Author’s response to reviews

Title: Acromioclavicular joint dislocation treated with Bosworth Screw and additional K-wire fixation: Results after in mean 7.8 years - Still an adequate procedure?

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Acromioclavicular joint dislocation treated with Bosworth Screw and additional K-wire fixation: Results after in mean 7.6 years - Still an adequate procedure?

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Dear Umile Giuseppe Longo, M.D.

Thank you very much for your letter of 3rd February 2017. We have carefully followed the verbatim comments of the reviewers and are enclosing a revised manuscript. All performed changes are marked in yellow for better identification. Responses to reviewers are listed below in detail.

Editor Comments:

Please include a statement regarding consent for participation in the Ethics and consent to participate section.

Answer: The missing part was included

Ethics approval and consent to participate

Ethical approval was obtained prior to study start by the corresponding ethic review board (Ethics committee of the Medical University of Vienna, Borschkegasse 8b/E06, 1090 Vienna), Medical University of Vienna (EK. No. 1218/2015).

Prior to investigation, ethics approval was obtained by the institutional review board. Informed consent was obtained written at follow-up investigation of each patient included.

Consent for publication:

Was obtained written at follow-up investigation.

Reviewer reports:

Reviewer 1: Acromioclavicular joint dislocation treated with Bosworth Screw and additional K-wiring: Results after 7.6 years -

Still an adequate procedure?

Reviewer: Antti Joukainen

Date: 03122016
This is a retrospective study of the results of 22 (of 29) patients with AC joint dislocation treated with a Bosworth screw and additional K-wiring. The method used in this study is not common nowadays in the treatment of AC dislocation, and the study has potential to describe the results of this rare and initially rigid technique of transfixation of clavicle and coracoid process.

The main concerns of the study are the low number of the patients (underpowered), lack of control group, rather low (76%) follow-up percentage, various AC dislocation types (types 2-5) and a large range of follow-up time (1 - 19 years). There is no possibility to compare the result of this series to the natural course of healing in AC dislocation patients. Unfortunately, I believe these drawbacks diminish the value of the present study.

Answer: We agree completely with the reviewer comment. However, surgically treated AC dislocations are rare, even when treated with this technique.

I also have to say that in regard to newer techniques we did use the Bosworth Screw very rarely in the treatment of AC dislocations.

In most cases we started to use the TightRope system, however lacking therefore with a valid number of two years follow-up patients, therefore no comparison is possible at that time. The next step will be a match pair analysis comparing our different techniques used for AC reconstruction.

There are myriads of different methods of AC joint reconstruction techniques, and if I understood correctly the data presented, these also have been used in the Institute where the Authors practice. The present study could have a stronger validity, if the results of Bosworth technique and pin fixation could be compared to some other surgical techniques, or even more important, to the results of conservative treatment. At least, the rationale how the patients were elected for this reconstruction technique and not for some other procedure should be presented.

Answer: Two surgical methods were used as a standard treatment of care for AC dislocations at our Department between 2003 and 2013 – the reconstruction with the LARS ligament and the reconstruction with the Bosworth screw and K-Wires. We started using the TightRope System in 2011, becoming the method of choice.

However, the method used was the surgeons’ own choice.

I would recommend presenting a flowchart describing the treatment methods of all ACJ dislocation patients of the Institute of this study during the study period (e.g. http://www.consort-statement.org/consort-statement/flow-diagram). A reader could then have an understanding of the AC joint dislocations treatment practice in the institute in general.
A flow diagram was added as recommended by the reviewer describing in detail the treatment of all AC dislocations at our Department. (Figure 1)

I am reluctant to agree on the conclusion of acceptable result with the method. There is a possibility that the same excellent result as in this study could be attainable with conservative treatment methods, but with rare complications and less costs.

Specific comments:

Abstract:

"Long-term results": the mean of follow-up time is 7.6 years, but at shortest the time is just one year, so it is not acceptable to describe the results being of "long-term". I recommend using the time span of follow-up time of the series, or "at least 1 year".

Answer: Changes were done as suggested.

See line 11 - 13...The overall mean clinical outcome at the latest follow up was: Constant 95, DASH 6.4, ASES 94.6, SST 99.02, UCLA 33.1, ACJI 91.82 and VAS 0.29 – representing a good-to-excellent long-term outcome in all patients after at least two years follow-up (two to nineteen years)... 

Material and methods and Results: There is discrepancy in the number of study patients: "All patients treated operatively…” but only 22 were analysed. I suggest revising.

Answer: See line 6 - 7...All patients treated operatively for AC joint dislocation with a Bosworth screw and additional K-wire fixation at our Department were asked to participate in this study...

Conclusion: Revising recommended, please see above.

Answer: The conclusion was revised as suggested by the reviewer.

Background:

Grade 1-3 AC dislocations are recommended to treat conservatively. I recommend adding something about the results of conservative methods in this chapter, because there is a patient in this series of grade 2 dislocation treated surgically, too.

Answer: In all three patients the indication for surgery was failure of conservative treatment, with recurrent pain and limitation of movement.
Please revise "golden standard" to "gold standard".

Answer: Changes were made as suggested

In the different techniques chapter, I recommend to add the techniques of CC ligament reconstruction with tendinous grafts.

Answer: Additional information has been added in the introduction section … In the last years anatomic reconstruction of the CC ligaments with autogenous grafts has reached popularity. The thought behind them was that the graft enabled natural healing of the torn CC ligaments. However, to this day, only limited data is available regarding this technique even when used in acute AC dislocations…

Materials and Methods:

P5L74: "70 months (□ 54.02)" : is it the standard deviation in brackets?
Answer: The numbers presented in brackets represent the standard deviation

P5L77: "range of motion": motion of what? Were there any other clinical tests?
Answer: The ROM of the shoulder joint was measured in all patients. In the acute phase of patients’ presentation at our trauma department, joint tenderness as well as the horizontal stability was tested if tolerated by the patient due to pain. Horizontal stability is tested with the examiner positioned behind the patient and in front of a mirror for a better visualization of the clavicle movements. The scapula is fixed with one hand while the other hand tests the horizontal stability by moving the lateral end of the clavicle anterior and posterior. This was done for both the injured and uninjured side. Peripheral sensibility and circulation is tested routinely.

P5L83: "one of these two," did this patient had only AC joint instability, but no other lesions, like osteoarthritis in the joint? Was ACJ unstable in the clinical examination?
Answer: It is not mentioned that there was initially any instability of the AC joint. However, because of recurrent pain in these patients surgery was mandatory.
The Bosworth screw is a 4.5mm non-cannulated screw from Synthes. Please describe the technique more specifically: was the surgery percutaneous or open? How were the CC-ligaments addressed? What drilling and screw diameters, and cannulated or not? How many K-wires? What aftertreatment?

Answer: Additional information was added as recommended by the reviewer. The Bosworth screw is a 4.5mm non-cannulated screw.

Reconstruction of the AC joint was performed according to well-established criteria, which were first described by Bosworth et al. in 1949. Patients were positioned in a beach chair manner and as recommended by the company’s technical guide - surgery was carried out using an image converter to confirm correct reduction on the one hand and optimal position of the drill hole on the other. Surgery was performed with a mini-open technique with a sagittal incision of 2 to 3cm about 3cm medial of the AC joint. After reduction of the AC joint with a raspatory, two K-wires were introduced parallel and percutaneously from the lateral side through the acromion and the AC joint into the lateral clavicle, thereby achieving a temporary transfixation. In the next step the holes for the Bosworth screw were drilled with a 3.5mm power drill from the lateral clavicle into the coracoid process. After that a 6.5mm thread was drilled in the clavicle and the coracoid process. After length measurement a Bosworth screw in adequate length was introduced. The K-wires were left in nearly all patients until healing of the ligaments and removed together with the Bosworth screw after a mean duration of 2.4 months (range; 0.6 to 4.8 months) (Figure 2.)

From our experience, an initial reduction of the AC joint dislocation with K-wires helps with implanting the Bosworth screw in the optimal position without losing the initial reduction, and is therefore the standard procedure at our institution. However, a disadvantage of the additional use of K-wires might be the potential migration or wire breakage.

Postoperatively, shoulders were protected with an arm-pouch sling for four weeks. Passive range-of-motion exercises were started on the second post-op day. During the first four weeks only pendulum exercises were allowed. After 4 weeks, the patient was allowed to start active mobilization of the shoulder joint up to 90 degrees abduction and flexion up until approximately 8 weeks when the screw should be removed under a short general anaesthesia.

Mobilization is only allowed below shoulder level because above 90 degrees of abduction and flexion, the clavicle undergoes rotation in the coronal plane and hence the screw will certainly
loosen but may also break. Sports and heavy weight bearing were not allowed before 12 weeks postoperatively.

P6L96-100: ROM: ROM of what joint? Were the ACJ studied (stability, palpation), and the skin? What x-ray projection (Zanca, or AP, or both? Stress radiographs preop - postop?); this needs to be presented in Methods section. What was measured in the radiographs? Were any radiographic abnormalities (arthrosis, calcifications) recorded?

Answer: Preoperative, postoperative and radiographs at final follow-up of the AC joint were done in every patients. The radiological examination consisted of standard radiographs (i.e. radiographs according to Rockwood, the “serendipity view”) for both AC joints and axillary radiographs for the injured shoulder. Stress radiographs of both the injured and uninjured AC joint were performed preoperatively and at latest follow-up. Radiographic abnormalities were recorded at pre- postoperative and latest follow-up when present.

SF-36, DASH and VAS are not just shoulder scores. There exist also ACJ specific scores, so why not these used for this study?

Answer: We found an additional AC joint specific score (Arthroscopically Assisted Stabilization of Acute High-Grade Acromioclavicular Joint Separations Markus Scheibel,*y MD, Silvia Dro¨schel,y MD, Christian Gerhardt,y MD, and Natascha Krausy Investigation performed at the Center for Musculoskeletal Surgery, Charite´-Universitaetsmedizin Berlin, Campus-Virchow, Berlin, Germany), which we could evaluate retrospectively with the data we had collected. This was additionally added.

The only difference was the radiographic image used.

We agree completely with the reviewer that SF 36 and VAS are not shoulder specific scores. However, SF 36 is one of the most representative scores for the life quality, and was therefore used. The VAS is the most representative score evaluating the pain situation in patients.

How were the patients classified in Rockwood AC dislocation grades? The authors should also give a breakdown of results according to Rockwood type, because the different types act differently.

Answer: The patients were classified according to our standard radiographs.
A breakdown of the results according to different Rockwood types were given in Figure 3.

P8 L43-: The clinical results of different Rockwood classification types should be presented.
Answer: The results of the different Rockwood classification types are presented in Figure 3.

A description of the clinical examination of AC joint stability and cosmetic results would also be valuable.
Answer:

When patients presented in the acute phase, joint tenderness and horizontal stability was tested, if tolerated by the patient due to the pain. Horizontal stability is tested with the examiner positioned behind the patient. The scapula is fixed with one hand while the other hand tests the horizontal stability by moving the lateral end of the clavicle anteriorly and posteriorly. This was done for both the injured and uninjured side. The peripheral neurovascular status was tested routinely.

P9L161-2: The differences in measurements between the healthy and injured AC joints were less in the latest radiographs than postoperatively, which is interesting, and could be analyzed more closely.
Answer: Final results have changed according to exclusion of one patient, inclusion of another patient, and the extension of follow-up time to 24 months in two patients.

New numbers are presented in the results table with the CC and AC differences. In regard to significances nothing changed.

P9, Complications: were there any screw or pin breakages?
Answer: We did not observe any screw or pin breakages in our patient collective. In one patient a loosening of the Bosworth screw occurred as described in the paper in the complications section.

P10L202: should be "statistically significant difference"
Answer: Changes were made as suggested.
The number of complication patients is low (underpowered), and thus this conclusion is not valid.

Answer: Additional information was added at the limitation section.

The diminishing difference of radiographic variables during the follow-up should be discussed. The last sentence of this chapter should also be revised, because very different kinds of ACJ dislocations have been treated in this series.

Answer: The AC and CC differences have changed according to the inclusion and exclusion of patients.

The last sentence of this chapter was deleted.

Limitations: Variable ACJ dislocations types, lack of clinical evaluation and cosmetic result of ACJs, underpowered setup of the study should be mentioned in this chapter.

Of the long follow-up time concerning Bosworth-technique reports: the study by Lowe and Fogarty (1977) had a mean follow-up time of 10 years.

Answer: Additional information was added at the limitations section.

Conclusion: I suggest adding something about the still existing uncertainty of the decision-making between conservative and surgical treatment.

Answer: Additional information was added in the conclusion section

see line ...however there is still a uncertainty between surgical and non-surgical treatment...

Reviewer 2: This study described the long-term follow up of the treatment of acromioclavicular joint dislocation using the Bosworth screw with additional K-wiring. The aim of the study was to present 'long-term' follow up outcomes after this particular procedure. There is no control group and the authors were not comparing surgical techniques. Twenty-two patients were included in the study with a mean follow up time of 91 months. The minimum follow up time was 12 months. For a long term follow up study, the authors should consider eliminating patients with a follow up time of less than 24 months and re-examine their data.
Answer: We agree with the reviewer comment. There were only three patients with a follow-up less than 24 months in our final collective of 22 patients. These patients were contacted and re-examined to reach > 24 months follow-up. One patient had to be excluded, another one reached the 24 months follow-up and was additionally included.

Other comments:

Lines 143-155: Is there any information on the clinical scores (Constant, DASH, ASES, SST, UCLA, VAS) before surgery? Comparing scores before and after surgery would strengthen the manuscript.

Answer: We totally agree with the reviewer comment, however, as this is a retrospective study with a long time period of treatment we do not have preoperative scores. This is also discussed in the limitation section.

Line 161 is not clear - please re-write and clarify your meaning

Answer: We deleted the misleading sentence… There was no difference presented in radiographs between post-operative and latest follow-up in regard to AC or CC distance.

Lines 160-165 - Did the authors examine the differences between the injured and uninjured sides?

Answer: Yes we examine the differences between the injured and the uninjured sides – preoperative, postoperative and latest follow-up (AC and CC differences)

The first paragraph of the discussion (starting with line 185) repeats the results and should not be included.

Answer: The first paragraph was rewritten as suggested by the reviewer.

Line 210 - The authors indicate a major advantage of the technique is that it is inexpensive. However, if patients require a second surgery, how does that add to the cost of the technique?

Answer: We agree with the concern of the reviewer and excluded the part of the costs of the technique in the whole manuscript.