

CONCLUDING MESSAGE: THESE RESULTS INDICATE THAT FOLLOWING SURGERY FOR VAGINAL PROLAPSE USING THIS MESH REPAIR SYSTEM, THERE WERE SUBSTANTIAL IMPROVEMENTS IN SEXUAL FUNCTION IN SEXUALLY ACTIVE WOMEN, MOST NOTABLY DUE TO THE RESOLUTION OF BULGE WITHIN THE PHYSICAL PORTION OF SEXUAL FUNCTION AS DESCRIBED BY THE PISQ-12. MOREOVER, THE RATES OF RESOLUTION OF PRE-EXISTING DYSPAREUNIA AND RESUMPTION OF SEXUAL ACTIVITY IN NON-SEXUALLY ACTIVE WOMEN ARE ENCOURAGING.

TABLE 1. TOTAL, SUB-SCALE AND INDIVIDUAL ITEM SCORES FOR PISQ-12 AT BASELINE AND 12 MONTHS AFTER VAGINAL MESH REPAIR OF PROLAPSE WITH VSD

PISQ-12 SECTION

BASELINE

MEAN (STD)

12 MONTHS

MEAN (STD)

Δ BASELINE TO

12 MONTHS

MEAN (STD)

TOTAL SCORE (N=73)

26.9 (13.7)

31.4 (12.9)

4.4 (16.9)*

SUB-SCALE

BEHAVIORAL/EMOTIVE SUBSCALE

8.1 (4.7)

8.6 (4.4)

0.4 (5.0)

PHYSICAL SUBSCALE

12.6 (6.6)

15.5 (6.4)

3.0 (9.1)**

PARTNER-RELATED SUBSCALE

6.2 (3.5)

7.2 (3.2)

1.0 (4.1)*

BEHAVIORAL/EMOTIVE

1. FREQUENCY OF FEELING SEXUAL DESIRE

2.1 (1.0)

2.2 (1.0)

-0.1 (0.8)

2. CLIMAX (ORGASM) WITH PARTNER

2.1 (1.3)

2.0 (1.3)

-0.1 (1.3)

3. FEELING SEXUAL EXCITEMENT

2.9 (1.0)

2.8 (1.0)

-0.1 (0.9)

4. SATISFACTION WITH VARIETY OF SEXUAL ACTIVITIES

2.7 (1.1)

2.8 (1.0)

0.1 (1.2)

PHYSICAL

5. FEELING PAIN DURING SEX

2.7 (1.2)

2.8 (1.1)

0.2 (1.4)

6. INCONTINENT OF URINE DURING SEX±

3.5 (0.9)

3.7 (0.7)

0.3 (0.7)*

7. FEAR OF INCONTINENCE (STOOL /URINE) RESTRICTS SEX±

3.4 (0.9)

3.6 (0.9)

0.3 (1.0)

8. AVOID SEX DUE TO BULGING IN THE VAGINA±

2.5 (1.3)

3.8 (0.7)

1.2 (1.4)***

9. NEGATIVE EMOTIONAL REACTIONS DURING SEX±

3.2 (1.2)

3.7 (0.8)

0.4 (1.2)*

PARTNER-RELATED

10. PROBLEM WITH ERECTIONS AFFECTS SEX±

3.0 (1.2)

3.0 (1.2)

0.2 (1.0)

11. PROBLEM WITH PREMATURE EJACULATION±

3.4 (1.0)

3.6 (0.8)

0.2 (0.9)

12. INTENSITY OF ORGASMS #

1.2 (0.8)

1.6 (0.8)

0.4 (0.9)**

P<0.05; ***P<0.01; *P<0.001; ITEM SCORES RANGED FROM 0-4; HIGHER SCORES INDICATE BETTER FUNCTION. TOTAL AND SUB-SCALE SCORES WERE ANALYSED FOR 73 SUBJECTS WHO COMPLETED THE PISQ-12 INSTRUMENT AT LEAST ONCE DURING THE STUDY. IN THE EVENT OF MISSING INSTRUMENTS DUE TO LACK OF SEX, TOTAL AND SUB-SCALE SCORES WERE SET TO 0. RESPONSE RATE FOR INDIVIDUAL ITEMS VARIED N=52; #N=50; ±N=51.**

FIGURE 1. SEXUAL DISPOSITION AT BASELINE AND 12 MONTHS AFTER SURGICAL REPAIR WITH MESH

Concluding message: These results indicate that following surgery for vaginal prolapse using this mesh repair system, there were substantial improvements in sexual function in sexually active women, most notably due to the resolution of bulge within the physical portion of sexual function as described by the PISQ-12. Moreover, the rates of resolution of pre-existing dyspareunia and resumption of sexual activity in non-sexually active women are encouraging.

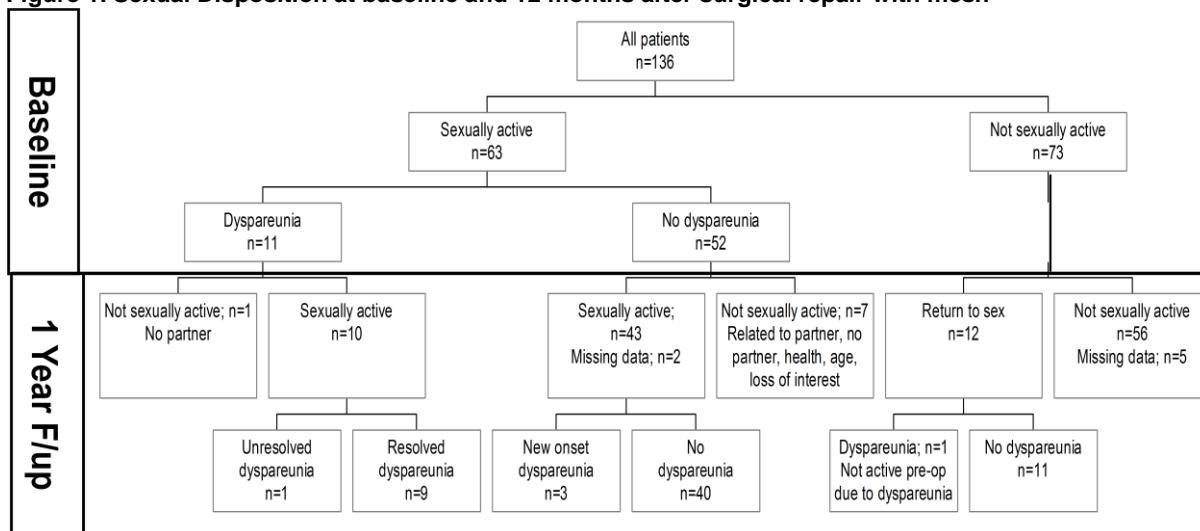
Table 1. Total, sub-scale and individual item scores for PISQ-12 at baseline and 12 months after vaginal mesh repair of prolapse with VSD

PISQ-12 Section	Baseline Mean (std)	12 Months Mean (std)	Δ Baseline to 12 months Mean (std)
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	Total Score (n=73)	26.9 (13.7)	31.4 (12.9)	4.4 (16.9)*
Sub-scale	Behavioral/Emotive Subscale	8.1 (4.7)	8.6 (4.4)	0.4 (5.0)
	Physical Subscale	12.6 (6.6)	15.5 (6.4)	3.0 (9.1)**
	Partner-Related Subscale	6.2 (3.5)	7.2 (3.2)	1.0 (4.1)*
Behavioral/E motive	1. Frequency of feeling sexual desire	2.1 (1.0)	2.2 (1.0)	-0.1 (0.8)
	2. Climax (orgasm) with partner	2.1 (1.3)	2.0 (1.3)	-0.1 (1.3)
	3. Feeling sexual excitement	2.9 (1.0)	2.8 (1.0)	-0.1 (0.9)
	4. Satisfaction with variety of sexual activities	2.7 (1.1)	2.8 (1.0)	0.1 (1.2)
Physical	5. Feeling pain during sex	2.7 (1.2)	2.8 (1.1)	0.2 (1.4)
	6. Incontinent of urine during sex [±]	3.5 (0.9)	3.7 (0.7)	0.3 (0.7)*
	7. Fear of incontinence (stool /urine) restricts sex [±]	3.4 (0.9)	3.6 (0.9)	0.3 (1.0)
	8. Avoid sex due to bulging in the vagina [±]	2.5 (1.3)	3.8 (0.7)	1.2 (1.4)***
	9. Negative emotional reactions during sex [±]	3.2 (1.2)	3.7 (0.8)	0.4 (1.2)*
Partner-Related	10. Problem with erections affects sex [±]	3.0 (1.2)	3.0 (1.2)	0.2 (1.0)
	11. Problem with premature ejaculation [±]	3.4 (1.0)	3.6 (0.8)	0.2 (0.9)
	12. Intensity of orgasms [#]	1.2 (0.8)	1.6 (0.8)	0.4 (0.9)**

*p<0.05; **p<0.01; ***p<0.001; Item scores ranged from 0-4; higher scores indicate better function. Total and sub-scale scores were analysed for 73 subjects who completed the PISQ-12 instrument at least once during the study. In the event of missing instruments due to lack of sex, total and sub-scale scores were set to 0. Response rate for individual items varied n=52; #n=50; ±n=51.

Figure 1. Sexual Disposition at baseline and 12 months after surgical repair with mesh



References

- References: Barber MD, Brubaker L, Nygaard I, et al. Defining success after surgery for pelvic organ prolapse. Obstet Gynecol 2009; 114:600-609.

Specify source of funding or grant	Ethicon, Inc
Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	There were 12 investigators who each sought may begin enrolment of patients after full approval of the protocol and adjunctive materials (e.g., informed consent form, etc) from a local MEC/IRB. Therefore there were multiple IRBs.
Was the Declaration of Helsinki followed?	Yes

Was informed consent obtained from the patients?

Yes
