Open Reduction and Internal Fixation Using Double Plating with Biological and Artificial Bone Grafting of Aseptic Non-unions of the Distal Humerus: Clinical Results

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Abstract

Aim: Intra-articular non-union of fractures is an uncommon but complex problem because in general, it is characterised by marked instability, pain, strength loss and significant functional limitation. The aim of this study is to report our prospective medium-term outcomes of the treatment of intra-articular, distal humeral aseptic non-unions using open reduction and internal fixation, augmented with artificial bone.

Materials and methods: A retrospective case series of 16 patients with intra-articular, aseptic non-unions of the distal humerus was analysed for range of motion, pain, Mayo Elbow Performance Scores (MEPS) and Oxford Elbow Scores (OES) after 12 months. Mean age was 44 years (range, 18–84 years) and mean total follow-up was 43 months (range, 24–62 months).

Results: All subjective and objective scores were significantly higher 12 months after treatment with internal fixation and artificial bone augmentation; the mean improvement on the MEPS was 18 points and 17 points on the OES. All patients returned to work, most without limitations. Autografts had worse outcomes compared to allografts regarding post-operative pain and time to return to work. No adverse events related to the artificial bone augmentation were seen and all fractures consolidated.

Conclusion: The use of two locking plates and bone graft augmentation with autografts or allografts with artificial bone grafts is a successful treatment of intra-articular distal humeral non-unions after hardware failure or biological limitations.

Clinical significance: The use of artificial bone in the treatment of septic non-unions of the upper limb is safe. When no autograft is possible because of concurrent morbidity, it can be used alone or combined with an allograft to reconstruct the affected bone without leading to extra morbidity or complications.

Keywords: Artificial bone grafting, Aseptic non-union, Distal humerus, Patient-reported outcomes, Reconstruction, Revision surgery.

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Introduction

Most often, a distal humerus non-union is located at the supracondylar level with the articular fragments having healed in a near-anatomic position.¹ Intra-articular non-union of fractures is an uncommon but complex problem because in general, it is characterised by marked instability, pain, strength loss and significant functional limitation.² The reported incidence of non-union after surgical treatment of distal humerus fractures ranges between 2 and 10%.³,⁴ Since the distal humerus is a unique anatomical structure that has to withstand forces in multiple planes and directions, treatment becomes different from that of other long bone fractures.² Anatomical restoration of length, alignment, rotation and the distal humeral cartilage maintains the optimal stabilising effects of the elbow and forearm muscles and therefore leads to better function and higher patient-reported outcomes.³,⁵ Complex fractures, poor bone quality, soft tissue lesions and patients’ comorbidities, particularly if associated with incorrect or inadequate internal fixation, favour complications. Open reduction and internal fixation (ORIF) with plates and screws is the treatment of choice in active patients.¹–³,⁶,⁷ If surgery is indicated, it must restore function in a long-lasting way as this is necessary to achieve painless bone union and to restore an acceptable range of motion (ROM).² Bone (allo)graft addition to the non-union focus is used more commonly in the upper limb during reconstructive surgery.²,⁸–¹⁰ After a septic non-union was ruled out using history, physical examination

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and laboratory tests (C-reactive protein, leucocyte count), the patients were informed in a clear and comprehensive way about the possible surgical and conservative alternatives during their outpatient visit at our referral centre. When they consented for a surgical revision of the non-union, they were treated according to the ethical standards of the Helsinki Declaration and were invited to read, understand and sign the informed consent form.

The aim of this study is to report our prospective medium-term outcomes of the treatment of intra-articular, distal humeral aseptic non-union using ORIF with allograft bone grafting.

Materials and Methods

Patient Selection

From a total of 34 patients with intra-articular, distal humeral non-unions, we included 16 patients with aseptic non-unions in this retrospective case series after using the following exclusion criteria: previous distal humeral fractures, oncological patients, age under 18 years, bone metabolism disease, pre-existent elbow osteoarthritis, rheumatoid disease, acute or chronic infections and ASAM non-union classification’s type A and C. Intra-articular fracture was defined as a primarily intra-articular fracture pattern, in which the articular surface was not necessarily the most problematic non-union site. The institutional review board of our institution approved this study.

Peri-surgical Care

Surgery took place in a prone position with the arm on a radiolucent support, or a padded post as either gives maximum freedom of space to a posterior approach of the elbow joint. A triceps-on, transtricipital approach was tried first to preserve triceps function; when the view on the articular aspect was insufficient, an olecranon osteotomy was performed. The ulnar nerve was always identified, released and protected during surgery. In the cases where the radial or median nerve were injured, the corresponding nerves were identified and neurolysed up to a level where the nerve seemed normal, but never transposed.

After exposure of the non-union focus, we removed the previous implant(s) and reamed the distal humeral shaft to remove fibrous tissue and to provide blood supply to the non-union site. Debridement of the fracture site was performed further until healthy, bleeding cortical bone was reached. This therefore resulted in shortening in some cases where the complete circumference of the distal humerus was affected, as the cortices of the proximal and distal side were opposed as much as possible with as much contact as possible in these cases.

After renewed reduction, fixation was performed with two plates (LCP®, DePuy Synthes™, Oberdorf, Switzerland) in orthogonal or parallel configuration, depending on the surgeon’s expertise in each specific case. Frozen, decellularised bone chips were put as an augmentation inside the humeral shaft and compressed until the canal and non-union/fracture site were filled. Only when patients denied the use of allografts, a fibular autograft was retrieved during the same surgery. Remaining cortical gaps were augmented using Putty® Biocollagen Crunch bone pasta (Biogen®, Bioteck™, Arcugnano, Vicenza, Italy), over the decellularised bone chips that were put inside the humeral shaft. At the end of the surgery, the result was inspected with fluoroscopy in three different views (antero-posterior, medial-lateral and false oblique) and dynamic tests of the elbow were performed to check for intra-articular screw placement. The triceps was re-attached with muscle side-to-side sutures using absorbable sutures, and the olecranon osteotomies were fixated using olecranon plates, screws or K-wire tension bending according to the surgeon’s preference, with regard to the patients’ characteristics.

After closure of the fascia and subcutaneous tissue, the skin was closed with metal staples. A resin semicircular cast was applied for the first 3 weeks. The cast ranged from the metacarpals to the humeral shaft, with the elbow flexed at 90°.

All patients underwent the same rehabilitation protocol (see Appendix 1, rehabilitation protocol). To study the bone healing on radiographs, we used the Non-Union Scoring System (NUSS) in retrospective mode (Table 1). Patients had a follow-up of 5 years, and after 1 year, the subjective and objective quality of life and the elbow function were measured by the Mayo Elbow Performance Score (MEPS), the subjective quality of life and the elbow function were measured by the Oxford Elbow Score (OES). Both questionnaires were set with 0 as ‘worst possible outcome’ and 100 as ‘best possible outcome’. Bone union was measured using the radiographic union score during follow-up as described by Radiographic Union Score (RUS). Pain visual analogic scores (VAS) were collected the same day that the radiographs were taken. As the evaluation endpoint was set at 12 months after surgery, the patients were asked for satisfaction and return to work at that time.

Statistical Analysis

Descriptive statistics were used to summarise the characteristics of the study group and subgroups, including means and standard deviations of all continuous variables. The Student’s t-test was used to compare continuous outcomes when normality was met; otherwise, the Mann–Whitney U test was used. The Fisher exact test was used in groups smaller than 10 patients to compare categorical variables. The statistical significance was defined as p <0.05. We used Pearson’s correlation coefficient (r) to compare the predictive score of outcomes and quality of life. Statistical analyses were performed with SPSS v.15.0 (SPSS Inc., IBM, Chicago, Illinois, USA). Mean ages (and their standard deviations) of the patients were rounded at the closest year. The predictive score of outcomes and quality of life and their standard deviations were approximated at the first decimal while the second decimal was approximated by Pearson’s correlation coefficient.

Cohen’s kappa coefficient (κ) is a statistic which measures inter-rater agreement for qualitative (categorical) items. With this parameter, we calculated the concordance between different qualitative values of the outcomes and the bone healing, the anatomical and biomechanical axes of the humerus from the radiological point of view, measured with the trochleocapitellar index. This parameter has an optimal value, as too much varus or valgus within the elbow joint does lead to worsened outcomes.

Results

Of the 16 included patients, the mean age was 44 years (range, 18–84 years) and mean follow-up was 43 months (range, 24–62 months). The injury pattern consisted of high-impact injuries in 11 cases, and most (9 patients) had a C2 fracture type when classified by the Arbeitsgemeinschaft für Osteosynthesefragen classification. The most used method of primary fixation was plate fixation (six parallel, six orthogonal, two single plates). Duration of non-union varied between 2 and 11 months, with four times fixation failure as the reason of non-union. Five patients had nerve damage, of which one had combined ulnar, median and radial nerve damage.
Table 1: Characteristics of the cohort

| Patient | Gender | Age (years) | Side | Follow-up (months) | Occupation                  | Associated injuries | Injury mechanism     | Type of fracture according to AO | Type of primary osteosynthesis | Elbow instability | Non-union duration (months) | Hardware failure | Neurological injuries | NUSS |
|---------|--------|-------------|------|--------------------|-----------------------------|---------------------|-----------------------|---------------------------------|--------------------------------|-------------------|--------------------------|-----------------|-------------------------|------|
| 1       | M      | 18          | R    | 45                 | Cook                        | None                | MVC                   | C1                              | K-wires                        | Yes               | 3                        | None            | None                    | 25   |
| 2       | F      | 43          | L    | 60                 | Construction worker         | Polytrauma          | Fall-suicide          | C3                              | Orthogonal plates             | No                | 6                        | Yes, radial plate | Radial nerve           | 35   |
| 3       | M      | 39          | L    | 48                 | Farmer                      | None                | High fall             | C2                              | Parallel plates               | Yes               | 4                        | None            | None                    | 36   |
| 4       | M      | 45          | L    | 62                 | Public Officer              | Polytrauma          | MVC                   | C1                              | Orthogonal plates             | Yes               | 5                        | None            | None                    | 32   |
| 5       | M      | 42          | L    | 36                 | Soldier                     | None                | Sport injury           | C2                              | Parallel plates               | Yes               | 4                        | None            | None                    | 45   |
| 6       | M      | 28          | R    | 48                 | Office worker               | Polytrauma          | MVC                   | C1                              | Orthogonal plates             | No                | 3                        | None            | None                    | 55   |
| 7       | F      | 42          | L    | 27                 | Teacher                     | Multiple            | Simple fall           | C2                              | Parallel plates               | No                | 8                        | Broken screws    | Radial nerve           | 60   |
| 8       | M      | 39          | L    | 32                 | Truck driver                | L humeral head L wrist | MVC                   | C2                              | Single ulnar plate            | No                | 2                        | Pullout screws    | Ulnar nerve            | 56   |
| 9       | M      | 29          | L    | 35                 | Student                     | L wrist             | Sport injury           | C1                              | Single ulnar plate Radial K-wire | Yes               | 5                        | None            | None                    | 45   |
| 10      | M      | 52          | R    | 38                 | Retired                     | Polytrauma          | MVC                   | C2                              | Orthogonal plates             | Yes               | 4                        | None            | None                    | 45   |
| 11      | F      | 84          | L    | 33                 | Retired                     | None                | Simple fall           | C2                              | Parallel plates               | No                | 5                        | Plates cut-out    | Median, ulnar and radial nerve | 75   |
| 12      | M      | 47          | R    | 60                 | Butcher                     | Polytrauma          | MVC                   | C2                              | Cannulated screws             | Yes               | 10                       | None            | None                    | 25   |
| 13      | M      | 41          | R    | 24                 | Plumber                     | Polytrauma          | High fall             | C1                              | Parallel plates               | Yes               | 7                        | None            | None                    | 45   |
| 14      | M      | 36          | R    | 40                 | Plumber                     | Lower limbs         | Work accident         | C2                              | Orthogonal plates             | Yes               | 11                       | None            | None                    | 36   |
| 15      | F      | 58          | L    | 57                 | Carpenter                   | L humeral head L wrist | High fall             | C3                              | Orthogonal plates             | No                | 9                        | None            | None                    | 38   |
| 16      | M      | 56          | R    | 48                 | Farmer                      | L humeral head R wrist | MVC                   | C2                              | Parallel plates               | No                | 8                        | None            | Radial nerve           | 62   |

F, female; M, male; L, left; R, right; MVC, motor vehicle collision; AO, arbeitsgemeinschaft für osteosynthesefragen; NUSS, non-union severity score
Table 2: Peri-operative results of the cohort

| Patient | Type of surgery | Length of surgery (minutes) | Bloodloss (mL) | Fluoroscopic reduction | Trochleocapitellar | Complications | Bone healing (months) | Time of rehabilitation (weeks) | Neurological recovery | Arthrolysis (months after union) |
|---------|-----------------|-----------------------------|----------------|------------------------|-------------------|---------------|---------------------|-----------------------------|-------------------|-----------------------------|
| 1       | PP              | 97                          | 747            | Anatomic               | 0.76              | —             | 6                   | 52                          | —                 | 9                          |
| 2       | OP              | 138                         | 893            | Satisfactory           | 0.34              | —             | 8                   | 24                          | —                 | —                          |
| 3       | PP              | 123                         | 888            | Anatomic               | 0.67              | Skin infection | 10                  | 42                          | —                 | —                          |
| 4       | OP              | 167                         | 713            | Satisfactory           | 0.56              | —             | 7                   | 46                          | —                 | 4                          |
| 5       | PP              | 129                         | 689            | Anatomic               | 0.74              | —             | 9                   | 37                          | —                 | —                          |
| 6       | PP              | 152                         | 757            | Anatomic               | 0.77              | —             | 11                  | 38                          | —                 | —                          |
| 7       | OP              | 148                         | 863            | Good                   | 0.43              | —             | 18                  | 60                          | Yes               | 5                          |
| 8       | PP              | 133                         | 782            | Good                   | 0.54              | Skin infection | 9                   | 42                          | Yes               | 4                          |
| 9       | PP              | 106                         | 774            | Anatomic               | 0.75              | —             | 38                  | 28                          | —                 | 6                          |
| 10      | PP              | 113                         | 872            | Satisfactory           | 0.63              | —             | 36                  | —                           | 6                 | 6                          |
| 11      | PP              | 242                         | 468            | Good                   | 0.64              | Skin infection | 3                   | 45                          | None              | —                          |
| 12      | OP              | 105                         | 632            | Satisfactory           | 0.49              | —             | 43                  | —                           | —                 | 6                          |
| 13      | OP              | 108                         | 378            | Good                   | 0.68              | —             | 48                  | —                           | —                 | —                          |
| 14      | PP              | 127                         | 456            | Anatomic               | 0.67              | —             | 37                  | —                           | 3                 | —                          |
| 15      | PP              | 131                         | 456            | Good                   | 0.62              | —             | 28                  | —                           | —                 | 5                          |
| 16      | PP              | 101                         | 823            | Anatomic               | 0.74              | Skin infection | 4                   | 47                          | Yes               | 7                          |

PP, parallel plates; OP, orthogonal plates.

This study showed good radiographic and clinical results after the use of augmentation in aseptic non-unions of the distal humerus. Correlation coefficient of patients who received an allograft performed better than those with autograft. This was significantly higher than the non-union period. The mean NUSS score was 45 points (range 32–57 points), further confirming the benefits of augmentation in aseptic non-unions of the distal humerus. The average time to full bone healing on radiographs was 24 weeks (range 16–32 weeks), and the average time to return to work was 36 weeks (range 24–60 weeks). The average time to return to their own work was 12 weeks (range 8–16 weeks). The average time to return to their own work was 12 weeks (range 8–16 weeks). The average time to return to their own work was 12 weeks (range 8–16 weeks). The average time to return to their own work was 12 weeks (range 8–16 weeks). The average time to return to their own work was 12 weeks (range 8–16 weeks). The average time to return to their own work was 12 weeks (range 8–16 weeks). The average time to return to their own work was 12 weeks (range 8–16 weeks). The average time to return to their own work was 12 weeks (range 8–16 weeks). The average time to return to their own work was 12 weeks (range 8–16 weeks).
Table 3: Outcomes of the cohort

| Patient | MEPS before initial trauma | MEPS during non-union | MEPS after 12 months arthrolysis (when performed) | OES before initial trauma | OES during non-union | OES after 12 months arthrolysis (when performed) | Return to work | Cohen’s k for RUS and VAS pain |
|---------|--------------------------|----------------------|-----------------------------------------------|--------------------------|---------------------|-----------------------------------------------|-----------------|-------------------------------|
| 1       | 100                      | 32                   | 68                                            | 94                       | 100                 | 22                                            | 80              | 90                            | Yes              | 0.041                         |
| 2       | 100                      | 42                   | 82                                            | —                        | 100                 | 42                                            | 80              | —                             | Yes              | 0.052                         |
| 3       | 100                      | 36                   | 78                                            | —                        | 100                 | 28                                            | 72              | —                             | Yes, with limitations | 0.35              |
| 4       | 100                      | 34                   | 64                                            | 78                       | 100                 | 32                                            | 66              | 74                            | Yes              | 0.46                          |
| 5       | 100                      | 54                   | 79                                            | —                        | 100                 | 44                                            | 79              | —                             | Yes              | 0.58                          |
| 6       | 100                      | 56                   | 76                                            | —                        | 100                 | 36                                            | 72              | —                             | Yes, with limitations | 0.078             |
| 7       | 90                       | 40                   | 58                                            | 72                       | 90                  | 40                                            | 58              | 76                            | Yes              | 0.069                         |
| 8       | 100                      | 38                   | 68                                            | 92                       | 100                 | 34                                            | 64              | 88                            | Yes, with limitations | 0.068             |
| 9       | 100                      | 28                   | 56                                            | 86                       | 100                 | 32                                            | 56              | 80                            | Yes              | 0.57                          |
| 10      | 96                       | 46                   | 64                                            | 98                       | 96                  | 60                                            | 54              | 96                            | Yes              | 0.048                         |
| 11      | 78                       | 0                    | 28                                            | —                        | 82                  | 0                                             | 14              | —                             | No               | —                             |
| 12      | 98                       | 36                   | 86                                            | —                        | 100                 | 26                                            | 88              | —                             | Yes              | 0.93                          |
| 13      | 98                       | 38                   | 78                                            | —                        | 100                 | 36                                            | 72              | —                             | Yes, with limitations | 0.038             |
| 14      | 96                       | 64                   | 82                                            | 76                       | 98                  | 42                                            | 74              | 72                            | Yes, with limitations | 0.042             |
| 15      | 98                       | 52                   | 56                                            | 72                       | 98                  | 44                                            | 60              | 70                            | Yes              | 0.041                         |
| 16      | 100                      | 28                   | 74                                            | 86                       | 100                 | 18                                            | 58              | 78                            | Yes, with limitations | 0.069             |

MEPS, Mayo elbow performance score; OES, Oxford elbow scale; RUS, radiographic union score; VAS, visual analogue scale

extra morbidity arising from autograft retrieval. The allograft has no extra patient morbidity in a patient group that mostly already has sustained a severe trauma. Artificial bone grafts may have the extra advantage that they are limitless available, have different options to choose from and do not require special storage conditions, such as refrigerators. However, their exact mechanism of work is still investigated. Moreover, the number of patients in our study is relatively low to draw well-founded conclusions. The superficial skin infection rate is high (25%) yet these cases were managed well with antibiotic therapy only and no deep infections occurred. In contrast to the mentioned study, antibiotics were given to our patients prior to surgery instead of during surgery after sampling of tissues for low-grade infections, and Augmentin treatment for 6 days after surgery was given on a regular basis after surgery. 

In this study, we have assessed return to work, which is an important outcome in this longstanding elbow pathology; the mean return to work was 38 weeks, which is more than the 90-day period which is important in other orthopaedic-traumatic pathology. Nevertheless, all patients who worked returned to work, with more than half without limitations after a mean follow-up of 43 months. However, the longer-term outcomes have to be awaited, as elbows are prone to post-traumatic degeneration. 

The patients who underwent arthrolysis had a further, expected, increase of ROM after arthrolysis. As described by Donders et al., it is possible to perform during the same surgery when deemed necessary. In our view, it is difficult to determine pre- or perioperatively which patient will develop a stiff elbow; therefore, the capsular release was very limited in our series to prevent more extensive bleeding and surgery time. The result is that more than half of the patients needed a second surgery, which was successful in all but one patient who did not improve on the MEPS and OES; the other eight patients who underwent arthrolysis benefited greatly.

However, this case series is an uncontrolled retrospective case review in a relatively small group of patients with a specific condition. Therefore, this technique is not validated in large cohorts and the extra value of the artificial bone grafting over allografts of autografts was not studied. Moreover, because of the specific nature of the aseptic, intra-articular non-unions of the distal humerus, no clear guidance on bone resection or generalisable surgical steps can be stated; every case has its specific details that need to be addressed. On the other side, the surgical technique as used for our patients relies on the concepts of proper fixation, adequate soft tissue envelope and favourable biologic circumstances at the fracture site. Because of the lack of a control group with only debridement and renewed fixation without any (artificial) bone grafting, we cannot elaborate on the effect of the bone grafts.

Regarding the definition of non-union, the time between primary management of the fractures and time to the re-intervention with our technique was not 6 months for all cases. In four of nine cases performed within 6 months, there was either hardware failure or evident inadequate fixation, and the other five patients had malalignment without callus; therefore waiting for a longer period was not warranted and we considered this as a non-union as further spontaneous union with good results was not to be expected in these cases.

Conclusion

The use of two locking plates and bone graft augmentation with autografts or allografts with artificial bone grafts is a successful
treatment of intra-articular distal humeral non-unions after hardware failure or biological limitations.

We did not encounter graft-related problems in our retrospective case series, yet a large proportion of patients needed an arthrolysis of the elbow because of secondary stiffness.

**Clinical Significance**

The use of artificial bone in the treatment of aseptic non-unions of the upper limb is safe. When no autograft is possible because of concurrent morbidity, it can be used alone or combined with an allograft to reconstruct the affected bone without leading to extra morbidity or complications.

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**Rehabilitation Protocol**

The purpose of our protocol is to provide the clinician with an orientation of the post-operative course of rehabilitation, to rationalise and to have the whole patient population conform to a single physiotherapy program.

**Week 1–3**

During the first three post-operative weeks the patients wore a resin cast from the humerus to the metacarpals with the elbow flexed in 90°.

**Week 4–6**

After the first three weeks the patient received a Hinged Elbow Brace.

- Week 4: Full elbow flexion, up to 30° of extension deficit.
- Week 5: Full elbow flexion, up to 20° of extension deficit.
- Week 6: Full elbow flexion, up to 10° of extension deficit.

**Strengthening Program**

Single plane active ROM elbow flexion, extension, supination, and pronation.

**Week 7–11**

Full range of motion of the elbow; discontinue the brace if adequate motor control.

- The patient may begin composite motions (i.e. extension with pronation).
- If at 8 weeks post-operatively the patient has significant range of motion deficits, therapist may consider more aggressive management after consultation with referring surgeon.

**Strengthening Program**

A progressive active-resistance exercise program is initiated for elbow flexion, extension, supination, and pronation.

**Week 12**

Standard removal of the Hinged Elbow Brace.

- The patient may initiate light upper extremity weight training.

**Strengthening Program**

Initiation of endurance program that simulates desired work activities/requirements.

- Stimulation of elbow and shoulder range of motion, strength and coordination.