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Clinical effect of plastic splint for treatment of new type of midshaft clavicle fracture: a retrospective study

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Abstract

Background: On the basis of conservative treatment of 81 midshaft clavicle fractures, a new type of midshaft clavicle fracture was proposed and the clinical effect of plastic splinting in the treatment of these fractures was observed.

Methods: Eighty-one patients with midshaft clavicle fractures treated with plastic splints from January 2018 to July 2020 were retrospectively analyzed. The fractures were divided into four types according to their displacement. All patients underwent plastic splint fixation for 4 weeks. The visual analog scale score, Constant–Murley shoulder joint score, patient satisfaction with the post-treatment appearance, nonunion rate, and malunion rate were examined at 1, 3, and 9 months after treatment.

Results: Seventeen patients had type I fractures, 18 had type II, 9 had type III, and 37 had type IV. For all four fracture types, the mean visual analog scale score and Constant–Murley score considerably improved from pretreatment to 9 months post-treatment. Seven patients were not satisfied with the post-treatment appearance. Five patients still had no obvious callus at 9 months after treatment, indicating non-healing; most of these patients had type III and IV fractures.

Conclusions: Use of the new type of midshaft clavicle fracture is more appropriate for evaluation of the clinical treatment effect because it has more guiding significance for the treatment and prognosis of midshaft clavicle fractures. A plastic splint can be used to treat midshaft clavicle fractures. The short-term clinical effect is safe, and fracture reduction is accurate. Although the

29 incidence of malunion after plastic splint treatment is high, most patients are still satisfied with the
30 appearance after treatment. This technique can be popularized in clinical practice. The functional
31 score and satisfaction with the post-treatment appearance were lower in patients with type III and
32 IV fractures than in those with type I and II fractures, and the rate of nonunion and abnormal
33 healing were relatively high. Other treatment methods should be considered as early as possible
34 for such patients to achieve the best treatment effect.

35 **Keywords:** Midshaft clavicle fracture; New clinical classification; Plastic splint; Clinical effect

36

37 **Background**

38 Fractures of the clavicle account for 2.6% to 5.0% of all fractures^[1]. They can occur at any age,
39 and indirect trauma is the main cause. The middle third of the clavicle is the most prone to fracture,
40 accounting for about 80% of all clavicle fractures^[2]. It is generally accepted that non-operative
41 treatment is optimal for most mid-clavicle fractures and is likely to be associated with a very low
42 nonunion rate of <1%^[3]. However, in most hospitals in China and abroad, surgical treatment is
43 often preferred for midshaft clavicle fractures. Since the beginning of the 21st century, Suzhou
44 Traditional Chinese Medicine Hospital has adopted a “one-size-fits-all” nonsurgical conservative
45 treatment method using a plastic splint for closed midshaft clavicle fractures with satisfactory
46 clinical results. However, accurate follow-up information and data collection regarding the clinical
47 efficacy of conservative treatment are lacking in previous studies. We retrospectively analyzed 81
48 patients treated for midshaft clavicle fractures from January 2018 to July 2020. The new type of
49 midshaft clavicle fracture proposed in this report can better reflect the variations in midshaft
50 clavicle fractures and is closely related to the clinical effect of a plastic splint. It can also better
51 guide the choice of clinical treatment.

52

53 **Methods**

54 *Patients*

55 In total, 81 patients who underwent treatment for middle clavicle fractures from January 2018 to
56 July 2020 were analyzed in this study. The patients comprised 45 men and 36 women ranging in
57 age from 18 to 82 years. All patients provided written informed consent before treatment, and the
58 Suzhou Traditional Chinese Medicine Hospital Ethics Committee approved the study. All patients

59 were treated with a plastic splint. Type I fractures were present in 17 patients, type II in 18, type
60 III in 9, and type IV in 37.

61

62 *Diagnostic criteria*

63 We referred to the Chinese Medical Association's Clinical Diagnosis and Treatment Guide -
64 Division of Orthopaedics Division for the diagnosis of midshaft clavicle fractures^[4]. The
65 diagnostic criteria were a clear history of trauma, occurrence in the middle one-third of the
66 clavicle, obvious local tenderness and swelling at the fracture site, and rubbing of the two
67 displaced bone fragments against each other. Combination of the physical examination and
68 imaging examination findings allowed for determination of the displacement and fracture type.

69

70 *Inclusion and exclusion criteria*

71 The inclusion criteria for this study were satisfaction of the diagnostic criteria for midshaft
72 clavicle fractures, the presence of a fresh fracture with no other treatment, complete imaging
73 findings, good patient compliance, age of >16 years, provision of informed consent, and treatment
74 with a plastic splint. The exclusion criteria were distal or proximal clavicle fractures, open
75 fractures, pathological fractures, multiple ipsilateral upper limb fractures, vascular nerve injury,
76 poor patient compliance, inability to undergo follow-up, and refusal of conservative treatment.

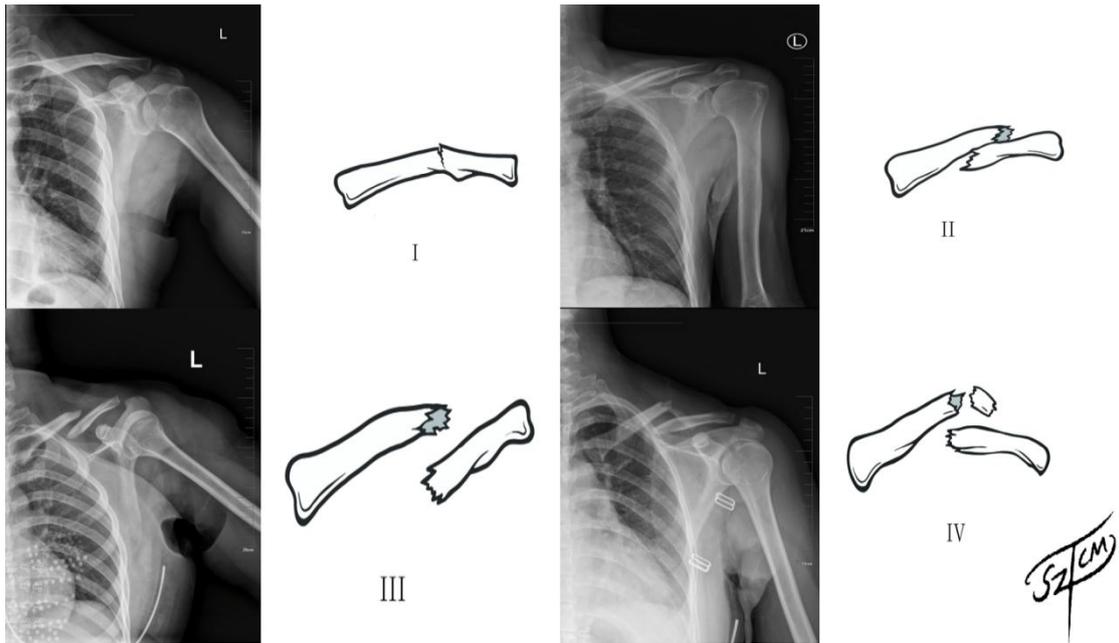
77

78 *New classification standards*

79 We proposed a new type of midshaft clavicle fracture according to the fracture displacement
80 during conservative treatment: type I, good alignment with no obvious displacement of the
81 fracture ends; type II, overlapping displacement of and contact between the distal and proximal
82 fracture ends; type III, separation (no contact) of the distal and proximal fracture ends; and type IV,
83 separation of the fracture ends with at least one free bone mass between them. The fracture types
84 are illustrated in Figure 1.

85

86 **Figure 1.** Midshaft clavicle fracture types



87

88

89 ***Surgical technique***

90 After admission, all patients were treated with plastic splinting using the following technique.

91 First, a plastic splint was created. The length of the splint was equivalent to the distance from the

92 neck edge to the acromion, and the width was twice the distance from the sternoclavicular joint of

93 the affected side to the highest point of the shoulder. The neck end was cut into a semicircle at the

94 center of the midpoint to ensure the ability to maximally cover the splint and neck with clothing.

95 The shoulder end was also cut into a concave shape toward the middle. To expose the acromion,

96 the front of the splint was cut into an oblique shape according to the direction of the clavicle. The

97 excess was trimmed from the edges to achieve better comfort. Second, the operator used digital

98 palpation to determine whether the fracture ends were displaced. The patient sat on a bench with

99 his or her head up, chest up, hands on the hips, and elbows turned outward. The assistant stood

100 behind the patient with his or her knee to the center of the patient's back. The assistant held the

101 outside of the patient's shoulders in both hands and performed slow back traction so that the

102 patient's shoulder was fully stretched, thereby restoring or improving any overlapping fracture

103 displacement. Third, after manual resetting of the fracture, the patient kept his or her hands on the

104 hips with elbows turned outward and with the chest and head up, and the surgeon placed a cotton

105 pad above the proximal end of the fracture. The splint was placed on the cotton pad, and a large

106 cotton pad was then placed in the bilateral armpits. From this starting point, a gauze bandage was

107 wrapped 8 to 12 times over the fracture end, bypassing the axilla, extending around the back to the
108 healthy shoulder, wrapping in front of the shoulder and around the axilla, and finally extending
109 from the back to the starting point. The affected limb was then fixed in the neutral position with a
110 triangular towel (Figure 2). Fourth, after resetting, the X-line was rechecked to determine whether
111 the reset was satisfactory. If the fracture ends were unsatisfactorily positioned, a secondary reset
112 was considered to ensure that the fracture ends came into the greatest contact possible. However,
113 the surgeon did not blindly pursue a perfect outcome by repeated and violent reduction. Thus,
114 improper reduction and damage to peripheral blood vessels and nerves was avoided. After
115 resetting, close observation during restricted activities was performed for 4 weeks, and the X-line
116 was regularly checked. After 4 weeks, active motion of the shoulder joint was carried out without
117 external fixation, and the range of motion was gradually increased according to the patient's
118 tolerance. Patients did not perform strenuous exercise for 3 months after fracture.

119

120 **Figure 2.** Images of plastic splint fixation



121

122

123 *Evaluation of efficacy*

124 After treatment, the following parameters were recorded to evaluate the clinical efficacy of plastic
125 splinting in patients with different types of midshaft clavicle fractures: the visual analog scale
126 (VAS) score^[5], the Constant–Murley shoulder joint score^[6], patient satisfaction with the
127 post-treatment appearance, and the nonunion rate.

128

129 *Statistical methods*

130 Statistical analysis was carried out using SPSS 26.0 (IBM Corp., Armonk, NY, USA).
131 Measurement data are expressed as mean \pm standard deviation. According to the homogeneity of

132 data variance, either the paired-samples t test or Mann–Whitney rank sum test was used for group
 133 comparisons. Count data are expressed as frequency and percentage. A P value of <0.05 indicated
 134 a statistically significant difference.

135

136 **Results**

137 ***VAS and Constant–Murley scores***

138 All 81 patients were followed up, and the VAS score and Constant–Murley shoulder joint score
 139 were significantly improved after treatment. The scores before and after treatment (1, 3, and 9
 140 months) are shown in Tables 1 and 2.

141

142 **Table 1.** Changes in VAS score before and after treatment

Time	Classification			
	I type	II type	III type	IV type
Pre-treatment	2.85±0.83	3.71±0.80	5.85±0.85	6.92±0.70
1 month	1.40±0.44	1.92±0.44	2.89±0.49	3.42±0.37
3 months	0.86±0.28	1.19±0.33	1.67±0.25	1.97±0.25
9 months	0.52±0.20	0.75±0.25	1.04±0.21	1.15±0.20

143

144 **Table 2.** Changes in Constant–Murley score before and after treatment

Time	Classification			
	Type I	Type II	Type III	Type IV
Pre-treatment	65.95±2.02	63.48±2.15	54.26±2.44	47.85±2.82
1 month	76.64±1.70	73.35±2.20	62.15±2.42	55.69±2.76
3 months	81.90±1.73	78.31±2.16	67.44±2.33	61.95±2.69
9 months	88.54±2.05	85.06±2.18	73.78±2.24	71.58±2.41

145

146 The mean pretreatment to 9-month post-treatment VAS score of all 81 patients decreased from
 147 2.85±0.83 to 0.52±0.20 for type I fractures, from 3.71±0.80 to 0.75±0.25 for type II fractures,

148 from 5.00±0.85 to 1.04±0.21 for type III fractures, and from 6.92±0.70 to 1.15±0.20 for type IV
 149 fractures. The mean pretreatment to 9-month post-treatment Constant–Murley shoulder joint score
 150 increased from 65.95±2.02 to 88.54±2.05 for type I fractures, from 63.48±2.15 to 85.06±2.18 for
 151 type II fractures, from 54.26±2.44 to 73.78±2.24 for type III fractures, and from 47.85±2.82 to
 152 71.58±2.41 for type IV fractures. All differences were statistically significant (P<0.05).

153

154 ***Patient satisfaction***

155 Seven of the 81 patients were not satisfied with the post-treatment appearance, mainly because of
 156 the high uplift of the fracture end; the remaining patients were satisfied (Table 3). Comprehensive
 157 analysis showed that the overall satisfaction rate was 91.36%.

158

159 **Table 3.** Patient satisfaction

	Type I	Type II	Type III	Type IV
Satisfactory	17	17	7	33
Not satisfied	0	1	2	4

160

161 ***Nonunion rate***

162 Five of the 81 patients still had no obvious callus 9 months after treatment, indicating non-healing;
 163 the overall non-healing rate was 6.17% (Table 4). Patients with fracture nonunion were treated by
 164 open reduction and internal fixation or other methods according to their own conditions and
 165 wishes.

166 **Table 4.** Nonunion

	Type I	Type II	Type III	Type IV
Healing	17	17	7	35
Non-healing	0	1	2	2

167

168 ***Malunion rate***

169 Of the 81 patients, 32 had malunion; the rate of malunion was 39.50% in combination with
 170 imaging findings (Table 5).

171

172 **Table 5.** Malunion

	Type I	Type II	Type III	Type IV
Normal healing	17	16	5	11
Deformity healing	0	2	4	26

173

174 **Discussion**

175 Fracture classification is an important basis for treatment selection and outcome prediction.
176 Clavicle fractures are generally classified according to their anatomical location^[7]. The Craig,
177 Allman, Neer, Edinburgh (later developed into Robinson), and OTA/AO classification systems are
178 commonly used^[8-11]. Among them, the Robinson classification system is the most appropriate for
179 midshaft clavicle fractures^[12]. However, this classification only divides midshaft clavicle fractures
180 into two types: non-displacement and displacement fractures^[13]. The classification makes no
181 mention of common clinical overlapping displacement and comminuted fractures. At present,
182 there is no specific and detailed classification system for midshaft clavicle fractures.

183 The main clavicle fracture classification systems are the Robinson, Craig, Allman, and Neer
184 systems. The treatment choices and prognosis of midshaft clavicle fractures are not uniform,
185 mainly because the classification is not comprehensive or perfect. We found that there are still
186 many defects and deficiencies in the Robinson classification in the course of clinical treatment of
187 midshaft clavicle fractures, resulting in some difficulties and obstacles in the treatment of these
188 fractures. Therefore, we further supplemented and perfected the Robinson classification system
189 and developed a new type of midshaft clavicle fracture classification.

190 The incidence of malunion in patients with midshaft clavicle fractures treated with plastic splints
191 is high. However, because of the scar caused by surgical treatment, most patients still choose
192 plastic splint treatment, which only causes slight fracture end uplift. This technique is thus
193 becoming popularized in the clinical setting.

194 In the present study, all patients' VAS scores and Constant–Murley shoulder scores were better
195 after than before treatment. However, patients with type III and IV midshaft clavicle fractures
196 were less satisfied with the post-treatment appearance than were patients with type I and II
197 fractures, and satisfactory results were not obtained in three cases of fracture nonunion. This may

198 have been related to the integrity of the fracture block and whether the fracture ends were in close
199 contact. Related studies have shown that patients' evaluation of the level of joint participation in
200 decision-making is the main factor influencing overall satisfaction^[14]. Therefore, we should
201 objectively inform patients of the potential complications and sequelae of different treatment
202 methods when deciding on the treatment plan so patients can participate in the decision-making
203 process and we can meet their treatment expectations^[15].

204 A plastic splint is effective in the treatment of most midshaft clavicle fractures and can obtain
205 satisfactory clinical results. However, patients should be surgically treated as soon as possible
206 when they have indications for surgery such as open fractures, nerve or vascular injuries,
207 extensive displacement, comminuted fractures^[16], and high-energy trauma such as floating
208 shoulder, shoulder impaction, and multiple trauma^[17]. In addition, among patients with type III
209 fractures with severe end separation and type IV comminuted midshaft clavicle fractures, we
210 suggest that those who have no contraindications be given priority for surgical treatment,
211 facilitating greater clinical efficacy and a lower incidence of complications. For type I and II
212 midshaft clavicle fractures, conservative splinting is recommended because it is a simple operation
213 with less pain, satisfactory clinical efficacy, and a low incidence of complications. Because of the
214 limited sample size in the present study, the clinical efficacy and complication rate of plastic
215 splinting in the treatment of midshaft clavicle fractures requires further confirmation and
216 discussion.

217

218 **Declarations**

219 **Acknowledgments**

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221 **Consent for publication**

222 The informed consent for publication was obtained from all participants for identifying
223 information/images in an online open-access publication.

224 **Authors' Contributions**

225 Authors XT Z, YT S, and JT L designed the study. Authors XT Z, YT S, YX D, S L, YF S, and ZJ M
226 collected the clinical data and conducted the statistical analysis. Author XT Z wrote the
227 manuscript. Authors JT L and H J revised the manuscript; all authors seriously and critically read

228 the manuscript to improve intellectual content. All authors read and approved the final manuscript.

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233 analyses, and manuscript writing.

234 **Availability of data and materials**

235 Raw data and materials of this study is deposited in the local server of Suzhou Hospital of
236 traditional Chinese Medicine Affiliated to Nanjing University of traditional Chinese Medicine for
237 safety and confidentiality purpose. Our data are available upon reasonable request from the
238 corresponding author. Please contact the corresponding author at okdoctor@163.com for more
239 information.

240 **Ehtics approval and consent to participate**

241 This study was conducted in accordance with the Declaration of Helsinki (WMA) and the
242 International Ethical Guidelines for Biomedical Research involving human subjects
243 (CIOMS). This research was approved by the ethics committee of the Suzhou Hospital of
244 traditional Chinese Medicine Affiliated to Nanjing University of traditional Chinese Medicine. All
245 patients or their families signed the informed consent and provided the consent to publish and
246 report individual clinical data.

247 **Competing interests**

248 The authors have no conflicts of interest, including specific financial interests and relationships
249 and affiliations, relevant to the subject of this manuscript.

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262

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