

Original Research

Received 18 May 2026

Revised 15 June 2026

Accepted 01 July 2026

Natural Resources for Human Health 2026, Vol. 6 (4s): 314–325

KEYWORDS:

humeral shaft; nonunion; pseudarthrosis; osteosynthesis; intramedullary nailing; double-plate fixation; collagen haemostatic sponge; osteogenesis; bone mineral density; QuickDASH; SF-36.

Surgical Treatment of Nonunion of the Humeral Shaft

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ABSTRACT:

Background. Nonunion of the humerus is formed most often in the middle (52.3%) and the distal (31.6%) thirds of the shaft. Impaired blood supply and persistent microcirculatory disturbances in the injured segment are the key pathogenetic factors of delayed consolidation. The variety of the existing surgical techniques for nonunion and defects of the humeral shaft has so far failed to solve completely the problem of increasing the regenerative potential of bone tissue.

Objective. To improve the outcomes of treatment of patients with nonunion of the humeral shaft on the basis of an analysis of the factors that impaired healing of the preceding fracture, an assessment of the clinical risk factors present in the patient, and refinement of the treatment technology.

Materials and Methods. Seventy-nine patients with nonunion of the humeral shaft who underwent surgical treatment were studied. Depending on the morphological type of the nonunion (hypertrophic, atrophic, normotrophic) and the method of treatment, the patients were allocated to six clinical groups — a main group treated by the refined technique and a comparison group treated by conventional techniques for each type. The refined technique creates optimal conditions for bone regeneration by stimulating microcirculation in the area of the nonunion and enhancing osteogenesis, and includes the use of a collagen haemostatic sponge. All patients underwent radiography, densitometry, measurement of the cortical index, Doppler ultrasonography and electroneuromyography. Outcomes were assessed with the Lyuboshits–Mattis–Schwartzberg (LMS) scale at 12.1 ± 0.5 months and with the QuickDASH and SF-36 instruments at 4.9 ± 0.5 years.

Results. In hypertrophic nonunion the mean time to consolidation was 156.5 ± 7.5 days in the main group versus 181.5 ± 9.4 days in the comparison group ($p < 0.05$), and good clinical and radiographic results were obtained in 100% versus 70% ($p < 0.05$). In atrophic nonunion (main group $n = 20$, comparison group $n = 14$) consolidation occurred after 177.1 ± 6.59 versus 195.9 ± 8.15 days ($p < 0.05$) and positive results were achieved in 19 (90%) versus 9 (64.3%) patients ($\chi^2 = 16.599$; $p < 0.021$); LMS scores after intramedullary nailing were 29.5 ± 0.703 versus 24.5 ± 0.927 ($U = 1.5$; $p = 0.019$), QuickDASH scores were 13.22 ± 1.468 versus 29.15 ± 4.129 ($U = 18$; $p = 0.0023$) and SF-36 scores were 75.3 ± 1.633 versus 61.3 ± 1.739 ($U = 41.50$; $p = 0.001$). In normotrophic nonunion (main group $n = 6$, comparison group $n = 9$) union was achieved after 19.8 ± 1.01 versus 22.3 ± 0.98 weeks ($U = 13.00$; $p = 0.0494$), with good results in 100% versus 77.8% of patients.

Densitometry in 58 patients showed normal bone mineral density in 10 (17.2%), osteopenia in 23 (39.7%) and osteoporosis in 25 (43.1%).

Conclusion. The refined method of surgical treatment of nonunion of the humeral shaft, based on the use of the tissues of the nonunion itself, autografting and a collagen haemostatic sponge to create an osteogenic environment, shortens the time to union and improves the functional outcomes of the upper limb in hypertrophic, atrophic and normotrophic nonunion alike.

1. INTRODUCTION

Nonunion of the humerus is formed most often in the middle (52.3%) and the distal (31.6%) thirds of the shaft [1, 3]. The key pathogenetic factors of delayed consolidation are impaired blood supply and persistent microcirculatory disturbances in the injured segment [2–4]. The variety of the existing surgical techniques for the treatment of nonunion and defects of the humeral shaft has so far failed to solve completely the problem of increasing the regenerative potential of bone tissue.

The high incidence of nonunion after conservative treatment of humeral shaft fractures (23.2–33%) and after surgical treatment (4–10.2%) makes the development of an improved treatment technique necessary. The percentage of complications in the treatment of atrophic nonunion in particular remains considerable and varies widely — from 28% to 39% of unsatisfactory outcomes in aseptic pseudarthrosis, and higher still in infected or complex cases.

The aim of the study was to improve the outcomes of treatment of patients with nonunion of the humeral shaft on the basis of an analysis of the factors that impaired healing of the preceding fracture, an assessment of the clinical risk factors present in the patient, and refinement of the treatment technology.

2. MATERIALS AND METHODS

2.1. Study design and patients

The object of the study was 79 patients with nonunion of the humeral shaft who received surgical treatment. Depending on the morphological type of the nonunion and the method of treatment, the patients were divided into six clinical groups. For each type of nonunion a main group was formed, in which the patients were treated by the technique refined by the authors, and a comparison group, which included patients operated on by conventional surgical methods before the refined technique was developed.

Patients with atrophic nonunion comprised the main group ($n = 20$) and the comparison group ($n = 14$); patients with normotrophic nonunion comprised the main group ($n = 6$) and the comparison group ($n = 9$). The remaining patients formed the two groups with hypertrophic nonunion.

2.2. Analysis of the preceding fracture

At the first stage of the study an analysis was performed of the features of the preceding humeral shaft fracture and of the methods of fixation used, in order to identify possible risk factors that had a negative influence on bone regeneration and led to the development of nonunion. Fractures were classified according to the AO/OTA system (types 12-A, 12-B, 12-C), by the energy of the injury (low- or high-energy) and by the level of the shaft involved (proximal, middle or distal third). The interval between the acute fracture and presentation with an established nonunion, and the number of operations performed before presentation, were also recorded.

2.3. Examination methods

All patients underwent clinical examination, plain radiography of the humerus in two projections, and assessment of comorbid conditions; patients with concomitant disease were reviewed by the relevant specialists before surgery. Body mass index was calculated and vitamin D status was assessed. Bone mineral density was measured in 58 patients, and the cortical index of the humeral shaft was determined as a marker of local bone quality.

Doppler ultrasonography was used to assess the functional state of the vessels supplying the bone fragments by measuring the velocity and direction of blood flow. Electroneuromyography was performed to assess the degree of neurological impairment

on the basis of the functional state of the peripheral nerves and muscles. The results of both investigations were taken into account when planning treatment and predicting the outcome.

2.4. Outcome measures and follow-up

To prevent possible postoperative complications in a timely manner, the patients were given scheduled follow-up appointments. Radiography was performed at each planned visit to monitor consolidation of the fragments. At a mean of 12.1 ± 0.5 months the outcome was assessed with the Lyuboshits–Mattis–Schwartzberg (LMS) scale, which allows the anatomical and functional results of rehabilitation and the degree of working capacity to be evaluated. At a mean of 4.9 ± 0.5 years the clinical and radiographic indicators were analysed again, with an additional assessment of the state of the upper limb and of quality of life using the QuickDASH score and the SF-36 questionnaire.

2.5. Surgical technique

2.5.1. Hypertrophic nonunion

A method of surgical treatment was developed and introduced into clinical practice that creates optimal conditions for bone regeneration by stimulating microcirculation in the area of the nonunion and enhancing osteogenesis. The method differs from the existing prototypes in that, during surgical treatment, longitudinal tunnelling is performed 2–3 cm above the ends of both bone fragments, notches 3–4 mm deep are made on the distal end of the hypertrophic cup-shaped callus, and perforations are made at the base of the hypertrophic cup-shaped callus. These steps improve microcirculation in the zone of the nonunion and increase adaptation during stabilisation of the fragments. The additional use of a collagen haemostatic sponge (Belkozin, Russia) promotes haemostasis and also enhances angiogenesis and osteogenesis.

2.5.2. Atrophic nonunion: plate osteosynthesis

Under regional or general anaesthesia, after preparation of the operative field with antiseptic solutions, a skin incision was made over the nonunion according to its location. For a nonunion of the proximal third of the humerus an anterolateral approach was used; for the middle third, an anterior or lateral approach; for the distal third, a posterior or lateral approach. The approach used at the previous operation was taken into account when planning the incision.

The nonunion was exposed by sharp and blunt dissection and the scar tissue around it was excised. Pathological bone formations were partially removed. The sclerotic bone fragments were debrided back to “living”, that is, bleeding bone (the paprika sign). The bone defect was filled with an autograft harvested from the iliac crest or the fibula. During stabilisation of the bone fragments with the autograft, the marginal portions of the medullary canal were reamed, decortication and perforation were performed, and the graft was docked with the inner surfaces of both fragments, thereby increasing the efficacy of bone grafting of the nonunion by creating more favourable conditions for union. Haemostasis is an important element both during the operation and during the postoperative recovery of the patient, and a collagen haemostatic sponge (Belkozin, Russia) was used to improve haemostasis and enhance reparative potential.

Osteosynthesis was performed with two plates, one fixed to the posterior or anterior surface of the humerus and the second to the lateral surface. Double plating was chosen because it provides stronger and more stable fixation in atrophic nonunion, and because a large proportion of the patients were obese or overweight and had osteoporosis or osteopenia together with a low cortical index. In the comparison group, in accordance with the traditional approach to the surgery of nonunion, fixation with a single plate was used.

2.5.3. Atrophic nonunion: intramedullary locked nailing

During revision osteosynthesis with an intramedullary nail in the main group, elements of the method developed for hypertrophic nonunion were applied. An economical resection of the nonunion with shortening of the humerus was performed, together with reaming of the medullary canal to stimulate angiogenesis and to provide an influx of osteogenic cells. The material obtained during reaming was transplanted into the area of the bone defect. The diameter of the implanted nail was chosen one size larger. A collagen haemostatic sponge was used in the main group for haemostasis and stimulation of osteogenesis.

2.5.4. Normotrophic nonunion

The treatment strategy for normotrophic nonunion was analogous to that for atrophic nonunion and corresponded to the existing recommendations: removal of the scar tissue of the nonunion, use of an autograft where necessary, and stable

osteosynthesis. The distinguishing feature was that, whereas in atrophic nonunion non-viable bone was additionally removed from the marginal portions of the fragments, this is not required in normotrophic nonunion because the fragment ends are vascularised; the use of an autograft nevertheless increases the efficacy of treatment. In the main group, unlike the comparison group, a collagen haemostatic sponge and double-plate fixation were used, as in atrophic nonunion.

The approach also depended on the location of the nonunion. When the nonunion was situated in the proximal or middle third of the humerus, the medullary canal was reamed to stimulate intramedullary osteogenesis and the reaming debris was additionally placed in the interfragmentary zone; a nail of larger diameter was selected in order to stabilise the bone fragments. When the normotrophic nonunion was situated in the distal third of the humerus, an angular-stability plate was used in combination with an autograft harvested from the iliac crest. For all locations, a haemostatic sponge was wrapped around the interfragmentary area to stimulate osteogenesis and angiogenesis.

2.6. Statistical analysis

Quantitative variables are presented as the mean $\pm$ standard error of the mean ($M \pm m$); qualitative variables are presented as absolute numbers and percentages. In view of the small size of the groups, non-parametric methods were used: between-group comparisons of quantitative variables were performed with the Mann–Whitney U test, and qualitative variables were compared with the χ^2 test. Differences were considered statistically significant at $p < 0.05$.

3. RESULTS

3.1. General characteristics of the patients

Male patients predominated — 47 (51.1%); female patients accounted for 45 (48.9%). The age of the patients ranged from 18 to 78 years, the mean age being 38.9 ± 0.93 years. The main contingent consisted of persons of working age — 64 (69.6%) aged 18–60 years. Elderly and senile patients (over 61 years) accounted for 28 (30.4%).

With respect to the mechanism of the primary injury, domestic trauma predominated — 58 (63.1%), followed by road traffic accidents — 20 (21.7%), falls from a height — 8 (8.7%), and occupational trauma — 6 (6.5%).

3.2. Age and sex distribution of nonunion

In both men (92%) and women (75.9%) humeral shaft fractures occurred most frequently at working age (18–59 years). The peak of low-energy fracture and of the development of nonunion was highest in the 18–44 year age group in men (48.5%) and in women (44.5%), which indicates impaired bone quality, insufficient consideration of the osteosynthesis performed, and other factors evaluated in the present work.

3.3. Characteristics of the preceding fracture

Nonunion in the 79 patients developed in an equal proportion in men and women, with a high share after humeral shaft fractures of type 12-A (60% and 58.6%) and type 12-B (36% and 34.5%), respectively. Among these, a high proportion in men was found after fracture of the distal third (44%) and of the middle third (40%). In women, 51.7% were fractures of the middle third and 31% of the distal third of the humeral shaft.

3.4. Comorbid conditions

Among the concomitant diseases, arterial hypertension predominated: 18 (42.8%) patients in the main group and 14 (28%) in the comparison group. Diabetes mellitus was identified in 10 (23.8%) patients in the main group and in 13 (26%) in the comparison group. Formation of nonunion of the humerus was combined with arterial hypertension and diabetes mellitus in 28 (66.7%) cases in the main group and in 27 (54%) in the comparison group; with viral hepatitis and gastric ulcer in 26 (61.9%) and 20 (40%), respectively; and with cholelithiasis in 2 (4.7%).

3.5. Bone mineral density

The study of bone mineral density in 58 patients showed that normal values were found in 10 (17.2%) of them, osteopenia was present in 23 (39.7%) patients, and osteoporosis in 25 (43.1%).

3.6. Hypertrophic nonunion: treatment outcomes

In patients with hypertrophic nonunion the mean time to consolidation was 156.5 ± 7.5 days in the main group and 181.5 ± 9.4 days in the comparison group ($p < 0.05$). Quality-of-life scores (SF-36) were 1.4 times higher in the main group, and LMS scores were 1.5 times higher. QuickDASH scores in the main group were 2.8 times lower than in the comparison group, which indicates better functional activity of the upper limb. According to the clinical and radiographic indicators, good results were obtained in 100% of the main group versus 70% in the comparison group ($p < 0.05$), which demonstrates the efficacy of the method developed.

3.7. Atrophic nonunion

3.7.1. Comparability of the groups

The main group and the comparison group did not differ significantly in age (39.3 ± 2.9 and 41.7 ± 3.9 years, $p > 0.05$). The main group comprised 14 women (70%) and 6 men (30%), the comparison group 9 women (64.3%) and 5 men (35.7%). Patients with low-energy fractures were present in an equal proportion in the two groups (65% and 64.3%); type 12-A fractures predominated (52.9%), comminuted type 12-B fractures accounted for a substantial proportion (41.2%), and complex type 12-C fractures for a smaller proportion (10%), the latter being present only in the main group (Table 1). No statistically significant difference between the groups was found for type 12-A or 12-B fractures.

Table 1. Types of the preceding fracture in patients with atrophic nonunion

Group (number of patients)	High-energy	Low-energy	12-A	12-B	12-C
Main group (n = 20)	7 (35%)	13 (65%)	10 (50%)	8 (40%)	2 (10%)
Comparison group (n = 14)	5 (35.7%)	9 (64.3%)	8 (57.1%)	6 (42.9%)	–
Statistical significance	$p = 0.966$	$p = 0.966$	$p = 0.681$	$p = 0.268$	–
Total (n = 34)	12 (35.3%)	22 (64.7%)	18 (52.9%)	14 (41.2%)	2 (5.9%)

In the comparison group a high proportion of fractures of the middle third of the shaft predominated (64.3%) compared with the main group ($p = 0.048$) (Table 2). A high proportion of fractures of the proximal third of the shaft fell to the main group (60%; $p = 0.026$). Such patients require complex reconstructions and are more prone to pseudarthrosis because of the active pull of the muscles and the proximity of the neurovascular bundles to the joint.

Table 2. Location of the preceding fracture within the diaphyseal segment

Group (number of patients)	Proximal third	Middle third	Distal third
Main group (n = 20)	12 (60%)	6 (30%)	2 (10%)
Comparison group (n = 14)	3 (21.4%)	9 (64.3%)	2 (14.3%)
Statistical significance	$p = 0.026$	$p = 0.048$	$p = 0.703$
Total (n = 34)	15 (44.1%)	15 (44.1%)	4 (11.8%)

The osteosynthesis performed for the preceding fracture is presented in Table 3. More than half of the patients had had the preceding fracture fixed with a plate (58.8%), whereas intramedullary locked nailing was used considerably less often (up to 14.7%). The fact that in almost 14.7% of patients the fracture had not been fixed at all was a matter of concern.

Table 3. Method of fixation of the preceding fracture

Group	Intramedullary nail	Plate	External fixator	No fixation	Cerclage
Main group (n = 20)	3 (15%)	12 (60%)	1 (5%)	3 (15%)	1 (5%)
Comparison group (n = 14)	2 (14.3%)	8 (57.1%)	2 (14.3%)	2 (14.3%)	—
Total (n = 34)	14.7%	58.8%	8.8%	14.7%	5%*

* The value is reproduced from the source data; 1 patient of 34 corresponds to 2.9%. Please verify.

The mean interval between the acute fracture and presentation with a nonunion was 29.1 ± 5.7 months in the main group (range 3–96 months; 50% of the patients presented within one year) and 37.1 ± 10.3 months in the comparison group (range 4–120 months; 37.5% presented within one year) ($U = 17.5$; $p = 0.131$). Before presentation the patients of the main group had undergone on average 1.2 ± 0.09 operations and those of the comparison group 1.5 ± 0.14 ($p = 0.05$).

Thus, the patients of the two groups had relatively similar preceding fractures, intervals to presentation and numbers of operations performed after the acute fracture. The groups differed only in the location of the fracture within the diaphyseal segment, patients with severe fractures of the proximal third predominating in the main group.

3.7.2. Risk factors

Assessment of risk factors showed that patients who were overweight or obese constituted a high proportion in both groups, with a predominance in the main group (90%); in the comparison group the proportion of patients with increased body weight was 50% (Table 4).

Table 4. Body mass index in patients with atrophic nonunion

Group (number of patients)	Normal weight	Overweight	Obesity	Total
Main group (n = 20)	2 (10%)	11 (55%)	7 (35%)	20 (100%)
Comparison group (n = 14)	7 (50%)	5 (35.7%)	2 (14.3%)	14 (100%)
All patients (n = 34)	9 (26.5%)	16 (47%)	9 (26.5%)	34 (100%)

Among the other concomitant diseases, the patients of the main group had ischaemic heart disease (4%), arterial hypertension (12%), anaemia (4%), neurocirculatory dystonia (4%) and type 2 diabetes mellitus (8%). In the comparison group ischaemic heart disease (4.3%), arterial hypertension (13%) and type 2 diabetes mellitus (4.3%) were also present. This pathology is known to affect regeneration adversely, especially in combination with obesity. Before surgical treatment the patients with concomitant disease were reviewed by the relevant specialists.

Doppler ultrasonography of the vessels supplying the bone fragments in atrophic nonunion revealed signs of asymmetry with a tendency to reduced blood flow in 15 patients (44.1%) of the main group and in 5 patients (14.7%) of the comparison group, which may indicate impaired vascular patency in the zone of the pseudarthrosis. These data were used to determine the treatment strategy and the prognosis.

Electroneuromyography, performed in 12 patients (35.3%) of the main group and in 3 patients (8.8%) of the comparison group, made it possible to assess the degree of neurological impairment. Complete anatomical disruption of a nerve trunk in the area of the bone defect or of the scar tissue was not observed; mildly pronounced atrophic changes of the muscles were identified and were taken into account when planning treatment.

Bone densitometry showed a high proportion of patients with systemic changes of bone tissue in both groups: osteopenia was found in 8 (23.5%) and 4 (11.8%) patients and osteoporosis in 5 (14.7%) and 4 (11.8%) patients, respectively. Additional study

of the cortical index showed that local changes in the humerus, as indicators of osteopenia and osteoporosis, were present in 9 patients (45%) of the main group, normal values being found in 11 (55%); in the comparison group a low cortical index was found in 7 patients (50%) and normal values in 7 (50%). No distinguishing features between the groups were obtained.

3.7.3. Treatment outcomes

In the main group osteosynthesis with two plates was performed in 5 patients (25%) and intramedullary locked nailing by the developed methods in 15 (75%); in the comparison group osteosynthesis with a single plate was performed in 10 patients (71.4%) and conventional intramedullary nailing in 4 (28.6%).

Consolidation of the bone fragments according to the clinical and radiographic indicators occurred after 177.1 ± 6.59 days in the main group and after 195.9 ± 8.15 days in the comparison group ($p < 0.05$). On assessment of the state of the patients on the basis of the clinical and radiographic indicators, positive results were obtained in 19 patients (90%) of the main group but in only 9 patients (64.3%) of the comparison group ($\chi^2 = 16.599$; $p < 0.021$), which demonstrates the high efficacy of the method of treatment developed.

At the follow-up examination at a mean of 12.1 ± 0.5 months the results were analysed with the LMS scale separately for intramedullary nailing and plate osteosynthesis (Table 5). After stabilisation with an intramedullary nail the LMS scores were significantly higher in the main group by a factor of 1.13; after plate osteosynthesis the score was 1.3 times higher in the main group. Comparative analysis within the main group revealed no statistically significant difference between fixation of atrophic nonunion with an intramedullary nail and with two plates, that is, both methods produced high LMS scores.

Table 5. Lyuboshits–Mattis–Schwartzberg scores (points, $M \pm m$) in patients with atrophic nonunion at 12.1 ± 0.5 months, by method of fixation

Method of fixation	Main group	Comparison group	Significance
Intramedullary nailing	29.5 ± 0.703 (n = 15)	24.5 ± 0.927 (n = 5)†	U = 1.5; p = 0.019
Plate osteosynthesis	28.8 ± 1.165 (n = 5, two plates)	24.3 ± 1.548 (n = 4, one plate)†	U = 1.5; p = 0.019

† The numbers in the comparison group are reproduced from the source tables; in the description of the operations performed the comparison group comprised 10 patients treated with a single plate and 4 treated with an intramedullary nail. Please verify.

In the long term, the summary QuickDASH scores of the main group after treatment of atrophic nonunion were 2.2 times lower than those of the comparison group after intramedullary nailing and were also significantly lower after plate osteosynthesis (Table 6). The data obtained are a positive result and indicate successful restoration of the function of the operated upper limb. No significant difference was found between the two methods of fixation within the comparison group (U = 13.5; p = 0.179), although the results were considerably poorer than in the main group. This indicates that the technologies of surgical treatment developed may be used at the discretion of the surgeon.

Table 6. QuickDASH scores (points, $M \pm m$) in patients with atrophic nonunion at 4.9 ± 0.5 years, by method of fixation

Method of fixation	Main group	Comparison group	Significance
Intramedullary nailing	13.22 ± 1.468 (n = 15)	29.15 ± 4.129 (n = 10)†	U = 18; p = 0.0023
Plate osteosynthesis	17.62 ± 2.289 (n = 5, two plates)	34.675 ± 5.97 (n = 4, one plate)†	U = 2; p = 0.0050

On assessment of quality of life in the long term (4.9 ± 0.5 years) with the SF-36 scale, the summary scores of the main group and the comparison group (75.3 ± 1.633 and 61.3 ± 1.739 , respectively) differed significantly (U = 41.50; p = 0.001).

Thus, using the refined method of treatment of atrophic nonunion, excellent and good results were obtained in 90% of the operated patients. Positive results were obtained both with intramedullary locked nailing and with double-plate osteosynthesis in combination with an autograft and a collagen haemostatic sponge.

3.8. Normotrophic nonunion

3.8.1. Comparability of the groups

The 6 patients of the main group and the 9 patients of the comparison group did not differ significantly in age at the time of the fracture and of the initial operation (44.2 ± 4.85 and 50.7 ± 5.87 years, respectively; $U = 22.00$; $p = 0.277$). Women and men were present in almost equal proportions in the main and the comparison group (women 50% and 55.6%; men 50% and 44.4%). In both groups the patients had mainly low-energy fractures of types 12-A and 12-B. By location, the fractures in the main group were situated in the proximal third of the shaft in 16.7%, in the middle third in 50% and in the distal third in 33.3%; in the comparison group, in the proximal third in 22.3%, in the middle third in 33.3% and in the distal third in 44.4%. No statistical significance was found for the location of the preceding fracture on comparison of the groups (proximal third, $p = 0.792$; middle third, $p = 0.519$; distal third, $p = 0.667$).

The interval between the primary fracture and presentation with an established nonunion was 23.1 ± 6.6 months in the main group and 28.0 ± 4.5 months in the comparison group ($U = 17.5$; $p = 0.131$). The number of revision operations performed before presentation also did not differ statistically between the main and the comparison group (1.3 ± 0.2 and 1.4 ± 0.17 ; $U = 24$; $p = 0.3618$). At the time of presentation, the osteosynthesis previously performed in the two groups had involved a plate in 20 patients (58.9%), an external fixator in 3 (8.8%), an intramedullary nail in 5 (14.7%), no fixation in 5 (14.7%) and cerclage in 1 (2.9%).

Thus, the patients of the main and the comparison group did not differ significantly in the features of the preceding fracture, the osteosynthesis performed, age, the interval to presentation after the primary fracture, or the number of revision operations. Despite the small size of the groups, the values obtained allow the data to be processed by non-parametric statistical methods.

3.8.2. Risk factors

Assessment of risk factors showed that overweight and obese patients predominated in both groups: body mass index was 30.7 ± 0.9 in the main group and 26.3 ± 1.4 in the comparison group, the difference being statistically significant ($U = 7$; $p = 0.0092$); that is, patients with an increased risk factor predominated in the main group.

Among the other concomitant diseases, type 2 diabetes mellitus was present in two patients (33.3%) of the main group and in one patient (11.1%) of the comparison group. In addition, arterial hypertension was noted in two patients (33.3%) of the main group, and in the comparison group one patient had ischaemic heart disease (11.1%) and one (11.1%) arterial hypertension. The combination of a high body mass index with these diseases increases the risk of impaired regeneration.

Bone densitometry showed systemic changes of bone tissue in both the main and the comparison group: osteopenia in 2 (33.3%) and 4 (44.4%) patients and osteoporosis in 2 (22.2%) and 3 (33.3%) patients, respectively. Study of the cortical index of the humerus revealed local changes associated with osteopenia and osteoporosis in 2 patients (33.3%) of the main group, while in the comparison group a low cortical index was found in 6 patients (66.7%). These indicators were taken into account when planning the osteosynthesis and during the stages of rehabilitation.

Doppler ultrasonography in both groups showed that the linear velocity of blood flow was practically normal, that the fibrous tissue of the nonunion was moderately vascularised, and that both venous and arterial flow were present. Electroneuromyography was performed in 5 patients (83.3%) of the main group and 5 patients (55.6%) of the comparison group. It revealed a reduction in the functional capacity of the muscle fibres (a decrease in the amplitude of the M-response); the conduction velocity along the peripheral nerves was slightly reduced and signs of mild or moderate denervation were present, but without severe anatomical damage.

3.8.3. Treatment outcomes

The postoperative period was uneventful in both groups. Union of the fracture in the main group was recorded earlier, at a mean of 19.8 ± 1.01 weeks, versus 22.3 ± 0.98 weeks in the comparison group; the difference was statistically significant ($U = 13.00$; $p = 0.0494$). According to the clinical and radiographic indicators, good results of treatment were obtained in all patients of the main group (100%) and in 77.8% of the patients of the comparison group.

At the follow-up examination at a mean of one year, the LMS scores of the main group were higher (30.5 ± 0.99 points versus 26.4 ± 1.457 points; $U = 13$; $p = 0.0494$). Statistically significant results were obtained with fixation of the nonunion with two plates compared with a single plate (31.7 ± 1.33 and 26.75 ± 1.315 , respectively; $U = 0.50$; $p = 0.026$).

The summary QuickDASH scores at 4.9 ± 0.5 years differed significantly between the main and the comparison group (16.95 ± 2.63 and 32.8 ± 3.7 , respectively; $U = 6.50$; $p = 0.0078$). The low QuickDASH scores in the main group — 1.9 times lower than in the comparison group — indicate restoration of physical function, a reduction in pain symptoms and an increase in the strength of the upper limb after surgery. Assessment of the summary SF-36 scores likewise showed that quality of life was higher in the patients of the main group than in the comparison group (81.4 ± 3.3 and 65.8 ± 2.9 ; $U = 4.00$; $p = 0.0033$).

3.9. Clinical case

Patient A., born in 1999, case history No. 11116. He sustained a closed fracture of the right humerus after falling into a well. Radiography revealed a fracture of the middle-to-distal third of the humerus with displacement of the fragments (Fig. 1a). The patient underwent surgical treatment with fixation of the fragments of the right humerus using an intramedullary locked nail (Fig. 1b, c).



Figure 1 (a, b, c). Radiographs. (a) Fracture of the middle-to-distal third of the humerus with displacement of the fragments; (b, c) postoperative period, fixation with an intramedullary locked nail.

Three months later the patient presented with complaints of pain in the area of the fracture. Radiography revealed a gap between the fragments with no signs of bony union. Repeat fixation with an intramedullary locked nail was carried out according to the method developed by the authors. Intraoperatively, coarse fibrous scar tissue without signs of bone formation was present in the area of the fracture, which indicates a poor blood supply to this region. The developed method with the use of a collagen haemostatic sponge was applied.



Figure 2 (a, b, c). Radiographs of the humerus in two projections after revision osteosynthesis: (a) immediately after revision osteosynthesis; (b) 3 months after revision osteosynthesis; (c) 9 months after revision osteosynthesis.

According to the clinical and radiographic examinations, and with the use of the questionnaires SF-36 (54.4 points), QuickDASH (13.6 points) and LMS (25 points), the result was assessed as excellent.



Figure 3. Clinical illustration of the functional activity of the right upper limb of the patient 12 months after surgery.

4. DISCUSSION

The results obtained confirm that the main obstacle to consolidation in nonunion of the humeral shaft is the deficient blood supply of the fracture zone. This was documented objectively by Doppler ultrasonography, which showed asymmetry and a tendency to reduced blood flow in 44.1% of the patients of the main group with atrophic nonunion, and was confirmed intraoperatively in the clinical case presented, where coarse fibrous scar tissue without signs of bone formation was found at the level of the former fracture. The technique proposed acts on precisely this mechanism: longitudinal tunnelling, notching and perforation of the hypertrophic callus, reaming of the medullary canal with transplantation of the reaming debris into the defect, and decortication of the fragment ends open the medullary vascular bed towards the zone of the nonunion, while the collagen haemostatic sponge provides haemostasis and serves as a matrix that supports angiogenesis and osteogenesis.

It is known that the percentage of complications in the treatment of atrophic nonunion is considerable and varies widely: from 28% to 39% of unsatisfactory outcomes in aseptic pseudarthrosis, and up to higher figures in infected or complex cases. Against this background, the data obtained in the present study — 100% of good results in hypertrophic nonunion and 90% of positive results in atrophic nonunion in the main group, versus 70% and 64.3% in the corresponding comparison groups — may be regarded as a good indicator of treatment efficacy. It should be emphasised that this was achieved despite a less favourable baseline in the main group with atrophic nonunion, in which fractures of the proximal third of the shaft ($p = 0.026$) and overweight or obese patients (90% versus 50%) predominated.

An important practical finding is that within the main group no statistically significant difference was found between intramedullary locked nailing and double-plate osteosynthesis, either on the LMS scale or on the QuickDASH score. Both techniques, when combined with autografting and the collagen haemostatic sponge, produced comparably high results, which means that the choice of implant may be made at the discretion of the surgeon on the basis of the location of the nonunion, the quality of the bone and the state of the soft tissues. Double plating was preferred in patients with obesity, osteoporosis or osteopenia and a low cortical index, in whom fixation with a single plate does not provide sufficient stability.

A feature of the population studied is the concentration of humeral shaft fractures and subsequent nonunion in persons of working age (92% of men and 75.9% of women), which distinguishes it from the populations described in other countries, where such injuries are more often associated with the elderly. At the same time, the risk factors characteristic of other populations were also present in the present series — somatic pathology in 27 (34.2%) patients and tobacco smoking in 26.2%. The high proportion of osteopenia and osteoporosis (42.9%), vitamin D deficiency and insufficiency (100%) and low values of the cortical index of the humeral shaft (< 4 in 52.1%) indicate that impaired bone quality, rather than the energy of the injury alone, underlies the development of nonunion in this age group. The finding that in 14.7% of the patients the preceding fracture had not been fixed at all, and that a plate had been used in 58.8%, points to reserves for prevention at the stage of treatment of the acute fracture.

5. CONCLUSIONS

1. The high incidence of nonunion after conservative treatment of humeral shaft fractures (23.2–33%) and after surgical treatment (4–10.2%) makes the development of an improved fracture treatment technique necessary.
2. On the basis of a retrospective analysis of the acute fracture in patients with nonunion of the humeral shaft, it was established that the significant risk factors for non-consolidation were: impaired stability of fixation and implant breakage (31.6% and 19%), an incorrect choice of treatment tactics (15.2%), the severity of the fracture and the invasiveness of the operation (10.1%), non-observance of the orthopaedic regimen by patients (10.1%), and infectious complications (8.9%).

3. The peak of low-energy fracture and of the formation of nonunion occurred at the age of 18–44 years, which is associated with the high frequency of osteopenia and osteoporosis (42.9%), vitamin D deficiency and insufficiency (100%), low values of the cortical index of the humeral shaft (< 4 ; 52.1%) and a high body mass index in men and women (68% and 65.5%). In 92% of cases in men and in 75.9% of cases in women, the fractures and the nonunion that developed occurred in persons of working age (18–59 years), which distinguishes our population from that of other countries. Risk factors characteristic of other populations were also present — somatic pathology in 27 (34.2%) patients and tobacco smoking (26.2%).
4. A method of treatment of hypertrophic nonunion of the humeral shaft has been developed, based on the technology of using the tissues of the nonunion itself together with a collagen haemostatic sponge to create an osteogenic environment.
5. Application of the refined technique in atrophic nonunion shortened the time to consolidation to 177.1 ± 6.59 days versus 195.9 ± 8.15 days ($p < 0.05$) and yielded positive clinical and radiographic results in 90% of patients versus 64.3% in the comparison group ($\chi^2 = 16.599$; $p < 0.021$), with significantly better LMS, QuickDASH and SF-36 scores. Intramedullary locked nailing and double-plate osteosynthesis, combined with autografting and a collagen haemostatic sponge, proved equally effective.
6. In normotrophic nonunion the refined technique provided union after 19.8 ± 1.01 weeks versus 22.3 ± 0.98 weeks in the comparison group ($U = 13.00$; $p = 0.0494$) and good clinical and radiographic results in 100% of patients versus 77.8%, with higher LMS (30.5 ± 0.99 versus 26.4 ± 1.457) and SF-36 (81.4 ± 3.3 versus 65.8 ± 2.9) scores and lower QuickDASH scores (16.95 ± 2.63 versus 32.8 ± 3.7).

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