A Novel, Multi-Planar and Less Invasive Approach to Distal Radius Fracture Fixation — Early Clinical Experience

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PURPOSE: The majority of surgically managed distal radius fractures are treated using volar locking plates. Although volar plating is effective for most patients, the need still exists for a solution that minimizes surgical trauma, avoids tendon irritation and addresses a broad range of fracture patterns.

This study introduces a novel fracture fixation system designed to address these needs using a universal, intramedullary scaffold to which fragments can be reassembled and stabilized using screws placed in any plane as dictated by the fracture pattern. The intramedullary fixation device has been previously shown to have comparable axial and bending stiffness to volar locked plates.

METHODS: A prospective case study was performed in patients undergoing internal fixation of a distal radius fracture using an expandable, intramedullary scaffold. Study protocol was approved within the clinical investigators’ respective institutions and countries. Patient outcome was assessed based on serial radiographs, adverse event reporting and DASH scores.

RESULTS: Twenty patients have undergone surgery (17 female; age range 50-90 years), with follow-up ranging from 1 to 50 weeks. In all cases, analysis of immediate postoperative radiographs showed acceptable reduction. Review of radiographs at subsequent follow-up revealed 19 of 20 cases with no loss of reduction compared to the immediate postoperative images. One case demonstrated approximately 3 mm of radial shortening due to inadequate proximal screw fixation; clinical outcome was not adversely affected (DASH score: 3).

Only one post-operative adverse event was documented – irritation of the superficial branch of the radial nerve – which resolved spontaneously.

DASH scores for 12 patients at 12 week follow-up all exhibited improvements compared with scores at the time of screening, with a mean score of 24.4 and a mean score improvement of 44.4 points (mean score reduction of 64.8%).

CONCLUSIONS: Early clinical experience with this new technique for intramedullary management of distal radius fractures is promising. This study demonstrates the technique’s ability to deliver stable fixation through a tissue-preserving approach and maintain reduction throughout the healing phase. Additional study is warranted.

FDA Approval Notice: The FDA has not cleared this device for the use described in this presentation.

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SURGICAL TECHNIQUE: Following provisional reduction with K-wires, a small incision and a 5mm diameter cortical hole are created on the lateral aspect of the radius, approximately 7 cm proximal to the fracture site. An expandable broach is inserted into the medullary canal and used to prepare the metaphysis for implant insertion. A compressed nitinol scaffold is then introduced into the canal and allowed to expand within the prepared metaphyseal site. Cannulated bone screws are inserted percutaneously over K-wires placed through fracture fragments and into the expanded scaffold to provide stable fixation. Screw quantity, type and orientation can be tailored to the individual fracture pattern.