Treatment of presumed aseptic non-union of the humeral shaft by osteosynthesis combining intramedullary nailing and screw plate

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In 2020, the most common treatment for presumed aseptic non-union of the humeral shaft seems to be decortication, often associated with bone autografting, and stabilized by a screw plate. We propose to evaluate an original technique of rigid osteosynthesis combining intramedullary nailing and screw plate. Between January 2004 and January 2020, 45 patients underwent treatment of presumed aseptic non-union of the humeral shaft by osteosynthesis combining intramedullary nailing and a screw plate. The minimum radio-clinical follow-up was one year postoperatively. The series included 19 men and 26 women with a mean age of 53 years (range 19-84 years). Bone consolidation was achieved in 43 patients, a rate of 95.5%. Comparing patients who achieved bone consolidation with the two failed consolidations did not reveal any statistically significant factor. Interobserver agreement was almost perfect (k=0.93) for the use of the RUST for humeral shaft fractures treated with intramedullary nailing and screw plate. In our study, the treatment of presumed aseptic non-union of the humeral shaft with an osteosynthesis combining intramedullary nailing and screw plate gives, with 95.5% of bone consolidation, results equal to or even superior to the different treatments currently described in the literature.

Keywords: non-union, nailing, plate, humerus.

INTRODUCTION

The literature describe a rate of humeral shaft non-union’s occurrence between 0 and 13% after surgical treatment. The risk factors found are multiple. They are linked to the patient (obesity, alcoholism and chronic smoking, unbalanced diabetes, osteoporosis), to the fracture’s type (open, comminuted, transverse and short oblique, with loss of substance, septic), and to the surgical treatments already received (excessive devascularization, distraction of the fracture site, unstable osteosynthesis, inadequate postoperative immobilization). According to Gianoudis, the conditions for obtaining bone consolidation are the supply of osteogenic cells and growth factors associated with an osteoconductive matrix, attached by a mechanically stable osteosynthesis. These conditions are more difficult to obtain when there have been previous surgical interventions.

In the current literature, multiple techniques are proposed for presumed aseptic humeral shaft non-union’s treatment. They often combine decortication, frequently associated with a bone autograft, stabilized by a screw plate. The absence of clinical, radiological, and biological criteria of infection at the time of care allows the presumed aseptic nature of the non-union to be established. Septic non-union requires specific treatment.

Our hypothesis is that intramedullary nailing avoids axis disorders by facilitating alignment of shaft’s fragments, and that reaming is beneficial for bone consolidation. Using a plate helps to counteract rotational forces and to provide compression. Finally, bone grafting may be necessary in cases of significant local bone loss.

The goal of this study is to analyze the success rate of bone consolidation of presumed aseptic humeral shaft non-union when intramedullary nailing is combined with a screw plate, without increasing the complication rate.

MATERIALS AND METHODS

We conducted a descriptive, retrospective, monocentric study between January 2004 and January 2020 in the orthopedic surgery department of the Centre Chirurgical Emile Gallé, 54000 Nancy, France. Inclusion criteria were being at least 18 years of age and having a presumed aseptic non-union of the humeral shaft. Exclusion criteria were the presence of clinical, radiological, and biological criteria of infection at the time of care allowing the presumed aseptic nature of the non-union to be established. Septic non-union requires specific treatment.

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Keywords: non-union, nailing, plate, humerus.
Treatment of presumed aseptic non-union of the humeral shaft by osteosynthesis

55 included patients treated for a suspected aseptic humeral shaft non-union by intramedullary nailing and an associated screw plate.

2 excluded patients: non-union on pathological fracture of primary or secondary neoplasia.

8 patients lost during follow-up: postoperative clinical-radiological follow-up < 1 year.

45 patients studied and monitored for up to 1 year of postoperative clinical and radiological follow-up.

Figure 1. — Flow chart of study inclusion and exclusion criteria.

Humeral shaft, previously operated or not. Exclusion criteria were proximal or distal metaphyseal non-union, pathological fractures, postoperative follow-up of less than one year. Fifty-five adult patients were treated for a presumed aseptic non-union of the humeral shaft with intramedullary nailing and an associated screw plate. Non-union was considered if radiological examinations showed no evolution of the consolidation process after at least 2 months after the last surgical or orthopedic treatment. Non-unions were presumed to be aseptic in the absence of clinical and biological signs of sepsis. Two patients were excluded from this study because they presented a non-union on a pathological fracture of primary or secondary neoplasia, and eight patients did not reach one year of postoperative follow-up. The study therefore included 45 patients (Figure 1). This study was initiated after the favorable opinion of the Committee for the Protection of Persons of the Clinical Research and Investigation Department of the Nancy Hospital and Regional University Center (number 2020PI187 21/08/2020).

The study included 26 women and 19 men with a mean age of 53 years (range 19-84). Seventeen were smokers, three were alcoholics and five were diabetics. The initial trauma was a mechanical fall in 33 patients.

Table 1. — Demographic characteristics of patients

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients studied n</td>
<td>45</td>
</tr>
<tr>
<td>Gender n (%) Male: n (%) Female</td>
<td>19 (20%): 26 (60%)</td>
</tr>
<tr>
<td>Average age in years</td>
<td>53 (range 19-84 years old)</td>
</tr>
<tr>
<td>Risk factor for non-union n (%)</td>
<td></td>
</tr>
<tr>
<td>Smoker</td>
<td>17 (38%)</td>
</tr>
<tr>
<td>Alcohol drinker</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>5 (11%)</td>
</tr>
<tr>
<td>Average BMI</td>
<td>27 (range 18.1-45 kg/m²)</td>
</tr>
<tr>
<td>Laterality n (%) Right: n (%) Left</td>
<td>23 (51%): 22 (49%)</td>
</tr>
<tr>
<td>Cause of fracture: n (%)</td>
<td></td>
</tr>
<tr>
<td>Mechanical fall</td>
<td>33 (74%)</td>
</tr>
<tr>
<td>Road accident</td>
<td>8 (17%)</td>
</tr>
<tr>
<td>Crushing</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Direct trauma</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Fracture n (%) Closed: n (%) Open</td>
<td>40 (89%): 5 (11%)</td>
</tr>
<tr>
<td>Primary non-union n (%)</td>
<td>5 (11%)</td>
</tr>
<tr>
<td>Non-union after surgical treatment n (%)</td>
<td>40 (89%)</td>
</tr>
<tr>
<td>Number of patients who already had 1 surgery</td>
<td>21</td>
</tr>
<tr>
<td>Number of patients with 2 previous surgeries</td>
<td>12</td>
</tr>
<tr>
<td>Number of patients with 3 previous surgeries</td>
<td>5</td>
</tr>
<tr>
<td>Number of patients with 4 previous surgeries</td>
<td>2</td>
</tr>
<tr>
<td>Orthopedic treatment n (%)</td>
<td>5 (11%)</td>
</tr>
<tr>
<td>Last surgical treatment: n (%)</td>
<td>40 (89%)</td>
</tr>
<tr>
<td>Intramedullary nailing</td>
<td>11 (25%)</td>
</tr>
<tr>
<td>Screw plate</td>
<td>14 (31%)</td>
</tr>
<tr>
<td>Fasciculated pinning</td>
<td>15 (33%)</td>
</tr>
<tr>
<td>Type of non-union: n (%)</td>
<td></td>
</tr>
<tr>
<td>Active hypertrophic</td>
<td>12 (27%)</td>
</tr>
<tr>
<td>Active oligotrophic</td>
<td>21 (46%)</td>
</tr>
<tr>
<td>Non active atrophic</td>
<td>12 (27%)</td>
</tr>
</tbody>
</table>

Figure 2. — Patients with hypertrophic, oligotrophic or atrophic aseptic non-union of the middle part of the left humeral shaft.
negative and three were positive. In case of positive bacteriological samples, the patients were treated with an adapted dual antibiotic therapy for six weeks.

Patients were immobilized in a shoulder sling for an average of four weeks depending on clinical evolution.

Postoperative follow-up was performed regularly up to one year after the operation. It included a clinical evaluation of pain on active and passive mobilization of the shoulder and elbow, as well as direct palpation of the non-union site, logged in the patient’s medical record. X-rays of the humerus from the front and the side were taken during each visit.

In our study, bone consolidation was assessed by combining a clinical criterion with indolence of the fracture site, and a radiological criterion with the formation of at least one cortical bone in continuity without signs of bone loosening.

As explained by Bhandari et al.\textsuperscript{13}, indolence on palpation of the fracture site is a widely used clinical criterion used to assess bone consolidation. The

<table>
<thead>
<tr>
<th>Radiographic Union Score for Tibial Fractures (RUST)</th>
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<tbody>
<tr>
<td>Cortical Fracture line: No callus (Score = 1)</td>
</tr>
<tr>
<td>Anterior</td>
</tr>
</tbody>
</table>

Figure 3. — Radiographic Union Score for Tibial Fractures (RUST) by Whelan et al. Frontal and lateral X-ray images of humerus after surgical treatment of aseptic non-union and osteosynthesis by intramedullary nailing and screw plate. RUST total score = 7.
radiological bone bridge is assessed by a Radiographic Union Score for Tibial Fractures (RUST) strictly greater than four as described by Whelan et al.\textsuperscript{14} (Figure 3). The RUST has been validated for nailed humeral shaft fractures\textsuperscript{15}. In our study, a separate review of all X-rays by two orthopedic surgeons was performed to determine the reproducibility of the RUST for humeral shaft fractures treated with intramedullary nailing and screw plates.

A RUST of 4 more than one year after surgery without any other radiological evidence of bone consolidation progression was considered as a treatment’s failure, with recurrence of non-union.

Secondary endpoints included the occurrence of complications associated with the surgical procedure.

The quantitative variables were described according to their dispersions, maximum and minimum values. Relationships between categorical variables were tested with the Fischer test. The significance level was set at 0.05.

A Cohen’s Kappa test was used to assess the interobserver reproducibility of the RUST for humeral shaft fractures treated with intramedullary nailing and associated screw plate.

### RESULTS

43 patients have bone consolidation after a one-year period at a rate of 95.5%. At the end of the follow-up, 36 patients had a maximum RUST of 12, with four cortical in continuity (Table II), meaning 83.7% of the patients obtained bone consolidation (Figure 4).

In our study, interobserver agreement was almost perfect (k=0.93) according to Landis and Koch\textsuperscript{16} for the use of the RUST on humeral shaft fractures treated with intramedullary nailing and screw plates.

At the end of a postoperative clinical and radiological follow-up, two patients still presented a non-union without evolution of the bone consolidation process on X-rays, with a RUST equal to four, confirmed by a CT scan.

These patients included a 32-year-old male smoker with an initially open fracture following a road accident, whose initial surgical care in another center for screw plate osteosynthesis was complicated by radial paralysis. Complete recovery of the radial nerve after neurolysis was obtained during a second surgical operation. The patient presented an atrophic non-union.

![Figure 4. — A 23-year-old patient with a closed fracture of the middle part of the left humeral shaft from direct trauma. After an initial surgical treatment by fasciculated pinning, he presented at 12 months with an oligotrophic aseptic non-union of the middle part of the left humeral shaft. A) Preoperative X-rays, B) Immediate postoperative X-rays, C) X-rays at 24 weeks post-op. RUST=12.](image)
of the middle part of the humeral shaft 16 months after
the last surgical treatment. The patient was not grafted
during our operation and the intraoperative samples
came back positive for Staphylococcus Epidermidis
and Cutibacterium Acnes. An adapted postoperative
antibiotic treatment was implemented for six weeks.
No clinico-biological signs of an active infectious
process were found during the patient’s follow-up. No
radiological evidence of bone consolidation was found
after more than one year.

The second patient was 43 years old and presented
no risk factors for non-union. He presented a closed
fracture of the middle part of the humeral shaft following
a mechanical fall. Initial surgical management in
another center with a screw plate was repeated after
one year for non-union with a new osteosynthesis with
a screw plate without bone graft. Eight months after,
he still had an active hypertrophic non-union. The
bleeding cancellous bone shavings from the humeral
end cuts were grafted. No bacteriological samples
were taken during surgery. No X-ray evidence of bone
consolidation was observed more than one year after
our procedure.

Therefore, these patients failed according to the
criteria of bone consolidation chosen in this study.
However, a new surgical procedure was not considered
because of indolence, no functional limitation for the
upper limb declared by the patient, and the absence
of clinical and biological signs of an active infectious
process in these two patients.

The small number of failures does not allow us to
identify a statistically significant factor for success or
failure of bone consolidation. Among the failures, only
one patient had a bone graft, which does not allow us to
determine its influence on bone consolidation.

After the operation, three patients (6%) had a
temporary radial paralysis, which fully recovered on its
own within a few weeks.

In addition, three patients suffered from transient
shoulder stiffness.

Finally, two patients underwent reoperation once
bone consolidation had been achieved, for removal of
the osteosynthesis material because of irritating pain
in relation to the osteosynthesis material. One of these
patients suffered pain from the proximal locking screw
of the nail, and the other had discomfort on the lateral
side of the arm in relation to the screw plate.

**DISCUSSION**

With a bone consolidation rate of 95.5%, this study
shows that the treatment of presumed aseptic non-
union of the humeral shaft by osteosynthesis combining
intramedullary nailing and screw plate gives results in
regards to bone consolidation that are equal to or even
superior to the various current treatments.

The occurrence of failures and complications in
our study allows us to identify its limitations. The
surgical procedures were performed by several con-
formed surgeons, inducing heterogeneity of the surgical
technique. It thus seems interesting to study the benefit
of a systematic bone graft. Indeed, Kontakis shows
in his meta-analysis that bone grafting remains a key
factor in bone consolidation whatever the type of non-
union (atrophic or hypertrophic) even if this point of
view is not shared by the whole scientific community.
Furthermore, multiple systematic intraoperative bacte-
riological samples seem to be essential to search for an
underlying septic cause, even in the absence of clinical
or biological infectious signs. One likely cause of failed
iterative non-union treatment may be the existence
of an unrecognized associated bone infection, which
is said to be present in 50 to 60% of recurrent non-
union, depending on the series. Moreover, our study
is limited by its structure, since it is a retrospective
descriptive study in which data derived solely from
the patients’ medical records. Thus, we have a regular
but non-standardized radio-clinical follow-up of the
patients. Similarly, data from standardized functional
scores of the elbow and shoulder would allow evaluation
of the active and passive functional results of the upper
limb. The literature does not offer an analysis of bone
loss and therefore of a possible difference in humeral
length compared to the contralateral side, which
seems interesting to study. The inclusion of a larger
number of patients in the study would also increase its
strength, although humeral shaft non-union remains an
infrequent pathology.

This homogeneous series with a one-year follow-up
is a strong point of this study. In addition, interobserver
agreement after review of all X-rays by two orthopedic
surgeons validates the use of the RUST to assess bone
consolidation of humeral shaft fractures treated with
intramedullary nailing and associated screw plates.
Finally, the patients included in our study had often
already undergone previous non-union treatments
(42%). Few studies are currently proposing to study
these patients with persistent non-union. In his series,
Pollon et al. found failure of bone consolidation in 25%
of patients, requiring revision surgery. In our study, no
patient was operated on again because of indolence and
because no X-ray evidence of bone loosening around
the osteosynthesis material was found.
Treatment of humeral shaft non-union by intramedullary nailing alone does not give satisfactory results. In fact, the humerus is mainly subjected to torsional and distraction stresses and little axial stress, unlike the tibia and femur, which are in the weight-bearing zone. Thus, the results of shaft non-union treatment after failed intramedullary nailing differ between the upper and lower limbs. While dynamization of tibial and femoral nails leads to consolidation, it is not effective in humeral shaft non-union. However, intramedullary nailing allows alignment of the shaft ends, and thus reduces sagittal and frontal axis disorders, especially in cases of significant loss of substance. In addition, systematic reaming before intramedullary nailing allows for the provision of growth factors that temporarily stimulate the consolidation process. At the femoral level, several authors have shown that reaming before intramedullary nailing reduces bone consolidation time and the rate of non-union occurrence. However, intramedullary nailing alone is not sufficient. The addition of a short DC plate ensures stability against torsional forces and compression. A plate with only six holes makes it possible to limit extensive dissection and its complications, including periosteal devascularization, as periosteal vascularization is an ally of the consolidation process. With three bicortical screws on either side of the non-union site, our technique uses shorter plates than those described in other studies. Although Healy suggests that plate fixation with at least three bicortical screws on either side of the non-union site is sufficient for stability, most studies suggest the use of long plates with at least four bicortical screws on either side, in order to obtain satisfactory stability. Some authors even suggest the association of two perpendicular plates to gain in stability. In the upper limb, treatment by adding a plate to a pre-existing intramedullary nailing that has been left in place has been described by Gessmann. He obtained a 97% consolidation rate in 37 patients. He explains that the combined extra- and intramedullary osteosynthesis provides increased stability while reducing the length of the plate used. However, by not changing the intramedullary nailing, he loses the benefit of reaming.

Thus, the combination of these two osteosynthesis systems at the humerus level seems justified to provide a mechanically stable environment as described by Frost, in accordance with the deformation theory of Perren, helping the process of bone consolidation. The combination of intramedullary and extramedullary osteosynthesis has been described in the lower limb and has not shown negative effects on bone consolidation. Although technically more demanding, bone grafting is possible in this surgical technique because the plate is short, and the diameters of the nail and screws are reduced. We did not determine any consensus criteria for the use of bone grafting. This was left to the judgment of the surgeon, depending on the loss of substance and the on-site condition. However, other studies observe higher consolidation rates when bone grafting is added. In the previously described technique, antegrade nailing is used with a short superior-lateral approach and a short opening of the rotator cuff. This approach had already been chosen many times for previous intramedullary nailing and we used it again for removal of the nails in place. Other studies describe complications associated with this approach, including retractile capsulitis and rotator cuff deficits. However, as Wen et al explain in their meta-analysis, the superior-lateral approach of antegrade nailing does not result in statistically significant functional limitation of the shoulder and elbow compared to the lateral humeral approach used for the screw plate.

There are currently other techniques with disparate results. In their meta-analysis, Peters et al. study the existing techniques in 36 articles and include their results in terms of bone healing. Although no consensus has been reached, the most widely described and studied technique (in 17 articles evaluating 672 patients) is decortication, followed by bone autograft and osteosynthesis with a screw plate. It results in a consolidation rate of 98% (range 75-100%). The same technique but without associated bone grafting gives lesser results with a consolidation rate of 95% (range 75-100%). However, screw plate techniques are prone to complications, including radial nerve damage during dissection to access the non-union site in 6% of patients. As previously described, the nailing technique combined with bone grafting results in a lower rate of consolidation of about 88% (range 56-100%), falling to 66% (range 29-95%) if not combined with bone grafting. In addition to the causes of failure related to biomechanical problems already described, the radial nerve is affected almost 7% of the time during this procedure. The external fixator technique (with Ilizarov circular or monolateral fixator) combined with bone grafting results in a 98% consolidation rate (range 89-100%). El-Rosasy et al. proposed an external fixator technique associated with intramedullary nailing in 18 patients, with 100% consolidation. These techniques are associated with radial nerve damage in only 3% of cases but are associated with infectious complications.
in 9% of cases, compared with only 4% for screw-plate techniques and 3% for intramedullary nailing. In addition, external fixators are often poorly tolerated by patients.

There is currently no recommendation regarding dissection and possible transposition of the radial nerve for its protection.

**CONCLUSION**

In our study, the treatment of presumed aseptic non-union of the humeral shaft with an osteosynthesis combining intramedullary nailing and screw plate results in 95.5% bone consolidation, which is equal or even superior to the different treatments currently described in published studies.

It also has several advantages, including the use of plates to avoid torsional forces and to allow compression. The plates are short to limit extensive dissection and its deleterious effects on bone consolidation. Nailing also allows to fight against axis disorders. Finally, systematic intramedullary reaming before nailing seems to be an ally of bone healing.

This original work calls for a larger standardized study. We note the importance of systematic multiple intraoperative bacteriological samples and standardized clinical and radiological follow-up. Studying the benefit of systematic bone grafting and assessing the proper function of the shoulder and elbow before and after surgery also seems relevant. Finally, bilateral analysis of humerus lengths and substance loss, as well as induced axis and rotation disorders, seems relevant.

**Conflict of interest:** none declared.

**REFERENCES**

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