



# Pain and Surgical Outcomes in Ankle Fracture and Syndesmosis Injury: Comparing Screw and Flexible Fixation Methods in a Cohort Study

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## Abstract

**Introduction:** Although the importance of anatomical repair and fixation for syndesmotic injury has been emphasized, the best surgical approach remains a topic of discussion. This study sought to evaluate and compare the post-operative pain and surgical outcomes between screw fixation and the suture endobutton method in patients with Weber type C ankle fractures.

**Methods:** A total of 56 consecutive patients with Weber type C ankle fractures participated in this prospective cohort study and underwent either screw fixation or suture endobutton surgery in 2022. Pain, infection, and the Foot and Ankle Outcome Score (FAOS) were monitored 3, 6, and 12 months' post-operation.

**Results:** The study included 14 women and 42 men, aged 18 to 47 years. There were no differences in age and sex between the two surgical groups. The pain score was significantly lower in the suture endobutton group compared to the screw fixation group three months after the operation ( $P=0.042$ ). However, the two groups had no significant differences in pain scores at six and twelve months. Within each treatment method, the pain scores were statistically significantly different over time ( $P_{total}<0.001$  in two groups). The suture endobutton method resulted in higher FAOS scores compared to the screw fixation method at three, six, and twelve months after surgery. The difference in this score within each group during the follow-up period was statistically significant ( $P_{total}<0.001$  in two groups).

**Conclusion:** The suture endobutton method has demonstrated advantages over screw fixation surgery. Patients have improved performance at three, six, and twelve months' post-surgery, indicating that it may be a potentially superior approach to treating syndesmosis injuries.

**Keywords:** Ankle Joint, Bone Screws, Injury, Orthopedic Fixation Devices, Surgery

## Introduction

Ankle injuries are frequent and can be linked to syndesmosis injuries<sup>1</sup>. It is estimated that 15 out of every 100,000 people suffer from syndesmosis injuries every year<sup>2</sup>. Approximately 10% of all ankle fractures and 20% of ankle fractures undergoing surgery are associated with

syndesmosis injury<sup>3, 4</sup>. Ankle fractures are classified in the literature in a number of ways<sup>5</sup>. One of these classifications is the Danis-Weber classification<sup>6</sup>.

Because the syndesmosis plays an important role in the stability of the ankle joint<sup>7</sup>, understanding the

detailed anatomy of the bony and ligamentous structures is essential for the interpretation of plain radiographs, CT and MR images, in ankle arthroscopy and therapeutic management<sup>3, 8, 9</sup>. Any damage to the syndesmosis can disrupt the anatomy of the ankle and, if treated improperly, increase the risk of early osteoarthritis<sup>9, 10</sup>. In acute ankle syndesmosis injury, pain and inability to bear weight on the affected limb are the main complaints of patients<sup>7, 11</sup>.

For syndesmosis injuries, open reduction and screw fixation are the typical treatment options<sup>12</sup>. Even if it is commonplace, the outcomes are not always pleasant. Malreduction may contribute to this issue<sup>13</sup>. Screw fixation can have additional side effects even if the insertion is done appropriately<sup>14</sup>. One such impact is that it can restrict the tibiofibular joint's normal range of motion, which can cause pain in the patient<sup>15</sup>. Any damage to the syndesmosis can disrupt the anatomy of the ankle and, if treated improperly, increase the risk of early osteoarthritis<sup>10, 16</sup>.

The endobutton suture is an alternative method for stabilizing the syndesmosis, but it is not the dominant technique<sup>2</sup>. It may be costlier and technically demanding<sup>17</sup>. However, changes in this process are anticipated, and the suture endobutton may become more popular in the future<sup>18</sup>.

This technique provides flexible stabilization of the syndesmosis, a fast, minimally invasive procedure with reproducible results. It also eliminates the need for routine implant removal, especially when four cortices (Tibia and Fibula) are involved during screw fixation. This technique allows initial weight bearing and eventual return to activities of daily living (ADL), sports, and work in a short time. Problems with the Suture endobutton method are often related to soft tissue<sup>19, 20</sup>.

Considering the complications of using screw fixation, examining an alternative treatment method and comparing its outcomes with the traditional method will help determine the most appropriate treatment method for syndesmosis injury for each patient. This is especially true since

the existing knowledge in this field is insufficient, and few studies have been done. Therefore, the purpose of this study was to compare the screw fixation with the suture endobutton method in patients referred to the Guilan Orthopedic Referral Hospital in 2022.

## Methods

### Study area, design, and population

This prospective cohort study was conducted in 2022 among patients with Weber type C ankle fractures (diagnosed using anteroposterior, Lateral, and mortise view ankle radiographs) referred to the Poursina Medical Education Center, an orthopedic referral hospital in northern Iran.

### Inclusion and exclusion criteria

The study's entry criteria were patients with Weber type C ankle fractures aged between 16 and 65. Patients who fulfilled these criteria and consented to participate in the study were assigned to one of two groups. There were no preferences, such as age, sex, or injury severity, in assigning patients to each treatment. The first patient was enrolled in the study on May 1, 2022, and the last was enrolled on October 8, 2022. All procedures complied with relevant laws and institutional guidelines and were approved by the Clinical Research Ethics Committee of Guilan University of Medical Sciences (IR.GUMS.REC.1401.016).

Patients with comorbid syndesmosis with other orthopaedic injuries, underlying diseases (such as diabetes and obesity), neuropathic arthropathy, and severe osteoporosis were excluded from the study.

### Sample Size

The sample size was determined using the AOFAS scores from Naqvi et al.'s study, which reported scores of  $86.5 \pm 9.6$  for the screw fixation method and  $89.6 \pm 8.6$  for the endobutton suture method<sup>20</sup>. In the present study, considering the test power of 80% the first type error of 5% and the minimum difference with clinical significance equal to  $\delta=10$ , the minimum sample size of 14 cases in each group was considered. Considering the two variables of age and gender and a 10% drop-out, the final sample volume of 28 patients was calculated in each group. Between May 1, 2022, and October 8, 2022, 228 patients underwent surgery for ankle fractures. Among them, 61 patients had associated syndesmotic injuries and were considered for inclusion in the study.

Three patients were excluded due to specific exclusion criteria, and two declined participations. Ultimately, 56 patients were included in the final analysis, with 28

patients assigned to the endobutton suture group and 28 to the screw fixation group (Figure 1).

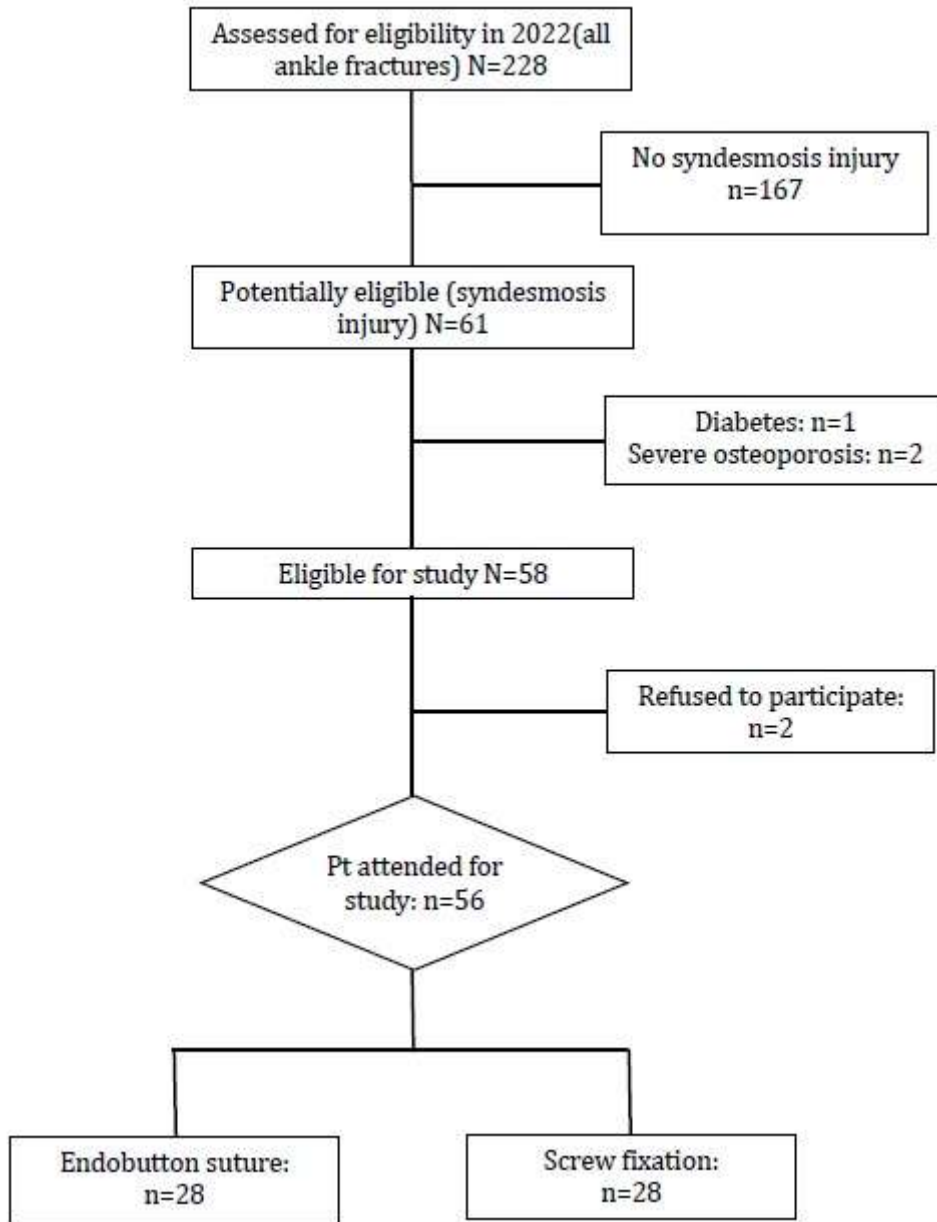


Figure 1: STROBE flow chart showing selection of patients. Pt, patient.

**Surgery methods**

The patient position in both methods was supine with a lateral approach, and the type of anesthesia (general or spinal) was based on individual patient factors, including medical history and patient preference. A single experienced surgeon performed all surgical procedures. In the screw fixation method, first, the

lateral malleolus fracture was fixed. Then, 1 to 2 cm proximal to the tibiotalar joint, a 30-degree posterior-to-anterior and parallel to the joint hole was drilled with a 2.5 mm drill-bit while the ankle was in a neutral position. A 3.5 cortical screw was used to fix the joint, placed through the plate hole. Three cortices were drilled with one screw. The syndesmosis screw, which

engages four cortices, is removed from the patient's foot approximately 10 to 12 weeks after surgery to prevent fracture. In cases of complications such as failure or infection, plans were made for removal.

In the suture endobutton technique, a hole is drilled 1 to 2 cm proximal to the tibiotalar joint, using a 30-degree posterior-to-anterior angle parallel to the joint, with a 3.7 mm drill bit through the four cortices of the fibula and tibia bones. A driver is inserted into the bone canal, reaching the medial cortex of the tibia. After removing the safety tab, the XP release button on the suture endobutton handle is retracted. Under fluoroscopy, the suture endobutton is positioned medially in a T shape by rotating the handle. The suture endobutton threads are released from the handle and extracted from the bone tunnel. Central sutures are secured before tightening. The round button is shifted laterally, and each suture is wrapped 2 to 3 times around the handle's axis. The sutures are then pulled back tightly. If the side button lies flat, the fixation is deemed complete. All suture buttons were purchased under the name TightRope from Arthrex Inc. (Naples, FL, USA) ® and 5.3 cortical screws from Motbakaran Parsian Derman (Tehran, Iran) ®. In the screw fixation method, patients can bear weight after the screws are removed, while in the TightRope technique, weight-bearing is allowed two months' post-surgery. Radiographic results of patient number 11, who underwent screw fixation surgery, are shown in (Fig2). Also Radiographic results of patient number 16 who underwent suture endobutton surgery are shown in (Fig3). These radiographs were obtained from the patients of both surgical techniques, the day following the procedure.



Figure 2: Post-operative ankle X-Ray of the patient with weber type c fracture using Screw fixation method



Figure 3: Post-operative ankle X-Ray of the patient with weber type c fracture using Tightrope method

### Procedures

Control radiographs were obtained from the patients using both surgical techniques on the day following the procedure. A molded below-knee cast was used for 2–6 weeks and removed 2–6 weeks after surgery. After cast removal, graduated weight-bearing was typically possible. Patients were encouraged to start range-of-motion exercises. Physiotherapy supervision may sometimes be required, but it is not mandatory. During the follow-up visit one month after the procedure, patients underwent clinical examination and routine tests to assess the presence or absence of infection at the operation site. The level of pain and FAOS of the patients in the 3-month and 6-month postoperative follow-ups in both groups were measured over the phone using the Visual Analogue Scale for pain(VAS) and the Foot and Ankle Outcome Score(FAOS) criteria, and the information was accurately recorded. Finally, the two groups were compared using statistical analysis regarding postoperative outcomes.

### Statistical analysis

All statistical analyses were performed using IBM SPSS for Windows (version 26.0; IBM Corp., Armonk, NY, USA). Qualitative variables were expressed as numbers (percentages), and quantitative variables were expressed as mean  $\pm$  standard deviation or median(IQR). The Shapiro-Wilk test was used to check normality. The tests revealed that only the age factor had a normal distribution. The frequency of the qualitative variable in the two studied methods was compared using the Pearson Chi-Square Test. The scores of outcomes in the two studied methods were

compared using the independent t-test, and if the assumption of normality was not met, the Mann-Whitney U test was used instead. Additionally, the scores of outcomes within groups were compared using the Friedman Test with pairwise comparisons adjusted by the Bonferroni correction. All P-values for the tests were two-sided, and P-values <0.05 were deemed statistically significant.

**Results**

**Patient demographics**

The study included 14 women and 42 men, ages ranging from 18 to 47. There were no differences in age between the two surgical groups. The mean age was 32.3 ± 7.7 and 31.8 ± 7.7 in the screw fixation and suture endobutton groups (P=0.643). No significant differences were found in sex between the two surgical groups (P=0.217) (Table 1).

**Clinical outcomes**

The pain score was significantly lower in the suture endobutton group compared to the screw fixation group three months after the operation (P=0.042). However, the two groups had no significant differences in pain

scores at six and twelve months (P=0.221 and P=0.202, respectively). Within each treatment method, the pain scores were statistically significantly different over time (Ptotal<0.001 in two groups). In the screw fixation group, the pain scores between the sixth and twelfth months did not differ, but in the suture endobutton group, there were significant differences between each of the two time points (Table 2).

The suture endobutton method resulted in higher FAOS scores compared to the screw fixation method at three, six, and twelve months after surgery, and the difference between the two surgical groups was statistically significant at these three time points (P=0.002, P<0.001, and P<0.001, respectively). The FAOS score rose from the third to the twelfth month in both treatment approaches (Ptotal<0.001). The FAOS score changes from the third to the twelfth month were approximately twice as high with the suture endobutton method compared to the screw fixation method (Table 3, Figure 4).

In this study, there were no complications or need for a second surgery in any of the patients.

Table 1: Comparison of demographic characteristics in two groups

		Screw Fixation(n=28)	suture endobutton(n=28)	P-Value
Sex, n (%)	Male	19(67.9)	23(82.1)	0.217†
	Female	9(32.1)	5(17.9)	
Age, y	mean±SD(range)	32.3±7.7(18.0-47.0)	31.8±7.7(18.0-47.0)	0.643‡

† Pearson Chi-Square Test ; ‡ Independent Samples Test

Table 2: Comparison of two treatment methods according to the pain score of the third, sixth, and twelve months after the surgery

Pain Score		Screw Fixation(n=28)	Suture Endobutton(n=28)	P-Value†
third months	mean±SD(range)	2.2±0.7(1.0-3.0)	1.8±0.7(1.0-3.0)	0.042
	median(IQR)	2.0(2.0-3.0)	2.0(1.0-2.0)	
sixth months	mean±SD(range)	1.3±0.5(1.0-2.0)	1.2±0.4(1.0-2.0)	0.221
	median(IQR)	1.0(1.0-2.0)	1.0(1.0-1.0)	
twelve months	mean±SD(range)	0.8±0.4(0.0-1.0)	0.6±0.5(0.0-1.0)	0.202
	median(IQR)	1.0(1.0-1.0)	1.0(0.0-1.0)	
P-Value‡		Ptotal<0.001 P3,6=0.001; P3,12<0.001	Ptotal <0.001 P3,6=0.025; P3,12<0.001; P6,12=0.025	

† Mann-Whitney U ; ‡ Friedman Test; Pairwise comparisons have been adjusted by the Bonferroni correction

Table 3: Comparison of two treatment methods according to the FAOS score of the third, sixth, and twelve months after the surgery

FAOS Score		Screw Fixation(n=28)	Suture Endobutton(n=28)	P-Value†
third months	mean±SD(range)	85.0±2.1(80.0-88.0)	86.6±1.0(85.0-89.0)	0.002
	median(IQR)	85.5(83.5-86.0)	87.0(86.0-87.0)	
sixth months	mean±SD(range)	86.3±2.1(82.0-90.0)	89.1±1.3(86.0-91.0)	<0.001
	median(IQR)	86.0(85.0-87.0)	89.5(88.0-90.0)	
twelve months	mean±SD(range)	87.3±2.2(84.0-90.0)	91.4±1.3(89.0-94.0)	<0.001
	median(IQR)	88.0(85.0-89.0)	92.0(91.0-92.0)	
P-Value‡		P <sub>total</sub> <0.001 P <sub>3,6</sub> =0.001; P <sub>3,12</sub> <0.001 P <sub>6,12</sub> =0.024	P <sub>total</sub> <0.001 P <sub>3,6</sub> =0.001; P <sub>3,12</sub> <0.001 P <sub>6,12</sub> =0.002	
† Mann-Whitney U ; ‡ Friedman Test; Pairwise comparisons have been adjusted by the Bonferroni correction				

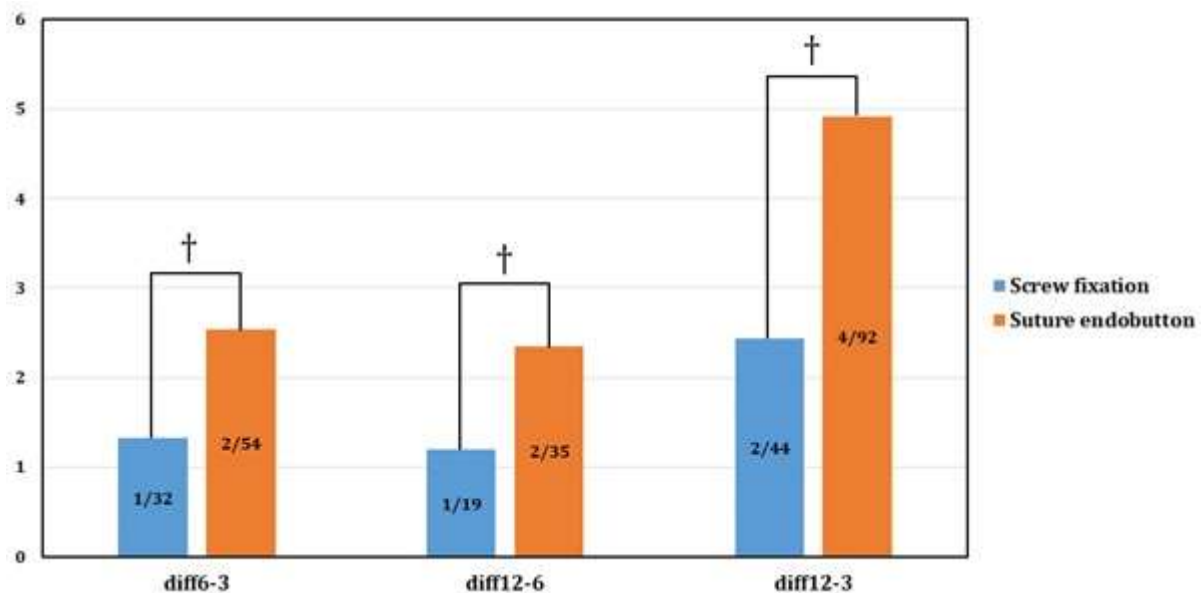


Figure 4: Comparison of the FAOS score changes at different measurement times in the two study groups

## Discussion

Three months' post-surgery, there was a difference in pain scores between the screw fixation and suture endobutton methods. However, by the sixth and twelfth months, the pain scores between the two groups showed no statistically significant difference. In the study by Høiness, short-term functional results of two types of syndesmotic fixation were assessed. There was no significant difference in Pain score after 1 year between the two methods<sup>21</sup>.

Pain scores in both treatments significantly decreased from the third to the twelfth month. Similarly, studies have confirmed that both screw fixation and the suture

endobutton method are effective in reducing patient pain<sup>22-25</sup>.

In this study, the FAOS score in the third, sixth, and twelfth months showed a statistically significant difference between the two surgical methods, with the suture endobutton method outperforming the screw fixation method. This finding is similar to the study of Ye, Zhang in China<sup>26</sup>. In a study comparing suture endobutton versus screw fixation in ankle syndesmosis 1-2 months after surgery, 34% of patients preferred to have the screw fixation removed<sup>18</sup>. A study found that screw fixation led to malreduction of the syndesmosis in one case, while the suture endobutton method caused

malreduction in seven cases. However, it was revealed that supporting the ankle at a 90-degree angle reduced the incidence of malreduction following the suture endobutton procedure<sup>27</sup>.

Chen's meta-analysis found no differences in functional outcomes or complications between the two methods<sup>28</sup>. However, the study's generalizability is questionable due to the limited number of studies available in 2017, the small sample size of only 397 patients, and the need for more comprehensive randomized controlled trials (RCTs) with larger populations<sup>29</sup>.

While screw fixation is acknowledged as the gold standard for treating syndesmotic injuries, other critical factors, such as discomfort and the necessity for reoperation, must be considered. Many orthopedists have recently shown interest in suture endobutton fixation devices. Potential benefits of this device include faster weight-bearing, a reduced chance of implant removal and recurring syndesmotic diastasis, quicker rehabilitation compared to screw fixation, and the ability to allow physiological mobility while maintaining the necessary reduction<sup>23</sup>. In the literature, there is still disagreement over the best surgical management<sup>30</sup>.

A study by Naqvi showed that the suture endobutton is a valuable technique for fixing syndesmosis as it stabilizes the syndesmosis, eliminates the need for routine implant removal, and makes dynamic fixation easier<sup>20</sup>. In a 2019 study by Sanders comparing the two fixation methods, it was emphasized that the suture endobutton method is more efficient than screw fixation<sup>24</sup>. The results of that study are consistent with the present study's findings. The study's cohort of 28 patients is relatively small, which may limit the statistical significance of the findings. Further studies with a larger sample size and extended follow-up periods are recommended.

## Conclusion

Both the suture endobutton and screw fixation techniques effectively alleviate patient pain, with neither method proving superior in this aspect. However, regarding the patient's FAOS, the suture endobutton technique outperforms the screw method. It enables patients to return to daily activities more swiftly and with a better quality of life. The suture endobutton method has shown enhanced patient performance from three to twelve months' post-surgery compared to the

screw fixation method, suggesting it may be more effective for treating syndesmosis injuries. Further research is necessary to explore these findings.

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## Conflict of Interest Disclosures

The authors declare that the research was conducted without any commercial or financial relationships that could potentially create a conflict of interest.

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## Authors' Contributions

Conception and design: A. A, K. A, A. F. Acquisition and analysis of data: A. A, K. A, M. Y. Verification of the underlying data: A. F, N. F. Formal analysis: M. Y. Supervision: A. A, K. A. Writing—original draft K. A, M. Y, N. F. Writing—review and editing: K. A, M. Y, N. F. All authors read and approved the final version of the manuscript.

## Ethical Statement

This study was performed in line with the principles of Declaration of Helsinki. Approval was by Ethics Committee of Guilan university of medical sciences (Code: IR.GUMS.REC.1401.016). We the authors state that informed consent was obtained from all participants and the participants were aware of the study purpose, risks and benefits.

## Declaration of Generative AI and AI-assisted technologies

Note cleared.

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