

The Effect On Healing Rate Of The Addition Of A Bioinductive Implant To A Rotator Cuff Repair. The Results Of A Randomized Controlled Trial In 124 Subjects.

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DISCLOSURES

The authors have a financial interest or other relationship with a commercial company or institution related directly to this CME activity. In particular:

- Within the past twelve months, they have served on the speakers bureau or have been paid an honorarium to present by Smith and Nephew
- They receive research or institutional support from Smith and Nephew
- They have received a grant to perform this current study from Smith and Nephew

Background:

There is a clear need for biologic enhancement of rotator cuff techniques. The Regeneten Bioinductive Implant (RBI) has been proposed as a biological alternative that could increase the healing chances and the quality of the repair.

Aim:

To determine the effect on the healing rate in MRI at 12-month follow-up of the addition of a RBI over a transosseous equivalent (TOE) repair of mid-sized supraspinatus tears.

Material and Methods: RCT design

- Subjects with repairable full-thickness supraspinatus tears
- (TOE Repair) vs. (TOE Repair + Bioinductive Implant)
- IRB Approved, randomized prospective clinical trial
- Spanish Multicentric (4 centres, 8 surgeons)
- Triple blinded (patient, examiner, statistician)
- Sample size estimation: 120 subjects (60 per group)

MATERIAL & METHODS

INCLUSION CRITERIA

- Supraspinatus tears(+/- IE)
- Full thickness tears
- < 3 cm retraction
- < 4 cm AP extension
- Fully reparable

EXCLUSION CRITERIA

- Fatty infiltration (Gout III-IV)
- Subscapularis or Tm tears
- Partial repair

OUTCOME ASSESMENT

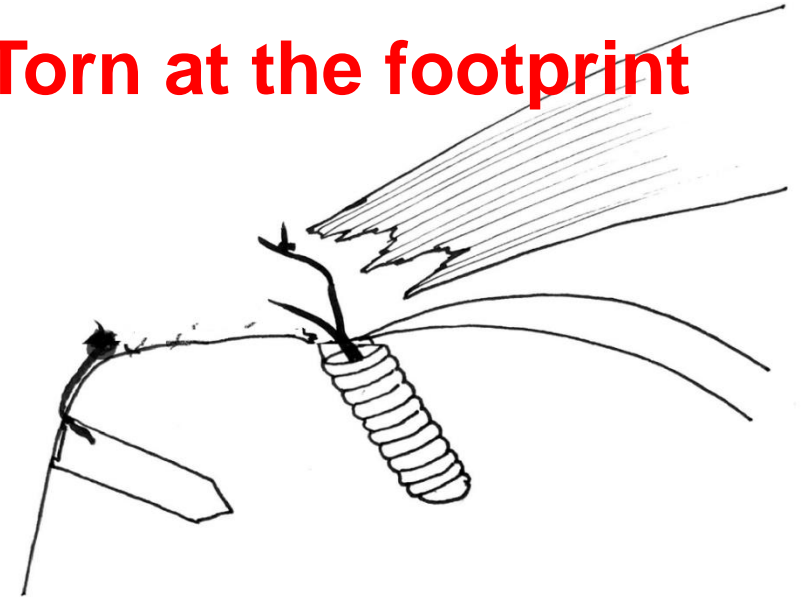
Complications

MRI at 1 year:

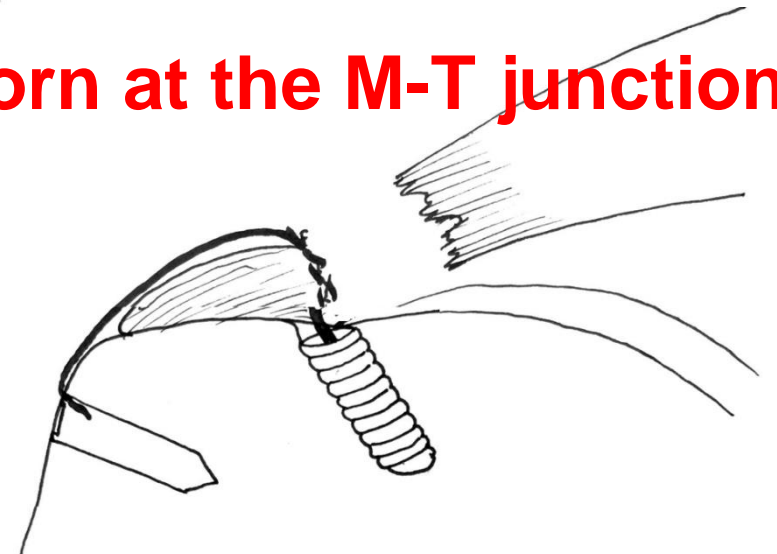
- Healed (Sugaya I-III) vs. torn (IV-V)
- Retear pattern (footprint vs M-T)
- Tendon thickness

Pain, Contant score, ASES score

Torn at the footprint



Torn at the M-T junction



Results

	Total	Regeneten group	Control group
Randomized	124	61	63
Excluded:	7	3	4
-Death unrelated to study	1	1	0
-Not available for final MRI	1	0	1
-Reoperated for re-tear	2	0	2
Available for MRI assessment	122	60	62
Available for 1 y. clinical follow-up	120	59	61

There were no differences between groups regarding: age, tear size, comorbidities, or other clinical or epidemiological parameters

RESULTS: Complications

Major:

- Two Deep infections (both in Control Group)

Minor:

- One superficial infection (RGT Group)
- One medial staple breakage that was addressed immediately
- four patients (1 in RGT group and 3 in control group) with significant pain that required SA injections

N.S.
differences

RESULTS: MRI Healing at 1-year (122 cases)

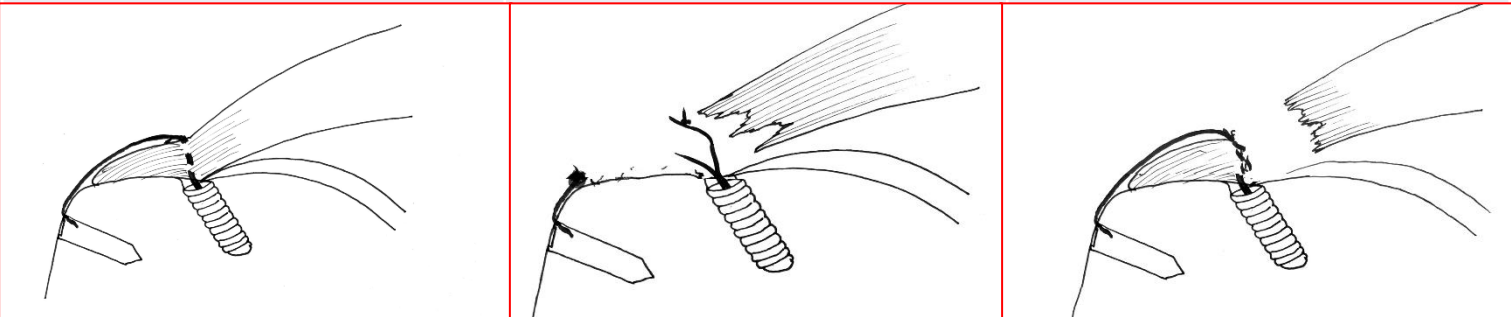
	Healed	Torn	Failure rate
Control (n=62)	46	16	25.8%
Regeneten (n=60)	55	5	8.3%

Sign. Diff.
p=0.010

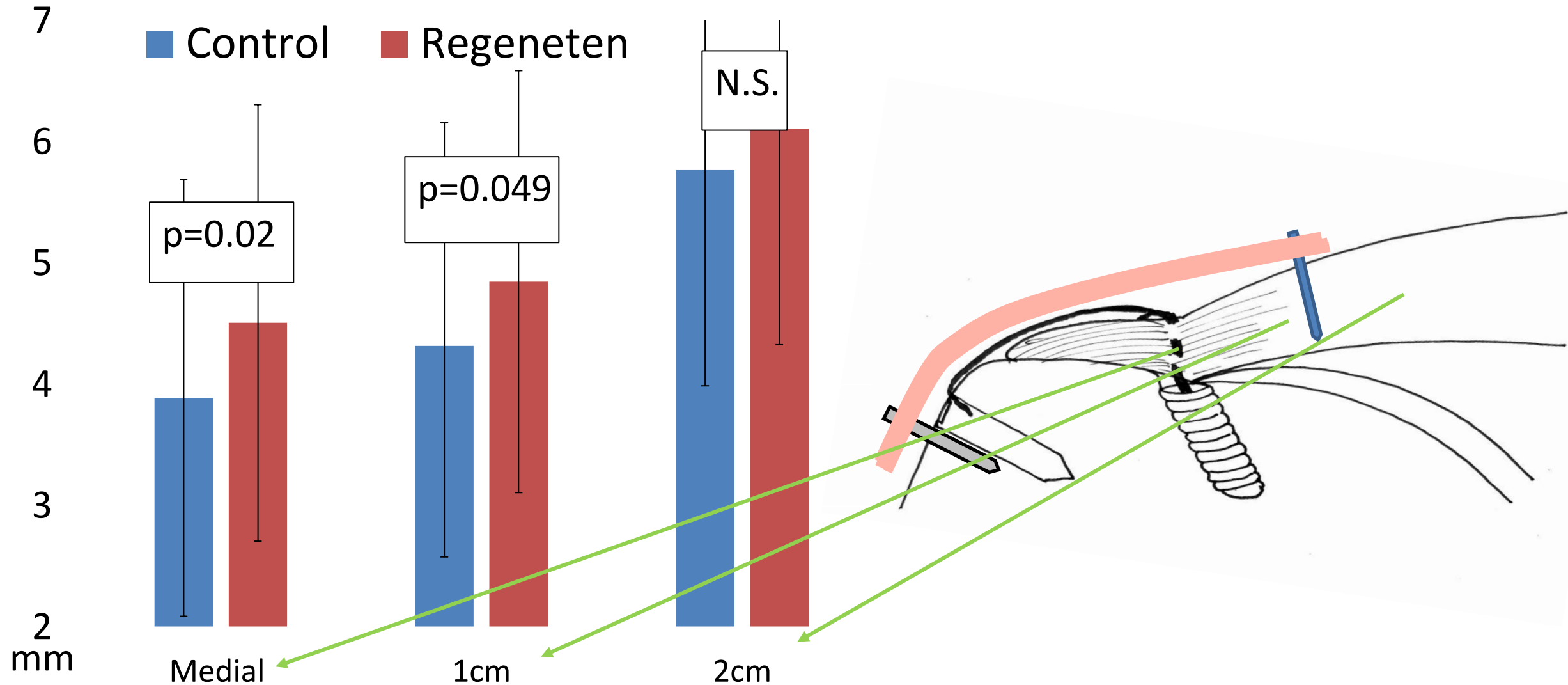
RESULTS: failure mode (122 cases)

Sign. Diff.
p=0.005

	Healed	Torn at footprint	Torn at M-T junction	M-T failure
Control (n=62)	46	2	14	22.6%
Regeneten (n=60)	55	2	3	5%



In the subjects with intact repairs, there was a significant increase in tendon thickness in the Regeneten group compared to the control group



Conclusions

- The results of this RCT strongly suggest that placing a REGENETEN Bioinductive Implant over a rotator cuff repair improves healing rates.
- This reduction in repair failures is at the expense of reducing musculo-tendinous junction failures
- The healed cuffs in the Regeneten group had also an increased tendon thickness
- This improvement is not associated with more complications

Thank you!

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