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### OUTCOMES FOLLOWING DYNAMIC SYNDESMOTIC FIXATION IN ANKLE FRACTURES WITH A SYNDESMOTIC INJURY: A RETROSPECTIVE COHORT STUDY FROM SOUTH AFRICA.

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# Abstract

# Background

Ankle fractures are common injuries, with approximately 33% involving syndesmotic disruption in South Africa. While static screw fixation (SSF) has traditionally been the standard treatment, dynamic fixation (DF) using suturebutton devices offers an increasingly popular alternative. This study evaluated the clinical outcomes of DF in managing syndesmotic injuries.

### **Materials and Methods**

A retrospective cohort study was conducted on 50 patients who sustained ankle fractures with associated syndesmotic injuries and underwent surgical fixation using suture-button devices at a regional hospital in KwaZulu-Natal. Outcomes were assessed using the American Orthopaedic Foot and Ankle Society (AOFAS) score at a one-year follow-up.

### **Results**

The mean age of patients was 36.9 years, and 70% were female. Most injuries were classified as Weber B and SER stage 4. All patients achieved fracture union and maintained syndesmotic reduction, with no malreductions, infections, or hardware failures reported. The mean AOFAS score was 91.7, with 92% of patients scoring above 75. Higher BMI (p = 0.019) and delayed surgery beyond 14 days (p = 0.002) were associated with lower scores. HIV-positive patients had slightly reduced scores, although this was not statistically significant. Smoking and elevated BMI did not increase complication rates. Functional outcomes were comparable between single and double suture-button fixation (p = 0.1).

### Conclusion

Dynamic syndesmotic fixation using suture-button devices is a safe and effective method for treating syndesmotic injuries, with excellent short-term functional outcomes and low complication rates. Patient-specific factors, including BMI and surgical timing, significantly influence recovery, highlighting the need for individualized care.

### Recommendation

Given the favorable outcomes and reduced complication profile, dynamic fixation should be considered a preferred treatment strategy for syndesmotic injuries, particularly in young, active patients. Further prospective studies are warranted to confirm long-term efficacy and guide broader implementation.

*Keywords:* ankle fracture, syndesmosis, syndesmotic fixation, dynamic fixation, tightrope, static screw fixation. *Submitted:* 2025-04-18 *Accepted:* 2025-05-11 *Published:* 2025-06-01

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### Introduction

Ankle fractures are among the most commonly encountered injuries of the lower limb. South African

data suggest that approximately 33% of these fractures involve syndesmotic disruption (1). The syndesmotic complex—comprising the anterior-inferior tibiofibular



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ligament (AITFL), posterior-inferior tibiofibular ligament (PITFL), inferior transverse ligament (ITL), and interosseous ligament (IOL) is essential for maintaining distal tibiofibular joint integrity and preserving ankle mortise congruity (2). Even subtle

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disruption can lead to joint instability, malalignment, and downstream consequences such as persistent pain, impaired function, and early degenerative arthritis (3-6). Precise anatomical reduction and secure fixation are therefore critical, as a 1 mm lateral shift of the talus has been shown to decrease tibio-talar contact area by up to 40%, adversely affecting weight-bearing mechanics (7). Static screw fixation (SSF) has historically been regarded as the gold standard for syndesmotic stabilization (8). However, it is associated with several limitations, including screw breakage, loosening, hardware irritation, and restriction of physiological joint motion (9-13). Additionally, removal of the screw has been linked to syndesmotic diastasis in 6.6% of cases, which may further compromise joint stability (14). As a result, dynamic fixation (DF) using suture-button systems has gained popularity as an alternative approach (15-17). This technique uses a non-absorbable fiber looped through metallic buttons to secure the syndesmosis while allowing for controlled physiological movement during loading (11).

Dynamic fixation offers potential advantages such as earlier mobilization, reduced risk of hardware-related complications, and avoidance of a second surgery for implant removal (18-20). Moreover, its dynamic properties may help maintain joint motion, contributing to improved post-operative function and reduced discomfort. However, high-level comparative data between DF and SSF remain limited, particularly about functional outcomes, complication rates, range of motion, and revision procedures (10, 21).

This study aims to assess the clinical performance of dynamic fixation in ankle fractures with syndesmotic involvement. Key outcomes will include union rates, fixation failure, complications, need for reoperation, and functional status as measured by the AOFAS score. As the use of suture-button devices becomes increasingly common, evaluating their utility in the South African population is vital for guiding management protocols and optimizing patient care.

Ankle fractures are among the most common injuries affecting the lower limb. Local data indicate that up to 33% of ankle fractures in South Africa involve syndesmosis (1). The syndesmotic complex, comprising four ligaments— the anterior-inferior tibiofibular ligament (AITFL), posterior-inferior tibiofibular ligament (PITFL), inferior transverse tibiofibular ligament (ITL), and interosseous ligament (IOL)—plays a crucial role in stabilizing the distal tibiofibular joint and maintaining the congruency of the ankle mortise (2). Even a minor disruption can lead to significant instability, mal-reduction, and subsequent complications, including persistent pain, functional impairment, and early osteoarthritis (3-6). Anatomic reduction and stable fixation of the syndesmosis are critical for ensuring proper joint function, as a 1 mm lateral shift in the talus can result in a 40% loss of tibio-talar contact area, dramatically impacting weight-bearing mechanics (7).

Traditionally, static screw fixation (SSF) has been the gold standard for syndesmotic stabilization (8). However, this approach is not without significant drawbacks. Complications such as screw loosening, breakage, metal irritation, and limited range of motion are commonly reported (9-13). Additionally, Screw removal surgery has been associated with syndesmotic diastasis in 6.6% of patients, which may contribute to joint instability (14). In response to these issues, dynamic fixation (DF) using suture-button devices has gained traction as an alternative (15-17). This method employs a non-absorbable suture looped through metal buttons to stabilize the syndesmosis, allowing for more natural physiologic movement during load-bearing while maintaining joint reduction (11).

The advantages of DF include earlier rehabilitation, reduced risk of hardware complications, and the avoidance of secondary surgery for hardware removal (18-20). Furthermore, the dynamic nature of this fixation allows the joint to maintain its natural motion, potentially improving functional outcomes and reducing post-operative discomfort. Despite its increasing popularity, there is still a lack of robust clinical evidence directly comparing DF to SSF in terms of functional outcomes, range of motion, complication rates, and the need for reoperation (10, 21).

This study aims to evaluate the efficacy of dynamic fixation in treating ankle fractures with associated syndesmotic injuries, with a focus on assessing rates of union, fixation failure, complications, reoperation, and clinical outcomes as measured by the AOFAS score. Given the growing use of suture-button devices, understanding their benefits and risks within the South African population is essential for improving treatment protocols and patient care in this setting.

### Materials and methods Study design

This study employed a retrospective cohort design, reviewing medical records of patients who sustained ankle fractures with associated syndesmotic injuries and underwent surgical management with dynamic fixation at a regional hospital in KwaZulu-Natal.

A retrospective analysis was conducted on all patients who sustained ankle fractures with associated syndesmotic injuries and underwent surgical treatment



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using dynamic syndesmotic fixation at a regional hospital in KwaZulu-Natal. Theatre records were canvassed between January 6, 2021, and June 11, 2021, and 50 patients were identified after applying inclusion and exclusion criteria.

### Page | 3 Study setting

The study was conducted at Addington Hospital, a regional public-sector hospital located in Durban, KwaZulu-Natal, South Africa. Addington Hospital serves as a referral center for district and rural healthcare facilities and provides orthopedic trauma care to a large and diverse patient population. The hospital operates within the provincial Department of Health and is affiliated with the University of KwaZulu-Natal's Department of Orthopaedics, with both undergraduate and postgraduate training responsibilities.

### **Inclusion criteria**

All patients aged 18 to 70 years who sustained an acute ankle fracture with an associated syndesmotic injury were treated with dynamic syndesmotic fixation.

### **Exclusion criteria**

Patients were excluded if they had open (compound) fractures, a history of previous foot or ankle surgery, polytrauma, inability to provide consent, symptomatic pre-injury ankle osteoarthritis, neurological impairment of the lower extremities, incomplete medical records, or less than one year of follow-up.

### **Operative technique**

The patient was placed in the supine position with a sandbag under the ipsilateral buttock. Lateral malleolar fractures were addressed using either an anatomical fibula or a straight plate. Surgical fixation of posterior malleolar fractures was performed when greater than 10% of the tibial plafond was involved, as assessed on the lateral radiograph. All associated medial malleolus fractures were fixed using either one or two partially threaded cancellous screws, depending on fracture configuration. Fluoroscopic guidance was used intraoperatively to confirm syndesmotic injury using the cotton test. Stabilization of the syndesmotic complex was achieved by using the ToggleLoc<sup>™</sup> ZipTight Fixation Device. Reduction of the ankle mortise was confirmed fluoroscopically, and the number of tightropes utilized was determined by intraoperative syndesmotic stress testing.

### **Post-operative regime**

All patients were initially immobilized in a below-knee backslap for two weeks, after which they attended a follow-up visit for suture removal and were placed in a plaster of Paris (POP) cast for an additional four weeks. Patients were instructed to remain non-weight-bearing for the total six-week period. Standard physiotherapy was offered following the removal of the cast. Patients were followed up at three months, six months, and one year postoperatively. At the one-year follow-up, functional outcomes were assessed using the American Orthopaedic Foot and Ankle Society (AOFAS) score.

### **Data collection**

Retrospective data were obtained from patient hospital records, covering demographics, medical comorbidities, fracture classification according to Lauge-Hansen and Denis Weber, operative details, device information, and intra- and immediate postoperative complications. Further data, including radiographic evaluations, AOFAS scores, and any adverse events or complications, were collected at a follow-up visit at least one year postoperatively, between January 24, 2022, and June 13, 2022.

### **Outcome measures**

The primary outcome measure was functional outcome scoring. The AOFAS score was used to assess functional outcomes, following its adoption in previous studies of this nature(15, 16, 22).

The secondary outcomes included assessing fracture union and the maintenance of syndesmotic reduction, which were evaluated radiographically at the 6-week, 3month, and 1-year follow-ups. Complications monitored included malunion, implant irritation, implant failure, and fracture-related infections. At the one-year follow-up, patients were evaluated for functional outcomes and any complications, with radiographic imaging conducted. Both preoperative and postoperative images were reviewed by a consultant orthopedic foot & ankle Surgeon to ensure accuracy and consistency in assessment.

### **Statistical Analysis**

Frequencies and percentages were used to summarise categorical data. Given the skewed distribution of numeric data, medians and interquartile ranges (IQR) were reported as summary measures. The two-sample Wilcoxon rank-sum (Mann–Whitney) test or the Kruskal-Wallis test was applied to evaluate differences in median total AOFAS scores across clinical characteristics. Statistical analyses were performed using Stata version 17, with a p-value of <0.05 indicating statistical significance.

### **Ethical consideration**

Ethical approval for this study was granted by the Biomedical Research Ethics Committee (BREC) of the



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University of KwaZulu-Natal. The study was approved on 07 February 2024 under ethical clearance number BREC/00006325/2023. Institutional permission was also obtained from the KwaZulu-Natal Department of Health to conduct the research at Addington Hospital.

### Page | 4 Results Demographics

# A total of 59 patients were initially identified from theatre records. Nine patients were excluded: one due to a lost file, one polytrauma patient, and seven who were lost to follow-up after the 12-week visit. This resulted in a final study cohort of 50 patients. The mean age at the time of surgery was 36.9 years (range: 19-63 years). Of the 50 patients, 35 were female and 15 were male, with a mean body mass index (BMI) of 29.3kg/m2. Five patients were smokers, and 15 patients were HIV positive (Table 1).

### **Table 1: Summary Data for the 50 Patients**

uninary Data for the 50 Patients					
Number of patients	50				
Age	$36.9 \pm 10.9$ years (19-63)				
BMI (kg/m2)	$29.3 \pm 4.4$ (21.7-43.0)				
Gender :	· · · ·				
Female	35, (70%)				
Male	15, (30.0%)				
Mean follow-up	$371.6 \pm 4.0$ days (367-383)				
Time to surgery	14±8 days(3-47)				
Fracture classification	· · · · ·				
Weber B / SER	40, (80.0%)				
Weber C/PER	10, (20.0%)				
Anatomical location	• • •				
Unimalleolar fibula fracture (SER4)	18, (36.0%)				
Bimalleolar fracture	(R2.13): 19, (38.0%)				
Trimalleolar fracture (only Bimalleolar fixation)	12, (24.0%)				
Trimalleolar with trimalleolar fixation	1, (2.0%)				
Comorbidities					
HIV	15, (30%)				
Epilepsy	1, (2%)				
None	34, (68%)				
Smoker	5, (10%)				
AOFAS					
Mean $\pm$ STD (Min-Max) N = 50	91. 7 ± 6.8 (74-100)				
Excellent = $95 - 100$	23, (46%)				
Good = 75 - 94	25, (50%)				
Fair = 51 - 74	2, (4%)				
Number of Syndesmosis Fixation Devices used					
1	8, (16%)				
2	42, (84%)				

BMI = Body Mass Index, BMI = Body Mass Index, SER= Supination External Rotation, AOFAS=American Orthopaedic Foot and Ankle Society score, PER= Pronation External Rotation, N = number of cases, STD = standard deviation

### **Time to Surgery**

The mean time from injury to surgery was 14 days (range: 3-47 days)(Table 1). Of the 50 patients in this cohort, 31 underwent surgery within 14 days. A total of 19 patients experienced surgical delays beyond this period. The reasons for the delay were documented for 16 of these patients, while data for the remaining three patients did not indicate a specific cause for the delay. Delays were attributed to factors such as patient transfers

from rural areas (9 patients), isolation periods following COVID-19 infection (1 patient), and the trauma load at the hospital (6 patients).

### **Intra-Operative Findings**

Fixation was achieved using a single syndesmotic fixation device in 8 patients (16%) and a double syndesmotic fixation device in 42 patients (84%). Eighteen patients (36%) required fixation of an



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associated fibula fracture. Nineteen patients (38%) sustained bimalleolar fractures, necessitating fixation of both the fibula and medial malleolus. Among the thirteen patients (26%) with trimalleolar fractures, twelve (24%) underwent bimalleolar fixation, while one patient (2%) required trimalleolar fixation (Table 1). Fixation of the

posterior malleolus was performed when the surgical indications previously mentioned were met. No intraoperative complications were reported, and all patients experienced an uneventful postoperative recovery until discharge.



Figure 1: Pre and postoperative x-rays of a Weber B bimalleolar (Supination External Rotation 4) treated with single syndesmotic fixation

### **Primary Outcomes: Functional Outcome**

The mean American Orthopaedic Foot and Ankle Society (AOFAS) score was 91.7 (range: 74-100). Two patients (4%) scored below 75, 25 patients (46%) scored between 75 and 94, and 23 patients (46%) scored above 95 (Table 1). Both patients with AOFAS scores below 75 had elevated BMIs of 39.8 and 36.5, respectively, and experienced longer-than-average waiting times before surgery (25 and 21 days).

### Secondary Outcomes: reduction/complications

All 50 patients (100%) achieved successful union and syndesmotic reduction at the one-year follow-up. No cases of malreduction, fracture-related infection, implant irritation, or implant failure were reported, and none of the patients required revision surgery within one year.

Number of	AOFAS score							
dynamic syndesmotic fixation devices	N	Media n	IQI	ł	Mi n	Ma x	p- valu e	Statistical analysis used
1	8	97.5	90	100	88	100		Two-sample Wilcoxon
2	42	92.5	88	96	74	100	0.1	rank-sum (Mann-
Total	50	94	88	97	74	100		Whitney) test
BMI								
Normal/overweig ht (BMI<30)	33	95	90	98	77	100	0.01	Two-sample Wilcoxon
Obese(BMI≥30)	17	90	83	94	74	100	9	rank-sum (Mann-
Total	50	94	88	97	74	100		Whitney) test
Smoking								
Yes	5	94	90	95	88	100		Two-sample Wilcoxon
No	45	94	88	97	74	100	0.86	rank-sum (Mann-
Total	50	94	88	97	74	100		Whitney) test
Fracture type								
Unimalleolar)	18	90.5	90	95	74	100	0.57	Kruskal-Wallis equality-

Table	2.	Statistical	analy		of r	oculte
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	1	1	-						
ankle fracture								of-populations	rank test
Bimalleolar) ankle fracture	19	95	87	100	74	100			
Trimalleolar) ankle fracture	13	95	90	97	88	100			
Total	50	94	88	97	74	100			
Days to surgery								-	
3-14	31	95	90	100	88	100	0.00	Two-sample	Wilcoxon
15-47	19	88	78	95	74	98		rank-sum	(Mann-
Total	50	94	88	97	74	100	2	Whitney) test	
HIV									
Negative	35	95	90	97	77	100	0.08	Two-sample	Wilcoxon
Positive	15	90	83	96	74	100		rank-sum	(Mann-
Total	50	94	88	97	74	100	9	Whitney) test	,

### Discussion

This study demonstrated favorable outcomes with dynamic syndesmotic fixation (DF) in treating ankle fractures with associated syndesmotic injuries, achieving a high rate of successful syndesmotic reduction. At the one-year follow-up, 100% of patients had a satisfactory reduction, with no cases of malreduction, implant irritation, or failure. These findings align with the growing body of evidence supporting DF as a viable alternative to static screw fixation (SSF) in managing syndesmotic injuries (23).

Several previous studies have reported similar success with suture-button fixation systems, particularly regarding their ability to preserve joint motion while providing stable fixation (16, 24). In this study, the mean AOFAS score was 91.7, representing excellent or good functional outcomes in 96% of patients. This indicates that dynamic fixation using suture-button devices provides consistently favorable functional recovery at one year. These outcomes are comparable to other studies using DF, where AOFAS scores typically range between 85 and 95 at the one-year follow-up(22, 25, 26). This reinforces DF's potential as an effective alternative to traditional static fixation techniques.

The complication rate in this cohort was notably low, with no reoperations or infections reported, further supporting the efficacy of DF in this patient population. Previous studies using SSF have reported higher complication rates, including hardware-related issues and the need for secondary surgeries (11). These findings suggest that DF reduces the risk of these complications, particularly the need for hardware removal, a common drawback of SSF(11).

In terms of fracture patterns, Weber B fractures accounted for 80% of the cases in this study, and most were classified as Supination External Rotation (SER) stage 4 according to the Lauge-Hansen classification. This homogeneity in fracture type may have contributed to the overall success, as previous studies have shown that Weber B fractures are generally associated with favorable outcomes following DF (27). The inclusion of Weber C fractures (20%) in this cohort provides additional evidence that DF can be effective across a range of injury severities.

This study demonstrated the impact of patient-specific factors, such as body mass index (BMI), HIV status, and time to surgery, on functional outcomes. Patients with a BMI  $\geq$  30 (n = 17) had statistically significantly lower AOFAS scores than those with a BMI < 30 (n = 33) (p = (0.019) (table 2). A surgical delay of over 14 days (n = 19) was also associated with statistically significantly lower AOFAS scores compared to cases operated on within 2 weeks (n = 31) (p = 0.002) (table 2). Two patients with AOFAS scores below 75 had notably high BMIs (39.8 and 36.5) and prolonged preoperative waiting times (21 and 25 days due to delayed referral), likely contributing to their poorer results. Although HIV-infected patients had lower scores, the difference was not statistically significant (p = 0.089) (Table 2). Prior studies have shown that obesity is associated with increased postoperative complications and poorer functional outcomes due to impaired wound healing and rehabilitation challenges (28). These findings underscore the importance of recognizing elevated BMI as a risk factor that may influence recovery trajectories and overall functional success following ankle fracture fixation. Additionally, delays in surgical fixation of ankle fractures, even within a 2 to 3-week timeframe, have been linked to worse functional outcomes and higher complication rates, emphasizing the importance of timely intervention (29, 30).

HIV status emerged as a significant comorbidity in this study, with 30% of patients being HIV-positive. Although HIV infection is typically associated with impaired wound healing and increased susceptibility to infection, none of the patients in this cohort experienced postoperative infections or wound-related complications (31). The absence of infection could be attributed to the



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pre-operative time to surgery, allowing the soft tissues to recover, and the strict postoperative care protocols. Additionally, the fact that most HIV-positive patients were on antiretroviral therapy, mitigated the effects of immunosuppression. However, the potential long-term impact of HIV on bone healing and joint

function remains a concern that warrants further

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investigation (32). While 10% of patients in this study were smokers and 34% had elevated BMI, these factors did not significantly impact overall complication rates. Smoking is a well-documented risk factor for postoperative infections and delayed bone healing (33, 34), yet no infections were observed in this cohort, possibly due to the small number of smokers and the factors mentioned before.

The use of a double syndesmotic fixation device in 84% of cases underscores the importance of achieving stable fixation in complex fractures, particularly those involving bimalleolar or trimalleolar injuries. The decision to use single or double fixation was guided by intraoperative external rotation stress testing (ERST) conducted after the placement of the first device. If ERST indicated persistent syndesmotic instability, a second device was implanted. This study did not reveal any statistically significant difference in outcomes between single and double suture-button fixation (p = 0.1) (table 2); however, the frequent need for a second device highlights the critical role of intraoperative testing in ensuring stability.

These results suggest that using suture-button systems like the ToggleLoc<sup>TM</sup> ZipTight fixation device, in conjunction with proper surgical technique, is a safe and effective method for managing these injuries. The absence of complications such as implant failure, infection, or irritation further supports the growing preference for DF over traditional SSF (35).

While this study did not perform a cost analysis, the reduced need for secondary procedures and fewer hardware complications with DF have been noted as potential cost-saving benefits(36). The literature suggests that DF can lead to overall cost reductions by minimizing reoperation rates and allowing for an earlier return to function(37).

### Generalizability

While this study was conducted at a single regional public hospital in KwaZulu-Natal, the patient population is representative of the broader South African context in terms of trauma burden, resource availability, and comorbidities such as HIV and obesity. As such, the findings may be generalizable to similar public-sector settings in low- to middle-income countries (LMICs) where healthcare systems face comparable challenges. However, caution is warranted in extrapolating these results to high-income countries or private healthcare environments, where surgical timing, follow-up resources, and patient demographics may differ substantially.

### Conclusion

Dynamic syndesmotic fixation using suture-button devices offers a reliable and effective treatment for ankle fractures with associated syndesmotic injuries, with excellent functional outcomes and low complication rates. These findings suggest that DF is a favorable alternative to SSF, particularly for patients at risk of hardware-related complications. Patient-specific factors, such as BMI, and time to surgery, were found to influence functional outcomes, underscoring the importance of individualized treatment plans. The low complication rate, with no reported infections, supports the safety and reliability of DF in managing complex syndesmotic injuries. Although DF did not significantly differ from single versus double suture-button fixation devices in terms of outcomes, the frequent use of double devices highlights the importance of intraoperative testing for ensuring adequate rotational stability. Given the growing body of evidence supporting this technique, further randomized controlled trials are warranted to establish DF as the gold standard for syndesmotic stabilization.

### Limitations

While this study provides valuable insights into the efficacy of DF in a South African patient population, several limitations must be acknowledged. First, the relatively small sample size (n=50) limits the generalizability of these findings. Additionally, the retrospective nature of the study and the relatively short follow-up period (a mean of 12 months) may not capture long-term complications or functional outcomes, such as the development of post-traumatic osteoarthritis.

Another limitation of this study is the absence of a comparative cohort utilizing static screw fixation (SSF). Without a direct comparison, it is not possible to determine whether dynamic fixation provides superior outcomes relative to SSF in this population. Further research, including prospective comparative studies, is necessary to better define the long-term benefits and potential advantages of dynamic fixation over traditional SSF, as well as to assess its cost-effectiveness, particularly in resource-limited settings where healthcare budgets are constrained.

### Recommendations

Based on the findings of this study, dynamic fixation using suture-button devices should be considered a



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reliable and effective alternative to static screw fixation for the treatment of ankle fractures with syndesmotic injuries, particularly in younger and active patients. Surgeons should be mindful of patient-specific factors such as elevated BMI and surgical delays, as these may adversely affect functional outcomes. Intraoperative stress testing remains essential in determining the need for single versus double fixation. Further multicentre, prospective studies are recommended to confirm long-

term functional outcomes, cost-effectiveness, and

applicability across various healthcare settings.

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### **List of Abbreviations**

- AOFAS American Orthopaedic Foot and Ankle Society
- AITFL Anterior-Inferior Tibiofibular Ligament
- **BMI** Body Mass Index
- **BREC** Biomedical Research Ethics Committee
- **DF** Dynamic Fixation
- HIV Human Immunodeficiency Virus
- IOL Interosseous Ligament
- ITL Inferior Transverse Ligament
- **KZN-DoH** KwaZulu-Natal Department of Health
- LMICs Low- to Middle-Income Countries
- **PITFL** Posterior-Inferior Tibiofibular Ligament
- SSF Static Screw Fixation
- UKZN University of KwaZulu-Natal

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### **Conflict of Interest**

The authors declare no conflict of interest.

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### **Author contributions:**

**Dr Ebrahim Peer:** Conception and design of the study, data collection, analysis and interpretation, drafting of the manuscript, and final approval of the submitted version.

**Dr. RF Snyders:** Supervised the study, critical revision of the manuscript for intellectual content, interpretation of data, and final approval of the submitted version.

**Dr JL Pretorius:** Co-supervision, contribution to study design, manuscript revision, interpretation of clinical findings, and final approval of the submitted version.

### **Data Availability**

The data supporting the findings of this study are available from the corresponding author upon reasonable request. Due to the retrospective nature of the study and patient confidentiality regulations, individual-level data are not publicly accessible.

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