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Response to Letter to the Editor regarding: "Fracture of pyrocarbon humeral head resurfacing implant: a case report"

In reply:

We note with interest the correspondence regarding our recently published article titled "Fracture of pyrocarbon humeral head resurfacing implant: a case report."[6] We thank the authors for the interest shown and their thoughtful comments.

First, we would like to clarify the concern the authors had regarding us not declaring our conflict of interest with a competing product. We did declare a conflict of interest with a company that manufactures a pyrocarbon implant; however, for unknown reasons this was not included in the final production of the article. We are currently hastily working in coordination with the production company and the *Journal of Shoulder and Elbow Surgery* to remedy this error, and we appreciate the authors bringing this to our attention.

Secondly, the authors state that the results and complications of the prosthesis in question ("PyroTitan"; Integra, Princeton, NJ, USA) have been previously published. Unfortunately, this statement is misleading: despite the fact that this pyrocarbon resurfacing implant has been used for more than 10 years, there is no publication found in the literature. The only and unique publication documenting the efficacy of this implant (as referenced in their letter to the editor) is "Hémiarthroplasties de resurfaçage en pyrocarbone de l'épaule. Résultats préliminaires (1 à 3ans) d'une étude prospective et multicentrique" in *Revue de Chirurgie Orthopédique et Traumatologique*.[4] This publication is not an entire manuscript but merely a less than a half-page abstract (in French) on page S363. The authors conducted a prospective evaluation of 94 pyrocarbon humeral head resurfacing implants "PyroTitan" in 90 patients with a mean age of 60.5 years (range, 24-79 years). They included patients with diagnosis of primary centered osteoarthritis noted 80% of the time; however, there is no mention of percentage of type of glenoid erosion according to Walch for their cohort. They report improvement in patient-reported outcome measures (Visual Analog Scale, Constant Score, American Shoulder and Elbow Surgeons) and active forward elevation and external rotation at both 1 and 2 years postoperatively. They also report 2 early implant fractures (2/94; 2.1%); however, they do not mention the final outcome of these 2 patients.

The other reference that the authors provide is the Annual Report of the Australian Orthopaedic Association National Joint Replacement Registry.[1] The authors state that "the revision rates for breakage of the PyroTitan implant in this database are 1.1% in the above-mentioned registry figures (4/383)." However, on careful review of the 2020 Annual Report, it states: "Prior to 2019, there had been 10 reported breakages of the PyroTITAN prosthesis. Three of these breakages were reported secondary to loosening" (page 309). This is clearly a larger number than what the authors reported in their letter to the editor, and this does not even include the 2019 and 2020 data. Also, table SP 16 on page 311 reports that 4.8% (22/458) of PyroTitan implants required revision. The reason for revision for these cases is unclear. However, the fact that so many implants have fractured, and the extent of this complication has not been reported as a full manuscript in a peer-reviewed international journal, is somewhat concerning.

Third, the authors call into question our reporting of the long-term clinical outcomes and revision rates of 10%-15% for hemiarthroplasty, and how these are not comparable to the 1.1% incidence of implant breakage at 5-year follow-up in their registry experience.[7,8] The Robinson et al[7] study documents the Mayo Clinic experience with humeral head replacement for glenohumeral osteoarthritis and reports the minimum 10-year follow-up, and mean 17-year clinical follow-up (range, 10-30 years). Further, Sperling et al[8] reported the minimum 15-year (mean, 16.8 years) follow-up of hemiarthroplasty in patients younger than 55 years old. They found that the estimated survival rate for hemiarthroplasty was 82% at 10 years and 75% at 20 years.[8] In comparison, the abstract referenced by the authors has 2-year follow-up of their "PyroTitan" implant, and their national registry results have 7-year follow-up data. The authors are not able to compare their revision and failure data to what has

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historically been published. We would encourage them to continue collecting clinical and radiographic outcomes to determine the mid- to long-term data of this implant. The implant breakage was encountered in our case report at 6 years after the primary implantation. This means that there may be further cases of implant breakage in the future and that a long-term survival curve of this pyrocarbon resurfacing implant must be established and analyzed.

Indeed, from our point of view, implant breakage represents a new and above all an ''avoidable'' complication related to the implant conception that makes it less resistant. Moreover, such complication is not reported in metal-resurfacing shoulder arthroplasty.

Our conclusion was: ''Our observation put into question the use of PyC as a humeral head resurfacing implant.'' We did not state that pyrocarbon should not be used at all in shoulder surgery or in hemiarthroplasty/humeral head resurfacing. We merely are making an observation based on this single case report that the breakage of the implant without major trauma puts into question its use. Further review of the Australian Orthopaedic Association National Joint Replacement Registry 2020 Annual Report demonstrates that this complication is well documented and seems to be more common than the authors have indicated in their letter to the editor. We encourage the authors to publish their surgical results at mid-term and long-term follow-up in peer-reviewed journals, like we did ourselves,[2] so that we can have further data to base our conclusions on this pyrocarbon resurfacing implant.

As E. Amory Codman, ''father of shoulder surgery'' and pioneer in outcomes research, mentioned in his book *The Shoulder*: ''… only long-term results matter.''[3] As he developed with his ''End-Result Idea'': following up on patients for years is crucial to track complications and see if their treatment was sufficient and if not, this should be reported in total transparency.[5] As no publication was found in the literature, by reporting this late complication of a ''new implant'' (on the market for 10 years), we believe that we did our duty. Our goal was to alert surgeons who use this pyrocarbon resurfacing implant, encourage them to call back their patients and make them ask themselves in case of failure, why this implant failed in order to prevent similar failure in the future. Thank you again for your consideration of our article.

Disclaimer

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