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Absolute or relative stability in plate fixation for simple humeral shaft fractures.

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ABSTRACT

Introduction: Minimal invasive plating (MIPO) techniques for humeral shaft fractures appear to have fewer complications and higher union rates compared to open reduction and internal fixation (ORIF). It is questionable if this also applies to simple humeral shaft fractures, as simple fractures are generally treated with absolute stability which cannot be obtained with MIPO. This raises the question whether biology or biomechanics is more important in fracture healing. This study was developed to investigate the biomechanical part of this equation. The aim of the study was to compare relative stability to absolute stability in simple humeral shaft fractures with regard to fracture healing

Methods: This was a retrospective study of all patients treated with plate fixation for AO/OTA type A1-B3 humeral shaft fractures. Patients were categorized into two groups: absolute stability and relative stability. Both groups were compared with regard to time to radiological union and full weight bearing

Results: Thirty patients were included in the relative-stability-group with either an AO/OTA type A (n = 18) or type B (n = 12) humeral shaft fracture and a mean age of 55 (SD 21) years. A total of 46 patients were included in the absolute-stability-group: 27 patients had a type A and 19 type B fracture. The mean age in this group was 45 (SD 19) years. Median follow-up was 12 months (IQR 8–13). Minimally invasive approach was used in 15 (50%) patients in the relative stability group.

Time to radiological union was significantly shorter in the absolute-stability-group with a median of 14 (IQR 12–22) versus 25 (IQR17-36) weeks and HR 2.60 (CI 1.54–4.41)($p < 0.001$). This difference remained significant after correction for type of approach (adjusted HR 3.53 CI 1.72–7.21) (p 0.001). There was no significant difference in time to full weight bearing. The addition of lag screws in the absolute stability group did not influence time to radiological healing or full weight bearing.

Conclusion: Absolute stability for simple humeral shaft fractures leads to a significantly shorter time to radiological union compared to relative stability. The addition of lag screws to gain interfragmentary compression does not reduce fracture healing time.

Introduction

Humeral shaft fractures represent 1%–3% of all fractures [1]. Classically these fractures have been treated conservatively. Due to a more demanding society, surgical fixation is becoming more popular in high income countries [2]. Both nail and plate fixation may be used. However, plate fixation is becoming the preferred method since the last decades [2]. This is likely caused by emerging evidence demonstrating shoulder pain, rotator cuff damage and periprosthetic fractures secondary to nailing [3]. Meta-analyses also suggest lower non-union rates for plating [4].

Plate osteosynthesis can be performed using either a minimally invasive approach (MIPO) or open reduction techniques (ORIF). MIPO provides relative stability and preserves fracture biology. ORIF involves direct visualization of the fracture fragments but at the cost of potentially devitalization of tissue and at a higher risk of nerve injury [5]. Absolute stability however can be achieved though this open approach which is generally advocated for simple fractures [6,7].

Several studies found higher union rates in patients treated with MIPO when compared to ORIF [3,8]. The actual reason behind this phenomenon remains unclear: Is biology (ORIF or MIPO) or

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biomechanics (absolute or relative stability) the main contributing factor for faster fracture healing?

This study was developed to analyse the biomechanical part of this equation.Several studies have demonstrated improved healing in simple fractures of the lower extremity by using an absolute stability construct compared to relative stability [6,7]. Clinical studies comparing both constructs for simple humeral shaft fractures are lacking.

The purpose of this study is to compare relative stability (using bridge plating) to absolute stability (with lag screw and neutralisation/compression plating) with regard to time to radiological union and full weight bearing in patients with simple humeral shaft fractures. By correcting for type of approach the true relation between type of construct and fracture healing can be appreciated.

The secondary aim is to assess complications and reoperation in both groups. Additionally we analysed whether there is any benefit in using multiple lag screws on time to radiological union and weight bearing.

Methods

Study design

This was a retrospective cohort study of all patients treated for a humeral shaft fracture in a level one Trauma center in Central Switzerland between January 2010 and January 2018. Plate fixation is considered the gold standard for operative treatment of humeral shaft fractures at the hospital where the study was performed.

Ethical approval was obtained from the Ethikkommission Nordwest- und Zentralschweiz in Switzerland (project number 2018-02308). This article is written in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [9].

Study population

Potentially suitable patients were identified using a diagnosis-specific code for humeral shaft fracture. Patients were included for analysis if they had undergone plate fixation for a simple shaft fracture. Simple fractures were defined as AO/OTA type A1-3 and B1-3 fractures [10].

Exclusion criteria included AO type C fractures, other treatment modalities (e.g. conservative treatment, nailing), follow-up shorter than 3 months, pathological fractures and patients younger than 18 years.

Patients were categorized into two groups: absolute stability and relative stability. Absolute stability was defined as direct anatomical reduction of the fracture using (plate dependent or independent) lag screws or compression plates to achieve interfragmentary compression.

Relative stability was defined as employing bridge plating constructs to achieve axial and rotational alignment without achievement of interfragmentary compression.

Surgical technique

The condition of the soft tissue and hemodynamic stability of the patient in case of multi-trauma determined if the fracture was temporarily immobilized using an external fixator or definitely fixed using plate fixation.

Patients were operated under general anesthesia in the supine or beach chair position. All patients received a single dose of cefazoline 30 min prior to surgery as antibiotic prophylaxis. In case of an open fracture 2200 mg amoxicillin with clavulate was administered in the emergency department. For grade 2 fractures according to Gustilo, amoxicillin was continued for 24 h, for grade 3 fractures it was continued for 5 days [11].

All procedures were performed under fluoroscopic guidance. The surgical approach (MIPO or ORIF), type of plate (either LCP 3.5 mm, 4.5 mm narrow plate, long Philos plate) and the use of a relative stability or absolute stability construct were left at the discretion of the treating surgeon.

Rehabilitation and follow-up

Postoperative treatment consisted of early non-weight bearing range of motion exercises as the patients' comfort permitted under guidance of a physiotherapist. A sling to augment patients' comfort was given for the first days. Radiographs were obtained at the first postoperative day.

Routine outpatient follow-up was performed at 6 weeks, 3 months and one year postoperatively. At every follow-up radiographs were obtained and clinical examination was performed. The choice to full weight loading was left at the discretion of the treating surgeon. Patients with either complications or healing problems were seen at regular basis (6 weeks interval) until healing was obtained.

Data collection

Data on baseline characteristics were extracted from the electronic patient records and included age, gender, comorbidities (diabetes, smoking, and osteoporosis), American Society of Anesthesiologists (ASA) Physical Status classification scores. The presence of osteoporosis was based on the Dual X-ray absorptiometry (DEXA-scan) results and was defined as having a T-score of -2.5 or lower for osteoporosis and a score between -1.0 and -2.5 for osteopenia [12]. Patients were classified as either high-energy trauma (HET) or low-energy trauma (LET) according the Acute Traumatic Life Support (ATLS) definition [13]. Radiographs at presentation were used to determine the type of fracture. Fractures were graded according the AO/OTA classification [14]. The Gustilo Classification was used in case of open fractures and based on documented photographs taken at presentation [15]. Radial nerve palsy was defined as an Oxford Score for Motor Function lower than M5 either with or without sensory loss [16].

Time to radiological fracture healing was measured. Radiological union was defined as bridging bone on a minimum of three cortices in the anteroposterior and lateral radiographic views. In case of direct fracture healing without callus formation, the disappearance of the fracture on radiographs was used to define consolidation. Time to full weight bearing was evaluated from the case records. It was defined as the ability to use the arm pain free and irrespective of weight-loading.

The maximum callus index was calculated by dividing the maximum diameter of the callus by the diameter of the bone on radiographs made during follow-up [17]. Plate span ratio and plate screw density were determined according to Gauthier et al [18].

Complications were assessed using the outpatient records. Superficial surgical site infections were classified as either superficial or deep according the definition of the Centers for Disease Control and Prevention [19]. Non-union was defined as the absence of bone healing after 6 months. Reoperation included all surgical procedures at the same surgical site after the index operation, including implant removal.

Statistical analysis

Statistical software package SPSS 20.0 was used to analyse the results. Descriptive statistics were provided of all baseline characteristics and study endpoints. Continuous variables were

described as means with standard deviation (SD) or medians with interquartile range (IQR). Differences were analysed using the independent *t*-test for normally distributed and Mann-Whitney-U-test for non-normal data. For categorical variables, the counts and percentages were calculated. Differences were analysed using the Fischer exact test.

Cox regression was used to analyse the difference between absolute and relative stability in time to radiological union and full weight bearing. Results were described as hazard ratio (HR) with corresponding confidence interval (CI) and adjusted for type of approach and other differences in baseline characteristics. A p-value under 0.05 was considered significant.

Results

Patients

One-hundred seventy two patients with the code for humeral shaft fracture were identified from the hospital database in the 8 year study period (Fig. 1). A total of 130 patients underwent surgical treatment. Plate fixation was performed in 102 patients. Eventually 76 patients had a type A1-B3 humeral shaft fracture and could be included in the final analysis.

A total of 30 patients underwent plate fixation using a relative stability construct (relative stability group) and 46 patients an absolute stability construct (absolute stability group). The median follow-up was 12 months (IQR 8–13).

Baseline characteristics

Patient characteristics for both the relative and absolute stability group are described in Table 1. Patients in the relative stability group were older with a mean age of 55 (SD 21) years versus 45 (SD 19)(p 0.048). Seventeen (37%) patients had primary radial nerve palsy in the absolute stability groups versus 4 (13.3%) in the relative stability group. This difference was statistically significant as well (p 0.035).

Surgical technique

A total of three (10.3%) patients in the relative stability group and 6 (13%) in the absolute stability group had an external fixator prior to definitive fixation. Definitive fixation was performed after a median interval of 16 h (IQR 8–92) versus 19 h (IQR 2–62) in these patients. All external fixators were removed during definitive plate osteosynthesis.

The mean operative time was almost equal in both groups: 156 (SD 12) minutes in the relative and 159 (SD 80) in the absolute stability group. There was a significant difference in approach used. MIPO was used in 15 (50%) patients in the relative stability group versus none in the absolute stability group. In the rest of this group either a paratricipital approach (n = 2, 2.6% versus n = 10, 21.7%), tricipital-split (n = 3, 10% versus n = 16, 34.8%) or anterolateral (n = 10, 33.3% versus n = 20, 43.4%) approach was used.

The following types of implants were used during the 8 years study period: locking compression plate (LCP) 3.5 mm (n = 13), LCP 4.5 mm narrow plate (n = 34), anatomical extra-articular distal humeral plate (DHP)(n = 7) and long Philos plate (n = 22).

In 28 patients of the absolute stability group either one (n = 7), two (n = 11), three (n = 5) or four (n = 5) lag screws were used.

The median hospitalisation duration was equal in both groups: 6 days (IQR 5–11) for relative stability and 6 days (IQR 4–11) for the other group.

Time to radiological union

The time to radiological union was significantly shorter in the absolute stability group with a median of 14 (IQR 12–22) versus 25 (IQR17-36) weeks and HR 2.60 (CI 1.54–4.41)($p < 0.001$)(Fig. 2). This difference remained significant after adjusting for type of approach, age and radial nerve palsy (adjusted HR 3.53 CI 1.72–7.21) (p 0.001).

There was no significant difference in median time to union in the absolute stability group according to the number of lag screws used (Table 2).

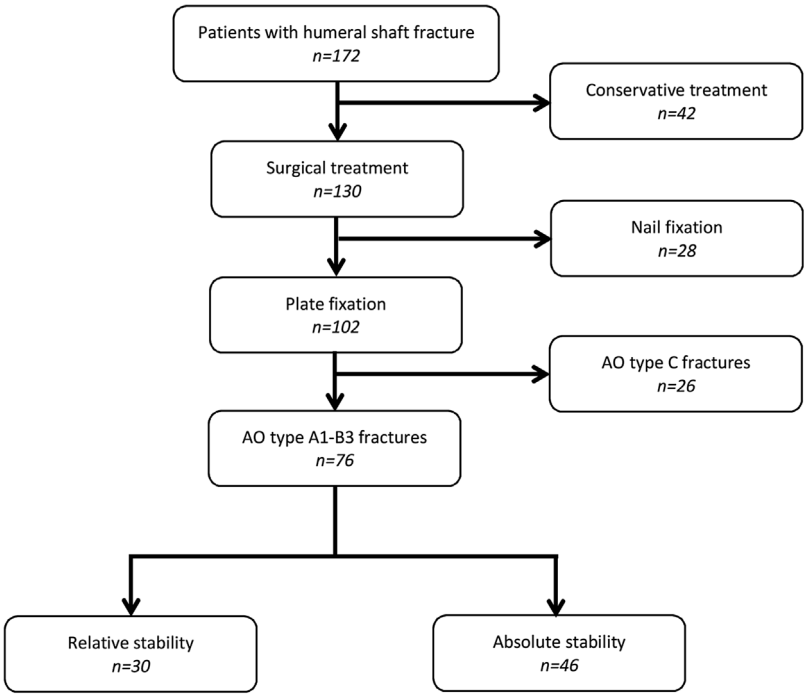

Fig. 1. Flowchart of study population.

Table 1
Baseline characteristics of relative versus absolute stability group.

			Relative stability (n = 30)	Absolute stability (n = 46)	P- value
Age (years)			54.5 (SD 21.2)	45.11 (SD 19.1)	**0.048**
Gender (male)			16 (53.3%)	26 (56.6%)	0.817
Comorbidities	ASA	I	0 (0%)	0 (0%)	0.488
		II	4 (13.3%)	13 (28.3%)	
		III	14 (46.7%)	18 (39.1%)	
		IV	12 (40%)	15 (32.6%)	
	Smoking	Current	3 (10%)	7 (15.2%)	0.521
		In the past	2 (6.7%)	1 (2.2%)	
	DM		6 (20%)	3 (6.5%)	0.186
	DEXA-scan	Osteopenia	0 (0%)	1 (2.2%)	0.335
		Osteoporosis	1 (3.3%)	0 (0%)	
Trauma intensity (HET)			8 (28.6%)	13 (28.9%)	0.977
AO classification	A		18 (60%)	27 (58.7%)	0.910
		A1	4 (13.3%)	9 (19.6%)	
		A2	4 (13.3%)	8 (17.4%)	
		A3	10 (33.3%)	10 (21.7%)	
	B		12 (40%)	19 (41.3%)	
		B1	6 (20%)	14 (30.4%)	
		B2	2 (13.3%)	2 (4.3%)	
		B3	2 (6.7%)	3 (6.5%)	
Gustillo classification	Uncomplicated		27 (90%)	39 (84.8%)	0.837
	Type I		2 (6.7%)	4 (8.7%)	
	Type II		1 (3.3%)	2 (4.3%)	
	Type III		0 (0%)	1 (2.2%)	
Primary radial nerve palsy			4 (13.3%)	17 (37%)	**0.035**

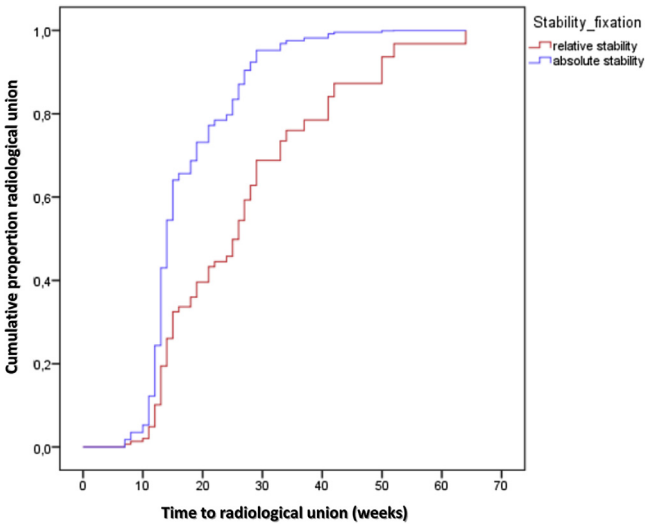

Fig. 2. Cumulative proportion of time to radiological union per group.

Time to full weight bearing

Median time to full weight bearing was 12 (IQR10-18) weeks in the relative and 14 (IQR 12–17) in the absolute stability group (Table 2). This difference was not significant (HR 0.94 CI 0.58–1.52) (p 0.807)(Fig. 3). There was also no significant difference according to the type and number of lag screws used.

Complications

Sixty-nine of the total group of patients (90.1%) recovered uneventfully. In the relative stability group 3 (10%) patients developed complications and/or required re-operation. This was 3 (6.5%) in the absolute stability group. This difference was not significant (p 0.169).

Both superficial and deep surgical site infections did not occur. Non-union was seen in two (6.7%) patients of the relative stability group. Removal and plate re-implantation with cancellous bone was performed in both patients. Both healed eventually.

Complete implant removal was performed in 1 (3.3%) patient in the relative stability group and 3 (6.5%) of the absolute stability

Table 2
Time to radiological union and time to full weight bearing in weeks for both groups.

		Time to radiological fracture union in weeks median (IQR)	Time to full weight bearing in weeks median (IQR)
Study cohort		15 (13-27)	13 (12-18)
Relative stability		25 (17-36)	12 (10-18)
Absolute stability		14 (12-22)	14 (12-17)
Lag screws	0 (n = 16)	15 (12-24)	15 (11-17)
	1 (n = 7)	14 (11-19)	14 (12-20)
	2 (n = 11)	14 (12-25)	15 (13-19)
	3 (n = 5	13 (12-13)	12 (12-13)
	4 (n = 5)	13 (13-28)	13 (11-14)

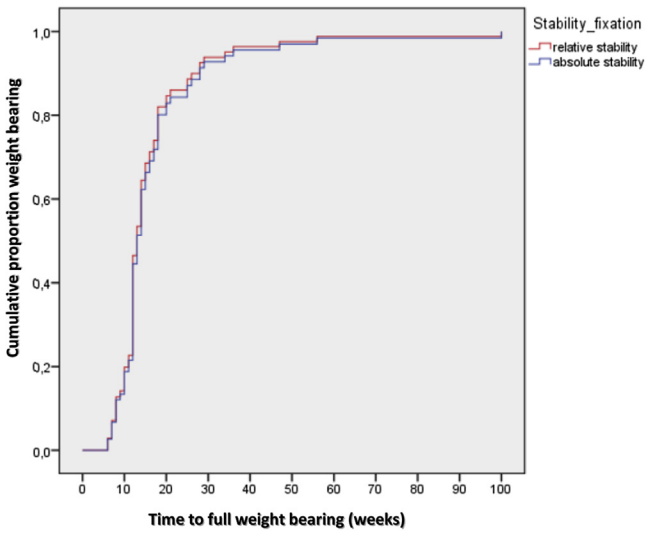

Fig. 3. Cumulative proportion of time to full weight bearing per group.

group. Removal was performed due to plate related complaints and whish of the patient.

Callus index

In the absolute stability group the mean callus index was 1.22 (SD 0.17) in the frontal and 1.16 (SD 0.11) in the sagittal plane (Table 3). One (2.8%) patient in this group healed with no callus formation (callus index 1.00). In this patient no lag screws were used. Compression of the fracture was obtained using the compression option of the plates. There was no significant difference in callus index in the absolute stability group with different number of lag screws used (p 0.197).

In the relative stability group the mean callus index was 1.32 (SD 0.33) in the frontal and 1.31 (SD 0.27) in the sagittal plane. The relative and absolute stability groups only differed in callus index on the sagittal plane (p 0.001).

Osteosynthesis construct

Facts about the osteosynthesis construct of both groups are described in Table 3.

The plate span width was 6.3 in the relative stability group and 7.2 in the other group (p 0.701). More screws were used in the proximal fragment in the absolute stability group leading to a significant difference in total plate screw density between both groups (0.55 relative stability group versus 0.64 absolute stability group)(p 0.013).

Discussion

The purpose of this study was to compare absolute to relative stability in simple humeral shaft fractures with regard to fracture healing. Absolute stability for simple humeral shaft fractures leads to a significantly shorter time to radiological union compared to relative stability without leading to more complications. The addition of lag screws to increase interfragmentary compression does not improve time to radiological union compared to using only compression plating or a minimal number of lag screws. There is no difference between an absolute and relative stability construct with regards to operative time, hospitalisation duration and complications.

Previous studies have demonstrated a similar principle of attaining faster radiological union with absolute stability for the lower extremity[5,6,20]. For humeral shaft fractures this has only been, indirectly, studied by Wong Yi et al[21]. Wong Yi studied the differences in primary and secondary bone healing. Union in patients with primary bone healing occurred at 12 weeks. This was 24 weeks for secondary bone healing. He also identified that a smaller fracture gap and mode of compression (using lag screws in combination with neutralization plate) was associated with the occurrence of primary bone healing. This suggests that anatomical reduction and interfragmentary compression leads to primary bone healing together with faster radiological union. Our study compared absolute to relative stability directly and came to the same conclusion. The use of direct and anatomical reduction (absolute stability) led to a median radiological union time of 14 weeks. This was 24 weeks in the relative stability group.

Although this study found a difference in time to radiological union, no difference in time to full weight bearing could be detected. The ability to fully weight bear was determined at fixed intervals due to the retrospective nature of the present study. Consequently this outcome is also determined by the length of the intervals. This applies to lesser extent for radiological fracture union as changes in radiographs require an interval of several weeks to become detectable.

The incidence of complications in the present study was rather low. Wound infection and non-union usually occur in approximately 7.8% and 7.4%, respectively, as described in recent meta-analyses [3]. No patient had a wound infection in our study and non-union occurred only in two (6.7%) patients. This might partly be due to chance and a relative small sample size. However as plate fixation is the golden standard in the study hospital, greater surgical experience might also have played an important role.

Interestingly there was no difference between number of lag screws used and callus formation. Theoretically application of lag screws leads to interfragmentary compression and therefore primary bone healing without callus. Although callus formation was lower in the absolute stability group, only one patient (2.8%) healed completely without callus. This suggests that in the majority of patients in the absolute stability group, no complete absolute stability was attained. The fact that the plate span width in the absolute stability group was below the advised threshold of 8, further supports that no complete absolute stability was achieved [18]. The lag screw therefore should be interpreted as a reposition screw rather than a lag screw.

It should be noted that the aim of this study was to compare relative to absolute stability without type of approach being a

Table 3
Facts about osteosynthesis construct.

		Relative stability (n = 30)	Absolute stability (n = 46)	P-value
Callus index (AP)		1.32 (SD 0.33)	1.22 (SD 0.17)	0.079
Callus index (lateral)		1.31 (SD 0.27)	1.16 (SD 0.11)	0.001
Plate span width		6.3 (SD 6.9)	7.2 (SD 10.6)	0.701
Plate screw density	Plate	0.55 (SD 0.13)	0.64 (SD 0.15)	**0.013**
	Proximal	0.62 (SD 0.23)	0.74 (SD 0.22)	**0.032**
	Distal	0.73 (SD 0.21)	0.80 (SD 0.21)	0.187

confounding factor. Minimally invasive techniques usually employ a relative stability construct as found in the present study. Recent meta-analyses have shown minimally invasive techniques tending to be superior to open plating [5]. Logically it may be suggested that the type of approach might have confounded the results. However in the present study we adjusted for this. Moreover, by correcting for age, nerve palsy and type of approach, the hazard ratio increased from 2.6 (CI 1.54–4.41) to 3.53 (CI 1.72–7.21). This strengthens the conclusion that faster radiological union is caused by type of stability irrespective of the approach or age.

From a clinical point of view, the results of this study support the use of open reduction techniques in order to gain absolute stability. Interestingly this completely contradicts the current literature claiming minimally invasive techniques to be superior with regard to union rates [3,8]. The possible explanation for this, lies in the fundamental question: Is biology or biomechanics the most important contributing factor in fracture healing? The fact that minimally invasive techniques achieve faster fracture healing despite the use of relative stability, suggest that biology is generally more important than biomechanics for the whole spectrum of humeral shaft fractures. However, in simple fractures there is no advantage to perform a MIPO approach in respect to biomechanics, but only in respect to omit radial nerve palsy since MIPO is usually performed with anterior plating without compromise of the radial nerve.

This study has certain limitations that should be taken into account. Firstly, due to the retrospective nature of the present study, selection bias cannot be excluded. There were some differences in baseline characteristics between the absolute and relative stability group, for which we corrected in our primary analysis. However, the occurrence of differences in observed characteristics, makes it more likely that there might be differences in unobserved characteristics as well, for which we logically cannot correct in the analysis.

Secondly, we collected our data through chart review which inevitably leads to certain amounts of information bias for outcome parameters. The determination of the moment in time for a patient to be able to fully weight-bare, was done by the treating surgeons at fixed intervals. This makes it dependent of the time intervals, as previously described, and, more importantly, subject to the experience, education and view of the treating surgeon.

Thirdly, excluded patients were either treated conservatively (n = 42) or operatively using humeral nailing techniques (n = 28). Furthermore, as no absolute stability can be obtained in AO 11 C fractures they have been excluded as well. Results of this study are therefore only applicable for patients with characteristics comparable to the study population and not generalizable to all patients with simple humeral shaft fractures.

Lastly, due to the limited amount of patients, we could not perform subgroup analyses to determine whether fracture pattern was related to our outcome of interest.

This is the first study to directly compare absolute to relative stability in simple humeral shaft fractures. To truly appreciate the relation between these constructs and fracture healing, additional prospective studies are needed. A randomized clinical trial would prevent the occurrence of selection as encountered in the present study. The ability to fully weight should ideally be measured on a day to day basis using a diary given to the patients.

Conclusion

This study showed that applying an absolute stability construct significantly reduces time to radiological union in patients with simple humeral shaft fractures when compared to relative stability irrespective of age or type of approach without increasing the risk of complications. There is no benefit in using additional lag screws with regard to time to radiological union or full weight bearing. Adding lag screws does not necessarily assure absolute stability. It may however aid in reduction. Additional research in the form randomised clinical trials however are needed to strengthen this conclusion.

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None.

Declaration of Competing Interest

The authors declare no conflict of interest.

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