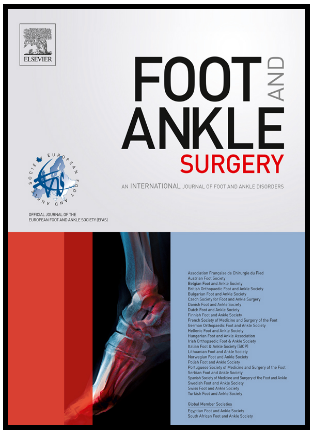
Journal Pre-proof



Angle bisector method to determine the accurate angle for tibiofibular syndesmotic fixation: A validation study with 3D-printed anatomical models

Bedri Karaismailoglu, Davut Yerlikaya, Ceren Ozdemir, Kubra Dalbudak, Tolga Barkan Komurcu, Musa Batuhan Yolcu, Arin Celayir

PII: S1268-7731(23)00077-2

DOI: https://doi.org/10.1016/j.fas.2023.04.008

Reference: FAS1885

To appear in: *Foot and Ankle Surgery*

Received date: 6 December 2022
Revised date: 20 April 2023
Accepted date: 22 April 2023

Please cite this article as: Bedri Karaismailoglu, Davut Yerlikaya, Ceren Ozdemir, Kubra Dalbudak, Tolga Barkan Komurcu, Musa Batuhan Yolcu and Arin Celayir, Angle bisector method to determine the accurate angle for tibiofibular syndesmotic fixation: A validation study with 3D-printed anatomical models, *Foot and Ankle Surgery,* (2023) doi:https://doi.org/10.1016/j.fas.2023.04.008

TITLE: Angle bisector method to determine the accurate angle for tibiofibular syndesmotic fixation: A validation study with 3D-printed anatomical models

Author names and affiliations:

Bedri Karaismailoglu[1,2,3], Davut Yerlikaya[2], Ceren Ozdemir[2], Kubra Dalbudak[2], Tolga Barkan Komurcu[2], Musa Batuhan Yolcu[2], Arin Celayir[1]

[1]Istanbul University – Cerrahpasa, Cerrahpasa Medical Faculty, Department of Orthopaedics and Traumatology, Istanbul, TURKEY

[2]CAST (Cerrahpasa Research, Simulation and Design Laboratory), Istanbul University-Cerrahpasa, Istanbul, TURKEY

[3]Foot & Ankle Research and Innovation Laboratory (FARIL), Massachusetts General Hospital, Harvard Medical School, MA, USA

Correspondence:

Dr. Bedri Karaismailoglu

E-mail: bedrikio@hotmail.com

Istanbul University – Cerrahpasa, Cerrahpasa Medical Faculty, Department of Orthopaedics and Traumatology, Istanbul, TURKEY

Acknowledgements

None.

Compliance with ethical standards

Conflict of interest

The authors declare no conflicts of interest.

Funding

This study was supported by EFAS RESEARCH FOUNDATION-MEDARTIS RESEARCH GRANT.

Ethical approval

The institutional review board approved this study (IRB number: 2022/31-375562).

ABSTRACT

Purpose: This study aimed to validate the angle bisector method on 3D-printed ankle models to reveal whether it aids in placing syndesmotic screws at an accurate trajectory that is patient- and level-specific and also not surgeon-dependent.

Methods: DICOM data of 16 ankles were used to create 3D anatomical models. Then the models were printed in their original size and two trauma surgeons performed the syndesmotic fixations with the angle bisector method at 2 cm and 3.5 cm proximal to joint space. Afterward, the models were sectioned to reveal the trajectory of the screws. The photos of the axial sections were processed in a software to determine the centroidal axis which is defined as true syndesmotic axis and analyze its relationship with the screws inserted. The angle between the centroidal axis and syndesmotic screw was measured by two-blinded observers 2 times with 2 weeks interval.

Results: The average angle between the centroidal axis and screw trajectory was 2.4° ± 2° at 2 cm-level and 1.3° ± 1.5° at 3.5 cm-level, indicating a reliable direction with minimal differences at both levels. The average distance between fibular entry points of the centroidal axis and screw trajectory was less than 1 mm at both levels indicating that the angle bisector method can provide an excellent entry point from fibula for syndesmotic fixation. The inter- & intra-observer consistencies were excellent with all ICC values above 0.90.

Conclusion: The angle bisector method provided an accurate syndesmotic axis for implant placement which is patient- & level-specific and not surgeon-dependent, in 3D-printed anatomical ankle models.

Keywords: syndesmotic fixation; syndesmotic axis, centroidal axis, ankle injury, angle bisector method

INTRODUCTION

Syndesmotic injuries accompany nearly 10% of all ankle injuries and malreduction can be frequently seen with rates up to 52% even after surgical management [1]. Accurate syndesmotic reduction plays an important role in clinical outcomes after ankle injuries since it was shown to be the only significant predictor of good functional outcomes [2]. In addition to the unsuccessful preliminary reduction of the tibiofibular joint, some studies have shown that any malalignment in syndesmotic fixation can also lead to iatrogenic malreduction despite successful initial reduction [3,4]. It was also shown that if the fixation is not placed perpendicular to the tibiofibular joint, the fibula may remain or become displaced [3,4].

The general recommendation for the level of fixation is 2 or 3.5 cm proximal to the tibial plafond and the angular direction is recommended to be between 20-30 degrees trajectory in the coronal plane by AO guidelines [5]. The ideal syndesmotic alignment is proposed to be the line connecting the centroids of the fibula and tibia [6], but the best method to determine the ideal fixation angle intraoperatively is unknown since the proposed angle by AO guidelines is neither patient- nor level-specific and the determination of the angular direction relative to the coronal plane is surgeon-dependent. These facts can lead to significant syndesmotic malalignment problems, especially in the hands of young trauma surgeons.

We proposed a new method to overcome this difficulty, which is called "angle bisector method". We claimed that the angle bisector of two lines tangential to anterior and posterior fibula & tibia provides the accurate trajectory for true syndesmotic axis. Our preliminary analysis on CT angiography of 50 consecutive patients without evident foot or ankle pathology revealed that angle bisector method can help estimate accurate syndesmotic axis with average differences of 2.1±2.1° at 2 cm and 0.6±1.3° at 3.5 cm level. It also provided an accurate estimate for the lateral fibular entry point of true syndesmotic axis with average differences of 1.0±0.9 mm at 2 cm and 0.4±0.4 mm at 3.5 cm level. This preliminary analysis performed by three blinded observers also showed an excellent correlation in all parameters (ICC>0.90), indicating that the angle bisector method is strongly reliable in predicting accurate direction for syndesmotic fixation, which is both patient- and level-specific [7].

The angle bisector method can be applied intraoperatively with the help of percutaneously placed K-wires tangential to anterior and posterior fibula & tibia, and the bisector of these K-wires can provide accurate direction for the syndesmotic axis. This study aimed to validate the angle bisector method on 3D-printed ankle models to reveal whether it aids in placing syndesmotic screws at the correct trajectory. We hypothesized that the angle bisector method provides an accurate angle for syndesmotic fixation which is patient- & level-specific and not surgeon-dependent.

MATERIALS AND METHODS

Obtaining 3D anatomical solid models

Bilateral lower extremity computed tomography (CT) angiography of eight patients (sixteen ankles) between 18 and 50 years old without any evident bone pathology were collected from available database of the hospital after obtaining ethical approval. The average patient age was 44.2 ±12.3 (30-54). Four patients were female, and four patients were male. CT data of the patients were stored as DICOM format and 3D images of ankles were reconstructed with Mimics v25 and 3-Matic v17 (Materialise, Leuven, Belgium). The optimal threshold for bone reconstruction which is Bone (CT) 226-3071 (Min-Max) was used. The reconstructed data was transferred to 3D printing software in stereolithography (STL) format and 3D anatomical models were generated in gcode format (Ultimaker Cura 5.1.0) which were exported to a 3D printer (Ultimaker 2+ Extended, Ultimaker B.V., the Netherlands) later for the reconstruction of solid models. Polylactic acid (PLA) filament (Porima, Turkey) was used as the 3D printing material. Processing parameters included: (1) 2.85 mm plastic filament diameter, (2) 0.1-mm layer height, (3) 50 mm/s printing speed, (4) nozzle temperature at 220 °C and (5) bed temperature at 60 °C. As a result, anatomical 3D bone models identical to the anatomy of selected patients were obtained.

Syndesmotic fixations with angle bisector method

Two different trauma surgeons applied the angle bisector method for syndesmotic screw fixation at two levels (2 cm and 3.5 cm proximal to the joint space) of the ankle models. Angle bisector method is the application of syndesmotic fixation in the direction of the bisector of angle formed by two K-wires tangential to anterior and posterior surfaces of fibula & tibia.

Each surgeon applied the procedure to anatomical 3D models of 8 patients including 4 females (2 left and 2 right extremities) and 4 males (2 left and 2 right extremities. A stratified randomization method was used to equally distribute the gender and side of the extremity

Anatomical 3D-printed models were stabilized before starting the fixations. For the application of “angle bisector method”; the surgeons placed and taped two 1.8 mm K-wires tangential to anterior and posterior surfaces of fibula and tibia, and parallel to the tibial plafond. The angle formed between these K-wires was measured with the help of a goniometer. Syndesmotic drill (2.7 mm) and screw (3.5 mm) were applied in the direction of the bisector of this angle engaging 4 cortices (Figure 1). The fixations were performed parallel to tibial plafond at two levels which are 2 cm and 3.5 cm proximal to tibial plafond. After that, the models were cut with a thin-bladed saw machine in axial plane just above the proximal syndesmotic fixation to reveal the fixation angle (Figure 1). After documenting the trajectory of proximal screw, another cut was made just above the distal syndesmotic screw.

Measurements

The trajectories of both screws were documented by high-resolution photos showing the axial plane and the photos were transferred to Mimics v25 and 3-Matic v17 (Materialise, Leuven, Belgium) for measurements. The centroidal syndesmotic axis of models was determined by finding the line connecting the trapezoidal or triangular centroids of tibia and fibula (Figure 2) [6]. The angles between the centroidal axis, angle bisector line and syndesmotic screw were measured. The distances between lateral entry points of centroidal axis, angle bisector line, and screws were also measured. The measurements were made by two-blinded observers 2 times with 2 weeks interval (Figure 2). The values close to 0 indicated a more accurate placement of the syndesmotic screw. General variability of patients, intra&inter-surgeon variability, and intra&inter-observer variability of measurements were tested.

Statistical analysis

Statistical studies report that the minimum sample size should be at least 15 in agreement (validity, reliability) studies when 2 observers exist, with alfa=0.05, beta=0.80, and ICC=0.9 values [8]. Therefore, we planned to include 16 anatomic 3D-printed models in this study. Mean, standard deviation, and range values were calculated for all measurements. Inter- & intra-surgeon variability and inter- & intraobserver consistencies were evaluated by ICC, in 2-way & mixed-effect model analyzing absolute agreement of exact measures. Independent samples, 2-tailed t-test was used to compare the values at 2 cm and 3.5 cm levels. Statistical analyses were performed using SPSS software (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.).

RESULTS

The analyses revealed that the average angle between the centroidal axis and angle bisector was 0.8° ± 0.9 at 2 cm and 0.4° ± 0.6 at 3.5 cm while the average angle between the centroidal axis and screw trajectory was 2.4° ± 2 at 2 cm and 1.3° ± 1.5 at 3.5 cm (Table 1) (Figure 2).

The average distances between the fibular entry points of centroidal axis vs. angle bisector line and also centroidal axis vs. screw trajectory were less than 1 mm indicating that angle bisector method can provide an excellent entry point from fibula for syndesmotic fixation (Table 1) (Figure 2). The average angle between two K-wires tangential to anterior and posterior tibia & fibula were significantly different at 2 cm (45.9°) and 3.5 cm (27.3°) proximal to ankle plafond ($p<0.001$) pointing out the great variations according to the level of fixation (Table 1). The correlation of inter- & intra-surgeon angular values and also inter- & intra-observer consistencies regarding measurements were excellent with all ICC values above 0.90. The variance of the angle formed by lines tangential to anterior and posterior fibula & tibia was high among patients (ICC<0.5), indicating high variance in syndesmotic angle between patients.

DISCUSSION

Angle bisector method was applicable in 3D-printed ankle models and provided excellent guidance for determining the correct syndesmotic axis. Both surgeons were able to place screws in the targeted direction with low variance.

The conventional method for finding the trajectory of syndesmotic fixation, which recommends aiming the fixation at 20-30 degrees anteromedial trajectory in the coronal plane [5], is not patient-specific and completely relies on the surgeon's angle perception. Furthermore, the reason behind syndesmotic malreduction can also be malaligned syndesmotic fixation [3,4]. Boffeli et al. showed that the syndesmotic axis can significantly differ between 8 and 38 degrees from patient to patient and also according to the level of fixation [9].

Several technical notes were reported to overcome the difficulty in finding the most accurate trajectory for syndesmotic fixation since intraoperative imaging is somewhat inadequate to determine the true syndesmotic angle in axial plane. Lee et al. suggested the use of a targeting drill guide under lateral fluoroscopy [10] and placing the tip of the anterior cruciate ligament guide to the true centroid of medial tibia. However, the technique relies on obtaining a true lateral view with external rotation of tibia and increases the fluoroscopy exposure. Kumar et al. suggested that malleolar tips can be used as reference points to accurately direct syndesmotic fixation [11]. But the recommendation was based only on a CT analysis and it still relies on the surgeon's visual perception when applied intraoperatively. Furthermore, it is not level-specific and recommends the same trajectory for all levels of fixation.

During surgery, the angle bisector method can be used to aid in the placement of syndesmotic screws and fibular plates by utilizing two K-wires tangential to the anterior and posterior surfaces of the tibia and fibula (Figure 3). We applied the angle bisector method in both clinical and cadaveric settings for a preliminary analysis of its applicability and effectiveness. To ensure neurovascular safety, we used the blunt side of K-wires to determine the points tangential to the tibia, after easily locating the tibial cortices percutaneously. The wires were not advanced further once the tangential point of the tibia was reached. The drill and syndesmotic screws were then applied in the direction of the angle bisector. If a fibular plate is required, the angle bisector method should be used to determine its optimal position, as an inappropriate plate position can dictate an incorrect entry point and direction for the syndesmotic screw. The plate should be secured only after confirming that the syndesmotic screw can be placed in line with the angle bisector. Thus, the angle bisector method not only provides the direction for the placement of the syndesmotic screw but also ensures the most appropriate position of the fibular plate, enabling accurate placement of the syndesmotic screw.

A CT analysis of a cadaveric specimen that underwent syndesmotic fixation using the angle bisector method revealed highly accurate screw direction. At 2 cm proximal to the joint line, the difference between the screw and centroidal axis was only 2°, while at 3.5 cm proximal to the joint line, the difference was only 1.1° (Figure 3). The lateral entry point was also precise, with a distance of 1.4 mm between the fibular entry points of the centroidal axis and screw at 2 cm proximal to the joint line, and 0 mm at 3.5 cm proximal to the joint line, where the angle bisector and centroidal axis intersected at the lateral fibular surface (Figure 3).

The use of reduction clamp is also recommended by some authors since it can help protect the syndesmotic reduction during fixation [12]. While medial clamp tine placement in the anterior third of the tibia has been suggested in certain studies, an exact location for its placement is not provided, and an incorrect clamp placement can also cause malreduction [13–15]. Due to its alignment with the original syndesmotic axis, the angle bisector method can also be effective in providing guidance for proper clamp placement.

Angle bisector method can provide a good alternative to the conventional method and can pave the way for designing a new surgical guide to find an accurate trajectory for syndesmotic fixation. The novel technique can be used both with screw and suture button devices. In the case of suture button fixation, it can also aid syndesmotic reduction during the tightening of suture-button device since it will pull in the correct syndesmotic axis. If divergent fixation is aimed, which gained some popularity in fixation with suture button implants for better coronal stability [16], it can also aid in giving specific divergence both anteriorly and posteriorly in axial plane at the same amount of angle with the help of attached goniometer. Moreover, understanding the relationship between syndesmotic axis and some bony landmarks can help us find new methods for accurate syndesmotic reduction.

This study has several limitations. First, it was a 3D-printed bone model study, so it was not possible to predict whether placed K-wires can disturb neurovascular structures or not, thus further cadaveric studies are needed for safety analyses. Moreover, the soft tissues around ankle might restrict the application of K-wires tangential to the fibula and tibia, which can also be investigated on cadaver specimens. However, 3D printed models are being used as a validation tool [17] since they are able to provide models identical to human bony architecture [18]. As the "angle bisector method" depends on solely bony landmarks, 3D models were great candidates for its initial validation.

CONCLUSION

Angle bisector method provided satisfactory direction for the original syndesmotic axis aiding the placement of implant in the targeted direction. It has the potential to be replicated intraoperatively and can pave the way for designing a novel surgical guide to determine the correct syndesmotic axis but safety analysis on cadavers should be conducted before clinical usage.

REFERENCES

[1] Gardner MJ, Demetrakopoulos D, Briggs SM, Helfet DL, Lorich DG. Malreduction of

the Tibiofibular Syndesmosis in Ankle Fractures. Foot Ankle Int 2006;27:788–92. https://doi.org/10.1177/107110070602701005.

[2] Weening B, Bhandari M. Predictors of Functional Outcome Following Transsyndesmotic Screw Fixation of Ankle Fractures. J Orthop Trauma 2005;19:102–8. https://doi.org/10.1097/00005131-200502000-00006.

[3] Vander Griend R, Michelson JD, Bone LB. Fractures of the ankle and the distal part of the tibia. Instr Course Lect 1997;46:311–21.

[4] Phisitkul P, Ebinger T, Goetz J, Vaseenon T, Marsh JL. Forceps Reduction of the Syndesmosis in Rotational Ankle Fractures. J Bone Jt Surgery-American Vol 2012;94:2256–61. https://doi.org/10.2106/JBJS.K.01726.

[5] Hahn DM & Colton CL. Malleolar fractures. AO Princ. Fract. Manag. 2nd Ed, 2007, p. 870–896.

[6] Kennedy MT, Carmody O, Leong S, Kennedy C, Dolan M. A computed tomography evaluation of two hundred normal ankles, to ascertain what anatomical landmarks to use when compressing or placing an ankle syndesmosis screw. Foot 2014;24:157–60. https://doi.org/10.1016/j.foot.2014.07.001.

[7] Karaismailoğlu B, Sahin E, Kara M, Tutuncu MN. Cortices of fibula and tibia can provide landmarks for accurate syndesmosis fixation angle: Computed tomography validation of angle bisector method. J Foot Ankle Surg 2023;April. https://doi.org/10.1053/j.jfas.2023.04.001.

[8] Bonett DG. Sample size requirements for estimating intraclass correlations with desired precision. Stat Med 2002;21:1331–5. https://doi.org/10.1002/sim.1108.

[9] Boffeli TJ, Messerly CG, Sorensen TK. Ideal Angle of Upper and Lower Syndesmotic Fixation Based on Weightbearing Computed Tomographic Imaging in Uninjured Ankles. J Foot Ankle Surg 2020;59:1224–8. https://doi.org/10.1053/j.jfas.2020.07.003.

[10] Lee D-O, Yoo J-H, Choi W-Y. Optimal Screw Fixation of Syndesmosis Using a Targeting Drill Guide: A Technical Note. J Foot Ankle Surg 2020;59:206–9. https://doi.org/10.1053/j.jfas.2019.05.005.

[11] Kumar A, Goel L, Chouhan D, Agnihotri A, Chauhan S, Passey J. Malleolar tips as reference points for positioning of syndesmotic screw: A preliminary CT based analysis. J Clin Orthop Trauma 2020;11:438–41. https://doi.org/10.1016/j.jcot.2019.09.015.

[12] Park YH, Ahn JH, Choi GW, Kim HJ. Comparison of Clamp Reduction and Manual Reduction of Syndesmosis in Rotational Ankle Fractures: A Prospective Randomized Trial. J Foot Ankle Surg 2018;57:19–22. https://doi.org/10.1053/j.jfas.2017.05.040.

[13] Putnam SM, Linn MS, Spraggs-Hughes A, McAndrew CM, Ricci WM, Gardner MJ. Simulating clamp placement across the trans-syndesmotic angle of the ankle to minimize malreduction: A radiological study. Injury 2017;48:770–5. https://doi.org/10.1016/j.injury.2017.01.029.

[14] Abarca M, Besa P, Mora E, Palma J, Lira MJ, Filippi J. The use of intraoperative comparative fluoroscopy allows for assessing sagittal reduction and predicting syndesmosis reduction in ankle fractures. Foot Ankle Surg 2022;28:750–5. https://doi.org/10.1016/j.fas.2021.10.003.

[15] Cosgrove CT, Putnam SM, Cherney SM, Ricci WM, Spraggs-Hughes A, McAndrew CM, et al. Medial Clamp Tine Positioning Affects Ankle Syndesmosis Malreduction. J Orthop Trauma 2017;31:440–6. https://doi.org/10.1097/BOT.0000000000000882.

[16] Parker AS, Beason DP, Slowik JS, Sabatini JB, Waldrop NE. Biomechanical Comparison of 3 Syndesmosis Repair Techniques With Suture Button Implants. Orthop J Sport Med 2018;6:232596711880420. https://doi.org/10.1177/2325967118804204.

[17] Shu J, Luo H, Zhang Y, Liu Z. 3D Printing Experimental Validation of the Finite Element Analysis of the Maxillofacial Model. Front Bioeng Biotechnol 2021;9. https://doi.org/10.3389/fbioe.2021.694140.

[18] Brouwers L, Teutelink A, van Tilborg FAJB, de Jongh MAC, Lansink KWW, Bemelman M. Validation study of 3D-printed anatomical models using 2 PLA printers for preoperative planning in trauma surgery, a human cadaver study. Eur J Trauma Emerg Surg 2019;45:1013–20. https://doi.org/10.1007/s00068-018-0970-3.

TABLES

Table 1. The summary of values at both 2 cm and 3.5 cm proximal to tibial plafond including average, standard deviation and minimum & maximum values.

LEVEL	Parameter	Average	Standard Deviation	Range (min-max)
2 CM	Angle between centroidal axis and angle bisector (°)	0.8	0.9	0 – 2
	Angle between centroidal axis and screw (°)	2.4	2.0	0 - 6.5
	Distance between fibular entry point of centroidal axis and angle bisector (mm)	0.2	0.4	0 – 1
	Distance between fibular entry point of centroidal axis and screw (mm)	0.3	0.5	0 - 1.4
	Angle between K-wires tangential to anterior and posterior fibula & tibia (°)	45.9	8.7	34 – 57
3.5 CM	Angle between centroidal axis and angle bisector (°)	0.4	0.6	0 - 1.5

Angle between centroidal axis and screw (°)	1.3	1.5	0 - 4.2
Distance between fibular entry point of centroidal axis and angle bisector (mm)	0.3	0.5	0 - 1.2
Distance between fibular entry point of centroidal axis and screw (mm)	0.2	0.3	0 - 1
Angle between K-wires tangential to anterior and posterior fibula & tibia (°)	27.3	3.5	21 - 33

LEGENDS TO FIGURES

Figure 1. Workflow of the study design. The anatomical models were created from computerized tomography data of the patients and the syndesmotic screws were placed by angle bisector method with the help of K-wires and a goniometer. After fixations the models were cut just above the screw levels at both 2 cm and 3.5 cm proximal to tibial plafond to reveal their trajectory.

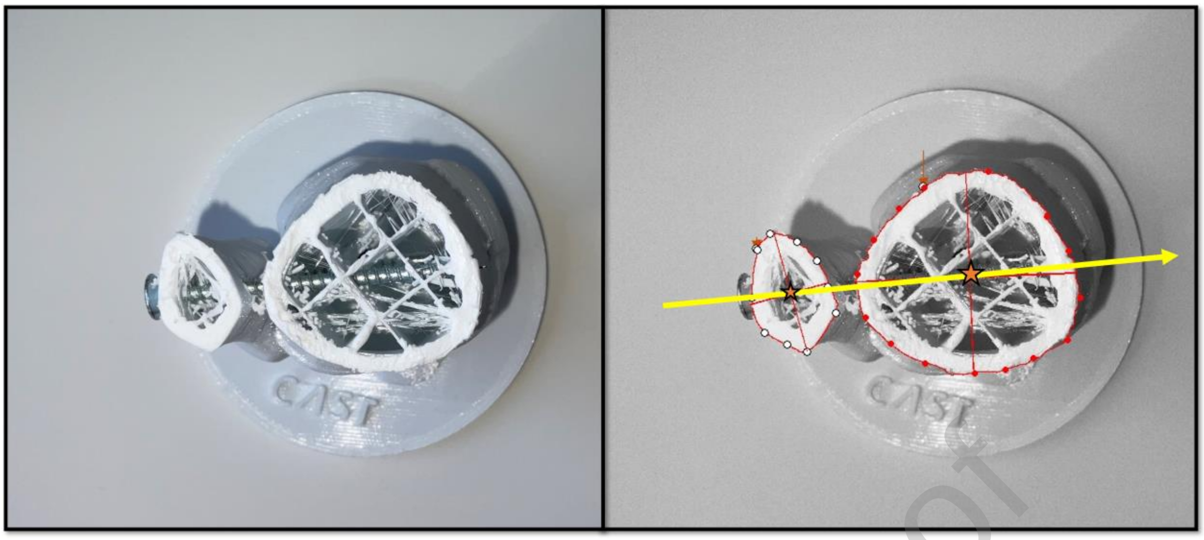


Figure 2. The screw trajectory was visible after cutting the models just above the screw levels. The centroids (shown as orange stars on the second image) were determined by a software. True syndesmotic axis which is the line connecting centroids of fibula and tibia was determined (yellow arrow) and the angle between centroidal axis and screw trajectory line, and also distance between the fibular entry points of both lines were calculated, which was completely overlapping in given example above.

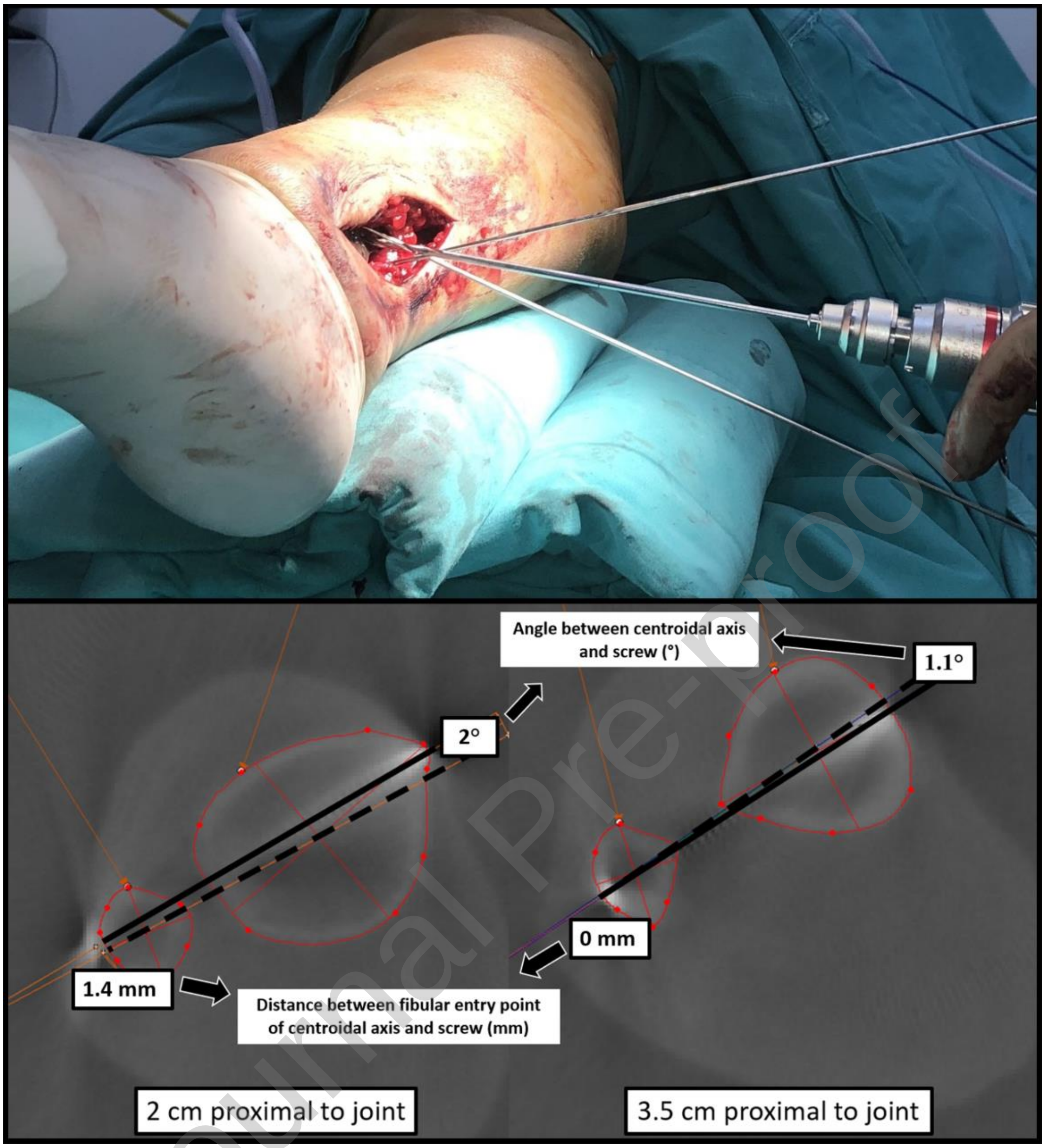


Figure 3. *Above:* Intraoperative application of angle bisector method on a patient who had syndesmotic injury. *Below:* CT sections of a cadaver who underwent syndesmotic fixation with angle bisector method at 2 and 3.5 cm proximal to joint space. CT analysis showed that the angular difference between the centroidal axis and screw trajectory was 2° at 2 cm and 1.1° at 3.5 cm. The distance between entry point of centroidal axis and screw was found 1.4 mm at 2 cm and 0 mm at 3.5 cm. (Dotted black line: Centroidal axis, Continuous black line: Screw trajectory)