A comparison of double single suture-button fixation, suture-button fixation, and screw fixation for ankle syndesmosis injury

A retrospective cohort study

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Abstract
Different methods have been used throughout the years for syndesmotic injury but there is no consensus on the ideal treatment. Some methods are expensive and some have more complications. The aim of this study is to compare single suture endobutton with double suture endobutton and screw fixation for syndesmotic injury.

Sixty-nine patients with syndesmotic injury with fibular fractures whom were treated with a single interosseous suture endobutton system (ZipTight\textsuperscript{TM}, Zimmer Biomet), a double interosseous suture endobutton system (ZipTight\textsuperscript{TM}, Zimmer Biomet) and 1 syndesmotic screw (TST, Istanbul, Turkey) were included in this study. Functional and radiological results from patient records between 2015 and 2018 were retrospectively evaluated.

Twenty patients were treated with the double interosseous suture endobutton, 23 were treated with the single interosseous suture endobutton, and 26 were treated with traditional AO screw fixation. Three patients from the screw fixation group (11.5%) required revision surgery \textit{(P} < .05). All the radiologic and clinical outcomes were statistic similar in all 3 groups.

Our findings showed that the interosseous suture endobutton system is at least as safe as the screw fixation technique for treatment of syndesmosis joint injuries and can be used as an alternative to the screw method. The interosseous suture endobutton system eliminates the need for a second surgery to remove the hardware, which minimizes the probability of re-diastasis. Since our results showed no statistical difference between single and double interosseous suture endobutton systems, the less costly single endobutton system may be the better alternative.

Abbreviations: AO = Arbeitsgemeinschaft für Osteosynthesefragen, AOFAS = American Orthopaedic Foot and Ankle Society, FADI = Foot and Ankle Disability Index, MCS = medial clear space, mm = millimeter, TFCS = tibiofibular clear space, TFO = tibiofibular overlap.

Keywords: ankle fracture, American Orthopaedic Foot and Ankle Society, screw fixation, suture endobutton, syndesmosis injury

1. Introduction
Syndesmotic injuries occur in approximately 10\% of all patients with ankle fractures, with an annual incidence of 1.5 per 100,000 people.\textsuperscript{1,2} Anatomic reconstruction of the ankle mortise and stable fixation of the disrupted syndesmosis following an ankle fracture are essential for optimal functional outcomes.\textsuperscript{3,4} Different methods have been used throughout the years for syndesmotic injury but there is no consensus on the ideal treatment.\textsuperscript{5} Tibiofibular syndesmosis should be strong enough to maintain reduction under weightbearing and early mobilization.\textsuperscript{6,6}

Diastasis screws are commonly used for syndesmotic injury, but intact screws can worsen functional outcomes,\textsuperscript{7} so the
screws are usually removed; however, this procedure increases workload, healthcare costs, and operative risks. In addition, previous studies have found reduction failure of the syndesmotic complex and instability following screw removal.

Button and suture construction with a medial-lateral metallic button and suture system offers an alternative method for repairing the distal tibio-fibular joint. Suture-button design has been shown to maintain the reduction, facilitating physiologic stability of the ankle mortise. This may allow early physiologic motion, leading to earlier ligament healing, and potentially earlier loading, which may produce better clinical results. However, this system is more expensive than the screw method and it may gradually relax under weightbearing conditions. Therefore, whether this device is a suitable alternative, and how many devices are needed for adequate stability are not yet known. There are no studies in the current literature that compare a double intersosseous suture endobutton system or single intersosseous suture endobutton system with the screw fixation method. In this retrospective study, we compared these 3 treatment methods in patients with syndesmosis injuries.

2. Methodology

Sixty nine patients with syndesmotic injury with fibular fractures were treated with a double intersosseous suture endobutton system (ZipTight™, Zimmer Biomet), a single intersosseous suture endobutton system (ZipTight™, Zimmer Biomet), or 1 syndesmotic screw (TST, Istanbul, Turkey). Functional and radiological results from patient records between 2015 and 2018 were retrospectively evaluated. Patients with other associated injuries, open fractures, delayed presentation or diagnosis were excluded from the study.

Parameters included age, gender, length of follow up, complications, interval to weightbearing, fracture pattern, postoperative American Orthopaedic Foot and Ankle Society (AOFAS) hindfoot-ankle score, Foot and Ankle Disability Index (FADI) scores, number of ZipTight™ devices used per patient, number of screws used per patient, and number of patients who required implant removal. Accompanying ankle injuries were treated as required, using the appropriate AO (Arbeitsgemeinschaft für Osteosynthesefragen) technique.

Preoperative, postoperative, and last follow-up radiographs from the Picture Archiving and Communications System were evaluated. All measurements were made on an anteroposterior radiograph, 1 cm proximal to the ankle joint. Medial clear space (MCS), tibiofibular clear space (TFCS), and tibiofibular overlap (TFO) measurements were recorded. It is a retrospective study and this research has been approved by the Institutional Review Board of the authors’ affiliated institutions (Sakarya University Medical Faculty/17122473/05.01.04/209).

2.1. Surgical techniques

Procedures were performed with the patient in a supine position on the operating table after either general or spinal anesthesia was administered. A carefully padded thigh tourniquet was applied to the ipsilateral thigh. Standard ankle orthosis techniques were used to internally fix fibula or tibia fractures requiring fixation, and a large ankle orthosis clamp with the ankle in neutral position was used to reduce and maintain syndesmosis. Reduction was confirmed under fluoroscopy. All 4 cortices were drilled from the fibular side, angled 30 degrees anterior to the coronal plane and placed approximately 3 cm above and parallel to the tibial plafond. If a plate was used for fibular stabilization, the drill hole was made through one of the empty plate holes, depending on the location of the plate. In patients treated with a syndesmotic screw, either a 3.5-mm or a 4.5-mm cortical screw was inserted through the drill hole, engaging all 4 cortices. In the ZipTight™ group, after the bone tunnels were prepared, we passed the ZipTight™ Fixation System pull strands through the tunnels from lateral to medial using the guide pin. Once the medial button was passed through the medial tibial cortex (confirmed by imaging), the assembly was tensioned by pulling the free ends of the FiberWire on the lateral side. If a second tightrope was needed, it was placed 1 cm more proximal using the same technique, except that we slightly altered our angle to ensure the tightropes were divergent to increase rotational stability.

All patients were immobilized in a below-the-knee, non-weightbearing cast for 6 weeks, followed by physical therapy, and weightbearing as tolerated. Patients were followed up in the clinic at 2 weeks, 6 weeks, 3 months, and after 3 months. In this study, the syndesmotic screws were routinely removed at approximately 10 weeks after surgery. Patients were reviewed at least 12 months after surgery for data collection.

2.2. Statistical analysis

Descriptive analyses were performed to provide information on the study populations’ general characteristics. The Kolmogorov–Smirnov test was used to evaluate normal distribution of the numerical variables. One-way ANOVA or Kruskal–Wallis tests were used for between-group comparisons of the numeric measures or total scores. Friedman tests were used to compare the total scores across 3 periods. The numeric measures or total scores were presented as the mean ± standard deviation or median and interquartile range. Chi-Squared tests were used to compare categorical variables, reported as frequency and percentage. P values <.05 were considered significant. Analyses were performed using IBM SPSS Statistics, Version 23.0 (Armonk, NY: IBM Corp.).

3. Results

3.1. Patient demographics and injury classification

Sixty nine patients were treated with either an intersosseous suture endobutton system or a screw over the 3-year study period. All surgeries were performed by the senior authors. Twenty patients were treated with the double intersosseous suture endobutton (Fig. 1), 23 were treated with the single intersosseous suture endobutton (Fig. 2) and 26 were treated with traditional AO screw fixation (Fig. 3). Summary data on the patients’ demographic characteristics, injury mechanisms, and fracture classification are presented in (Table 1).

3.2. Radiographic measurements

Mean preoperative and postoperative values are presented in Table 2. The primary outcome measure, reduction of syndesmosis, was diagnosed based on the predefined criterion of a 2 mm
difference in width from the contralateral side. In the double interosseous suture endobutton group, the mean medial clear space was 2.8 mm (range 2.00–4.00 mm) postoperatively and 3 mm (range 2.00–4.00 mm) at last follow up. In the single suture endobutton group, the mean medial clear space was 2.6 mm (range 2.00–4.00 mm) postoperatively and 3.1 mm (range 2–4 mm) at last follow up. There were no hardware failures noted in either the double suture endobutton group or single suture endobutton group. In the screw group, the mean medial clear space was 2.8 mm (range 2–4 mm) postoperatively and 3.4 mm (range 2–5 mm) at last follow up.

Reduction was observed postoperatively in all groups, reduction failures were seen in 3 of the screw group cases and were revised during follow up ($P < .05$).

3.3. Clinical outcomes

The mean time to allow full weightbearing was 9.1 weeks (range 6–12) in the double suture endobutton group, 8.5 weeks (range 6–12) in the single suture endobutton group, and 9.5 weeks (range, 6–13) in the syndesmotic screw group ($P = .152$).

The mean postoperative AOFAS hindfoot-ankle score was 88 (range 70–95) in the double suture endobutton group, 86 (range 65–95) in the single suture endobutton group, and 84 (range 65–95) in the screw group. There was no statistically difference between groups.

The mean postoperative FADI score was 81 (range 65–92) in the double suture endobutton group, 79 (range 65–90) in the
single suture endobutton group, and 77 (range 55–90) in the screw group. There was no statistically difference between groups. Complications included lateral button irritation in 2 patients (10%) in the double suture endobutton group and 1 patient (4.3%) in the single suture endobutton group, which resolved without removal. One patient (5%) was treated for superficial infection in the double suture endobutton group, 2 patients (8.6%) were treated for superficial infection in the single suture endobutton group, and 3 were treated for superficial infection in the screw group, all of which resolved with oral antibiotics. Three patients from the screw fixation group (11.5%) required revision surgery ($P < .05$).

### 4. Discussion

We compared interosseous suture endobutton systems with screw methods for repairing syndesmotic injury in patients with ankle fractures and found that the interosseous suture endobutton method is safe and stable. There were no significant functional or clinical differences between the screw and suture endobutton methods. In addition, we found that the use of a double suture endobutton did not significantly affect the functional and clinical results.

Various methods have been used in the treatment of syndesmotic injuries such as screw fixation, bioabsorbable screw

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### Table 1

|                      | 2 Endobutton (n = 20) | 1 Endobutton (n = 23) | Screw (n = 26) | Test values | $P$ values |
|----------------------|-----------------------|-----------------------|---------------|-------------|------------|
| Gender (male)        | 14 (%70)              | 16 (%69.6)            | 17 (68.1)     | $^*0.144$   | .930       |
| Side (left)          | 7 (%35)               | 11 (%47.8)            | 11 (42.3)     | $0.724$     | .696       |
| Age (yr)             | 36.90±14.44           | 36.83±13.25           | 40.58±15.96   | $0.521$     | .597       |
| Follow-up time (mo)  | 15.96±3.02            | 18.04±3.14            | 17.77±3.51    | $2.589$     | .083       |
| AOFAS                | 86 [10]               | 86 [10]               | 84 [10]       | $3.598$     | .165       |
| FADI                 | 81 [15]               | 79 [15]               | 77 [11.3]     | $1.747$     | .417       |
| Infection (yes)      | 1 (%5)                | 2 (%8.7)              | 3 (%11.5)     | $0.645$     | .725       |
| Button irritation (yes) | 2 (%10)            | 1 (%4.3)              | NA            | *           | .590       |
| Revision (yes)       | 0                     | 0                     | 3 (%11.5)     | $6.084$     | .048       |
| Load Bearing (wk)    | 9.1±1.62              | 8.57±1.38             | 9.5±1.9       | $1.938$     | .152       |
| Distance from Tibial Plafonda (Distal) | 25 [4]  | 31 [6] | 31.7 [8] | $15.728$ | <.001  |

**Injuries Pattern**

- BIMALLEOL: 5 (%25) vs 8 (%34.8) vs 6 (%26.1)
- TRIMALLEOL: 6 (%30) vs 6 (%26.1) vs 7 (%26.9)
- WEBER TYPE B: 5 (%25) vs 5 (%21.7) vs 4 (%15.4)
- WEBER TYPE C: 4 (%20) vs 4 (%17.4) vs 6 (%23.1)

**Table 2**

|                      | 2 Endobutton (n = 20) | 1 Endobutton (n = 23) | Screw (n = 26) | Test values | $P$ values |
|----------------------|-----------------------|-----------------------|---------------|-------------|------------|
| TFCS                 |                       |                       |               |             |            |
| Pre-op               | 9.5 [3.75]            | 9.6 [2]               | 9.9 [3]       | 0.952       | .621       |
| Post-op              | 4 [2]                 | 4.2 [2]               | 4.9 [2]       | 8.336       | .015       |
| Last follow up       | 5.8 [2.75]            | 4.6 [1]               | 5.9 [2.25]    | 14.309      | <.001      |
| $^*$Test values       | 37.455                | 42.323                | 46.323        |             |            |
| $P$ values            | <.001                 | <.001                 | <.001         |             |            |
| TFO                  |                       |                       |               |             |            |
| Pre-op               | 1.9 [3]               | 2.2 [2]               | 2.4 [2.25]    | 0.913       | .634       |
| Post-op              | 7.5 [1]               | 7.7 [2]               | 6.8 [2]       | 3.027       | .220       |
| Last follow up       | 7.3 [1]               | 6.9 [2]               | 5.8 [2]       | 11.59       | .003       |
| $^*$Test values       | 35.567                | 43.053                | 37.796        |             |            |
| $P$ values            | <.001                 | <.001                 | <.001         |             |            |
| MCS                  |                       |                       |               |             |            |
| Pre-op               | 8.5 [3.75]            | 8 [2]                 | 9 [3]         | $0.879$     | .644       |
| Post-op              | 2.8 [1]               | 2.61[1]               | 2.8 [0.25]    | 1.39        | .499       |
| Last follow up       | 3 [2]                 | 3.1 [2]               | 3.4 [1]       | 4.221       | .121       |
| $^*$Test values       | 38                    | 42.883                | 48.202        |             |            |
| $P$ values            | <.001                 | <.001                 | <.001         |             |            |

* Chi-Squared test values.
* ANOVA test values.
* Kruskal–Wallis test values.
Data were shown as count (percentage), mean ± standard deviation, or median [interquartile range].

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fixation, and suture-button management, with screw fixation being the traditional method. The advantage of the screw method is that it ensures the continuity of syndesmotic reduction under any weight condition.\[^{17}\]

Biological absorbable screw methods have been used to eliminate metallic screw complications.\[^{13}\] Cox et al found no difference between the biological and metallic screw method,\[^{19}\] but some disadvantages have been observed. For example, the strength of bioabsorbable screws is lower than that of metal screws. In addition, osteolytic and inflammatory reactions to bioabsorbable screws may develop.\[^{20}\]

The AO group recommended trans fixation screws to repair syndesmotic injury\[^{21}\] and other studies have discussed the number of screws that should be used, how far they should be placed from the joint, and how many cortices to pass.\[^{22}\] There is also controversy regarding whether to later remove the screw. In a systematic review, Schepers\[^{23}\] examined 7 studies with and without screw removal and found little evidence to support screw removal. Hamid et al\[^{24}\] showed that patients with broken or screw lysis have better ankle scores, and that it is advantageous to retain micro motion in syndesmosis. Today, most surgeons prefer to remove the screw/screws, but the removal time varies.\[^{25}\]

Van den Bekerom et al\[^{26}\] summarized the available literature regarding syndesmotic screw placement and recommended that: the ankle should be in the neutral position during tightening; 3.5 mm screws are adequate for stabilization but 4.5 mm screws may be used in larger patients or larger fibulas; double tricortical screws provide secure fixation but are less secure than quadracortical screws; quadracortical screws should definitely be removed before weight bearing to avoid screw breakage; and quadracortical screws are more likely to break because of rigid fixation. Although the optimal time to remove screws is not fully known, it should not be removed before 6 to 8 weeks to allow the ligaments to heal in the correct position prior to removal. We used a single screw as 4 cortices with screw distance 32 mm from the joint, and we removed screws at approximately 10 weeks after surgery.

Since the syndesmosis joint is movable, studies have reported that additional problems occur with rigid fixation using screws and that additional surgery may be needed because of screw breakage and loosening.\[^{27}\] By contrast, the suture endobutton system allows dynamic movement between the tibia and fibula during ankle movements.\[^{28}\]

The normal migrational changes and physiologic motion of the fibula during weightbearing and gait cycle have been identified.\[^{29}\] Scranton et al\[^{30}\] showed the importance of the fibula in dynamic function, stability, and maintenance of the ankle mortis. The fibula migrates distally with lateral displacement while maintaining a rotational component under weightbearing. Studies have shown that long term syndesmotic joint stabilization with a screw that protects weightbearing and prolonged immobilization can lead to decreased functional capacity.\[^{31}\] Stabilization of the syndesmotic joint with screws changes contact pressure on the talus,\[^{32}\] which can decrease joint harmony, adversely affect the tibiotar joint kinematics, increase contact stress, and cause chondrocyte degeneration and joint arthrosis.\[^{29}\]

The suture endobutton system permits dynamic stabilization and micromotion in the syndesmotic joint. Ligamentous fibers might reorganize and repair with less scar deposition because of the controlled micromotion.\[^{33}\] In addition, the endobutton system is a permanent placement and does not require removal. This eliminates both the need for a second operation and the debate regarding when to remove the screw.\[^{23}\] Thorne et al\[^{34}\] reported that CT images at the third postoperative month showed that no patients had loss of reduction with suture endobutton fixation. We did not remove any single or double endobutton implants in our patients and none of our patients experienced reduction failure.

Five of our full patient sample, (6.6%) experienced recurrent diastasis after screw removal. Schepers et al\[^{35}\] reported that 8.9% of their sample experienced recurrent diastasis after screw removal, after excluding patients with insufficient data. In our study, 3 patients in the screw fixation group (11.5%) experienced reduction failure; no patients in the endobutton groups experienced reduction failure.

A cadaveric study\[^{36}\] showed that some of the medial structures are at risk during endobutton placement. During medial dissection, 4 cases (10%) of greater saphenous vein perforation by the guidewire were observed. In half of the cases the button was placed under the saphenous vein. The actual incidence of venous perforation may be higher since it is difficult to show venous perforation in cadaveric specimens.

Studies have reported that suture endobutton removal was needed in some cases because of soft tissue inflammation and tibialis tendon entrapment from the medial button.\[^{37}\] Bondi et al reported 1 case (1.8%) of soft tissue irritation on the lateral side requiring removal of the implant at 6 months.\[^{38}\] We did not observe any tibialis tendon entrapment or medial tissue inflammation in our patients, but we encountered lateral button irritation in 2 patients (10%) in the double intersosseous suture endobutton group and 1 patient (4.3%) in the single intersosseous suture endobutton group. However, the patients improved after medical treatment and the implants did not need to be removed.

Coetzee and Ebeling\[^{39}\] reported that the AOFAS ankle and hindfoot score for their suture endobutton group was 94 (range 82–100) and for their screw fixation group was 88 (range 80–100). They reported a trend of slightly better scores for the suture endobutton group,\[^{39}\] but no statistically significant differences between the suture endobutton and syndesmotic screw groups. In a similar study, Qamar et al\[^{40}\] reported a mean AOFAS score of 86 (range 48–100) in patients receiving the suture endobutton for syndesmotic joint injury. In our patients, the mean AOFAS hindfoot-ankle score was 88 (range 70–95) in the double suture endobutton group, 86 (range 65–95) in the single suture endobutton group, and 84 (range 63–95) in the screw group. Although the mean score was highest in the double suture endobutton group, these score differences were not statistically significant.

We observed mean FADI scores of 81 in the double suture endobutton group, 79 in the single suture endobutton group, and 77 in the screw group. There was no statistically significant difference between the groups. This is consistent with a previous study that reported mean FADI scores of 82 in a suture endobutton group and 81 in a screw group and there was no statistically significant difference.\[^{41}\]

Amarjit et al\[^{42}\] reported that patient outcome was not related to the number of suture endobuttons used or the presence of concomitant fibula fracture plating with Tightrope\textsuperscript{TM} fixation of syndesmotic injuries in Weber C ankle fractures. Similarly, we did not find any difference in functional scores between the double and single suture endobutton groups.
4.1. Limitations

This study has some limitations, including the limitations inherent in all retrospective studies. In addition, the relatively small number of patients and short follow-up period are limitations. However, to the best of our knowledge, there are no previous reports in the literature that compared the outcomes of a double interosseous suture endobutton system, a single interosseous suture endobutton system, and screw methods.

5. Conclusion

Our findings showed that the interosseous suture endobutton system is at least as safe as the screw method for treatment of syndesmosis joint injuries and can be used as an alternative to the screw method. The interosseous suture endobutton system eliminates the need for a second surgery to remove the hardware, which minimizes the probability of re-diastasis. Since our results showed no statistical difference between single and double interosseous suture endobutton systems, the less costly single endobutton system may be the better alternative.

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