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Research Article

SURGERY FOR PELVIC ORGAN PROLAPSE: THE CASE FOR AN ANCHORLESS IMPLANT REPAIR

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ABSTRACT

Introduction: The use of mesh kits in pelvic organ prolapse has been curtailed because of attendant complications thought related specifically to the mesh anchoring technique. **Material and Methods**: A retrospective analysis of vaginal prolapse objective and subjective outcome analyzing 3 Groups: transvaginal anchored mesh (Group 1), native tissue repairs (Group 2) and anchorless implant (SRS) repairs (Group 3). **Results**: Groups 1,2,3 included 106, 49 and 70 patients respectively. Follow-up was comparable in the groups with Group 2 patients generally older and Group 3 having a lower mean parity. Group 3 had greater preoperative Ap measurements (Group 1 = -0.62 cm, Group 2 = -0.82 cm and Group 3 = - 1.8 cm; $P < 0.05$) and Bp measurements (Group 1 = 0.32 cm, Group 2 = 0.79 cm and Group 3 = -1.49 cm; $P < 0.05$) with significantly better postoperative Aa measurements (Group 1 = -2.31 cm, Group 2 = -1.07 cm and Group 3 = -2.87 cm; $P < 0.05$) and Ba measurements (Group 1 = -2.08 cm, Group 2 = -0.87 cm and Group 3 = -2.81 cm ; $P < 0.05$). Group 3 reported a higher mean difference improvement in PFDI-20 scores (Group 1 = 15.94, Group 2 = 9.8 and Group 3 = 49.01; $P < 0.05$). Overall the SRS cases experienced less postoperative complications, less recurrent prolapse and less risk of revisional surgery. **Conclusions**: The SRS is safe and effective with improved anatomical outcome accompanied by less prolapse recurrence and improved subjective symptoms.

INTRODUCTION

Pelvic organ prolapse (POP) affects half of parous women with a lifetime risk of POP surgery ranging between 3-19% overall [1, 2]. The high reported rates of recurrence following primary POP repair and the experience of mesh use in inguinal hernia and stress urinary incontinence translated over the last 20 years to the adoption of mesh in POP surgery either as an alternative or as an augmentation to traditional POP repairs [3]. The popularity of sling kits for stress urinary incontinence led to a range of mesh kits for vaginal prolapse being introduced into the surgical market, despite the lack of established data concerning individual safety and efficacy [4]. The spate of reported mesh-related complications including exposure and extrusion, chronic pelvic pain and dyspareunia [5, 6] occasioned two FDA warnings in 2008 and 2011 on transvaginal mesh use for POP [7]. Ultimately the FDA completed an order to reclassify surgical mesh for transvaginal repair in POP as class III and requiring the submission of premarket approval (PMA) applications as part of the agency's most stringent device review pathway. On April 2019 the FDA determined that the manufacturers who had submitted a PMA application failed to demonstrate a reasonable assurance of safety or effectiveness for their devices and as a result, a request was made for sales and distribution of these products to cease[8]. Currently, most countries in Europe (along with Israel) have recommended a reassessment of the indications for mesh in POP patients, whilst pelvic floor surgeons continue with its selective use.

The balance between complications and recurrence is technique-dependent and related to the inherent design and biomechanics of each mesh[9]. However, expert opinion would suggest that mesh anchoring techniques may be a direct cause of particular complications [10]. These specific problems

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include inadvertent organ perforation during anchoring of the mesh, excessive scar formation at anchoring sites and deleterious mechanical effects of mesh contraction and folding [(11)]. Based upon these observations, an anchorless mesh, the Self-retaining Support (SRS) implant, was developed. The SRS is designed to mimic the normal pubocervical fascia reaching down to the level of the ischial spines, thus providing both level I and level II support. The device has been shown to be safe and effective in a preliminary 2-year follow-up study of 20 women [(12)]. This paper retrospectively analyzes our POP surgical cohorts comparing the outcomes of anchored mesh implants, the anchorless SRS implant and native tissue repairs.

MATERIAL AND METHODS

All patients included in these cohorts presented with a symptomatic anterior and/or apical prolapse stage II and higher. Surgical outcome data were compared for 3 groups: Group 1 – Transvaginal, anchored mesh implantation, Group 2 - Native tissue repairs (including anterior and posterior colporrhaphy with or without vaginal hysterectomy, sacrospinous fixation and Manchester-Fothergill procedures) and Group 3 – anchorless mesh - Self retaining Support (SRS).The SRS data were collected from a multicenter study incorporating 4 participating centers in Israel and Hungary: Ziv Medical Center, (Tzfat, Israel), Shamir (Assaf Harofe) Medical Center, (Zrifin, Israel), MayneiHaYeshua Hospital, (Bnei Brak, Israel) and Szeged University Hospital (Szeged, Hungary). This latter ongoing study has received ethical approval from the local institutional Boards of Review and our local hospital ethics committee approved the inclusion and analysis of our additional data derived from this group.

All participating patients were provided with a detailed explanation concerning their surgeries including the information known at the time regarding vaginal mesh implants. All patients signed an informed consent for surgery. Patients with symptomatic prolapse failure after previous vaginal mesh surgery were excluded from analysis. Clinical data regarding prolapse, urinary, bowel and sexual symptoms were obtained using a structured symptom questionnaire administered by a consultant. Evaluation of the vaginal compartments in the lithotomy position during a maximal Valsalva maneuver and prolapse staging was recorded with the Pelvic Organ Prolapse Quantification (POP-Q) system[(13)]. Demographic data were collected including age, BMI, parity, co-morbidities, smoking history and previous hysterectomy. Patients were contacted by telephone and invited for a follow-up visit to assess for possible complications. Each participant completed the Pelvic Floor Distress Inventory (PFDI-20), a validated, condition-specific quality of life questionnaire [(14,15)]. Concerning the surgical technique, patients in Group 1 underwent insertion of Grade A polypropylene mesh with 4 corner anchoring, using bilateral sutures fixating the mesh to the sacrospinous ligament proximally and to the obturator membrane distally. Group 2 patients underwent repair of level II prolapse with a colporrhaphy using absorbable sutures in 2-3 layers to reconstruct the pubocervical fascia combined with a level I repair with unilateral sacrospinous ligament fixation or a Manchester-Fothergill procedure using delayed absorbable sutures. The SRS technique, used in Group 3, was developed based upon data from cadaveric implantation and insertion in animal models [(16)] and has been previously described [(12)]. Briefly, the device comprises an ultra-light titanium-polypropylene mesh (16 g/m^2) stretched into a U-shaped biocompatible polymeric frame which is anticipated to be retained without securing sutures and without the risk of contraction or folding. Following an anterior colpotomy and dissection of the para-vesical space as far as the ischial spines, the SRS device is inserted between the bladder and the vagina. Whenever the uterus is preserved, the cervix is sutured to the proximal edge of the mesh.

Subjective outcome was compared using the PFDI-20 QoL-questionnaire and objective anatomical outcome was defined based upon the POP-Q measurements and the NIH criteria as outlined by Barber *et al*.[(17)]. Data were collected preoperatively and at 6, 12, 24 and 36 postoperative months, with objective and subjective postoperative data presented for the last visit as of April 2019. Statistical analysis was conducted with the SPSS Version 12.0 software (Chicago, IL). The Tukey's p*ost hoc* test was used to determine in which groups the samples differed by comparison of means. Subjective success in PFDI-20 assessment was recorded if there was an improvement in the component portions of the questionnaire where there was a minimally important difference (MID) > 15 points per domain (or a total score difference of 45 points). The Chi-square or Fisher's exact test were used where appropriate with *P* values < 0.05 considered significant. Approval for the conduct of this retrospective analysis was provided by the local hospital Ethics committee with data obtained from the Division of Female Pelvic Medicine at the MayneiHayeshua Hospital, Bnei Brak, Israel covering the period between January 2009 until April 2019. Ethical committee approval numbers: MHCM-12-087 and MHCM-16-0036 (issued 30/10/2016). The SRS studies are registered in clinicaltrials.gov numbers: NCT03195361 and CT02209337.

RESULTS

At the time of analysis, Group 1 (anchored transvaginal mesh) included 106 patients; Group 2, with a range of native tissue repairs, included 49 patients and Group 3 (anchorless SRS Implant) included 70 patients. *Table 1* shows demographic data of the three cohorts.

Table 1 Demographic data of the patient cohort (total n = 225)

	Age Mean (Range)	BMI Mean (Range)	Parity Mean (Range)	Follow-up in months Mean (Range)
Group 1 Anchored mesh	61.87	27.3[a]	5.76	27.34
(n = 106)	(42-83)	(18-41)	(1-14)	(0.5-70)
Group 2 NTR	66.4[b]	27.5	5.61	31.96
(n = 49)	(51-83)	(17-47)	(1-16)	(0-67)
Group 3 SRS	63.06	27.12[c]	4.56[b]	26.24
(n = 70)	(43-79)	(20.3-36.6)	(1-16)	(6-41)

Legend: NTRNative tissue repair
[a]Data available on 82 cases
[b]P < 0.05
[c]Data available on 67 cases

Patients in Group 2 were older than Group 1(mean age: 61.8, 66.4 and 63 years, respectively, *P*=0.002). All three groups were found comparable regarding the follow-up periods. The SRS group was found to have lower parity when compared

with Group 1 but were comparable with Group 2 (5.76, 5.61 and 4.56 respectively, *P*= 0.04).

Table 2 shows the POP-Q measurements before surgery and at last follow-up. Before surgery, patients in Group 1 had lower point D measurements (-3.35, -5.14, -4.69 cm, *P*=0.002). Patients in Group 2 had a shorter total vaginal length (TVL) prior to surgery. Patients in Group 3 had lower preoperative Ap measurements (SRS vs. Mesh, *P*=0.002 and SRS vs. NTR, P=0.02) and Bp measurements (SRS vs Mesh, *P*=0.0008, SRS vs NTR, P=0.0003). Group 3 patients showed significantly better anatomical results, as manifested by specific POP-Q measurements (Aa, Ba) which were consistently better when compared with the other groups (*Table 2*). Post-operative C point measurements were comparable between groups. All patients in Group 2 underwent a posterior colporrhaphy and achieved significantly better results for posterior wall prolapse (Ap and Bp measurements) when compared with the other techniques.

Table 2 Measurable POP-Q data for the treated groups (* No. of cases assessed).

Parameter	Group I [Anchored Mesh].		Group II [Native Tissue Repair]		Group III [Self Retaining Support]	
Aa						
Pre-op	**No. * 106**	**2.32cm (-3, +3)**	**No. * 49**	**2 cm (-3, +3)**	**No. * 70**	**2.06 cm (-1, +3)**
Post-op	**103**	**-2.31cm ¥ (-3, +3)**	**45**	**-1.07 cm ¥ (-3, +3)**	**70**	**-2.87 cm ¥ (-3, 0)**
Ba						
Pre-op	106	3.34 cm (-3, +8)	49	3.63 cm (-3, +10)	70	3.16 cm (-2, +6)
Post-op	104	-2.08 cm ¥ (-3, +6)	45	-0.87 cm ¥ (-3, +4)	70	-2.81cm ¥ (-3, 0)
C						
Pre-op	106	0.54 cm (-8, +8)	49	1.51 cm (-8, +11)	70	0.37 cm (-8, +6)
Post-op	102	-5.74 cm (-9, +6)	45	-6.51 cm (-8, +4)	70	-6.79 cm (-10, +1)
gh						
Pre-op	106	5.01 (2,8)	43	4.91 cm (3,6)	NA	-
Post-op	79	4.42 (3,4)	45	4.42 cm (2,6)	NA	-
pb						
Pre-op	106	2.42 cm (2,5)	42	2.45 cm (2,3)	NA	-
Post-op	79	2.72 cm (2,4)	45	2.73 cm (2,4)	NA	-
TVL						
Pre-op	106	8.42 cm (6, 10)	49	7.92 cm ¥ (7, 12)	70	8.36 cm (5,12)
Post-op	84	7.65 cm (6,9)	45	7.49 cm (5,8)	70	8.09 cm (6, 11.5)
Ap						
Pre-op	97	-0.62 cm (-3, +3)	49	-0.82 cm (-3, +3)	70	-1.8 cm ¥ (-3, +3)
Post-op	103	-2.23 cm (-3, +3)	45	-2.76 cm ¥ (-3, +1)	70	01.98 cm (-3, +1)
Bp						
Pre-op	95	0.32 cm (-3, +8)	48	0.79 cm (-3, +10)	70	-1.49 cm ¥ (-3, +6)
Post-op	103	-2.05 cm (-3, +6)	45	-2.76 cm ¥ (-3, +1)	70	-1.95 cm (-3, +1)
D						
Pre-op	66	-3.35 cm ¥ (-8, +8)	44	-5.14 cm (-8, 0)	63	-4.69 cm (-10, +5)
Post-op	32	-6.91 cm (-9, -5)	5	-6.40 cm (-8, -5)	54	-7.47 cm (-10, -2)

Table 3 compares PFDI-20 score changes at latest follow-up with the pre-operative scores showing that patients in the SRS group achieved a higher mean difference when compared with Group 1 and with Group 2. *Table 4* shows the type and incidence of postoperative complications. No cases of organ perforation were observed. Mesh erosions were documented in 14.2% of Group 1 anchored cases and - erase with frame erosion in 1.4% of the anchorless SRS Group 3 cases (*P*=0.001). Recurrent anterior wall prolapse was documented in 15.1% of Group 1 patients *vs.* 1.4% of Group 3 cases (*P*=0.006). Recurrent surgery was needed in 16% of Group 1 cases, 8.2% of Group 2 patients and in none of Group 3 patients (P = 0.003).

Table 3 PFDI-20 Quality of Life Scoring between the 3 groups

		No.	Mean Difference	Minimum Difference	Maximum Difference	P value
(PFDI-20)	Group I MESH	84	15.94	0	56.0	
	Group II NTR	45	9.8	0	44.0	
	Group III SRS	70	49.01	0	170.0	P<0.05

The PFDI-20 = Pelvic Floor Distress Inventory Questionnaire is scored between 0-300 points over 3 domains.
NTR = Native tissue repair
SRS = Self retaining support device

Table 4 List of Postoperative Complications

	Group I Mesh (N=106) n (%)	Group II NTR (N=49) n (%)	Group III SRS (N=70) n (%)	P value
Perforation/injury	-	-	-	
Erosion	15(14.2)	-	1 (1.4)	0.001
Recurrent prolapse	16 (15.1)	13 (26.5)	1 (1.4)	0.006
Fecal complaints	3 (2.8)	3 (6.1)	4 (5.7)	
Urinary complaints	37 (34.9)	12 (24.5)	19 (27.1)	
Recurrent surgery	17 (16)	4 (8.2)	-	0.003

DISCUSSION

This study, comparing anchorless (SRS) implant to anchored mesh and native tissue repairs has shown clinical advantage for the SRS patients, with a lower rate of POP recurrence, reduced need for repeated surgery and lower risk of mesh erosion. These findings were accompanied by better anatomical outcome for anterior vaginal wall prolapse (POP-Q points Aa and Ba) and by significant improvement in subjective outcome. As far as we are aware, this is the first study in patients with symptomatic POP comparing surgical outcome following vaginal anchorless implant, anchored mesh and native tissue repair.

The management of POP patients continues to be challenging where native repairs in many centers have a poor success rate and where mesh repairs fare better but where their use is balanced against specific complications many of which will require surgical reintervention [18,19]. In a matched study by Dias *et al.* [20] comparing traditional colporrhaphy with transvaginal mesh for advanced vaginal anterior wall prolapse, higher anatomical success was achieved in the mesh group although both groups reported similar improvement in recorded QoL. Since the FDA posted public notifications concerning mesh-related complications, a number of systematic reviews have been published which highlight the range of postoperative complications following vaginal mesh surgery[21-23], as well as management options [24] and impact on quality of life[25]. According to available FDA data, the majority of mesh-related complications occur within the first 6 postoperative months, with the principal complaints being mesh erosion, contraction and pain, predominantly related to the graft anchoring mechanism [11]. Mesh contraction and

bunching, observed to occur with the currently available mesh-fixation kits, have the potential for nerve entrapment, chronic pelvic pain and dyspareunia and are caused by excessive tension following mesh deployment or where there is disproportionate scarring at the points of fixation. Reports on resolution of pain in most patients following partial mesh removal at the fixation points and a revisional reduction of tension on the implant has corroborated the assumption that mesh anchoring has a central role in postoperative complications[11]. These reports, along with a better understanding of the mechanisms of pelvic floor support have led to the search for an optimal transvaginal mesh which can fulfil the criteria of safety and efficacy.

Prior evidence has shown other non-anchored vaginal support devices to be safe and effective when compared with tension-free mesh implants [26], and to induce lower immunological reactivity and mesh fibrosis when lighter-weight mesh types are used[27]. The SRS implant was developed in order to provide the advantages of an ultra-light weight mesh without the drawbacks related to mesh fixation. Preliminary evidence has shown such complications are avoided by utilizing a light-weight vaginal frame [28]. In the only published clinical study on the SRS implant so far, there is demonstrated efficacy and durability with minimal risk of erosion, pelvic pain or the need for reoperation [12].

In the current study, postoperative measurements of the anterior vaginal wall (points Aa and Ba) were significantly better in the SRS group when compared with both the anchored mesh group and the native tissue repair group. Our patients in both Groups 1 and 2 showed comparable anatomical outcomes when compared with a recent Cochrane study assessing anchored transvaginal repair with native tissue repairs [28]. This was accompanied by similar postoperative POP-Q measurements. Besides demonstrating a better objective anatomical outcome with the SRS implant, our data also suggest a better subjective outcome with a greater overall improvement in PFDI-20 scores following SRS placement when compared with other surgeries. Currently,a nchored mesh implantation is commonly selected for treatment of advanced POP in young and sexually active patients, in order to provide the best possible long-term outcome and so as to reduce the recurrence rate.

Unfortunately, the significant improvements achieved with vaginal mesh surgery in urinary, defecatory and sexual functioning may be offset by the deleterious impact of mesh complications, particularly mesh erosion [29]. In our community hospitals in Israel, a high percentage of patients present with advanced prolapse at a young age due to high parity. The impact of mesh-related complications in this sexually active population may be devastating [30]. Because of the low risk of erosion and recurrent POP the SRS implant may provide an excellent long-term solution for young, active women initially presenting with very advanced POP. The one case of erosion documented in Group 3 was related to the solid frame and not to the polypropylene net and was likely caused by insufficient dissection. The promising results of this preliminary study should be viewed with some caution given its retrospective design and the demographic differences in age and parity between the study groups. We also acknowledge that there are likely to be inherent differences in several health domain scores, when comparing our cohort of women undergoing transvaginal mesh implants with women from other regions. Furthermore, we could not collect information on post-operative sexual function, as a large proportion of our patients were of strict religious background and declined to complete a PISQ-12 questionnaire. In conclusion, this retrospective analysis has shown that anchorless implant repair in POP is safe and effective, more readily restoring measurable parameters of anterior vaginal wall prolapse and enhancing quality of life when compared with anchored mesh implants or native tissue repairs. Larger studies are needed in order to ascertain the potential benefit of the SRS implant particularly on quality of life. These data favor the institution of a prospective, randomized controlled clinical trial which incorporates an SRS arm, and which compares outcome in the different surgical techniques.

Conflict of Interest Statement

Dr. Gil Levy is the developer of the SRS implant and shareholder in the developing company. None of the other authors have any conflict of interest to declare.

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