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Platelet Rich Plasma Following Arthroscopic Repair Of Rotator Cuff Tears: A Double Blind Randomized Controlled Trial

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Summary:
ASPIRE is a multi-centre, blinded, RCT in arthroscopic repair on a rotator cuff tear comparing the effect of using platelet rich plasma (PRP) versus a placebo (saline).The primary outcome measure is pain scores at 6 weeks post-operatively, which analysis suggested improved in the overall patient population from initial pain scores pre-operatively.

Abstract:
Introduction:
Rotator cuff tears are a common cause of shoulder pain and disability. Although pain management through conservative therapies such as rest, physiotherapy, non-steroid anti-inflammatory drugs and cortisone injections can be effective, these techniques do not always improve function. Given the increasing popularity of whole blood and its derivatives to promote the healing process associated with these tears, we explored the effect of using platelet rich plasma (PRP) injections intra-operatively and post-operatively on pain scores versus a placebo at six weeks post-surgery.

Methods:
We conducted a multi-centre, blinded, RCT in arthroscopic repair on a rotator cuff tear. To be included, patients must have been diagnosed with a rotator cuff tear within 18 months of surgery. Patients also could not have any pre-existing conditions associated with upper extremity pain such as arthritis or nerve pathology, or uncontrolled diabetes. Subjects were randomized to either PRP or saline, a placebo, and received two ultrasound guided injections of the randomized product; intra-operatively and 4-weeks post-operatively. The primary outcome measure was shoulder pain demonstrated using a visual analog scale (VAS) at 6 weeks. Secondary outcomes included additional quality of life measurements including the DASH Questionnaire, the WORC Questionnaire, the EQ-5D Questionnaire, and the Constant Score. Outcome measures are taken pre-operatively, and at two, four and six weeks. The trial with 50 patients was powered to detect a clinically important reduction in VAS scores at 6 weeks and an interim analysis at 50% of the sample size was conducted (25 patients) to ensure safety and evaluate need for early stopping. An independent, blinded adjudication committee evaluated all major outcome (adverse) events. We present, here, the findings of our interim analysis.

Results:
At interim analysis, we recruited 25 patients, 6 females and 19 males, at two clinical sites in Ontario with ages ranging from 40 to 65 years of age. Of the 25 subjects, 24 were followed until six weeks (12 in PRP group, 12 in Placebo group); one subject was lost to follow-up after the 4 week visit. At the time of abstract submission, 6 week data for two subjects (1 in PRP group and 1 in Placebo group) was outstanding. There were a total of 4 adverse events (excessive pain, infection at the site of injection, hand swelling from IV and nausea and dizziness post-

operatively). Overall, mean pain scores decreased from 4.83 (st.dev = 3.07) at baseline to 3.82 (st.dev = 2.71) at 6 weeks (p=0.140). Alternatively, mean DASH scores were relatively similar from 69.01 (st. dev = 16.84) at baseline to 71.71 (st. dev = 19.38) at 6 weeks (p=0.789). At the time of abstract submission, we have not broken the blind and will conduct the full comparative analysis by November 2012. The efficacy of PRP vs. placebo will be fully presented (and available at time of ISAKOS presentation).

Conclusions:
An interim analysis of patients suggested that overall pain scores improved from initial pain scores pre-operatively. The other quality of life assessment analyzed at the time of abstract submission, the DASH score, suggested that 6-weeks post-operatively, patients may regain as much function as they had in their shoulder pre-operatively.

[PRP efficacy against placebo will be unblinded after September 2012, and presented in full at ISAKOS meeting]