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.

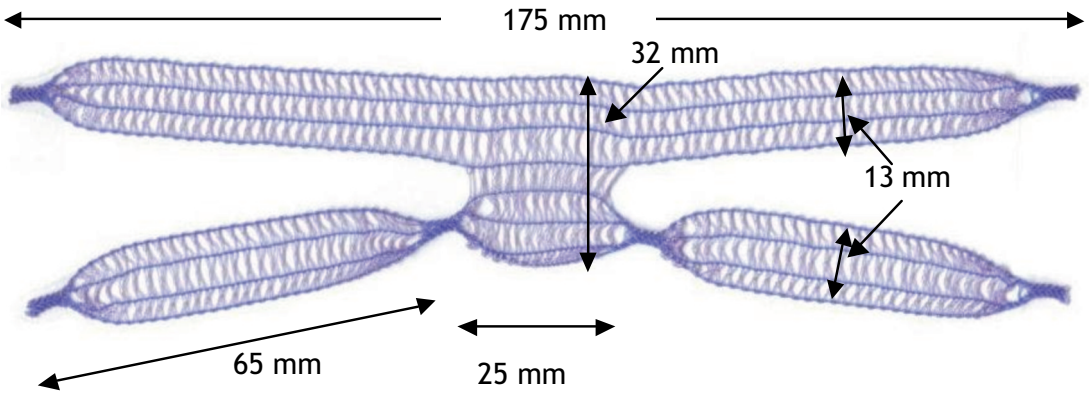

Figure 1. - Seratom PA MR MN.

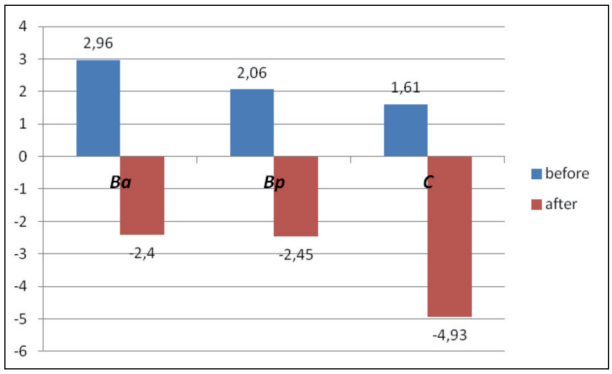

Figure 2. - Mean points Ba, Bp and C before and 6weeks after the operation.

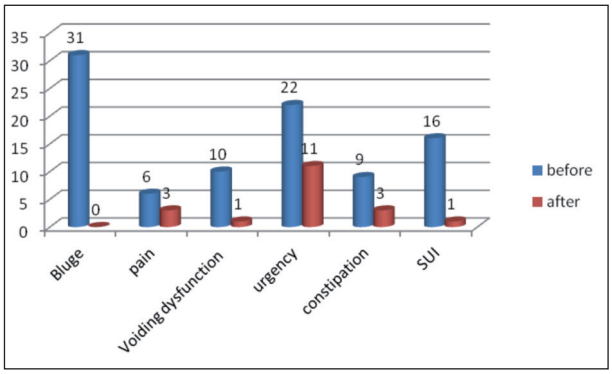

Figure 3. - Patient's symptoms before and 6 weeks after the operation.

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.

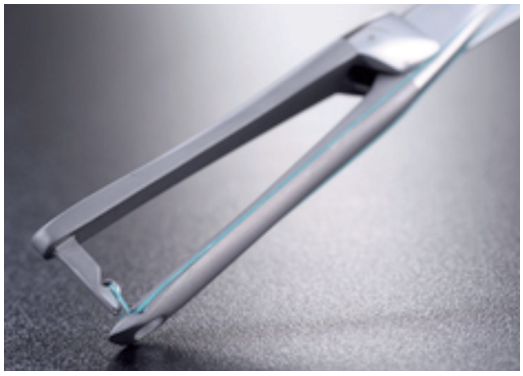

Figure 1. - The tip of the SERAPRO® RSD-Ney suturing device.

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