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R. Taday, E. Schiffner, S.V. Gehrmann, M. Prost, J. Windolf, D. Latz

Suggested Citation:
Taday, R., Schiffner, E., Gehrmann, S. V., Prost, M., Windolf, J., & Latz, D. (2025). Volumetric assessment of the soft tissue envelope in unilateral closed ankle fractures using a portable 3D scanner. The Journal of Foot and Ankle Surgery, 64(4), 426–433. https://doi.org/10.1053/j.jfas.2025.01.015

The Journal of Foot and Ankle Surgery 64 (2025) 426–433

Contents lists available at ScienceDirect

The Journal of Foot and Ankle Surgery

journal homepage: www.elsevier.com/locate/yjfas

Volumetric assessment of the soft tissue envelope in unilateral closed ankle fractures using a portable 3D scanner

R. Taday, M.D. [a], E. Schiffner, M.D., P.D. [a,*], S.V. Gehrmann, M.D., Prof. [b], M. Prost, M.D. [a], J. Windolf, M.D., Prof. [a], D. Latz, MD, P.D. [a]

[a] Department of Orthopedic and Trauma Surgery, University Hospital Düsseldorf Moorenstraße 5 40255 Düsseldorf, Germany
[b] Department of Orthopedic and Trauma Surgery, Katholisches Karl- Leisner Klinikum, Albersallee 5-7 47533 Kleve, Germany

ARTICLE INFO

Level of Evidence:
2 - Diagnostic Level 1 - Prognostic Level 1 - Prospective comparative study Level 2

Keywords:
Ankle fracture
Volumetry
Three- dimensional imaging
Soft tissue management
Artec EVA

ABSTRACT

Management of ankle fractures necessitating surgery is impacted by soft tissue swelling, often delaying open reduction and internal fixation (ORIF). Subjective evaluations are inconsistent, and traditional measurement methods are often inaccurate or impractical. This prospective observational study included 17 adults with unilateral closed ankle fractures requiring surgical fixation. A measurement protocol on regions of interest (ROI) was utilized, employing a handheld 3D scanner for daily volume scans of the fractured ankle, comparing these measurements with subjective assessments of swelling using a numerical scale. The 3D scanner detected significant soft tissue volume reductions of the ROI over 14 days, with reductions of 25 ± 25 % in the lower limb and 16 ± 9 % in the ankle. Significant swelling reduction was noted from day 8, preceding surgeons' assessments (days 11-14). The scanner exhibited high reproducibility, providing an objective tool for comparative studies on decongestive measures in perioperative soft tissue management.

Introduction

Management of ankle fractures requiring surgical intervention primarily depends on the extent of posttraumatic soft tissue swelling, with definitive (ORIF) typically advised only after significant swelling reduction, especially in unstable fractures [1]. Initial treatment often involves closed reduction and external fixation or casting until the soft tissue envelope is deemed acceptable [2,3]. Surgery performed on extensively swollen tissues is associated with complications, including septic osteomyelitis, skin necrosis, and wound dehiscence [1,2]. Clinical evaluation of the ankle's soft tissue is subjective, relying on the surgeon's experience, which leads to variable management approaches lacking standardized consensus [4]. Current valid measurement tools like tape measures, ultrasonography, and water plethysmography either fail to accurately represent swelling around the ankle or are impractical, particularly with external fixators [5–7]. Delayed definitive ORIF of ankle fractures due to soft tissue swelling contributes to prolonged hospitalization for patients [8–11]. To reduce delay, many decongestive treatment strategies are recommended for which there is varying evidence and acceptance in clinical routine [8,12]. To compare decongestive strategies effectively and to optimize surgical timing, a reliable method for measuring soft tissue swelling is essential. The portable Artec EVA 3D scanner provides efficient, objective, and reproducible visualization of limb surface and volume measurements of the limbs with accuracy comparable to the gold standard of water plethysmography [7, 13–18]. Established regions of interest (ROI) around the ankle demonstrated the scanner's reliability in quantifying local soft tissue volume changes [19]. This study conducts a prospective clinical investigation on whether the Artec EVA 3D scanner can validly and reliably detect differences in volume between the soft tissue mantle of the traumatized and the healthy ankle and whether it is possible to follow up on the course of the decongestion process. This was compared to results with surgeons' subjective soft tissue assessments.

Abbreviations: ORIF, open reduction and internal fixation; CREF, closed reduction and external fixation; ROI, regions of interest; ED, Emergency Department; OR, Operating Room.

* Corresponding author.
E-mail addresses: roman.taday@med.uni-duesseldorf.de (R. Taday), erik.schiffner@med.uni-duesseldorf.de (E. Schiffner), sebastian.gehrmann@kkle.de (S.V. Gehrmann), max.prost@med.uni-duesseldorf.de (M. Prost), joachim.windolf@med.uni-duesseldorf.de (J. Windolf), david.latz@med.uni-duesseldorf.de (D. Latz).

https://doi.org/10.1053/j.jfas.2025.01.015

Available online 28 January 2025

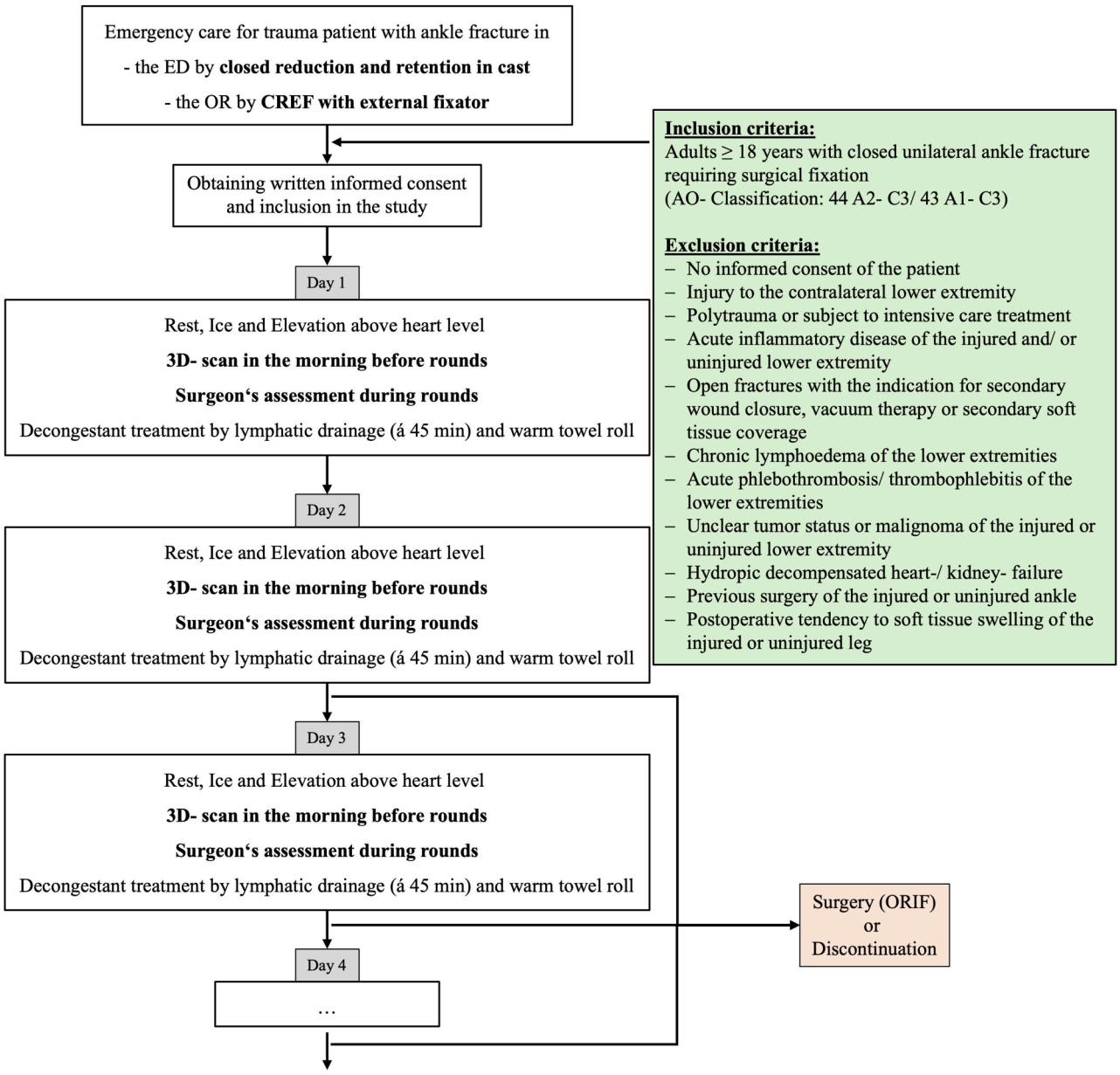


Fig. 1. Flowchart of the study process.
ED = Emergency Department; OR = Operating Room; CREF = Closed Reduction and External Fixation; AO = Arbeitsgemeinschaft für Osteosynthesefragen; ORIF= Open Reduction and Internal Fixation
The timing of the definitive surgery was determined by the treating surgeons on the basis of the clinical assessment, independent of the 3D scans and the surgeon‘s assessment collected for this study.

Patients and methods

Population and study environment

The study was conducted at a Level 1 Trauma Center over two years (05/2022 to 05/2024). Written informed consent was obtained from all participants. Adults (≥18 years) requiring surgical fixation for closed unilateral ankle fractures were eligible. Exclusion criteria are shown in Fig. 1. Initially, twenty participants were included in the study, but three were excluded due to noncompliance or withdrawal, resulting in a final cohort of seventeen participants (8 female, 9 male) for analysis. Prior to assessment, the anatomical position of the ankle mortise was restored by closed reduction during emergency treatment in all participants, either by external fixation or with a cast. The severity of ankle fractures was classified using the AO classification (Arbeitsgemeinschaft für Osteosynthesefragen) (Table 1) [20,21]. Eleven patients were treated with closed reduction and external fixation (CREF) in the OR. Six patients were sufficiently retained in a cast. All participants received standardized preoperative care based on the Trauma Center’s soft tissue management protocol for ankle fractures. The affected ankle was elevated above heart level and ice packs were applied based on participant’s preference. Daily decongestive treatment was provided by physiotherapists using 45-minute lymphatic drainage and a warm towel roll once per day (Fig. 1). The technique followed Vodder’s method, with manual lymphatic drainage starting at the lymph node regions and proceeding in the direction of lymph [22,23]. No other decongestant treatment was carried out in this study population. Sixteen patients had definitive surgery with ORIF after an average of 12± 4 (SD) days. One patient, with advanced osteoporosis and critical soft tissue conditions, was treated with a permanent external fixator (61 years old, diabetes

Table 1
Population characteristics (N = 17).

Age (N = 17)	48± 15 years
BMI (N = 17)	27.8 ± 3.1 kg/m^2
Time to first clinical presentation (N = 17)	2 ± 0.9 h
Time to CREF (N = 11)	4.5 ± 1.4 h
Time to definitive treatment (N = 16)	12± 4 days
Preclinical treatment	15 Reposition and SAM- Splint 2 Non
Injury Severity (AO classification) (N = 17)	
44- B1	3
44- B2	3
44- B3	5
44- C3	2
43- B1	1
43- B3	1
43- C2	1
43- C3	1
Comorbidities	Non (N = 8) Pre- existing illnesses (N = 9) Normal pressure hydrocephalus (N = 1) Diabetes mellitus type II (N = 2) Hypothyroidism (N = 2) Arterial Hypertension (N = 2) PAD grade II (N = 1) CAD (N = 1) Depression (N = 1) Pseudotumor cerebri (N = 1) Chronic ethyl toxic pancreatitis (N = 1) Hemithyreoidectomy (N = 1) Hip arthroplasty (injured side; N = 1) Knee arthroscopy (injured side; N = 1)

CREF = Closed reduction external fixation; PAD = peripheral arterial disease; CAD= coronary heart disease.

mellitus, diabetic polyneuropathy, and skin necrosis). One patient developed full-thickness skin necrosis after ORIF during inpatient stay. The study was performed according to the guidelines provided by the Declaration of Helsinki and was approved by the ethical committee of the University of Düsseldorf (Ethikkommission an der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf; APPROVAL NUMBER 2019-475).

3D image processing and scanning procedure

Images were captured using the portable Artec EVA 3D scanner (Artec EVA; Artec Group, 4 Rue Lou Hemmer, l-1748 Senningerberg, Luxembourg), which employs structured light triangulation to generate mid- size 3D models with high data acquisition speed (2 million points/s), resolution (0.5 mm), and accuracy (0.1 mm) [19]. The scanner is an approved and validated instrument in various technical fields, medical engineering and science [14,15,17,19,24]. The scanner utilizes visible light through two cameras to record topography without harmful radiation, while a third camera captures texture information via hybrid geometry and color tracking. The Artec Studio 13 software (Arctec Group, Luxemburg) processes the images, fusing them to create textured 3D scans (Fig. 2).

All scans were conducted by a single examiner in the participant's rooms using the Artec EVA scanner. Subsequent scans were performed daily after emergency treatment and hospital admission according to protocol in Fig. 1. Participants were positioned supine, with the injured leg suspended in a fixator held by a device allowing 360° scanning. The uninjured leg was similarly positioned in an apparatus with the ankle in a neutral position and at a 90° angle to the leg (Fig. 2). The same apparatus was used for injured legs stabilized by a cast, which was removed before scanning. Cast immobilization was only used for stable fractures, so that no significant fracture dislocation is assumed when the plaster splint is carefully and skillfully removed by the physician. The occurrence of pain during cast removal would have led to withdrawal from the study, but this did not occur in any of the participating patients. The examiner moved the scanner around the exposed ankle to capture the entire ROI, repeating the process for the healthy leg (Fig. 2). The Artec Studio 13 software (Version 13, Artec Group, Luxembourg) generated a real-time 3D model, guiding optimal scanning distance and alignment (Fig. 2). Unwanted elements in the raw material of the 3D scan model, such as the external fixator or parts of the holding device, were manually removed using the Artec software so that an accurate 3D representation of the scanned limb was achieved. Anatomical landmarks, including the medial and lateral malleoli, were marked on the 3D model, and ROI were selected as described previously, with the software calculating volume across nine segments (V1–V9) at 2.5 cm intervals [19].

Evaluation of the surgeon's assessment

The subjective assessment of soft tissue swelling by the attending physician was documented daily using a numerical scale of 1 to 10, based on the Tscherne and Oestern classification system for categorizing the severity of associated soft tissue injuries in closed fractures (Fig. 5) [25,26]. Additionally, the physician assessed if he found skin wrinkling and whether the participant was fit for surgery.

Statistical analysis

A priori power analysis (G*Power 3.0.10) determined that a sample size of 15 would yield 80 % power at a significance level of $p \leq 0.05$, based on previous studies [7,19,27]. Statistical analysis was conducted using Graph Pad Prism 9 (Version 9.5.1). Untreated contralateral legs served as controls to confirm scanner reproducibility and the daily volume differences between the injured and healthy leg were utilized to normalize the volumetric data for the entire cohort. For calculation of an average percentage volume change of the ROI in the injured leg, the volume differences of the daily repeated measurements were set in relation to the first base line measurement. Normality was assessed using the Shapiro-Wilk test. Ankle volume changes were analyzed using two-way repeated measures ANOVA (when normal distribution and equal variance were met) or Mixed Effect Model ANOVA with p-values $\leq$ 0.05 indicating significance. A Mixed Effects analysis evaluated the surgeon's assessment, and Pearson correlation coefficients examined the relationship between mean volume changes and surgeon assessments over time. Simple linear regression showed solid linearity of the datasets of the mean volume differences of all ROI: lower limb V4-V9 (r^2=0.51; $p < 0.004$); ankle V2- V3 (r^2= 0.8; $p < 0.0001$); foot V9 (r^2=0.65, $p < 0.001$) and the surgeon's assessment (r^2= 0.7; $p < 0.0003$).

Results

3D volumetric assessment

On average, patients underwent 10± 4 (mean± SD) volume measurements for both the injured and healthy leg (330 images total) before definitive treatment decision. No significant volume changes were observed in the healthy legs over time, indicating high reproducibility and measurement quality. To ensure comparability between the patients, daily differences between the injured and healthy leg volumes were calculated for each subject at each time point and revealed significant volume differences between injured and healthy legs ($p < 0.05$) (Fig. 3). Post hoc Dunnet tests showed a significant reduction in ankle volume from day 8 ($p \leq 0.02$) (Fig. 4). Prior to definitive surgery, no injured leg's volume restituted to the corresponding healthy leg's volume. Three patients with 44-B1 fractures had significantly shorter times to surgery (6 ± 1 days; $p \leq 0.01$) (Fig. 5), though relative initial swelling and soft tissue decongestion were not significantly different between fracture types.

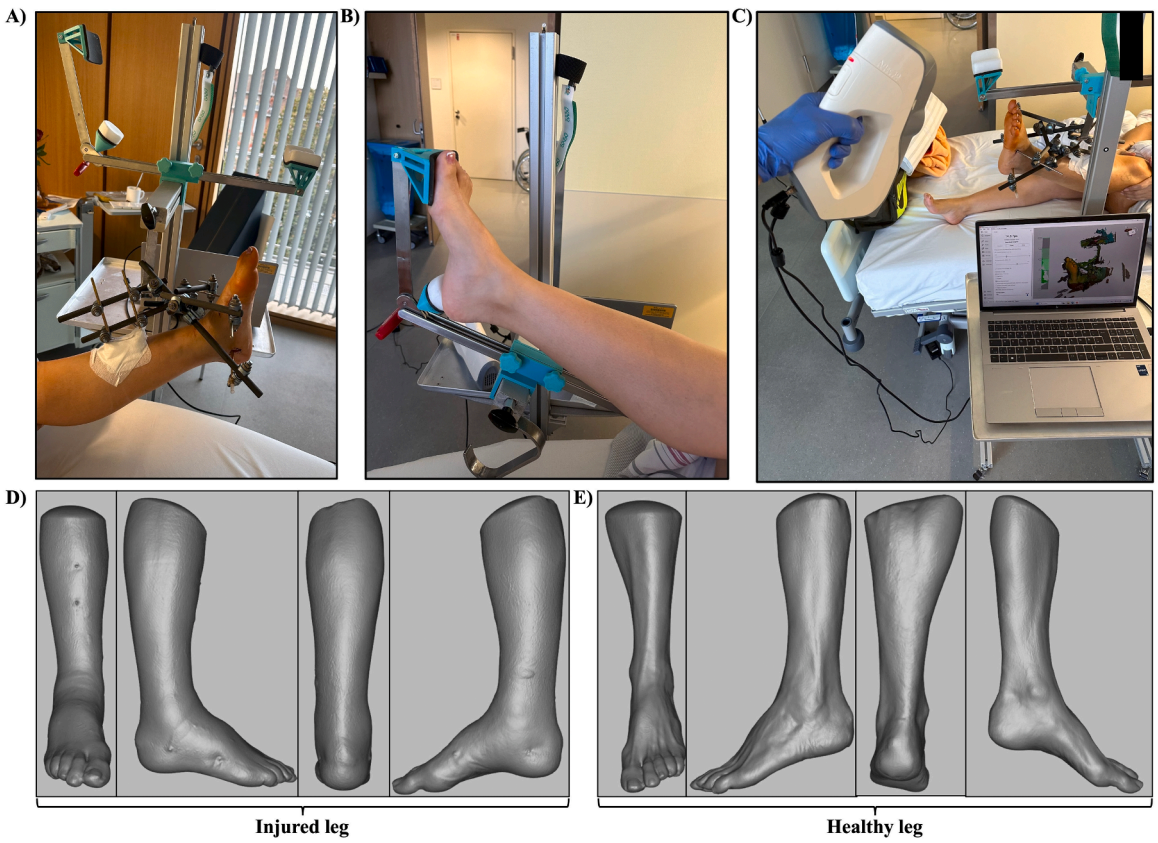


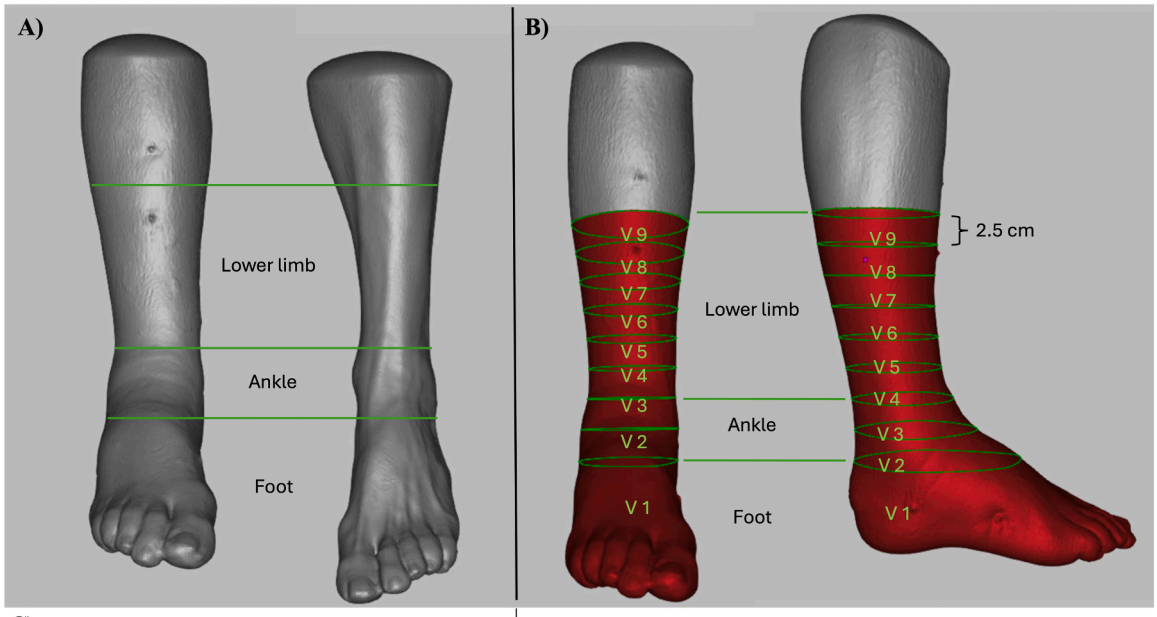
Fig. 2. Representative pictures of the setup for scanning procedure and texturized 3D pictures of an injured and healthy leg. (A) Picture of an injured left leg. Participant suffered a bimalleolar ankle fracture (AO 44- B3) and was treated with closed reduction and external fixation. (B) Picture of an uninjured right leg. (C) Depiction of the scanning process. The Artec Studio 13 software program displays a raw data 3D model on the laptop in real time and specifies the optimal scanning distance and alignment of the hand scanner. (D) a.p.; lateral; p.a., medial view of another patient's injured right leg (AO 43- C3) (E) a.p.; lateral; p.a., medial view of the healthy leg after final processing.

Surgeon's assessment

On average, the surgeon assessed the soft tissue mantle of the injured leg 11 ± 2 (SD) times before definitive surgery, with the mean initial evaluation scoring 6 ± 1 (SD) and the final assessment scoring 2.8 ± 0.5 (SD). There was a significant ($p < 0{,}05$) decrease of volume examination score over the monitoring time ($p < 0{,}0001$). Two peaks were observed in the cohort where the swelling status of the ankle joints was deemed operable (Fig. 5), likely due to early operability of fractures such as type 44- B1, which were assessed as operable significantly earlier by the treating surgeons.

Discussion

This study demonstrated that the 3D Artec EVA hand scanner can accurately measure and monitor significant volume differences of the soft tissue between the fractured ankle and the healthy contralateral joint over time. In our patient population, a significant decrease in mean volume was demonstrated over a period of 14 days for the respective ROI. Compared to the baseline the decrease is significant from day 8 for the ROI ankle. Apparent trends of volume decrease of the lower limb and foot were not significant. Since measurements were taken during routine clinical practice, patients moved freely and positioned their legs variably in bed, wheelchairs, or on crutches, potentially introducing inconsistencies in the ROI of the lower limb and foot. As previously described, soft tissue assessments must consider patient health and compliance [28]. The 3D scanner's segmentation method may introduce higher volume variances in the lower limb (V4- V9) due to decongestive treatments and posture-related shifts in the soft tissue envelope. Foot volume (V1) showed high variance, often caused by difficulty maintaining a 90° ankle position post-cast removal, despite positioning support. This study limitation may have influenced volume measurements, particularly in the larger soft tissue areas of the lower limb and foot. Nevertheless, there was a significant reduction in volume of the ankle area V2- V3 over time. We assume, that due to posttraumatic swelling by hematoma formation and following reactive soft tissue edema the volume of the ankle increases between one to three days after trauma before the volume starts to decrease over time. The ROI ankle V2- V3, which encompasses the typical surgical access routes for ankle fracture surgery [3,19], is crucial for the surgeon's subjective assessment of the soft tissue mantle prior to definitive surgery; hence, we compared the surgeon's assessment with volume measurements of this region and found a strong correlation. In comparison, scan results from ROI V2- 3 showed a significant reduction in volume on average on day 8 in our population, while the surgical assessment considered skin folding and operability from day 11- 14 in most cases. This indicates that the 3D



C)

	Mean volume first measurement (± SD)	Mean volume final measurement (± SD)
Injured Lower limb (V4- V9)	908.5 ± 202.9 ml	838.3 ± 168.2 ml
Injured Ankle (V2- V3)	311.9 ± 65.8 ml	290.2 ± 56.5 ml
Injured Foot (V1)	865.6 ± 169.8 ml	849.9 ± 176.2 ml
Healthy Lower limb (V4- V9)	800.4 ± 187.9 ml	804.3 ± 196.5 ml
Healthy Ankle (V2- V3)	230.7 ± 40.8 ml	230.3 ± 40.8 ml
Healthy Foot (V1)	787.8 ± 142 ml	789.5 ± 146.8 ml
Mean volume difference ***Lower Limb V4- V9 (p < 0.001)***	*123.8± 79.6ml*	*78.3± 69.1ml*
Mean volume difference ***Ankle V2- V3 (p < 0.0001)***	*81.1± 35.1ml*	*68.9± 27.2ml*
Mean volume difference ***Foot V1 (p < 0.001)***	*78.2± 68.1ml*	*61.5± 59.9ml*

Fig. 3. Images of the Eva Artec 3D scan of healthy and injured leg. A) Representative a.p. images of an injured right leg (AO 43- C3) and corresponding healthy left leg in comparison subdivided by green lines in the respective ROI. B) Representation of the region of interest V9- V4: lower limbs; V3- V2: ankle; V1: foot on the injured leg. For volume measurement, the circumferences V1- V9 were marked and divided into segments of 2.5 cm. The volume of each segment was then calculated using the software program Artec Studio 13 (Version 13, Artec Group, Luxembourg). C) Display of the average measured volume values of the first measurement compared to those of the last measurement subdivided into the ROI. Significant volume differences between injured and healthy legs ($p < 0.05$) were found. No significant volume changes occurred in the healthy legs over time (lower limb: $p = 0.547$; ankle: $p = 0.51$; foot: $p = 0.378$).

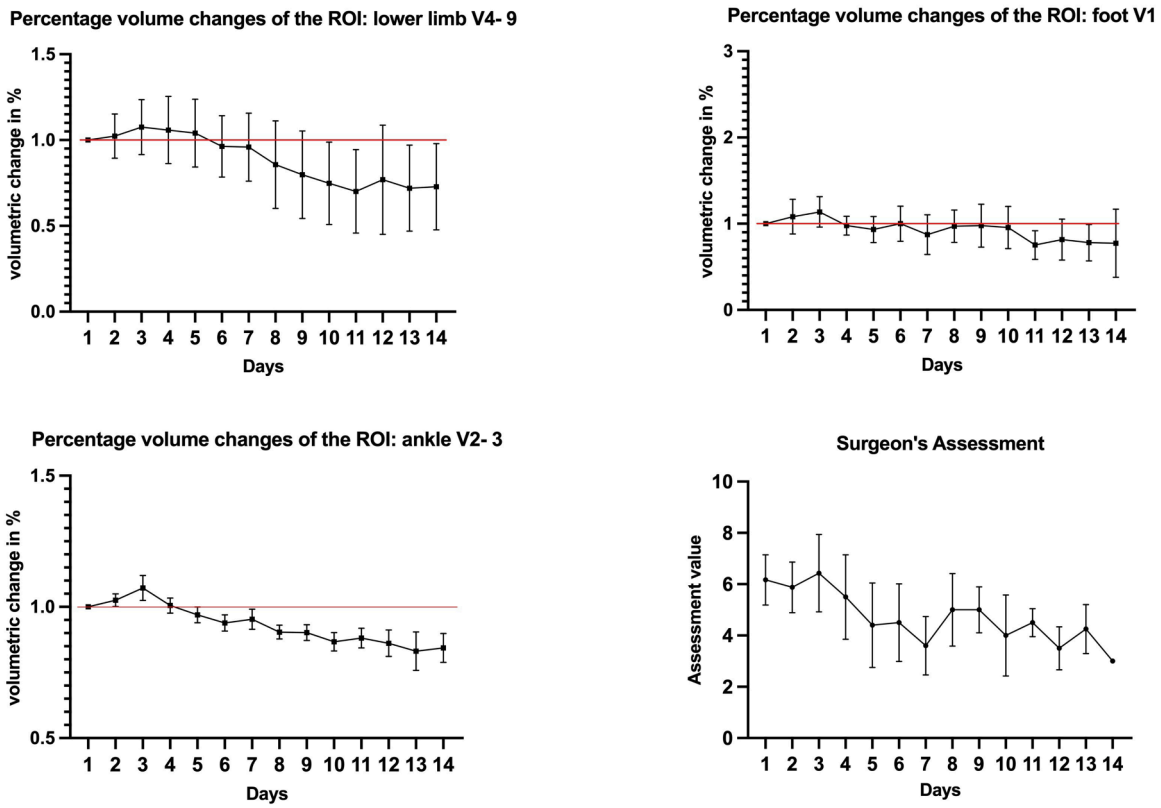
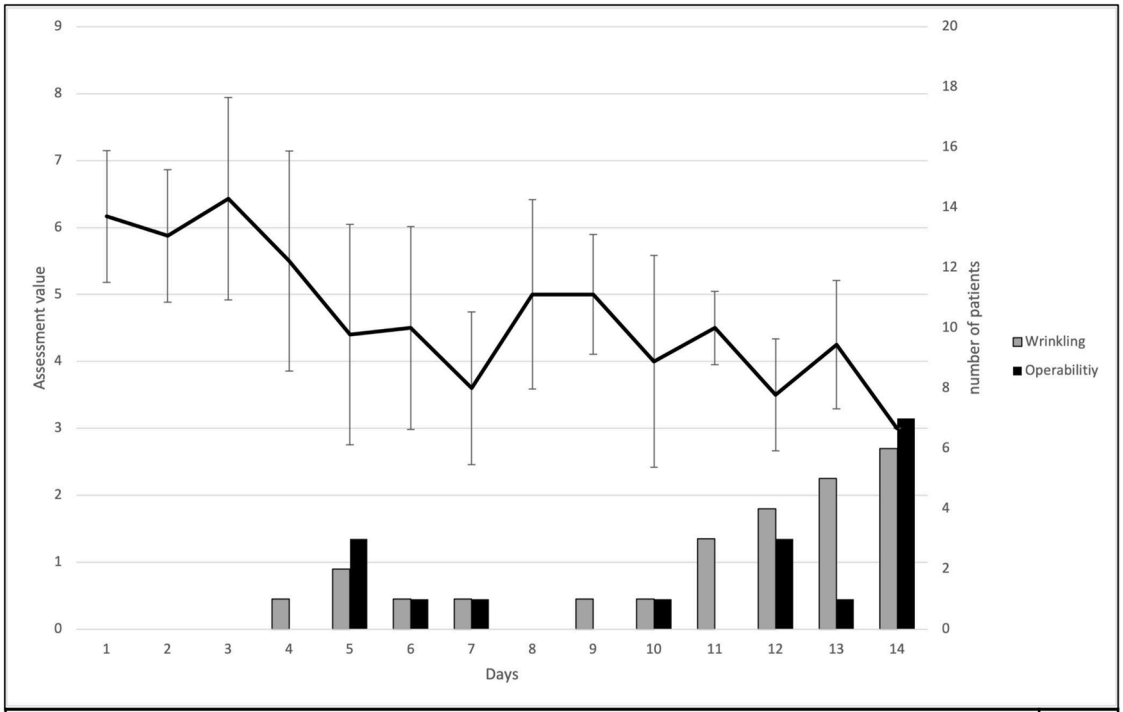


Fig. 4. Graphic display of percentage volume change of the ROI and Surgeon's assessment. The volume differences of the respective segments between the injured and healthy leg were normalized against the first volume measurement value for each patient. For each participant (N = 17) the first volume difference of the injured and healthy leg of the respective ROI was defined as 1.0 (red line). The volume differences of injured and healthy leg measured during follow up were set in relation to the first volume value to graphically display the mean percentage decrease. Significant volume differences for all ROI between the injured and healthy leg ($p < 0{,}05$; lower limb V4- V9: $p < 0.001$; ankle V2- V3: $p < 0.0001$; foot (V1): $p < 0.001$) was found. Subsequent analysis showed a significant reduction of ROI ankle volume from day 8 ($p \leq 0.02$). Mean volume reduction of the ROI: lower limb = 25 ± 25 %; ankle = 16 ± 9 %; foot = 23 ± 39 %. A Pearson correlation coefficient of ≥ 0.65 for all ROI showed a significant correlation ($p < 0.005$) between the percentage volume changes of the ROI and the surgeon's assessment.

scanner can detect significant volume changes earlier and with greater accuracy than the subjective assessment, which had deemed the patient operable only after the swelling had already significantly subsided several days prior. As previously noted, it is not susceptible to interobserver variability [7]. The utilized subjective assessment of the soft tissue mantle has limitations. Although, a good intra- and interobserver reliability applies to the Tscherne and Oestern classification [25], the assessments may be prone to error, potentially influenced by the surgical experience of the evaluating surgeons. Furthermore, this was a single-center study with a relatively small study population. Standard operating procedures and treatment strategies may vary between different centers. It should be noted that the data obtained in this study does not constitute a recommendation for primary clinical use. Clinical assessment of the soft tissue by the treating surgeon remains the current standard of care. Additionally, one of the most important limitations of this study is the small number of patients. However, the results of this study justify multicenter study designs to generate larger study populations. This study did not investigate how comorbidities, patient compliance and open fractures influence ankle swelling. The aim of this study was to see whether the scanner is reliable to follow up volume differences between the traumatized and the healthy extremity on the course of the decongestion process. Comorbidities associated with an increase in the circumference of the lower extremities (see exclusion criteria; Fig. 1) would have been variables that could not be assessed in this context. There is growing interest in an objective and easy-to-use method for determining the volume of injured limbs using a hand held 3D scanner like EVA Artec [9,29,30]. The utilization of the 3D handheld scanner and the protocol outlined in this study will facilitate reliable and valid investigations into comorbidities influencing swelling and surface changes such as blistering and hematoma formation, as well as enhance the comparability of various decongestive interventions in future research of larger cohorts. This includes previously described methods like vascular impulse technology [12], foot pumps [8,31], hyperbaric oxygen therapy [32], device-based negative pressure treatment [33], as well as manual physiotherapeutic techniques [22,30]. Establishing consensual and standardized approaches to soft tissue management for severely injured lower extremities in clinical practice will reduce duration of hospitalization and soft tissue complications. In conclusion, we found a 3D scanner like Artec Eva is an objective and reliable tool, identifying significant volume changes after ankle fractures earlier than subjective soft tissue assessments. The standardized 3D scanning protocol employed in this study is recommended for assessing the efficacy of perioperative decongestive management strategies in traumatized limbs, facilitating further data collection and comparative studies to standardize soft tissue management for ankle fractures and establish consensus therapy algorithms for perioperative care.



Degree 0 *No or only insignificant soft tissue injury*	1 2
Degree I *Superficial contusion or contusion due to fragment pressure from the inside*	3 4 5
Degree II *Deep, skin abrasion, deep skin or muscle contusion due to direct exposure to force, localized small blistering, impending compartment syndrome*	6 7 8
Degree III *Extensive skin or muscle contusions, skin bruising, huge blistering or muscle destruction, decompensated compartment syndrome*	9 10

Fig. 5. Graphic display numeric scale of surgeon's assessment. The assessment values (left y- axis) according to severity classification of closed fractures by Tscherne and Oestern are shown as the black graph with SD. The bar charts show the time of surgery in absolute numbers (right y- axis) in black and the considered skin wrinkling in gray. There are two peaks around days 5- 7 and 11- 14. Around days 5- 7 five participants with injury severity 44- B1 and no external fixator were operated with ORIF.

Ethics approval and consent to participate

Informed written consent was obtained from all participants prior to the procedure. The study was performed according to the guidelines provided by the Declaration of Helsinki and was approved by the university ethical committee (APPROVAL NUMBER 2019-475).

Consent for publication

Informed written consent was obtained from all participants prior to the procedure.

Availability of data and materials

All data generated or analyzed during this study are included in this published article.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Competing interests

The authors declare that there is no conflict of interest. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article. The authors received no financial support for the research, authorship, and/or publication of this article.

Acknowledgements

We thank Tobias Ruhrmann and Tibor Höfler for excellent technical assistance and Pierre Koppetsch for supply of technical devices.

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