falsely moralistic, short-sighted and also obsolete!

The search for improved health conditions of women who are victims of genital mutilation does essentially and substantially not differ from the demand for health and well-being of western women who wish to live a long, healthy and painless life but please notice how this topic is often dealt with by providing it with an opposite meaning.[4]

Besides the Surgery in the true sense of the word, which in this scope is made available to the public mostly with regard to Labiaplasty, there is much more. Currently, excellent results have already been achieved by researchers in the aesthetic and functional improvement of cutaneous-mucosal vulvovaginal hypo-atrophy; to this end, there are many resources available: Hyaluronic Acid,[5, 6] CO2 and Erbium Lasers,[7] LED technology and other important techniques provided by the Regenerative Medicine as the PRP (Platelet Rich Plasma) and the Fat Graft.[8]

Perhaps the time has come to face this topic with a truly scientific attitude (which is not irrespective of ethical issues); exactly the same attitude we are everyday showing in our surgeries and towards our patients; with the same scientific approach taken towards every other science-related topic, including FGM.

The time has come to provide our society with "numbers". In addition to transferring individual experiences verbally, we must focus on cold, hard figures. As a matter of fact, information must be protected to avoid that its scientific meaning is distorted and, above all, we must prevent information from being used for one of the many scoops advertised in non-scientific publications, only for the purpose of increasing the relevant scores in the mediatic battle.

So, please, focus on numbers: we need cold, hard figures!

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First results with mini vaginal mesh implant for pelvic floor prolapse repair: a prospective multi-center study

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OBJECTIVE

Several surgical solutions with vaginal mesh implants for Pelvic Organ Prolapse (POP) repair have been published in the last decade with different cure and complications rates. Although obvious advantage for mesh implants over native tissue repair have been demonstrated, there is a huge debate regarding the use of vaginal mesh implants due to different complications reports and the recent FDA warning. Some of the mesh-related complications might be related to excessive implanted mesh mass. Thus, implanting of reduced size vaginal mesh might reduce the complications rate.

The aim of the current study was to verify the efficacy, cure rate and complications rate of a new reduced-size vaginal mesh which was design for POP repair. The study findings might help surgeons and patients to choose the favorable mesh for POP repair.

METHODS

This is an open prospective multi-center study, design to enroll 100 patients. Research protocol was approved by the ethic committee for each center. First patients were recruited in October 2013 and the research is still on-going. The mesh used in the study is the SERATOM™ PA MN (SERAG WEISSNER), the smaller mesh available today in the market (Figure 1). The fixation of the posterior arms is to the Sacro-Spinous ligament with Prolene 0 sutures. The fixation of the additional anterior and/or posterior arms is optional in cases of anterior and / or posterior prolapse. The mesh can be used without the additional arms (A/P reduced). Hysterectomy for uterine prolapse is not part of the protocol. Patients are asked to fill Quality of Life Questionnaires (PFDI-20 and the PISQ-12) before and 6 months after the operation. Patients will be seen at 6 months and once yearly up to 5 years.

The data collected for this report included: Pre-op patient's symptoms, POP-Q and additional Stress urinary incontinence (SUI). Operation time and hospital stay. Intra and post-operative complications. First follow up at 6 weeks including symptoms and POP-Q.

RESULTS

31 patients were enrolled up to this report. Mean age 64 (range 44-80), mean parity 2.8 (range 1-6) and mean BMI was 25. For the majority of patients the operation was the first for POP repair (30/31). 3 patients were after hysterectomy. All patients presented grade 3 prolapses. 17 patients presented with 3 compartment prolapse. Mean points Ba, Bp, and C before and 6 weeks after the operations are presented in Figure 2. 11 patients had a 4 armed mesh procedure, 15 had anterior two armed mesh and 5 had posterior two armed mesh. 16 patients had pre-op SUI and had an additional sling procedure during the operation. No intra-operative complications were reported. Mean operation time was 43min (range 31min-59min) and the majority of women were released on day 1 post-op (28/31). Post-operative complications included 2 hematomas, 1 UTI and 4 transit bladder outlet obstruction. Patients symptoms before and 6 weeks post-op are presented in Figure 3. Bulge symptoms were resolved for all patients. De novo Urgency observed in 3 patients, de novo SUI 1 patient.

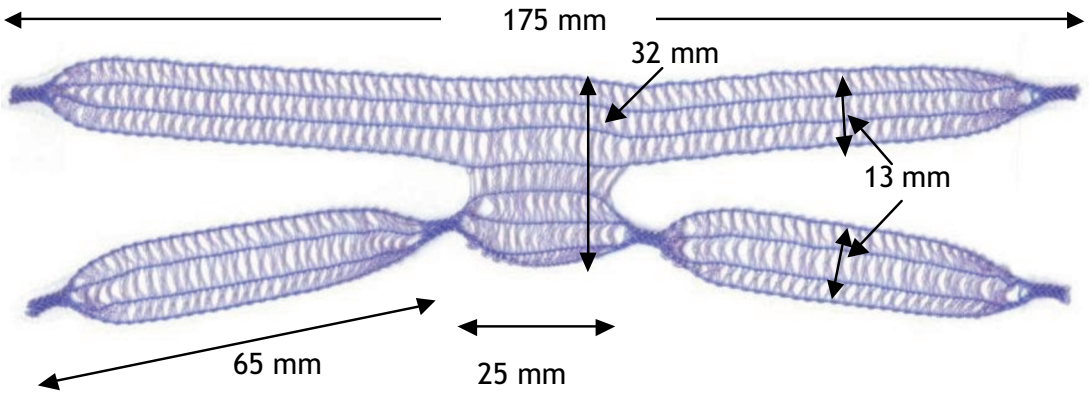

Figure 1. - Seratom PA MR MN.

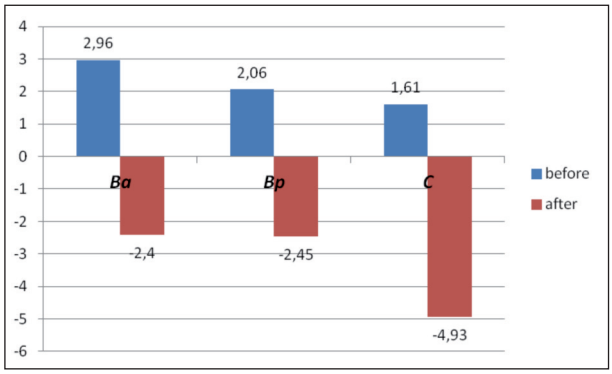

Figure 2. - Mean points Ba, Bp and C before and 6weeks after the operation.

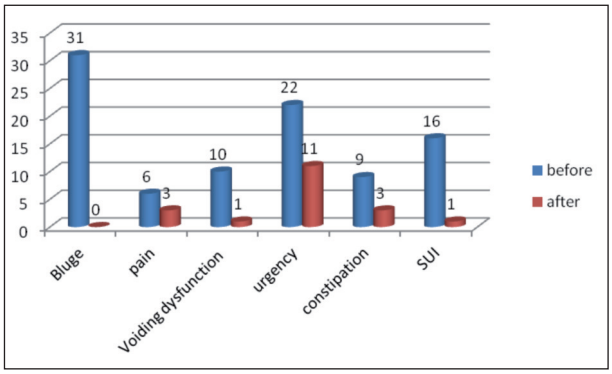

Figure 3. - Patient's symptoms before and 6 weeks after the operation.

CONCLUSIONS

The ability to repair POP with reduced size mesh is demonstrated in this first results study. The procedure was found to be fast, efficient and safe. We continue to enrolled patients and follow the results in order to determine long term cure rate and complications.

DISCLOSURE

Menahem Neuman is consultant for Serag-Wiessner.

The SERAPRO®, an innovative re-usable suturing device for trans-vaginal Sacro-Spinous fixation: Feasibility and Safety study

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OBJECTIVE

Pelvic organs prolapse is estimated to affect approximately 11% of the female population. Sacrospinous fixation is one of the most common surgical techniques to correct apical (level 1) prolapse. The objective of this study was to evaluate the feasibility and safety of SERAPRO® RSD-Ney (Serag-Wiessner, Germany), an innovative suturing device for vaginal sacrospinous fixation (SSF).

METHODS

A single surgeon descriptive study was performed through a retrospective medical records review. Fifty five women who underwent vaginal sacrospinous fixation (SSF) procedure between April 2013 and September 2013for apical (level 1) prolapse bilateral repair using SERAPRO® suturing device instrument and a non-absorbable mono-filament synthetic suture material, were included in the study. All patients were reviewed and examined one first month after surgery and interviewed again 2 months later.

RESULTS

Overall, 55 women included in the study (Table 1). Twenty for women had additional anterior mesh placement, 20 women had posterior mesh and 7 women had both anterior and posterior mesh insertion. In 23 cases additional mid-urethral sling was placed for the treatment of stress urinary incontinence (SUI). The SSF using the SERAPRO® RSD-Ney suturing device was feasible in all cases. No significant difficulty was noted during the procedure. None of the patients had significant or long term morbidity (Table 2). A mean 3 months follow-up demonstrated significant improvement in anatomical and functional parameters (Table 3).

TABLE 1. – Patient's characteristics (n=55).

Age in years (average, range)	62.36 (42-85)
BMI (average, range)	26.98 (21-41)
Deliveries (average, range)	3.8 (1-9)
Major health problems*	14 (25.4%)
Previous hysterectomy	7 (12.7%)
Previous POP surgery	7 (12.7%)
Previous SUI surgery	8 (14.5%)

POP- pelvic organs prolapse, SUI-stress urinary incontinence
*10 women with diabetes, 10 hypertension, 2 asthma, 1 cardiac arrhythmia

TABLE 2. – Complications (n=55).

Complication	**No. of patients**		**Remarks**
Voiding difficulty	6		In 4 resolved spontaneously, 2 needed release of mesh arms
Intraoperative bleeding	1		No need for reoperation nor for blood transfusion
Infection	2	Urinary tract infection	Treated with oral antibiotics
Fever	3	Unknown origin	Treated with oral antibiotics
Cystotomy	1	Unrelated to SSF	Sutured during surgery
Pain	6	3 anal and defecation pain, 2 sacral pain, 1 radiating pain to left leg	All symptoms resolved after 3 month follow-up
Dyspareunia	2		Resolved after 3 months
De-novo SUI	1		
OAB	1	Increased severity of preoperative symptoms	Treated with anticholinergic drugs

TABLE 3. – POPQ and urinary symptoms before and after surgery (n=55).

	Pre-operative	**Post-operative**
Point C	0.58	-6.18
Point Bp	0.9	-2.61
Point Ba	2.43	-2.58
Urgency	27 (49.0%)	7 (12.7%)
Frequency	28 (50.9%)	7 (12.7%)
Nocturia	29 (52.7%)	12 (52.7%)

CONCLUSIONS

Performing sacro-spinous fixation for advanced apical prolapse using the SERAPRO® RSD-Ney suturing device is feasible and safe.

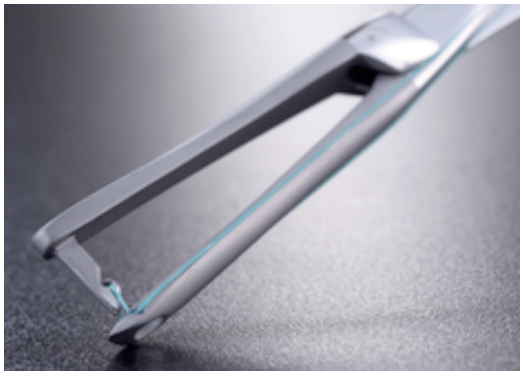

Figure 1. - The tip of the SERAPRO® RSD-Ney suturing device.

Figure 2. - The SERAPRO® RSD-Ney suturing device.

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