

# Effective Compression and a Minimally Invasive Rail Plate to Optimize Bone Transport in Distraction Osteogenesis

## New Concepts

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**Background:** Bone transport in distraction osteogenesis is an effective, well-known procedure. However, bone compression is an aspect of this technique for which there is no objective information. The lack of direct bone compression measurements may result in a lack of uniformity in the bone transport process, which can result in its ineffective application and may be contributing to its underutilization. This study describes the results of applying objectively measured compressions to achieve a distraction regeneration zone and docking site consolidation during bone transport in distraction osteogenesis.

**Methods:** This prospective study describes the results of a single cohort of 32 patients who underwent distraction osteogenesis with bone transport utilizing a combination of a minimally invasive rail plate and monolateral external fixation. The patients were categorized into 2 groups: (1) those with hypertrophic, atrophic, or infectious pseudarthrosis-nonunion (the pseudarthrosis-nonunion group), and (2) those with bone loss due to trauma or osteomyelitis (the bone loss group). The initial bone compression was measured during the latency phase, and the final compression was measured during the distraction phase. The healing index, external fixation index, healing time, consolidation time, and docking time were calculated for each patient. The Mann-Whitney U and Kruskal-Wallis tests were used for comparisons between and within groups.

**Results:** In this study, 28 (88%) of the patients were male. The mean patient age was  $44.93 \pm 16.21$  years. The median values were 3.2 Nm for the initial compression and 3.4 Nm for the final compression, with no significant difference between or within groups of patients. The osseous results were excellent in 29 patients (91%), and the functional results were good or excellent in 31 patients (97%).

**Conclusions:** This study is the first to objectively measure compression in the bone transport process. Our findings showed that all patients who had an initial compression of  $\geq 3.2$  Nm achieved 100% consolidation of the distraction regeneration zone, and those who had a final compression of  $\geq 2.9$  Nm achieved complete docking site consolidation without complications. These 2 values thus represent effective compression and highlight the role of bone compression in bone transport.

Level of Evidence: Therapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.

B one transport in distraction osteogenesis is an effective, well-known procedure that has been widely used since it was first described<sup>1-17</sup>. The application of bone transport in distraction osteogenesis should consider the treatment time (bone healing and distraction degeneration zone) and the time

to final bone healing<sup>1,6,10,18-24</sup> as well as the development of possible complications, including those due to prolonged use of the external fixator (pin-track infection, joint instability, and stiffness), refracture after removal of the fixator<sup>1,17,20,22-36</sup>, failure in the distraction regeneration zone (DRZ), and nonunion or

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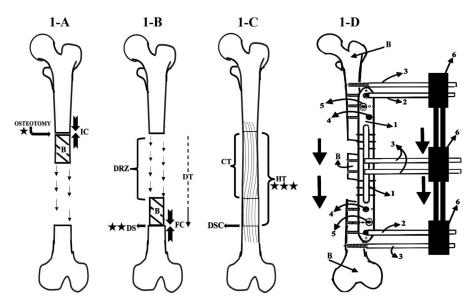


Fig. 1

**Figs. 1-A through 1-D** Bone transport with an MIRP. Radiographic follow-up was first performed at the beginning of the latency phase (time 0; star), continued at the docking site during the distraction phase (2 stars) and the consolidation phase (allowing determination of the HT), and for an additional 6 months (3 stars). B = bone. **Fig. 1-A** Latency phase: This phase begins with osteotomy and measurement of the initial compression (IC), in Nm (defined as the torque resulting from a force of 1 Newton applied perpendicular to the end of a moment arm that is 1 meter long<sup>55</sup>). Its duration is the number of days for which the initial compression was applied. **Fig. 1-B** Distraction phase: At the end of this phase, the bone has been transported to the docking site (DS), and the measurement of the final compression (FC) in Nm is performed. The duration of this phase is the docking time (DT). DRZ = distraction regeneration zone. **Fig. 1-C** Consolidation phase. The duration of this phrase is the regenerate consolidation time (CT). The healing time (HT), from osteotomy to when consolidation of all bone has been completed, is the sum of the latency, distraction, and consolidation phases. Docking site consolidation = DSC. **Fig. 1-D** Diagram illustrating the bone transport process. 1 = rail plate, 2 = locking Schanz pin, 3 = simple Schanz pins, 4 = locking screw, 5 = conventional screw, and 6 = MEF (similar to the Orthofix product Monolateral External Fixator to Limb Reconstruction and Bone Elongation).

the need for new surgical procedures to achieve docking site consolidation (DSC)<sup>9,17,22,24,37-40</sup>.

The utility of bone compression in external fixation for the management of pseudarthrosis-nonunion (PN), infection, or bone loss or for the reestablishment of bone continuity has been

discussed since 1948<sup>41</sup>. Bone compression has been described as stimulating the bone-healing process in infectious and non-infectious PN<sup>15,17,21,25-32,38,42-53</sup>. However, until now, compression in bone transport has been applied using mostly pragmatic criteria, rather than based on objective information. Previous studies

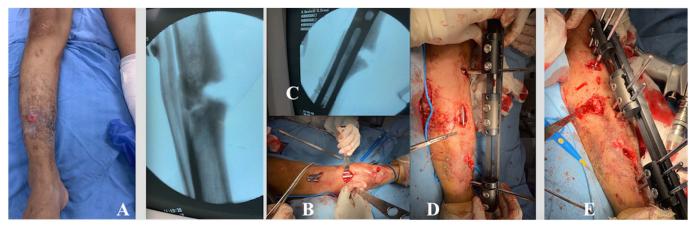


Fig. :

Figs. 2-A through 2-E Patient 1. Fig. 2-A An infected PN in the right tibia. Figs. 2-B and 2-C The minimally invasive technique for percutaneous plate insertion. Fig. 2-D Placement of the locking Schanz pin to serve as a guide for external fixator placement, and Gigli saw osteotomy. Fig. 2-E Completion of the MIRP and MEF application.

Patient No.	Age (yr)	Sex	Bone	Side	Group	Location	Osteotomy Method	No. of Previous Surgeries	Type of BT	DRL (cm)
1	26	Male	Tibia	Right	SPS	Medial	Gigli saw	1	Proximal-distal	2.4
2	56	Male	Tibia	Left	OBL	Distal	Reciprocating saw	2	Proximal-distal	7.4
3	46	Female	Humerus	Right	APS	Medial	Gigli saw	1	Distal-proximal	2.5
4	43	Male	Tibia	Right	TBL	Medial	Reciprocating saw	2	Proximal-distal	6.5
5	23	Male	Tibia	Left	HPS	Medial	Gigli saw	1	Proximal-distal	2
6	20	Male	Tibia	Right	HPS	Medial	Gigli saw	1	Distal-proximal	1.8
7	51	Male	Tibia	Right	SPS	Medial	Gigli saw	1	Distal-proximal	1.5
8	45	Male	Tibia	Left	HPS	Medial	Gigli saw	1	Distal-proximal	1
9	76	Male	Femur	Right	TBL	Proximal	Reciprocating saw	2	Distal-proximal	5
10	24	Male	Tibia	Right	APS	Distal	Gigli saw	1	Proximal-distal	3
11	23	Male	Tibia	Right	HPS	Medial	Gigli saw	1	Proximal-distal	1.2
12	43	Male	Tibia	Right	APS	Distal	Reciprocating saw	2	Distal-proximal	1.8
13	20	Male	Tibia	Right	HPS	Medial	Gigli saw	2	Distal-proximal	1.5
14	54	Male	Tibia	Left	SPS	Medial	Reciprocating saw	1	Distal-proximal	1.1
15	57	Male	Tibia	Left	SPS	Distal	Reciprocating saw	1	Proximal-distal	1.5
16	32	Male	Femur	Right	TBL	Distal	Reciprocating saw	0	Proximal-distal	8.5
17	42	Male	Humerus	Left	HPS	Medial	Gigli saw	2	Distal-proximal	0.8
18	61	Male	Tibia	Right	HPS	Medial	Reciprocating saw	2	Proximal-distal	1
19	43	Female	Humerus	Right	HPS	Medial	Gigli saw	3	Distal-proximal	1.4
20	61	Male	Tibia	Right	HPS	Medial	Reciprocating saw	3	Distal-proximal	1
21	51	Male	Tibia	Right	HPS	Distal	Osteotome	4	Proximal-distal	1.1
22	50	Male	Tibia	Right	OBL	Proximal	Gigli saw	2	Distal-proximal	6
23	52	Female	Humerus	Left	APS	Proximal	Gigli saw	2	Distal-proximal	1.2
24	22	Male	Humerus	Left	TBL	Medial	Gigli saw	2	Distal-proximal	10.5
25	56	Male	Tibia	Left	TBL	Distal	Reciprocating saw	2	Proximal-distal	15.2
26	45	Male	Tibia	Left	HPS	Medial	Reciprocating saw	1	Distal-proximal	1.3
27	23	Male	Tibia	Right	HPS	Medial	Reciprocating saw	2	Distal-proximal	2.4
28	41	Male	Tibia	Left	OBL	Distal	Reciprocating saw	1	Proximal-distal	1.2
29	64	Male	Femur	Left	TBL	Medial	Reciprocating saw	2	Distal-proximal	6.4
30	60	Male	Femur	Left	HPS	Medial	Reciprocating saw	1	Proximal-distal	8
31	48	Male	Tibia	Left	TBL	Distal	Reciprocating saw	2	Proximal-distal	1
32	80	Female	Tibia	Right	HPS	Proximal	Reciprocating saw	1	Proximal-distal	3

\*BT = bone transport, DRL = distraction regenerate length, SPS = septic pseudarthrosis, OBL = bone loss due to osteomyelitis, APS = atrophic pseudarthrosis, TBL = traumatic bone loss, and HPS = hypertrophic pseudarthrosis.

have not directly measured the effect of the magnitude of the force used for compression on the success of bone transport or correlated the variations in the magnitude of bone compression with the clinical result of bone transport for distraction osteogenesis. This lack of scientific, evidence-based surgical practice can contribute to the underutilization of this technique for a variety of conditions<sup>2,5,7,10-12,14-16,31,42</sup>.

A minimally invasive rail plate (MIRP) consists of a special low-contact plate with a rail, holes for locking screws, and holes for conventional screws. It is used with monolateral external fixation (MEF) (similar to the Orthofix Monolateral

External Fixator to Limb Reconstruction and Bone Elongation) and a locking Schanz pin system (Fig. 1) and is placed with a minimally invasive technique. At each end of the rail plate is a locking hole for the locking Schanz pin. This allows the rail to be used to guide the initial placement of the MEF and to maintain the same orientation until the end of the docking process. C-arm fluoroscopy is used during placement (Figs. 2-A, 2-B, and 2-C). MIRP and MEF for bone transport can provide measurements of the compression that are specified in the 2 specific points of transport, the initial and final compression values, in Nm, during the treatment of PN



Figs. 3-A through 3-E Patient 1. Fig. 3-A Compression measurement (in Nm) with a digital dynamometer. Fig. 3-B Initial compression in the process of bone transport has resulted in immediate recovery of the alignment and length of the bone. Fig. 3-C Early rehabilitation, with partial weight-bearing support with a crutch 24 hours after the surgical procedure. Fig. 3-D Eradication of infection and completely healed bone with trabeculae in the DRZ (achieved with 3.2-Nm initial compression) and the DSC (achieved with 3.5-Nm final compression). Fig. 3-E Complete recovery of normal gait and leg shape and length.

(infected and non-infected) and of bone loss (due to trauma or osteomyelitis).

To our knowledge, this study is the first to describe the results of applying objectively measured compression to achieve a DRZ and DSC in patients undergoing bone transport. We hypothesized that it is possible to obtain a DRZ and DSC with fewer complications using objectively measured compression applied under appropriate conditions during the phases of bone transport.

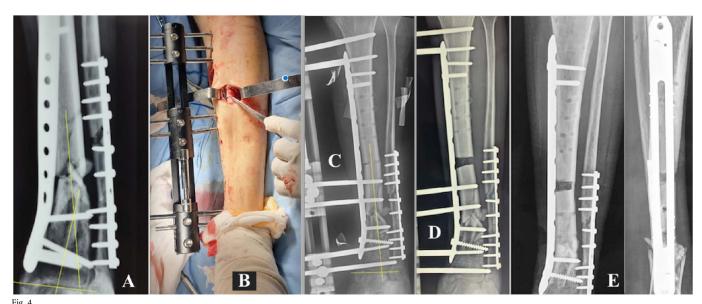
#### **Materials and Methods**

#### Study Population and Data Sources

This was a single-center, prospective study of 32 patients undergoing distraction osteogenesis with bone transport

in the lower extremity (femur or tibia) or upper extremity (humerus). The study was conducted between March 2019 and November 2021. All patients were adequately informed about the study's objectives, procedures, and risks. Informed consent was obtained from all patients, and the Helsinki statement guidelines were followed<sup>54</sup>.

The participating patients included 2 groups: (1) patients with PN, which includes hypertrophic, atrophic, and infected or septic forms; and (2) patients with bone loss, due to osteomyelitis (requiring resection of the involved bone) and traumatic loss (involving open fractures). The inclusion criteria were PN or bone loss involving a long bone (tibia, humerus, or femur). For the PN group, ≥1 surgical procedures must have failed previously (Table I).



Figs. 4-A through 4-E Patient 15. Fig. 4-A Infected nonunion of the distal third of the left tibia. A previous osteosynthesis attempt failed, with 24° varus deviation of the distal fragment and joint. Fig. 4-B Removal of osteosynthesis material and placement of the MIRP (minimally invasive technique) and the initiation of osteotomy. Fig. 4-C Immediate correction of the tibial and joint axes. Fig. 4-D Control of docking by means of the MIRP rail, with final compression on the infected PN. Fig. 4-E Removal of the device and docking site consolidation healing of the infected PN (4.4-Nm final compression), and

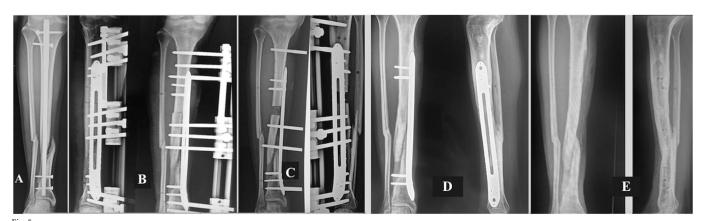
Bone compression was measured in Nm (defined as the torque resulting from a force of 1 Newton applied perpendicular to the end of a moment arm that is 1 meter long<sup>55</sup>), using a digital dynamometer at 2 points on the bone transport (by having sufficient resistance when the bones come into contact): initial compression immediately after the osteotomy (Fig. 1-A), compression during the latency phase, and final compression when bone-to-bone contact (docking) has been achieved at the end of the distraction phase (Fig. 1-B).

formation of osseous trabeculation in the distraction regeneration zone.

#### Surgical Procedure

All patients underwent bone transport using a combination of an MIRP and MEF (Fig. 1). Osteotomies were performed with a reciprocating saw, a Gigli saw, or an osteotome (Table I). All patients in the PN group had undergone at least 1 previous treatment, which had failed.

For the PN group (Figs. 2 through 5), the MIRP placement was preceded by simple lavage and the preservation of existing tissue and cells (previously present and newly formed: fibrocartilaginous tissue, inflammatory cells, and undifferentiated



Figs. 5-A through 5-E Patient 10. Fig. 5-A Atrophic PN of the right tibia, secondary to failure of fixation with an intramedullary nail. Fig. 5-B Initiation of bone transport with the MIRP. Fig. 5-C Docking at the end of the bone transport process is controlled by means of the MIRP rail, and final compression of 4 Nm and dynamization of the external fixator have been performed. Fig. 5-D Healing of the PN has been achieved by effective compression. Fig. 5-E Completely healed bone after removal of the MIRP.



Figs. 6-A through 6-E Patient 16. Fig. 6-A Bone loss (8.5 cm) caused by a firearm projectile in the distal third of the right femur. Fig. 6-B MIRP and MEF application, resulting in immediate correction of femoral length and orientation. Fig. 6-C The minimally invasive technique. Fig. 6-D Passive knee motion is begun 24 hours postoperatively. Fig. 6-E Partial weight-bearing with a walker.

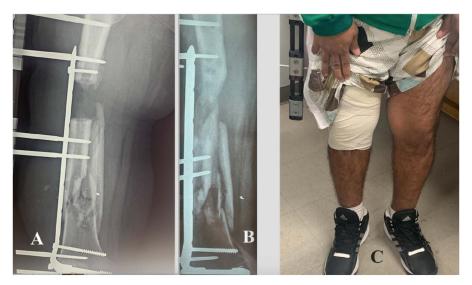
cells<sup>15,29,30,43,44,46,52</sup>) and prophylactic antibiotic treatment. The MIRP system was applied and controlled compression over the docking site was used until consolidation was obtained<sup>17,21,24,25,32,41,48,56</sup>. In cases in which a previous osteosynthesis attempt had been performed, only the material that hindered MIRP placement, bone shaft alignment, and osteotomy was removed (Figs. 4 and 5).

For patients with bone loss due to trauma, surgical management did not involve the manipulation of the edges of the affected bone and the tissue interposed between the osseous fragments (Figs. 6, 7, 8, and 9); however, it is an advantage of the technique if the angulation of the fracture is corrected so that the axis of the bone is normalized. For patients with

osteomyelitis (Fig. 10), resection of the diseased bone was performed.

All surgical procedures for both groups of patients were performed by 2 surgeons on the same surgical team of 5 surgeons. All patients underwent early rehabilitation beginning at 24 hours postoperatively (Figs. 3-C, 6-D, 6-E, and 8-D).

Bone transport began at the end of the latency period, at a rate of 1 mm/day (0.25 mm every 6 hours). Once the bone docked at its destination, compression force was increased until resistance to it increased and was measured with an objective measurement to achieve DSC (Fig. 1). The separation of the external fixator from the bone is part of the dynamization<sup>57</sup> that began after the arrival of the bone at the docking site.



Figs. 7-A, 7-B, and 7-C Patient 16. Fig. 7-A Bone arrival at the docking site 135 days after the surgical procedure. The final compression is 3.4 Nm. Fig. 7-B Bone trabeculation has formed in the DRZ when dynamization begins, separating the external fixator from the bone and then continuing to progressively remove the Schanz pins. Fig. 7-C Recovery of normal leg length, axis, and function, including gait that allowed the patient to carry out activities of daily living with partial support.

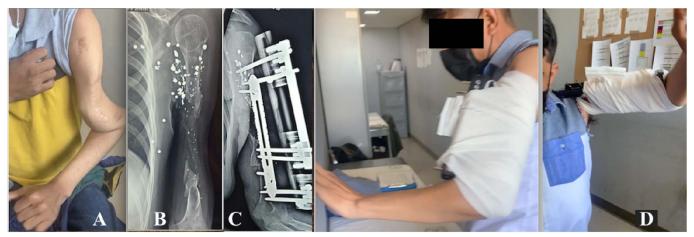


Fig. 8

**Figs. 8-A through 8-D** Patient 24. **Figs. 8-A and 8-B** Bone loss (10.5 cm) in the left humerus due to a firearm projectile. **Fig. 8-C** Initial compression is applied in the latency phase after placement of the MIRP, which has resulted in immediate recovery of bone length, orientation, and stability. The mechanobiological principle refers to the fact that the mechanical stability offered by MIRP does not interrupt the biological process of distraction osteogenesis. **Fig. 8-D** Immediate rehabilitation with the external fixator.

The removal of the external fixator was performed once the bone transport was concluded and bone mineralization began in the DRZ, indicating the beginning of the DSC (Figs. 3, 4-D, 4-E, 5-C, 5-D, 7, 9-A, 9-B, and 9-C, 10-G, and 10-H). External fixator dynamization and removal occurred in the surgeon's office.

#### Primary Outcome

The clinical team in charge of the surgical procedures performed data collection and evaluation of the intervention outcomes. In all cases, rehabilitation and follow-up were possible until complete resolution of the condition that had prompted the surgical procedure. The postoperative data collected included whether the involved location was in the proximal, medial, or distal portion of the bone (Table I); the direction of the bone transport (proximal to distal or vice versa); initial compression (Fig. 1-A); and final compression (Fig. 1-B).

Anteroposterior and lateral radiographs were made every 3 to 4 weeks during the distraction period (Fig. 1-B) and every month during the consolidation period (Fig. 1-C) until bone continuity was reestablished. Bone continuity was defined as sufficient consolidation in the DRZ and solid docking site union with signs of osseous consolidation in at least 3 cortices (Figs. 1-C, 3-D, 5-D, 5-E, 9-C, and 10-H).

Functional, clinical, and radiographic outcomes were evaluated as excellent, good, fair, or poor based on the Association for the Study and Application of the Method of Ilizarov (ASAMI) criteria established by Paley et al. <sup>22,37-40,42,49,58-61</sup> (Table II). Complications were categorized as minor or major <sup>22,23</sup>. Each patient underwent an additional 6-month follow-up after the consolidation time (CT) of the regenerate was reached (Fig. 1-C, Table III).

#### Secondary Outcomes

In addition to the functional and radiographic results, we recorded the docking time, defined as when the transported bone reaches its final destination (the culmination of the distraction phase, and the initiation of the final compression). The CT is the time that it takes to consolidate the DRZ, and starts at the end of the distraction phase. The external fixation time (EFT) is the time spent in the fixator before its removal—in our study, until DSC occurs. The DSC time was recorded as the time (in days) that it takes to consolidate the docking site, measured from when the final compression is begun at the docking site until DSC is obtained. The healing time (HT) was recorded as the time elapsed between the placement of the external fixator and the end of the consolidation phase (marked by callus in at least 3 cortices at the docking site and distraction zone callus). The HT is the sum of the latency phase (days of initial compression), the distraction phase, and the consolidation phase.

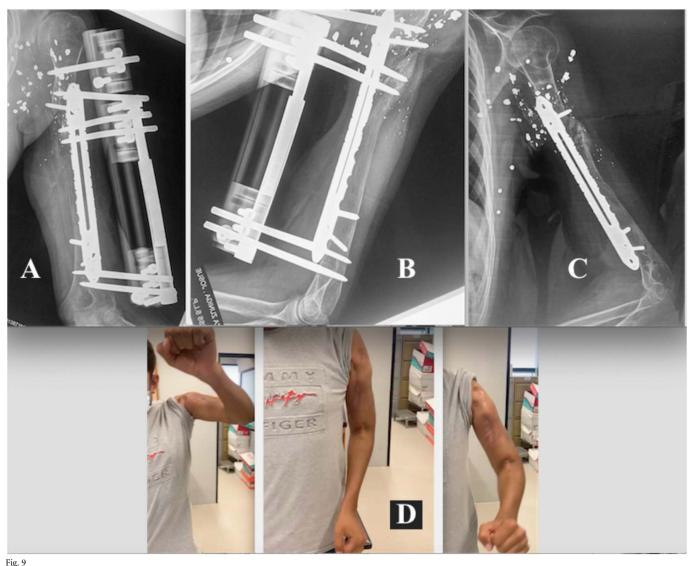
Finally, we calculated (1) the external fixation index (EFI) as the duration of external fixation in months divided by the lengthening in centimeters (EFT/distraction regenerate length [DRL]), and (2) the healing index (HI) as the time for complete bone healing in months divided by the lengthening in centimeters (HT/DRL)<sup>1,22,37-39,42,49,58-61</sup> (Table IV).

#### Statistical Analysis

We used the Mann-Whitney U and Kruskal-Wallis tests to compare continuous variables between and within groups. The Pearson r value was used to evaluate correlations. In all analyses, the significance level used was p < 0.05. The analysis was performed using RStudio (version 2023.06.1+524; The R Foundation).

#### **Results**

T he study included 32 patients; 28 (88%) were male, and 4 (13%) were female. The patient ages ranged from 20 to 80 years, with a mean (and standard deviation) of 44.93  $\pm$  16.21 years. The group with bone loss included 10 patients (31%), all male. Seven patients in this group had traumatic bone loss, and



Figs. 9-A through 9-D Patient 24. Fig. 9-A Bone transport has ended with docking at the destination. Final compression is 3.2 Nm. Fig. 9-B The distraction regeneration zone and docking site have consolidated. Fig. 9-C Consolidation has resulted in completely healed bone with normal length and alignment. Fig. 9-D The patient begins to recover the function of the arm progressively. Previously, the arm did not have any function.

the remaining 3 had osteomyelitis. The PN group included 22 patients, of whom 14 had the hypertrophic form, 4 had the atrophic form, and 4 had the infectious form. The involved bone was the tibia in 23 patients (72%), the humerus in 5 (16%), and the femur in 4 (13%) (Table I).

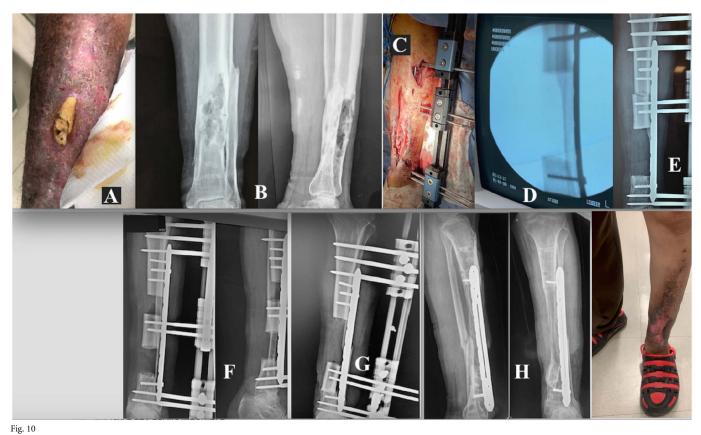
# Primary Outcomes: Compression Values and Functional and Radiographic Outcomes

The median initial compression was 3.2 Nm and the median final compression was 3.4 Nm, with no significant difference between the 2 patient groups or among their subgroups (Table V). Radiographic results were good or excellent in 31 patients (97%) and poor in 1 patient (Patient 21; 3%). Functional results were excellent in 27 patients (84%), good in 4 patients (13%), and poor in 1 patient (3%). Seven minor complications

were observed: delayed consolidation in the DRZ in 4 patients (13%) and lack of skin closure of <2 cm in the wound when inserting the plate resulting in MIRP removal after complete healing of the bone in 3 patients (9%) (Table III).

It is important to note that 6 (19%) of our 32 patients were ≥60 years of age. All of them underwent treatment for conditions in the lower limbs and had excellent osseous results and good or excellent functional results. Only 1 of these patients had a minor complication that did not require a new surgical procedure.

Only 1 patient had a major complication (Patient 21, Tables I and IV). This patient did not achieve DSC because he did not have alignment in the bone axis, had final compression of the bone that was <2.9 Nm, and had segments with <50% of the contact surface in the docking site. As a result, it was necessary to repeat the



Figs. 10-A through 10-H Patient 2. Fig. 10-A Osteomyelitis in the distal third of the left tibia. Fig. 10-B The involved bone segment. Fig. 10-C Placement of the MIRP. Fig. 10-D Resection of infected and necrotic bone tissue. Fig. 10-E Initial compression of 3.5 Nm. Fig. 10-F The MIRP rail is used for transport of the bone to its final destination and control of its docking. Fig. 10-G Completion of bone transport, with a final compression of 3.1 Nm. Fig. 10-H Complete consolidation has resulted in functional, uninfected bone.

surgical procedure to correct the alignment of the bone. The final compression during the repat procedure was 3.9 Nm, and DSC was achieved, with consolidation involving >50% of the contact surface at the docking site.

### Secondary Outcomes

The docking time (p < 0.001), healing time (p < 0.001), and EFT (p = 0.0002) were significantly shorter for the patients in the PN group compared with those in the bone loss group. The

Score	Osseous Result	Functional Result				
Excellent	Osseous union, no infection, deformity <7°, limb-length discrepancy <2.5 cm	Ability to perform previous activities of daily living, no pain or mild pain				
Good	Osseous union, failure to meet 1 of the other criteria	No limp, no soft-tissue sympathetic dystrophy, knee or ankle or shoulder or elbow joint contracture $<\!5^\circ,$ loss of joint motion $<\!15^\circ$				
Fair	Osseous union, failure to meet 2 of the other criteria	Ability to perform most activities of daily living with minimal difficulty, no pain or mild pain, failure to meet 2 of the other criteria				
Poor	Nonunion or refracture, failure to meet 3 of the other criteria	Significant pain requiring narcotics, failure to meet 3 of the other criteria				

<sup>\*</sup>Data in this table were obtained from: Paley D, Catagni MA, Argnani F, Villa A, Benedetti GB, Cattaneo R. Ilizarov treatment of tibial nonunions with bone loss. Clin Orthop Relat Res. 1989 Apr;(241):146-65<sup>90</sup>. †The upper limb included the humerus.

Patient No.	Total Follow-up (days)	Functional Result	Osseous Result	Complications*
1	363	Excellent	Excellent	None
2	421	Excellent	Excellent	Minor
3	362	Excellent	Excellent	None
4	401	Excellent	Excellent	None
5	297	Excellent	Excellent	None
6	266	Excellent	Excellent	Minor
7	347	Excellent	Excellent	None
8	345	Excellent	Excellent	Minor
9	354	Good	Excellent	None
10	402	Excellent	Excellent	Minor
11	272	Good	Excellent	Minor
12	357	Excellent	Excellent	None
13	314	Excellent	Excellent	None
14	371	Excellent	Excellent	Minor
15	327	Excellent	Excellent	None
16	606	Excellent	Good	None
17	285	Excellent	Excellent	None
18	315	Excellent	Excellent	Minor
19	374	Excellent	Excellent	None
20	294	Excellent	Excellent	None
21	283	Poor	Poor	Major
22	385	Good	Excellent	None
23	299	Good	Good	None
24	478	Excellent	Excellent	None
25	541	Excellent	Excellent	None
26	327	Excellent	Excellent	None
27	323	Excellent	Excellent	None
28	371	Excellent	Excellent	None
29	428	Excellent	Excellent	None
30	281	Excellent	Excellent	None
31	328	Excellent	Excellent	None

\*Classified according to the ASAMI criteria.

HI and EFI were significantly higher in the patients in the PN group (p < 0.001 for both) (Table V).

Within the bone loss group, no significant differences were observed between patients with trauma and those with osteomyelitis. However, within the PN group, the docking time, DSC time, EFT, and healing time were significantly lower in patients with hypertrophic PN (Tables IV and V).

#### **Discussion**

A lthough bone transport has been effectively applied for quite some time, direct measurement of compression applied at the beginning and end of bone transport can be

challenging. Currently, the compressive force applied during the bone transport process is based mainly on subjective criteria, which may lead to a higher risk of treatment failure due to a defective DRZ and a failure to achieve DSC<sup>1,9,17,20-24,34-37,40</sup>. To our knowledge, this is the first study to report direct compression measurements during the bone transport process.

This study reports on the use of bone transport for the surgical management of 2 distinct pathologies: PN and bone loss. In both, the bone transport goes through the same phases of latency, distraction, and consolidation, and it is therefore possible to optimize their management by taking advantage of the

TABLE IV Cor			DT (d )	DCOT ( )	FFT ( )	LIT ( ! )	OT ( )	EEL (m. / )	111.7- ( )
Patient No.	IC (Nm)	FC (Nm)	DT (days)	DSCT (days)	EFT (days)	HT (days)	CT (days)	EFI (mo/cm)	HI (mo/cm)
1	3.2	3.5	65	58	133	183	108	1.84	2.5
2	3.5	3.1	126	39	175	241	105	0.79	1.08
3	3.2	3.5	55	34	122	182	117	1.62	2.42
4	3.0	3.2	110	40	160	221	101	0.82	1.13
5	3.1	3	30	29	69	117	84	1.15	1.95
6	2.2	3.8	16	20	56	86	129	1.03	1.59
7	3.2	4.0	42	55	107	167	115	2.3	3.7
8	2.3	3.2	15	33	58	165	140	1.93	5.5
9	3.5	3.8	74	30	114	174	90	0.76	1.1
10	3.3	4.0	66	66	142	222	146	1.57	2.4
11	3.1	3.0	15	30	56	92	69	1.5	2.5
12	2.2	3.8	42	56	108	177	125	2.0	3.2
13	4.1	4.2	25	34	74	134	99	1.64	2.9
14	2.4	2.9	29	70	116	191	150	3.5	5.7
15	3.7	4.4	25	50	90	147	110	2.0	3.2
16	5.0	3.4	135	62	220	426	273	0.86	1.6
17	3.3	3.0	10	30	50	105	85	2.0	4.3
18	2.4	3.0	15	30	55	135	132	1.83	4.5
19	4.7	3.4	37	30	84	194	140	2.0	4.6
20	3.6	4.5	15	28	53	114	89	1.7	3.8
21	3.0	2.3	17	NA	65	103	76	1.9	3.0
22	3.4	3.2	99	40	149	205	96	0.82	1.1
23	3.2	2.9	27	22	60	119	90	1.6	3.3
24	3.3	3.2	179	55	248	298	105	0.78	0.94
25	3.5	3.1	165	66	256	361	180	0.56	0.79
26	4.0	3.2	18	32	70	147	109	1.79	3.7
27	3.5	3.4	14	30	59	143	102	1.96	4.7
28	3.2	3.1	96	40	147	191	85	0.76	0.9
29	3.1	3.2	128	50	192	248	110	0.8	1.0
30	2.8	3.2	16	30	56	101	75	1.86	3.3
31	2.9	3.2	48	30	88	148	90	0.97	1.6
32	3.0	3.5	8	35	53	110	92	2.5	5.2

\*IC = initial compression, FC = final compression, DT = docking time, DSCT = docking site consolidation time, EFT = external fixation time, HT = healing time, CT = consolidation time of the regenerate, EFI = external fixation index, HI = healing index, and NA = not applicable.

stability provided by an MIRP. Likewise, these common characteristics make it possible to study the effect of bone compression on achieving the DRZ and DSC. The objective of bone transport is to achieve the DSC; however, in the treatment of PN, maintaining compression in the final phase of distraction, until achieving the DSC, produces healing and consolidation. However, this compression must have the characteristics of what we call effective compression.

In our study, we identified effective initial and final bone compression levels objectively as those that always produced 2 results during bone transport: (1) consolidation of the DRZ without complications (which was found to occur consistently at an initial compression of  $\geq$ 3.2 Nm), and (2) achieving the DSC when there was adequate alignment of the bone axis, stability during distraction, and contact at >50% of the docking site (which occurred consistently at a final compression of  $\geq$ 2.9 Nm). All patients achieved the DSC without subsequent procedures when the identified effective compression level of  $\geq$ 2.9 Nm was applied during the final stage of distraction. Effective bone compression also led to few complications and subsequent surgical procedures compared with previous studies<sup>17,22-24,40,62-65</sup>.

	Bone Loss Group									
	OBL	TBL	P Value†	Group Median	APS	HPS	SPS	P Value†	Group Median	Between-Group P Value
CBT (Nm)	3.4	3.3	0.8175	3.35	3.2	3.1	3.2	0.9338	3.2	0.2885
CBT (Nm)	3.1	3.2	0.1390	3.2	3.65	3.2	3.75	0.5504	3.4	0.4351
OT (days)	99	128	0.5167	118	48.5	15.5	35.5	<b>0.0029</b> §	21.5	<b>&lt;0.001</b> §
OSCT (days)	40	50	0.4875	40	45	30	56.5	<b>0.0099</b> §	32	0.0962
FT (days)	149	192	0.5167	167.5	115	57	111.5	<b>0.0022</b> §	67	<b>&lt;0.001</b> §
HT (days)	205	248	0.5167	231	179.5	115.5	175	<b>0.0147</b> §	139	<b>0.0002</b> §
CT (days)	96	105	0.3021	103	121	95.5	112.5	0.1826	108.5	0.9838
EFI (mg/cm)	0.79	0.8	0.8186	0.795	1.61	1.845	2.15	0.0875	1.85	<b>&lt;0.001</b> §
HI (mg/cm)	1.08	1.1	0.5664	1.09	2.81	3.75	3.45	0.3080	3.3	<b>&lt;0.001</b> §

\*PN = pseudarthrosis-nonunion, OBL = bone loss due to osteomyelitis, TBL = traumatic bone loss, APS = atrophic pseudarthrosis, HPS = hypertrophic pseudarthrosis, SPS = septic pseudarthrosis, ICBT = initial compression during bone transport, FCBT = final compression during bone transport, DT = docking time, DSCT = docking site consolidation time, EFT = external fixation time, HT = healing time, CT = consolidation time, EFI = external fixation index, and HI = healing index. †Mann-Whitney U test. †Kruskal-Wallis test. §Significant.

The EFT was shorter among patients with bone loss than that reported for the Ilizarov technique. Moreover, the mean EFI of patients with bone loss was 0.79 months/cm, <50% of the 1.7 months/cm reported for the use of the Ilizarov circular ring<sup>45,58</sup> and comparable with that reported for bone transport using an intramedullary nail<sup>61,66</sup> or minimally invasive plate osteosynthesis<sup>37,46,59</sup>.

Notably, we observed that the placement of this device is well tolerated even among elderly patients. The 6 patients between 60 and 80 years of age had no loosening of the pins, which can be attributed to the adequate distribution of loads (by the MIRP and MEF) and the improvements in angular stability offered by the locking screw and the locking Schanz pin<sup>67-69</sup>.

Aside from allowing the direct measurement of compression applied during bone transport, the MIRP-MEF combination facilitates control and stability at the proximal and distal sites in the bone. The combination provides direct fixation, neutralizing the loads during the distraction phase and the negative effect of cantilever bending that would deliver asymmetric compression to the fracture site<sup>52,57,70-76</sup>. Furthermore, these characteristics spare the patient from pain and promote fibrous union during consolidation, resulting in the prevention of sagittal deformity by adequately protecting the distraction callus during early mobilization<sup>37,58-63,77-82</sup>.

An additional benefit of MIRP is the transport of the bone segment from its initial site to its final site on a rail, which avoids deviation from the bone axis and thus displacement at the docking site, and enables an uninterrupted distraction osteogenesis cascade<sup>37,70,71,83-89</sup>. That additional advantage, added to its compact design (which reduces the patient's loss of mobility), makes this combination a better alternative than the Ilizarov device for patients needing bone transport in an upper limb<sup>20,22-24,34,54,63,66,75,80</sup>.

A potential source of bias in this study is the evaluation of patients by the surgeons who performed the procedures. However, radiographic evidence confirmed the results of the evaluation. Despite limitations such as a small sample size and the lack of comparison with traditional treatment, the results suggest that combining MIRP and MEF in distraction osteogenesis, along with the use of compression forces within specific ranges, offers several advantages over other procedures, including structural stability, ease of use, lower failure rates, more reliable achievement of the DSC, and shorter treatment times. However, these conclusions should be corroborated in further studies comparing the MIRP-MEF combination with the conventional technique (the Ilizarov circular ring).

In conclusion, all patients who received initial compression of  $\geq$ 3.2 Nm had consolidation of the DRZ without complications such as delayed consolidation, a distraction zone defect, axial deviation, retraction of the transported segment, or refracture. Additionally, our data suggest that the application of this device with a minimum final compression of  $\geq$ 2.9 Nm achieves the DSC in patients who have adequate alignment of the bone axis, stability during distraction, and contact at >50% of the docking site, and avoids the development of complications such as delayed consolidation, nonunion, and retraction of the transported segment 6-9,20,22,24,35,37,40,58,60,73,89. The initial and final compression values of  $\geq$ 3.2 and  $\geq$ 2.9 Nm can therefore be termed effective compression levels.

We hope to contribute to optimizing a surgical technique described >40 years ago, making it more attractive to a new generation of orthopaedists to resolve complications related to fracture (PN, osteomyelitis, and bone loss).

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