Augmentation plate with bone graft in the management of humeral aseptic nonunion after Intramedullary Nailing: Is nail removal mandatory?

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Background

Surgical treatment of aseptic nonunion after intramedullary nail humerus (IMN) offers a wide range of options starting from bone marrow injection to nail removal and usage of alternative fixation methods. There is no consensus regarding nail retaining or nail removal.

Patients and methods

Total 28 patients who had aseptic nonunited fracture humerus after intramedullary nail were treated by a 3.5 locked compression plate using a posterior approach and bone graft with the nail in situ. The study was conducted between January 2019 and December 2022. The age average was 38.6 years old. All nonunions were diaphyseal, with 20 cases having an oligotrophic type while 8 had a hypertrophic type. All nails which were previously used were antegrade with 1 distal locking screw and 2 to 3 proximal locking screws. All nails were seated well without protrusion or encroachment on the supraspinatus tendon. We evaluated pre and post-DASH (Disabilities of arm, shoulder, and hand) scores and visual analog scale (VAS) of pain along with the radiologic union.

Results

The time-lapse between the IMN application and our intervention average was 15.6 months. The patient's follow-up average was 13.8 months. The final DASH score average was 4.8 (the preop DASH score average was 22). The final VAS pain scale average was 0.6 (the preop VAS pain scale average was 2.8). All cases united after an average of 4.3 months. Two cases had a superficial infection that healed by antibiotics according to culture and sensitivity and repeated dressings.

Conclusion

In this study, surgical treatment obtained excellent clinical and radiological results in aseptic nonunion humerus fractures after IMN failure using 3.5 mm locked compression plate and bone graft with the nail in situ, as long as the conditions of nail retaining are met.

Keywords:

Aseptic humerus shaft fracture nonunion, augmentation plate, intramedullary nail humerus failure, revision without nail removal

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Introduction

The outcome of locked intramedullary nail humerus (IMN) in the humerus did not match those used for lower limb fractures, due to different limb biomechanics and lack of the weight-bearing presented for lower limb fractures [1]. However, regarding union, many studies [2–7] had no significant differences between outcomes when comparing plate osteosynthesis versus IMN in humeral fractures with the IMN having higher complications regarding shoulder impingement, radial nerve injury, and need for implant removal [8–11]. The presence of IMN complicates humeral shaft nonunion, whether the nail is removed or not.

In literature, nail exchange like that was done for lower limbs nonunion was not successful [12]. Nail

removal and replacement by plate osteosynthesis is a viable option, yet it carries the risk of larger incisions, increased infection rate, technical problems regarding nail removal, and most importantly; further damage to the rotator cuff during the extraction of deeply seated nail [13–16]. The purpose of this study is to analyze the outcome and describe a method using an augmentation-locked compression plate (3.5 LCP) and bone graft with the nail in situ and to evaluate the necessity of nail removal.

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Patients and methods

This study was conducted between January 2019 and December 2022, 28 patients who had aseptic nonunited fracture humerus after intramedullary nails were presented to the Zagazig University trauma unit clinic. Age ranged between 19 to 55 years old (average 38.6). 21 (75%) patients were males and seven (25%) were females. The side affected was right in 16 patients and left in 12 patients. All nonunions were diaphyseal with 20 cases having an oligotrophic type while eight had a hypertrophic type. All nails which were previously used were antegrade with static 1 distal locking screw and 2 proximal locking screws (20 cases) to 3 (8 cases). All nails were deeply seated without protrusion or encroachment on the supraspinatus tendon. Associated Comorbidities included diabetes (2 cases), associated previous skeletal injuries in the pelvis and lumbar spine (3 cases), and one case with a neurogenic pain at the fracture site (it was found during operation that radial nerve was entrapped within fibrous tissue around the fracture with no motor or sensory peripheral deficits). Table 1.

Preoperative evaluation included a plain radiography to assess the type of nonunion, size of the gap, presence of bone loss, and determine the status of the nail (depth and number of locking screws). It is of utmost importance to exclude infection as a cause of nonunion so erythrocyte sedimentation rate and C reactive protein were routinely done (all were found to be normal). Disabilities of arm, shoulder, and hand (DASH) score preoperatively ranged from 12 to 55 (average 22). Preoperative visual analog scale (VAS) of pain ranged from 0 to 5 (average 2.8). Clinical examination showed the full range of motion of the elbow and pain at the fracture site during shoulder rotation. All patients had a limited active range of motion of the shoulder because of nonunion but the passive range of motion was slightly affected and there was no shoulder stiffness (seven patients had limited passive range averaging 10°-20° in flexion, abduction, and external rotation)

Table 1 Preoperative demographics and criteria

| Age years (mean, range) | (38.6) 19–55 |
|--|---------------|
| Sex (male/female) | 21/7 |
| Side (right/left) | 16/12 |
| Nail (anterograde/retrograde) | 28/0 |
| Initial open/closed fracture | 3/25 |
| Type of nonunion (atrophic/hypertrophic) | 20/8 |
| Comorbidities (present/absent) | 5/23 |
| Time-lapse (months) from (IMN) to augmentation | 8–19 |
| | (average15.6) |

Patient selection was based on the following

Inclusion criteria

- (a) Humeral shaft fractures nonunion after IMN fixation.
- (b) Oligotrophic and hypertrophic nonunions.

Exclusion criteria

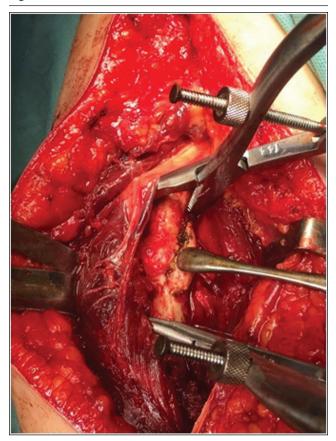
- (a) Infected nonunion.
- (b) Proud nails causing rotator cuff impingement mandating nail removal.
- (c) Presence of soft tissue loss.

Surgical technique

All patients were operated upon using general anesthesia in the lateral decubitus position to facilitate simultaneous access to the iliac crest for graft harvest. We used the posterior triceps splitting approach from the tip of the olecranon along the posterior midline of the arm proximally. The deep fascia was incised in line with the skin incision. The interval between the long and the lateral heads of the triceps muscle is developed proximal to distal. The radial nerve with the profunda brachii was identified and protected in the humeral spiral groove. If needed, the axillary nerve and posterior circumflex humeral artery can be identified and protected proximally. After establishing the approach, the distal locking screw can be removed (done in all but 2 cases) through a separate anterior small incision (dynamizing the nail). The fracture site in most cases was not obvious, Fig. 1 and needed to be identified due to fibrous tissue or hypertrophic callus, so we applied one bone-holding forceps above and another one below and did a twisting maneuver so that fragments moved at the fracture site. Once identified, the fracture site was cleaned of all fibrous tissues, and the edges were freshened using a scalpel, rongeurs, and osteotomes Fig. 2.

Afterward, the fracture gap is compressed and the remaining distance is assessed to estimate the amount of the graft needed. 3.5 mm LCP eight holes minimum (8-10) was applied (which yields minimum screw holding of 6 cortices above and 6 below the fracture site) and coapted at bone surface. The plate has combi holes: locked holes for maximum plate bone purchase (either bicortical if the nail allows or unicortical if not) and nonlocked holes to allow nonlocked screws to be applied in an oblique direction to gain bicortical purchase around the nail. Surgical site wash is done using a saline fluid with Garamycin antibiotic. The corticocancellous bone graft is harvested from the iliac bone and fashioned accordingly in and around the fracture gap and fixed by circulage if needed. 1 gm vancomycin antibiotic powder is poured into the surgical site, the

Figure 1



Twisting maneuver to identify the nonunion site.

portovac drain is attached, and the wound was closed in layers. Intraoperative manipulation of the shoulder was done for patients with a limited range at the end of the procedure.

Postoperative visits for wound care and patient assessment were arranged every week for 2 weeks, then monthly for 3 months, then every 3 months for 1 year, and eight patients had longer follow-ups (average of 13.8 months). The motion of the elbow started immediately postoperatively as tolerated, and shoulder motion commenced after stitches removal after 2 weeks with a physiotherapist. All patients were present for the final assessment (12 months or more), but not all of them attended the routine follow-up visits. The radiological assessment included implant position, fracture healing based on four cortices union (two cortices in anteroposterior radiography and another two cortices in lateral view), and complications detection if present. Clinical assessment included postoperative DASH score, postoperative VAS of pain, detection of deficit in elbow and shoulder range of motion, and complications surveillance if present.

Statistical assessment of the data was conducted by an independent biostatistician. Data collected throughout

Figure 2



Fracture nonunion site (blue arrow) and the intramedullary nail exposed.

the study were coded, entered, and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0, Microsoft, Chicago, Illinois) software for analysis. Qualitative variables were compared by χ^2 test, and quantitative variables in two parametric groups were compared by t-test. The P value was set at less than 0.05 for significant results.

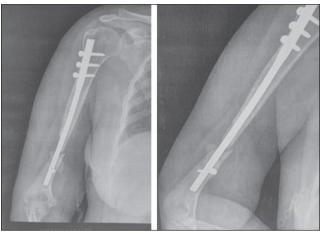
Results

The time-lapse between the IMN application and our intervention ranged between 8 and 19 (average 15.6) months. Patients' follow-ups ranged between 13 to 34 (average 13.8) months. All cases united after 3-5.5 (average 4.3) months. On the last visit, the DASH score ranged between 0 and 8 (average 4.8). Statistically, the DASH score change from preoperative to last visit score was found to be significant (P value: 0.034). The final VAS pain scale ranged between 0 to 2 (average 0.6). Statistically, the VAS pain scale change from preoperative to the final record was found to be significant (P value: 0.04). There was no deficit in the elbow and shoulder range of motion at the final visit. Two cases had a superficial infection that healed by antibiotics according to culture and sensitivity and repeated dressings. One intraoperative finding was

Table 2 Postoperative results and data

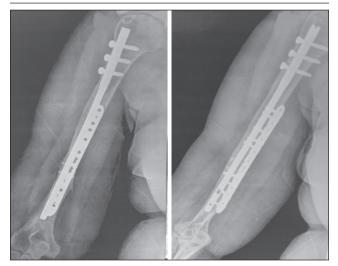
| Operation time (min, range) | 92 (65–160) |
|--------------------------------------|-------------------------|
| Union rate (%) | 100 |
| Time to union (month, range) | (Average 4.3) 3 to 5.5 |
| Follow-up (month, range) | (Average 13.8) 13 to 34 |
| VAS score (average pre/average post) | 2.8/0.6 |

Figure 3



Case (1) preoperative (left) anteroposterior and (right) lateral radiography 9 months nonunion.

Figure 4



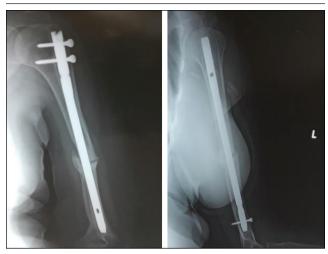
Case (1) 16 months postoperative (left) anteroposterior and (right) lateral radiography.

adhesions around the radial nerve in the spiral groove which was released, consequently relieving neurogenic pain at the fracture site by the entrapped nerve. Table 2 shows postoperative data, Case (1) is shown in Figs 3 and 4. Case (2) is shown in Figs. 5 and 6. Figure 7 shows pre and post operative DASH score for each patient.

Discussion

The use of locked IMN in fracture humerus has advantageous mechanical and biological aspects.

Figure 5



Case (2) preoperative (left) anteroposterior and (right) lateral radiography 18 months nonunion.

Figure 6

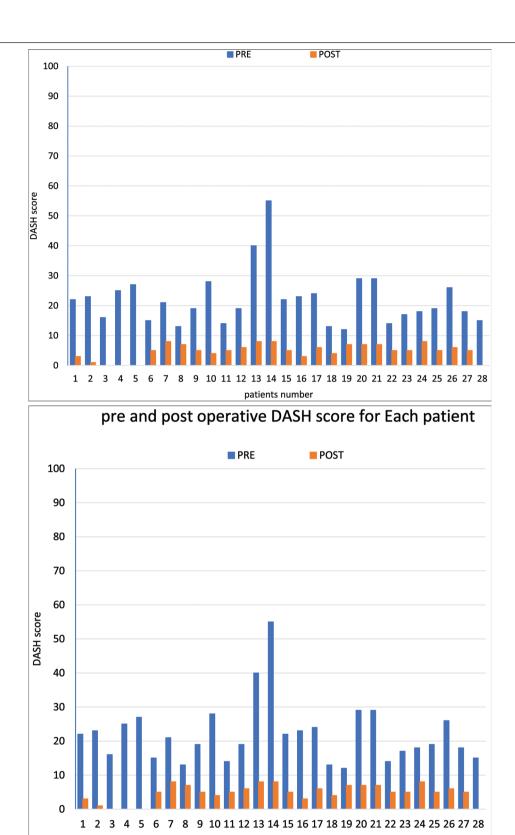


Case (2) postoperative (left) anteroposterior and (right) lateral radiography 13 months follow-up.

Locked IMNs are load-sharing devices and facilitate the healing process without bone exposure at the fracture site. IMN is aligned with the mechanical axis of the humeral shaft and therefore is subjected to lower bending stresses [16]. In our institute, we were confronted with considerable numbers of patients with nonunion after locked IMN requiring intervention. This may be attributed to poor fracture selection, inadequate nail working length, inadequate distal locking (one screw only), poor reduction, and inadequate nail diameter. An additional explanation can be the lack of compressive forces in contrast to lower limb IMN so dynamization was not a feasible option in IMN humerus delayed union or nonunion.

The operative intervention of diaphyseal nonunion fracture humerus is more complex after previous

Figure 7



patients number

Pre and postoperative DASH score for each patient..

IMN than after previous nonoperative treatment or previous plate osteosynthesis. This can be explained by the injury to the rotator cuff that occurred with the antegrade insertion of IMN, with further damage if the nail extrudes from the proximal humerus, and

bone loss due to excessive motion of a loose IMN [17]. An additional injury can occur during IMN removal. If the IMN was properly sunk below the cortex, it can be hard to detect and retrieve. In a substantial number of cases, a variable amount of bone must be removed,

causing further injury to the rotator cuff. When the IMN is firmly fixed to the distal fracture fragment or adjacent cortices, forceful removal can cause iatrogenic fracture intraoperatively, especially in osteoporotic patients [18].

While revising and managing the causes of the nonunion after IMN humerus in our institute, we had to select suitable intervention options for these patients. In this study, we planned to counter mechanical causes by using locked plate fixation, and counter the biological causes by iliac bone graft in both hypertrophic and oligotrophic nonunions to fill the gaps and give these patients the best chance, avoiding further intervention. The logical question was: is nail removal mandatory? In this study, we selected the patients for whom nail removal is either technically demanding or even harmful causing further damage to the rotator cuff (deeply seated IMN). IMN retaining while revising the fixation and adding bone graft was supported in the literature [13–15] we hypothesized that nail removal in these selected patients would be unnecessary, and the addition of plate fixation with bone graft would be adequate.

Gessman et al. [13] in 2016, conducted a retrospective study, using anterior augmentation plate in 37 patients (mean age 51) who had aseptic diaphyseal nonunion (31 atrophic and three hypertrophic) with previous IMN (10 retrogrades and 27 antegrade nails). Gerber et al. [15] in 2003 used wave contoured plate and autologous bone graft prospectively on six patients through an anterior approach, and Ring et al. [16] in 2004 used locked plates prospectively on six patients. Allende et al. [19] prospectively used minimally invasive osteosynthesis (long 3.5 locked plates) bridging the nonunion in nine patients with oligotrophic aseptic diaphyseal nonunion after IMN humerus (seven antegrade and two retrogrades) through two 4-6 cm incisions one proximal trans deltoid and one distal releasing and protecting the radial nerve. In this study, 28 patients (20 oligotrophic and eight hypertrophic nonunion after antegrade IMN) were operated upon prospectively using a posterior approach (as surgeon preference) to expose, protect and perform neurolysis of the radial nerve if needed.

Gessman et al. [13] reported union in 97% in a mean of 6 months, with one case of iatrogenic median nerve palsy (recovered spontaneously after 6 weeks), one case of a peri-implant stress fracture which needed exchange of the plate, there were no infections, and all patients had free range of motion in elbow and shoulder. Gerber et al. [15] reported union in 100% of their six patients with full function at the elbow and shoulder in all except one patient who had postoperative radial nerve palsy (recovered partially, and needed no intervention). Ring et al. [16] reported union in 100% of their six patients with one patient having a slight limitation of shoulder motion and another one having a slight limitation in elbow motion. All previously mentioned studies did not use functional objective scores for clinical assessment and did not describe in degrees motion limitation if present.

Allende et al. [19] reported union in 100% of their nine patients in average 4.8 months with full function at the elbow and shoulder. They used the DASH score, Constant's score of shoulder function, and the VAS pain scale for clinical assessment. They had no infection or postoperative nerve palsy. Our study shows matched results regarding rates of union (100% of our 28 patients) and timing of union (average 4.3 months). We used the DASH score and VAS pain scale for clinical assessment and the results coincide with Allende et al. [19]. In this study, no postoperative nerve palsy or periprosthetic fracture, or another surgical interference was needed. Only two cases had a superficial infection which healed by antibiotics according to culture and sensitivity.

When choosing to retain the IMN in place and to add a plate, it is important to assess (a) the type of IMN used (to identify the locking system and protrusion beyond the cortex), (b) the type of nonunion (to exclude infection, determine bone contact and the size of the bone gap), and (c) amount of the medullary canal occupied by the IMN (to estimate the length of the plate and type, direction and presumed length of the screws to be used) [20]. In this study, we agreed with the previously mentioned IMN retaining studies that leaving the IMN in situ when there were no removal prerequisites (e.g. infection or protrusion) much decreases the risk of shoulder injury; it reduces operative time compared with revision by extraction of previous IMN and helps reducing hospitalization time.

The advantage of using 3.5 mm LCP included fixation enhancement in thinned humerus cortices (by the windshield effect of loose IMN), It allowed the use of monocortical screws in segments where the retained IMN occupies most of the medullary canal leaving no space for placement of bicortical screws, The screws limit the space around the nail preventing further windshielding or further bone loss and improve implant-bone interface stability.

This study achieved important goals: realizing the size of the problem of aseptic nonunion after IMN humerus (28 patients in our institute) (changing our perspective toward the IMN humerus as a tool), outlining detailed prerequisites for nail retaining described reproducible surgical technique and accomplished excellent objective and subjective outcomes with minimal complications. The shortcomings in this study include a lack of comparison between results in IMN retaining and nonretaining, the study is not large enough to introduce a consensus, and the lack of longer follow-up. Future studies should address the previously mentioned points and favorably provide us with a meta-analysis and clear edge guidelines.

Conclusion

Surgical Treatment of humerus aseptic nonunion after intramedullary nailing using an Augmentation 3.5 LCP and bone graft with a nail in situ achieved excellent clinical and radiological outcomes with minimal complications and so, as long as the criteria of nail retaining are met, nail removal is not mandatory.

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Institutional review board statement

The Institutional Review Board have reviewed this research and allowed the experimental protocol.

Data availability statement

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Author contributions

Conceptualization, investigation, methodology, formal analysis, software writing-original draft: S.E.-A., A.H.I. and Y.S.; investigation, methodology, formal analysis, validation, re-sources: S.E.-A., A.H.I.; resources, data curation, validation, writing-review and editing, visualization and funding acquisition: Y.S. All authors have read and agreed to the published version of the manuscript.

Conflicts of interest

There are no conflicts of interest.

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