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CAN CARDIAC STENT & INTRAOCULAR LENS TECHNOLOGY BE APPLIED TO PELVIC FLOOR REPAIR WITH MESH SAFELY AND EFFECTIVELY?

Hypothesis / aims of study

Use of mesh kits has increased substantially in recent years, but some questions remain over the body's reaction to the implanted graft. PC is a polymer that has been designed to minimize the body's inflammatory responses to foreign bodies and bacterial adhesion (1,2). This technology has been successfully applied to cardiac stents, intra-ocular and contact lenses, as well as other applications (3). In theory, treating a mesh implant with such a substance could reduce protein and fibroblasts on the mesh with consequent reduction in inflammation, pain, scarring, and possible mesh exposure. We report the results of a pilot study to test the efficacy and safety of phosphorylcholine (PC) treated polypropylene mesh grafts for mesh for the surgical repair of pelvic organ prolapse.

Study design, materials and methods

Surgeons from 5 U.S. clinical sites entered data into a secure, password-protected, on-line, self-reported registry that collected data on patients implanted with a range of AMS prolapse repair products. All surgeons complied with the informed consent requirements of their IRB. All patients implanted with Perigee Intepro Lite + PC baseline from June 2009 to April 2010 are included in this study. Data collected included demographics and prolapse severity assessed by the Pelvic Organ Prolapse Quantification System (POP-Q) or Baden-Walker (B-W) scales. Inclusion criteria were female patients who were at least 21 years of age with anterior compartment prolapse of POP-Q or B-W scale 2 or more, that were candidates for surgical repair. Exclusion criteria included patients who were pregnant or had evidence of active/latent infection or tissue necrosis. Intraoperative data, including concomitant procedures and complications, was recorded. At follow-up, subjects were assessed for anatomical outcomes, symptomatic improvement, and complications, particularly mesh exposure. Anatomical success was defined as POP-Q or B-W scale 0 or 1.

Results

37 subjects met the inclusion criteria. The last follow-up visit reported for subjects was: 5-7 months (81%, 30/37). The mean age was 59 years (range 36 - 78 years) and the mean BMI was 28 (range 20 - 40). 29 of 37 subjects were post-menopausal (78%). Previous pelvic surgery included: hysterectomy (54%, 20/37), anterior compartment repair (8%, 3/37), posterior compartment repair (5%, 2/37), and incontinence procedures (8%, 3/37). 86% (32/37) were evaluated with B-W and 14% (5/37) were evaluated with the POP-Q scale. Preoperatively 5.4% (2/37) had a stage 4, 54.1% a stage 3 (20/37) and, 40.5% (15/37) had a stage 2 anterior compartment prolapse.

Concomitant surgery included hysterectomy (32%, 12/37), suburethral sling (86%, 32/37), rectocele repair (49%, 18/37), enterocele (24%, 18/37), and vault suspension (35%, 13/37). All subjects received general anesthetic. The mean blood loss was 111 cc (range 30 - 300 cc). The mean operating time, including concomitant repairs, was 97 minutes. 59% (22/37) of Perigee PC meshes were trimmed as part of the procedure and 19% (7/37) had trimming of the anterior vaginal mucosa. No intra-operative complications were noted.

The success rate was 97% at 1-11 weeks (33/34), 100% at 3-4 months (14/14) and 100% at 5-7 months (30/30). See Table below.

Anterior Staging				
	Baseline	1-11 weeks	3-4 months	5-7 months
Stage 0	--	82%, 28/34	100%, 14/14	77%, 23/30
Stage 1	--	15%, 5/34	--	23%, 7/30
Stage 2	41%, 15/37	--	--	--
Stage 3	54%, 20/37	3%, 1/34	--	--
Stage 4	5%, 2/37	--	--	--
Success (Stage<2) [Confidence Interval*]		97%, 33/34 [85%,100%]	100%, 14/14 [77%, 100%]	100%, 30/30 [88%, 100%]

* 95% exact Clopper-Pearson interval.

There were no reported mesh extrusions. 19 patients were sexually active at baseline. Dyspareunia rates decreased from 26% (5/19) at baseline to 8% (1/12) at 5 - 7 months follow-up. There was no de novo dyspareunia noted.

Adverse post-operative events are noted in the table below and include atrophic vagina, UTI, dysuria, and pelvic pain.

Adverse events reported as related to Perigee with IntePro Lite + PC				
Reported complications	**Number**	**Concomitant surgery**	**How managed**	**Sequelae**
Atrophic Vagina	1	MiniArc, TVH, anterior plication	Medication	Continuing
Infection – UTI	1	MiniArc	Medication	Resolved
Pain – dysuria	1	MiniArc, TVH	Medication	Continuing
Pain – pelvic	1	MiniArc, Elevate Posterior & Apical	Medication, Surgery	Resolved

Interpretation of results

There was 1 anatomical failure with a recurrence of a stage 3 anterior compartment prolapse noted within 11 weeks of implantation; all other patients had a successful anatomical outcome. Four adverse events were reported as device-related; however, there were no complications directly relating to the Perigee PC mesh. One patient had pelvic pain but this resolved after cutting of an arm of the implanted Elevate Apical and Posterior.

Concluding message

This is the first multi-center study looking at the efficacy and safety of surgical mesh treated with PC for anterior compartment prolapse. Initial data suggests that Perigee with IntePro Lite + PC is a safe and effective treatment for anterior compartment prolapse. Long term follow-up with a larger study population is required to confirm these findings and to underscore the superiority, if any, over a non PC treated mesh.

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References

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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	**Clinical Trials.gov, NCT00388947**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Lutheran Health Network, Schulman Associated IRB, Brookville Hospital IRB, Spectrum Health IRB, Trident Health IRB**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**