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Cable-assisted bone transport versus circular external fixators-assisted bone transport in the management of bone defects of the Tibia: clinical and imaging results

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Abstract

Purpose The aim of this study was to compare the efficacy, clinical outcomes, and complications of cable-assisted bone transport (CAST) and circular external fixator-assisted bone transport (CEFT) methods in the management of bone defects of the tibia.

Methods A retrospective analysis was conducted on 32 patients who underwent segmental bone transport for tibial bone defects between January 2006 and January 2020 and met the study inclusion criteria. Patients were categorized into two groups: CAST group ($n = 16$) and CEFT group ($n = 16$). The primary outcome measures included radiological parameters (External Fixator Index (EFI), Radiological Consolidation Time (RCT), and Radiological Consolidation Index (RCI)), functional independence (Lower Extremity Functional Index, LEFI) and functional outcomes (ASAMI Bone and Functional Scores). Secondary outcomes included pain levels (Visual Analog Scale, VAS), and complication rates (Paley's and Checketts-Otterburn classifications).

Results The CAST method resulted in significantly reduced pain scores during distraction (VAS: 4.81 ± 0.98 vs. 6.75 ± 0.86 ; $p = 0.001$). Pin-tract infection rates were significantly lower in the CAST group compared to the CEFT group (50% vs. 93.8%; $p = 0.013$). There was no significant difference between the groups in radiological (EFI, RCT, RCI) and functional outcomes (ASAMI scores) ($p > 0.05$).

Conclusion Both CAST and CEFT methods are effective and reliable options in the management of bone defects of the tibia. However, CAST offers advantages such as lower pin-tract infection rates and less pain during distraction, resulting in greater patient comfort and compliance. Given its less invasive nature, CAST may be preferable in patients at higher risk of infection or with a low pain threshold. However, the technical complexity of this method requires experienced surgical application.

Keywords Tibial fractures, Bone defects, External fixator, Distraction osteogenesis, Fracture healing, Bone regeneration, Pain measurement, Complications, Infection, Functional recovery, Treatment outcome

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Introduction

Tibial bone defects are one of the most challenging and complex problems encountered in orthopaedic practice, occurring for various reasons such as high-energy trauma, nonunion, osteomyelitis or tumor resection. Such defects are often accompanied by many comorbid conditions such as soft tissue loss, deformities, limb shortness, infection and joint motion limitations [1–3]. All these factors both prolong the treatment process and negatively affect the final functional outcome [1, 2]. Successful management of bone defects involves not only the restoration of bone integrity but also a complex approach aimed at long-term infection control, correction of deformity and restoration of the patient's functional independence.

Various surgical methods have been developed for the management of bone defects of the tibia, including vascularized free fibula grafts, the Masquelet-induced membrane technique, acute shortening, and segmental bone transport [4–8]. Each of these methods has advantages as well as disadvantages and limitations [9–12]. Although vascularized fibula graft provides biological reconstruction in the treatment of large defects with good union rates, loading before graft hypertrophy occurs carries a fracture risk [13, 14]. The Masquelet technique provides periarticular space advantage, but the increasing need for autograft as the defect size increases will cause donor site problems. Furthermore, it requires a two-stage procedure and long recovery times [15]. Acute shortening and bone transport techniques allow biological reconstruction, and although defects ≤ 3 cm can often be treated with these methods, defects > 4 cm usually require distraction osteogenesis with segmental bone transport methods [10, 16–19]. Despite advances in treatment modalities, achieving full functional recovery remains a complex and time-consuming process.

Segmental bone transport is one of the most effective methods in the management of large bone defects [20], which can be achieved through the utilisation of a variety of techniques. Circular external fixator-assisted methods and cable-assisted bone methods are among the methods most used. While circular external fixator-assisted bone transport (CEFT) offers advantages in terms of deformity correction and stability, complications such as the numerous transosseous wires penetrating the skin and pin-tract infection have been reported [21–25]. Cable-assisted bone transport (CASt) offers a less invasive alternative, reducing the risk of these complications [26, 27]. However, in cases where the cable system does not provide adequate compression at the docking site, additional surgical interventions may be needed [26].

The aim of this study was to compare CASt and CEFT methods used in the management of bone defects of the tibia and to evaluate the efficacy, complications, and

clinical and radiological results of these two methods. The study hypothesis was that the CASt method would have similar effectiveness but with some advantages.

Methods

Study design and ethical approval

This retrospective comparative study was conducted in accordance with the Declaration of Helsinki with Institutional Ethics Committee approval (Approval Number:3031, Date: 24/11/2020). Informed consent was obtained from all patients for the use of their medical data for research purposes.

Study population

Patients who underwent segmental bone transport surgery for tibial bone defects between January 2006 and January 2020 were retrospectively analyzed through the institutional hospital patient data registry system.

The study included patients who met the following inclusion criteria:

- Patients with tibial bone defects,
- Treatment with segmental bone transport method,
- Completed treatment and adequate follow-up for at least 12 months.

The exclusion criteria were defined as:

- Bone defects < 4 cm,
- Patients for whom the final treatment was not a segmental bone transport method.

A total of 37 patients were identified as having tibial bone defects and undergoing segmental bone transport treatment. A total of 5 patients were excluded from the study; 4 due to insufficient follow-up data or treatment completion issues, and 1 with a bone defect < 4 cm. Consequently, 32 patients met the eligibility criteria and were included in the study.

Patient selection for management modalities

The selection of cable-assisted bone transport (CASt) or circular external fixator-assisted bone transport (CEFT) was determined by the individual clinical preferences of two experienced surgeons. In their respective practices, these surgeons routinely prefer different segmental bone transport techniques. Patients presenting at their respective clinics were treated with the method preferred by the attending surgeon.

A formal sample size calculation was not performed due to the retrospective nature of the study and the limited number of eligible patients available during the study period. However, the study included all eligible patients who met the defined inclusion criteria.

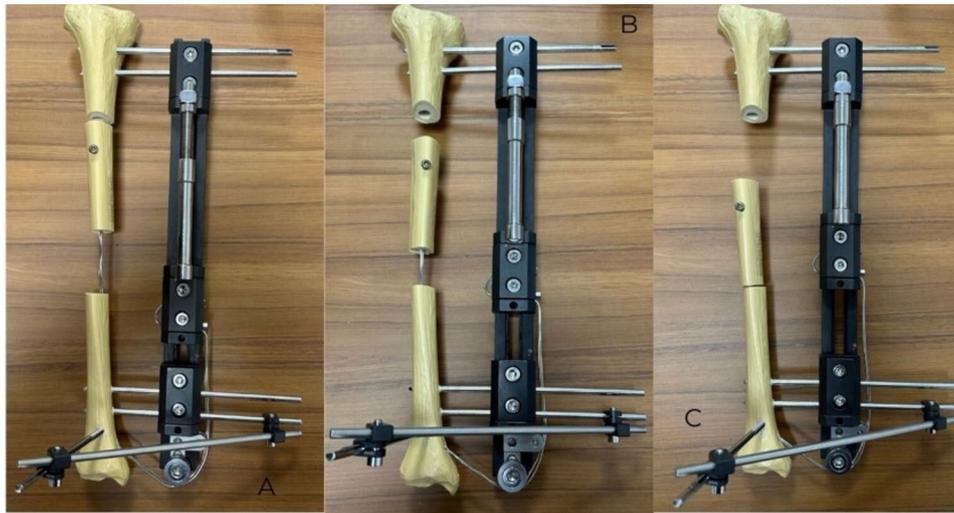


Fig. 1 (A–C). Demonstration of the cable-assisted segment transport (CAST) technique on a tibial bone model; (A) Initial setup with the segment in its starting position, (B) Gradual advancement of the segment along the transport rail, (C) Final position near the docking site for consolidation



Fig. 2 Bone debridement; the necrotic and infected bone is debrided, and the bone ends are levelled to ensure proper alignment before segment transport

Surgical techniques: cable-assisted bone transport (Fig. 1)

The defective area was opened, bone debridement was performed and the bone ends were levelled (Fig. 2). The bone length and axis were corrected and the LRS type external fixator system was applied to bridge the defect area. The cable was folded in half and advanced intramedullarily into the segment to be transported antegrade or retrograde. When it reached a sufficient level, one

steel cannulated screw was applied through the centre of the cable loop and the segment to be transported was connected to the cable (Fig. 3). The cable system was advanced through the medulla in the proximal or distal fixed medulla, and was passed around one Schanz screw placed in the anteroposterior direction and removed from an area with little soft tissue such as the medial malleolus in the distal or the tibial condyle in the proximal. This Schanz screw acts as a pulley in the area where the

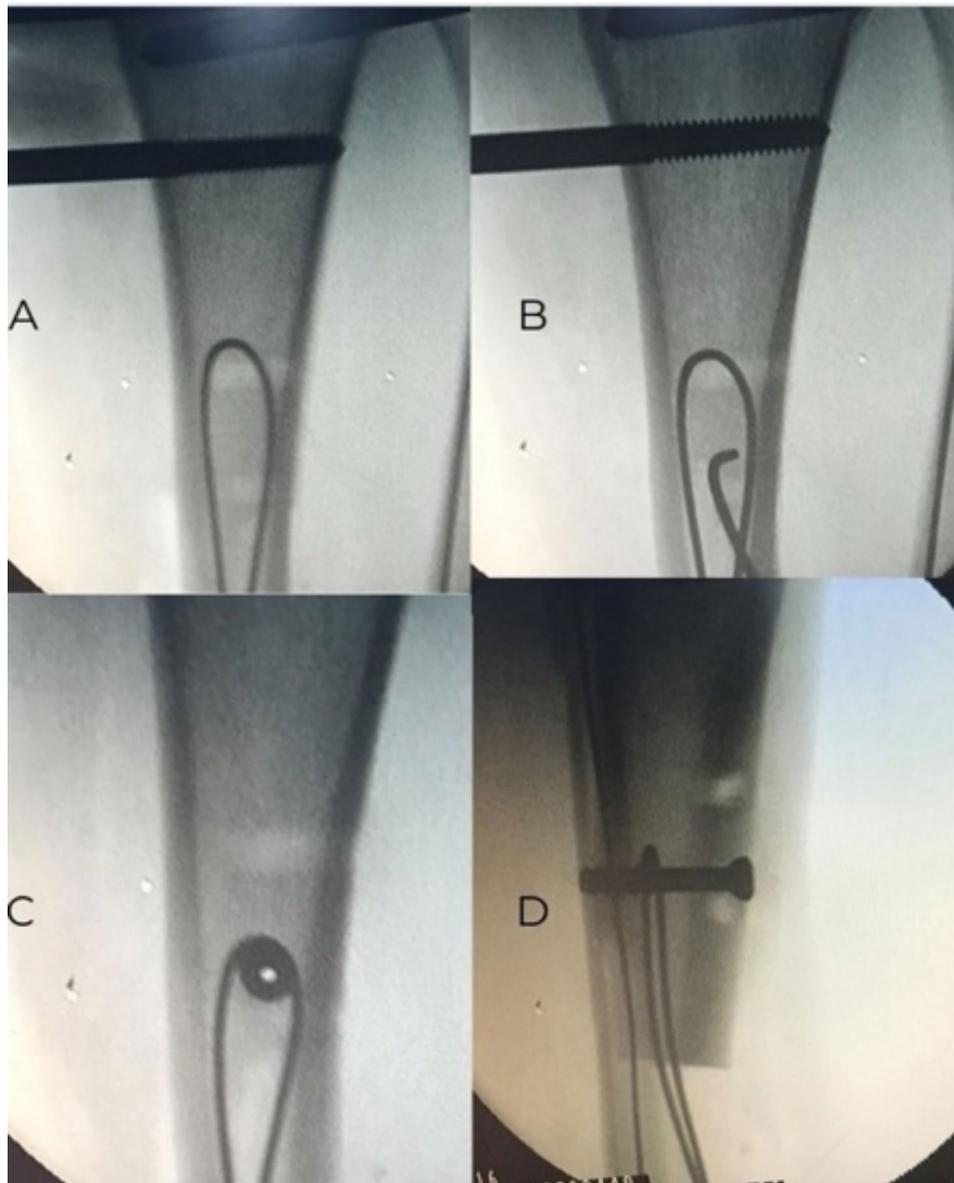


Fig. 3 (A-D). Fixation of the cable to the segment to be transported; **(A)** The cable is folded and advanced intramedullarly within the segment, **(B)** Once at the appropriate level, a cannulated screw and K-wire are passed through the cable loop, **(C)** Application of the cannulated screw in the AP plane, **(D)** Application of the cannulated screw in the lateral plane

cable will exit the bone and provides stability to the system in the second stage. Thus, the intramedullary cable also acts as a guide for the transported segment and prevents axis deviations. It was applied to the clamps of the LRS type external fixator specially prepared for the cable system, and the system was locked after ensuring the appropriate tension (Fig. 4). Osteotomy was performed using a drill at the appropriate level in the segment to be transported and the transport process was controlled with the help of a distractor on the rail. After the distraction process was completed, the steel cannulated screw and cable were removed. The Schanz screw was applied

to the transported segment and compression of the docking site was provided (Fig. 5).

Surgical techniques: circular external fixators-assisted bone transport

The defective area was opened, bone debridement was performed and the bone ends were levelled. Proximal and distal bone fragments were fixed to the circular rings with wire and Schanz screws. The bone was osteotomized using a drill. The conventional segmental bone transport protocol was performed.

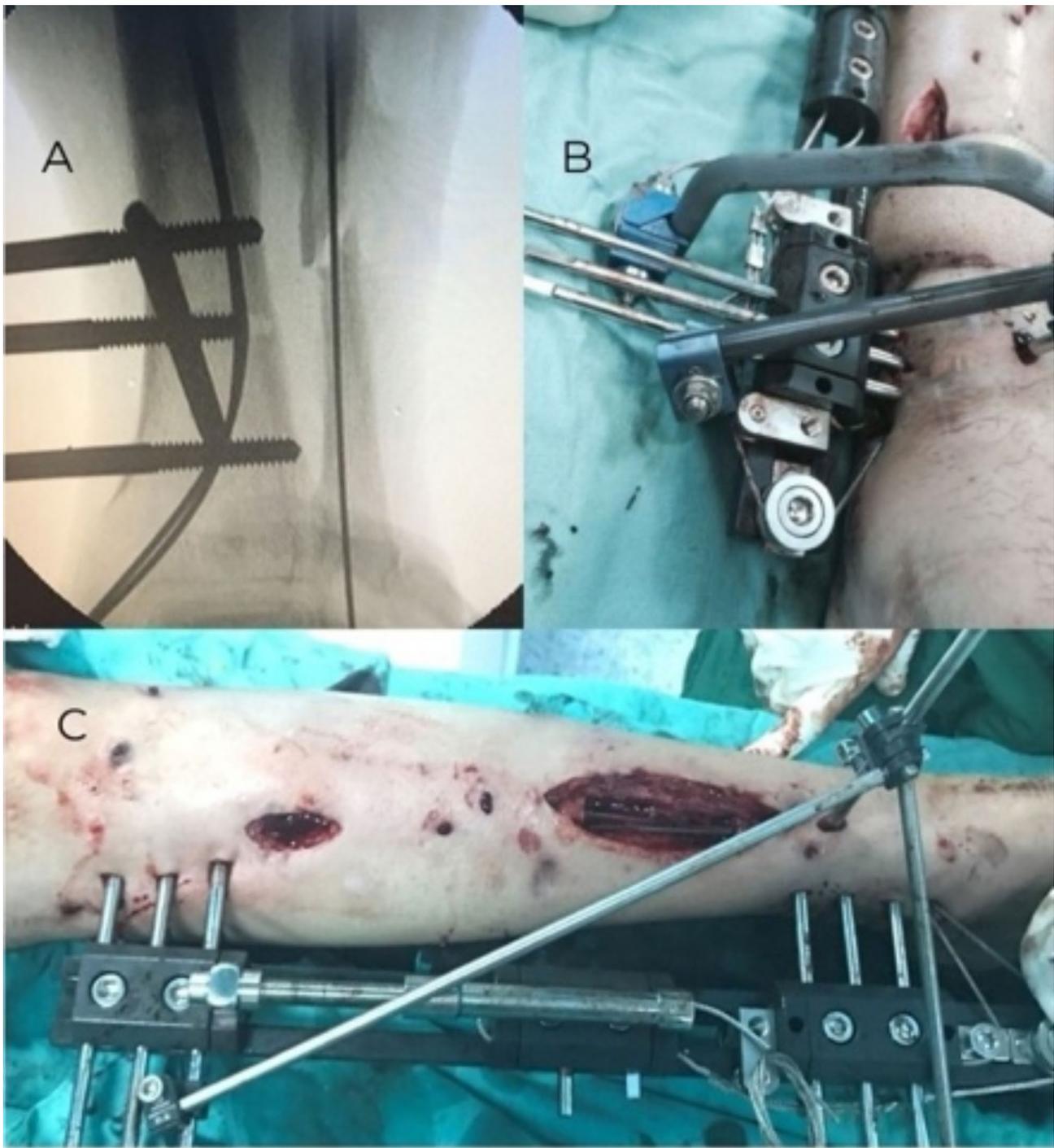


Fig. 4 (A-C). Intramedullary advancement and system adaptation of the cable; (A) The cable is looped around the distal Schanz screw, (B) General view of the external fixator system, (C) The cable is connected to the system through pulleys and locked in place

Post-operative management and follow-up protocol

Distraction was usually initiated between postoperative days 5 and 7. Distraction was performed at a rate of 1 mm per day in 4×0.25 mm increments, in accordance with distraction osteogenesis protocols. Patients were given detailed training on how to perform the distraction procedure and pin-tract care. The fixators were removed

once regenerate maturation was achieved and the docking site was fused (Figs. 6 and 7).

Outcome measures

Demographic and preoperative data

The demographic characteristics of the patients, including age, gender, etiology of bone loss, amount of bone



Fig. 5 The cable system is easily removed and compression is applied with a Schanz screw

loss, segmental bone transport method, and bone transport distance, were recorded. Open fractures were evaluated using the Gustilo-Anderson open fracture classification, and bone defects were classified preoperatively using Paley's tibial pseudoarthrosis classification [28].

Primary outcome measures

- Radiological parameters including the External Fixator Index (EFI), Radiological Consolidation Time (RCT), and Radiological Consolidation Index (RCI).
- Functional outcomes were assessed using the ASAMI Bone and Functional Scores.
- Patient-reported functional independence, assessed using the Lower Extremity Functional Index (LEFI).

Secondary outcome measures

- Pain levels during distraction, evaluated using a Visual Analog Scale (VAS).
- Complications were assessed according to Paley's classification [28] and Checketts-Otterburn classification for pin-tract infections.

All measurements were conducted using standardized radiographic and clinical assessment protocols.

Radiological parameters were evaluated by two independent orthopedic surgeons blinded to the patient treatment groups, and clinical outcomes were assessed using validated scoring systems [28].

Statistical analysis

The statistical analysis of this study was performed using NCSS (Number Cruncher Statistical System) (Kaysville, Utah, USA). Continuous variables were tested for normality using the Shapiro-Wilk test. Normally distributed data were compared with the Student's t-test, and non-normally distributed data with the Mann-Whitney U test. Categorical variables were compared using Pearson's chi-square test or Fisher's exact test where appropriate. The level of statistical significance was set at $p < 0.05$.

Results

A total of 32 patients were included in the study, of which 16 of were treated with the CAST method (Group 1) and 16 with the CEFt method (Group 2).

Demographic and preoperative data

All details regarding demographic and preoperative data (Etiology, Gustilo Anderson Classification, Paley Classification, Follow-up) are summarized in Table 1 and

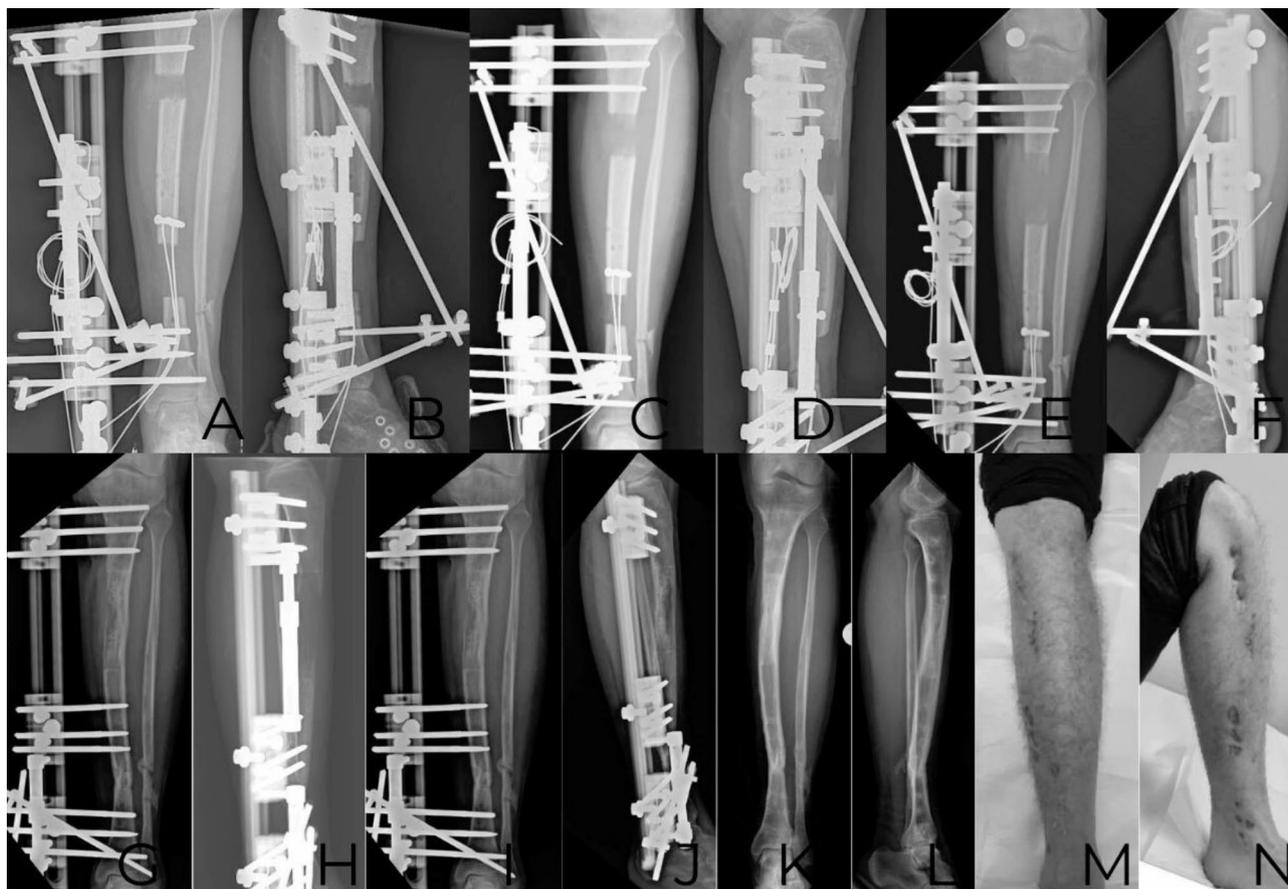


Fig. 6 (A-N) A 25-year-old male patient with a 7 cm defect in the tibia after a Type 3 A open fracture of the left tibia caused by a motor vehicle accident. Bone transport with cable-assisted bone transport; (A-F) Segment transport with cable-assisted technique, (G-J) Regeneration and union at the docking site, (K-N) final follow-up radiograph and functional status

no statistical difference was found between the groups ($p < 0.05$).

Radiological and clinical outcomes

The data of the radiological and clinical outcomes are summarized in Table 2. There were no significant differences between the groups in terms of bone defect size, residual shortness, external fixator duration, external fixator index, time to radiological consolidation, and radiological consolidation index ($p > 0.05$) (Fig. 8). The pain level during the distraction period, evaluated with VAS, was significantly lower in Group 1 ($p = 0.001$) (Fig. 9). There was no significant difference in pain level during daily activities ($p = 0.560$).

Bone and functional outcomes

The ASAMI bone and functional results and Lower Extremity Functional Index evaluations are summarized in Table 3. The ASAMI bone and functional results showed no significant difference between the groups ($p > 0.05$). The LEFI results were similar with no statistical difference between the groups ($p > 0.05$).

Complications

The evaluation of complications according to Paley classification by groups is shown in Table 4 and the incidence of pin-tract infections is shown in Table 4. According to the Paley classification, 23 complications were reported in Group 1 and 30 in Group 2. Pin-tract infection was detected in 50% in Group 1 and 93.8% in Group 2 ($p = 0.013$; Table 4).

According to the Checketts-Otterburn Classification, a total of 8 patients in Group 1 developed pin-tract infections. Among these infections, 5 patients were classified as Grade 1 and 3 patients as Grade 2. In Group 2, a total of 15 patients developed pin-tract infections; 7 were classified as Grade 1, 6 as Grade 2, and 2 as Grade 3 (Fig. 10).

Management of complications

All complications were managed based on their severity, as follows:

- Pin-tract infections: Treated with pin-tract care, local antiseptic dressings, and oral antibiotics when needed.

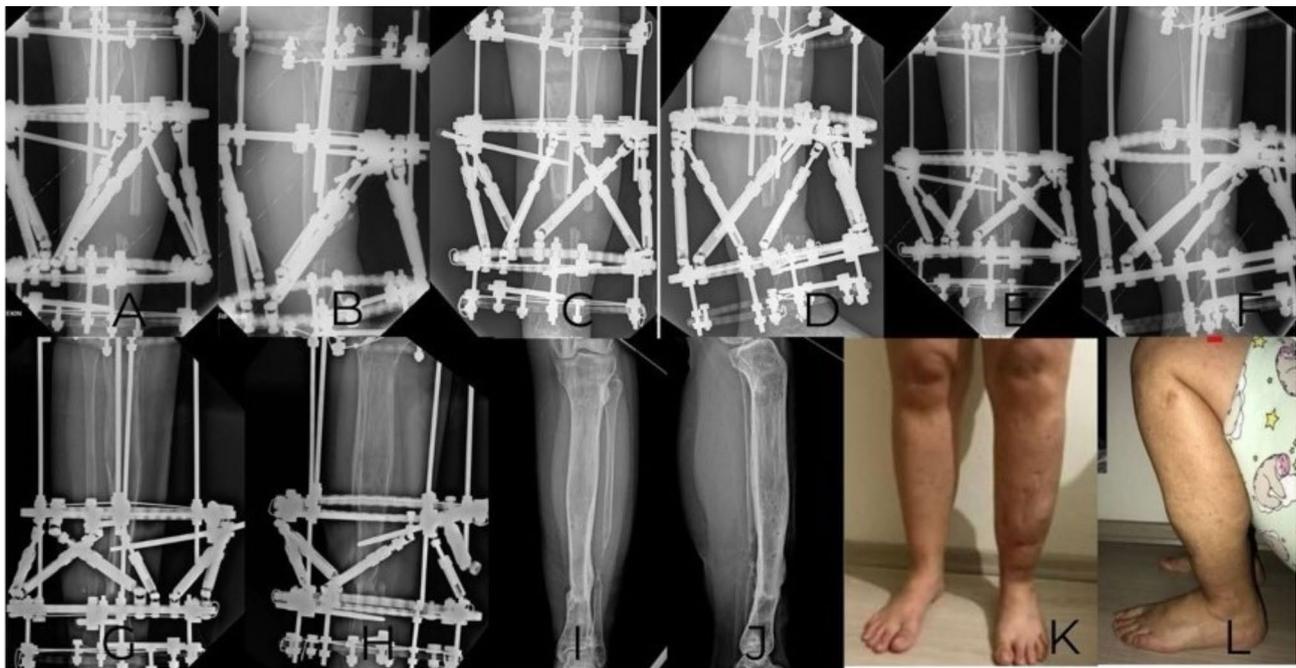


Fig. 7 (A-L) A 22-year-old female patient with a 6.5 cm defect in the tibia after a Type 3 C open fracture of the left tibia caused by a gunshot injury. Bone transport with circular external fixator-assisted bone transport; **(A–F)** Segment transport with circular external fixator-assisted bone transport, **(G–H)** Regeneration and union at the docking site, **(I–L)** Final follow-up radiograph and functional status

Table 1 Demographic and preoperative data (GI: gunshot injury, PTA: pedestrian traffic accident, IVTA: In-Vehicle traffic accident, MC: motorcycle crash, CI: crush Injury)

	Group 1 (n=16)	Group 2 (n=16)	p value
Age (years)	31.75 ± 10.77	32.63 ± 12.99	0.837
Gender (F / M)	1/15	2/14	1.000
Etiology (GI/ PTA/ ICTA/ MC/ CI)	6/2/1/5/2	8/3/1/1/3	0.499
Gustilo Anderson Classification (0/ tip 2/ 3a/ 3b/ 3c)	0/3/7/2/4	1/4/5/2/4	0.955
Paley Classification (B1/ B3)	8/8	5/11	0.280
Follow-up (months)	66.56 ± 49.40	61.31 ± 34.78	0.610

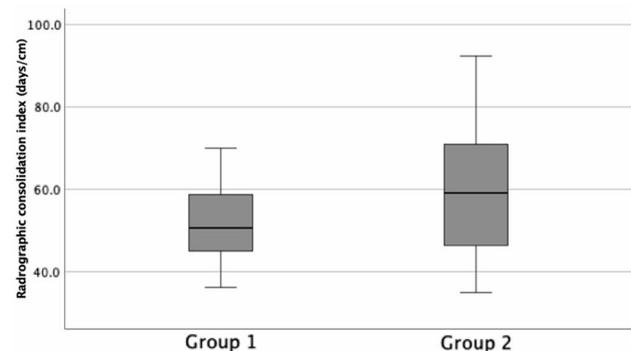


Fig. 8 Boxplot comparison of the radiographic consolidation index (days/cm) between Group 1 and Group 2

Table 2 Radiological and clinical outcomes (For variables marked with ‘a’, effect size could not be calculated due to the use of a non-parametric test)

	Total (n=32)	Group 1 (n=16)	Group 2 (n=16)	Cohen's d	95% CI Lower	p value
Bone defect (cm)	7.78 (range 4 to 12)	8.09 (range 4 to 12)	7.46 (range 4 to 12)	0.260	(-0.438-0.954)	0.468
Duration of surgery (min)	177.81 ± 29.21	174.38 ± 33.36	181.25 ± 25.00	-0.233	(-0.383-0.930)	0.515
Segment shift amount (cm)	7.45 ± 2.46	8.09 ± 2.84	6.81 ± 1.91	0.530	(-0.180-1.232)	0.144
Residual shortness	0.83 ± 0.87	1.00 ± 0.95	0.66 ± 0.77	a	a	0.339
External fixator duration (days)	557.38 ± 237.20	586.19 ± 288.15	528.56 ± 177.42	0.241	(-0.457-0.934)	0.501
External fixator index (days/cm)	74.72 ± 16.92	71.08 ± 14.48	78.36 ± 18.81	-0.433	(-1.131-0.272)	0.23
Radiological consolidation time (days)	418.00 ± 169.12	424.06 ± 194.65	411.94 ± 145.41	0.071	(-0.623-0.763)	0.843
Radiographic consolidation index (days/cm)	55.48 ± 13.86	51.47 ± 9.62	59.50 ± 16.44	-0.623	(-1.301-0.117)	0.102
VAS score – at rest	5.78 ± 1.34	4.81 ± 0.98	6.75 ± 0.86	a	a	0.001*
VAS score- with daily activity	1.75 ± 0.67	1.69 ± 0.70	1.81 ± 0.66	a	a	0.56

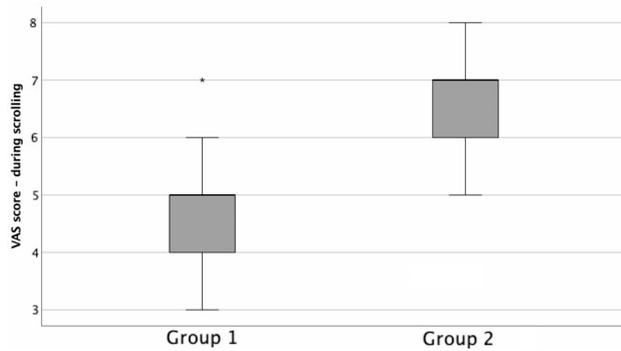


Fig. 9 Boxplot comparison of the VAS score – during scrolling between Group 1 and Group 2

- Loss of joint motion: Physical therapy and rehabilitation programs were used to help patients regain their ability to move.
- Delayed regenerate maturation, delayed consolidation, and delayed healing at the docking site: Managed with autologous bone marrow-derived mesenchymal stem cell (MSC) injections and bone grafting when necessary. Compression was additionally performed as needed for delayed healing at the docking site.
- >2.5 cm limb shortening: Patients were followed up and required limb elevating insoles or shoe modification.

- Re-fracture: Managed using circular external fixators to provide stability and allow for proper healing.

Discussion

The most important conclusion of this study is that both the CAST and CEFT techniques are efficacious in the management of tibial bone defects, and provide similar clinical and radiologic results. However, CAST offers certain advantages over CEFT, including lower pain scores during distraction and a lower incidence of pin-tract infection. These findings support the hypothesis that the CAST method would have similar efficacy while providing certain benefits.

Various external fixator systems can be used to treat bone defects using the principles of distraction osteogenesis. The most commonly used methods are circular external fixators and monolateral external fixators. Both methods have similar union and functional scores and have high success rates [29]. It has been shown that monolateral fixators are often preferred due to ease of application and lower patient discomfort, while circular fixators allow better deformity correction and stability [30].

Although the CAST method is known to have a more limited structure in terms of mechanical stability compared to the CEFT method, it is thought that this method may positively affect the consolidation process because it is less invasive and there is less soft tissue damage [31]. It

Table 3 Bone and functional outcomes

		Total (n = 32) n (%)	Group 1 (n = 16) n (%)	Group 2 (n = 16) n (%)	p value
ASAMI Bone Results	Excellent	17 (53,1)	8 (50,0)	9 (56,3)	1,000
	Good	12 (37,5)	6 (37,5)	6 (37,5)	
	Poor	3 (9,4)	2 (12,5)	1 (6,3)	
ASAMI Functional Results	Excellent	9 (28,1)	6 (37,5)	3 (18,8)	0,553
	Good	19 (59,4)	9 (56,3)	10 (62,5)	
	Fair	3 (9,4)	1 (6,3)	2 (12,5)	
	Poor	1 (3,1)	0 (0)	1 (6,3)	
Lower Extremity Functional Index	Mean ± SD	74,42 ± 5,64	75,02 ± 5,82	73,83 ± 5,58	0,747

Table 4 Complications based on Paley classification

		Group 1 (n = 16), n	Group 2 (n = 16), n	p value
Problems	Pin tract infection	8	15	0.013*
	Loss of joint motion	4	4	1.000
	Delay in regenerated maturation	2	1	0.544
	Delayed union in the docking site		1	0.310
Obstacles	Delay in regenerated maturation	3		0.069
	Recurrence of infection	1	1	1.000
	Delayed union in the docking site	1	2	0.544
	Deviation in the docking site		1	0.310
	Skin fold in the docking site		1	0.310
True Complications	> 2.5 cm shortness	1	1	1.000
	Loss of movement in the ankle joint	1	2	0.544
	Re-fracture	2	1	0.544

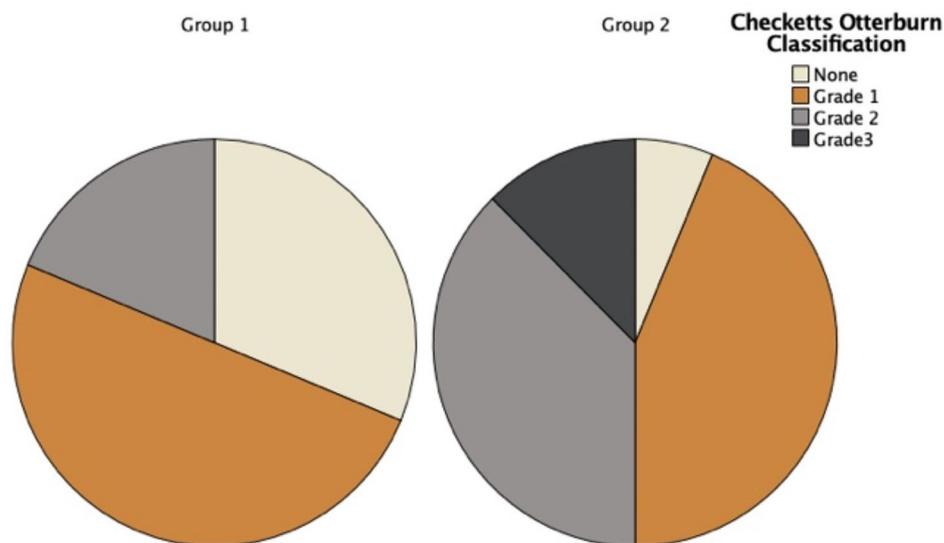


Fig. 10 Distribution of the Checketts-Otterburn Classification Grades between Group 1 and Group 2

has been documented that regenerated mineralisation is more pronounced in monolateral fixators than in circular fixators [32]. This hypothesis is supported by the observations of this study. Although no significant difference was observed between the two groups in terms of EFI and RCI, the values for these parameters were found to be lower in the CAST group.

The use of an external fixator presents a significant challenge for patients. It has been reported that patients who used monolateral fixators for the treatment of tibial bone defect were more satisfied with the postoperative results and their quality of life improved. The use of monolateral fixators in the management of bone defects of the tibia has therefore been recommended [33]. The lengthy nature of the management process can have a detrimental impact on patients' mental health, both during and after the course of treatment. This negative effect is most evident during the distraction phase and is significantly higher in patients undergoing management with a circular external fixator [34]. This may have an impact on the patients' perception of pain and comfort during the course of treatment, and may be one of the reasons why the VAS scores in the distraction phase, were significantly lower in the CAST group in this study.

The present study demonstrated that pain scores (VAS) during distraction were significantly lower in the CAST group. This may be attributed to the fact that the CAST method minimises skin irritation and soft tissue complications by reducing the utilisation of transosseous pins. The use of Schanz and taut pins in the CEFT method results in the tearing of the skin during segmental sliding, consequently leading to an increase in the pain sensation (Fig. 11) [35].

The disappearance of the notable disparity in the distraction phase observed in this study following treatment lends support to this notion.

The functional results evaluated with ASAMI scores demonstrated no statistically significant difference between the two groups. Nevertheless, the fact that patients in the CAST group had an earlier return to activities of daily living and fewer problems such as limping and joint stiffness compared to the CEFT group can be considered an indicator of the advantages of this method. This is supported by the slightly higher rate of excellent functional outcome in the CAST group. Previous research has similarly indicated that both techniques are efficacious in facilitating functional independence [21, 36–38].

The most prevalent complication associated with segmental bone transport is the development of pin-tract infection [8, 39]. The rate is increased by prolonged treatment time, a larger defect, transosseous advancing wires and Schanz pins [20]. Nevertheless, it has been emphasized in the literature that the implementation of appropriate pin-tract care and infection control protocols can mitigate the long-term effects of these complications [1, 40, 41].

In the current study, among the most common complications encountered was pin-tract infection, which exhibited a significantly lower incidence in the CAST method. It was thought that this discrepancy can be attributed to the reduction in the number of Schanz and pins utilised in CAST, which has the effect of preserving the integrity of the surrounding soft tissue.

Additional complications associated with segmental bone transport include diminished joint mobility, pain, re-fracture, delayed regeneration, and complications at the docking site. Specifically, patients with large bone



Fig. 11 Skin tear (arrow) associated with taut pin segmental shift after CEFT procedure

defects showed decreased joint mobility and delayed regenerative maturation. The majority of these complications are associated with the dimensions of the bone defect and the prolonged use of external fixation devices, as previously discussed [20].

Delayed regenerated maturation, delayed consolidation, and delayed healing at the docking site were managed with autologous bone marrow-derived mesenchymal stem cell (MSC) injections and bone grafting when necessary, which are the recommended methods. Although meta-analyses have not demonstrated a significant effect,

patients were also supported with calcium and vitamin D supplementation [42]. Moreover, adjunctive approaches such as low-intensity pulsed ultrasound (LIPUS), extracorporeal shock wave therapy (ESWT), and pneumatic compression therapy, which are recommended in the literature to enhance bone healing and promote regenerate maturation, were not utilized in the treatment [43, 44]. Three patients with re-fracture were successfully treated with a circular external fixator.

The results of this study demonstrate that both CAST and CEFT techniques can be employed effectively in the management of tibial bone defects. Furthermore, the findings indicate that the CAST method is an efficacious management modality that mitigates the adverse effects associated with conventional techniques and enhances patient comfort. It should be noted, however, that CAST is a management method with a relatively high learning curve and therefore requires a significant investment of time to master.

Limitation

This study had several limitations, primarily that the retrospective design may have posed a methodological limitation due to the lack of timely observation of events. Secondly, due to the relatively small sample size, the results obtained may be insufficient to detect smaller differences between groups. Furthermore, the data used in the study were collected from a single centre, which may make it difficult to generalise to patient groups in different geographical regions and involving different management approaches. Being aware of the limitations, the results obtained were interpreted carefully by taking these factors into consideration.

Conclusion

The results of this study demonstrated that both CAST and CEFT methods are effective in the management of bone defects of the tibia and provide similar clinical and radiological outcomes. However, the CAST method has the potential to improve patient comfort with lower pain scores and complication rates. Given the less invasive nature of CAST, this may be preferable in patients at higher risk of infection or with a low pain threshold. However, the technical complexity of the method requires experienced surgical application.

Author contributions

GA, MK, RA, YS, YA, and OTE made substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of data used in the study. GA, MK, YS drafted the manuscript or substantively revised it. All authors approved the submitted version of the manuscript (and any substantially modified version involving their contributions) and agreed to be personally accountable for their contributions. They also ensured that questions related to the accuracy or integrity of any part of the work, even those not personally involved in, are appropriately investigated, resolved, and documented in the literature.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

This retrospective study was approved by the Clinical Research Ethics Committee of the University of Health Sciences, Şişli Hamidiye Etfal Training and Research Hospital, Health Practice and Research Center (Approval Number: 3031, Date: 24/11/2020). All procedures were conducted in accordance with the latest revision of the Declaration of Helsinki. Informed consent was obtained from all participants, and patient data were anonymized to ensure confidentiality throughout the study.

Consent for publication

Prior to the study, all participants signed an informed consent form agreeing to the publication of the information/images in this research. The subject of the images signed the consent form agreeing to publication in an online open-access journal.

Footnote

This article is based on Güngör Alibakan's thesis entitled "Tibia Kemik Defektlerinin Tedavisinde Kablo ve Sirküler Eksternal Fiksator ile Segment Kaydırma Yönteminin Karşılaştırılması" in 2021 year. Thesis Approval E-48865165-302.14.01-2372.

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Patient consent

All patients provided written informed consent prior to their inclusion in the study, in accordance with institutional and ethical guidelines.

Competing interests

The authors declare no competing interests.

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