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Is Iliosacral Screw Removal Useless? A Causal Analysis of Prospective Observational Data

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Purpose: Removal of iliosacral screws following pelvic fractures has been theorized to relieve posterior pelvic pain, yet there are no data to support this idea. We hypothesized that iliosacral screw removal would reduce pain compared to screw retainment after a pelvic ring fracture.

Methods: In a prospective cohort study, we enrolled 59 patients (mean age, 39 years [standard deviation (SD), 16]; 68% male) with pelvic pain 4 to 6 months after iliosacral screw fixation of a pelvic ring fracture at a Level I trauma center. Patients undergoing screw removal were matched (n:1) to a control group of patients retaining screws. Matching was based on days post-initial fixation and their Brief Pain Inventory score at the follow-up visit prior to hardware removal. The primary outcome was postoperative pain within 6 months of screw removal, assessed using the validated Brief Pain Inventory. The secondary outcome was pelvic function within 6 months of screw removal, measured using the Majeed Pelvic Outcome Score. We used a linear regression model to estimate the mean difference in pain and function between the removal and retention groups adjusted for pre-treatment levels.

Results: The mean pain in the screw removal group was 4.7 (SD, 3.0) before and 3.7 (SD, 2.7) after screw removal, compared to 4.7 (SD, 3.0) before and 3.3 (SD, 2.5) after the same 6-month time period in the control group. We found no evidence that screw removal reduced pain compared to the control (difference, 0.23 points; 95% confidence interval [CI], -1.0 to 1.5; P = 0.71). The mean function in the screw removal group was 57 (SD, 20) before and 68 (SD, 18) after screw removal, compared to 57 (SD, 28) before and 64 (SD, 24) after the same time period in the control group. Similarly, we found no evidence that screw removal significantly improved pelvic function (difference, 3 points; 95% CI, -5 to 11, P = 0.42).

Conclusion: Although pelvic pain and function do improve over time after iliosacral screw removal, we found no evidence that improvements differed from a matched controlled group with similar levels of baseline pain. The best available evidence, supported by our prospective data acquisition and rigorous analytic approach, suggests that iliosacral screw removal is unlikely to benefit most patients. Clinicians should consider these data when offering this procedure to patients.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device they wish to use in clinical practice.