Author’s response to reviews

Title: Detection of articular perforations of the proximal humerus fracture using a mobile 3D image intensifier. – A cadaver study

Authors:

Jan Theopold (jan.theopold@medizin.uni-leipzig.de)
Kevin Weihs (kevinweihs@web.de)
Bastian Marquass (bastian.marquass@medizin.uni-leipzig.de)
Christine Feja (christine.feja@medizin.uni-leipzig.de)
Christoph Josten (christoph.josten@medizin.uni-leipzig.de)
Pierre Hepp (pierre.hepp@medizin.uni-leipzig.de)

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Author’s response to reviews:

Dear editor,

Thank you very much for reviewing our manuscript and giving us the opportunity to resubmit it after consideration of the reviewers’ comments. We are particularly grateful to the reviewers, who helped with their expertise to improve our manuscript.

The manuscript has been carefully revised and the problems mentioned by the reviewer could be clarified. On a point-by-point basis we have answered the reviewers’ comments as seen in the pages attached.

Yours sincerely,
Editor Comments:

1. Please change the titles of the first two sections of the abstract to 'Background' and 'Methods'.
   Answer: The authors apologize the wrong title and corrected it as suggested.

2. Please remove the Design, Level of Evidence, Disclosure and Trial registration details as these details are covered in the declarations section.
   Answer: The authors removed the mentioned parts as suggested by the editor.

3. Please change the title of the 'Introduction' to 'Background'.
   Answer: In accordance to the editor concerns the title of the “Introduction” section was changed to “Background”.

4. Please change the title of the 'Materials and Methods' section to just 'Methods'.
   Answer: In accordance to the editor concerns the title of the “Materials and Methods“ section was changed to “Methods”.

5. Please provide a list of abbreviations before the declarations section and after the conclusions section.
   Answer: As suggested by the editor a list of abbreviations was placed before the declarations section and after the conclusions section. Now read in line 217.

6. Please include the tables in the main manuscript file at the end of the main text (after the references) rather than uploading them in an additional file.
Answer: As suggested by the editor the tables were placed at the end of the main text (after the references). Now read in line 350.

Reviewers comments and answers:

Reviewer #1:

1. In the methods, the authors state that SPSS Chi square analysis was used. In the results there is no mention of statistical analysis, results or significance level. While this may seem intuitively obvious, authors should clarify and confirm.

Answer: As requested by the reviewer the authors clarified the subject by adding the following passage now to read in line 127:

“Significantly more perforations were detected in 30° ER compared to 45° ER (p=0.041). There were no significant differences between the other AP views (p>0.05).”

2. At line 79 it states that all k-wire locations are confirmed visually. But at line 110 it states that some wires were excluded after image analysis. This is confusing. Is the visual confirmation not the 'gold' standard? If yes, please revise. If not please clarify.

Answer: The reviewer correctly ascertained that 4 K-wires had to be excluded from further analysis after the 3D scan. All K-wire perforation were confirmed visually prior to the 3D scan while evaluation of the fluoroscopic images showed one wire not perforating the subchondral bone an further three K-wires overpenetrating the subchondral bone. These K-wires may have accidentally displaced after initial proper placement.

To clarify this subject the authors changed the Paragraphs:

In line 59ff:

“Five 1.8 mm K-wires were guided into anterior, superior-anterior, inferior, superior-posterior, and posterior positions using a locking plate with a targeting device (Winsta PH, Axomed, Freiburg, Germany), which ensured a reproducible placement of the K-wires. The wire placement was performed by a single surgeon experienced in shoulder surgery (JT).

Each proximal humerus was positioned horizontally to ensure the maximum projection of the greater humeral tuberosity on a two-dimensional AP view. The perforations were verified by confirming them visually (Figure 1). “
In line 92-99:

“K-wires that did not match the aforementioned inclusion criteria were excluded from further analysis.

The fluoroscopy images, the multiplanar reconstructions and the specimen of the non-detected perforations were subsequently reevaluated. This revealed a secondary displacement of four wires. One K-wire did not perforate the subchondral bone. Three further K-wire perforations were visible in all 110 images. The analysis of the specimen revealed a secondary K-wire dislocation. For all remaining k-wires the initial placement was confirmed.”

3. It would be appreciated if some comment could be made relative to anticipated radiation exposure difference.

Answer: For the used mobile Ziehm Vision FD Vario 3D© data regarding this matter does not exist. Though in comparison to computed tomography of the shoulder the latest Ziehm Vision RFD 3D© has shown a 50% reduction in radiation dose. Those data are not published, yet.

4. Many hospitals do not yet have portable 3D fluoroscopy. Can the authors state whether multiplanar analysis on a 3D capable portable C arm is likely to be equivalent to moving the patient’s arm through an equivalent arc of motion during 'live' fluoro with a conventional C arm?

Answer: To move the patient’s arm during “live” fluoroscopy is not equivalent to 3D scan of the shoulder. The authors appreciate the reviewer’s request and added the following in line 173:

“The advantage of the intraoperative fluoroscopic 3D scan compared to conventional live fluoroscopy is the defined number of images together with multiplanar reconstruction. Moreover, the operating personnel can leave the operating room which reduces the radiation exposure. For the analyzed 5 screw configuration at least 4 determined images (30° IR, 30° ER, AP, axial) are needed to examine all screws properly. Finding the right plane involves several control images especially as an exact axial plane is not reproducible with certainty. Altogether this would lead again to a higher amount of radiation exposure at least for the personnel in the operating room.”

5. Is there anything unique about the brand of 3D C arm and associated software used in this study? Can the authors confirm they received no support from this manufacturer or any other commercial source?
Answer: As described in line 77 a unique feature about the used device is the variable isocentric C-arm design which increases its mobile radius and reduces the radiation exposure of the patient.

The authors can confirm, as they did in the declaration section, that there is no support from the manufacturer or any commercial source concerning this study.

Reviewer #2:

1. K-wire placement line 74-5 is confusing: Wires were perforating the subchondral bone but also just below the cartilage? Are these perforating into the joint or not? How visible are they if they are below the cartilage? Were all as good visible as on the figure provided?

Answer: As cartilage in not visible on fluoroscopy imaging, the perforation is defined by penetration of the subchondral bone. With an estimated cartilage thickness of 2-3 mm wire perforations below the cartilage level were visible in all fluoroscopic images.

As requested by the reviewer the authors clarified the subject by adding the following passage in line 59ff:

“Five 1.8 mm K-wires were guided into anterior, superior-anterior, inferior, superior-posterior, and posterior positions using a locking plate with a targeting device (Winsta PH, Axomed, Freiburg, Germany), which ensured a reproducible placement of the K-wires. The wire placement was performed by a single surgeon experienced in shoulder surgery (JT).

Each proximal humerus was positioned horizontally to ensure the maximum projection of the greater humeral tuberosity on a two-dimensional AP view. The perforations were verified by confirming them visually (Figure 1).”

2. Who defined the position of the K-wires? One or more observers? This is important to define as it is the gold standard.

Answer: The position of the K-wires were defined by the guiding device of the plate as mentioned in line 61. The guiding device ensured the K-wires were always placed in an reproducible fashoin. The wire placement was performed by a single surgeon experienced in shoulder surgery (JT).

The authors appreciate the reviewer’s concerns and added the following passage now to read in line 59ff:

“Five 1.8 mm K-wires were guided into anterior, superior-anterior, inferior, superior-posterior, and posterior positions using a locking plate with a targeting device (Winsta PH, Axomed,
Freiburg, Germany), which ensured a reproducible placement of the K-wires. The wire placement was performed by a single surgeon experienced in shoulder surgery (JT).

3. Who performed the analysis of the images? Was this one or were there more observers? Experience? Blinded?

Answer: The authors appreciate the reviewer’s concerns and added the following passage now to read in line 73ff:

“Each fluoroscopic image was analyzed (MagicWeb VA60C_0212, Visage Imaging GmbH Berlin, Germany) by 3 of the authors (JT, PH, KW)…..”

4. How reliable are the results that are being presented, i.e. number of observers, observer variation?

Answer: The authors appreciate the reviewer’s concerns and added the following passages:

In line 103:

“Cronbach’s Alpha statistic was used to evaluate inter-observer error in image analysis.”

In line 110:

“A high inter-observer reliability of 0.93 (Cronbach’s Alpha) was found.”

5. How realistic is the use of a 3D image intensifier in proximal humeral fracture treatment. Do the authors have experience with this?

Answer: The authors see the use of a 3D image intensifier in proximal humeral fracture treatment as a useful tool with encouraging results leading to significant reduction of intraoperative screw perforations. The cited paper „Multiplanar reconstruction with mobile 3D image intensifier. Surgical treatment of proximal humerus fractures“Unfallchirurg 2014 (29) demonstrates the first experience of the authors. Further experience with clinical experience is submitted for publication.

6. Elaborate on the differences with the other studies, i.e. why did Bengard et al not found similar results? What are the additional strengths of this study with respect to the others?

Answer: The authors appreciate the reviewer’s concerns and added the following passages:
In line 155:

“… in contrast to our study…”

In line 162ff:

“With intraoperative 3D fluoroscopy and multiplanar reconstruction standardized imaging with CT-like quality can be obtained. At the same time the findings of our study suggest that the investigated procedure holds the potential to detect 100% of primary screw perforations as one of the most common intraoperative complications.”