EARLY CONTROLLED PASSIVE MOTION IMPROVES EARLY FRACTURE HEALING IN A RABBIT MODEL: A RANDOMIZED PRE-CLINICAL EFFICACY TRIAL

**INTRODUCTION:**
This project examines the introduction of early controlled passive mobilization (ECPM) into the management of closed, extra-articular hand fractures. Early controlled motion (ECM) has been recommended as an alternative to immobilization (IM) in a variety of clinical situations following a closed, extra-articular hand fracture. However, clear clinical parameters for the ‘safe’ introduction of ECPM have not been defined.

**OBJECTIVE:**
To conduct a pre-clinical efficacy study, investigating if ECPM is likely to cause harm with regard to affecting the quality and rate of early, closed, diaphyseal fracture healing. This study used a non-weight bearing limb, rabbit forepaw, closed, right, 3rd metacarpal shaft, (simulated hand), fracture-healing model.

**CLINICAL PARAMETERS:**
- **Pre-clinical, Efficacy Study:** Can ECPM work in a simulated hand, closed, diaphyseal fracture? Cause No Harm: Is EPM the same or better than standard care (IM)?
- **Primary Clinical Endpoint:** Day 28, the point when hand fracture immobilization normally ends. Primary Clinical Outcome Measure: 4-pt bending Modulus (Clinical Stability).
- **Secondary Clinical Outcome Measure:** Dorsal Angulation (Clinical Fracture Alignment).

**RESEARCH QUESTION:**
During the initial 28 days post-fracture, when compared to fractures treated with immobilization, how will early controlled passive motion beginning on the 5th post-fracture day affect: 1) early fracture callus 4-pt bending modulus, and 2) early fracture callus dorsal angulation.

**STUDY DESIGN:**
A Block Randomized, Pre-clinical, Efficacy Trial: 3-Conditions (BL, IM, & ECPM) X 3-Time Periods (5Days, 14Days, & 28Days).

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<thead>
<tr>
<th>Baseline</th>
<th>Immobilized</th>
<th>Early Passive</th>
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<tbody>
<tr>
<td>n=11</td>
<td>n/a</td>
<td>n/a 5days</td>
</tr>
<tr>
<td>n/a</td>
<td>n=8</td>
<td>n=8 14days</td>
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<tr>
<td>n/a</td>
<td>n=10</td>
<td>n=11 28days</td>
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**METHODS:**
Forty eight, mature, female, New Zealand White, rabbits were introduced into the study at a rate of 2 or 3 rabbits per week. Rabbits were preconditioned to a right forelimb, non-weight bearing brace for one week. On Day 0, a closed, transverse, right 3rd metacarpal fracture was created in anesthetized rabbits using specially adapted 3-pt bending pliers. Fractures were reduced under fluoroscopy, placed in a custom molded fracture brace and immobilized for four days. On Day 5, the rabbits were randomly block allocated to treatment condition (BL, IM, or ECPM). The ECPM rabbits received two daily sessions [4 cycles / minute x 15 minutes = 60 full motion cycles / session] of full arc passive digital motions with additional 3-pt ‘pinch’ fracture stabilization. ECM was done by experienced hand therapists. The IM group received no further intervention. At the allocated time-period (5Days, 14Days, or 28Days), the rabbits were sacrificed, the forelimbs were disarticulated, labeled and fresh frozen until further blinded outcome evaluation. This study received institutional ethical approval and was in compliance with the Canadian Council on Animal Care (CCAC) guidelines.

**OUTCOME EVALUATION:**
The 3rd metacarpals were serially dissected out of the frozen forepaws. Digital X-rays and Peripheral Quantitative Computed Tomography (pQCT) images were taken of the frozen specimens. Specimens were thawed to room temperature and tested to structural failure in quasi-static, 4-pt bending mode (Dynamight, Instron Corp, Canton, MA) in the dorsal-volar direction at a rate of 1mm/sec.

**STATISTICAL ANALYSES:**
- **Primary:** Two-way Analysis of Variance (3x3 -Treatment Condition x Timeline) Post-Hoc: LSD Multiple Comparisons and Independent T-Test (ECPM vs IM @ 28 days).

**RESULTS:**
- **4-pt Bending Modulus:** Both ECPM and IM fractures show statistically significant improvements in bending modulus over 28 days (p<.001), with the majority of this improvement occurring between 14 and 28 days (IM p=.007; ECPM p=.001). At the 28 days time period, ECPM fractures showed 25% greater stiffness than IM fractures, but the difference was not statistically significant (difference 38, p=.43). (See Figure 1)
- **Fracture Dorsal Angulation:** IM fractures did not show a significant decrease in dorsal angulation over 28 days (19% improvement, -5.2 degrees, p=.28). In contrast, ECPM fractures did show a significant improvement over 28 days (52% improvement, -12.3 degrees, p=.001) with the majority of this improvement occurring between 5 and 14 days (-6.2 degrees, p=.03). In addition, at the 28 days time period, ECPM fractures show significantly less dorsal angulation than IM fractures (34% less angulation, -7.1 degrees, p=.05). (See Figure 2)

**DISCUSSION / CONCLUSION:**
Findings from this study indicate that ECPM significantly reduces the degree of early fracture dorsal angulation, as well as, improves early fracture callus 4-pt bending modulus. The improvement in dorsal angulation in the ECPM fractures from a mean of 29.7 degrees at baseline compared to a mean of 17.4 degrees at 28 days (52% improvement) is likely do to the 3-pt ‘pinch’ stabilization of the fracture during ECPM. This counter-pressure seemingly molds the malleable fractures during this early fracture healing period. Improved dorsal fracture angulation with ECPM is an important clinical finding. ECPM fractures calluses also have a 25% greater bending modulus at 28 days than do IM fracture calluses, although the difference was not statistically significant. This finding suggests that ECPM calluses may be healing with greater material stiffness, possibly due to greater mineralization of the calluses during this early healing period. Better early callus mineralization with ECPM would be an important clinical finding as this suggests that ECPM may actually improve the quality and rate of early fracture healing.

**CLINICAL SIGNIFICANCE:**
ECPM does not cause harm with regard to affecting either the quality or rate of early fracture healing. Therefore, early controlled mobilization following closed diaphyseal hand fractures warrants further clinical study.

**FUTURE RESEARCH DIRECTIONS:**
PQCT densitometric and histomorphologic studies are planned to determine if there are any quantitative morphologic differences in fracture calluses treated with ECPM compared to IM.

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