

Introducing the Surgical Therapeutic Index in Trauma Surgery: An Assessment Tool for the Benefits and Risks of Different Operative Fracture Treatment Strategies

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Background/Purpose: The concept of the Surgical Therapeutic Index (STI) has been described as an indicator of the benefits and risks of surgical treatment in other fields of surgery. The index is calculated by dividing the cure rate of an operative treatment by the complication rate and should be interpreted as expressing a certain level of safety; the higher a procedure's STI, the safer the procedure. The STI introduces a concept to critically evaluate the pros and cons of surgical fracture treatment in general. The optimal treatment of clavicle fractures has been a topic of debate for many years. Although many of these fractures may be treated successfully without surgery, displaced midshaft clavicle fractures (DMCFs) are often treated surgically. This study compares the indices for surgical plate fixation (PF) and intramedullary fixation (IMF) for the treatment of DMCF. The purpose of this study is to introduce the concept and philosophy of the STI into fracture treatment by using operative clavicle fracture fixation as an example.

Methods: In a randomized controlled fashion 120 patients were assigned to either PF (n = 58) or IMF (n = 62) with follow-up at 6 weeks, 3 months, 6 months, and 1 year after surgery. Cure was defined by a Disabilities of Arm, Shoulder and Hand (DASH) score of 8 or less. Complications were noted as present or not present for each follow up moment. In addition, a panel of experts provided weights to encountered complications in order to correct for the gravity of their consequences, resulting in unweighted and weighted STIs. After bias correction and using nonparametric bootstrapping, STIs were reported along with their 95% confidence intervals. The higher a procedure's STI, the higher the benefit/risk balance of that procedure.

Results: One year after surgery 50 patients (86%) in the PF group and 55 patients in the IMF group (89%) were considered cured (P = 0.67). Superficial infection occurred in 3 (5%) patients in the PF group and 4 patients (7%) suffered from a complication requiring major surgical revision. The IMF failed in 2 patients (3%) and the rate of implant-related soft-tissue irritation was 55%. The nonweighted STI after 6 weeks was significantly higher in the PF group. During further follow-up the differences leveled out and turned nonsignificant. When weighing the complications the indices decrease but are significantly in favor of the PF group at 6 weeks and 6 months after surgery. At 1 year postoperatively, differences are not significant.

Conclusion: The STI may be a reliable tool to assess the benefits and risks of operative fracture treatment. Further studies on clavicle and other fractures with consistent results of this new scoring system are needed, before conclusions can be generalized. When de-

terminating the indices of PF and IMF, a significant difference in favor of PF was observed during the early phase of recovery, which was prolonged when correcting for the gravity of consequences of complications by using severity weights. One year postoperatively, the STI for PF and IMF were similar.

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