Barber FA, Burns JP, et al. A Prospective, Randomized Evaluation of Acellular Human Dermal Matrix Augmentation for Arthroscopic Rotator Cuff Repair. Arthroscopy 2012;28(1):8-15.

Design: In the setting of arthroscopic repair of rotator cuff tears, does the addition of human dermal matrix to the repair improve tendon healing?

Population/sample size/setting:

- 42 patients (31 men, 11 women, mean age 56) treated for rotator cuff tears at surgical facilities in Texas, California, and Ontarioi
- Eligible patients were between 18 and 75 with large rotator cuff tears at least 3 cm in width with 2-tenedon involvement but still amenable to arthroscopic repair, could perform postoperative exercises, had at least 90 degrees of elevation in the non-operative arm, and could read and understand English
- Exclusion criteria were irreparable tears more than 5 cm, subscapular tendon disruption, revision surgery, inflammatory or autoimmune disease, smoking, evidence of active infection, and having no reasonable expectation of participation in followup protocols

Main outcome measures:

- All patients had arthroscopic repair following the surgeon's standard operation, attaching the cuff to the abraded bone surface of the greater tuberosity using established techniques
- Randomization was done at the time of surgery when eligibility criteria had been assessed; a sealed envelope was opened, and the rest of the procedure was done accordingly
- Randomization was to either human dermal matrix augmentation (n=22) or standard repair without augmentation
    - The dermal matrix is prepared from human dermis which has been rendered acellular but in which the collagen matrix is left intact to provide a scaffold for host tissue to regenerate
    - The dermal matrix augmentation was done after the basic repair had been completed
    - The graft was overlaid and then sutured medially at the musculotendinous area and the graft was cut to a size which would cover the entire tuberosity footprint laterally
    - Operative time for the augmentation group was 30 to 60 minutes longer than for the control group

- The postoperative rehabilitation in both groups consisted of 4 to 6 weeks of an abduction sling with daily pendulum motion exercises, followed by supervised PT at 4 weeks, and strengthening exercises beginning at 12 weeks
- Primary outcome was MRI arthrogram assessment of tendon repair at 12 months by a blinded radiologist, where healing was defined as complete excursion of the repaired tendon to the greater tuberosity with no leakage of gadolinium
- Secondary outcomes were the ASES, UCLA, and Constant scores
- In the augmentation group, 20 of the 22 patients consented to MR arthrography, and 15 of the 20 non-augmentation (control) group consented to MRA
    - Mean time after surgery to MRA was 14.5 months
    - Tendons were judged to be intact in 17 of the 20 augmentation patients but were intact in only 6 of the 15 control patients
- Secondary measures generally favored the augmentation group
    - The ASES score in the augmentation group improved from 48.5 to 98.9; improvement in the control group was from 46.0 to 94.8 (p=0.035)
    - The Constant score in the augmentation group improved from 41.0 to 91.9; improvement in the control group was from 45.8 to 85.3 (p=0.008)
    - The UCLA score in the augmentation group improved from 13.3 to 28.2; improvement in the control group was from 15.9 to 28.3 (p=0.43)
    - No correlation between clinical scores and MRA findings was found
- There were differences in re-tear rates between the two groups; in the augmentation group, there were 3 re-tears; in the control group there were 9
- No adverse effects of augmentation were reported

Authors' conclusions:

- Larger rotator cuff tears often fail to repair completely after surgery, but dermal matrix augmentation increases the rate at which MRA scans show intact cuffs more than one year after surgery (85%) compared to the control group intact cuff rate of 40%
- Clinical outcomes such as the ASES and Constant scores were also improved in the augmentation group

Comments:

- Randomization at the time of surgery controls biases arising from patient selection into the treatment groups and is a strength of the study
    - The opening of the envelopes appears to have been done after the tendon was determined to be reparable but before the rotator cuff repair was completed
    - There were 6 patients in the control group who had distal clavicle resection (Mumford procedure), but none in the augmentation group

    - While it is not known that distal clavicle resection is associated with re-tear rates after rotator cuff repair, the groups did differ on this procedure
- There is some lack of clarity with respect to the primary outcome; the MRA was the stated primary outcome, but the sample size calculation for planning the study appears to have been based on the expected rate of rotator cuff re-tears, the control of which is part of the reason to research the effectiveness of augmentation
- Re-tears seem to have been classified as a complication of surgery, and the authors reported that the number of complications was too small to draw meaningful data from them
    - It is not clear how the comparison of complication rates was done, but the re-tear rate of 9 in the control group (45%) and 3 in the augmentation group (14%) has a chi-square of 5.05 with one degree of freedom, which would be statistically significant
    - The total complication rates (bursitis, fibrosis, cellulitis, etc) similarly appear to be lower in the augmentation group than the control group
    - Because only 15 of 20 control patients consented to the MRA scan, the re-tear rates, which appear to have been determined by other means, would also appear to be a more relevant measure of the performance of the augmentation procedure
    - No revision procedures had been done at the end of the trial, and it is not clear whether such procedures were planned for the patients with recurrent rotator cuff tears

Assessment: adequate for some evidence that acellular dermal matrix augmentation of reparable rotator cuff tears larger than 3 cm but less than 5 cm may improve tendon repair and reduce the rate of recurrent rotator cuff tears in the first 12 to 24 months after surgery, provided that the patients are nonsmokers