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Syndesmotic fixation in unstable ankle fractures: Does early post-operative weight bearing affect radiographic outcomes?

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ABSTRACT

Objective: To analyse whether early post-operative full weight bearing following syndesmotic ankle fixation affected radiographic outcomes suggestive of diastasis.
Design: Retrospective comparative cohort study over a two year period.
Setting: Level 1 trauma centre
Patients/Participants: 152 consecutive patients sustaining an unstable ankle fracture requiring syndesmotic stabilisation were included. Exclusions were 49 patients who had trimalleolar fixation without syndesmosis screws, one patient who had concomitant ankle and talar fracture. Five patients were lost to follow up and eleven patients were followed up in other centres. A total of 86 patients were analysed
Intervention: Protected or full weight bearing.
Main Outcome Measurement: The primary outcome measure was early diastasis. The secondary outcomes were late diastasis, wound complications and re-operation. Analysis of variance was used for the predictor variable of weight bearing status. We assumed *a priori* that p values of less than 0.05 were significant.
Results: Median age was 36 (IQR 30), with 54 males and 32 females. Median follow up was 12 weeks (IQR 6). There was no significant difference when comparing weight bearing status and change in radiographic measurements intra-operatively compared to 6 and 12 week follow up radiographs (tibiofibular clear space p = 0.799, tibiofibular overlap p = 0.733 and medial clear space p = 0.261).
Conclusion: After surgical stabilization of an unstable syndesmotic injury, full weight bearing did not lead to syndesmotic diastasis in the early post-operative period. Full weight bearing is recommended following ankle fixation which includes syndesmotic fixation.

Introduction

Ankle fractures are relatively common injuries, with an incidence of 14.8 per 10,000 person years in the United Kingdom [1]. The majority of ankle fractures are stable, requiring conservative methods to reduce pain and swelling before optimising function [2]. In unstable ankle fractures, injury to the syndesmosis can occur, leading to tibiofibular diastasis. Failure to recognise, anatomically reduce and stabilise the syndesmosis has been shown to lead to early post-traumatic arthritis and correlates with negative clinical outcomes [3–6].

The decision to weight bear patients following stabilisation of ankle fractures with syndesmotic instability remains controversial and varies both within and between centres [7–9]. The benefits of early weight bearing and mobilisation in these injuries has been shown to reduce rates of thromboembolic events as well as increase functional outcome, with an earlier return to work. Additionally, there is a quicker return to pre-morbid state, particularly in the young [10,11]. In the United Kingdom, national standards produced by the "British Orthopaedic Association" and the "British Orthopaedic Foot and Ankle Society" specify that the syndesmosis should be assessed following ankle fracture fixation and stabilised if required, allowing full weight bearing unless concerns regarding peripheral neuropathy or condition of the soft tissues (BOAST 12) [12]. Despite this, treating surgeons vary in their post-operative protocol, with some allowing full weight bearing (FWB) within two weeks (allowing any wounds to settle), and some protecting weight bearing (PWB) (either toe-touch or up to 50%) for six weeks. The authors aimed to analyse whether early full weight bearing following syndesmotic fixation affected early and late radiographic outcomes suggestive of diastasis.

Ethical permission was not obtained as this was an audit of service against a national standard.

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Materials and methods

This was a retrospective comparative cohort study over a two-year period from January 2016 - January 2018. The trauma database in the unit was used to identify all ankle fractures treated operatively and followed up for a minimum of six weeks. All patients were followed up in consultant led fracture clinics. The decision to weight bear was left to the treating physician's discretion.

A total of 152 patients underwent stabilization for unstable ankle fractures with syndesmotic injury, but without fracture of the posterior malleolus, within this time-period. Fractures were classified using the Weber and Lauge-Hansen classification [13], defined as all supination external rotation stage IV injuries and any pronation abduction or pronation external rotation injuries of stage III or more. Syndesmotic instability was defined as tibiofibular diastasis occurring during external rotation stress testing, identified with intra-operative fluoroscopy. The method of syndesmotic fixation was decided by the treating surgeon, size of screw, level of fixation and number of cortices engaged was analysed given there is no consensus in the literature on this matter [14–16].

A total of sixty-six patients were excluded. This comprised 49 patients who had trimalleolar fixation without syndesmosis screws, one patient who had concomitant ankle and talar fracture fixation, four patients who were lost to follow up, one patient followed up for under six weeks and 11 patients were followed up in other centres following their operation. Those without posterior malleolus fracture and fixation were excluded given the increased severity of this injury, increased complexity of operation and fixation as well as rehabilitation. All of these factors were considered confounding and outwith the boundaries of standardization of the injury cohort to be analysed. A total of 86 patients were therefore eligible for final analysis.

Radiographic analysis

Radiographic parameters were compared between final intra-operative images, and six and twelve week follow up radiographs. Patients underwent non-weight bearing anterior-posterior and lateral views at follow up episodes unless weight bearing views were specifically requested. This allowed a valid comparison to be made to intra-operative imaging.

Only anterior-posterior views were used to identify radiographic syndesmotic widening. This is based on evidence from Pneumaticos et al [17] who demonstrated that tibiofibular clear space in the anteroposterior plane is unaffected by rotation, and should be used to detect subtle diastasis. In addition to tibio-fibular clear space, the tibio-fibular overlap and medial clear-space was also assessed on this view. These measurements have previously been defined extensively in the literature [18–21].

The measurements (in millimetres) were defined as below and shown in Figs. 1a–1c:

1. Tibio-fibular clear space - the distance between the medial border of the fibula and the lateral border of the posterior tibial incisura at a level of 10 mm above the tibial plafond.
2. Tibio-fibular overlap - the maximum amount of overlap of the distal fibula and anterior tibial tubercle at 10 mm above the tibial plafond.
3. Medial clear space - the distance between the lateral border of the medial malleolus and the medial border of the talus, at the level of the talar dome.

Radiographs were analysed by two independent orthopaedic residents not involved in the operations, with blinding of the each reviewer's measurements. This was done to assess inter-observer reliability.

Fig. 1a. Radiographic measurement of tibiofibular clear space.

Fig. 1b. Radiographic measurement of tibiofibular overlap.

Statistical analysis

All data, such as patient demographics, co-morbidities (smoking and diabetes), follow up, complications and radiographic measurements, was stored on a secure database to protect patient confidentiality.

Analysis was undertaken with IBM "SPSS" Statistics version 23 (IBM Corp. Released 2015. IBM SPSS Statistics for Windows,

Fig. 1c. Radiographic measurement of medial clear space.

Version 22.0. Armonk, NY: IBM Corp). Descriptive statistics were used for categorical data and Shapiro-Wilkes testing for normality for any continuous data. Parametric data was expressed as mean and standard deviation, with non-parametric data as median and interquartile range (IQR). Collinearity testing via data tolerance and variance inflation factors (VIF) for independent variables was carried out. No correlation was found between measurements. A split-plot repeated measures analysis of variance (ANOVA) was utilised for the continuous primary outcome of early diastasis. This comprised tibio-fibular clear space, tibiofibular overlap and medial clear space measurements. A split-plot ANOVA was done to account for repeated measurements between two groups. An increased tibio-fibular clear space was considered a negative patient outcome indicative of diastasis, with the other two being positive outcomes indicative of retained stability.

The independent variables assessed between subjects were: weight bearing status alone and weight bearing status in either a boot or cast. The independent variables within subjects was the intra-operative and post-operative syndesmotic measurements.

Secondary outcome measures included any infection, wound breakdown, nerve injury and screw breakage. Binary logistic regression was used to assess association of these with weight bearing.

Inter-observer reliability of radiographic measurements was assessed using Cohen's Kappa coefficient. Interpretation of agreement was undertaken using the Landis and Koch reference values [22], where a Kappa value of < 0 indicates no agreement, 0–0.20 as slight agreement, 0.21–0.40 as fair agreement, 0.41–0.60 as moderate agreement, 0.61–0.80 as substantial agreement, and 0.81–1 as almost perfect observer agreement.

For the secondary outcome of late diastasis, linear regression was utilized to assess association between negative radiographic outcomes and length of follow up regardless of weight bearing.

Mixed ANOVA was used to assess association between negative radiographic outcomes and only patients who had 12 week follow up or more with weight bearing as a predictor and type of fixation used. It was assumed *a priori* that p values of less than 0.05 were significant.

Results

Demographics

Median age was 36 (IQR 30), with fifty-four males and thirty-two females. Of the eighty-six patients, twenty–three (23/86) were followed up for six weeks with sixty-three (63/86) patients followed up for a minimum twelve weeks. Median follow up was 12 weeks (IQR 6). There were forty-six (46/86) right sided injuries with the remaining forty (40/86) left sided. Seventy-seven (77/86) of these injuries were closed with the remaining nine (9/86) open. When examining level of injury, fifty-seven (57/86) were Weber C injuries (eleven (11/86) pronation abduction (6 PWB, 5 FWB), forty-six (46/86) pronation external rotation (31 PWB, 15 FWB) with twenty-nine (29/86) Weber B injuries supination external rotation (11 PWB, 18 FWB). Duration of follow up according to initial weight bearing is shown in Table 3.

For the twenty-three (23/86) patients not followed up for more than six weeks, four (4/86) were discharged, sixteen (16/86) were offered an open appointment for six months and three (3/86) did not attend follow up at 12 weeks. All those given an open appointment or discharged showed satisfactory progress at follow up and outcome of appointment was down to clinician discretion.

The type of fixation varied between patients. A detailed breakdown of this according to initial weight bearing status is shown in Tables 4 and 5.

Primary outcome

Following syndesmotic stabilisation, 38 patients were FWB within two weeks from their surgery, with 48 PWB. Of those FWB, 28 were in a fixed ankle boot, and 10 in a walking cast. In those PWB, 29 were in a fixed ankle boot with the remaining 19 in walking cast. Mean and standard deviation values for all radiographic measurements are presented in Table 1. No patients met the radiographic criteria of early diastasis in our study at six week follow up.

Split-plot ANOVA did not show a significant difference when comparing weight bearing status and change in radiographic measurements intra-operatively compared to six week follow up radiographs (tibiofibular clear space $p = 0.799$, tibiofibular overlap $p = 0.733$ and medial clear space $p = 0.261$).

In those FWB, there was no significant difference found when immobilised in fixed ankle boot or cast (tibiofibular clear space

Table 1
Mean (standard deviation) radiographic measurement values (mm).

	Intra-tibiofbular clear space	Intra-tibiofibular overlap	Intra-medial clear space	Post-tibiofbular clear space	Post-tibiofibular overlap	Post-medial clear space
Full Weight bearing	5.9 (1.4)	5.6 (1.2)	4.4 (0.9)	5.3 (1.2)	4.5 (1.3)	3.9 (0.7)
Protected weight bearing	3.8 (1.3)	4.6 (1.5)	4.6 (0.9)	5.2 (1.3)	4.5 (1.2)	4.1 (0.7)
All patients	5.9 (1.4)	4.6 (1.4)	4.5 (0.9)	5.3 (1.2)	4.5 (1.2)	4.0 (0.7)

p = 0.522, tibiofibular overlap p = 0.896 and medial clear space p = 0.221). In those PWB, there was no significant difference found when immobilised in fixed ankle boot or cast (tibiofibular clear space p = 0.533, tibiofibular overlap p = 0.285 and medial clear space p = 0.443).

Inter-observer reliability was moderate for tibiofibular clear-space (κ = 0.59) and tibiofibular overlap (κ = 0.561), with substantial reliability for medial clearspace (κ = 0.702).

Secondary outcomes

One patient (1/86) had evidence of a deep infection. Four patients (4/86) had altered sensation in the superficial perineal nerve distribution at six week follow up and eleven patients (11/86) sustained late broken screws. Of those eleven, six (6/11) were PWB and the remaining five (5/11) FWB, this was not significant ($p > 0.05$).

One (1/11) PWB patient had a broken screw at six weeks with no further re-operation or complications. Nine patients (9/11) had a broken screw at 12 week follow up, one of whom in the FWB group required elective screw removal for soft tissue impingement. The remaining one patient (1/11) was found to have a broken screw at 20 weeks with no further intervention required.

One patient (1/86) sustained an early superficial wound dehiscence that required re-operation. This patient was PWB. There was no significant association between negative secondary outcomes and weight bearing status ($p > 0.05$). A breakdown of these results is presented in Table 2.

Late diastasis

No patients met the radiographic criteria of diastasis at minimum 12 week follow up in our study. Linear regression assessing did not show an association between negative radiographic outcomes and increasing length of follow up regardless of weight bearing status (tibiofibular clear space p = 0.629, tibiofibular overlap p = 0.417 and medial clear space p = 0.285).

Of the 63 patients who had minimum 12 week follow up, there was no association between weight bearing status and radiographic outcomes (tibiofibular clear space p = 0.696, tibiofibular overlap p = 0.459 and medial clear space p = 0.700).

There was no association between radiographic outcomes and number of screws (tibiofibular clear space p = 0.548, tibiofibular overlap p = 0.459 and medial clear space p = 0.987)., size of screws used (tibiofibular clear space p = 0.805, tibiofibular overlap p = 0.719 and medial clear space p = 0.654) and number of cortices engaged (tibiofibular clear space p = 0.537, tibiofibular overlap p = 0.509 and medial clear space p = 0.843).

There was no association between negative radiographic measures and overall fixation method (tibiofibular clear space p = 0.899, tibiofibular overlap p = 0.756 and medial clear space p = 0.824).

Discussion

This study demonstrates that in unstable ankle fractures with concomitant syndesmotic injury requiring internal fixation, FWB patients in the immediate post-operative period has no significant effect on radiographic outcomes compared to those under PWB. Furthermore, there is no association between weight bearing status and negative secondary outcomes.

Table 2
Follow up based on initial weight bearing status.

	6 week follow up	Minimum 12 week follow up	Total
Full weight bearing	13	25	38
Protected weight bearing	10	38	48

Table 3
Secondary outcomes breakdown.

	Full weight bearing	Protected weight bearing	Total
Infection	1	0	1
Nerve injury	2	2	4
Wound dehiscence	0	1	1
Metalwork breakage	2	4	6

The ankle syndesmosis normally sustains large three-dimensional loads during daily activity and plays a vital role in stabilising the ankle mortise whilst maintaining a degree of micromotion [23–25]. Despite its importance, there remains a paucity of evidence regarding the timing of FWB following syndesmotic fixation regardless of method used including screws and tightrope systems [26–28]. Cadaveric biomechanical studies have previously shown that syndesmotic set screws are unable to resist syndesmotic widening when load equivalent to body weight is applied [29]. This has contributed to the traditional post-operative management of ankle injuries with prolonged PWB in cast before the patient is allowed to return to normal load [5,30]. This can come at a significant cost to the patient, both with regards to functional rehabilitation and the financial penalty of a late return to work [31].

A 2008 United Kingdom survey of orthopaedic trauma surgeons revealed that 73% of surgeons advise patients who have had syndesmotic fixation, to remain non-weight bearing in the short term post-operative period, with only 9% advising FWB. [32] Proponents of PWB argue that the syndesmosis requires at least 6 weeks to heal and fixation should not be compromised, as recurrence of syndesmotic diastasis can lead to post-traumatic arthritis and functional restriction [33]. Furthermore, it has been postulated that early weight bearing can cause screw breakage rates of up to 29% [34,35]. It has also been demonstrated that the syndesmotic screw can lead to reduced tibiotalar external rotation and that the screw should be removed prior to weight bearing to improve functional outcomes [36]. The technical difficulty of removing a broken screw therefore can lead to failure of such an operation and disadvantageous outcomes long term. Similar issues with soft tissues have also been reported in tightrope fixation [37]. However, this has also been countered with evidence suggesting that a broken syndesmotic screw led to paradoxical improved clinical outcomes [38]. Despite these biomechanical indications, the evidence is still lacking, without any real consensus in the orthopaedic community as to whether PWB should remain the gold standard treatment [32].

Conversely, the authors of this study present the notion that early FWB in the absence of absolute indications is both pragmatic and desirable. Ankle fractures with syndesmotic injury are predominantly an injury of the young [39], with our cohort demonstrating a median age of 36. Therefore the major goal of any post-operative regime should be to minimise recovery time and attain FWB as early as possible [8,40]. Early FWB allows for earlier range of motion of the ankle joint, which has been demonstrated to be beneficial to damaged articular cartilage [41,42]. Additionally, further previous studies have not shown any significant objective difference in clinical outcome for those who were advised to remain non-weight bearing post-operatively [42,43]. Full weight bearing in the immediate period has also not been shown to increase infection, wound complication or loss of reduction, and it has even been recommended in the elderly population [43]. With regards to radiographic outcomes, this has been scarcely studied. A previous United Kingdom study looked at operatively managed

Table 4
Breakdown according to specific fixation method.

		Full weight bearing	Protected weight bearing	Total
Number of screws	1	18	17	35
	2	16	29	45
	3	3	2	5
Size of screw	3.5 mm	37	46	83
	4.5 mm	0	1	1
Number of cortices	3	4	3	7
	4	33	45	78
Tightrope		0	1	1

Table 5
Overall fixation method.

	1 screw, 3.5 mm, 3 cortices	1 screw, 3.5 mm, 4 cortices	2 screws, 3.5 mm, 3 cortices	2 screws, 3.5 mm, 4 cortices	3 screws, 3.5 mm, 4 cortices	Tightrope	Total
FWB	2	16	2	14	3	1	**38**
PWB	3	14	0	29	2	0	**48**

unstable ankle fractures with or without syndesmotic injury. There was no correlation between weight bearing and increased medial clear space on radiographic examination. Additionally patients in the FWB group returned to work a mean 36 days quicker, with no difference in functional outcomes [44]. However, more detailed radiographic examination of the syndesmosis was not undertaken as per our study.

To the authors' best knowledge, this study is the largest of its size to analyse radiographic outcomes after fully weight bearing patients with fixed syndesmotic injuries. Furthermore, it was performed in a major trauma unit, where a large volume of these injuries is managed routinely. Independent evaluation of radiographic measurements by means of inter-observer reliability is a further strength of this study which contributes to the validity of any association made. The results can therefore be considered more robust. Further work is required to assess longer term radiological outcomes and functional scores for these patients, ideally on a more prospective basis.

Limitations of the study include its design, being retrospective, observational and based on case notes and non-standardised radiographs. There were no functional outcomes collected and no measure of whether patients complied with post-operative instructions. The follow up period of 12 weeks is relatively short and this paper does not show If there was any evidence of diastasis beyond this. All these are significant limitations and future work should address these.

Conclusion

After surgical stabilization of an unstable syndesmotic injury, full weight bearing did not lead to syndesmotic diastasis in the early post-operative period. Full weight bearing ankle fixation which includes syndesmotic fixation appears to be safe. The authors recommend a formal prospective study to reaffirm these findings.

Conflicts of interest and source of funding

No conflicts of interest. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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