

LONG TERM RESULTS OF THE THE ACELLULAR HUMAN DERMAL ALLOGRAFT SLING WITH TRANSVAGINAL BONE ANCHORS

Hypothesis / aims of study

We reviewed the long-term results of an acellular human dermal allograft (Repliform*) sling with transvaginal bone anchors for the treatment of stress urinary incontinence.

Study design, materials and methods

A retrospective analysis was performed on 61 consecutive patients that underwent a transvaginal sling with an acellular human dermal allograft and transvaginal bone anchors for stress urinary incontinence. All procedures were performed by one surgeon. Postoperatively all patients received a questionnaire evaluating continence, pelvic pain, and satisfaction with the procedure. Patients who did not return the questionnaire were contacted by phone (if they could be located) and encouraged to participate.

Results

Thirty-one of the sixty-one patients completed the questionnaire for a response rate of 51%. Follow-up ranged from 14-63 months (mean = 33.5 months). Twelve of the thirty-one patients responded only after being contacted by phone. Four of the thirty patients that did not participate were located and contacted by phone, but elected not to participate. Outcomes are based on the 31 patients who chose to participate. Overall 22.5 % of the patients reported being completely dry while 70.9% noted incontinence with minimal to moderate activity. Forty-eight percent of patients use 1 or more pads per day and 19.3% never use a pad.

No patient had an infectious complication. Two patients (6.5%) developed new pelvic or lower abdominal pain and 4 patients (12.9%) reported dyspareunia that started after surgery.

When questioned on satisfaction with the results of the surgery, 45.1% report being satisfied, 35.4% are not satisfied, and 19.3% report being unsure. When asked how their urine control is compared to before surgery, 51.6% report that it is significantly better, 25.8% report being slightly better, 12.9% report no change, and 9.6% report being worse.

Interpretation of results

Current gold standard anti-incontinence procedures demonstrate greater than 75% cure or improved rates. With a mean follow-up of 33.5 months the acellular human dermal allograft sling with transvaginal bone anchors was found to have an overall poor success rate with less than 30% of patients either dry or having leakage only with strenuous activity. Thus over 70% reported leakage with mild to moderate activity. Despite these poor results close to 50% of patients reported satisfaction with the procedure and improvement in their urinary control. While no osseous complication occurred, 12.9% of patients developed dyspareunia after the procedure. With multiple techniques reporting long term success rates of greater than 70% one must question if the technique studied in this report should be performed.

Concluding message

We conclude that the transvaginal sling with an acellular human dermal allograft and the use of bone anchors has poor long-term results as an anti-incontinence procedure. The use of bone anchors did not seem to increase the risk of osseous complications.

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HUMAN SUBJECTS: This study was approved by the University Hospitals of Cleveland IRB and followed the Declaration of Helsinki Informed consent was obtained from the patients.