Intra-articular Platelet-Rich Plasma for Acetabular Labral Tears

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Intra-articular platelet rich plasma in the management of acetabular labral tears: a prospective study

Study Protocol

PRP preparation method (see appendix 1): Patients will have 45mL of blood drawn, which will be processed to result in 9mL of neutrophil-poor PRP utilizing an in-office centrifuge. All subjects will have 1-2mL of whole blood and 1mL of PRP analyzed (leaving 8mL for injectate).

Blood analysis: We will utilize a cell counter for full analysis (a complete blood count [CBC]) with differential tests on subjects' whole blood and their prepared PRP. Importantly, we will include all data required in the PRP minimum reporting standards, including "platelet count, differential leukocyte, and red cell analysis of all samples" (14).

Injection: All subjects will have their blood drawn and analyzed, as above (see "blood analysis" subsection). All subjects will then undergo a therapeutic ultrasound-guided intra-articular hip injection with PRP by an experienced sports medicine provider (at least five years post-fellowship). To described the injection in further detail, patients will be placed in the supine position. Ultrasound will be utilized to identify the hip joint and safe trajectory. Using sterile technique up to 5 mL of 1% lidocaine will be used to anesthetize the injection trajectory. Up to 8 mL of PRP will then be injected into the hip joint. Patients will then be observed for up to 10 minutes post-injection to monitor for any adverse reaction/complication. Standard post-injection instructions will be provided along with the post-injection protocol as below.

Pre-injection and post-injection protocol: All subjects will be required to avoid NSAIDs for one week before and two weeks after the injection. Recommended activity limitations for 1-week post-injection will

be provided (ex: avoidance of activity requiring deep hip flexion of >90 degrees, etc.) along with a standardized home exercise program.

Questionnaire: We will collect the following information: Demographics (i.e., age, sex, body mass index (BMI), etc); Clinical characteristics (i.e., duration of symptoms, visual analog scale (VAS), functional outcome scores [i.e., Harris Hip Scores (HHS), International Hip Outcome Tool (iHOT-12)], EQ-5D (quality of life measure), and patient global assessment score, etc). Additional medical information: (prior hip surgeries/injections, analgesic medication usage in the last 3 months, comorbidities, etc.); Imaging characteristics: Classification of labral tear, presence of chondral injury, Tonnis grade, other radiographic measurements (i.e., alpha angle, lateral center edge angle, etc.) (19-21). Subsequent surveys will ask about subsequent hip surgery, VAS, HHS, global assessment score, global impression of change, and global patient satisfaction (GPS). We will administer surveys and store data in REDCap (22, 23)

Data collection time points and follow-up: Follow-up data will be administered electronically. Subjects will be queried by email, text message, in person, and/or by telephone regarding treatment outcomes at 0 (baseline), 1, 3, 6, and 12 months after the therapeutic injection.

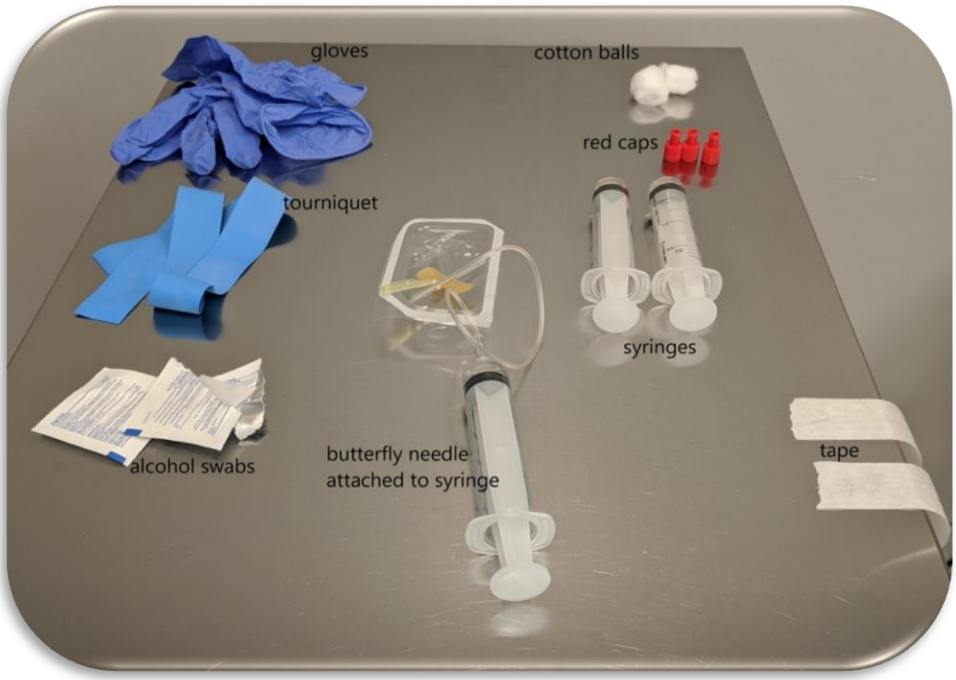
Sample size: The primary analysis will be improvement in HHS and VAS over six months. The prior pilot study demonstrated significant findings with 8 subjects (13). Power analysis was conducted to calculate the required sample size for this study. To detect significant changes in VAS and HHS over time using a one-way repeated-measures ANOVA, with an α level of 0.05, a power of 0.80, a correlation among repeated-measures of 0.5, and an effect size, f, of 0.25 (= medium effect size), the required sample size was estimated to be 27, accounting for 10% attrition rate. We will recruit 30 subjects to account for attrition.

Statistical analysis: Descriptive statistics will be calculated for patent demographics and clinical characteristics as well as for pre-injection (baseline) and post-injection (at 1, 3, 6, and 12 months) data for VAS and HHS. A one-way repeated-measures analysis of variance (ANOVA) will be used to examine VAS and HHS over time. In case of the significant ANOVA, pairwise comparisons with the Holm's sequential Bonferroni correction will be conducted to identify the difference in the scores between each time point. In addition, an association between platelet counts within the PRP and VAS or HHS will be examined using the Pearson correlation coefficient, separately for each time point.

Appendix 1: Low-Cost Platelet Rich Plasma (LC-PRP) Preparation Method

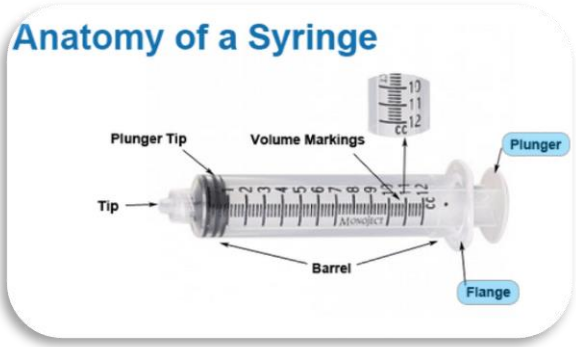
Step	
1	Ensure name and date-of-birth of subject.
2	Put stickers on all syringes, ensuring proper name & DOB throughout procedure
3	Add 2mL of NaCit into 3 x 20mL syringes

4	Venipuncture using butterfly needle

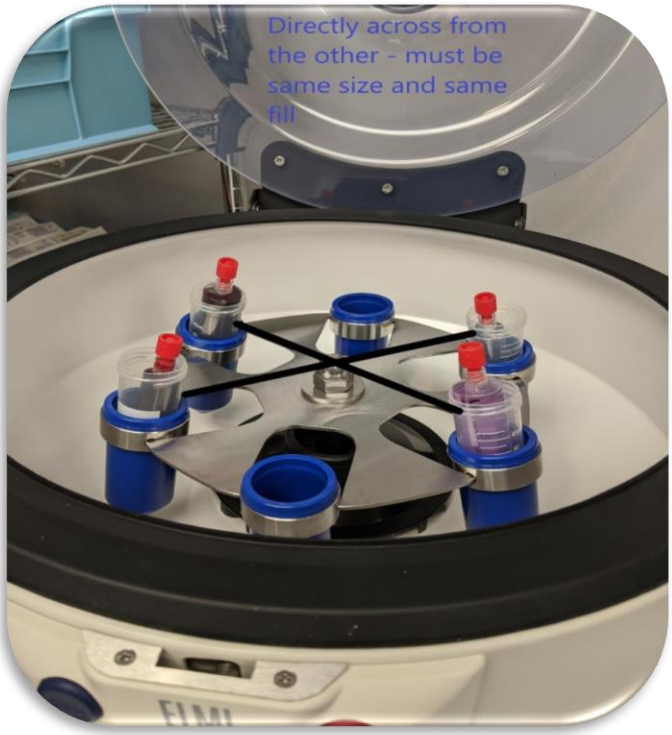


5 Draw 13mL blood (15mL total including 2mL NaCit) into 20mL syringe - syringe 1
6 Draw 13mL blood (15mL total including 2mL NaCit) into 20mL syringe - syringe 1
7 Draw 13mL blood (15mL total including 2mL NaCit) into 20mL syringe - syringe 1
8 Draw 1-2mL blood into 5mL syringe for complete blood count (CBC) testing

9 If extra blood is drawn up on any needle, properly dispose of extra blood to leave exactly 15mL
10 Cap each syringe (qty 4) - 3 for PRP and 1 for CBC
11 Mix all syringes by themselves with a rocking motion, back and forth
12 Using shears, cut off the plunger and both flanges from each syringe



13 Place syringes in the centrifuge, opposite each other

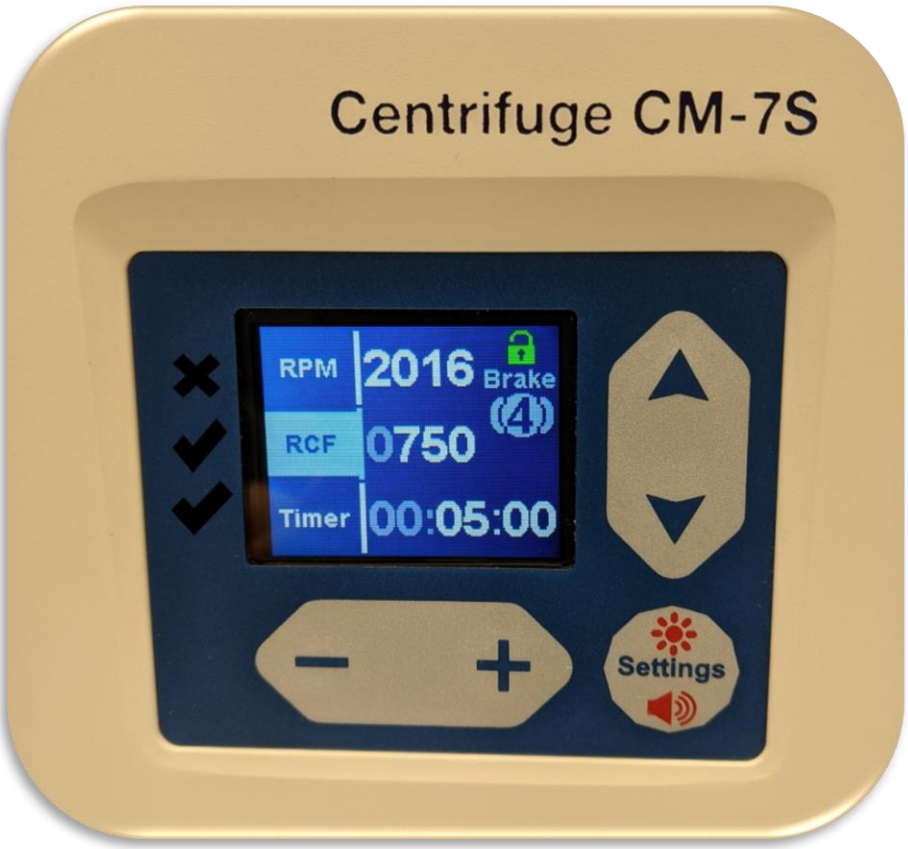


14 A fourth syringe will be used as a counterbalance, filled with saline

15 Using a scale, syringes will be emptied (~0-0.5mL) to match weights for counterbalance

16 Close centrifuge lid

17 Centrifuge at 750G for five minutes



18 Ready stopcock - one "waste" syringe (20mL) and one "PRP" syringe (10mL)

19 For each of 3 syringes, perform the following:

20 - Hold syringe upright and attach to bottom of stopcock

- Distribute upper portion of plasma into "waste" syringe, leaving 3mL of plasma
- Rotate stopcock from "waste" syringe to "PRP" syringe
- Distribute remaining 3mL of plasma into "PRP" syringe

This will leave 9mL in the "PRP" syringe

Mix syringe with rocking motion (to ensure homogeneity)

From the "PRP" syringe, inject 1mL into separate 5mL syringe for CBC testing

This will leave 8mL in the "PRP" syringe

Physician will perform injection after local anesthetic administration, name/DOB verification, and sterile preparation

Perform CBC testing on both PRP and whole blood samples

Important points to note:

1. Sterility will be ensured

2. Appropriate storage of sodium citrate
3. Do not use single-use vials multiple times
4. Use gloves and mask at all times
5. Only use sterile syringes, stopcocks, needles
6. Filling syringes to exact amounts is imperative. Avoid over- or under-filling.
7. If a syringe becomes contaminated in any way, it must be disposed of appropriately and not continue to use it in the PRP preparation process.
8. All blood must have a label on it to ensure that no patient receives another patient's blood

Supplies:

- Alcohol wipes
- Gloves
- Elastic tourniquet
- Butterfly/winged infusion set
- 20 mL BD syringes (dual ribbed)
- 18G blunt tip filling needles
- Anticoagulant (single use vials): 4% sodium citrate
- 50cc conical tubes
- Red caps
- Shears
- 3-way stop cock
- Injection syringe with needle
- Centrifuge
- Measuring scale
- Vortex machine (x3) to help with shaking, if necessary