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"Platelet Derived Growth Factors in Rotator Cuff Repair"
a prospective randomized study: preliminary results

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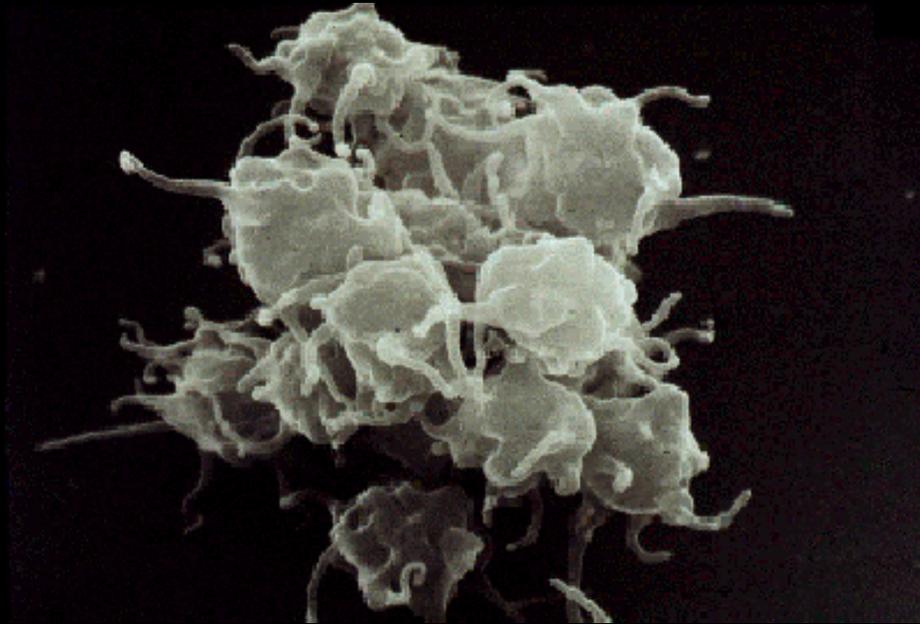Centro di Chirurgia dell'Anca

Aim of the study

We prospectively evaluated a series of patients with full thickness rotator cuff lesions treated using a standard arthroscopic technique with delivering of Platelet Derived Growth Factors (PDGF) on the repair.

The patients were evaluated to demonstrate:

- The method's effectiveness
- The timing of functional recover
- The pain control due to the methods and PDGF application
- The relationship between the lesion's parameter (lesion's dimension and number of suture) and clinical results.
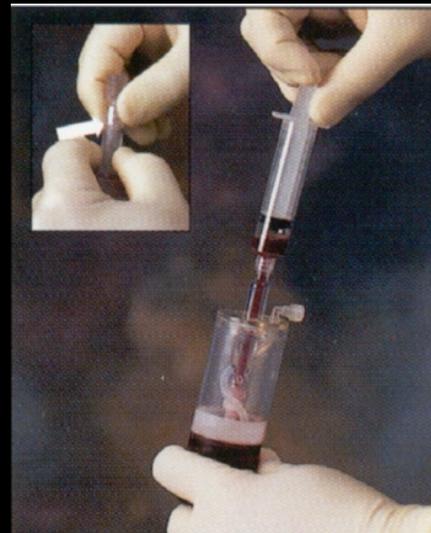
Materials and Methods

- 14 Consecutive Shoulders (14 patients, 4 left, 10 right) (6 female, 8 men)
- Mean age of the sample was 66 (median 67), range 48-79 years
- Complete torn rotator cuff (Snyder C, mean C 2,9)
- Arthroscopic treatment with the implement of autologous PDGF
- All the patients gave their informed consent to the procedure.
- The cases were randomized, without selecting the size of the lesion and the level of pre-op. pain.

Pre-op. evaluation
- The screening of the patients was obtained with routine blood exams. All the patients had a pre-op. MRI without contrast ed X-Rays (true a/p and outlet view)
- Clinical evaluation with Costant, UCLA and VAS (Visual Analogic Scale) scores.
- Strict inclusion/exclusion criteria

Materials and Methods

- Cefazolin 2 gr. E.v.

- Interscalene block + general

- The PDGF fluid solution was obtained using 54 ml of autologous blood, centrifugated 12 min. with a sterile device (Biomet Merck).

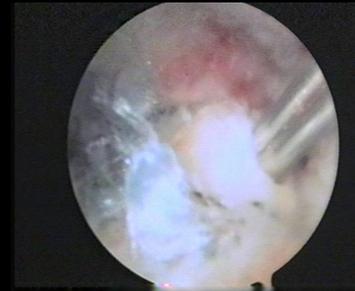- Autologous Trombin, was obtained by another blood centrifugate (needed to activate the solution)

Materials and Methods

- Full Arthroscopic Repair
- The lesion has been prepared with a basket on the tendon side and with a burr on the great tuberosity

Tendon to Bone Repair (Titanium anchors, Cork with Fiber-Wire, Arthrex Fl., Usa).

Side to Side Repair (with fixation on the hum. Head) (Ethibond, Ethicon, Ms,USA)

- Acromioplasty (Sampson's cutting block)
- Cannulas removal, DRY procedure
- The pdgf will be delivered at the level of the lesion, beetwen the tendon and the bone and over the tendon repair
- No suction drains.
- Portals suture with Nylon. Wound dressing.
- Ultrasling 1, Don Joy.

Follow-Up

- Day and night sling for 10 days (instead of 28). Night sling till the day 30th (instead of 45th).
- Day 1. Starting flexion/extension of elbow and wrist. The external rotation of the shoulder is allowed to the neutral position. Post-op. X-rays control (standard)

- Day 10 starting Passive Exerc, 3 times per week + self administred exerc. till day 35th.

- Day 30 VAS evaluation + Costant + UCLA +MRI (Comaparative with pre-op MRI) and starting with active ROM rehabilitation, start with swimming (no crol)

- Day 60 VAS evaluation + Costant + UCLA
- Day 90 VAS evaluation + Costant + UCLA
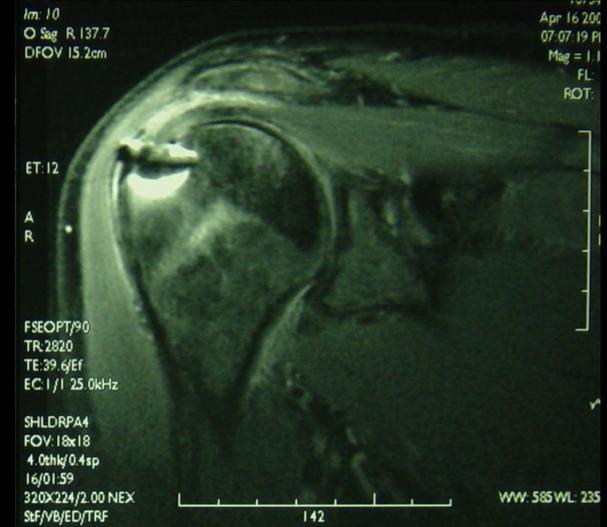- Day 180 VAS evaluation + Costant + UCLA

A statistical analysis was obtained by SPSS software (Spearman Index and Student's t test)
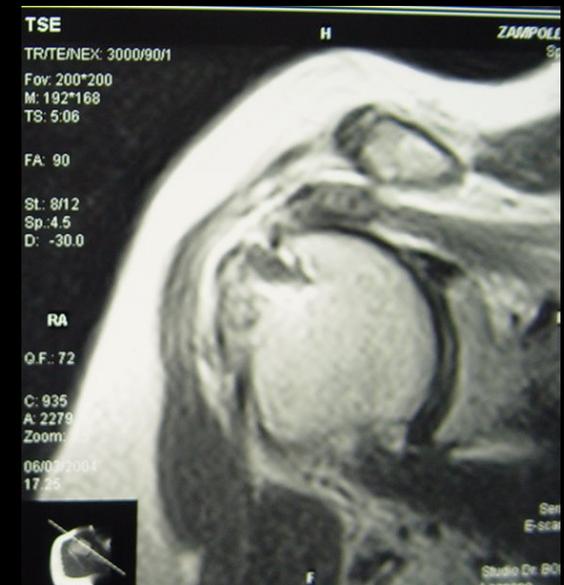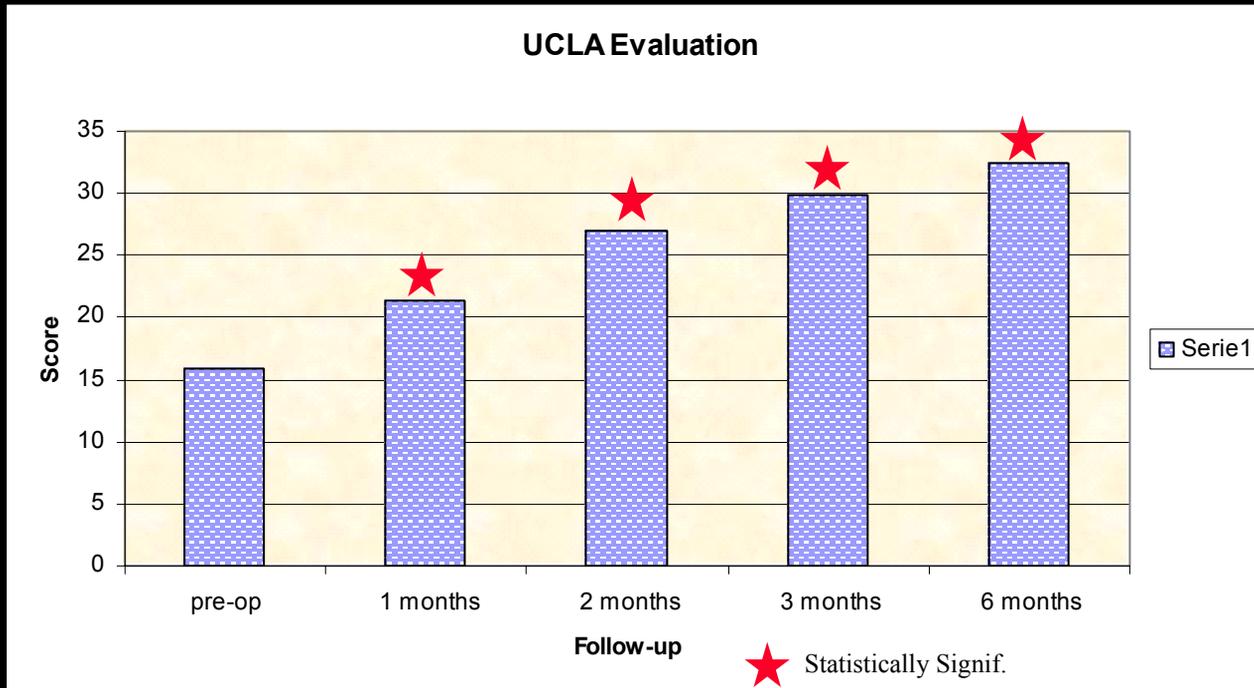
Results

Pre-op.

Post-op.

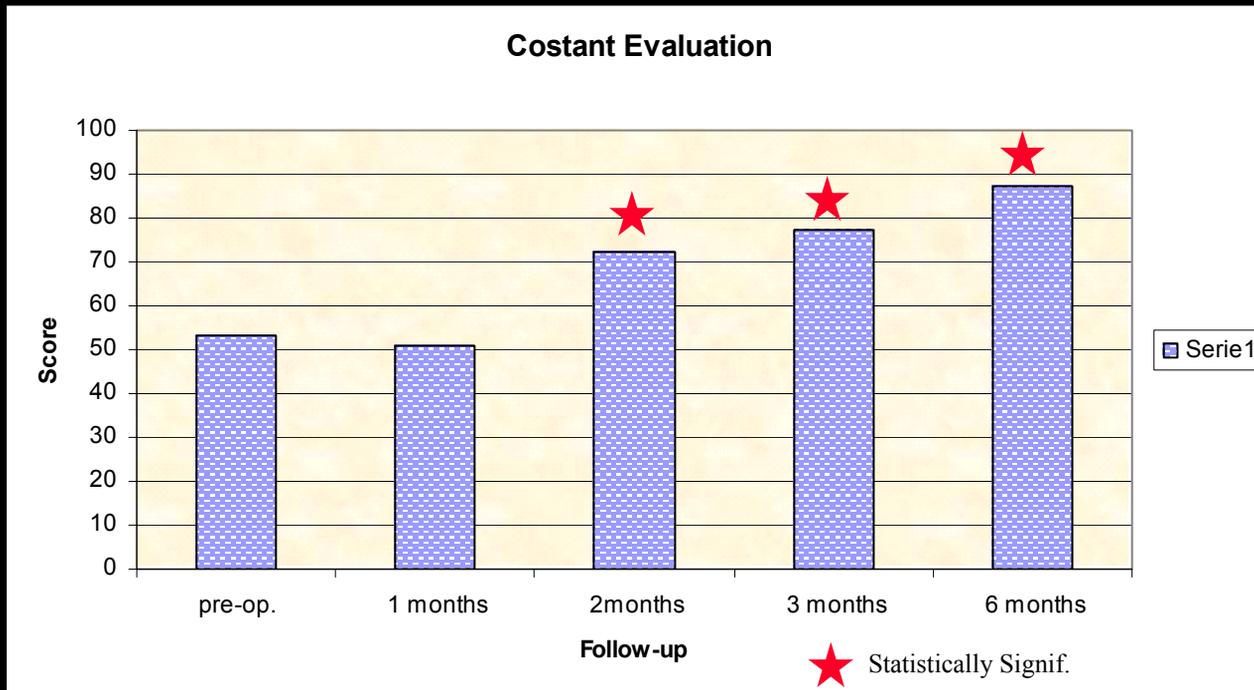• MRI Evaluation

All Shoulders Healed

Results

UCLA Evaluation

The overall UCLA scores after surgery were significantly improved at 30 days (t-test, $p<0,05$), with a mean of 21 points (range 7-33).
This data was <u>strongly confirmed</u> at 60, 90 and 180 days post-operatively (t-test, $p<0,01$).

Results

Costant Evaluation

The Overall Constant score showed an high (t-test, p<0,01) statistical significance at 2 months after surgery with a mean value of 73 (range 38-90).

At 6 months post-op. the mean Costant score was 87 (range 47-100) (t-test, p<0,01)

Results

- The UCLA score decreased related to the dimension of the lesion. A wide lesion gave worst outcome (t-test, $p<0,05$).
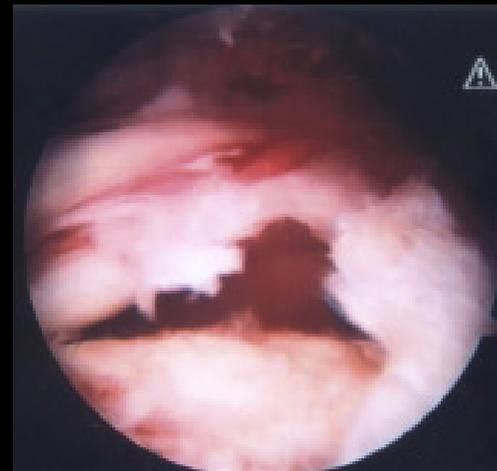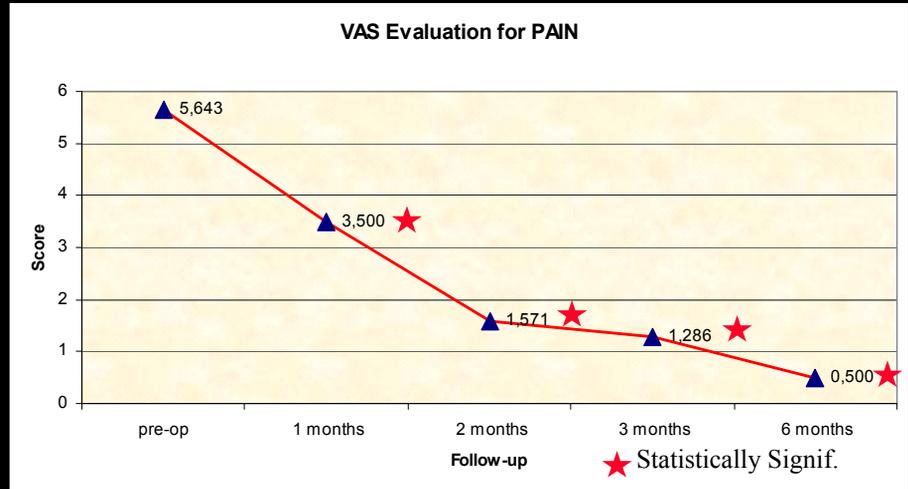

- Aged patients showed results inferior to the younger with both evaluations (UCLA $p<0.02$, Costant $p<0.05$).

Results
PAIN

- The pain was reduced already at 30 days in both UCLA and Costant scores (t-test, p<0,05)
- The trend was confirmed at 1,2,3,6 months too (t-test, p<0,01).

- At 6 months post-op. the VAS was 0.5 (range 0-2).

- A complete analysis of the pain was conducted statistically and showed that the bigger were the lesions than the most important was the pain before surgery at VAS score, with a mean of 5.64 (range 2-8) with an high level of significance (t-test, p<0,01).

VAS Evaluation for PAIN

Score vs Follow-up:
- pre-op: 5,643
- 1 months: 3,500
- 2 months: 1,571
- 3 months: 1,286
- 6 months: 0,500
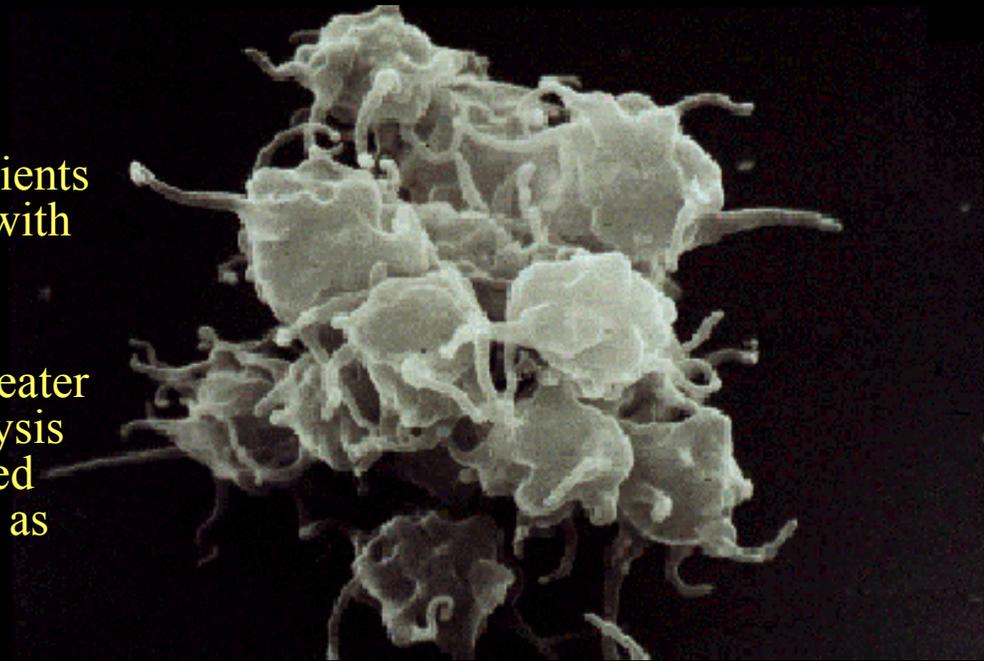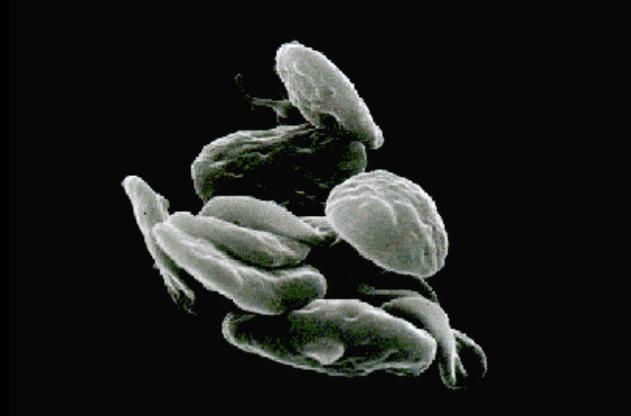
★ Statistically Signif.

Results
Lesions and Repair

- The VAS at 30 days post-op was significatively higher in patients where the shoulder was treated for a wide lesion (t-test, $p<0,01$) and in those which had several anchors needed for the repair (t-test, $p<0,05$).

- The shoulder where the lesion was treated with several anchors, or sutures, showed a better functional UCLA and Constant score (t-test, $p<0,05$), at 90 days after surgery.

Conclusions

- This Study statistically demonstrates that:

- Arthroscopic rotator cuff repair implemented with PDGF and with an accelerated rehabilitation protocol has a dramatic increase, statistically significant, of the Costant and UCLA scores, already at 2 months post-op.

- Pain at 2 months post-op. is reduced greatly.

- At the final 6 months follow up the patients had a satisfactory results, comparable with healthy people.

- We confirmed that pre-op. pain was greater in patients with wide lesions. The analysis confirmed even a slower recover in aged patients, especially with larger lesions, as could be expected.

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Grazie ed Arrivederci