

## PREVALENCE AND RISK FACTORS FOR MESH EROSION AFTER MINIMALLY INVASIVE SACROCOLPOPEXY.

### Hypothesis / aims of study

Mesh erosions are usually defined as visible portions of surgical material, usually mesh or suture, which has become exposed through the epithelium of the vagina or into adjacent visceral organs. Mesh erosion rates with sacrocolpopexy range from 2-10% in the literature [1-2]. Although these complications are relatively uncommon, the consequences of erosions range from negligible to severe. Minimally invasive sacrocolpopexy (MISC) utilizes slightly different techniques than the traditional open abdominal sacrocolpopexy and thus carries potentially different risks of erosion. The purpose of this study was to identify rates and risk factors for mesh erosion in women undergoing MISC using various techniques. It is our hypothesis that the mesh erosion rate is higher in subjects undergoing concomitant hysterectomy compared to those women who are post-hysterectomy.

### Study design, materials and methods

This was an IRB approved retrospective chart review of all MISC performed at the two institutions in our fellowship-training program between 11/2004 and 2/2009. Baseline and historical characteristics of the subjects, and the surgical procedures including hysterectomy were evaluated as potential risk factors for mesh erosion. MISC was performed as a robotic assisted laparoscopic sacrocolpopexy (RALSC) or a standard laparoscopic sacrocolpopexy (LSC). In all cases, monofilament suture was used to secure type I polypropylene mesh to the vagina. Those women with a uterus who underwent RALSC all had a supracervical hysterectomy (SCH) and intracorporeal suturing of mesh to the vagina and sacrum. Those who underwent LSC either had a total vaginal hysterectomy (TVH) with mesh attachment transvaginally prior to the laparoscopic portion of the procedure (VALSC) or they had a TVH followed by mesh attachment laparoscopically after vaginal closure of the cuff (VHLSC). Chi squared, Fischer's exact, and t tests were used to explore relationships between mesh erosion and risk factors. Variables with  $p < 0.10$  were entered into a multivariable regression model to identify odds of mesh erosion with 95% confidence intervals (OR; 95%CI).

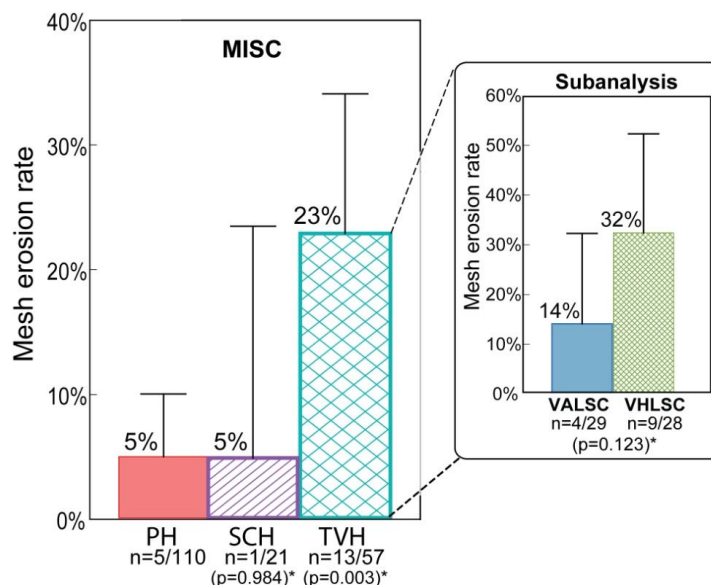
Our power analysis was based on a study of open abdominal sacrocolpopexy by Thompson et al who found that subjects who had previous hysterectomy had a mesh erosion rate of 0.7%, while those who underwent concomitant total abdominal hysterectomy had an erosion rate of 13.6% [3]. We would need at least 50 subjects in each arm in order to detect a difference in mesh erosion rate with  $\alpha=0.05$  and 80% power.

### Results

A total of 196 women underwent MISC and 96% (62 RALSC and 126 LSC) had sufficient data for follow-up. The mean age of the 188 women was  $61 \pm 9$  years and median prolapse stage of 3. Median follow up was 20 (3-124) weeks in the RALSC compared to 14 (2-171) weeks for LSC group, ( $p = 0.280$ ). A total of 34% (21) in the RALSC and 44% (57) in the LSC group had concomitant hysterectomy. Of those who had a TVH, 29 had the mesh attached to the vagina transvaginally (VALSC) while 28 had the mesh attached laparoscopically (VHLSC). Mesh erosion rates were 5% in both the post-hysterectomy and SCH groups ( $p=0.984$ ). In the concomitant TVH group mesh erosion rates were 23% ( $p=0.003$ ). A subanalysis was performed on the subjects with TVH who were divided into VALSC and VHLSC. VHLSC had a higher erosion rate than VALSC although this difference was not statistically significant (Figure 1).

There were no differences in age, parity, weight, preoperative prolapse, duration of surgery, postoperative anemia, or predisposing medical conditions (diabetes, smoking, hormone use) between subjects who did and did not develop erosion. The mean time to mesh erosion detection was  $23 \pm 21$  weeks (range 3-86 weeks) with a median of 14 weeks (all 19 subjects). There was only one subject in the SCH group with mesh erosion which occurred at 6 wks. The mean time to erosion for the post-hysterectomy subjects were  $31 \pm 29$  weeks (median 27,  $n=5$ ) and  $21 \pm 17$  weeks (median 12,  $n=13$ ) for the TVH subjects, this difference did not meet statistical significance ( $p=0.661$ ).

Figure 1.



PH - post-hysterectomy (reference group)  
 SCH - supracervical hysterectomy  
 TVH - total vaginal hysterectomy  
 VALSC - vaginally assisted laparoscopic sacrocolpopexy (transvaginal placement of mesh)  
 VHLS - vaginal hysterectomy prior to laparoscopic sacrocolpopexy (laparoscopic placement of mesh)

\*Fisher's exact test

Multivariable regression models included posterior colporrhaphy and hysterectomy. Only TVH remained a significant risk factor for mesh erosion compared to post hysterectomy (5.67; 1.88-17.10). There was no difference in mesh erosion between SCH and post hysterectomy (0.99; 0.11-9.03). A subanalysis revealed a trend towards higher mesh erosion with laparoscopic placement of mesh after TVH compared to vaginal (2.96; 0.79-11.09) but this finding was not statistically significant. Of the 19 erosions, 15 were initially treated with vaginal estrogen. Only 3 (20%) resolved with estrogen therapy. A total of 10 (53%) required additional surgical procedures while 5 (26%) opted for expectant management.

**Interpretation of results**

Erosions may be asymptomatic and inconsequential or they may present with severe infection or result in fistulae. Identification of modifiable risk factors for the development of this complication is critical. Our study demonstrates a 6-fold increase risk of mesh erosion when TVH is performed at the time of MISC compared to subjects who had MISC post-hysterectomy or with SCH. After careful analysis of all potentially contributing variables, only the TVH remained a significant modifiable risk factor. Only 20% of those with erosions responded to conservative estrogen therapy alone.

Mesh erosion may result from a combination of bacterial infection and devascularization of the vaginal cuff. Opening of the vaginal cuff with exposure of the surgical bed to vaginal flora may be a key component in the evolution of subsequent erosion. Our reported mesh erosion rate of 23% for subjects who had concomitant TVH with MISC is higher than rates reported in the literature for TAH with ASC. There are several possible explanations for this finding. TVH inherently differs from TAH in the amount of surgical bed exposure to vaginal flora which may result in higher risk of infection. This is supported by the observation that subjects who underwent a supracervical hysterectomy at the time of their sacrocolpopexy had the same rate of erosion as the post-hysterectomy group.

**Concluding message**

In conclusion, post-hysterectomy MISC and MISC associated with concomitant SCH have acceptably low rates of mesh erosions. However concomitant TVH results in a high rate of mesh erosion with a 6-fold increased risk. Based on these data surgeons should consider SCH as the procedure of choice in association with MISC unless removal of the cervix is otherwise indicated.

**References**

1. Diwadkar, G.B., et al., Complication and reoperation rates after apical vaginal prolapse surgical repair: a systematic review. *Obstet Gynecol*, 2009. 113(2 Pt 1): p. 367-73.
2. Cundiff, G.W., et al., Risk factors for mesh/suture erosion following sacral colpopexy. *Am J Obstet Gynecol*, 2008. 199(6): p. 688 e1-5.
3. Thompson, P.K., J.E. Pugmire, and H. Sangi-Haghpeykar, Abdominal Sacrocolpopexy Utilizing Gore-Tex in Genital Prolapse: Unresolved Issues. *Journal of Pelvic Medicine & Surgery*, 2004. 10(6): p. 311-317.

<b>Specify source of funding or grant</b>	None
<b>Is this a clinical trial?</b>	No
<b>What were the subjects in the study?</b>	HUMAN
<b>Was this study approved by an ethics committee?</b>	Yes
<b>Specify Name of Ethics Committee</b>	University of California, San Diego Institutional Review Board Kaiser Permanente San Diego, Institutional Review Board
<b>Was the Declaration of Helsinki followed?</b>	Yes
<b>Was informed consent obtained from the patients?</b>	No