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A prospective multicenter clinical study of the Discovery elbow

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Background: Semiconstrained total elbow arthroplasty is used to improve elbow function and reduce pain. Although effective, high complication rates exist, with the polyethylene bushing especially susceptible to failure. The Discovery Elbow System (Biomet Inc, Warsaw, IN, USA) contains a spherical bearing designed to minimize polyethylene wear. This prospective, multicenter clinical study investigated the 4-year (mean) outcomes of this elbow.

Methods: From 2002 to 2009, 92 patients (71 women, 21 men; mean age, 63.9 years; range, 33.4-88.7 years) received 99 Discovery elbows at 4 centers. The study cohort was limited to 46 elbows with complete preoperative and minimum 2-year clinical (modified American Shoulder and Elbow Surgeons elbow score) and radiographic follow-up.

Results: Mean follow-up was 4.1 years (range, 2-5.9 years). All American Shoulder and Elbow Surgeons elbow score components improved significantly ($P < .001$). Mean flexion-extension arcs increased from 81° to 121° and pronation-supination arcs from 134° to 163° ($P < .001$). Loose locking screws in 2 elbows (first-generation screws), a loose polyethylene bearing in 1 (history of falls), and a condyle/bearing in 1 (deep infection) were exchanged. Among the 46 elbows, gross survivorship was humeral/ulnar components, 100%; condyles, 97.8%; bearings, 95.7%; and screws, 95.7%. One humeral component (2.2%) was radiographically loose but not revised. An additional elbow (elbow 47) that did not meet the criteria for inclusion (<2 years of follow-up) was revised due to a loose humeral component and was reported separately.

Conclusion: The Discovery elbow increased function and decreased pain with high survivorship at a mean of 4.1 years.

Level of evidence: Level IV, Case Series, Treatment Study.

Keywords: Discovery elbow; outcomes; prostheses; semiconstrained; survivorship; total elbow arthroplasty

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Proper elbow motion is more critical to upper-extremity function than that of any other associated joint.[11] For instance, a 100° arc of motion is required to accomplish the activities of daily living.[2,10] Since the 1970s, total elbow arthroplasty (TEA) has been increasingly used as a salvage technique to decrease pain, increase joint stability, and

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improve overall range of motion.[10] The first TEA prostheses were fully constrained and hinged, with metal-on-metal articulation and no significant varus or valgus laxity.[3,10] Unfortunately, these led to metallic particulate synovitis, loosening rates as high as 45% due to force transmittance through the hinged articulation to the bone–cement interface, and implant failure.[5,10,29] In response, semiconstrained and nonconstrained prostheses were developed and have been used exclusively during the past decade.[29]

Unlinked, or minimally constrained, TEA prostheses are elbow resurfacing devices that can allow for a more anatomic ulnohumeral articulation.[29] Although such designs may reduce the risk of loosening, they may increase the risk of dislocation and have limited application in cases of bone loss or ligamentous deficiency.[10] Semiconstrained TEA prostheses contain a hinged linkage to help resist dislocation and is "sloppy," in that it allows for some varus/valgus motion, better replicating the kinematics of the natural elbow, and can be used in the presence of bone or ligamentous deficiency.[10,27] Also, force transfer across the bone–cement interface is lower than for constrained devices,[27,29] thus reducing the potential for loosening.

TEA is effective, but the results generally have not been as good as those for total hip or knee replacement,[17,29] although rheumatoid elbow patients are an exception because patients with diffuse disease place less demand on their elbow.[6,8,17,27-29] TEA tends to be associated with a high rate of complications (eg, 14%-80%),[17] partially due to the difficult nature of surgery in this complex joint with thin soft tissue coverage.[2] In particular, deep infection and septic loosening are a concern, with rates as high as ~10% reported.[2,22] Ulnar neuropathy has also been reported to occur in up to 21% of patients within a few days of surgery, with the rate of permanent dysfunction ranging from 0% to 10%.[26] High rates of polyethylene bushing failure/wear have been reported for semiconstrained prostheses.[6,10,11,19,20,24,27] For instance, rates of 14% to 47% have been cited for the Coonrad/Morrey prosthesis (Zimmer, Warsaw, IN, USA)[6,11,19,20] and 15% for the Solar Elbow System (Stryker, Mahwah, NJ, USA).[24] Semiconstrained devices can also experience hinge failure, as noted by a systematic review by Little et al,[17] to occur in 6% of patients.

The Discovery Elbow System (Biomet Inc, Warsaw, IN, USA) was developed to address some of the issues associated with semiconstrained TEA prostheses, including 1 spherical bearing designed to reduce wear and allow for simple polyethylene exchange, if required.[10,11] Previous clinical reports on this system have been limited by small numbers of patients (ie, 1-2),[2,11] short mean follow-up of <2 years,[30] or the provision of only a brief, overall clinical summary.[9] As such, a need remains for a detailed, clinical assessment of this system. Our purpose was to (1) determine the short-term to midterm survivorship of the Discovery elbow and (2) report the clinical and radiographic outcomes of a multicenter study, comparing these results with those reported for other semiconstrained TEA prostheses.

Materials and methods

The Discovery Elbow System

The Discovery Elbow System has been described by Hastings and Theng[11] and Hastings.[9,10] Lateral and posterior views of the prosthesis are shown in Figures 1 and 2, respectively. Two cobalt chromium molybdenum condylar hemispheres lock into the distal humeral component with a medial and lateral Ti6Al4V screw, respectively. These articulate with congruent ArCom polyethylene (Biomet Inc) bearing surfaces captured within the proximal ulnar component with a locking pin, providing 7° of varus/valgus laxity.

The humeral stem is made of Ti6Al4V and contains a posterior bow, including a 5° lateral offset and 5° internal rotation to reproduce the anatomy. The distal humeral flange resides outside of the canal and hooks around the distal anterior humeral cortex to resist posteriorly directed forces of the implant in the distal humerus. The flange is designed to sit flush against the distal anterior humeral cortex to obviate the need for a bone graft and potential graft resorption. The ulnar stem, made of the same alloy, contains a lateral bow with a 23° anterior neck angle and a lateral offset to properly position the joint axis in an anatomic position. The humeral and ulnar components can be first cemented into place and later coupled together. Alternatively, the humeral and ulnar components can be preassembled and then implanted.

Clinical study design

Four clinical centers participated in this prospective study. Written informed consent was obtained from each patient. Inclusion criteria were noninflammatory joint disease, including osteoarthritis and avascular necrosis; inflammatory arthritis; revision where other devices or treatments have failed; correction of functional deformity; and treatment of acute fractures or nonunion about the elbow. Exclusion criteria included patients aged <18 years, pregnancy, metabolic disorders that could impair bone formation, marked bone loss, active or suspected infection about the elbow or distant foci of infections that could spread to the implant site, unwillingness or inability to comply with the rehabilitation program, and factors that could limit the patient's ability to conform to the prescribed follow-up schedule.

Hastings[9] described the technique for implanting the Discovery elbow using 3 surgical approach options: triceps-off (reflecting), triceps-off (splitting), and triceps-on (sparing).

Postoperatively, patients with primary arthroplasty were immobilized in a bulky dressing and splint for 5 days. If the wound was sealed at that time, active, passive range of motion was initiated. An extension splint was used at night as needed to maintain full elbow extension. Activities of daily living were encouraged. In cases in which the triceps was detached for exposure, no extension against resistance was allowed for 6 weeks after surgery. Patients were given a lifting restriction of 5 lbs.

Patients were clinically and radiographically evaluated preoperatively and at the postoperative follow-up intervals of 3 months, 6 months, 1 year, then annually thereafter up to 5 years. To the