JMS 2021;4(2):76-85
UDC:616.718.5-089.84

COMPRESSION - DISTRACTION OSTEOGENESIS WITH ILIZAROV APPARATUS IN THE TREATMENT OF TIBIAL NON-UNIONS WITH BONE DEFECT

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Abstract

Treatment of the long bones defects and non-unions are among the most challenging cases to solve in the orthopaedic surgery. In these rare and difficult cases the method of compression - distraction osteogenesis can be the only limb salvage procedure to promote healing of the bone with comprehensive approach to all aspects of the condition.

Objective of this retrospective one centred study is to perform both radiological and functional evaluation of the treatment of tibial non-unions with segmental bone defects or significant axial deviation using the method of compression - distraction osteogenesis with the Ilizarov apparatus. In the period between 2006 and 2018 15 patients were surgically treated using this method (in 9 of them as an intercalary bone transport and in other 6 as a continuous distraction with correction of axial deviation). There was an average of 22.9 months from injury and all of them underwent previous surgeries with an average of 2.3/patient.

ASAMI (Association for studying and application of Ilizarov methods) scoring system was used for both radiological (bone) and functional results. Also patient's satisfaction with the achieved results was ranked postoperatively. 80% of the patients achieved satisfactory (good and excellent) bone results and 73% satisfactory functional results. Approximately 87% of the patients were personally satisfied with the achieved results.

The method of compression - distraction osteogenesis using Ilizarov apparatus proved to be effective as a limb salvage procedure with high degree of excellent and good both radiological and functional results.

Keywords: compression-distraction osteogenesis, Ilizarov, non-union, bone defect

Introduction

Treatment of the tibial segmental bones defects and non-unions are among the most challenging cases to solve in the orthopaedic surgery. Numerous causes can lead to both non-unions and further on to bone defects. Usually the development of a tibial non-union is related to the type of injury and its severity but also factors like degree of bone comminution, whether the fracture is open, degree of periosteal and soft tissue stripping and complications like infection or compartment syndrome can predispose a patient to development of non-union with consequent bone defect [1].

Seen from their both clinical and economical aspect these pathological entities continue to represent burden of the disease and still a great challenge to solve. Despite a need for evidence based decision making there is still lack of consensus even around their definitions. In general, a "critically-sized" defect is regarded as one that would not heal spontaneously despite surgical stabilization and requires further surgical intervention.

Non-union on the other hand was defined according to the definition of Brinker and O'Connor as a fracture that, in the opinion of the treating surgeon, has no possibility of healing without further intervention. This only can give us a glimpse that at the end the treatment is still and

mostly based on individual approach. Current therapeutic approaches include bone grafting like autogenous or free vascular fibular graft, compression - distraction osteogenesis, induced membrane ("Masquelet") technique etc. There are also some researches and development of tissue engineering strategies and products that can provide all three of the factors deemed essential for bone healing: osteoconductive scafold, growth factors for osteoinduction, and cells with osteogenic potential [2].

But all of these methods have their disadvantages like morbidity of the donor site and stress fractures in the method of bone grafting as well as limitations according the size of the bone defect. Besides that, none of them can simultaneously solve all the complications due the main pathology like soft tissue defects, adjacent joint contractures etc.

Ilizarov first reported on the technique of distraction osteogenesis in the 1950s [3].

The method of compression - distraction osteogenesis is a technique of spontaneous production of vascularised bone during a process of lengthening reconstructive procedure of the bone within its surrounding soft tissues. This technique utilizes the bone's natural capacity for regeneration under tension. A corticotomy is made in healthy bone at a distance from the defect site in order to create a free segment of living bone which is further distracted (transported) to the defect site.

During this strictly controlled process bone production of new vascularised bone is seen between the two corticotomy surfaces. The process of bone formation in the distraction gap is histologically similar to intramembranous ossifcation [4, 5].

Compression - distraction transport is achieved mechanically by attaching the segmental fragments to a circular frame (Ilizarov apparatus) with tensioned wires, which allows distraction at the corticotomy site and afterwards compression at the docking site. The principle of compression - distraction osteogenesis can be also used in treating nonunions without segmental bone defects but with great axial deviation. In those cases with or without performing corticotomy near or through the non-union new bone formation and consequently healing of the non-union is achieved by continuous distraction-correction of the axial deformity [6]

The method of compression-distraction osteogenesis with the Ilizarov apparatus trough out the literature proved to be effective in the treatment of non-unions with segmental bone defects of the long bones of the lower extremities.

Material and Methods

Objective of this retrospective one centred study is to perform both radiological and functional evaluation of the treatment of tibial segmental bone defects and non-unions using the method of compression - distraction osteogenesis with the Ilizarov apparatus.

In the period between 2006 and 2018, 15 patients were treated using this method in the Special hospital for orthopaedic surgery and traumatology "Sv. Erazmo" – Ohrid, North Macedonia. Nine of them underwent an intercalary bone transport and other six continuous distraction with correction of axial deviation, with overall female to male ratio 0.25 (f:m=3:12).

All the patients were evaluated pre operatively in terms of previous number of surgical treatment, chronicity of the situation (measuring the time from injury to the beginning with the present treatment), size of cortical defect in cm, angular axial deviation in degrees, presence of infection and presence of contractures in adjacent joints. (Table 1)

Table.1 Preoperative evaluation of subjects

	Age	Months from injury	Sex	Diagnose	Surgeries	Bone defect in cm	Degrees of angulation	Infection	Contracture of adj. joints
1	64	105	M	Deviation	5		70	Yes	No
2	36	21	M	Defect	1	8		Yes	No
3	66	7	M	Defect	4	7		Yes	No
4	30	16	M	Defect	1	5		Yes	Yes
5	39	20	F	Defect	1	7		Yes	Yes
6	23	9	M	Defect	3	6		Yes	Yes
7	29	33	M	Defect	4	5		No	Yes
8	29	6	M	Defect	2	10		Yes	Yes
9	34	11	M	Deviation	1		35	No	No
10	63	23	M	Deviation	0		40	No	Yes
11	52	34	F	Deviation	2		45	No	No
12	33	29	M	Defect	4	4		No	No
13	69	13	F	Deviation	0		38	No	No
14	19	9	M	Deviation	5		44	No	No
15	51	8	M	Defect	2	4		Yes	Yes

The average age of patients was 42.5 years (range from 19 to 69) and all the patients were previously treated for the given condition. The chronicity of the non-union was approximately 22.9 months from the injury to the described treatment and the patients underwent previously an average of 2.3 surgical treatments before the proposed treatment. (Image 1)

Image 1. Preoperative condition with skin defect and necrotic bone sequester

In the patients with a segmental bone defect the average length of the defect was measured 6.2 cm (ranging from 4cm to 10cm) and in 78% of them there was an accompanied osteomyelitis which required block resection of the bone before the intercalary bone transport.

In the group of patients that were treated with gradual correction of axial deviation only one patient presented with infection on admission, the average deviation was measured 45.33 degrees cumulatively in both planes and two thirds of them needed an additional corticotomy to achieve the gradual correction and healing of the non-union. During preoperative clinical investigations in 7 of the patients (47% of the group) a contracture of ankle joint and foot was noted which required simultaneous correction with a system upgraded to the Ilizarov frame (Image 2).

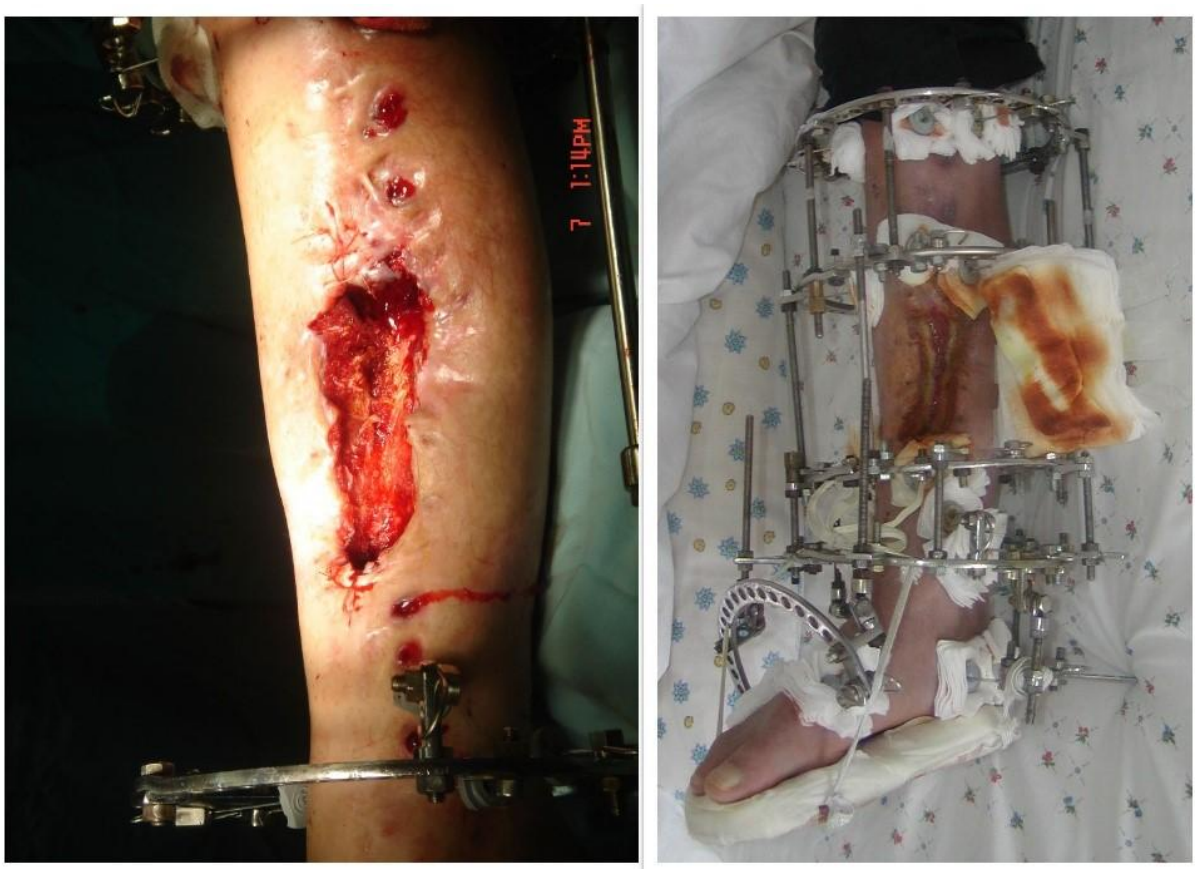

Image 2. Situation after bone tresection and application of Ilizarov apparatus

Inclusion criteria applied to all patients were:

- Age 18 or over
- Consent for surgery and anaesthesia
- Presence of tibial non-union with segmental bone defect or significant axial deviation which could not be corrected on manipulation
- Treatment achieved through the principle of compression - distraction osteogenesis using Ilizarov apparatus
- Possibility of follow up and postoperative evaluation according ASAMI criteria

Two standard radiographic views (anteroposterior and lateral view) were used to evaluate segmental bone loss and/or axial deviation of the bone in two planes preoperatively. In all patients complete laboratory blood analysis were done and in ones with wound or skin defect a swab was made for microbiological analysis.

All the surgeries were done in spinal anaesthesia. We used usually fixation of the bone in 4 segmental rings with using 3,2,2,3 wires respectively. Additionally in the patients that had contracture

of the ankle joint and foot a system for correction of the foot was constructed and complemented to the frame. Intraoperative radiological investigations were made to evaluate the need for alignment of the frame and fragments.

During the surgery intravenous antibiotics were administered and the antibiotic regime was continued for at least five days postoperatively, or in cases with infection for at least 4-6 weeks. Postoperatively thromboprophylaxis with low molecular heparin products was continued for at least 5 weeks.

All the patients starting from the second postoperative day started walking with minimal to partial weight bearing with tendency further on to full weight bearing. In patients with corticotomy there was a latency period of 5-7 days before starting with a gradual distraction/correction of the bone. In patients with intercalary bone transport the distraction rate was set at 1 mm/day divided in 4 times by 0.25mm (Image 3).

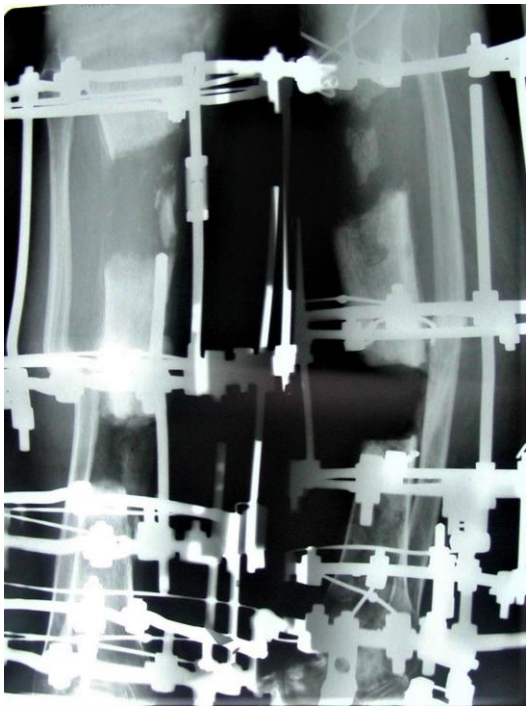

Image 3. X-rays during the distraction phase of the bone transport

In patients with gradual axial correction with distraction the distraction rate was the same but only on the planned rods with occasionally loosening and adjustment of the joints of the frame in the plane of correction.

None of the patients with intercalary bone transport needed additional surgery for adjustment of the docking site and the compression of the docking site was performed without opening. After gaining the previously planned length of the bone regenerate or the adequate axial correction concluding the distraction phase, the Ilizarov apparatus was set in a regime of fixation with further occasional compression performed at the docking site.

During the whole distraction phase the patient remained in hospital, and afterward regular check-ups and dressing were made once weekly and control x-rays once on every 4-6 weeks during the consolidation phase. The consolidation of the bone regenerate and of the non-union was confirmed when there was no visible cortical radiolucency line on at least 3 of 4 cortices on x-rays in both planes. After that another surgery was planned in short iv anaesthesia for removing the Ilizarov device and a cast imobilization for weight bearing was applied for additional 3-4 weeks. Control x-rays were done 1 month after removing the Ilizarov frame, and functional scoring 3-6 months from removing the frame. (Image 4)

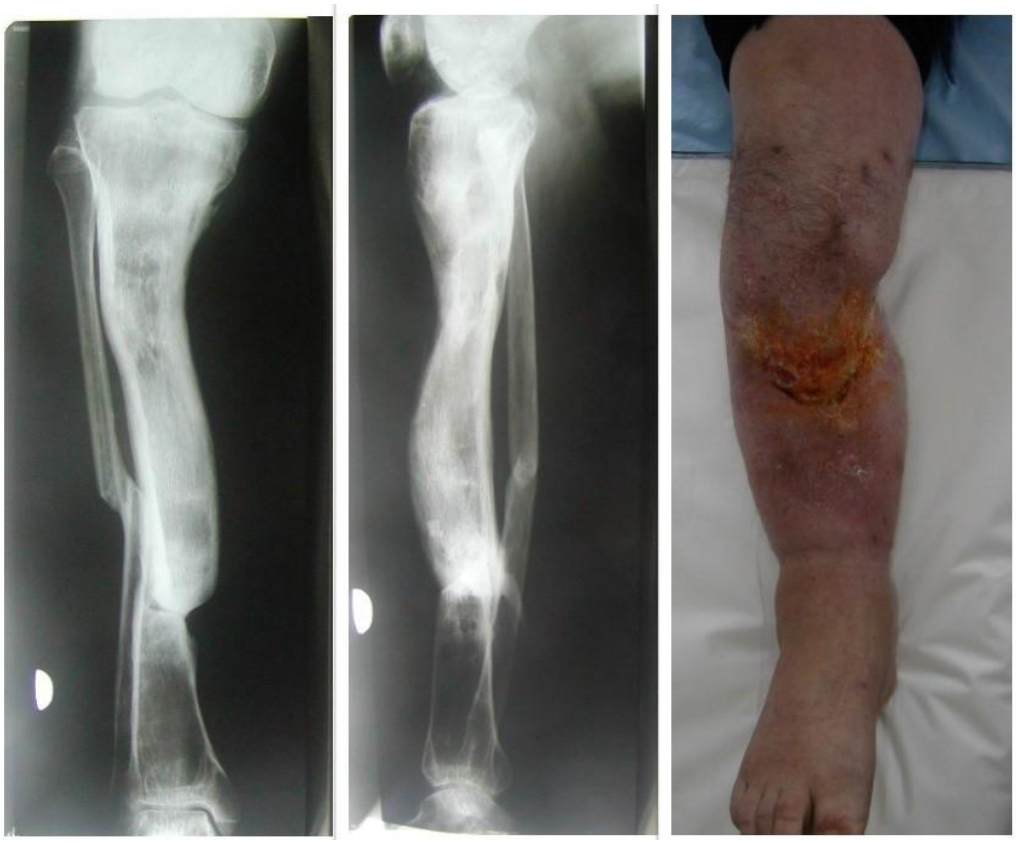

Image 4. Postoperative photo after removing the Ilizarov frame showing consolidation of the bone, skin and soft tissue defect during the bone transport process

Results

All the patients were evaluated post operatively after the removing the Ilizarov frame and we calculated: External Fixation Time (the whole period of treatment from application till removing the frame) and in cases with bone transport Healing Index (External Fixation Time per centimetre gained in distraction), Radiographic Consolidation Index (months until radiographic consolidation per centimetre of distraction).

Patients were also evaluated according the ASAMI (Association for studying and application of Ilizarov methods) scoring system for both radiological (bone) and functional results and ranked in four categories: excellent, good, fair and poor. (Table 2)

Table.2 Postoperative evaluation of subjects

	External fixation time (days)	Healing index (days/cm)	Radiografic consolidation index (days/cm)	ASAMI bone score	ASAMI functional score	Satisfaction from treatment
1	359			3	3	4
2	326	40.	29.8	4	3	4
3	316	45.	33.7	3	3	4
4	215	43	31	4	4	4
5	361	51.	40.1	4	3	4
6	339	56.	44.8	3	2	3
7	386	77.	63.2	3	3	3
8	434	43.	32.4	4	4	4
9	179			4	4	4
10	149			4	3	4
11	246			4	3	4
12	343	85.	73.3	2	2	2
13	126			3	3	3
14	249			2	2	3
15	263	65.	53.3	1	1	1

Bone results were based on four criteria: reaching bone union, persistence of infection postoperatively, axial deformity of the bone more/less than 7 degrees and leg length discrepancy (LLD) more/less than 2.5 cm.

The functional results were calculated on five criteria: presence of pain (no or mild vs. significant pain); ability to return to normal activities of daily living (ADL); presence of limp; ankle or knee deformity or contracture as compared to more/less than 5 degrees; ankle and/or knee loss of range of motion compared with the preoperative range with more/less than 15 degrees of lost of motion and presence of soft tissue sympathetic dystrophy.

During the postoperative evaluation all the patients were asked to rank their satisfaction with the results achieved in a scale 1 to 4 (1 meaning"highly dissatisfied" and 4 representing"highly satisfied").

The average measured External Fixation Time in all the patients was 289.07 days, in patients with intercalary bone transport was 331.44 days and in patients with gradual correction was 218 days. In the first group the calculated average Healing Index was 56.57 days/cm or 1.9 months/cm (range from 40.75 to 85.75 days/cm), and Radiographic Consolidation Index of average 46.14 days/cm (1.5 months/cm).

According to the postoperative results from ASAMI scoring system regarding the radiological (bone) scoring results 12 patients (80% of the subjects) had satisfactory results with 58% of them as excellent and 42% of them as good bone results. Remaining there were 2 patients (13% of all patients) with fair and only one subject (7% of the group) with poor bone results.

Considering the functional results 11 patients (73%) achieved satisfactory results with 27% of them as excellent and 73% of them as good functional results. The rest 4 patients were scored 3 of them as fair and 1 of them as poor.

On the other hand when all the patients during the functional scoring were asked to rank their satisfaction with the results achieved in scale 1 to 4, 13 patients or 87% stated their satisfaction as 3 and 4, one patient ranked 2 and one patient ranked as 1.

Using the Mann-Whitney U test for testing the significance between two ordinal variables we tested the significance between the bone and functional scores as well as the satisfaction ranking.

We only found significant difference between the functional scoring and satisfaction ranking with value p=0.03593 (stating p<0.05 as significant).

Discussion

The method of compression - distraction osteogenesis with the Ilizarov frame is widely used in the treatment and reconstruction of the posttraumatic conditions of the lower extremities. This method enables useful tool to the clinicians in the treatment of difficult cases as: reduction deformity of lower extremities, infected non-unions with bone and soft tissue defects, big angular and rotational deformities, joint contractures as well as treatment of open fracture with seriously damaged soft tissue coverage[7].

In a prospective observational study of 416 patients from 41 trauma centres that underwent operative treatment of tibial shaft fractures, delayed healing or non-union occurred in 13%.

In open fractures with wounds greater than 5 cm, the likelihood of delayed healing or non-union was 5.7 times greater than that for closed fractures [8, 9].

Main advantages of the proposed method are: minimal invasive approach which reduces the risk of infection, possibility for regeneration of bone tissue from a healthy non-traumatized bone-donor, addressing the bone defect simultaneously with all the concomitant soft tissue defects and complications as severe joint contractures. At the same time it enables the patient partial to full weight bearing on the injured extremity that lowers the risk of postoperative sympathetic algodistrophy.

On the other hand the proposed method has some disadvantages among which the main is lengthy treatment with need of long hospitalization especially during the distraction phase. Also there is need for further frequent outpatient visits during the treatment.

Besides that there is psychological and social burden of the patient including: pain (which is most intense during the distraction phase), stress and long term disability that limit the everyday activities of the patient. [10].

During the distraction phase when we are at the same time treating both bone and soft tissue defects patients report significant pain due to muscles and nerves stretching which can afterwards lead to joint contracture. That's why we accent the need of continuous rehabilitation program and treatment for maintenance of the joint mobility. In the presented series in 93% of the patients there was no reduction of the adjacent joints mobility compared to preoperatively.

During the treatment there is also possibility of developing some complications most of them with low risk to jeopardize the treatment results as local pin tract infection. That is usually treated with more frequent local dressings and short term oral antibiotics. In the researched group in 73% of the patients we encountered these complications and all of them were treated successfully. In one patient (7% of the subjects) during the distraction phase there was an indication of reconstruction of the frame due to deviation of the bone fragment during the intercalary transport. That procedure was done in short iv anesthesia without long term consequences on the treatment itself.

When we are considering the duration of the treatment, the clinical data from other studies report Healing Index between 0.4 and 2.1 months per centimeter gained bone. In this research group the average Healing Index is 1.9 which is in the published data range.

In some other clinical researches there is a suggestion that bone defects bigger than 6 cm should be treated with trifocal bone transport or with concomitant usage of intramedullary nails. In their opinion in that way we can reduce the treatment time with presenting data of Healing Index as low as 0.4 [11, 12].

According to one meta-analysis of 37 studies of bone transport 2.6% of the patients had an amputation of the limb, and half of those were required by the patients [13].

In our research we don't have similar data, but therefore we once more claim that all the patients should be preoperatively fully informed for the type and duration of the treatment as well as their meticulous preoperative selection.

There are few limits of this study. It is a retrospective one-centered study with small number of research subjects which raises questions about the possibility of generalization or eventual bias of the results. The size of the group also limits complete statistical evaluation of the results.

Another limit was that we didn't have possibility for a long term follow-up and evaluation of the patients. Only in half of the patients we have data for a functional scoring one year after removing the Ilizarov apparatus. But besides the mentioned limits, we still think that these small series are

important in giving additional support that the method of compression - distractional osteogenessis with the Ilizarov apparatus can be a method of confidence in reaching bone healing and correction in these difficult reconstructive challenges.

The possibility of acquiring excellent bone result even in the worse bone surroundings does not guarantee also a good functional result except the patient has good neurovascular status of the limb.

The functional result is predetermined of the condition of the muscles, nerves, vessels, adjacent joints, and in smaller amount by the bone tissue status [14].

Further with an accent of creating defined protocol pre and post operatively, and with a special accent of the rehabilitation, the patients are enabled for achieving acceptable functional results.

On the other hand in this research we got a statistically significant difference between the personal satisfaction of the patient with the treatment and the functional outcome of it.

That is due to the length of the given condition and presence of numerous previous unsuccessful treatments, as well as an ever-present possibility of amputation of the limb in all phases of treatment. In that manner satisfaction of the treatment in patients is multiplied even by achieving bone healing and ability of weight bearing after removing the frame.

Conclusion

The method of compression - distraction osteogenesis with the Ilizarov apparatus proved to be an effective in the treatment of the tibial non-unions with concomitant bone defects and severe axial deviation.

The treatment evaluation shows high percentage of overall bone healing of the non-unions with also high percentage of excellent and good both radiological and functional results. There is also a high level of personal patient satisfaction with the treatment results.

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