

THE ANAL SPHINCTER CAN BE SAFELY REINFORCED WITH BIOLOGICAL IMPLANTSHypothesis / aims of study

To evaluate the safety of using a biological implant in the anal area.

Tissue enhancers have been used in other areas to augment the weakened structures (1,2). They may improve the poor long-term results of an overlapping sphincter repair which are very poor in the long term (3). However the safety of using these products in the anal area is unknown. Permacol® is a porcine-derived acellular dermal sheet which is crosslinked. It is minimally biodegraded in the human body.

Study design, materials and methods

Under IRB approval ten female patients were enrolled to undergo an overlapping sphincter repair with sphincter augmentation using Permacol®. Selected patients had fecal incontinence for at least six months, had trialed medical therapy and had a defect in the external anal sphincter alone or both internal and external anal sphincter muscles on endoanal ultrasound. Patients who had inflammatory bowel disease, diabetes, perianal infection, were immunosuppressed or were HIV positive were excluded. The Permacol® mesh was placed between the two overlapping muscle or under the repair if it was not possible to overlap the muscles. Patients were followed up at 10 days, 1, 3 and 6 months. Quality of life was evaluated with the Fecal Incontinence Quality of Life Scale (FIQL) and continence was evaluated by the Fecal Incontinence Severity Index (FISI) preoperatively and at 6 months.

Results

The mean age of the patients was 62 years. There was no deviation of the technique from that utilized for anal sphincter dissection from the traditional sphincter repair without augmentation. Permacol® was incorporated into the repair using 2-0 PDS sutures. There was no change in the preoperative or postoperative management from that used for the traditional repair. The mean length of stay was 1 day. There were no intraoperative, immediate or 30 day complications after surgery. No wound infections were reported. Preoperative mean FIQL scores were 8.61 and FISI scores were 32.4. At 6 months all patients reported a decrease in their incontinence episodes a week by >90%.

Interpretation of results

Using a biological implant does not cause delayed or non healing of the perineal wound and does not predispose to any infection of the wound.

Efficacy in the long term needs to be studied.

Concluding message

Biological implants like Permacol® are safe to augment the anal sphincter. Long-term follow up is needed to evaluate efficacy.

References

1. Gaertner WB, Bonsack ME, Delaney JP. Experimental evaluation of four biologic prostheses for ventral hernia repair. J Gastrointest Surg 2007; 11(10):1275-85
2. Hessami SH, Chang DT. Use of Biomaterial as interposition graft in vesicovaginal fistula Jour. of Pelvic Surg ,2007 ;13(1) 39-42
3. Karoui S, Leroi AM, Koning E, et al. Results of sphincteroplasty in 86 patients with anal incontinence. Dis Colon Rectum 2000 45(3):345-8

Specify source of funding or grant	Department of Colorectal Surgery
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Institutional Review Board Cleveland Clinic Foundation , Cleveland, Ohio
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes