

# Clinical efficacy analysis of minimally invasive intramedullary nailing in the treatment of humeral shaft fractures combined with radial nerve injury

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**Abstract. – OBJECTIVE:** The aim of this study was to research the therapeutic effectiveness of radial nerve damage paired with a humeral shaft fracture and intramedullary nailing.

**PATIENTS AND METHODS:** Retrospective research was performed on the medical records of 58 individuals who had humeral shaft fractures and radial nerve injuries. The admission period was between June 1, 2020, and June 31, 2022. All study subjects that satisfied the requirements for inclusion were separated, using the random number table approach, into two groups: one for internal fixation (group N), which included 29 cases, and one for minimally invasive procedures (group W), which included 29 patients. Group W received minimally invasive intramedullary nail treatment, and group N received internal fixation with compression plates. The changes in the clinical effects, surgery-related indicators, joint function, nerve function, and levels of stress indicators of the two groups of treatment were analyzed. The changes in adverse reactions and satisfaction of patients were compared.

**RESULTS:** The effective rate of group W was 89.66% (26/29), and that of group N was 72.41% (21/29). Although group W's effective rate was higher than group N's, there was no discernible disparity between the two groups ( $p>0.05$ ). Surgical blood loss and incision length were much smaller in group W than in group N, and overall operation duration and length of stay were considerably shorter in group W than in group N ( $p<0.05$ ). The excellent and good rate of elbow joint function in group W was 93.10% (27/29), whereas the excellent and good rate of group N was 65.52% (19/29). The excellent and good rate of elbow joint function in group W was considerably greater than that of group N ( $p<0.05$ ). In group W, the excellent and good rate of shoulder joint was 96.55% (28/29), and that in group N was 68.97% (20/29), and group W had a considerably greater probability of excellent shoulder joint function than group N ( $p<0.05$ ); the excellent and good rate of neurological function was 82.76% (24/29) in group W and 58.62% (17/29) in group N, and group W had much greater rates of excellent and good neurological function than group N ( $p<0.05$ ). prostaglandin E-2 (PGE2),

C-reactive protein (CRP) and Substance P (SP) levels in the W group and the N group were substantially higher after the surgery than they were prior to it ( $p<0.05$ ), and in the W group, the aforementioned stress markers were much lower than they were in the N group ( $p<0.05$ ). Group W experienced a 3.45% (1/29) rate of adverse events, while group N saw a 24.14% (7/29) incidence. The incidence of adverse responses was substantially lower in group W than in group N ( $p<0.05$ ). The contentment rate of group W was 93.10% (27/29), and that of group N was 72.41% (21/29). Group W had a much greater contentment percentage than group N ( $p<0.05$ ).

**CONCLUSIONS:** Minimally invasive intramedullary nailing is a successful therapeutic approach for humeral shaft fractures with radial nerve damage, which may successfully enhance patients' shoulder and elbow joint function and nerve function, reduce patients' stress response, and has the characteristics of minimal adverse responses and high contentment, which is worthy of popularization and deployment.

## Key Words:

Minimally invasive intramedullary nail, Humeral shaft fracture, Radial nerve injury, Clinical efficacy.

## Introduction

Humeral shaft fractures are a prevalent type of fragility fracture in the general population. According to relevant statistics<sup>1,2</sup>, humeral shaft fractures account for about 4% to 5% of all systemic fractures, and the incidence rate increases with the increase of age in patients. In addition, due to the close anatomical relationship between nerves, bones, and vascular tissues, peripheral nerves in patients are prone to injury<sup>3</sup>. The radial nerve, the most common of these nerve injuries, is often injured in fractures of the humeral shaft and usually occurs at the time of the initial injury. Studies<sup>4-6</sup> have found that the probability of radial nerve injury in patients with humeral shaft fractures may be between 7% and 16%. In

the past, splints, functional braces, plasters, and so on were mainly used for fixation in clinical practice, and certain effects have been achieved. However, when splints, functional braces, or plasters and other treatment methods are prone to certain adverse reactions, including fracture refractory healing, nonunion, etc., and their incidence rate exceeds 30%, this has a negative impact on patients' life quality<sup>7-9</sup>. Surgical treatment has been increasingly popular in recent years. Plate therapy is an important treatment method, but postoperative varus deformity and screw penetration, and other situations may occur<sup>10</sup>. With the development of science and technology, minimally invasive techniques are widely used in the treatment of humeral shaft fractures. Intramedullary nailing treatment has the advantages of relatively high resistance to varus and valgus and can effectively reduce the damage to the blood supply of soft tissues and reduce or avoid the formation of fractures around the hematoma<sup>11</sup>. However, studies<sup>12-14</sup> indicated that the incidence of rotator cuff tears rose considerably in patients treated with intramedullary nailing. The purpose of the research was to investigate the effects of minimally invasive intramedullary nailing on joint function, nerve function, and inflammatory responses in patients with humeral shaft fractures and radial nerve injury in order to offer a better reference for clinical disease treatment.

## Patients and Methods

### Subjects

This study was approved by the Hospital Ethics Committee (approval number: 2022CJ1405). The medical records of 58 patients with humeral shaft fractures combined with radial nerve injury were randomly selected for retrospective analysis. The admission period was between June 1, 2020, and June 31, 2022. All subjects matching the inclusion criteria were randomly divided into the least invasive group (group W) and internal fixation group (group N) using the random number table method (n=29 cases).

### Inclusion Criteria

(1) Patients who had an imaging-confirmed humeral shaft fracture; (2) patients with symptoms such as wrist extensor weakness or drooping hands; (3) patients who had a clear cognitive function and could cooperate with the relevant work in the study; (4) patients and their families

understood the research's essential content and signed the permission form.

### Exclusion Criteria

(1) Patients with compressive neuropathy; (2) patients with neuropathic diseases such as peripheral nerve sheath tumor and diabetic peripheral neuropathy; (3) patients with underdeveloped bones; (4) patients with previous humeral injuries.

### Methods

(1) Group W: the patients were treated with minimally invasive intramedullary nailing. Patients were placed in a supine position while under general anesthesia. An opening of about 3 cm was made at the acromion, the edge of the humeral cartilage, and the beginning of the greater tubercle, and the skin was released layer by layer. The position was determined by imaging examination, and the intramedullary nail was correctly placed in the medullary cavity until the reduction was satisfactory; the position of the intramedullary nail and its reset condition were determined, the wound was sutured, bandaging for hemostasis, and the drainage device was placed.

(2) Group N: the patients were given compression plate internal fixation. The patients' upper arm was abducted at 90°, the forearm was rotated, and an appropriate incision was made in the gap between the biceps and deltoid according to the position, and the surrounding connective tissue was removed. The fracture site was fully exposed, and an adequate internal fixation plate was chosen based on the curvature of the humerus at the fracture site and put into the area between the deep surface of the muscle tissue and the superficial periosteum. The reduction of the fractures was detected by imaging, and the fracture was locked under pressure. The wound was sutured and bandaged for hemostasis, and a drainage device was placed. (3) All patients underwent radial nerve exploration. The specific treatment was based on the intraoperative radial nerve exploration, and external neurolysis (for those with intact radial nerve epineurium), partial nerve suture (for those with partial dissection), and epineurium end-to-end anastomosis (for those with complete dissection of the nerve) were practiced, respectively. Care should be taken to protect the nerve during surgery to avoid secondary damage to the nerve. Antibiotics were given to prevent infection after the operation, and early rehabilitation activities were encouraged.

### Observation Indicators

(1) Clinical effect: analysis of the clinical outcomes of therapy for individuals with humeral shaft fracture and radial nerve injury, including markedly effective, effective and ineffective, and the effective rate was calculated.

Effective rate (%) = (markedly effective + effective) ÷ total number of cases (29 cases) × 100%.

(2) Surgical-related indicators: the changes in relevant indicators during the surgical treatment of patients were detected and recorded, including changes in surgical blood loss, incision length, total operation time, and length of stay.

(3) Joint function and nerve function: patients' elbow and shoulder joints were identified using the Constant-Merley shoulder joint score and the Mayo elbow joint grade, both of which had a maximum value of 100. The better the joint function, the higher the grade. Joint muscle strength grades 4 and 3 were recorded as excellent and good, respectively. Otherwise, it was relatively poor.

Excellent and good rate (%) = (excellent + good) ÷ total number of cases (29 cases) × 100%.

(4) Stress indicators: before and one week after surgery, variations in the levels of serum stress markers were detected using an enzyme-linked immunosorbent test, including prostaglandin E-2 (PGE2), C-reactive protein (CRP) and Substance P (SP) levels.

(5) Adverse reactions: during the course of the treatment, changes in the frequency of adverse responses were noticed.

(6) Satisfaction: a self-made satisfaction scale was used to analyze the satisfaction status, including complete satisfaction, partial satisfaction, and dissatisfaction.

Satisfaction (%) = (complete satisfaction + partial satisfaction) ÷ total number of cases (29 cases) × 100%.

### Statistical Analysis

SPSS 24.0 (IBM Corp., Armonk, NY, USA) was used to conduct all data analysis for this research, and the count data such as clinical effects, joint function, nerve function, incidence of adverse reactions, and satisfaction were expressed by [n (%)], and pairwise comparisons were performed by independent samples, using the  $\chi^2$  test; measurement data such as surgery-related indicators and inflammatory factors were expressed by ( $\bar{x} \pm s$ ), and pairwise comparisons were passed by independent sample *t*-test, and the statistical results were considered statistically significant if  $p < 0.05$ .

## Results

### Clinical Information

In terms of fundamental statistics such as age, nerve injury, fracture site, disease duration, gender, fracture type, and injury cause, there was no statistically meaningful disparity between group W and group N ( $p > 0.05$ ) (Table I and Table II).

**Table I.** Analysis of basic data of the two groups [n (%), ( $\bar{x} \pm s$ )].

Groups	n	Age (years)	Nerve damage (%)		Fracture site (%)			Course of disease (d)
			Contusion	Fracture	Proximal	Middle	Remote	
Group W	29	38.45±3.49	19 (65.52)	10 (34.48)	4 (13.79)	8 (27.59)	17 (58.62)	5.16±1.42
Group N	29	39.27±3.30	15 (51.72)	14 (48.28)	5 (17.24)	9 (31.03)	15 (51.72)	5.42±1.50
$\chi^2/t$		0.917	1.137		0.295			0.671
<i>p</i>		<b>0.363</b>	<b>0.286</b>		<b>0.863</b>			<b>0.505</b>

**Table II.** Analysis of basic data of the two groups [n (%), ( $\bar{x} \pm s$ )].

Groups	n	Gender (%)		Fracture type (%)			Cause of injury (%)			
		Female	Male	Horizontal	Spiral	Oblique	Fall injury	Traffic injury	Knife cut	Others
Group W	29	8 (27.59)	21 (72.41)	6 (20.69)	14 (48.28)	9 (31.03)	7 (24.14)	13 (44.83)	2 (6.90)	7 (24.14)
Group N	29	10 (34.48)	19 (65.52)	8 (27.59)	15 (51.72)	6 (20.69)	5 (17.24)	15 (51.72)	1 (3.45)	8 (27.59)
$\chi^2$		0.322		0.920			0.876			
<i>p</i>		<b>0.570</b>		<b>0.631</b>			<b>0.831</b>			

W group means minimally invasive group; N group means internal fixation group.

### Clinical Effect Analysis of the Two Groups

In group W, 58.62% of patients (17/29) were markedly effective, 31.03% (9/29) were effective, 10.34% (3/29) were ineffective, and the effective rate was 89.66% (26/29); in group N, 48.28% patients (14/29) were markedly effective, 24.14% (7/29) were effective, 27.59% (8/29) were ineffective, and the effective rate was 72.41% (21/29). Although group W's effective rate was higher than group N's, there was no discernible disparity between the two groups ( $p>0.05$ ) (Table III and Figure 1).

### Investigation of Surgically-Associated Indications in the Two Groups

When compared to the N group, the W group's blood loss and incision length were much lower, and their overall operation time and hospitalization time were shorter (Table IV and Figure 2).

### Analysis of Patients' Joint and Nerve Function

The excellent and good rate of elbow joint function in group W was 93.10% (27/29), whereas the excellent and good rate of group N was

65.52% (19/29) (Figure 3). The excellent and good rate of elbow joint function in group W was considerably greater than that of group N ( $p<0.05$ ). In group W, the excellent and good rate of shoulder joint was 96.55% (28/29), and that in group N was 68.97% (20/29), and group W had a considerably greater probability of excellent shoulder joint function than group N ( $p<0.05$ ) (Figure 4); the excellent and good rate of neurological function was 82.76% (24/29) in group W and 58.62% (17/29) in group N, furthermore, the rate of outstanding and good neurological function in group W was much higher than that in group N ( $p<0.05$ ) (Table V, Figure 5).

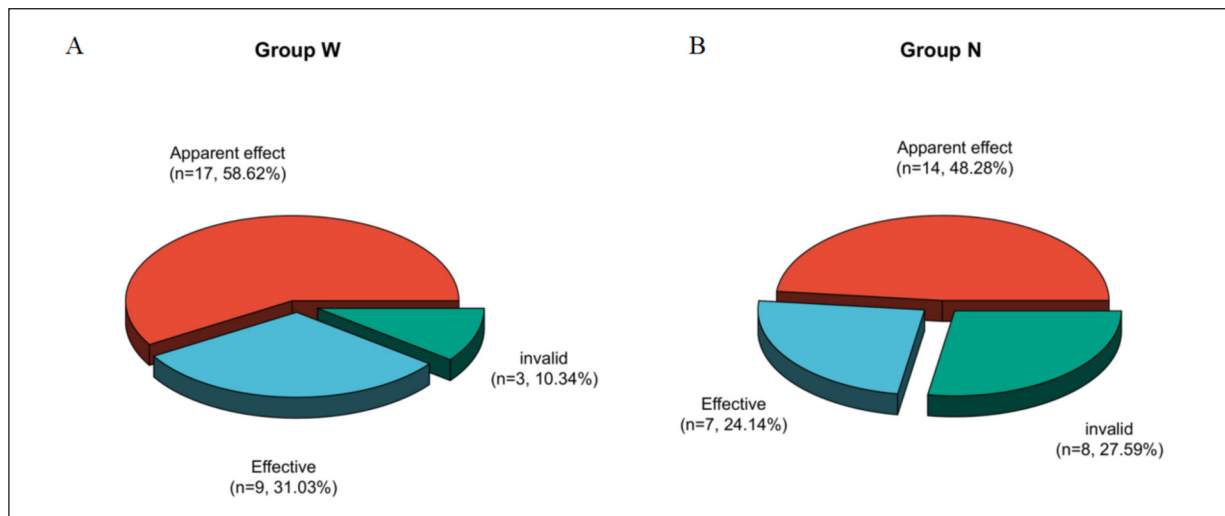
### Analysis of Stress Index Levels

There was no discernible disparity between group W and group N's serum PGE2, CRP, and SP levels before surgery ( $p>0.05$ ); PGE2, CRP, and SP levels in groups W and N were both considerably higher following surgery than they were prior to it ( $p<0.05$ ), and in comparison to group N, the above stress markers in group W were much lower ( $p<0.05$ ) (Table VI, Figure 6).

**Table III.** Analysis and comparison of clinical effects between the two groups [n (%)].

Groups	n	Markedly effective	Efficient	Invalid	Efficient
Group W	29	17 (58.62)	9 (31.03)	3 (10.34)	26 (89.66)
Group N	29	14 (48.28)	7 (24.14)	8 (27.59)	21 (72.41)
$\chi^2$					2.805
$p$					0.094

W group means minimally invasive group; N group means internal fixation group.

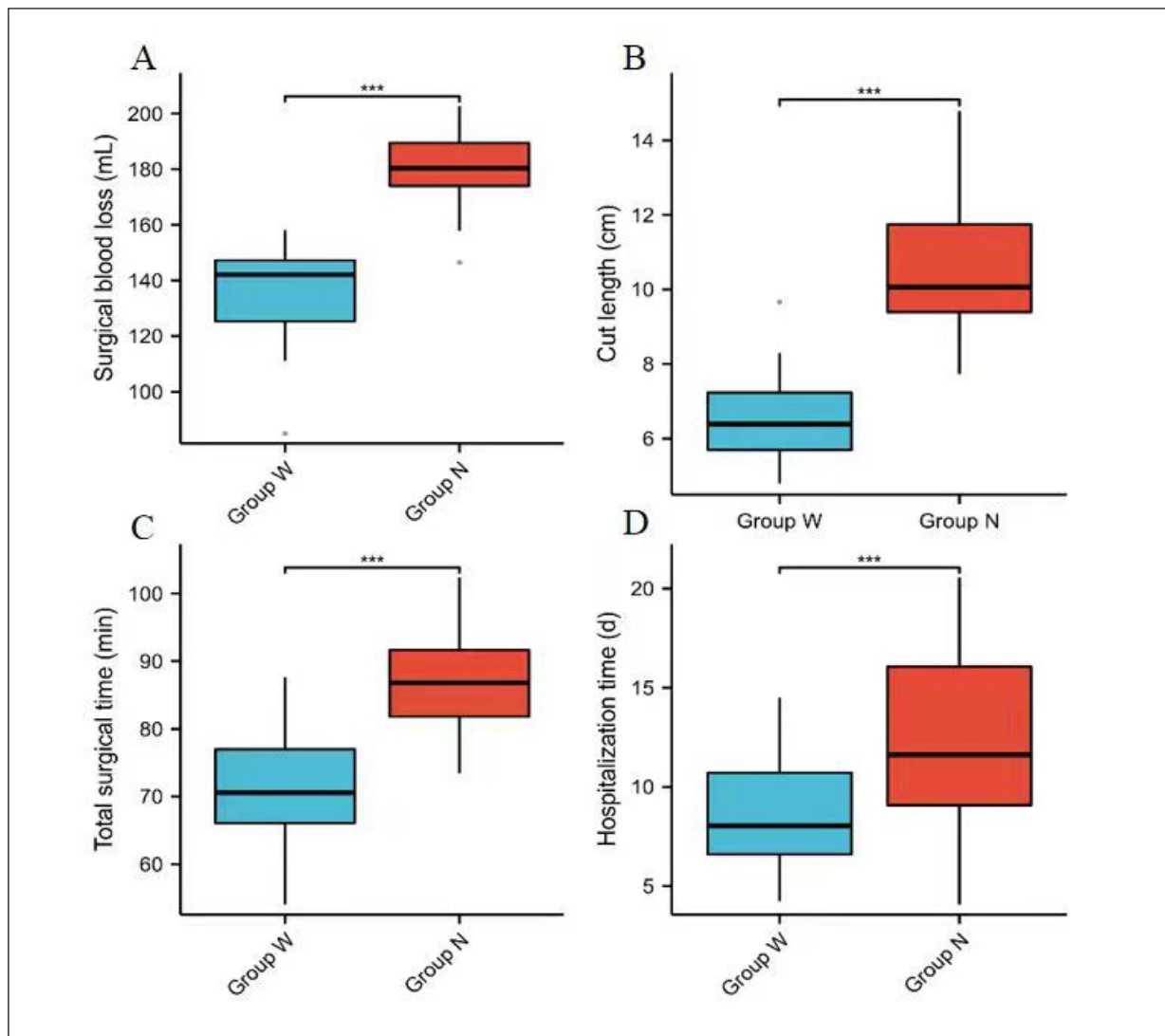


**Figure 1.** Distribution map of clinical effects in the two groups.

**Table IV.** Analysis and comparison of surgery-related indicators between the two groups ( $\bar{x}\pm s$ ).

Groups	n	Surgical blood loss (mL)	Incision length (cm)	Total operation time (min)	Length of hospital stay (d)
Group W	29	136.07 $\pm$ 16.74	6.57 $\pm$ 1.17	71.46 $\pm$ 8.64	8.79 $\pm$ 2.70
Group N	29	178.64 $\pm$ 13.79	10.45 $\pm$ 1.85	86.71 $\pm$ 7.82	12.56 $\pm$ 4.58
<i>t</i>		10.568	9.540	7.045	3.819
<i>p</i>		<0.001	<0.001	<0.001	<0.001

W group means minimally invasive group; N group means internal fixation group.

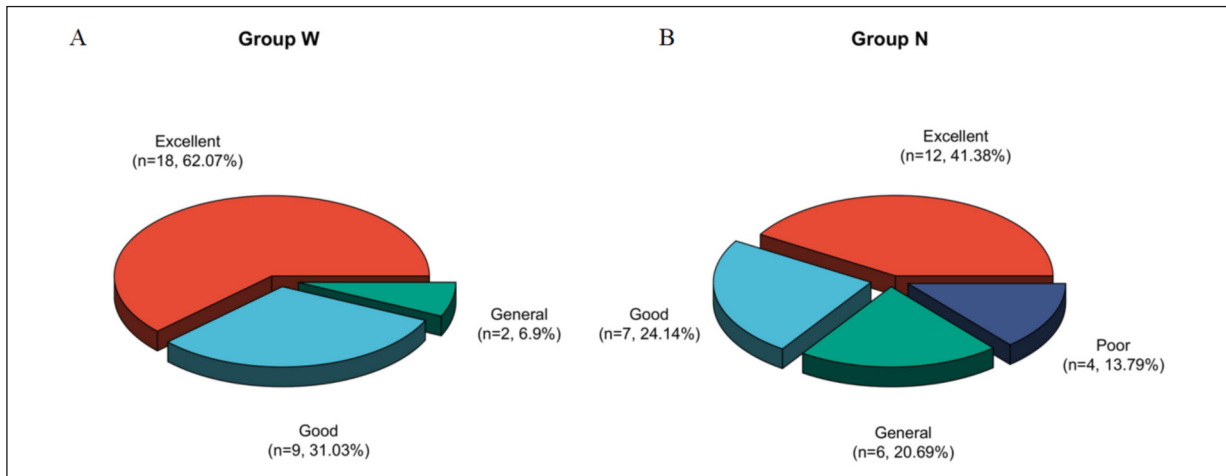
**Figure 2.** Comparison of the surgically-associated indicators between the two groups. \*\*\*indicates that in comparison of group W and group N,  $p < 0.001$ .

### Analysis of Adverse Reactions

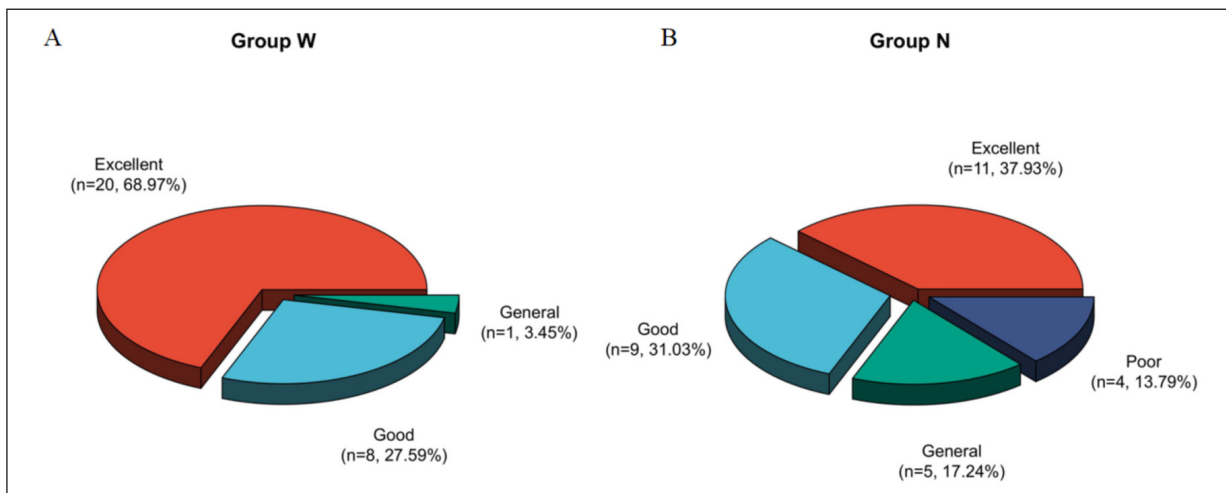
In group W, shoulder and the incidence of elbow discomfort was 3.45% (1/29), and the

incidence of adverse reactions was 3.45% (1/29); in group N, the incidence of infection was 6.90% (2/29), and that of fracture nonunion





**Figure 3.** Comparison of the elbow joint functions between the two groups.



**Figure 4.** Comparison of the shoulder joint functions between the two groups.

was 6.90 % (2 /29), that of shoulder and elbow discomfort was 10.34% (3/29), and the frequency of negative effects was 24.14% (7/29). The incidence of adverse responses was substantially lower in group W than in group N ( $p<0.05$ ) (Table VII, Figure 7).

#### **Analysis of Patient Satisfaction**

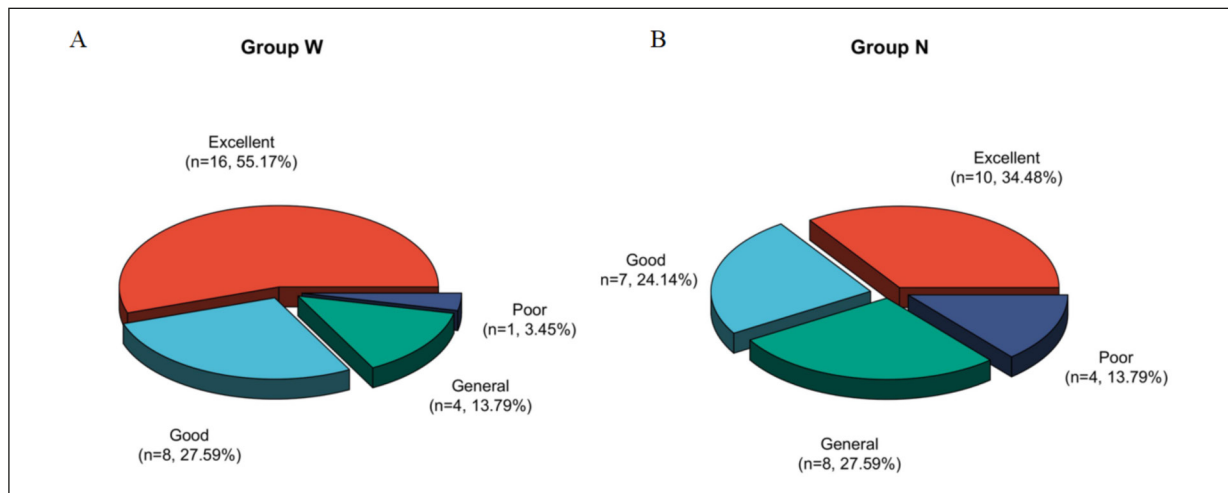
In group W, 72.41% of cases (21/29) were completely satisfied, 20.69% (6/29) were partially satisfied, 6.90% (2/29) were dissatisfied, and the satisfaction rate was 93.10% (27/29). In group N, 41.38% of patients (12/29) were completely satisfied, 31.03% (9/29) were partially satisfied, 27.59% (8/29) were dissatisfied, and the satisfaction rate was 72.41% (21/29). Group W had a much greater contentment percentage than group N ( $p<0.05$ ) (Table VIII, Figure 8).

#### **Discussion**

Humeral fractures are one of the common diseases in orthopedic surgery. According to statistics<sup>1,2</sup>, the incidence of humeral fractures can account for about 4% to 5% of all fractures in the whole body, second only to hip fractures and distal radius fractures. Radial nerve injury is a common peripheral nerve injury in humeral shaft fractures, and its incidence is relatively high. Surgery is a common method for treating diseases, and plate fixation is the gold standard for treatment of humeral fractures. However, the incidence of postoperative adverse reactions is relatively high, and the occurrence risk of postoperative varus deformity and fixation wear-out and others is relatively high<sup>16,17</sup>. With the development of minimally invasive techniques, intramedullary

**Table V.** Analysis and comparison of joint function and nerve functions between the two groups [n (%)].

Groups		n	Excellent	Good	General	Poor	Excellent rate
Elbow	Group W	29	18 (62.07)	9 (31.03)	2 (6.90)	0 (0.00)	27 (93.10)
	N group	29	12 (41.38)	7 (24.14)	6 (20.69)	4 (13.79)	19 (65.52)
	$\chi^2$						9.416
	<i>p</i>						0.002
Shoulder joint	Group W	29	20 (68.97)	8 (27.59)	1 (3.45)	0 (0.00)	28 (96.55)
	N group	29	11 (37.93)	9 (31.03)	5 (17.24)	4 (13.79)	20 (68.97)
	$\chi^2$						7.733
	<i>p</i>						0.005
Radial nerve	Group W	29	16 (55.17)	8 (27.59)	4 (13.79)	1 (3.45)	24 (82.76)
	N group	29	10 (34.48)	7 (24.14)	8 (27.59)	4 (13.79)	17 (58.62)
	$\chi^2$						4.078
	<i>p</i>						0.043

**Figure 5.** Comparison of radial nerve functions between the two groups.

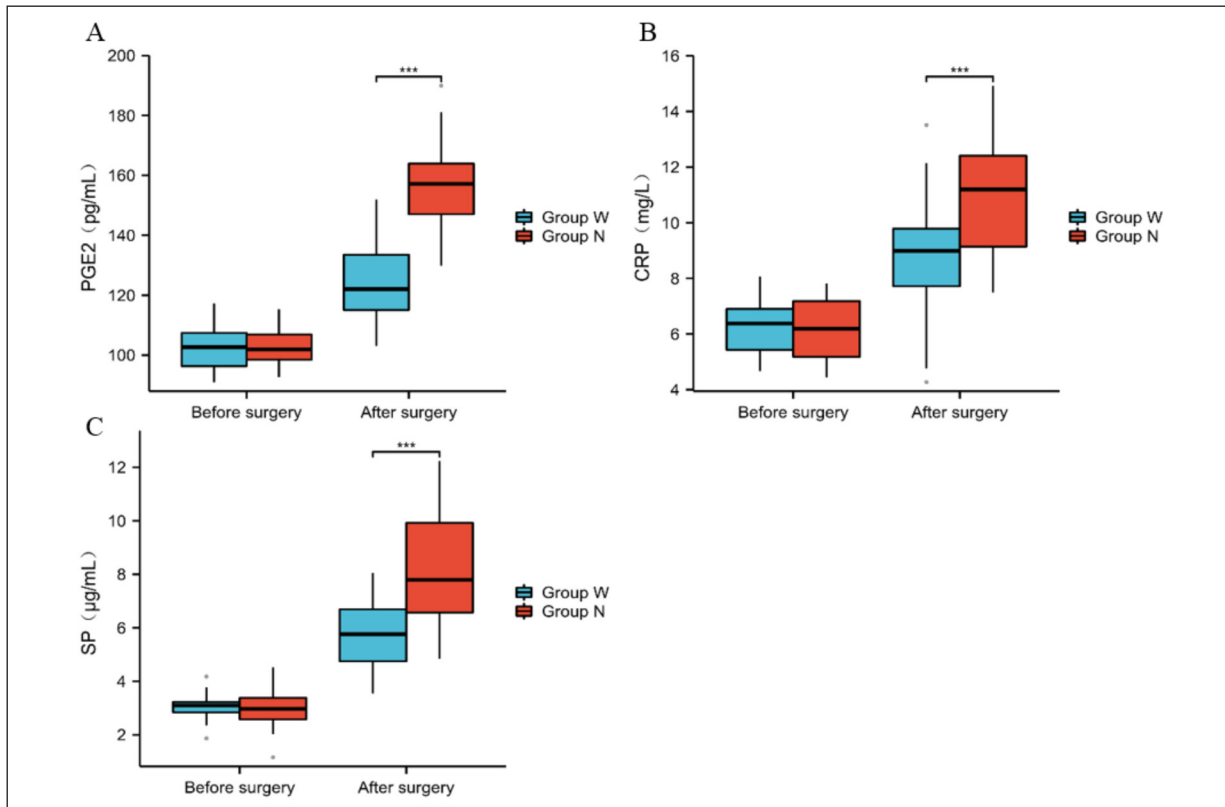
nailing has gradually been applied to the treatment of humeral shaft fractures. It has been found in a study<sup>18</sup> that the incidence of complications of intramedullary nailing in the treatment of tibial fractures is significantly lower than that of percutaneous plate fixation. The purpose of this research was to look at the clinical effects of minimally invasive intramedullary nailing in the treatment of humeral shaft fractures with radial

nerve damage. The research's findings revealed that group W's effective rate was 89.66%, which was greater than group N's (72.41%), but there was no meaningful disparity between the two groups ( $p>0.05$ ). The incidence of adverse reactions in group W was 3.45%, which was significantly lower than that in group N (24.14%) ( $p<0.05$ ). It was shown that both intramedullary nailing and compression plate internal fixation are effective

**Table VI.** Analysis and comparison of stress index levels between the two groups ( $\bar{x}\pm s$ ).

Groups	n	Time	PGE2 (pg/mL)	CRP (mg/L)	SP (μg/mL)
Group W	29	Before surgery	102.85±7.47	6.25±1.04	3.04±0.46
		after surgery	124.28±13.27* #	8.76±2.02* #	5.68±1.27* #
Group N	29	Before surgery	102.64±5.46	6.18±1.08	3.02±0.69
		after surgery	157.31±14.60*	11.02±2.09*	8.09±2.05*

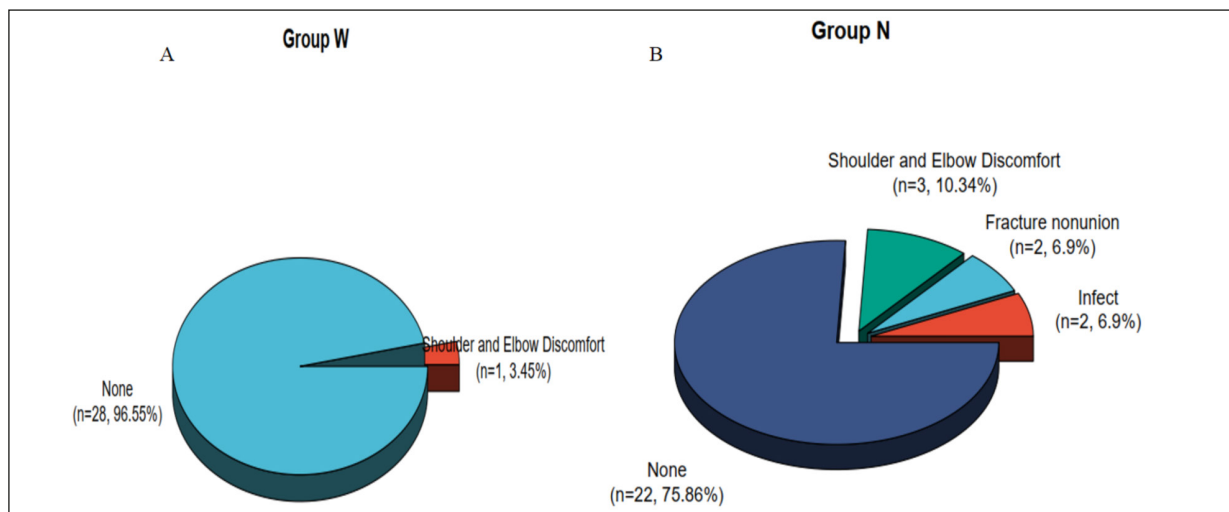
W group means minimally invasive group; N group means internal fixation group. \* $p<0.05$  compared with prior to operation, # $p<0.05$  compared with group N after the operation. Prostaglandin E-2 (PGE2), C-reactive protein (CRP) and Substance P (SP).



**Figure 6.** Comparison of stress indicators between the two groups. \*\*\* indicates the comparison of group W and group N,  $p < 0.001$ .

**Table VII.** Analysis and comparison of adverse responses between the two groups [n (%)].

Groups	n	Infect	Fracture nonunion	Shoulder and Elbow Discomfort	Total
Group W	29	0 (0.00)	0 (0.00)	1 (3.45)	1 (3.45)
Group N	29	2 (6.90)	2 (3.90)	3 (10.34)	7 (24.14)
$\chi^2$					5.220
$p$					0.022

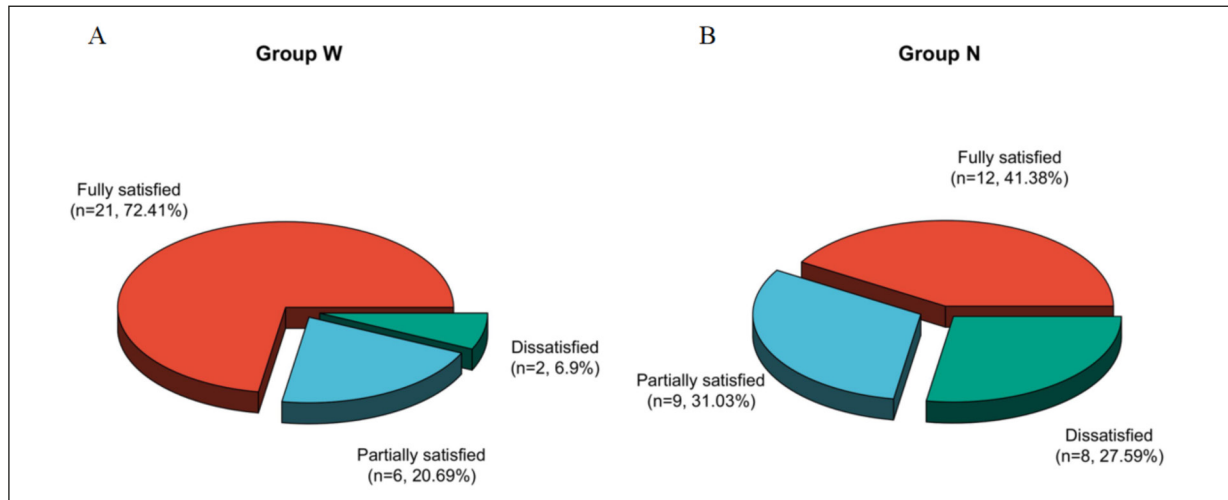


**Figure 7.** Distribution of adverse reactions in the two groups.



**Table VIII.** Analysis and comparison of patient satisfaction between the two groups [n (%)].

Groups	n	Completely satisfied	Partially satisfied	Dissatisfied	Satisfaction
Group W	29	21 (72.41)	6 (20.69)	2 (6.90)	27 (93.10)
Group N	29	12 (41.38)	9 (31.03)	8 (27.59)	21 (72.41)
$\chi^2$					4.350
<i>p</i>					0.037

**Figure 8.** Satisfaction distributions in the two groups.

methods of treatment, and both can achieve relatively good results, but intramedullary nailing has fewer adverse reactions. It may be because the intramedullary nail treatment causes less trauma to the patients and shortens the operation time, and it can be a load-sharing device for minimally invasive techniques, which can reduce soft tissue damage, thereby reducing surgical blood loss<sup>19,20</sup>. The results of this study were similar.

Fracture healing is a process of bone reconstruction, during which the functions of the elbow and shoulder joints may be affected to some extent<sup>21-23</sup>. In the results of this study, the rates of excellent and good elbow and shoulder joints in group W were 93.10% and 96.55%, respectively, which were substantially higher than the rates of excellent and good elbow and shoulder joints in group N (65.52% and 68.97%) ( $p>0.05$ ), and the rate of outstanding and good neurological function in group W was 82.76%, which was considerably greater than in group N (58.62%) ( $p<0.05$ ). It demonstrates that minimally invasive intramedullary nail treatment can improve the functionalities of the patients' shoulder and elbow joints, as well as the function of the patients' radial nerve. To explore the reasons, due

to the special anatomical position of the humeral shaft, the internal fixation of the compression plate may damage the physiological structure of the shoulder and elbow, thereby causing damage to the shoulder joint and elbow joint, affecting the functions of the shoulder joint and elbow joint. Minimally invasive plate osteosynthesis (MIPO) is a minimally invasive operation that can avoid unnecessary damage to the shoulder and elbow tissues, reduce periosteum damage, and avoid damage to the radial nerve so as to maintain shoulder and elbow joint functions and promote patients' joint function and neurological function recovery<sup>24,25</sup>. Some meta-analyses<sup>26,27</sup> for the treatment of humeral shaft fractures using non-operatively, with open reduction and plate osteosynthesis (ORPO), MIPO, or with intramedullary nails (IMN) demonstrated that MIPO is currently the most effective treatment for humeral shaft fractures. Moreover, compared with compression plate fixation, IMN may be a better choice of internal fixation for humeral shaft fracture<sup>28</sup>.  $\alpha$ -lipoic acid is the first choice for patients with mild-moderate carpal tunnel syndrome, and the physical treatment mainly is proprioceptive neuromuscular facilitation<sup>29-31</sup>.

Successful fracture healing is based on the carefully coordinated interaction between inflammatory cells and bone-forming cells. Inflammation response is one of the important factors that can aggravate patients' pain and delay their recovery<sup>32,33</sup>. Prostaglandins have been linked to bone resorption in response to inflammation and metastatic bone disease, as well as bone production in response to fracture repair and heterotopic ossification. According to research<sup>34</sup>, PGE2 is a key regulator of bone metabolism with an anabolic influence on fracture healing. According to reports<sup>35,36</sup>, CRP and SP, and others are all stress-related indicators, that can stimulate the transmission of nerve endings and regulate the body's stress responses. According to the findings of this study, the levels of PGE2, CRP, and SP in the W group after surgery were significantly lower than those in the N group. It is shown that minimally invasive intramedullary nailing plays an important role in reducing the levels of stress indicators in patients. Furthermore, the findings of this study revealed that patients in the W group were more satisfied. Analyzing the reasons, due to the stimulation of the operation, the secretion of inflammatory factors in the body increases. While the minimally invasive intramedullary nailing treatment is a minimally invasive operation, the trauma of the patients is relatively small, so the secretion of inflammatory factors is inhibited, the stress degree of the patients is reduced, and the postoperative recovery is faster, thereby increasing the satisfaction rate of patients.

## Conclusions

Minimally invasive intramedullary nailing for humeral shaft fracture combined with radial nerve injury is an effective treatment method, which can effectively improve shoulder and elbow joint and nerve function, reduce stress responses of patients, and have less adverse reactions and high satisfaction rate, which is worth popularizing and to apply. Although we have achieved certain results, our research still has certain limitations, including a small sample size, a single source, a relatively short time, and so on, which may result in some mistakes in the research results. Later on, the follow-up period can be increased, and large-sample, multi-center, and prospective studies can be conducted to improve the accuracy of the research conclusions.

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## Authors' Contributions

Shaoyan Shi conceived the structure of the manuscript. XiaoLong Du did the experiments and made the figures. Xuehai Ou reviewed and edited the manuscript. All authors read and approved the final manuscript.

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## Availability of Data and Materials

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

## Ethics Approval

This study was conducted in accordance with the ethical regulations of the Declaration of Helsinki. The experiments were approved by the Ethics Committee of the Honghui Hospital, Xi'an Jiaotong University; the number of the Ethics Committee's acceptance is 2021092809.

## Conflict of Interest

The authors declare that they have no competing interests.

## Informed Consent

All patients signed the informed consent form.

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