Author’s response to reviews

Title: Radiological changes do not influence clinical mid-term outcome in stemless humeral head replacements with hollow screw fixation: A prospective radiological and clinical evaluation

Authors:

Philipp R. Heuberer (philipp.heuberer@kh-herzjesu.at)

Georg Brandl (georg.brandl@kh-herzjesu.at)

Leo Pauzenberger (leo.pauzenberger@kh-herzjesu.at)

Brenda Laky (brenda.laky@kh-herzjesu.at)

Bernhard Kriegleder (bernhard.kriegleder@kh-herzjesu.at)

Werner Anderl (werner.anderl@kh-herzjesu.at)

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Author’s response to reviews:

Dear editor, co-editors and reviewers, thank you for your detailed revision of our work! Please find below our answers to the reviewers’ comments:

Reviewer reports:

Olufemi Rolland Ayeni, M.D. FRCSC (Reviewer 1):
1. I believe, the paper should delete names of specific companies ie eclipse and use generic name such as stemless humeral head arthroplasty.
2. Sample size calculation needs better justification, since only 73 patients are included.
3. What is the rationale for including both total arthroplasty and hemi arthroplasty, clearly the forces the implant respond to are different.
4. What was the agreement levels of the radiographic analysis, kappa values or ICC?
5. Discussion needs a total revamp, what are the strengths, weaknesses, limitations, and future directions to improve the understanding of this surgery? Learning curve impact etc.
6. Tables need better organization, compare the findings of hemi arthroplasty versus total arthroplasty in 1 big comprehensive table.
7. Why have a table on operative time (non contributory).

Authors’ answers to reviewer 1:

Ad 1.) As suggested, we deleted the specific name of the implant were applicable (see page 10/13, line 254/330).
Ad. 2.) Since we were planning a follow-up over a longer time period and patients requiring implants are not the youngest, we knew that we will lose participants over time; thus, we enrolled more patients than the calculated required number. However, we now defined in- and exclusion criteria more precisely (Methods see page 5, line 111-122), reworded sample size (Statistical Analysis see page 8, line 188), and described the loss of follow-up in the results section (Results see page 8, line 200-201).
Ad. 3.) The present study’s focus was especially on the humeral head, we therefore included all patients with humeral head replacements regardless of the glenoid. Furthermore, we did not assume that the forces regarding the humeral head implant would be different between HSA and TSA. In fact that is also supported by our results that did not reveal any difference in radiographic outcome between HSA and TSA (Table 4).
Ad 4.) Information on rater agreement has been included in the Methods (page 7, line 162,164).
Statistical Analysis (see page 8, line 194-195), and Results (see page 9, line 221-223) section. Ad. 5.) We reworded the Discussion section to better elucidate strengths including steep learning curves (page 11/12/12, line 289/306/311-313), weaknesses/limitations (page 12-13, line 315-316), and future directions (page 13, line 322-325). Ad. 6.) Indeed, we did compare HSA to TSA (Table 3 and Fig 6) and it was one of our secondary objectives; however the main purpose of the study was to evaluate the influence of radiological changes on clinical mid-term outcome (Table 5) after stemless humeral head replacement (pointing radiologically to the humeral head and not to the glenoid). We believe that combining the already 1-page large Table 4 (radiological outcome of 73 cases including those with revision surgery) with our main aim Table 5 (radiology combined with clinical outcome including only cases without revision surgery) would be an overload of information and technically virtually impossible. Ad 7.) We do agree that operative times do not directly contribute to our main aim (radiological changes around the humeral head); however, we believe that the comparison of surgery times between stemless and stemmed prosthesis, which are not often reported, is an interesting objective for orthopedic surgeons. 

Carlo Biz (Reviewer 2): Methods 1. This section contains enough information to understand and possibly repeat the study. However, it contains several results that should move in Results section. 2. Further, only Constant score was performed to patients' evaluation. Why did not other scores or SF-be used for clinical assessment? This is an important limitation of the study that should reported in the discussion like a weakness. 3. Ex: "A total of 95 eligible patients with 100 stemless humeral head implants (were included in the implants) were lost to follow-up or had missing data. Clinical and radiological data of 73 shoulders (1 patient bilateral) were prospectively collected before, two years (short follow-up) and at least 48 months (mid-term follow-up) after surgery, or until indicated revision surgery". I suggest the authors accurately read the Strobe Statement-Checklist for cohort studies before revising their manuscript. Discussion 4. The length and content of the discussion communicates the main information of the paper. However, the results are discussed more with arthroplasty papers rather than anatomical shoulder replacement. Please add few papers reporting anatomical shoulder replacement experiences and quote for reverse shoulder arthroplasty: Treatment of proximal humeral fractures with reverse shoulder arthroplasty in elderly patients. Iacobellis C, Berizzi A, Biz C, Camporese A. Musculoskelet Surg. 2015 Apr;99(1):39-44. doi: 10.1007/s12306-014-0331-2. Epub 2014 Jun 11. Tables and Figures 5. The number and quality of tables and figures are appropriate to transmit the main information of the paper. However, legends and tables should move at the end of the paper and be presented in a better way, with more space between the results to appear clearer. Authors’ answers to reviewer 2: Ad 1.) As suggested we moved results (especially regarding data of patients included in the study) into the Results section (see page 8, line 200-201). Ad. 2.) The study was planned before 2005. At that time, we did not perform further evaluations (especially before surgery) other than the Constant score. We included the leakage of in-depth subjective assessments in the limitation section (see page 12-13, line 315-316). Ad. 3.) According to the STROBE Statement-Checklist for cohort studies we defined in- and exclusion criteria more precisely (Methods see page 5, line 111-122), reworded sample size (Statistical Analysis see page 8, line 188), and described the loss of follow-up (Results see page 8, line 200-201). Ad 4.) Thanks for the suggestion to include your paper regarding treatment of proximal humeral fractures with reverse shoulder arthroplasty. However, our aim was to report and discuss the most recent studies on anatomical shoulder arthroplasty, especially regarding stemless arthroplasty. We would love to include the mentioned work in our discussion, but we believe that starting a new topic (reverse shoulder arthroplasty) would prolong the already quite long discussion section. Ad. 5.) We have removed Tables and Figures to the end.