Physiological Widening of the Medial Clear Space and Syndesmosis with Stress Examination

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Purpose: Both cadaveric and clinical studies have validated the use of stress radiographs for evaluation of ankle stability after fractures to the fibula. However, to our knowledge no study has reported the amount of physiological widening that occurs with manual external rotation stress test in uninjured ankles. The purpose of this study was to assess the amount of medial clear space widening that occurs with a manual external rotation stress test in uninjured ankles.

Methods: A cohort of adult patients undergoing operative fixation of unstable ankle fractures were prospectively enrolled to have their contralateral ankle undergo manual external rotation stress examination. The study was IRB-approved and all patients signed an informed consent. Exclusion criteria were age less than 18 years, prior ankle injury or known instability to the unaffected extremity, systemic musculoskeletal disorders, polytrauma, and incidental abnormal radiographic findings. Fluoroscopic images of the unaffected ankle were performed in the operating room prior to fixation of the injured ankle. A nonstressed mortise view and manual external rotation stress view were obtained with a standardized marker to correct for magnification differences. The images were de-identified and presented in a randomized order to three separate reviewers. The reviewers were blinded as to whether the images were stress or nonstress images. Each reviewer measured the medial clear space. A power analysis performed based on prior studies measuring medial clear space widening, as well as a post hoc analysis of our data, determined that 7 subjects were needed for adequate statistical power. Statistical analysis comparing means between stress and nonstress examinations, average amount of medial clear space widening, and incrobserver reliability were performed.

Results: 30 fluoroscopic images on 15 separate patients were obtained with a mean medial clear space on the nonstress mortise of 3.1 mm (SD 0.69; range, 1.9 to 4.2; 95% CI 2.75, 3.45) compared with the stressed mortise mean of 3.3 mm (SD 0.71; range, 2.0 to 4.7; 95% CI 2.94, 3.66). This difference was not statistically different (P = 0.43). The change in clear space from the nonstressed to the stressed view ranged from -0.7 mm to 1.5 mm with the majority (93%) widening less than 0.7 mm (95% CI -0.3, 0.7). Interobserver reliability was excellent between all observers (intraclass correlation coefficient [ICC] 0.92).

Conclusion: Previous literature suggests that a medial clear space of 5 mm or an increase in width of medial clear space by 2 mm after stress examination are evidence of ankle instability in the setting of fibula fractures. Our data show that no physiologically healthy ankles widened beyond these established cutoffs either before or after the manual external rotation stress. Therefore these values remain valid assessments of ankle stability, and the use of manual external stress radiographs is unlikely to result in false positives using these thresholds.

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.