Prediction of Tibial Nonunion at the 6-Week Time Point

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Purpose: Tibial shaft fractures are the most common long bone fracture and nonunions are frequent. Early prediction of nonunion at the 6-week postoperative time point would have clinical utility and has not yet been explored in the literature. We hypothesized that a predictive model of tibial shaft fracture nonunion at 6 weeks postoperative from reamed intramedullary (IM) nail fixation could be developed based on commonly collected clinical variables and the Radiographic Union Score for Tibial fractures (RUST).

Methods: All tibial shaft fractures treated with IM nail fixation at our Level I trauma center from 2007 to 2014 were retrospectively reviewed. Only patients with minimum follow-up until healing of the fracture or until secondary operation to address nonunion were included and those with planned prophylactic nonunion surgery were excluded as were those with critical fracture gaps defined as 3 mm or greater for any of the four cortices of the tibia. Of the 323 patients included for study, 50 (15%) had gone on to nonunion. 42 commonly collected clinical and radiographic variables that had been previously hypothesized to be associated with nonunion were recorded and analyzed. Bivariate and multivariate regression analyses were used to determine variables significantly associated with nonunion.

Results: Using bivariate and multivariate regression models, four variables were found to have statistically significant associations with nonunion (odds ratio [OR] > or <1.0; P< 0.01). These variables included infection within 6 weeks of operation, standard RUST, modified RUST, and the previously reported Nonunion Risk Determination (NURD) score. The NURD score is based on a time zero nonunion prediction model created using clinical variables available at the time of definitive fixation. No other variables were significantly associated with nonunion. Both standard (OR = 0.64; P < 0.01) and modified RUST (OR =0.74; P < 0.01) were significant predictors of nonunion and there was no significant difference between the two scores. While the difference between standard RUST and modified RUST score was not statistically significant, the standard RUST showed a stronger association with nonunion and was therefore used for further regression models. When using infection within 6 weeks, standard RUST, and the NURD score in a regression model, sensitivity and specificity for nonunion were both 82%. The NURD score was increasingly predictive with decreasing RUST score (Table 1). Based on this finding, patients were stratified into three categories of RUST scores including high (RUST 10 or greater), medium (RUST 6-9), and low evidence of healing (RUST<6 or infection within 6 weeks). All patients in the high RUST score group went on to union, regardless of NURD score. In the medium RUST score group, 25% of patients with a NURD score 7 or greater went on to nonunion. In the low RUST score group, 69% of patients with a NURD score 7 or greater went on to nonunion.

See pages 49 - 106 for financial disclosure information.

Table 1. Number of patients that went on to nonunion based on NORD and RUS1 scores									
NURD Score:	High Evidence of Healing (RUST ≥ 10)			Medium Evidence of Healing (RUST 6-9)			Low Evidence of Healing (RUST < 6 or infection)		
	Number of	Total	%	Number of	Total	%	Number of	Total	%
	nonunions	patients		nonunions	patients		nonunions	patients	
0-1	0	11	0	0	22	0	0	4	0
2-3	0	5	0	2	71	3	1	17	6
4-6	0	9	0	6	80	8	15	50	32
7+	0	1	0	6	24	25	20	29	69

Table 1. Number of patients that went on to nonunion based on NURD and RUST scores

Conclusion: Three variables (RUST, presence of infection, NURD score) were found to best predict nonunion surgery based only on data available 6 weeks following reamed IM nail fixation of the tibia. Utilizing these variables we created a clinical prediction tool of nonunion that could aid in discussing prognosis with patients as well as in clinical decision making.

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.