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Subjective and novel objective radiographic evaluation of inflatable bone tamp treatment of articular calcaneus, tibial plateau, tibial pilon and distal radius fractures

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ABSTRACT

There is a growing need to develop tools that allow for better reductions of difficult to treat fractures in minimally disruptive ways. One such technique has been developed using the inflatable bone tamp and a fast setting calcium phosphate. KYPHON® XPANDER Inflatable Bone Tamp and the KYPHON® Osteo Introducer® System were used to reduce the articular fractures and a fast-setting calcium phosphate was introduced into those voids and metal hardware was applied as deemed necessary. Subjects were skeletally mature patients treated for articular fractures of the calcaneus, tibial plateau, tibial pilon, or distal radius. Post-operative day zero and week 12 radiographs were objectively and subjectively evaluated by three independent orthopaedic surgeons. Their objective scores were then translated into subjective categories based on the Heiney–Redfern scaled scoring (H-R score) system established herein. Overall, the thorough radiographic analysis by independent reviewers indicates that the technique is capable of obtaining and maintaining articular reductions in a good or adequate manner at 12-weeks post-operatively. Introduced is a potential novel evaluation scale scoring system for these articular fractures that evaluates the important anatomic considerations reproducibly in fracture reductions. There are many potential benefits that remain speculative to this type of tool within a procedure, and therefore this tool and technique warrants further research.

Introduction

Calcaneus, tibial plateau, tibial pilon, and distal radius fractures continue to increase in numbers in modern society with a growing economic cost related both to the expense of treatment as well as ongoing disability.[1] Articular fractures in these locations are especially known for their high rates of wound complications.[2,3] Co-morbidities including but not limited to obesity, diabetes mellitus and smoking continue to complicate wound and fracture healing.[4–6] The significance of these complications is heightened by the fact that these fractures often occur in younger patients and our society continues to live longer.[7,8]

In order to reduce fracture non-unions and wound complications, new minimally invasive techniques for fracture management continue to be developed. It has been shown that minimal internal fixation with calcium phosphate cement can result in good outcomes in tibial plateau fractures.[9] One minimally invasive technique that has had great success in clinical practice is balloon Kyphoplasty (Medtronic Spine LLC, Sunnyvale, CA),[10,11] which until recently has been relegated to the treatment of compression fractures of the spine. Several studies on balloon Kyphoplasty in the spine, including a prospective randomized controlled trial,[10] have reported improved quality of life, improved disability measures and a reduction of back pain using this technique.[10,12] Kyphoplasty is generally performed using an inflatable balloon, known as the Inflatable Bone Tamp (Fig. 1; IBT, Medtronic Spine LLC, Sunnyvale, CA). The IBT is designed to "compress cancellous bone and/or move cortical bone as it inflates".[13] The characteristics of the device allow it to be used in potentially any bone, simply as a conventional bone tamp or as a percutaneous bone tamp with fluoroscopic guidance. Pre-market testing in cadaveric fractured tibial plateaus and unfractured vertebrae has been performed, demonstrating that IBTs can reduce cortical fractures and create voids in cancellous bone in the same manner as conventional bone tamps. Safety testing also demonstrated no increase in risk over conventional bone tamps.[13]

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Fig. 1. KYPHON® XPANDER Inflatable Bone Tamp is comprised of three biocompatible parts: a proximal luer fitting, a central catheter, and a distal inflatable tip with radiopaque markers.

The placement of fast-setting calcium phosphate cements into fresh orthopaedic fracture sites has been proven beneficial in filling bone voids, such as those that remain after reduction of impacted articular fractures.[9,14,15] Fast-setting calcium phosphate cements have several advantages over other bone fillers, which have been shown clinically in multiple studies.[9,16] They decrease pain at the fracture site, which may allow earlier mobilization[15,17] and several studies have demonstrated improved functional outcomes with use of calcium phosphate cement.[15,17] Other authors have demonstrated that calcium phosphate cements are superior to traditional bone graft or no bone graft with respect to preventing fracture subsidence.[9,15,17] Additionally, the need for allograft or autograft is eliminated, such that there is no risk of potential shortage of cadaveric bone material, patient objections, allograft disease transmission, or donor site morbidity.[18,19]

Attempts have been made to modify traditional instruments in order to obtain articular reductions in a minimally invasive fashion.[20] The lead author (henceforth referred to as the author) has previously reported a potentially minimally invasive technique for addressing wound concerns, as well as providing several other advantages (e.g. void creation for calcium phosphate), for the reduction of the articular surface itself using the Kyphoplasty IBT in a non-traditional way.[21] Since then, this tool has been developed by Medtronic Spine LLC to fit specific needs of extremity articular fracture reduction (personal communication; InflateFX™).

The purpose of this study is to determine whether the novel technique, balloon reduction and minimally invasive fixation (BRAMIF), developed by the author, using a Kyphon inflatable bone tamp, results in radiographically satisfactory outcomes in the reduction of calcaneus, tibial pilon, tibial plateau and distal radius fractures. Using a novel scoring system described herein for quantifying radiographic outcomes of fracture treatments, including the rate of successfully and satisfactorily reduced fractures, the quality of the reduction and its maintenance at the 12 week follow-up appointment is evaluated.

Materials and methods

Study design

This retrospective review of patient charts and radiographs was approved by the ProMedica Health System Institutional Review Board prior to the collection of data. All skeletally mature patients, between the ages of 18 and 95 years of age, who were treated for the reduction of calcaneus, tibial plateau, tibial pilon, or distal radius fractures from August 2008 through August 2010 using the BRAMIF technique (Fig. 2A–H) as previously described[21] at ProMedica Health System were included in the study. Patients who were not being treated in follow-up by the lead author, were missing radiographic evaluations either post-operatively or at 12 weeks post-operatively, had radiographs which were felt to be inadequate for review were excluded from the study. In total, 51 patients underwent the procedure, of which 41 were eligible to be included in the review.

Study product/therapy/technique

The study reviewed the quality of fracture reduction achieved by first using the KYPHON® XPANDER Inflatable Bone Tamp and the KYPHON® Osteo Introducer® System, with bone filler. The

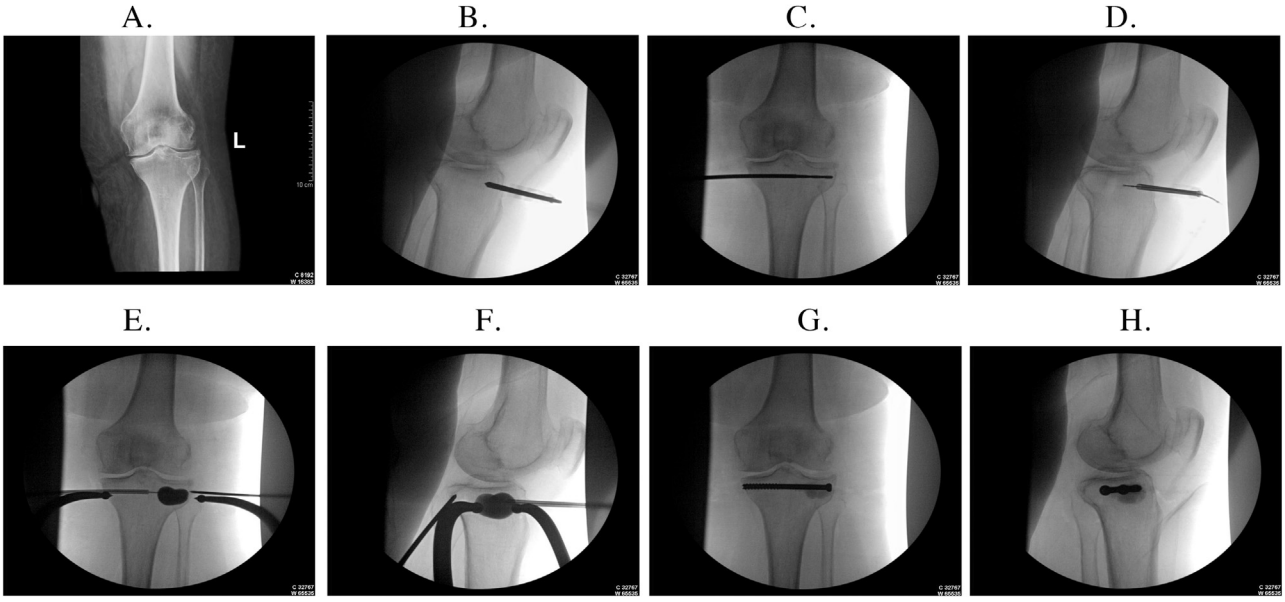

Fig. 2. (A) Pre-operative radiographic AP of a tibial plateau fracture with a large soft tissue envelope. (B) Fluoroscopic lateral with insertion of the trochar. (C) Fluoroscopic AP demonstrating the insertion of the hand drill bit underneath the fracture. (D) Fluoroscopic lateral with IBT placed underneath the fracture depression. (E) Fluoroscopic AP noting reduced articular surface with IBT inflation, there is also a percutaneously placed peri-articular clamp to prevent the split from widening during inflation and a guide wire for a cannulated screw can be noted. (F) Fluoroscopic lateral noting reduced articular surface with IBT inflation, there is also a percutaneously placed peri-articular clamp to prevent the split from widening during inflation. (G) Fluoroscopic AP with final reduction, hardware and calcium phosphate having filled the void. (H) Fluoroscopic lateral with final reduction, hardware and calcium phosphate having filled the void.