

A Randomized Controlled Trial of Locked Plating versus Retrograde Nailing for Periprosthetic Distal Femur Fractures

Aaron Nauth, Rosa Park, Michael D McKee¹, Jeremy Hall², Amir Khoshbin³, Milena Vicente⁴, Matthew Raleigh⁵, Ashmanie Brijmohan⁶, Emil H Schemitsch⁷, Cots Canadian Orthopaedic Trauma Society⁸

¹Banner - University Medical Center Phoenix, ²St. Michael's Hospital, ³University of Toronto, ⁴St. Michael's Hospital, ⁵Division of Orthopedic Surgery, Department of Surg, ⁶Division of Orthopaedic Surgery, ⁷University of Western Ontario, ⁸COTS

INTRODUCTION:

Periprosthetic fractures of the distal femur (PPDFs) above a total knee arthroplasty (TKA) are challenging to manage, with these injuries continuing to increase in prevalence due to the growth in the number TKAs performed and the aging and increasingly active population. There remains substantial controversy regarding the ideal fixation strategy for these fractures, with debate occurring between the use of locked plating (LP) and retrograde intramedullary nailing (RIMN). Both methods are generally accepted as viable options for the treatment of PPDFs, with contrasting advantages and disadvantages cited by their respective proponents and critics. Given this, we conducted an international multi-centre randomized controlled trial of LP versus RIMN for the treatment of PPDFs.

METHODS:

This was a registered, prospective multi-centre randomized controlled trial comparing locked plating (LP) to retrograde intramedullary nailing (RIMN) for the management of PPDFs (NCT01973712). Patients were recruited from 13 trauma centres internationally between 2014-2022 and randomized to either LP or RIMN (see Figure 1). Blocked randomization was performed with stratification on the basis of a pre-operative diagnosis of osteoporosis. Following randomization and surgery, patients were followed for 2 years. Follow-up occurred at 2 weeks, 6 weeks, 3 months, 6 months, 12 months and 24 months. The primary outcome measure was the timed up and go (TUG) test at 3 months. Secondary outcomes included the Knee Society Score (KSS), as well as rates of nonunion, malunion, re-operation and mortality. Nonunion and malunion were graded by the treating surgeons. Radiographic alignment in the coronal and sagittal plan, as well as length were assessed. Fractures healing with > 5 degrees of malalignment in any plane or > 1 cm length discrepancy were defined as malunions.

Necessary sample size to detect a significant difference in TUG scores by means of an independent two-sample t-test was determined based on review of the existing literature. Targeting a power of 0.8 and α of 0.05 and assuming a standard deviation of 13, 43 patients per group would be required to detect an 8 second difference in TUG scores. Accounting for a further 10% loss to follow up, we calculated that a total sample size of 94 patients would be required.

Independent samples t-tests or Mann-Whitney U Tests were conducted to compare the means of the two groups for continuous variables (TUG, KSS scores), as appropriate. Fisher's exact test was employed to assess the association between categorical variables (union outcome). Multiple imputation was employed for the primary analysis (TUG at 3 months) and other TUG timepoints, assuming that missing data occurred at random and with missing data imputed only for patients with some TUG data available. All tests were two-tailed and a $p < 0.05$ was considered statistically significant.

RESULTS: A total of 94 patients were randomized, with 53 patients were randomized to LP and 41 patients to RIMN. Follow-up data for our primary outcome was available for 82% of patients. No significant differences were observed between groups in the results of the TUG test at 3 months (56.5 ± 57.0 seconds in LP group vs 50.0 ± 51.5 seconds in the RIMN group, $p = 0.62$), or any time point thereafter (see Figure 2). Similarly, no significant differences were observed in KSS scores at any time point. Nonunion occurred in 3/40 (7.5%) of patients in the LP group at 1 year versus 0/30 (0%) patients in the RIMN group ($p = 0.25$, see Figure 3). Malunion was less common in the LP group 4/43 (9.3%) vs the RIMN group 13/36 (36.1%) ($p = 0.003$, see Figure 3). Reoperation occurred in 5/40 (12.5%) patients in the LP group at 1 year versus 1/30 (3.3%) patients in the RIMN group ($p = 0.23$). Mortality rates were similar in both groups at 1 year (13% LP group versus 14.3% RIMN group, $p = 1.0$).

DISCUSSION AND CONCLUSION:

This multicentered randomized controlled trial of LP versus RIMN for the treatment of PPDFs did not demonstrate any significant differences between the two fixation strategies with respect to functional outcomes. Malunion was significantly more common in the RIMN group. Nonunion and re-operation occurred more frequently in the LP group, although the differences were not significant and both events were infrequent. Both LP and RIMN are acceptable treatment options for the management of PPDFs above a TKA.



Figure 1 – Representative Radiographs. Representative radiographs of healed periprosthetic distal femur fractures treated with locked plating and retrograde intramedullary nailing, respectively.

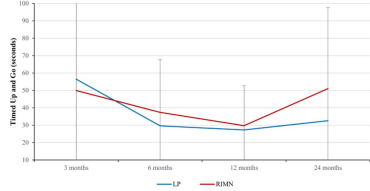


Figure 2 – Timed Up and Go Test. Results of timed up and go test results for locked plate and retrograde intramedullary nail groups. No significant differences were demonstrated at any time point between groups from 3 months to final follow-up at 24 months. Data is demonstrated as mean and standard deviation. LP = locked plating, RIMN = retrograde intramedullary nail.

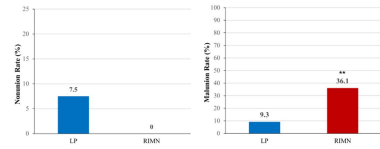


Figure 3 – Rates of Nonunion & Malunion. Rates of nonunion and malunion are demonstrated between groups. No significant differences were demonstrated between groups for rates of nonunion. Significantly greater rate of malunion was found in the RIMN group compared to LP group. LP = locked plating, RIMN = retrograde intramedullary nail. ** denotes $p < 0.01$.