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RISK FACTORS FOR MESH/SUTURE EROSION FOLLOWING SACROCOLPOPEXY

Hypothesis / aims of study:
Abdominal sacrocolpopexy (ASC) is a commonly performed procedure for the surgical treatment of apical pelvic organ prolapse. Despite recognition of the risk of erosion, synthetic graft materials have been preferred over autologous grafts for ASC because they are durable, avoid the morbidity and operative time of harvesting fascia, are readily available and are relatively inexpensive. Our objective was to identify demographic and surgical parameters associated with mesh/suture erosion in participants in the Colpopexy andUrinary Reduction Efforts (CARE) trial. The methods and primary outcome of this trial have been previously reported [1, 2]. The level 1 evidence from this trial provides an excellent opportunity to look for potential risk factors for mesh/suture erosion in a large cohort of well-described patients that underwent a sacrocolpopexy with standardized physical exams at set intervals during the two-year follow-up.

Study design, materials and methods:
This prospectively planned analysis included baseline, surgical and post-operative outcome data, as well as complication and safety data collected throughout the 2-year postoperative follow-up period of the CARE trial, a study of the Pelvic Floor Disorders Network. Sacrocolpopexy via laparotomy was the clinically selected surgery whereas the Burch colposuspension was the research procedure in the CARE trial. Therefore to enhance generalizability, the study permitted variations in ASC technique that were not thought to influence the primary and secondary outcomes of the trial. Participants underwent the a standardized Pelvic Organ Prolapse Quantification (POP-Q) examination [3] at baseline, the 6 weeks, 3 months, 12 months and the 2-year postoperative visit. A speculum exam to screen for mesh or suture erosion was performed at each post-op visit.
Selected graft and sutures material (from a list generated during study inception that reflected their common clinical practice) included autologous tissue, synthetic material including woven polyester, polypropylene, soft weave polypropylene, expanded polytrafluroethylene, allograft material and xenograft material. Synthetic absorbable material was not allowed. Graft material was sutured to both the anterior and posterior vaginal walls and then anchored to the anterior longitudinal ligament of the sacrum in such a way as to avoid tension on the anterior portion of the graft with a minimum of two stitches to secure the graft to the sacrum. Technical aspects of the sacrocolpopexy procedure, including performance of concurrent procedures for anterior and posterior prolapse, culdoplasty, and reperitonealization were left to surgeon preference but were recorded. Adverse events forms were completed for each episode of mesh or suture erosion and were updated after any procedure or treatment for this complication. For this analysis, two surgeon authors reviewed all foreign body adverse events inclusive of surgical reports to confirm the nature of the surgical material complication, treatment and last known status.
The groups were compared at baseline by age, body mass index (BMI), and prolapse stage; subsequent analyses were not adjusted for these measures since they were similar in both groups. Fisher's exact test is used to compare the proportion of erosions in those with a specific material to the proportion of erosions in those not using the material; all p-values are two-tailed.

Results:
There were 20 (6%) mesh/suture erosions reported within two years of surgery. Three of the erosions involved suture only, while 17 had exposed mesh. The mean interval from surgery to erosion was 313 days (range 45-744). Current smoking was more common in subjects with mesh/suture erosion [5/20(25%) versus 18/302 (6%), OR 5.2 (CI 1.7, 16.0), p=0.009]. There were no other statistically significant demographic differences between subjects with and without mesh/suture erosion, operating time, estimated blood loss, or intraoperative and postoperative complications. Concurrent hysterectomy was performed in 83/322 (26%) of subjects, and was more common in the group with mesh/suture erosion [60% versus 24%, OR 4.9 (CI 1.9, 12.4), p=0.0009]. Table 1 shows the variety of graft and suture materials.

Table 1		Mesh Erosion N=20	No Erosion N=302	% with Erosion	P-value
Graft	Braided polyester *	10	124	7.5%	0.49
	Polypropylene†	8	148	5.1%	0.49
	Porcine dermis ‡	2	20	9.1%	0.64
	ePTFE#	0	5	0%	1.0
	ePTFE+ other synthetic graft	4	12	25.0%	0.012
Vaginal suture	polypropylene††	2	24	7.7%	0.69
	Braided polyester**	1	37	2.6%	0.49
	ePTFE##	15	157	8.7%	0.063
Suture to sacrum	polypropylene††	0	9	0%	1.0
	Braided polyester**	7	149	4.5%	0.25
	ePTFE##	13	139	8.6%	0.11

*Mersilene ™ Ethicon Inc, Sommerville NJ, †Prolene ™ Ethicon Inc, Sommerville NJ) or Gynemesh ™ (soft weave polypropylene) Ethicon Women's Health & Urology, Cincinnati, ‡Pelvicol ™ , (hexamethylene diisocyanate cross-linked porcine dermis) CR BARD, Murray Hill, NJ, #Gore-Tex®, GORE™ Medical, Newark DE, ††Prolene™, Ethicon Inc, Sommerville NJ, **Ethibond™, ™ Ethicon Inc, Sommerville NJ, ##Gore-Tex®, GORE™ Medical, Newark DE

Interpretation of results:
The risk of mesh complications was nearly four-fold higher if ePTFE (Gore-Tex®) mesh was used compared to a non- ePTFE mesh. Although only 6% of patients had their ASC performed with ePTFE material, the 4-fold association was significantly strong and clinically relevant.
Concurrent total abdominal hysterectomy was performed in 26% of our subjects and these subjects had a 14% risk of erosion compared to just 4% in women who had a previous hysterectomy and, therefore, had their colpopexy performed on an intact vaginal cuff. This is a five-fold increased risk of erosion with concomitant hysterectomy.

Concluding message:
There are modifiable surgeon and patient risk factors that are associated with an increased risk of mesh or suture erosion.

References

1. Control Clin Trials 2003;24(5):629-42.
2. N Engl J Med. 13;354(15) (2006 Apr):1557-66.
3. Am J Obstet Gynecol. 1996 Jul;175(1):10-7.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**This trial is registered at clinicaltrials.gov as NCT00065845.**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**This trial was registered and received IRB approved at all participating sites (Univeristy of Michigan, Loyola, University of Alabama at Birmingham, Johns Hopkins, University of Pittsburgh, University of Texas, University of North Carolina and University of Iowa) prior to enrollment of women planning sacrocolpopexy for Stage II-IV prolapse without symptoms of stress incontinence between March 7, 2002 and February 7, 2005.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**