Does Progressive Radiographic Healing Result in Better Function? A Prospective Evaluation of PCS and RUST Scoring in Tibial Shaft Fractures Treated with IM Nailing

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Background/Purpose: Multiple large trials have reported validated patient-based outcomes of tibial nailing at final follow-up, while others have reported on the problems of patients with nonunions. However, there are no data on the recovery of function over time, or how progressive radiographic healing is related to outcome. The purpose of this study is to describe the recovery curve of patients after intramedullary (IM) nailing using the SF-36 PCS (36-Item Short Form Health Survey, physical component summary score) and to evaluate its association with progressive healing using the RUST score (radiographic union score of the tibia).

Methods: In a prospective multicenter trial 501 patients were treated with IM nailing and followed at 6, 12, 18, 26, 38, and 52 weeks with SF-36 PCS at all visits and radiographs at each visit until an independent adjudication committee determined the fractures to be healed (defined as remodeled callus on 3 cortices). All radiographs were scored and adjudicated using the RUST method based on the callus on each of the 4 cortices. All disagreements in scoring were resolved by an adjudication panel resulting in a consensus decision. The association of PCS with RUST and with time from surgery was determined using a repeated-measures analysis. In a separate analysis, the PCS over time (recovery curve) of patients with delayed union (defined as not healed by 6 months) were compared with those patients who were united by 6 months.

Results: The recovery curve (mean PCS) and the mean RUST scores per visit are seen in Figure 1 for all patients. PCS plateaus at 6 months for the group as a whole. The PCS curve and the RUST curve have a strong statistical association (P < 0.001). PCS was also associated with time from surgery and decreased age after adjusting for the RUST score. Patients who were not healed by 6 months had statistically different PCS scores at all time points after 6 weeks than those who were healed by 6 months (Figure 2). The recovery curve for patients with delayed union was shifted to the right compared with those united by 6 months, indicating a strong association of progressive healing with PCS.

Figure 1 PCS blue, RUST green.

Figure 2 Healed <6 mos vs. >6 mos.



Conclusion: Recovery after tibial nailing is strongly associated with progressive radiographic healing. The average SF-36 PCS plateaus near 6 months for the majority of patients. This plateau is delayed until 52 weeks for patients with delayed union (not healed by 6 months). PCS was also associated with time from surgery and age. This is the first large trial to demonstrate the association of progressive healing with patient-based outcome, and to demonstrate the recovery curve after tibial nailing. Patients may be counseled regarding their expected outcomes based on their radiographic progress towards union.

The FDA has not cleared this drug and / or medical device for the use described in this presentation (i.e., the drug or medical device is being discussed for an "off label" use). For full information, refer to page 600.