Comparative Study between Ilizarov Techniques and Induced Membrane Technique in Management of Bone Defects in the Tibia

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Abstract: Background: Tibia, as subcutaneous bone, is more exposed to fracture (62%) which often complex and may result in nonunion and bone loss. Reconstruction of critical size bone defects is often challenging and associated with lengthy healing or rehabilitation times and unpredictable union rates, or they use methods that are poorly tolerated. Current management options include intercalary bone transport and distraction osteogenesis, vascularized bone transfer, non-vascularized bone transfer, and recently, use of induced membranes has shown potential as an alternative reconstruction method for critical size bone defects. **Objective:** Comparison study between Ilizarov techniques (distraction histogenesis through bone transport) and induced membrane technique in management of bone defects of the tibia, in thirty patients in Al-Azhar University Hospitals (El Hussein and Bab El Sheryia Hospitals). **Patients and Methods:** This is a prospective study on thirty patients with tibial non-union with bone defect more than 4 centimeters, operated at Al-Azhar University Hospitals from September 2011 and March 2016. The bone defect in this current study due to traumatic bone loss, traumatic fracture complicated by infection, osteomyelitis, and tumors. The cases of the study were classified into two groups, group A which included fifteen patient managed by induced membrane technique and group B which included fifteen patient managed by bone trans port technique. All patients agreed to be included in this study. In this study evaluations the results of their using association for study and application of methods of Ilzarov (ASAMI) scoring system. **Results:** This study was carried over period of three years. In our study According to (ASAMI) score. In group A, 5 patients (33.3%) had excellent, 5 patients good (33.3%), and 5 patients (33.3%) had a poor radiological results. Regarding the functional ASAMI scoring system 3 patients (20 %) had excellent, 7 good (46.7%), and 5 patients (33.3%) of poor functional results. According to (ASAMI) score in group B, 10 patients (66.7%) had excellent radiological results, 4 patients good (26.7%), and one patient (6.7%) had a poor radiological results. Regarding the functional ASAMI scoring system 3 patients (20 %) had excellent, 11 good (73.3%), and one patient (6.7%) of poor functional results. **Conclusion:** Tibial bone defect can be managed by the induced membrane if complex procedures to reconstruct the soft tissue are excluded otherwise bone transport technique more reliable.

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Keywords: Tibial bone defect, Induced membrane, Bone transport.

Introduction

Tibia, as subcutaneous bone, is more exposed to fracture (62%) which often complex and may result in nonunion, osteomylitis and bone loss. Bone defects may result from a variety of causes. They may be due to trauma, bone infection, congenital defects or extensive excision of malignant tumors. The "critical size defect" defines the smallest sized defect, in a specific bone of a species, which will not heal or undergoes less than 10% regeneration. It is often considered to be the case when the length of the deficiency is 2–3 times the diameter of affected bone ***(Ashman and Phillips, 2013).***

Reconstruction of large segmental bone defects is often challenging. However, most techniques for reconstruction of significant bone loss are associated with lengthy healing or rehabilitation times and unpredictable union rates, or they use methods that are poorly tolerated. Current management options include intercalary bone transport and distraction osteogenesis, vascularized bone transfer, non vascularized bone transfer, massive cancellous autograft transfer, and synthetic calcium-based fillers ***(Taylor et al., 2012).***

The choice of treatment in a given case must be based on an assessment of local factors and on the general condition of the patient. Local factors which must be taken into consideration include regional blood supply, the presence, severity and location of any nerve lesions, and the residual articular and muscular function. Reconstruction is indicated only if local factors suggest that a good functional recovery may be predicted ***(Lavini et al., 2010).***

Recently, use of induced membranes as an alternative reconstruction method for large segmental bone defects. This technique was discovered largely by accident; the induction of this membrane was an unanticipated finding. ***Masquelet and Begue (2010),***

used cement spacers to manage infected nonunions with bone loss, and the resultant membrane was initially maintained at the time of final grafting only to limit surgical devitalization and subsequent blood loss. A bioactive membrane is created via placement of a temporary polymethyl methacrylate (PMMA) spacer, and the membrane is later filled with cancellous autograft ***(Taylor et al., 2012).***

2. Patients and Methods:

This is a prospective study was carried out on thirty patients with tibial non-union with bone defect more than 4 centimeters, operated at Al-Azhar University Hospitals from September 2011 and March 2016. The bone defect in this current study due to traumatic bone loss, traumatic fracture complicated by infection, osteomyelitis, and tumors. The cases of the study were classified into two groups, group A which included fifteen patient managed by induced membrane technique and group B which included fifteen patient managed by bone transport technique. In group A the mean age was 28.8 years (10-44 years) and in group B the mean age was 28.93 (14-50 years). Regarding to gender two female and 13 male in group A, one female and fourteen male in group B. the patients will be assessed clinically and radiologically using AP, lateral views, and scanogram or long film x ray will be used to assess deformity and limb length discrepancy. The result was evaluted using the Association for the Study and Application Methods of Ilizarov (ASAMI) Scoring System ***(Lavini et al., 2010).***

Surgical technique of induced membrane

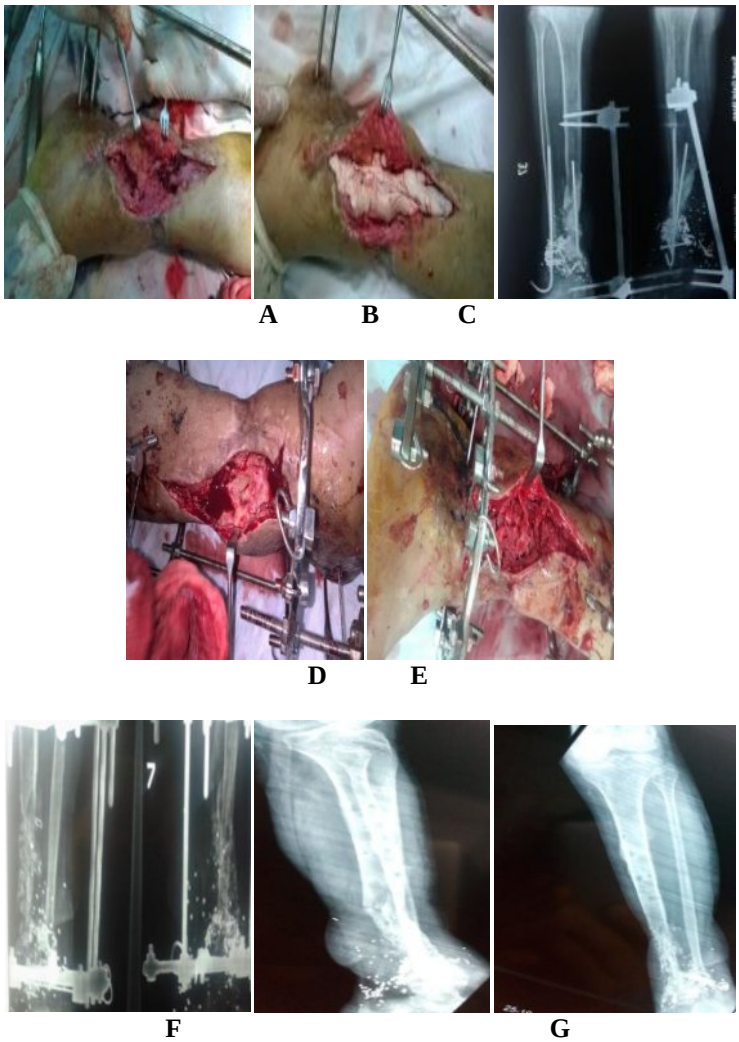


Fig. 1: A-intra operative photo demonstrate the defect. B-intra operative photo demonstrate cement filling the defect. C-post operative x ray after first stage. D-demonstrate membrane intra operative. E-filling the defect with bone graft. F-follow up x ray after six month. G- demonstrate bony union.

The technique formed of two steps:

1. Removal of all devitalized bones (debridement), reconstruction of the soft tissue and filling the bone defect by bone cement poly methylmethaclyate (PMMA). Fixation of the bone by external or internal fixator.

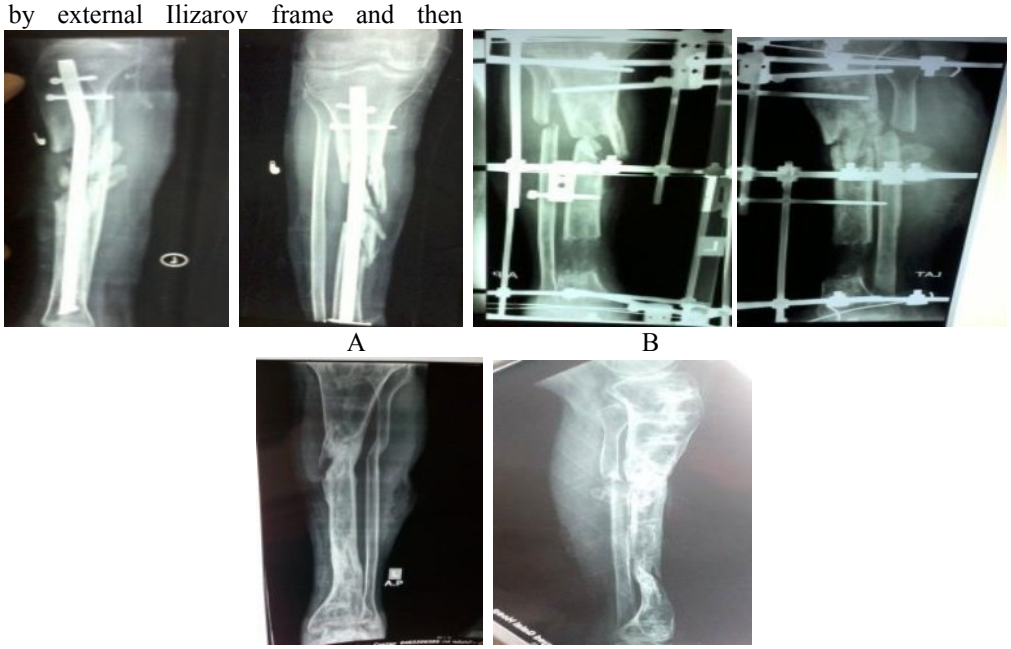
Six week later bone cement was removed and the defect filled with auto graft or auto and allograft (3:1). Fixation of the bone using Ilizarov frame (fig1).

Surgical technique of bone transport:

1. All devitalized bones were removed (debridement), and soft tissue coverage. Fixation of the bone by external Ilizarov frame and then cortictomy was done submetaphyseal. Fibular osteotomy was carried out only in cases associated with shortening to manage the large bone defect (more than 6cm).

2. Bone transport initiated after latency period of seven to ten days postoperative according to the site of corticotomy, bone and soft tissue condition. The rate of transport was 1mm distraction and 2 mm compression until the docking site sowed compression and the calculated defect was compensated (fig.2).

3. If the docking site showing sing of non-union bone grafting were done (nine patients).



A B C

Fig. 2: A- Pre-operative x ray. B-Demonstrate distraction histogensis and bone transport to the docking site. C- Demonstrate bony union.

All patients were motivated to do active range of knee and ankle motion, heel cord passive stretch and isotonic quadriceps exercise on the first day after surgery and follow up in the out patient clinic monthly.

Statistical analysis

Data were analyzed using Statistical Program for Social Science (SPSS) version 20.0. Quantitative data were expressed as mean ±standard deviation (SD). Qualitative data were expressed as frequency and percentage.

The following tests were done:

- Independent-samples t-test of significance was used when comparing between two means.
- Chi-square (X2) test of significance was used in order to compare proportions between two qualitative parameters.
- Probability (P-value)
  - P-value <0.05 was considered significant.
  - P-value <0.001 was considered as highly significant.
  - P-value >0.05 was considered insignificant.

3. Results

All demographic data according to age, gender, occupation, time of interval between onset of complaint and operation (days), and, affected side were non statistically significant.

Table (1) shows no statistically significant difference between both groups according pathology. This table show statistically significant difference between group A versus group B according to the skin condition in which three teen cases in group A were done local flaps versus eight cases in group B, and five cases were done free flaps in group A versus one case in group B. In group A four patient done many plastic operation (three done gastrocnemius flap then free flap, and one done fascio cutaneous flap then done free flap).

Table (1): Comparison between groups according pathology and skin condition

	Group A (n=15)		Group B (n=15)		Chi-square	
	No.	%	No.	%	x2	p-value
Pathology						
▪ Atrophic non union	1	6.7%	4	26.7%	4.316	0.229
▪ Chronic osteomyelitis	2	13.3%	3	20.0%		
▪ Post traumatic	12	80.0%	7	46.7%		
▪ Tumor	0	0.0%	1	6.7%		
Skin Condition						
▪ Local flap	13	86.7%	8	53.3%	9.664	0.008
▪ Free flap	5	33.3%	1	6.7%		

Complications:

Postoperative complications were classified according to ***Paley (1990),*** he classified complications into:

- Problems (minor complications) that did not require additional surgery.
- Obstacles (major complications) that resolved with additional surgery.
- Sequelae (true complications) are those complications that remained unresolved at the end of the treatment period.

Group A:

1. Pin tract infection as all of patient we fix the bone with Ilizarov frame. most of PTI is grad one except two patient grad II treated by removal of the infected schinz and debridement.
2. Revision of the technique: two patients due to infection.
3. Deformity: one patient has external rotation and one patient had recurvatum.
4. Limb length discrepancy: one patient had < 2.5cm and four had ≥2.5cm.
5. Failure of the technique: in five patients. two patients due to infection of the bone cement with big ulcer in the skin 2.5 x 5, and one patient had infected cement and sinus discharging pus, so those shifting to done bone trans port technique to avoid complex plastic operation, one patient had Amputation as demand of his request after lost free flap and one patient due to lots of free flap and no other option to reconstruct the leg except bone trans port technique.

Group B:

1. Pin tract infection as all of patient we fix the bone with Ilizarov frame. Most of PTI is grad one except Two cases with grade 2 infection, were treated with intravenous antibiotics, and two cases had grade 3 infection which resolved by exchange of the pin in the three cases.
2. Weak callus: in three patients treated by bone marrow injection and compression distraction method.
3. Revision of the technique: one patient due to premature consolidation before reaching to docking site as the patient is neglect himself treated by osteotomy in the distal fragment
4. Deformity: one patient has plastic deformation (procurvatum) due to early removal of the frame and one patient had equinus.
5. Limb length discrepancy: two patient had <2.5cm and two had≥2.5cm.
6. Failed technique and done amputation in one patient had recurrent osteosarcoma and metastatis.

Table (2): Comparison between groups according complications

Complication	Group A		Group B		Chi-square	
	No.	%	No.	%	x^2	p
Pin tract infection	15	100.0%	15	100.0%	7.344	0.196
Weak callus	0	0%	3	20.0%		
Stiff ankle	3	20.0%	7	46.7%		
Stiff knee	2	13.3%	0	0.0%		
Limb bength discrepancy						
<2.5cm	1	6.7%	2	13.3%		
≥2.5cm	4	26.7%	2	13.3%		
Revision of technique	2	13.3%	1	6.7%		
Failed technique	5	33.3%	1	6.7%		
Deformity	2	13.3%	3	20.0%		

Complications / patients [Group A& B "2.3" respectively].

This table shows no statistically significant difference between both groups according complications.

Time of treatment (days):

Table (3): Comparison between groups according time of treatment (days)

Time of treatment (days)	Group A	Group B	t-test	p-value
Mean±SD	271±131.7	402±116.1	10.960	**<0.001 (HS)**
Range	150-360	240-630		
Mean of healing index (per centimeter)	31.99±18.74	52.22±30.59	3.193	**0.002 (S)**

This table shows highly statistically significant difference between both groups according time of treatment (days).

Additional procedure:

- ***Group A:*** no additional procedure.
- ***Group B:*** nine patient had done bone graft at the docking site to enhancement union (other patient we don't done bone graft at docking site due to bad skin condition, and three patient had done bone marrow injection due to weak distraction callus.

Table (4): Comparison between groups according additional procedure

Addition procedure	Group A		Group B		Chi-square	
	No.	%	No.	%	x2	p
Grafting	0	0.0%	9	60.0%	20	0.001
Bone marrow injection	0	0.0%	3	20.0%		

This table shows statistically significant difference between both groups according additional procedure.

Bone results

Table (5): Comparison between groups according bone results

Bone results	Group A		Group B		Chi-square	
	No.	%	No.	%	x2	p-value
Union	10	66.6	14	93.3	0.213	0.645
Infection	0	0.0	0	0.0	-	-
Deformity						
Equinus	1	6.7	1	6.7	2.000	0.572
Ext. Rotation	1	6.7	0	0.0		
Procurvatum	0	0.0	1	6.7		
Recorvatum	1	6.7	1	6.7		
Limb discrepancy						
<2.5cm	1	6.7	2	13.3	0.056	0.813
>2.5cm	4	26.7	2	13.3		
Refracture	0	0.0	0	0.0	-	-
Outcome						
Excellent	5	33.3	10	66.7	4.444	0.108
Good	5	33.3	4	26.7		
Poor	5	33.3	1	6.7		
Fair	0	0.0	0	0.0		

This table shows no statistically significant difference between both groups according bone results.

Table (8) shows statistically significant difference between both groups according limping and knee motion, the rest have insignificant.

Discussion

In this current study either induced membrane technique or bone transport technique have advantage and disadvantage.

Advantage of induced membrane technique in tibia:

1. Simple if the sometimes complex procedures to repair of soft tissue are excluded.
2. Less demanding for the patient.
3. Shorter time is need for union in large defect.

Table (8): Comparison between groups according functional results

Functional results	Group A		Group B		Chi-square	
	No.	%	No.	%	x2	p-value
Activity						
Active	10	66.7	14	93.3	0.266	0.606
Amputation	1	6.7	1	6.7		
Limping	5	33.3	6	40.0	0.001	0.996
Pain	0	0.0	0	0.0	-	-
Knee motion						
Complete range	0	0.0	13	86.7		
Good	1	6.7	0	0.0		
Loss >15 degree extension	0	0.0	1	6.7	26.802	<0.001
Normal	9	60.0	0	0.0		
Stiff	2	13.3	0	0.0		
Ankle motion						
Loss >15 degree	5	33.3	6	40.0	4.556	0.105
Normal	3	20.0	0	0.0		
Stiff ankle	3	20.0	7	46.7		
Outcome						
Excellent	3	20.0	3	20.0		
Good	7	46.7	11	73.3	3.556	0.169
Poor	5	33.3	1	6.7		
Fair	0	0.0	0	0.0		

Disadvantage of induced membrane technique in tibia:

1. Technically demanding for soft tissue coverage.
2. Two stage operation.
3. Hazard of complication from massive harvest graft.
4. In massive bone defect when shorting was done can't regain the length of bone and deformity may be occur.

Advantage of ilizarov technique (bone transport):

1. No hazard of massive bone graft.
2. Less need to complex procedure to repair soft tissue.
3. Can correct the length of limb and deformity.

Disadvantage of ilizarov technique (bone transport):

1. Technically demanding for surgeon and patient.
2. Hazard and complication of osteotomy and lengthening.
3. Longer time was need for union in massive defect.

Group A:

In our study on fifteen cases on bone defect on the tibia managed with induced membrane technique with bone defect ranging from 5cm to 12cm with mean 8.47cm. soft tissue reconstruction need in fourteen cases (thirteen case done local flaps and five cases done free flaps, because four cases of them done local and free flaps). Five cases are considering failed the technique, (foure cases managed with Ilizarov technique, three cases of them to avoid new flap of plastic operation, one due to loss of free flap and one case request amputation after the first stage, due to failed of local pedicular flap and free vascularized free flap of him. In study done by ***Wang et al. (2016)***, on thirty two cases of post-traumatic osteomyelitis. Within this group there were twenty tibias and twelve femurs with a mean defect of 5cm (1.5 to 12.5cm). Five tibial cases had a problem with skin coverage and required reconstructive surgery.

In study conducted by ***Masquelet and Begue (2010),*** on thirty five reconstructions of long bone segmental defects ranging from 5 to 24cm after debridement. Lower limb was involved in twenty nine cases and the majority of cases were post traumatic septic non unions of the leg (twenty three cases). Upper limb was concerned in six cases. Soft-tissue repair by flaps was needed in twenty eight cases (fourteen free flaps and fourteen pedicular flaps). Immediate complications concerned the failure of the free flaps in three patients who were treated successfully by other techniques of reconstruction (Papineau and Ilizarov procedures).

In study conduct by ***Apard et al. (2010),*** on twelve patients, were treated for a crush injury of the leg. Were operated for segmental tibial bone loss greater than 6cm (bone loss was a mean 8.7cm range, (6-15 cm)), resulting from injury (four cases) or

aseptic necrosis (one case) or septic necrosis (seven cases). A free muscle flap (ten patients) or a pediculated fasciocutaneous flap (two patients). was necessary during this first step to cover the site and provide good conditions for secondary bone growth.

Another study conduct by ***Schöttle et al. (2005),*** on six patients underwent a two-stage reconstruction to treat an infected nonunion of the tibia, the soft tissue was reconstructed with a free microsurgical muscle flap. The flap was covered with a split-thickness skin graft, used the serratus anterior in four cases and the latissimus dorsi in 2 cases. The length of the bony defect after debridement ranged from 5 to 8cm. One case had a thrombosis of the free flap anastomoses, requiring revision. Three patients developed a hematoma at the free flap recipient site, and one at the free flap donor site, all of which required operative drainage.

In study conduct ***Karger et al. (2012),*** on seventy nine men and five women, The bone segments included the tibia in sixty one cases (70% of cases)., (including fifty four with the fibula), the femur in thirteen cases, the humerus in six cases and the forearm in four cases. Forty-six flap covers were performed before actual bone reconstruction. Eight failures (10%) involved severe leg traumas associating extensive bone defects, soft tissue lesions and infection and required amputation in six cases.

So when the technique failed or the patient need complex plastic operation bone transport more reliable.

In this current study, in ten cases we use mixture of cancellous iliac bone auto graft and allograft (3:1 respectively) to fill the defect. All cases were fixed by circular Ilizarov frame. The mean healing time was 271±131.7 days (9 months) ranging from 150-360 days (5-12 months). The result of this study according to ASMI score clinically was (Functional results) three cases excellent, seven cases good, and five cases poor, the radiological result (bone result) five cases excellent, five cases good, and five cases poor (union rate is about 66%).

In a study conducted by ***Masquelet and Begue (2010),*** on twenty three cases the mean healing time was 8.5 months (range: 6–17 months) and the union rate was about 87%. In another study done by ***Wang et al. (2016),*** on twenty cases the mean healing time was ten months, the result of those study were excellent in twelve cases, good in six cases, fair in two cases, (radiological) (union rate in those study is 90%).

In study conduct by ***Stafford et al. (2010),*** on twenty five patients with twenty seven segmental defect non unions. Reamer–irrigator–aspirator bone graft used in all patients. Those used adjunctive material (allograft bone or BMP) in twenty-three (85%) of the twenty-seven non unions. At six months, nineteen (70%) of the twenty-seven non unions were healed both clinically and radiographically. At last follow up, twenty-four (90%) of twenty seven non unions were healed clinically and radiographically (seven of eight femora and seventeen of nineteen tibiae). The average time to healing was ten months. The remaining three nonunions, one had undergone additional bone grafting, one had a below knee amputation for chronic deep infection and one had been lost to follow-up.

In the study conducted by ***Apard et al. (2010),*** twelve patients, the results of this study were complete weight-bearing at a mean four months (range, 3-7 months). The second step was done 2-6months after frist stage. All patient bones were fixed with inter-loking nail. The cancellous bone grafts were then packed into the cavity bordered by the membrane around the nail, tricalcium phosphate bone substitute was added to the graft material for all the patients except one had apparently healed (complete weight-bearing with no pain). In the ten cases, union was obtained with the nail in place (83.3%). Apard et al. who reported an infection rate of 41.7%. They also reported late infection.

In study conducted by ***Karger et al. (2012),*** on sixty one cases of the leg, (including fifty four with the fibula), the reconstruction graft was usually cancellous or corticocancellous bone, alone or associated with bone substitutes. In seven cases, this was associated with a vascularized graft (four iliac crests, two fibulas, one rib). Fifteen intertibiofibular grafts were performed in the sixty one tibiae. Growth factors were added in twenty five patients. Union was obtained in 90% of cases, a mean 14.4 months after the first stage of the reconstruction.

The results of this study are comparable to most of the mentioned study. While the successful rate of the technique may be appear lower than the previous other studies because five cases (33.3%) not complete the technique (four cases managed with Ilizarov technique, three cases of them to avoid new flap operation, one due to loss of free flap and one case request amputation due to, due to failed of local pedicular flap and free vascularized free flap of him), so when the technique failed or the patient need complex plastic operation bone transport more reliable. And the mean healing time longer than some study due to in our study use corticocancellous bone, alone or associated with allograft without addition of any growth factor.

GROUP B

In this current study all cases were operated using unifoal bone transport except one case was operated by using bifocal bone transport. The external fixation index was 1.74 month/cm.

In a study conducted by ***Yin et al. (2014),*** on sixty six patient with infected nonunion tibia, The average length of the bone defects after radical debridement was 6.27cm (range 3-13cm). The mean external fixation index was 1.38 months/cm (range 1.15-1.58 months/cm).

In study conducted by ***Liu et al. (2011),*** twenty-three consecutive patients with tibial bone defects and limb-length discrepancy caused by osteomyelitis. Mean amount of bone defect was 3.6cm (range, 1.5-6.2cm) as measured on plain radiographs. Mean leg-length discrepancy was 4.0cm (range, 0-8.0cm). Mean external fixation index was 48.0 days/cm (range, 40.7-66.5 days/cm).

In study conducted by ***Paley and Maar (2000),*** on nineteen patients with tibial bone defects were treated by the Ilizarov bone transport method. The mean bone defect was 10cm, thirteen patients were treated by single-level transport and six patients by double-level transport. The mean of external fixator index were reported to be 2.1 months/cm in a single-level bone transport and 1.2 months/cm in a double-level bone transport. While another study conducted by ***Chaddha et al. (2010),*** on 22 patients with the mean length of bone defect at the time of frame application was 8.9cm (range: 5-17cm). And mean external fixator index was 0.98 months/cm.

In study conducted by ***Yin et al. (2015),*** on one hundred and ten patients with infected nonunion of tibia and femur treated by bone transport. The site of infected nonunion involved seventy two tibiae and thirty eight femora. The mean length of the bone defects after radical debridement was 6.15cm (range: 3–13 cm). The mean external fixation index was 1.48 months/cm (range: 1.15–1.71 months/cm).

Another study conducted by ***Manish and Rabi (2012),*** twenty-five cases. The mean of bone defect was 6.53cm (range: 4 to 12cm). The mean time taken for union, per centimeter of bone gap was found to be 1.7 months/cm.

In our study eleven cases had soft tissue defect, eight of them managed by local flap, one by free flap and two by vacuum sealing drainage. In a study conducted by ***Yin et al. (2015),*** he used open dressing changing or vacuum sealing drainage (VSD) were made to close the wound in cases with soft tissue defect.

Paley and Maar (2000), on nineteen patients, eight patients had substantial soft-tissue defects, secondary to either the debridement or the initial injury, and were treated with soft-tissue transport in concert with the bone transport. The remaining eleven patients had previously undergone soft-tissue coverage with a free-vascularized muscle flap.

In this series the total number of complications was thirty four types, with a 2.2 / person complication rate. ***Paley and Maar (2000) and Iacobellis et al. (2004),*** reported complication rates per patient for their bone transport groups as 2.9, and 2.08 respectively that was comparable to this study.

In this series according to Association for the Study and Application of the Method of Ilizarov (ASAMI) classification, the bone (radiological) results were excellent in ten patients (66.6%), good in four patients (26%), and poor in one patient (6.6%); while the functional results were excellent in three patients (20%), good in eleven patients (73.3%), and poor in one patient (6.6%).

Yin et al. (2014), in their study of sixty six patients with infected nonunion tibia. According (ASAMI) classification, bone results were excellent in forty four patients (66.6%), good in fifteen patients (27%), fair in five patients (7.5%) and poor in two patients (3%); functional Results were excellent in twenty four patients (36%), good in twenty six patients (39.4%), fair in ten (15%) and no poor.

Paley and Maar (2000), in their study on nineteen patients with tibial bone defects they had bone results were graded as fifteen (78.9%) excellent, three (15.7%) good, and one (5.2%) fair. The functional results were graded as twelve (63.2%) excellent, six (66.6%) good, and one (5.2%) poor.

Manish and Rabi (2012), in their study on twenty-five cases of gap non-union of the tibia. The bone healing results were excellent in 92% of cases and good in 8% of cases. The functional results were excellent in 84% of cases, good in 12% and fair in 4% of cases.

The results of the current study are comparable to those done with unifocal transport, while they are below those done with bifocal or trifocal bone transport. While the rate of complications and their type (problems, obstacles, and sequelae), were comparable to most of the mentioned study.

Conclusion

Tibial bone defect can be managed by the induced membrane if the complex procedures to reconstruct of the soft tissue are excluded otherwise bone transport technique more reliable and safe.

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