

Blood Flow Restriction Therapy Following Closed Diaphyseal Femur Fractures: A Prospective Randomized Trial

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Purpose: Blood flow restriction therapy, which involves the use of a tourniquet to restrict partial arterial inflow and venous outflow while exercising, has been shown to be an effective strategy to improve limb strength at lower loads. We hypothesized that outcomes would be better among patients with closed diaphyseal femur fractures randomized to physical therapy with versus without blood flow restriction.

Methods: This prospective, multicenter randomized trial (RCT) assigned adult patients to a standardized physical therapy program with (intervention) or without (control) the use of blood flow restriction. The program started within 42 days of definitive fixation and was delivered over 8-12 sessions. The primary outcomes were hip and knee flexor and extensor strength (newtons, N), hip and knee flexion and extension range of motion (ROM), and muscle volume. For each outcome, we estimated the treatment-specific mean difference relative to the contralateral leg and compared these means using a 2-sample t-test at 3 and 6 months post definitive fixation. Secondary outcomes included 3- and 6-month Patient-Reported Outcomes Measurement Information System (PROMIS) physical function (PF) and pain intensity (PI).

Results: There were 194 patients (intervention: n = 96, control n = 98) enrolled at 8 centers over 5 years. The 3-month difference in knee extension strength in the injured relative to the contralateral limb was 122 N in the intervention group and 154 N in the control group (difference: 31 N, 95% confidence interval [CI]: 1-61, P = 0.04). The 3-month difference in knee flexion ROM in the injured relative to the contralateral limb was similar (4° in the intervention group and 6° in the control group (difference: 1.2, 95% CI: -1.8, 4.2, P = 0.09). There were no differences in hip strength or ROM, or muscle volume. There were no differences in PROMIS PF or PI at 3 or 6 months. No complications related to blood flow restriction were reported.

Conclusion: Results of this RCT demonstrate that blood flow restriction therapy is safe to use following diaphyseal femur fractures. The trial observed a relatively small improvement in knee extension strength following therapy, but no benefits in ROM or patient-reported outcomes.