Safety and Anatomic Efficacy of Transvaginal Prolapse Repair Augmented with a Novel Decellularized Human Dermal Allograft*

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BACKGROUND / OBJECTIVE

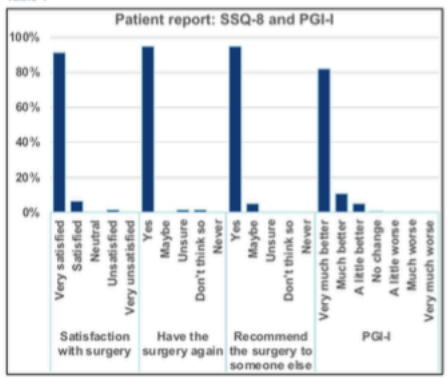
- Traditional transvaginal correction of vaginal wall defects through native tissue repair relies on the use of compromised muscular and connective tissue elements. Such repairs exhibit variable durability as evidenced by an overall re-operation rate approaching 30%.[1]
- Determine the safety and effectiveness of transvaginal pelvic organ prolapse repair employing native tissue reinforced with a novel decellularized human dermal allograft (DHDA)*.

METHODS

- A retrospective review of patients who received anterior-apical and/or posterior-apical prolapse repair augmented with DHDA* between March 2017 and January 2018.
- DHDA* is a novel decellularized human dermal allograft processed with dCELL® Technology which results in the removal of >99% of DNA content, yet fully maintains an intact ECM including key collagen proteins, vascular channels, key proteoglycans and glycosaminoglycans. Such proprietary processing results in the preservation of a greater volume of matrix and vasculature for new tissue growth and angiogenesis, respectively.[2,3]
- Surgical technique included anterior or posterior colporrhaphy with midline plication employing delayed absorbable suture, reinforced with a trapezoidal piece of DHDA* configured to patient anatomy, including "arms" which were fashioned proximally to reach the sacrospinous ligaments bilaterally and secured with permanent suture (Figure 1). Anteriorly, the DHDA* "arms" were configured distally to extend to the distal sulcus on either side for fixation. Posteriorly, the distal portion of the DHDA* was secured to the perineal body. Patients who had enterocele repair alone received a trapezoidal piece of DHDA*affixed to pubovesical or rectovaginal fascia distally and to the sacrospinous ligaments proximally.
- The retrospective review included patient information on the following: demographics, intraoperative complications, and postoperative adverse events (AE's) the presence or absence of bulge symptoms as per question #3 of the Pelvic Organ Prolapse Distress Inventory (POPDI). Anatomic efficacy was determined by the Pelvic Organ Prolapse Quantification System (POP-Q). Prospectively administered were the Surgical Satisfaction Questionnaire (SSQ-8) and the Patient Global Impression of Improvement Scale (PGI- I).
- Patients will be followed for 12 months in this study. This data represents an interim analysis.
- This study received IRB exemption.

Figure 1: Trapezoidal piece of DHDA* configured to patient anatomy

Table 1



*Decellularized Human Dermal Allograft (DHDA) is DermaPure®. DermaPure® and dCELL® are registered trademarks of TissueRegenix PLC or an affiliate.

RESULTS

- A total of 44 patients were implanted with DHDA*. Mean age was 54.2; mean BMI was 25.3; 25 (57%) patients were on some form of estrogen therapy; seven (16%) reported previous prolapse surgery; and eight (18%) were current smokers. Intraoperative complications included one (1) cystotomy which was repaired without long term sequelae.
- Mean follow-up was 10 months and all patients had follow-up through 3 months (range 3–18 months). AE's included seven (7) patients with de novo incontinence; one (1) dysuria; one (1) voiding dysfunction; four (4) fecal incontinence; seven (7) constipation; and one (1) urinary urgency. One patient had a documented urinary tract infection at the 12-week mark. Forty-two (95%) reported absence of bulge symptoms as per question #3 of the POPDI. Upon examination, 44 patients (100%) exhibited absence of bulge beyond the hymen at follow-up. No patient was re-operated on for anatomic failure in the target compartment. As per the PGI-I, 36 (82%) patients were "very much better", 5 (11%) "much better", 2 (5%) "a little better" and 1 (2%) reported "no change". As per the SSQ-8, 40 (91%) were "very satisfied" with "results for your surgery", 3 (7%) "satisfied" and 1 (2%) "unsatisfied"; 42 (95%) responded "yes" to "Would you have the surgery again?", 1 (2%) "unsure" and 1 (2%) "don't think so"; 42 (95%) responded "yes" to "Would you recommend this surgery to someone else?" and 2 (5%) responded "maybe".

CONCLUSION

Transvaginal pelvic organ prolapse repair augmented with DDHA* was found to be safe and effective at a mean follow-up of 10 months resulting in good anatomic durability, resolution of bulge symptoms, patient perception of improvement and high patient satisfaction.

REFERENCES

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