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Pyrocarbon interposition shoulder arthroplasty: preliminary results from a prospective multicenter study at 2 years of follow-up

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Background: The concept of free interposition arthroplasty proved successful for small joints of the hand, wrist, and foot, particularly after the use of implants coated with pyrocarbon, which enhanced their tribologic and elastic properties. The present study reports preliminary outcomes of a pyrocarbon-coated interposition shoulder arthroplasty (PISA) implant.

Methods: This was a prospective study of 67 consecutive patients who underwent shoulder PISA at 9 centers. The mean age at surgery was 51 years, with only 12 patients older than 60 years. The indications for surgery were primary glenohumeral arthritis in 42, avascular necrosis in 13, and secondary arthritis in 12 patients.

Results: Revision surgery was performed in 7 patients (10.4%), 2 (3.0%) were lost to follow-up, and the outcome assessments were incomplete in 3 (4.4%). This left 55 patients, aged 49.3 ± 12.0 years, with complete outcomes assessments at a mean follow-up of 26.8 ± 3.4 months. The Constant score improved from 34.1 ± 15.1 preoperatively to 66.1 ± 19.7 postoperatively. The radiographic findings revealed erosion in 6 glenoids and thinning of 3 humeral tuberosities.

Conclusion: In a cohort of young arthritic patients, PISA renders clinical scores and implant survival comparable to those of hemishoulder arthroplasty but remain inferior to those results reported for total shoulder arthroplasty. The study enabled identification of contraindications and potential causes of failure that were

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related to the concept of free interposition and smaller radius of curvature of the sphere. Until long-term results are available, this type of innovative implant should remain to be tested in a few specialized shoulder centers.
Level of evidence: Level IV; Case Series; Treatment Study

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The first interposition arthroplasty was performed in 1889 by Ollier[34] using fascia lata to treat wrist arthropathy. More than a century later, the concept of interposition arthroplasty was reintroduced using silicone implants, yielding satisfactory clinical results but generating considerable debris and subsequent failures.[27,32,47] Nowadays, the use of pyrolytic carbon (pyrocarbon) contributes to the concept of free interposition arthroplasty, with excellent midterm and long-term outcomes, notably relief of pain and functional recovery.[1,5,20,36,39]

Pyrocarbon is a highly biocompatible material that has been used for heart valves since the 1970s[8,9,22,23] and for hand and wrist arthroplasty since the 1990s.[4,13,15,37] The coherent findings of different authors suggest that pyrocarbon is a durable implant material that generates little or no wear[19,20] and therefore provides longevity.[19,35]

Various shoulder arthroplasty systems exist for the treatment of degenerative glenohumeral joints. Total shoulder arthroplasty (TSA) is used for patients with intact rotator cuffs, and reverse shoulder arthroplasty (RSA) is preferred in patients with deficient rotator cuffs or glenoid deficits.[48] Hemishoulder arthroplasty (HSA) is primarily used in patients with healthy glenoid cartilage[26,41,44,49] or to avoid frequent glenoid complications and revisions observed after TSA in younger patients.[17] Recent comparative studies demonstrate, however, that TSA offers better clinical outcomes than HSA.[26,38,40,42] The reason for this discrepancy is believed to be erosion or damage of glenoid bone by hard metallic prosthetic heads.[30,42]

To address this issue, a pyrocarbon interposition shoulder arthroplasty (PISA) implant, designed to be freely positioned in a reamed cavity within the proximal humerus, was designed to replace metal articular surfaces by pyrocarbon-coated graphite. Pyrocarbon has superior tribologic properties than metal because it can slide against bone and cartilage without causing pain or damage.[7,12] The present study reports the clinical and radiographic outcomes of this new PISA, implanted for osteoarthritis (OA), at a minimum follow-up of 2 years. The hypotheses were that the implant would (1) grant improvement of pain and function equivalent to those reported for TSA and (2) would cause little or no detectable erosion to the glenoid articular surface.

Materials and methods

Study design

The study prospectively included 67 consecutive patients who underwent shoulder interposition arthroplasty using the Inspyre implant (Tornier SAS, Montbonnot Saint Martin, France) at 9 centers between March 2010 and October 2012. The implant consists of a graphite sphere coated with pyrocarbon, which is freely positioned in a reamed cavity within the proximal humerus, articulating directly against the glenoid. The main criteria for the use of the Inspyre implant were similar to the indications for HSA with preservation of glenoid bone stock, notably young age or high activity level, or both. All patients were informed of the innovative nature of this implant and provided their consent to participate in the study.

The initial cohort included 33 women (49%) and 34 men (51%) aged 50.7 ± 11.4 years (median, 52; range, 18-77 years; Fig. 1). Surgery was performed on 45 right shoulders (67%), with no bilateral patients, and 45 cases (67%) involved the dominant side. The indications included 42 shoulders (63%) with primary OA, 13 (19%) with avascular necrosis (AVN), and 12 (18%) with secondary OA postinstability or postfracture. The activity level was strenuous in 10 patients (15%), moderate in 46 (69%), and inactive or sedentary in 11 (16%). Previous operations had been performed on 27 (40%) shoulders: 8 for instability, 7 open reductions with internal fixation for proximal humeral fractures, 6 subacromial decompressions, 3 tenotomies of long head of biceps, 2 rotator cuff repairs, and 12 other procedures (some shoulders had more than 1 procedure).

Preoperative assessments

Preoperative clinical assessment was completed using the absolute Constant score. Radiologic assessments were performed by a central observer (J.G.) on frontal anteroposterior x-ray views (external, neutral, and internal rotations) and supraspinatus outlet views. Magnetic resonance imaging or computed tomography scan images were used to evaluate the native glenoid morphology according to the Walch classification.

Surgical technique

All patients were operated on under general anesthesia in the beach chair position. The deltopectoral approach was used in 66 shoulders (98.5%), with tenotomy or peeling of the subscapularis from the lesser tuberosity, followed by its reinsertion using transosseous sutures. Tenotomy and tenodesis of the long head of biceps were performed in 54 shoulders (81%) and anterior juxtaglenoid capsulotomy to release internal rotation contracture in 27 shoulders (40%). The glenoid surface was not reamed in any of the shoulders.

Humeral head resection was performed at the anatomic neck level, and the measured dimensions of the resected bone were 46.5 ± 4.9 mm superoinferiorly, 43.1 ± 4.7 mm anteroposteriorly, and thickness was 14.5 ± 3.7 mm. A cavity was then reamed in the center of the humeral metaphysis using hand-operated compactors and motorized reamers, leaving a 2-mm-thick peripheral bony rim at the equator. To maintain adequate tension within the rotator cuff, the