Efficacy of autologous dermal fibroblast injection in reducing retear rate after arthroscopic rotator cuff repair: a prospective randomized controlled clinical trial

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INTRODUCTION:

There are growing interests in various biological augmentations for improving bone-tendon interface (BTI) healing in patients after arthroscopic rotator cuff repair (ARCR). Dermal fibroblasts, known to express collagen synthesis similar to tenocytes, have been reported to be effective in BTI healing after surgical repair of chronic RC tear model of rabbit. However, there have been no human clinical trials so far. So, the purpose of this prospective randomized controlled clinical trial was to evaluate the clinical efficacy of ADFs for BTI healing after ARCR in patients with full-thickness RCT.

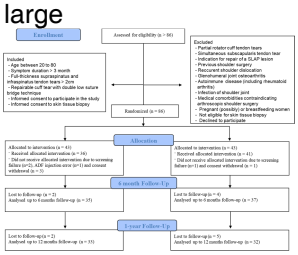
METHODS: Eighty-six patients were prospectively enrolled and randomized into two groups; additional ADF injection between bone and tendon during ARCR (Group I), or ARCR alone (Group II). Skin biopsy for obtaining ADF was performed from the buttock, and ADF were cultured for about 4 weeks before surgery. Surgical technique of ARCR was unified as double-row suture-bridge technique to decrease the heterogeneity from different repair methods. Primary variable for the efficacy of ADF was to evaluate the retear rate using MRI at 6 months postoperatively. Secondary variable was to compare clinical outcomes between two groups including range of motion (ROM), American Shoulder and Elbow Surgeons (ASES) score, Constant score and simple shoulder test (SST) at baseline, 6 and 12 months postoperatively.

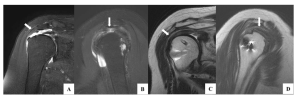
RESULTS: Fourteen patients were dropped out for reasons such as involved subscapularis tendon tear, follow up loss or withdrawer of consent (8 in Group I, 6 in Group II). Demographics and preoperative clinical scores were not significantly different between two groups (all $p > 0.05$). The retear rate was significantly lower in Group I (2.9%, 1 of 35) than Group II (16.2%, 6 of 37) (p=0.012). Clinical outcomes were not statistically different between two groups at 6 months and 12 months (all $p > 0.05$).

DISCUSSION AND CONCLUSION:

The most important finding of this prospective randomized controlled study was that the retear rate was significantly lower in the intraoperative injection group of ADFs than ARCR alone group as documented with MRI 6 months after double-row arthroscopic rotator cuff repair (P = 0.012). And all PROMs at 6 and 12 months postoperatively were significantly improved compared with the preoperative scores (all Ps < 0.001) without any ADF-related complications.

Therefore, ADF injection could be a promising biological supplements to enhance BTI healing in patients with medium-to-large rotator cuff tear.





MRI Results of the Primary Outcome: Sugaya classification

	ADF group (n = 35)	Control group (n=37)	P value
Healed	34	31	0.315
Sugaya I	4	4	
Sugaya II	18	19	
Sugaya III	12	8	
Retear	1	6	**0.012**
Sugaya IV	0	2	
Sugaya V	1	4	