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RESEARCH ARTICLE

Comparative CT Study on Syndesmosis Mobility after Static or Dynamic Fixation for Ankle Fractures with Syndesmotic Rupture: A Pilot Study

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Abstract

Background: The objective of this prospective randomized pilot study is to compare, by computed tomography (CT), the mobility of syndesmosis after static fixation (SF) or dynamic fixation (DF) in ankle fractures with syndesmotic rupture (AFSR) in adults, and to compare this mobility with that of healthy ankles.

Methods: Forty-two patients with an AFSR were randomized to 2 groups: SF (N=21) or DF (N=21). Seven patients were lost to follow-up. Ultimately, 35 patients (SF, N=20; DF, N=15) were analyzed. The clinical results were assessed with the American Orthopedic Foot and Ankle Society scale. To assess syndesmosis mobility, CT in 30° of plantar flexion (PFlex) and 20° of dorsal flexion (DFlex) was performed on both ankles one year after the fracture. Four parameters were measured: anterior tibiofibular distance, posterior tibiofibular posterior distance, angle of fibular rotation (AFR), and anteroposterior fibular translation.

Results: The AFR between DFlex and PFlex was more similar to the non-affected side in the DF group. The other three parameters showed no statistical differences between types of fixation. The mean loss of AFR compared with the non-affected side was 1.2° in the SF group and 0.1° in the DF group. No clinical differences between the SF group and the DF group were found. No correlation between clinical and radiological results was observed.

Conclusion: The AFR was more similar to the non-affected side in the DF group. However, this finding did not correlate with a better clinical result.

Level of evidence: II

Keywords: Ankle, CT scan, Dynamic fixation, Fracture, Static fixation, Syndesmosis mobility

Introduction

Ankle injuries are one of the most frequent pathologies observed by orthopedic surgeons. According to the most recent studies, the incidence of ankle fractures in the American population is 4.22 fractures per 10,000 inhabitants/year and 23% present partial or complete damage at the level of the syndesmosis (1–3). This incidence represents 9% of all fractures observed in trauma services and predominantly affects a young adult population, with a mean age of 37 years (3). The diagnosis of distal tibiofibular syndesmosis injury has attracted attention due to its complexity in some cases. Instability caused by trauma can often be hidden (4).

Ankle fractures occur between 107 and 187 fractures

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per 100,000 inhabitants each year (5, 6). Of these, complete injury to the syndesmosis occurs in 10%-13% of cases, implicating the need to stabilize the syndesmosis during surgery (7).

Many radiographic measurements have been described in the three basic ankle projections to detect separation of the tibia and fibula or instability of the syndesmosis under specific manipulations with anesthesia or during the surgical procedure. Computed tomography (CT) is the most accurate technique to evaluate the bony structure of the syndesmosis (8). Studies employing this technique reveal a variable syndesmotic morphology, showing a range of shapes, from a joint with a marked concavity on the tibial side, called “crescent shape”, present in two-thirds of the population, to morphology with a more flattened tibial cartilage, called “rectangular morphology”, present in the remaining third of the people. Four radiological measurements employing CT have shown the most relevance and the least variability. All of them are performed on an axial slice at 1 cm from the articular cartilage of the tibial pilon (8, 9). These measurements are as follows: the distance between the anterior edge of the fibula and the anterior end of the tibial cartilage (anterior tibiofibular distance [ATFD]); the distance between the posterior border of the fibula and the posterior end of the tibial cartilage (posterior tibiofibular distance [PTFD]); the angle of the anteroposterior axis of the distal fibula with respect to the anterior edge of the tibia (angle of fibular rotation [AFR]); and the distance between the perpendicular to the anterior border of the tibial fissure and the anterior edge of the fibula, called anteroposterior fibular translation (APFT) [Figure 1]. A poor reduction is defined as when the differences with respect to a healthy ankle are greater than 2 mm in the ATFD or PTFD, or when the difference in the AFR is greater than 5° (10).

There are multiple approaches to achieving an adequate reduction of the syndesmosis in the literature, such as manual direct reduction techniques and those assisted with forceps, clamps, K-wires, or stabilizing and positioning screws (11, 12). Treatment of syndesmosis injuries requires both anatomical repair of the ankle and stabilization to restore physiological mobility of the syndesmosis. The classic treatment of syndesmosis rupture is based on static fixation (SF): implanting a cortical thread screw from the fibula to the tibia with attachment to 3–4 cortices, without compression (position screw), once the rest of the lesions have been anatomically restored and synthesized and the syndesmosis has been reduced (13,14). However, SF requires a second surgery to remove the positioning screw. New techniques have recently been introduced that does not require implant removal, such as dynamic fixation (DF), which has the advantage of not requiring a second surgery to remove the fixation material (15-17).

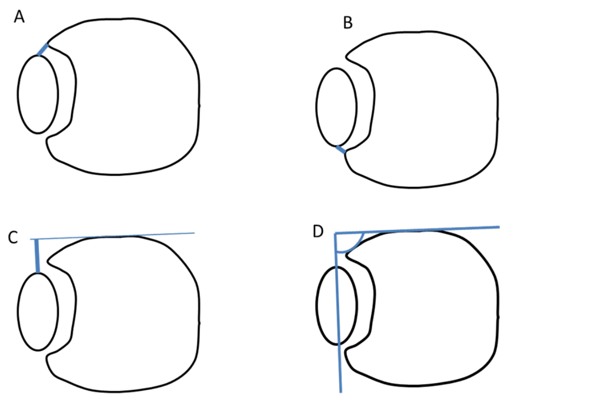

Figure 1. Measurements to assess the reduction of the syndesmosis: (A) Anterior tibiofibular distance (ATFD) (in blue); (B) posterior tibiofibular distance (PTFD) (in blue); (C) anteroposterior fibular translation (APFT) (in blue); (D) angle of fibular rotation (AFR).

The first objective of this study was to investigate whether there were radiological differences in the mobility of the syndesmosis after surgical treatment of ankle fractures depending on which of the following two stabilization methods was applied: SF with suprasyndesmal screw (with the removal of the screw after 12weeks); or DF with suprasyndesmal Invisiknot (Smith & Nephew), which does not require removal. The second objective was to assess whether radiological differences in syndesmosis mobility would correspond to differences in clinical results.

Materials and Methods

For the study, we prospectively recruited all patients with ankle fractures with syndesmosis rupture treated by the “Fracture and Polytrauma Unit” of our hospital between 1 September 2018 and 31 August 2019. All patients had the study explained orally and in writing, and all their questions were answered. They then signed the informed consent document and were randomly included in one of the two treatment groups. A randomization table was created using the Pinetools online application with a limit of 100 numbers. It generated a list of values 1 and 2 distributed to the members of our unit responsible for the operating room. Each patient was included in their corresponding random group at all times, and the groups were updated after each inclusion.

Two groups were established: The patients included in the SF group underwent stabilization of the syndesmosis once the corresponding fracture had been synthesized, and the syndesmosis was reduced using a 3.5-mm tricortical screw placed in the suprasyndesmal area between 2 and 3.5 cm above the joint line and parallel to it. The patients in the DF group underwent stabilization of the syndesmosis once the fractures had been synthesized and reduced using an Invisiknot implant. The implant consists of 2 buttons (1 medial and one lateral) connected by a high molecular weight polyethylene suture tape. The metal buttons allow the polyethylene thread to slide and are anchored in the medial cortex of the tibia and the lateral cortex of the fibula or on the synthesis plate and are then manually tightened. The medial button has dimensions of 3.25 mm x 10 mm. The suture has a 1-way sliding knot that allows reduction of the lateral button and locks once tensioned. The Ethics Committee of our hospital approved the study. This study has been submitted to the National Registry of Clinical Studies (pending registration). The protocol applied during the study was subdivided into the following stages and visits:

Inclusion visit

During this first visit, patients who attended the Emergency Department of our hospital with an ankle fracture and possible lesion of the syndesmosis were informed of the study, given an informed consent document to sign, and were told of the possibility of inclusion in the study if during the surgical procedure a reliable lesion of the syndesmosis requiring stabilization was found. Given that the injury to the syndesmosis could not be established with certainty in the Emergency Department, all patients with transyndesmal or suprasyndesmal ankle fractures (Weber types B and C) were informed of the possibility of entering the study (18).

Surgical procedure

During the surgical procedure, once the malleoli had been synthesized and the deltoid ligament reinserted (if necessary), fibular traction and forced external rotation maneuvers were performed under radioscopic control to check for a syndesmosis lesion. If positive, definitive inclusion in the study and stabilization were performed according to the group to which the patient had been assigned. A suprasyndesmotic screw (SF group) or an Invisiknot type anchorage device (DF group) was implanted. Patients who did not require stabilization of the syndesmosis because the instability of the syndesmosis was not demonstrated, or if there were reasonable doubts, even if the stabilizing device was implanted, were not included in the study.

Hospital discharge

All patients were instructed in the usual early active and passive mobilization exercises and were prohibited from weight-bearing until four weeks after the intervention. Subsequently, they were allowed to load progressively, assisted with two canes, until full support was achieved at six weeks. Patients were discharged without any immobilization and were allowed to recover range of motion according to tolerance. During the first week, they were prescribed Paracetamol 1g/8h alternating with Metamizole 575mg/8h.

Visit 1 (3 months post-surgery)

According to the American Orthopedic Foot and Ankle Society (AOFAS) assessment scale for the hindfoot and ankle, a clinical examination was performed radiographically using regular ankle projections (19). Achieving a maximum score of 100 on the AOFAS assessment scale for the hindfoot and ankle implies that the patient has no pain, has complete ankle and hindfoot joint balance, no instability, adequate ankle, and hindfoot alignment, can walk more than six blocks on any type of surface, has no observable limp, does not require support for ambulation, and can perform daily activities and recreational activities without restrictions (19). At 6-10 weeks, all patients included in the SF randomization group had undergone suprasyndesmotic screw removal outpatient. We did not have any cases of broken screws because the screws were removed very close to starting full weight-bearing activities.

Visit 2 (6 months post-surgery)

A new clinical evaluation was performed using the AOFAS assessment scale for hindfoot and ankle and radiographic monitoring with simple ankle projections (19).

Visit 3 (12 months post-surgery)

A new clinical evaluation was performed using the AOFAS assessment scale for hindfoot and ankle (19). A CT scan was performed with two series of images in 2 symmetrical positions in both ankles using a device that held both lower limbs and ensured a similar flexion-extension position [Figure 2]. In the first sequence, the study was performed with both ankles at 20º of dorsal flexion, and in the second sequence, it was performed with both ankles at 30º of plantar flexion. In all the studies, the principal investigator placed the device during the scan to define the smallest area of exposure necessary for the test and adequate compliance with the protocol. The device used in all cases was the CANON Aquilion ONE volumetric dynamic scanner (Canon Medical Systems, USA).

In conjunction with the musculoskeletal system section of the Radiology Department of our hospital, radiographic measurements were taken of both ankles in the two positions of 20º of dorsal flexion and 30º of plantar flexion. For this purpose, the Agfa IMPAX 6.6.1.3525 radiological image management program was used. The slices of each series were performed at a maximum vertical resolution and horizontal resolution of 0.01 mm.

Once the CT scan was performed, the images were processed with the Agfa mentioned above IMPAX 6.6.1.3525 program in the reading room of the Radiology Department of our hospital and with the help of the members of the musculoskeletal section of our department. A 3-dimensional reconstruction

Figure 2. Holding device for CT (computed tomography) scan in the dorsal flexion position.

Figure 3. 3-D reconstruction of the CT (computed tomography) scan. Coronal section where the marker is placed 10 mm from the articular surface of the tibia, which will later be taken as a reference when obtaining the axial sections for the measurements.

was performed on each ankle (operated and healthy) independently. The coronal section was measured at a distance of 1 cm from the articular line of the tibial pilon, perpendicular to the articular axis and in line with the longitudinal axis of the tibia. Once a digital mark was established at the height of 1 cm, a new window was opened with the axial section corresponding to that mark, where the four corresponding measurements were taken: ATFD, PTFD, AFR, and APFT [Figure 3]. This procedure was repeated four times for each patient, given the measurements were taken in plantar flexion of the operated ankle, dorsal flexion of the operated ankle, plantar flexion of the contralateral healthy ankle (control), and dorsal flexion of the contralateral healthy ankle.

Once the appropriate axial section was obtained 1 cm from the articular surface, the following points and lines were marked: anterior border of the fibula, posterior border of the fibula, anterior border of the tibial fissure, posterior border of the tibial fissure, the anteroposterior axis of the fibula (the line joining the anterior border with the posterior border of the fibula), and the line tangent to the anterior surface of the tibia at its most anterior point.

The following measurements were performed: ATFD, PTFD, AFR, and APFT (all of which were measured in the axial section at 1 cm from the articular cartilage of the tibial pylon) (8, 9). Therefore, eight measurements were performed on each ankle: 4 in dorsal flexion and 4 in plantar flexion [Figure 4]. The APFT measurement was performed, unlike Endo et al. about the tangent of the anterior surface of the tibia at its most anterior point. We used this approach because it was, in our opinion, more reliable insofar as the anterior edge of the incisure showed a less precise shape in our sample, as shown in [Figure 1] (9).

All measurements were performed in duplicate by the principal investigator during the first 10 cases and showed variability in the data of 0.3 mm (0-1.6 mm) on average and 1.2° (0°-3.2°). Adjusting the measurement parameters and exact references reduced these differences in the following cases to 0.1 mm (0-0.6 mm) on average in the distance measurements and to 0.4° (0°-1.1°) in the angles in the following 10 cases. The clinical data on the patients, the individual values of each of the sections of the AOFAS scale, and the radiological measurements of the CT scan were included in an Excel database according to the indications of the Statistics Department of our hospital for further analysis.

It is important to mention that sometimes with dorsi flexion and plantar flexion some saggital motion may occur in the tibia at the same time. Therefore, in order for the axial plane to be used for the measurement it is necessary to define specifically which sagittal and coronal planes are chosen. For this it is necessary to work on a Multiplanar Reconstruction (MPR) screen, otherwise the results would not be reliable and repeatable (20).

Statistical analysis

According to the Statistics Department of our hospital, the power of the sample was good to be considered a pilot study. With a significance level of 0.05, a mean effect size, and a sample size of 35, the estimated statistical power would be 0.91. Power = 1- ß = 1 – 0.0946 = 0.9054.

A mathematical analysis of the data and description tables was performed by the Statistics Department of our hospital together with the principal investigator to determine the best approach to comparing the variables. The statistical analysis was performed with the SAS version 9.4 program. (SAS® 9.4 SAS/STAT Base. 2013, SAS Institute Inc., Cary, NC, USA). Statistically significant differences were considered those with a probability of error of less than 5% ($P < 0.05$). For the description

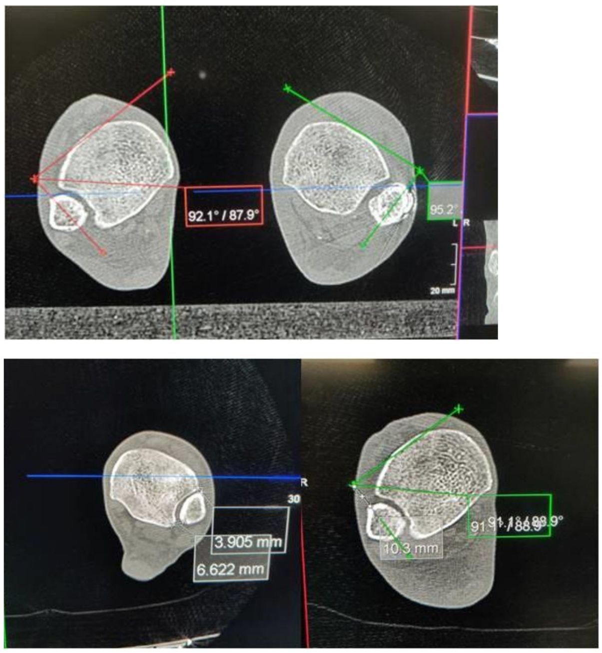

Figure 4. Photograph of the measurement of the anterior tibiofibular distance (ATFD), posterior tibiofibular distance (PTFD), and anteroposterior fibular translation (APFT); and the angle of fibular rotation (AFR) in the CT (computed tomography) scan.

of continuous quantitative variables, the mean and the standard deviation were used. Absolute frequencies describe qualitative variables, and relative frequencies are expressed as percentages.

Comparisons between continuous quantitative variables between independent groups were mainly performed using nonparametric Kruskal–Wallis or Mann–Whitney U tests. Paired comparisons between continuous quantitative variables were performed using the nonparametric Wilcoxon test. For longitudinal analysis of measurements at 3, 6, and 12 months, a repeated-measures analysis of variance was used together with the Greenhouse-Geisser test. When the result was significant, it was complemented with the Bonferroni *a posteriori* test to explore possible differences between time points compared two by two.

A frequency analysis between qualitative variables was performed using the chi-squared test or Fisher's exact test when necessary (if $N < 20$, or if any value in the table of expected values was less than 5). When the Chi-squared test was used, the Yates correction was applied in all cases. A correlation analysis between continuous quantitative variables was performed using Pearson's "R" correlation coefficient.

To compare the mobility measures of the syndesmosis and avoid variations due to the size of the individual patients, we compared the variations in 3 measures (ATFD, PTFD, APFT) using their percentages. Thus, for the same ankle, we calculated the percentage of variation in the measurement occurring between the positions of dorsal flexion and plantar flexion to compare with the contralateral ankle and determine whether this mobility was greater, lesser, or equal and whether this variation was a consequence of the lesion of the syndesmosis and its subsequent fixation using screw (removed) or Invisiknot.

This percentage was determined using the following formula:

ATFD variation percentage = ATFD in dorsal flexion minus ATFD in plantar flexion / ATFD in plantar flexion and the result multiplied by 100.

Similar results were obtained for PTFD and APFT. The AFR variations were expressed as the difference between dorsal flexion and plantar flexion positions in degrees, not assuming any distance measure. Once the mobility percentages of the syndesmosis in each ankle were defined, we proceeded to establish the Delta % (percentage difference), defined as the subtraction between the mobility percentage of the healthy ankle with respect to the operated ankle, applied to each of the three distances. The AFR Delta was established as the difference in the rotation variations between the healthy and operated ankles.

Results

Forty-two patients were included in the study. Of these, 35 completed the study, and three patients did not complete the follow-up, two because they moved house, and one was lost to follow-up. One patient was excluded because he had a deep infection that required removal of material and conversion to external fixation; 2 patients were excluded because they could not perform early mobilization after surgery due to defect coverage that required intervention by the Plastic Surgery Department and subsequent immobilization; 1 patient in the SF group was excluded due to insufficient reduction of the syndesmosis in the CT study but who refused the intervention due to good clinical tolerance. Of these excluded patients, two belonged to the SF randomization group and 5 to the DF group. The sample that ultimately formed the study consisted of 35 patients, 20 included in the SF stabilization with screw group and 15 in the DF stabilization with Invisiknot elastic anchorage group. The patients were 21 males and 14 females, with a mean age of 45.5 (range 17-64, SD +/- 13.4) years, slightly older in group 1, with a mean age of 49.1 years compared with 40.7 years in group 2 [Table 1].

The AFR between the dorsal flexion and plantar flexion positions increased from a mean of 89.8° (3.7°) in plantar flexion to 92.1° (2.4°) in dorsal flexion in the healthy ankles. This result implies that the AFR increased by 2.3° in the healthy ankles from plantar to dorsal flexion. In the operated ankles, the mean AFR increased from 89.8° (3.6°) in plantar flexion to 91.3° (3.5°) in dorsal flexion, a variation of 1.5° in the operated ankles [Table 2].

Analyzed pairwise between the healthy and operated sides, syndesmosis mobility between the dorsal and plantar flexion positions demonstrated very high statistical significance, with $p < 0.001$ in the ATFD, APFT, and AFR measures in both the healthy and surgically intervened ankles. This significance was not found for PTFD, which, although on the healthy side, was not significant by a small margin ($P < 0.051$). Comparing between the healthy and operated sides, on the operated side, PTFD shows no significance at all ($P < 0.77$), which might suggest that this distance varies less once the ankle

Table 1. Demographic details of this study. SD = standard deviation; SF = Static fixation; DF = Dynamic fixation

	SF group Media (SD)	DF group Media (SD)
Age	49.05 (12.32)	40.73 (13.79)
Men	12 (60%)	8 (40%)
Women	9 (60%)	6 (40%)
Number (percentage) of Weber type B fractures	16 (61.5%)	10 (31.8%)
Number (percentage) of Weber type C fractures	5 (54.5%)	4 (45.5%)

has been operated on or is altered by trauma [Table 3].

Before comparing treatment groups, the following results were observed in the overall sample analysis: ATFD between dorsal flexion and plantar flexion positions declined from a mean of 4.7 mm (1.3 mm) in dorsal flexion to 4.2 mm (1.4 mm) in plantar flexion in healthy ankles. This result implies that the percentage variation of the ATFD was 14% between the dorsal flexion and plantar flexion positions of the healthy ankles. The mean ATFD went from 5.4 mm (1.8 mm) in dorsal flexion to 4.9 mm (1.6 mm) in plantar flexion, a variation of 9.5% in the operated ankles (*P < 0.51*).

The PTFD between the dorsal flexion and plantar flexion positions went from a mean of 4.9 mm (1.9 mm) in dorsal flexion to 5.2 mm (1.4 mm) in plantar flexion in the healthy ankles. This result implies that the percentage variation in PTFD was 4% between the dorsal flexion and plantar flexion positions of the healthy ankles. The mean PTFD declined from 5.04 mm (1.9 mm) in dorsal flexion to 4.99 mm (1.5 mm) in plantar flexion, a variation of 0.1% in the operated ankles (*P < 0.57*).

Table 2. Mean values of ATFD, PTFD, APFT (measured in mm) and AFR (measured in degrees). HPF = healthy ankle in plantar flexion; HDF = healthy ankle in dorsal flexion; OPF = Operated ankle in plantar flexion; HDF = Operated ankle in dorsal flexion. SD = standard deviation

Position	Variable	Mean	SD
Plantar flexion	ATFD		
	SF	4.6	1.5
	DF	5.3	1.6
Plantar flexion	PTFD		
	SF	4.9	1.2
	DF	5.1	1.9
Plantar flexion	APFT		
	SF	6.3	2.6
	DF	7	3.4
Plantar flexion	AFR		
	SF	89.4	2.7
	DF	90.2	4.5
Dorsal flexion	ATFD		
	SF	5	1.6
	DF	5.8	1.9
Dorsal flexion	PTFD		
	SF	4.9	1.6
	DF	5.2	2.2
Dorsal flexion	APFT		
	SF	6.8	2.5
	DF	7.3	3.4
Dorsal flexion	AFR		
	SF	91.2	2.9
	DF	91.4	4.3

ATFD = Anterior tibiofibular distance; PTFD = Posterior tibiofibular distance; APFT = Anteroposterior fibular translation; AFR = Angle .of fibular rotation

The APFT between dorsal flexion and plantar flexion positions increased from a mean of 6.8 mm (3.1 mm) in dorsal flexion to 7.2 mm (3 mm) in plantar flexion in the healthy ankles. This result implies that the percentage variation of the APFT was 9% between the dorsal flexion and plantar and positions of the healthy ankles. The mean APFT decreased from 7 mm (2.9 mm) in dorsal flexion to 6.6 mm (3 mm) in plantar flexion, a variation of 7.8% in the operated ankles (*P < 0.29*).

When analyzing the radiographic measurements obtained and their differentials compared by treatment group, a significant difference was found in the AFR, indicating that in the DF group, the difference in rotation between the healthy and operated ankle was less than in the SF group, with a *P < 0.023*. The difference in fibular rotation between plantar flexion and plantar extension positions was more similar to the healthy ankles in the DF group than in the SF group. The differences in variation between healthy ankles and operated ankles compared by the group found no statistically significant differences for ATFD, PTFD, or APFT [Table 4]. The Delta % (percentage difference) was defined as the difference between the percentage of mobility of the healthy ankle with respect to the operated ankle, applied to each of the three distances. In other words, first, the variation between the dorsal and plantar flexion positions was calculated for each ankle, then compared with the healthy side, and the percentage of variation was established. The smaller the percentage, the more similar was the mobility in the operated ankle to the healthy one. Therefore, the Delta value already included the flexion and extension positions.

Regarding the results of both groups in the clinical assessment using the modified AOFAS ankle scale, the following was found: The mean AOFAS score at three

Table 3. Differences found in distances when the ankle changed from plantar flexion (PF) to dorsal flexion dorsal (DF). Means are compared between healthy ankles (H) and operated ankles (O). Statistical significance is shown as p-values indicating differences in measurements taken between the two positions in the same ankle. SD = Standard deviation

Pair of measurements	Mean difference (mm)	SD	P
DTPA (HPF) /DTPA (HDF)	-0.5	0.52	< 0.001
DTPP (HPF) / DTPP (HDF)	0.22	1.07	<.0.051
TAPP (HPF) / TAPP (SHDF)	-0.44	0.68	<.0.001
ARP (HPF) / ARP (HDF)	-2.29	2.67	<.0.001
DTPA (OPF) / DTPA (ODF)	-0.48	0.49	<.0.001
DTPP (OPF) / DTPP (ODF)	-0.061	0.76	<.0.77
TAPP (OPF) / TAPP (ODF)	-0.39	0.96	<.0.001
ARP (OPF) / ARP (ODF)	-1.52	1.69	<.0.001

ATFD = Anterior tibiofibular distance; PTFD = Posterior tibiofibular distance; APFT = Anteroposterior fibular translation; AFR = Angle of fibular rotation

Table 4. Analysis of the variables of measurement difference between ankles and their differences by treatment group. In the delta angle of fibular rotation (AFR), healthy/operated (H/O) there was a significant difference, with a greater similarity in external rotation between the healthy and operated ankle in the DF (dynamic fixation) group treated with InvisiknotR. SD = standard deviation

Difference in mobility between healthy ankle and operated ankle by group		Mean difference	SD	*P*
Delta ATFD H/O	Group SF	5.5	12.8	0.51
	Group DF	2.4	10.2	
Delta PTFD H/O	Group SF	-5.3	17.1	0.57
	Group DF	-3	18.6	
Delta APFT H/O	Group SF	-1.8	17.1	0.29
	Group DF	5.1	10.5	
Delta AFR H/O	Group SF	-4.8	3.4	0.023
	Group DF	-2.4	3.8	

ATFD = Anterior tibiofibular distance; PTFD = Posterior tibiofibular distance; APFT = Anteroposterior fibular translation; AFR = Angle of fibular rotation

months for the entire series was 79 (6.7) points, at six months, it was 88 (6.6) points, and at the final assessment at 12 months it was 92 (5.8) points. The alignment values remained constant at three visits, and the improvement was as expected in the segment that assessed ankle function.

There was no difference between the SF and DF groups regarding the AOFAS clinical assessment scale at 3, 6, and 12 months. When the pain, function, and alignment variables were analyzed separately and compared by group, there were no significant differences [Table 5]. A significant linear change over time was found in both groups, both globally and at all times ($P < 0.001$). However, this change was not significantly different between the two groups ($P = 0.927$).

There was no significant correlation between the AOFAS score at 3, 6, and 12 months and the mobility variation values between healthy and operated ankles (delta ATFD, delta PTFD, delta APFT, and delta AFR), showing that the radiographic differences are probably not clinically relevant.

Table 5. Mean values of the AOFAS (American Orthopedic Foot and Ankle Society) scale at 3, 6 and 12 months (3M, 6M, 12M) compared by treatment group. SD =Standard deviation; SF = Static fixation; DF = Dynamic fixation

AOFAS / Group		AOFAS (SD)	Confidence interval
AOFAS 3M	Group SF	79 (6)	76.1-81.8
	Group DF	79.7 (7.7)	75.4-84
AOFAS 6M	Group SF	87.9 (7.4)	84.4-91.4
	Group DF	87.7 (5.7)	84.6-91
AOFAS 12M	Group SF	92.8 (6)	90.5-95.1
	Group DF	91.8 (5.7)	89-94.6

Discussion

This study aimed to compare the dynamic radiographic values and their correlation with the clinical assessment between two methods of syndesmosis fixation. We considered the screw as a rigid fixation and Tightrope as a semi-rigid fixation of the syndesmosis. We aimed to assess the adequacy and maintenance of the reduction and its correlation with the clinical assessment. Our results showed comparable outcomes between the two methods of fixation.

This pilot study showed that both the DF and SF fixation of the syndesmosis resulted in comparable outcomes. Although patients treated with the Invisiknot technique probably had a more physiologic rotation at the syndesmosis than patients treated with screws, the difference might not have been clinically significant (the AOFAS scores were similar).

The ideal stabilization of the syndesmosis preserves the stability necessary for adequate healing while respecting the mobility of the syndesmosis once healed (4).

Reviews of comparative articles between the two techniques initially showed promising results in favor of suture-type anchors. However, they lacked comparisons with control groups, and some of them included different fixation methods, which weakened their conclusions (12, 21).

McKenzie et al. performed a meta-analysis including six comparative studies, two prospective randomized, two retrospective cohorts, and two prospective nonrandomized studies between fixation with a suprasyndesmal screw and fixation with anchor suture (15). They found a lower risk of reoperation (regardless of the scheduled removal of the suprasyndesmal screw) in patients treated with anchor suture and a better overall score on the AOFAS scale for this same group. However, it only reached statistical significance in one of the studies, in which one of the authors is the inventor of the Tightrope. There are limitations to the evidence from this study in that the clinical rating scales are not the same, and the data tables are not fully available for correlation (22).

In 2019, Stiene et al. reported a systematic review of the literature regarding DF and SF of the distal tibiofibular syndesmosis to determine any clinical differences between the two procedures (23). The weighted AOFAS score was 91.70 for DF patients, and the weighted average was 86.48 for SF patients. A secondary procedure to remove the fixation device was performed in 7.7% of DF patients and 39.4% of SF patients when studies with 100% device removal were excluded. The mean time to weight-bearing was 5.96 weeks for patients who underwent DF and 10.45 weeks for those who had SF. The cost for DF was less than that for SF when secondary procedures for device removal were considered. Based on similar clinical, functional scores, lower secondary procedure rates, faster time to full weight-bearing, and lower costs to patients, Stiene et al. concluded that DF of the distal tibiofibular syndesmosis could be a superior option compared with SF (23).

Until the initiation of this study, no report had attempted to correlate biomechanical parameters or radiological measurements established by high-definition techniques such as CT scanning with clinical outcomes. The CT scan favors the use of Invisiknot instead of the screw. The mobility of the syndesmosis in the affected ankle was more similar than that of the healthy ankle. In other words, there was no difference between the treatment groups except for the fibular rotation, which remained closer to normal in the Invisknot group.

Various methods have been described to study the mobility of syndesmosis. Although radiographic assessment with simple orthogonal projections guides us in our clinical practice when diagnosing a lesion of the syndesmosis, it is not very sensitive when studying the physiological mobility of the same due to its poor spatial definition and variability depending on the projection obtained (24-26). Other methods, such as radiostereometry, have been used to measure the mobility of the syndesmosis, with limited efficacy (27).

Dynamic CT scanning has emerged in the last decade as a test that can reveal alterations in the spatial relationships of the syndesmosis and analyze the changes that occur in the positions that the ankle adopts, from neutral to flexion position when loading. Shakoor and Osgood published two studies with the same dynamic CT scan. In the first, they studied 14 patients who had been referred for poor clinical evolution after presenting an ankle injury with Weber type B or C fracture. On performing the dynamic CT scan, they found differences in 2 of the measurements (posterior tibiofibular distance and rotation of the fibula) between the unloaded and loaded positions in these patients. In a second study, these same authors evaluated the changes between loading and unloading in patients without previous ankle injury, finding that the distances that measure the mobility of the syndesmosis did not vary significantly (28, 29).

The measurements used to assess syndesmosis have been shown to have variable reproducibility in the literature; thus, there is interest in determining the best measures to study the biomechanical alterations of the syndesmosis. The four measures used in our study have been shown to be reproducible in several studies, although their absolute values and range of "normality" have not yet been delimited (6, 30, 31).

In an attempt to standardize measurements, syndesmosis measurements were performed on 100 ankles CT scans from the center's database for the traumatic indication (calcaneal or talus fractures) without injury to the syndesmosis. Three different observers performed the measurements, and they found a strong correlation between the measurements performed by each observer. The author concluded that although the established measurements help assess the evolution of the same ankle over time, they are not so helpful in establishing a range of standard values for the population due to the wide anatomical variability between patients (30).

We performed CT scan measurements limited to 30° plantar flexion and 20° dorsal flexion to include the maximum number of patients. Dorsal flexion increases the external rotation of the talus in cadaver studies by 2.5°, forcing the fibula to perform measurable external rotation and separation. Plantar flexion produces a slight internal rotation of the talus of approximately 1° (31).

No significant differences were found between the two groups in the other three parameters measured by CT scan, i.e., ATFD, PTFD, and APFT.

The difference in AFR loss in patients treated with screws (SF) compared with those treated with elastic sutures (DF) could be due to different mechanical conditions during syndesmosis healing. A more rigid fixation could limit the passage of load and tension to the scar tissue and induce a less organized collagen pattern. When the healing area is more exposed to physiological loads, the collagen healing pattern orients its fibers to maintain the tension and elasticity to which the structure being repaired was subjected.

As an essential secondary finding not described in the literature reviewed, syndesmosis mobility was statistically significant in 3 of the four parameters measured between the 20° dorsal flexion and 30° plantar flexion positions, with high significance values of $p < 0.001$ for ATFD, PTFD, and AFR in both healthy and operated ankles. Although healthy and operated ATFD, PTFD, and AFR were significantly different between both positions, PTFD did not appear to vary between positions, making it a less sensitive parameter to assess syndesmosis mobility.

These results are congruent with those found by Peter et al in the study on syndesmosis mobility measurements, who found in their cadaver model and with the same dorsal and plantar flexion positions a 2° variation in fibula rotation and a 1.5 mm mean separation between the fibula and tibia (8). In the study by Michelson and Helgemo Jr, they found 3.5° variations in fibula rotation between the 25° dorsal flexion and 35° plantar flexion positions (32).

The results found with our CT measurement method are aligned with those found in the literature in cadaveric studies and have the added value of having been performed *in vivo*; thus, it could be a valid test for measuring syndesmosis mobility in clinical practice.

In 2019, Kohake et al reported that syndesmotic rupture did not influence clinical and radiological result parameters after Weber B-type ankle fractures but caused a significant limitation in dorsal flexion of the ankle joint (33).

In 2020, Graff et al studied whether there was a difference in pressure inside the distal tibiofibular joint between a screw fixation and a TightRope. They found that the screw fixation was stronger and yielded a larger surface contact zone. Therefore, they concluded that screw fixation provided better stability in the ankle articulation (34).

In 2021, Longo et al attempted to define how the extent of tibiofibular syndesmotic ligament injury affected the comprehensive stability of the ankle articulation in a cadaver model. They observed that coronal and sagittal plane diastases of the tibiofibular syndesmosis were explicitly influenced by sequential lesions entailing the interosseous membrane). In contrast, augmented external rotation of the ankle most depended on the deep deltoid ligament. Therefore, recognizing the precise syndesmotic and deltoid ligament injuries was paramount to comprehending which lesions require surgical treatment (35).

The main limitations of this study were the small number of cases, that all measurements were performed by a single person (the principal investigator), and that in our technique the measurement of fibular motion was only performed in the axial plane. It is known that fibular motion can be detected in the axial, sagittal and coronal planes (20).

In conclusion, patients with ankle fractures with open syndesmosis treated with DF showed more significant physiologic fibular rotation in plantar flexion and dorsal flexion than patients treated with SF of the syndesmosis. No differences in the other syndesmosis measures performed were identified between the two groups. However, the more significant physiologic fibular rotation was not correlated with a better clinical result. Considering that SF and DF of the open syndesmosis yielded similar results, we advocate DF because it does not require further surgery for screw removal.

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References

1. Kellett JJ. The clinical features of ankle syndesmosis injuries: a general review.Clin J Sport Med. 2011; 21(6):524-9.
2. Purvis GD. Displaced, unstable ankle fractures: classification, incidence, and management of a consecutive series.Clin Orthop Relat Res. 1982; 165:91-8.
3. Scheer RC, Newman JM, Zhou JJ, Oommen AJ, Naziri Q, Shah NV, et al. Ankle fracture epidemiology in the United States: patient-related trends and mechanisms of injury. J Foot Ankle Surg. 2020; 59(3):479-83.
4. Rammelt S, Zwipp H, Grass R. Injuries to the distal tibiofibular syndesmosis: an evidence-based approach to acute and chronic lesions. Foot Ankle Clin. 2008; 13(4):611-33.
5. Jensen SL, Andresen BK, Mencke S, Nielsen PT. Epidemiology of ankle fractures. A prospective population-based study of 212 cases in Aalborg, Denmark. Acta Orthop Scand. 1998; 69(1):48-50.
6. van Staa TP, Dennison EM, Leufkens HG, Cooper C. Epidemiology of fractures in England and Wales. Bone. 2001; 29(6):517-22.
7. Court-Brown CM, McBirnie J, Wilson G. Adult ankle fractures—an increasing problem? Acta Orthop Scand. 1998; 69(1):43-7.
8. Elgafy H, Semaan HB, Blessinger B, Wassef A, Ebraheim NA. Computed tomography of normal distal tibiofibular syndesmosis. Skeletal Radiol. 2010; 39(6):559-64.
9. Endo J, Yamaguchi S, Saito M, Morikawa T, Akagi R, Sasho T. Changes in the syndesmotic reduction after syndesmotic screw fixation for ankle malleolar fractures: One-year longitudinal evaluations using computer tomography. Injury .2016; 47(10):2360-5.

10. Sagi HC, Shah AR, Sanders RW. The functional consequence of syndesmotic joint malreduction at a minimum 2-year follow-up. J Orthop Trauma. 2012; 26(7):439-43.
11. Peter RE, Harrington RM, Henley MB, Tencer AF. Biomechanical effects of internal fixation of the distal tibiofibular syndesmotic joint: comparison of two fixation techniques. J Orthop Trauma. 1994; 8(3):215-9.
12. Wang C, Ma X, Wang X, Huang J, Zhang C, Chen L. Internal fixation of distal tibiofibular syndesmotic injuries: a systematic review with meta-analysis. Int Orthop. 2013; 37(9):1755-63.
13. Krähenbühl N, Weinberg MW, Hintermann B, Haller JM, Saltzman CL, Barg A. Surgical outcome in chronic syndesmotic injury: a systematic literature review. Foot Ankle Surg. 2019; 25(5):691-7.
14. Nousiainen MT, McConnell AJ, Zdero R, McKee MD, Bhandari M, Schemitsch EH. The influence of the number of cortices of screw purchase and ankle position in Weber C ankle fracture fixation. J Orthop Trauma. 2008; 22(7):473-8.
15. McKenzie AC, Hesselholt KE, Larsen ML, Schmal H. A systematic review and meta-analysis on treatment of ankle fractures with syndesmotic rupture: suture-button fixation versus cortical screw fixation. J Foot Ankle Surg. 2019;58(5):946-53.
16. Xie L, Xie H, Wang J, Chen C, Zhang C, Chen H, et al. Comparison of suture button fixation and syndesmotic screw fixation in the treatment of distal tibiofibular syndesmosis injury: A systematic review and meta-analysis. Int J Surg. 2018; 60:120-31.
17. Zhang P, Liang Y, He J, Fang Y, Chen P, Wang J. A systematic review of suture-button versus syndesmotic screw in the treatment of distal tibiofibular syndesmosis injury. BMC Musculoskelet Disord. 2017; 18(1):286.
18. Lauge-Hansen N. Fractures of the ankle: II. Combined experimental-surgical and experimental-roentgenologic investigations. Arch Surg. 1950; 60(5):957-85.
19. Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, Sanders M. Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. Foot Ankle Int. 1994; 15(7):349-53.
20. Mousavian A, Shakoor D, Hafezi-Nejad N, Haj-Mirzaian A, de Cesar Netto C, Orapin J, et al. Tibiofibular syndesmosis in asymptomatic ankles: initial kinematic analysis using four-dimensional CT.Clinical Radiol. 2019;74(7):571.e1-571.e8.
21. Schepers T. Acute distal tibiofibular syndesmosis injury: a systematic review of suture-button versus syndesmotic screw repair. Int Orthop. 2012; 36(6):1199-206.
22. Thornes B, Shannon F, Guiney AM, Hession P, Masterson E. Suture-button syndesmosis fixation: accelerated rehabilitation and improved outcomes. Clin Orthop Relat Res. 2005; 431:207-12.
23. Stiene A, Renner CE, Chen T, Liu J, Ebraheim NA. Distal tibiofibular syndesmosis dysfunction: a systematic literature review of dynamic versus static fixation over the last 10 years. Foot Ankle Surg. 2019; 58(2):320-7.
24. Kortekangas T, Savola O, Flinkkilä T, Lepojärvi S, Nortunen S, Ohtonen P, et al. A prospective randomised study comparing TightRope and syndesmotic screw fixation for accuracy and maintenance of syndesmotic reduction assessed with bilateral computed tomography. Injury. 2015; 46(6):1119-26.
25. Beumer A, van Hemert WLW, Niesing R, Entius CAC, Ginai AZ, Mulder PGH, et al. Radiographic measurement of the distal tibiofibular syndesmosis has limited use. Clin Orthop Relat Res. 2004; 423:227-34.
26. Pneumaticos SG, Noble PC, Chatziioannou SN, Trevino SG. The effects of rotation on radiographic evaluation of the tibiofibular syndesmosis. Foot Ankle Int. 2002;23(2):107-11.
27. Beumer A, Valstar ER, Garling EH, Niesing R, Ranstam J, Löfvenberg R, et al. Kinematics of the distal tibiofibular syndesmosis: radiostereometry in 11 normal ankles. Acta Orthop Scand. 2003; 74(3):337-43.
28. Osgood GM, Shakoor D, Orapin J, Qin J, Khodarahmi I, Thawait GK, et al. Reliability of distal tibio-fibular syndesmotic instability measurements using weightbearing and non-weightbearing cone-beam CT. Foot Ankle Surg. 2019;25(6):771-81.
29. Shakoor D, Osgood GM, Brehler M, Zbijewski WB, de Cesar Netto C, Shafiq B, et al. Cone-beam CT measurements of distal tibio-fibular syndesmosis in asymptomatic uninjured ankles: does weight-bearing matter? Skeletal Radiol. 2019; 48(4):583-94.
30. Nault M-L, Hébert-Davies J, Laflamme G-Y, Leduc S. CT scan assessment of the syndesmosis: a new reproducible method. J Orthop Trauma. 2013; 27(11):638-41.
31. Warner SJ, Fabricant PD, Garner MR, Schottel PC, Helfet DL, Lorich DG. The measurement and clinical importance of syndesmotic reduction after operative fixation of rotational ankle fractures. J Bone Joint Surg Am. 2015; 97(23):1935-44.
32. Michelson JD, Helgemo Jr SL. Kinematics of the axially loaded ankle. Foot Ankle Int. 1995; 16(9):577-82.
33. Kohake MBJ, Wiebking U, O'Loughlin PF, Krettek C, Gaulke R. Mid- to long-term outcomes after Weber B-type ankle fractures with and without syndesmotic rupture. In Vivo. 2019;33(1):255-61.
34. Gräff P, Alanazi S, Alazzawi S, Weber-Spickschen S, Krettek C, Dratzidis A, et al. Screw fixation for syndesmotic injury is stronger and provides more contact area of the joint surface than TightRope®: A biomechanical study. Technol Health Care. 2020;28(5):533-9.
35. Longo UG, Loppini M, Fumo C, Lanotte A, Trovato U, Risi Ambrogioni L, et al. Deep deltoid ligament injury is related to rotational instability of the ankle joint: a biomechanical study. Knee Surg Sports Traumatol Arthrosc .2021; 29(5):1577-83.