

# Factors Affecting Time to Healing in Humeral Shaft Fractures Treated with SIGN Intramedullary Nailing

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**How to cite this paper:** Duru, N.E., Iyidobi, E.C., Udemezue, C.O., Oguzie, G. and Muoghalu, O. (2022) Factors Affecting Time to Healing in Humeral Shaft Fractures Treated with SIGN Intramedullary Nailing. *Journal of Biosciences and Medicines*, 10, 73-85.

<https://doi.org/10.4236/jbm.2022.1012007>

**Received:** October 21, 2022

**Accepted:** December 13, 2022

**Published:** December 16, 2022

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## Abstract

There is a tendency to treat humeral fractures with the use of splintage in resource poor countries due to a perceived high rate of complications with operative fixation. The Surgical Implant Generation Network (SIGN) intramedullary nail has provided an alternative in the management of humeral shaft fractures. Due to the paucity of research work in this area, our study evaluated factors that influence the time to fracture union in humeral shaft fractures. Fifty-eight humeral Diaphysial fractures were treated over six years. It is a retrospective study. Case notes and the database were analysed. The statistical analysis was done using the SPSS 24 software. The time to fracture healing was the primary outcome variable and how it was influenced by patient and implant variables was studied. The mean time to fracture healing was 17.38 weeks. All 58 fractures united. The mean time to fracture healing in the 20 - 29 years was 16.00 weeks which was lower than in older age groups. Fractures in males healed at 16.33 weeks and in females at 18.76 weeks. Patients with Diabetes Mellitus had a mean healing time of 29.00 weeks, while third proximal fractures healed in a mean time of 15.25 weeks. Age and sex had no significant influence on the time to fracture healing while Diabetes Mellitus, longer duration of antibiotic use, open fractures, and presence of fracture gap post fixation and third middle fractures had increased time to fracture healing.

## Keywords

Humerus, Shaft, SIGN, Interlocking Nail, Fracture Healing

## 1. Introduction

Fractures of the Shaft of the Humerus account for 1% - 3% of fractures [1] [2]. The humeral shaft constitutes 13% of all humeral fractures [3]. There is a tendency to manage these fractures with the use of cast and splintage in Nigeria due to a perceived high rate of non-union and complications with operative fixation [4]. Over the past couple of decades, there has been a preference to treat acute humeral shaft fractures conservatively [5] [6] with resultant long periods of immobilization. However, the desire of patients for early return to full function has led to advances in implants like the intramedullary nailing devices with their advantages of being load sharing, shorter immobilisation time and early rehabilitation [7] [8]. The use of Intramedullary nails in the femur and tibia shaft fractures has been successful but earlier attempts to use the same nail designs in the humerus led to shoulder stiffness, rotator cuff injuries and poor fracture stability [9]; in light of this, the Surgical Implant Generation Network (SIGN) intramedullary nail (which is stainless steel, solid nail successfully used treat femur and tibia shaft fractures) is also designed for use in fractures of the humeral shaft without the need for image guidance as it uses an external jig aided distal locking device [10]. Controversy has persisted on the right choice of implant for treating humerus shaft fractures; Singiseti showed that though plating of humeral shaft fractures may lead to the earlier union, he concluded that no single treatment option is superior in all circumstances for a particular fracture [11]. We must also remember that there is a lot of radiation exposure to patients and surgeons during minimally invasive closed techniques as Srinivas had demonstrated, which is eliminated by open reduction and internal fixation [12] as used in the SIGN nail fixation. Our study was prompted by the paucity of research work on humerus shaft fractures treated with intramedullary nailing in our country and the near total absence of any studies on the factors influencing the time to union of fractures treated with SIGN nails, our study evaluated the use of the nails and the variables that influence the time to fracture union.

## 2. Methodology

The study was done in a regional Orthopaedic Hospital. It is a retrospective study. Case notes and radiographs of the patients were used. All Humerus shaft fractures that were treated with Surgical Implant Generation Network (SIGN) Intramedullary nails that met the inclusion criteria were studied. The inclusion criteria were mid-shaft fractures, open fractures, pathological and non-united fractures at presentation, patients who came for follow-up clinic at least once every 6 weeks till fracture healing. Exclusion criteria were supracondylar humeral fractures, fractures with intra-articular extension, fractures that were infected at presentation and patients who did not attend follow-up clinics for any period longer than 6 weeks before fracture healing. We defined the diaphyseal fractures according to Tytherleigh-Strong *et al.*, as one occurring between the superior border of the insertion of the pectoralis major and the area immediately above

the supracondylar ridge [13].

Preoperative measurements of the implant are done using standard radiographs and the patient's good contra-lateral arm. The nail length is estimated by measuring from the lateral acromial tip to the lateral epicondyle and subtracting 5 cm [10]. There was no need for fluoroscopy. The patient is placed supine or semi-recumbent. There is usually a bump placed between the shoulders. General anesthesia was used in all patients. A third-generation cephalosporin and an anti-anaerobic antibiotic were given with induction of anesthesia. After cleaning with chlorhexidine/cetrimide solution, the entire upper limb was draped free. An incision was made across the tip of the acromion, antero-laterally down about 6 cm in length. The deltoid was split along the course of its fibers, the supraspinatus tendon was also split along the course of its fibers. On the direct vision of the tip of the greater trochanter, an awl was used to gain access into the medullary cavity through it. The canal was reamed until chatter and the nail size used is 2 mm less than the last reamer size used. Fracture reduction was done openly. Distal screw was applied using the SIGN external jig after fracture reduction while the fracture was compressed with a slap hammer before the proximal screw insertion.

The patients were seen in the out-patients clinic every 4 - 6 weeks to look for fracture union, screw loosening or loss of implant stability. We defined fracture union as the absence of pain and tenderness at the fracture site and the presence of bridging callus in at least three cortices on two different views of the fracture on radiographs [14]. The time to fracture healing was analyzed as the primary outcome variable and the influence on it by the following variables was studied including age, sex, co-morbidities like Diabetes Mellitus and Hypertension, duration of antibiotic treatment, mechanism of injury, time from injury to surgery as was documented in the case notes, fracture location on the humeral shaft, open or closed fracture types, presence of non-union, size of fracture gap, The AO classification on the initial x-rays after injury, previous treatment for the fractures prior to presentation in our hospital and surgical site Infection was measured. All the variables were measured and documented. The Student's T-test, Chi-Square test and One Way ANOVA test were used to analyze significant differences in individual and group variables, p-value was set at 0.05.

### 3. Results

The age range was between 16 and 82 years (mean 41.91 years, median 39.0 years). The sex and age characteristics are represented in **Table 1** and **Table 2**.

There were 55 closed fractures (94.9%) and 3 open fractures (5.1%). Fracture variables including Fracture location, Fracture type, size of fracture gap, and Association for the study of Osteosynthesis (AO) classification of fractures based on initial radiographs are presented in **Tables 3-6**.

Road traffic accident was the most common cause of fractures 53 (91.4%), 4 (6.9%). The etiology of the fractures, Prior treatments received for the fractures

**Table 1.** Sex distribution.

Sex	N	%
Male	33	56.9
Female	25	36.1
Total	58	100

**Table 2.** Age distribution.

Age Range (Years)	N	%
10 - 19	1	17.0
20 - 29	9	15.5
30 - 39	20	34.5
40 - 49	13	22.4
50 - 59	7	12.1
60 - 69	6	10.3
70 - 79	1	1.7
80 - 89	1	1.7
Total	58	100

**Table 3.** Fracture location.

Fracture Location	N	%
Proximal 1/3 <sup>rd</sup>	4	6.9
Middle 1/3 <sup>rd</sup>	46	79.3
Distal 1/3 <sup>rd</sup>	8	13.8
Total	58	100

**Table 4.** Fracture type.

Type	N	%
Closed	55	94.9
Gustillo IIIA	2	3.4
Gustillo IIIB	1	1.6
Total	58	100

**Table 5.** Fracture gap.

Fracture gap	N	%
Nil	19	32.8
<1 mm	8	13.8
1 - 3 mm	19	32.8
4 - 5 mm	2	3.4
Comminuted	3	5.2
Free-wedge fragment	7	12.1
Total	58	100

before presentation for surgery as well as co-morbidities of the patients, and the duration of antibiotics administered are presented in **Tables 7-10**.

The commonest nail used was 9 mm, while the commonest nail length was 240 mm, Majority of the nails 31 (53.4%) were locked with one proximal and one distal locking screw. 7 nails (12.1%) were locked with 2 proximal and distal screws. 5 nails (8.6%) had only one proximal and 2 distal locking screws.

The nail-related variables are presented in **Table 11** and **Table 12**.

The mean time to fracture healing was 17.38 weeks (SD 5.30). The median time was 17.00 weeks. The minimum time was 8 weeks while the maximum time was 40 weeks. All 58 fractures united.

**Table 6.** AO type.

AO Type	N	%
A1	6	10.3
A2	15	25.9
A3	17	29.3
B1	4	6.9
B2	10	17.2
B3	2	3.4
C1	2	3.5
C2	1	1.7
C3	1	1.7
Total	58	100

**Table 7.** Etiology of the fractures.

Etiology	N	%
Road Traffic Accident	53	91.4
Falls	4	6.9
Gun Shot Wound	1	1.7
Total	58	100

**Table 8.** Previous treatment of the fractures before presentation.

Prior Treatment	N	%
Nil	40	69.0
Traditional Bone Setters	8	13.8
Plate and Screw fixation	5	8.6
Intra-medullary nail	1	1.7
POP Cast	4	6.9
Total	58	100

**Table 9.** Co-morbidities.

Co-morbidity	N	%
Nil	43	74.1
Diabetes mellitus	2	3.5
Hypertension	2	3.5
Osteoporosis	8	13.8
Villi-nodular Synovitis of the elbow	1	1.7
HIV	1	1.7
Psychiatric patient	1	1.7
Total	58	100

**Table 10.** Duration of antibiotics.

Duration	N	%
<1 week	45	77.6
1 - 2 weeks	10	17.2
>2 weeks	3	5.2
Total	58	100

**Table 11.** Length of nails.

Length (mm)	N	%
220	9	15.5
240	19	32.8
260	14	24.1
280	16	27.6
Total	58	100

**Table 12.** Diameter of nails.

Diameter (mm)	N	%
8	25	43.1
9	28	48.3
10	5	8.6
Total	58	100

The mean time to fracture healing in the 20 - 29 years, 30 - 39 years age ranges were 16.00 weeks (SD 4.47) and 16.16 weeks (SD 3.89) which was lower than 40 - 49 years age range 18.00 weeks (SD 3.92), 50 - 59 years 17.57 weeks (SD 4.89) and 60 - 69 at 17.67 weeks (SD 7.34). The difference was however not statistically significant ( $p = 0.99$ ).

There was also no significant difference in the mean time to fracture healing

in males 16.33 weeks (SD 3.98) though shorter than females 18.76 weeks (SD 6.49).  $p = 0.08$ .

### Fracture Variables

Proximal 3<sup>rd</sup> fractures had the shortest time to fracture healing of 15.25 weeks (SD 5.74) compared to fractures in other locations (**Table 13**).

The closed fractures were 55 (94.8%) healed at a mean time of 16.84 weeks (SD 4.40). The Open fracture 1 (1.7%) was a Gustillo type IIIA open fracture while 2 (3.4%) were Gustillo type IIIB open fractures. The open fractures healed in a meantime of 27.33 weeks (SD 11.02).  $p = 0.003$ .

The fractures that were well compressed had the shortest mean healing time 15.47 weeks (SD 3.72), compared to other fractures with a fracture gap and comminuted fractures (**Table 14**).

The AO C-Type had a long time to fracture healing, as shown the table below (**Table 15**).

There were 36 fractures (62.1%) that presented as non-union and they healed at a mean time of 18.22 weeks which was shorter than that of other fractures 22 (37.9%), which healed at a mean time of 16.00 weeks.  $p = 0.122$ .

The fractures caused by Road Traffic Accidents healed at a mean time of 17.09 weeks (SD 5.13). While those caused by falls and they healed at a mean time of

**Table 13.** Fracture location on healing time.

Location	N	Healing time in weeks (mean)	Standard Deviation
Proximal 1/3 <sup>rd</sup>	4	15.25	5.73
Middle 1/3 <sup>rd</sup>	46	17.17	4.48
Distal 1/3 <sup>rd</sup>	7	16.71	3.30
Segmental	1	40.00	
Total	58	17.38	5.30

$p = 0.001$

**Table 14.** Fracture gap on mean time to fracture healing.

Fracture gap	Mean Healing Time (weeks)	Standard Deviation
Nil	15.47	3.72
<1 mm	18.50	4.99
1 - 3 mm	17.53	4.77
4 - 5 mm	28.00	16.97
Comminuted	21.33	1.16
Free-wedge fragment	16.14	4.41
Total	17.38	5.30

$p = 0.017$

20.00 weeks (SD 7.48), 1 fracture (1.7%) was due to Gunshot Injury and healed at 22.00 weeks.  $p = 0.395$ . The differences were not statistically significant.

The healing time in fractures without prior surgery was 16 weeks (SD 3.74) which was not significantly different from those who had prior surgery 16.17 weeks (SD 3.25)  $p = 0.918$  but was significantly less than the time to healing when specifically compared to those fractures treated by traditional bone setters which healed in 23 weeks SD 4.79 ( $p = 0.001$ ) and those earlier treated by Manipulation and cast application which healed in 23.50 weeks SD 11.47 ( $p = 0.004$ ).

The patients with Diabetes Mellitus had the longest healing time of 29.00 weeks (SD 15.56) followed by 8 patients with osteoporosis who had a mean healing time of 21 weeks (SD 5.42). The mean healing time of fractures in patients without comorbidities was 16.02 weeks (SD 3.84) was less than that of diabetic patients.  $p < 0.001$  (Table 16).

**Table 15.** AO classification on mean time to fracture healing time.

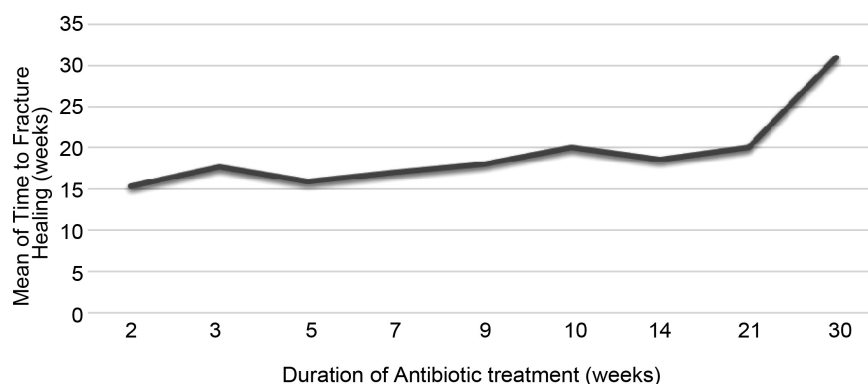
AO Classification	Mean healing time (weeks)	Standard deviation
A1	15.67	3.20
A2	16.07	4.62
A3	17.06	4.70
B1	16.75	2.99
B2	16.20	3.05
B3	20.00	.00
C1	26.00	5.66
C2	40.00	
C3	22.00	
Total	17.38	5.30

$p = 0.001$

**Table 16.** Co-morbidity on time to fracture healing.

Co-morbidity	Mean healing time (weeks)	Standard Deviation
Nil	16.02	3.84
Diabetes mellitus	29.00	15.56
Hypertension	17.50	6.36
Osteoporosis	21.50	5.42
Villi-nodular Synovitis Of the elbow	20.00	
HIV	18.00	
Psychiatric patient	16.00	
Total	17.38	5.30

$p = 0.001$



**Figure 1.** Duration of antibiotics on time to fracture healing.

The duration of antibiotic administration after surgery ranged from 2 - 30 days. Ceftriaxone and Tinidazole were used, and the duration depended on the wound infection. 45 patients (77.6%) who got antibiotics for 1 week or less had fracture healing in 16.42 weeks (SD 3.99), 10 patients (17.2%) got antibiotics for two weeks or less but more than a week. Their fractures healed in 18.70 weeks (SD 5.79). 3 fractures (5%) received antibiotics for more than 2 weeks and their fractures healed in 27.33 weeks.  $p = 0.001$ . this is presented in **Figure 1**.

13 patients (22.4%) presented within the first 2 weeks, and they had the shortest time to fracture healing of 15.31 weeks (SD 4.19). The mean time to fracture healing of all other 45 patients (77.6%) was 17.93 weeks  $p = 0.72$ .

The diameter of the nails used ranged from 8 mm (43.1%) healed in 17.92 weeks (SD-6.54), 9 mm (48.3%) healed in 16.86 weeks (SD-4.43) to 10 mm (8.6%) which healed in 17.60 weeks (SD-2.60).  $p = 0.77$ . There were no significant differences in the time to fracture healing.

The commonest complication was Shoulder stiffness (8.6%), 3 patients (5.2%) had superficial surgical site infection, one patient (1.7%) had recurrent shoulder pain. One patient (1.7%) had a deep surgical site infection; the number was too small to study any significant influence on fracture healing.

#### 4. Discussion

The mean time to fracture healing of 17.38 weeks was similar to Moon *et al.*, whose study had a healing time of 17.6 weeks [15] but Chapman *et al.* recorded a shorter healing time of 16 weeks [16]. A possible reason for the longer healing time is the high number of fractures presenting as non-union. Though not statistically significant, a shorter healing time was observed in the younger age groups (20 - 29 years and 30 - 39 years) and according to Dan Clark *et al.*, there is decreased healing potential and increased complications observed during fracture healing in elderly patients [17].

The proximal 3<sup>rd</sup> fractures had the shortest healing time, followed by distal and middle 3<sup>rd</sup> fractures in that order; this was opposite to the study by Ali *et al.*, where the union rate was higher in middle 3<sup>rd</sup> fractures with proximal 3<sup>rd</sup> fractures having the least union rate, the study was however for humeral fractures

treated by non-operative treatment [18].

The closed fractures healed in a shorter time than Open fractures. The healing time for open fractures in our study was lower than reported by Schoots *et al.*, with an average healing time of 9.5 weeks though two of his fractures healed in 42 weeks [19]. Thakur *et al.* reported an average healing time of 10.5 weeks [20] but all the fractures they studied were presented early. We had 3 open fractures two of which were non-unions hence the longer time to union.

Well-compressed fractures after surgery had a shorter mean healing time compared to fractures with a gap. In vitro studies by Meeson *et al.* have shown that increasing gap size did not affect construct stiffness, but did reduce the interfragmentary stiffness, with a doubling of the incidence of non-union [21]. Claes *et al.* also demonstrated in in-vitro studies that good reduction of a fracture with small interfragmentary gaps is important for its revascularization and healing [22].

The AO classification [23] for Humeral shaft fractures is based on simple criteria- type A (simple fractures with two fragments) had a similar healing time to type B fractures (three fragments), but a shorter healing time to type C (complex fractures with four or more fragments or comminuted) This is because of the greater degree of bony comminution and soft tissue contusion in the type C fractures. Our fracture frequency of Type A, B and C was similar to the findings of Campochiaro *et al.*, who had Type A (63%) and Types B and C (26.6% and 10.4% respectively) [24] however we agree with Obruba *et al.* whose study showed a higher rate of non-union in Humeral B3 and C fractures treated with Hackethal's technique of intramedullary bundle nailing [25] although unlike the SIGN nail it is a flexible nail. The AO type A (A1, A2, A3) healed in a mean time of 16.27 weeks, the type B fractures (B1, B2, B3) healed in a mean time 17.65 weeks while the longest healing time was for the C fractures (C1, C2, C3) with a mean healing time of 23.3 weeks. While there are hardly any articles comparing the time to fracture healing with the AO classification, the increased time to healing in Type B and C fractures could be due to the greater degree of comminution and displacement as supported by Foster *et al.* that displaced, comminuted, or segmental fractures are at risk of non-union at one fracture site or at both [9].

Fractures that had prior non-surgical attempt at fracture reduction like Traditional Bone Setters and cast application had a longer period to fracture healing. Dada *et al.* suggested that traditional bone setting usually involves massaging and pulling and may usually lead to heterotrophic ossification and non-union [26]. Our study was however not in keeping with that done by Konda *et al.*, who posted that Humeral shaft nonunion following initial operative fixation of the index fracture is more resistant to achieving union when compared to non-unions forming after initial non-operative treatment [27]. But, Ayotunde *et al.* showed that fractures that had previous treatment with traditional bone setters had a long time to union of 20 weeks than those treated by orthodox means

which healed in 12 weeks [28].

Patients with Diabetes Mellitus had the longest healing time of 29.00 weeks (SD 15.56). Loder demonstrated a significantly higher incidence of delayed union, non-union, and a doubling of the time to healing of the fracture in diabetic compared with non-diabetic patients [29]. A shorter course of antibiotic treatment was associated with an equally shorter time to fracture healing. Mathias *et al.* suggested that there is a negative influence of ceftriaxone on human bone cell viability and in vitro mineralization potential and it is concentration and time dependent [30].

There was one case of deep surgical site infection which healed in 20 weeks (not significantly longer than the mean healing time of 17.38 weeks for aseptic fractures) after wound debridement and application of gentamicin impregnated calcium sulphate beads and parenteral antibiotics.

## 5. Conclusion

Factors that led to increased time to fracture healing in these fractures treated with the SIGN nail include Co-Morbidities, Increased duration of antibiotic use, Open fractures, fracture gap post fixation, Prior non-surgical attempt at fracture treatment, Middle 1/3<sup>rd</sup> fractures and AO type C fractures.

## Study Limitations

It is a retrospective study with a limited sample size, multi-Centre studies with a bigger sample size will improve the outcome of the research.

## Conflicts of Interest

The authors declare no conflicts of interest.

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