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Interpositional Bioresorbable Scaffold-Anchor Versus Standard Anchor for Rotator Cuff Repairs

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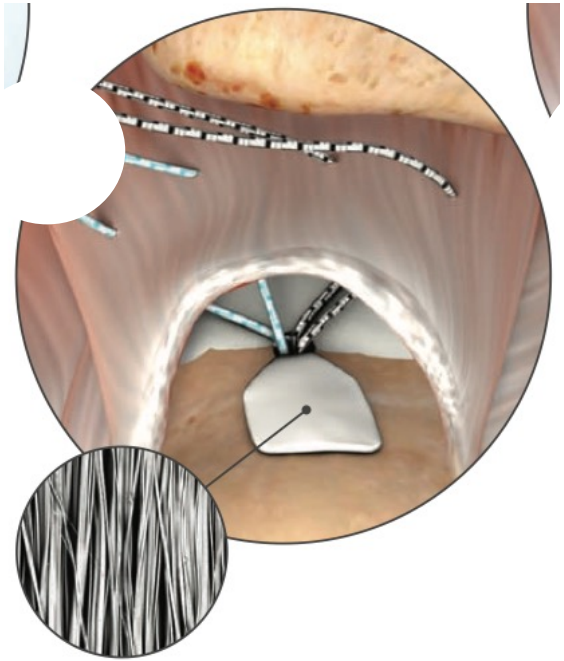
Disclosure of Interest

- Dr. Lin is a consultant with IP for Tornier/Stryker and Arthrex, Inc. However, this author, their immediate family, and any research foundation with which they are affiliated did not receive any financial payments or other benefits from any commercial entity directly related to the subject of this presentation.
- Dr. Kelly is a consultant with DePuy, A Johnson & Johnson Company. However, this author, their immediate family, and any research foundation with which they are affiliated did not receive any financial payments or other benefits from any commercial entity directly related to the subject of this presentation.

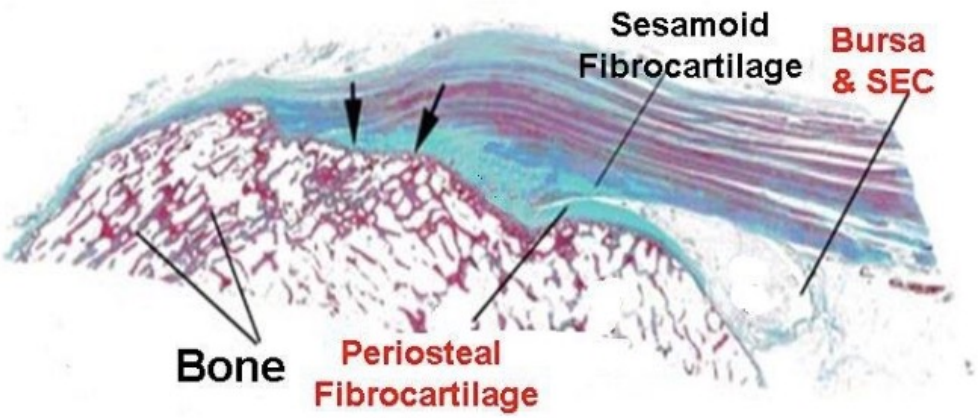
What is an Interpositional Bioresorbable Scaffold-Anchor?

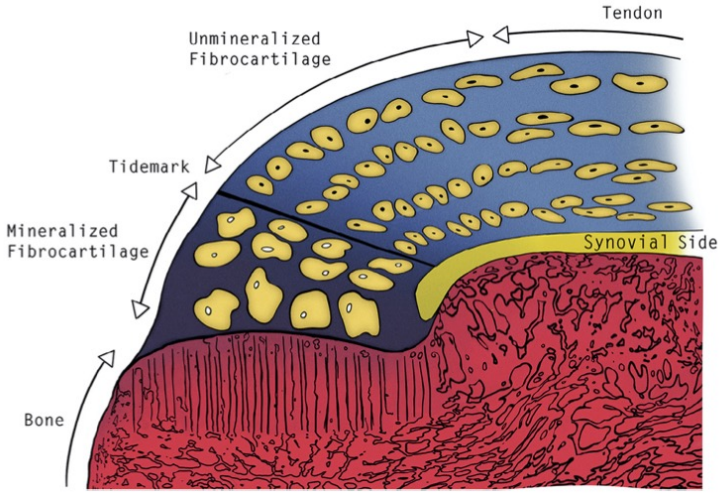


- A standard anchor (either biocomposite or all-suture design) with an attached scaffold
- Scaffold “wick” is composed of aligned, PLGA microfibers designed to mimic fiber alignment of the extracellular matrix (collagen) in the rotator cuff tendon
- Arthroscopically deployed between the tendon and bone interface

Why was it developed?

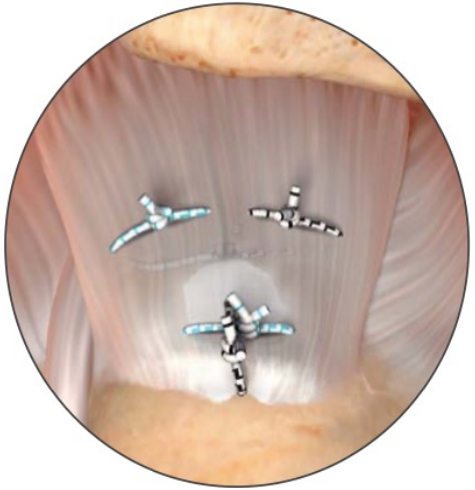
- The major problem in the treatment of RC tears is the inadequate healing of torn tendons
- The enthesis does not regenerate its native structure; instead, it heals in a scar mediated fashion
- This scar is biomechanically inferior

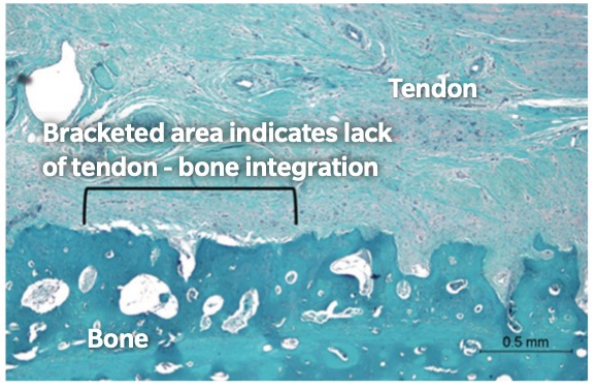




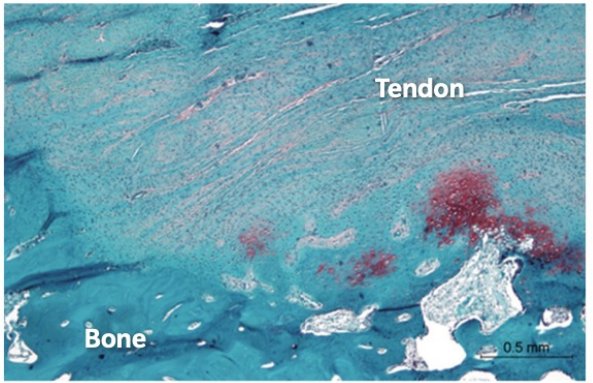
Intended effect of the interpositional scaffold "wick"?

- Higher percentage of tissue integration and perpendicular fibers at the tendon-bone interface
- Higher levels of new bone formation and type III collagen at the tendon-bone interface
- An industry sponsored Randomized Controlled animal study at Colorado State University demonstrated through histology:
  - Higher percentage of tendon-bone integration with tissue
  - Greater new bone formation at the tendon-bone interface





Standard Anchor @ 12 weeks



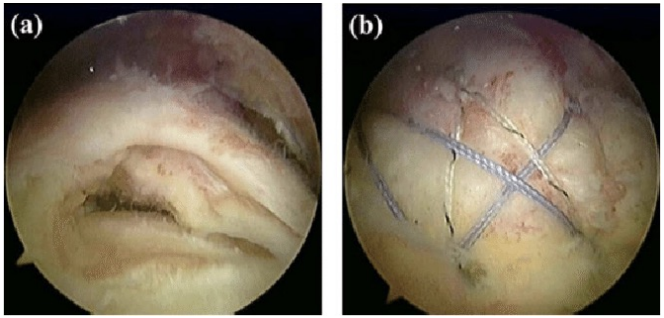
Novel Anchor @ 12 weeks

Objectives

Does this animal study translate to an actual clinical difference?

- Decreased Retear Rates?
- Improved ROM?
- Increased Strength?

Materials/Methods



- Prospective, Randomized, Controlled, and Blinded Study
- 99 patients enrolled
  - 49 patients in the “Control” Group/Standard Anchor (SA)
  - 50 patients in the “Test’’ Group/Novel Anchor (NA)
- All cuffs were repaired with a Double Row Technique
  - Constructs included the same anchor design and configuration
- The primary outcome was **rotator cuff repair integrity** assessed via ultrasound at 6 months post-operatively
- Secondary outcomes assessed pre- and post-operatively at 3 and 6 months included:
  - Visual Analog Scale (VAS) pain scores
  - American Shoulder and Elbow Surgeons (ASES) Score
  - Simple Shoulder Test (SST)
  - Strength
  - Active range of motion (AROM)

Results: Patient Demographics

	Novel Anchor (NA)	Standard Anchor (SA)	P-value
Number of Patients	50	49	
Age	54.1 (6.1)	54.7 (6.2)	0.6553
Smoking Status	8.0 (16.0%)	11.0 (22.45%)	0.4153
Laterality (R)	36.0 (72.0%)	35.0 (71.5%)	0.9417
Size of Tear (A/P)	17.4 (6.6)	17.8 (7.8)	0.7128
Size of Tear (M/L)	13.3 (7.4)	12.2 (6.4)	0.6598

- No statistically significant baseline differences between groups

Results: 3 Months

	Novel Anchor (NA)			Standard Anchor (SA)			P-Value
	Preoperative	3-Month	Delta	Preoperative	3-Month	Delta	
ASES	47.2	60.2	13	45.7	62.6	16.9	0.4056
Simple Shoulder	5.6	5.9	0.3	5	6.3	1.3	0.3054
Pain Score	4.8	2.6	-2.2	4.8	2.4	-2.4	0.6680
Flex (degree)	117.8	109.5	-8.3	116.3	115.3	-1.0	0.4327
ER (degree)	55.8	49.2	-6.6	56	53.1	-2.9	0.4136
IR (level)	12	15.2	3.2	11.2	14.5	3.3	1.0000
Fflex Strength (N)	66.6	66.8	0.2	61.1	66.9	5.8	0.3352
ER Strength (N)	39.5	37.7	-1.8	36.8	36.7	-0.1	0.6745
IR Strength (N)	56.9	54.1	-2.8	54.2	52.6	-1.6	0.7369
Abd Strength (N)	34.1	31.9	-2.2	32.9	32.9	0.0	0.6600

Results: 6 Months

	Novel Anchor (NA)			Standard Anchor (SA)			P-Value
	Preoperative	6-Month	Delta	Preoperative	6-Month	Delta	
ASES	49.2	84.1	34.9	45	78.2	33.2	0.7113
Simple Shoulder	5.8	9.9	4.1	5	9.4	4.4	0.7112
Pain Score	4.6	1	-3.6	4.8	1.5	-3.3	0.6555
Flex (degree)	115.8	144.6	28.8	116.3	139.9	23.6	0.5403
ER (degree)	56.3	61	4.7	57.2	62	4.8	0.9901
IR (level)	11.8	13	1.2	11	12.7	1.7	0.5828
Fflex Strength (N)	67.7	78	10.3	61.1	74.4	13.3	0.6788
ER Strength (N)	39.8	48.7	8.9	37.1	47.5	10.4	0.7541
IR Strength (N)	57.5	62.3	4.8	53.3	63.5	10.2	0.2652
Abd Strength (N)	34.2	42.7	8.5	33.2	45.8	12.6	0.4713
Retear Rate		9.0 (21.95%)			10.0 (23.26%)		0.8864

Conclusion

- At 6 month follow up, no significant difference in retear rates
  - Retear rate was **22%** for the NA group vs **23%** for the SA group
- Secondary outcomes, including VAS pain scores, ASES, SST, strength, or AROM measurements **did not differ significantly** between the two cohorts at 3 or 6 months follow-up
- There were no complications identified in either study group

Significance of Findings

- The interpositional scaffold-anchor is a novel design with the potential to augment bone-tendon healing, however it **did not** demonstrate superior clinical improvements compared to a standard anchor in our study
- Although theoretically and scientifically there is a reasonable rationale the NA has an advantage, the sample size required to realize that difference may be difficult to attain
- With limited documented clinical benefit, implant cost must be considered
  - **Currently, this amounts to a 3-fold cost increase with using the NA**
- Healthcare systems may find the cost to benefit ratio to be prohibitive

Questions

- Are there any questions?