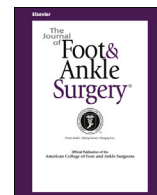




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Percutaneous Kirschner Wire Versus Commercial Implant for Hammertoe Repair: A Cost-Effectiveness Analysis

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ABSTRACT

Hammertoe deformities are one of the most common foot deformities, affecting up to one third of the general population. Fusion of the joint can be achieved with various devices, with the current focus on percutaneous Kirschner (K)-wire fixation or commercial intramedullary implant devices. The purpose of the present study was to determine whether surgical intervention with percutaneous K-wire fixation versus commercial intramedullary implant is more cost effective for proximal interphalangeal joint arthrodesis in hammertoe surgery. A formal cost-effectiveness analysis using a decision analytic tree model was conducted to investigate the healthcare costs and outcomes associated with either K-wire or commercial intramedullary implant fixation. The outcomes assessed included long-term costs, quality-adjusted life-years (QALYs), and incremental cost per QALY gained. Costs were evaluated from the healthcare system perspective and are expressed in U.S. dollars at a 2017 price base. Our results found that commercial implants were minimally more effective than K-wires but carried significantly higher costs. The total cost for treatment with percutaneous K-wire fixation was \$5041 with an effectiveness of 0.82 QALY compared with a commercial implant cost of \$6059 with an effectiveness of 0.83 QALY. The incremental cost-effectiveness ratio of commercial implants was \$146,667. With an incremental cost-effectiveness ratio of >\$50,000, commercial implants failed to justify their proposed benefits to outweigh their cost compared to percutaneous K-wire fixation. In conclusion, percutaneous K-wire fixation would be preferred for arthrodesis of the proximal interphalangeal joint for hammertoes from a healthcare system perspective.

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Hammertoe deformities are estimated to affect one third of the general population, making it one of the most common foot deformities encountered within foot and ankle practices (1). The etiology is multifactorial, with popular theories suggesting derivations from weak intrinsic or extrinsic musculature, leading to an imbalance of forces within the foot (2). This, in turn, causes the hallmark flexion at the proximal interphalangeal (PIP) joint of the digits and hyperextension of the metatarsophalangeal joint (3). A number of conditions are associated with developing hammertoes, such as hallux valgus, diabetes mellitus, trauma, inflammatory arthritis, and neuromuscular

abnormalities (3–6). Patients often complain of pain, corns/calluses, an unsightly appearance, and difficulty with shoe gear in the presence of the condition (2). In addition, the deformity can result in secondary conditions, including crossover digits, transverse plane deviation, and subluxation or dislocation of the metatarsophalangeal joint, leading to similar patient frustration (3). Initial treatments focus on symptom control with taping or strapping, accommodative padding, shoe modifications, and associated callus debridement (2,4–7). Surgery is indicated when conservative measures fail to alleviate the symptoms.

A multitude of surgical techniques have been described for the correction of hammertoes. The most popular has been PIP joint arthroplasty for flexible deformities and PIP joint arthrodesis for fixed and/or more complex deformities (4,5,7–12). Most studies have concluded that operative treatment is generally effective in reducing pain and restoring toes to a more anatomic alignment (2,4,5,7–9,13–18). Temporary placement of 1 or 2 percutaneous Kirschner (K) wires has traditionally been a popular method of fixation among foot and ankle surgeons. The technique is associated with low costs, is technically simple to perform, and is generally well tolerated by patients (7,19–21). K-wire fixation in the setting of PIP joint arthroplasty has been found to provide better toe stability and sagittal plane correction than arthroplasty procedures performed without K-wire fixation (20). Holinka et al (20) analyzed 62 hammertoe surgeries in their practice and found a lower rate of recurrence (7% to 12%) in patients treated with K-wire fixation than in those treated only with bracing/strapping.

Although many patients undergoing PIP joint arthrodesis and/or arthroplasty treated with percutaneous K-wire fixation have reported satisfactory postoperative results, some studies have suggested that as many as 10% of patients will experience recurrent deformity, transverse plane malalignment, and/or persistent pain (7). Many of these patients will elect for further (revision) surgery. Another complication encountered with percutaneous K-wire fixation is pin tract infection, which has been reported to occur in 0% to 4.7% when the wires were left in place for ≤ 4 weeks postoperatively (2,7,19,22,23). When K-wires are left in place for longer periods (≤ 6 weeks), the rate of pin tract infection has been reported in $\leq 18\%$ (24). Residual deformity, revision surgery, and treatment of postoperative infection results in extra costs to the healthcare system and can have similar negative consequences on patients' quality of life.

The use of internal fixation and commercial intramedullary implants designed to facilitate PIP joint arthrodesis has increased in popularity in recent years (25–28). These techniques could potentially reduce the rate of complications by eliminating the need for external wires and providing more predictable osseous union rates at the PIP joint (27). Currently, 16 implantable devices are available for use in the United States and European Union, only 5 of which have received any significant discussion in the published data. Guelfi et al (29) recently reported a systematic review comparing commercially available hammertoe implants, although the vast majority of data used in their study had study sizes of < 10 . They found good to excellent results in terms of patient satisfaction; however, they commented on each device's high cost (29). In studies that directly compared newer implants to K-wire fixation, no statistically significant differences were found with respect to the reoperation or recurrence rates (29), although most studies possessed short follow-up in their analysis. Guelfi et al (29) suggested that neither technique can be seen as truly superior without a formal cost-effectiveness analysis that also considers the long-term outcomes because the recurrence rates might be lower with implants.

Jay et al (27) performed a randomized controlled trial comparing a commercially available intramedullary implant with a single percutaneous K-wire for PIP joint fusion. The investigators did not find a statistically significant difference between the 2 groups with respect to complication rates but did note that the implant group reported

greater scores on patient satisfaction and functionality surveys. The implant group was also more likely to achieve osseous union of the joint by 6 months postoperatively. Similar to Guelfi et al (29), Jay et al (27) also reported the need for a formal cost-effectiveness analysis (CEA). They argued that hammertoe implants might mirror what has recently been seen in the orthopedic data, in which many treatment options typically associated with greater upfront costs initially are proving to be more cost effective during the course of a patient's lifetime (30,31).

The purpose of the present study was to examine whether commercial implants for hammertoe surgery with PIP joint arthrodesis are more cost effective during a patient's lifetime despite the potentially greater upfront costs compared with percutaneous K-wire fixation. To the best of our knowledge, this is the first CEA to formally compare 2 surgical strategies for hammertoe arthrodesis correction: percutaneous K-wire fixation and commercial implant.

Materials and Methods

Design

The study followed the National Institute for Health and Care Excellence (NICE) guidelines for performing a CEA, with the exception of discounting rates, for which U.S. rates were used. A healthy individual with a hammertoe deformity of the second, third, or fourth toes that has been recalcitrant to nonoperative measures and required surgical management was assumed to be the base case. An extensive literature search was performed to identify the studies with the greatest levels of evidence that reported postoperative outcomes after percutaneous K-wire fixation or commercial implants for hammertoe correction for PIP joint arthrodesis. Please see supplemental materials available online for full disclosure of the published articles used to obtain the probability of each outcome. All types of commercial implants were included in the model given the low volume of data currently available for a single device type. The longest follow-up time identified in the available data was an average of 3 years postoperatively (7,25,32).

Decision Model

A decision analytic tree using a cohort approach was built in TreeAge Pro Healthcare 2017 (TreeAge Software, Inc., Williamstown, MA). The model was used to conduct a CEA that compared the costs and overall effectiveness of operative intervention for hammertoes using percutaneous K-wire fixation versus commercial implant. For each surgical scenario, the 2 strategies were compared in terms of 2 outcomes: incremental healthcare costs and incremental quality-adjusted life years (QALYs). The 2 outcomes were combined in the form of incremental cost-effectiveness ratios (ICERs). We calculated the short-term results using the longest follow-up time from the available published data (i.e., 3 years). To address the possibility of movement between health states, a second, separate decision tree analysis with the addition of a Markov model was performed to allow those that entered resolution at any time in the model to switch to a hammertoe recurrence state. The analysis studied the lifetime outcomes (i.e., long-term results) starting after the 3-year postoperative period. This model was continued out to 45 years and was a secondary model to the decision analytic tree, which we believed was the more appropriate analysis for the study question.

The costs were evaluated from the healthcare system perspective and are expressed in 2017 U.S. dollars. The costs were derived from the relevant data and using Medicare 2017 fee schedules. For the long-term analysis, future costs and QALYs were discounted at a 3% annual rate. In the base case, the cost of an implant was set at \$1000 based on current values within the published data, which range from \$500 to \$1500 (7,33–36). The cost of K-wire fixation was set at \$20 for the base case. Relevant costs included the procedural cost of the index surgery, the cost of complications, outpatient follow-up visits, and radiographs postoperatively, and prescription costs. Revision surgery was assumed to be on an outpatient basis. All patients with an end result of "hammertoe recurrence" were assumed to have incurred costs associated with obtaining a supportive insole with both strategies. Health-related quality of life data were obtained from previous studies that used the EQ-5D, the preferred measure of health-related quality of life in adults according to the National Institute for Health and Care Excellence guidelines. If data were not available, the algorithm derived from Ara and Brazier (37) was used to convert Short-Form 36-item Survey scores to health utility indexes (HUIs). For situations in which Short-Form 36-item Survey data were not available from the published data, the documented HUI of similar foot pathologies was used, and the final HUI was agreed on by those of us who are physicians treating the ailments in question on a consistent basis (37–43). The HUI assigned to the base case was 0.72 using the described method. All the patients entered the model at the same HUI.

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