Mid-Term Clinical Outcomes of the PUMA System™

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Background

The PUMA System (Panther Orthopedics, Sunnyvale, CA) is a superelastic, nitinol based fixation device for the ankle syndesmosis which provides stabilization without over-compression or loosening with cyclical loading. Nitinol has a proven safety record in foot and ankle surgical repair and reconstruction implants. The spring-like design of the PUMA System allows physiological micro-motion while maintaining continuous compression without creep. This syndesmotic stabilization provides more normal ankle biomechanics without the risk of stiffness as seen with screws and loosening over time as seen with suture/endobutton type implants.

Methods

Clinical data from 49 patients with syndesmotic disruption treated with the PUMA System was reviewed retrospectively. Objective outcome measures were evaluated via adverse event rates, radiographic evaluations for syndesmosis integrity and revision surgery rates.

Results

All 49 patients had successful repair of their ankle syndesmosis. The mean age of patients at operation was 41 years (range 15 – 68). There were 22 females (22/49, 44.9%) and 27 (27/49, 55.1%) males. Postoperative radiographic evaluations confirmed satisfactory syndesmosis healing with reduction in the ankle mortise in 49/49 (100%) patients. There was no evidence of lysis, device migration or syndesmotic widening. There were no infections or soft tissue complications. No devices required removal and there were no revision surgeries.

Conclusions

The PUMA System provides anatomical stabilization due to the design features that allow for continuous compression without creep. The superelastic implant design moves with the body and obviates the need for routine removal. The implant's low-profile buttons without suture and knot tying requirements eliminate the concern for subcutaneous knot irritation and slippage.

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