Reconstruction Plate Compared with Flexible Intramedullary Nailing for Midshaft Clavicular Fractures: A Prospective, Randomized Clinical Trial

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Purpose: Previous studies have shown good clinical results in patients with midshaft clavicular fractures treated with reconstruction plate fixation or elastic stable intramedullary nailing (ESIN). The objective of this study was to compare these methods in terms of functional results, radiographic parameters, postoperative pain, satisfaction rates, and complication rates. We hypothesized that there would be no difference between the treatment groups in terms of functional results.

Methods: This is a single-center, prospective, randomized controlled trial, with IRB approval. 59 patients between 16 and 65 years of age with a displaced midshaft clavicular fracture were randomly assigned to receive either reconstruction plate or ESIN fixation. The primary outcome was the Disabilities of the Arm, Shoulder and Hand (DASH) score at 6 months The secondary outcomes were the following: DASH score at 12 months, Constant-Murley scores at 6 and 12 months, radiographic parameters (time to union and residual shortening), visual analog scale (VAS) for pain on the first postoperative day, patient satisfaction rate, and complication rates, divided into minor and major complications.

Results: 29 patients in the plate group and 25 in the ESIN group completed the follow-up. The mean DASH score at 6 months was 9.9 in the plate group and 8.5 in the ESIN group ($P = 0.329$). Similarly, there were no differences in the DASH score at 12 months and the Constant scores at 6 and 12 months. The mean time to union was 16.8 weeks in the plate group and 15.9 weeks in the ESIN group ($P = 0.352$), whereas the residual shortening was significantly greater in the plate group ($P = 0.032$) but was not clinically relevant (0.4 cm). The VAS scores for pain and patient satisfaction rate were similar between the groups. Regarding minor complications, the rate of implant bending was significantly greater in the plate group (11 patients) than in the ESIN group (1 patient) ($P = 0.003$), whereas the rate of hardware-related pain was greater in the ESIN group (10 patients) than in the plate group (4 patients) ($P = 0.035$). There were similar rates of major complications in both groups, with one case of nonunion in the ESIN group, and no cases in the plate group ($P = 0.463$).

Conclusion: Reconstruction plates and ESIN yielded similar functional results, time to union, postoperative pain, and patient satisfaction rates in patients with displaced midshaft clavicular fractures. Reconstruction plates were more susceptible to implant bending, whereas ESIN caused more hardware-related pain. Both methods were safe in terms of major complications.

See pages 99 - 147 for financial disclosure information.