Effectiveness of Complex Combined Deformity Nonunion/Malunion Correction, Utilizing a Hexapod External Fixator

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Background/Purpose: Management of complex tibial nonunions / malunions with deformity has evolved from complex Ilizarov frames to accurate hexapod ring fixators. Few studies, all with limited patient numbers, have reported on their effectiveness with minimal data documenting the effectiveness to achieve mechanical axis realignment and deformity correction. The purpose of this study was to determine the efficacy of hexapod frames and their ability to achieve six-axis correction when treating complex tibial nonunions and malunions with deformity. Our hypothesis is that hexapod fixators can reproducibly correct complex limb deformities, restore mechanical axis alignment, and achieve union in patients with complex tibial nonunions and malunions.

Methods: This consecutive retrospective case series compared the pre- and postoperative mechanical axis in patients with hexapod frames applied for posttraumatic tibial nonunions or malunions. From 2003-2014, 57 patients met the inclusion criteria, of a tibial nonunion / malunion with a combined oblique plane deformity of greater than 5° in any plane, with accompaning deformities of translation, malrotation, and axial malalignment. Patients were excluded from the study who were less than 18 years of age, had combined tibial deformities less than 5°, or less than 1 year of follow-up. Patients were treated by the senior author with a hexapod device. Preoperative mechanical axis deviation, deformity parameters, and union status were assessed. Deformity data were computed and continual recalculation of correction parameters was performed at each follow-up visit using long alignment films with routine clinical follow-up examination. Postoperative anatomic and mechanical axis determination, adequacy of union, and additional procedures necessary to complete treatment were recorded. Final assessment of deformity included not only mechanical axis correction, but included adequacy of union, and any residual leg-length discrepancy, translation, or malrotation.

Results: The cohort consisting of 57 patients treated with a total of 60 frames (45 nonunions and 15 malunions) met the inclusion criteria. There were 41 male and 19 female patients with a mean age of 47.9 years (range, 25-78) and mean follow-up time of 106 weeks (range, 54-316 weeks). The mean treatment time of hexapod fixation was 164 days (SD 88.4). Average combined preoperative deformity was greater than 17.96° (SD 10.89) and was corrected to 9.68° (SD 5.33). Average mechanical axis was restored within 5° of the desired goal in all categories except in patients with severe preoperative valgus deformities. Two patients had a residual leg-length discrepancy that resulted in shoe lifts. 80% of patients achieved union without any additional bone grafting procedures. Union was accomplished with initial compression for 3 weeks to stabilize the nonunion and allow neovascularization to occur. This was then followed by slow distraction through the nonunion achieving regenerate bone that allowed deformity correction and consolidation to union. Six residual nonunion patients had continued deformity, with 3 patients opting for additional correction with a

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second frame application. Overall, the study group demonstrated 95% (57/60) union rate at the end of treatment. All malunions healed without complication, through their corticotomy sites that were performed for correction.

Conclusion: Hexapod devices with their associated software treatment algorithms can be used as an accurate and reproducible treatment modality. Their ability to correct complex combined deformities with significant mechanical axis deviation is well demonstrated. Findings from this study reveal that complexity of the deformity did not demonstrate any difference with regard to achieving union. Both groups demonstrated considerable deformity correction with a more precise correction seen in the malunion group consistently achieving all goals. Additionally, patients treated only with compression/distraction techniques demonstrated a very high success rate with a minimum of complications and without the use of adjuvant bone grafting in 80% of the cases.

Tables

Table 1

All Patients (60)	
Descriptive Statistics	
Age	47.87 years old (25-78)
Sex	41M 19F
Location of Fracture	Proximal (11) , Middle (6), Distal (43)
Length of Frame Application	164.7 days (SD: 82.16) Range 49-467
Closed vs. Open Fracture	Closed (19), Open (41)
Previous Soft Tissue Flap/Transport	Yes (12), No (48)
Mechanism	Low (18) vs. High (42)
Type of Nonunion	Hypertrophic (32), Normotrophic (4), Atrophic (9)
Persistent LLD during treatment	2/60 Needed Shoe Lift post op
Prior Bone Defects	Yes (19), No (41)
Prior Bone Grafting	Yes (14), No (46)
Prior Antibiotics Beads	Yes (5), No (55)
Previous Infections	Yes (28), No (32)
Bone Grafting During Treatment	Yes (12), No (48)
Antibiotic Beads During Treatment	Yes (3), No (57)
Soft Tissue Flap/Transport During Procedure	Yes (2), No (58)
Residual Nonunions	6
Smoking History	Yes (33), No (27)
Diabetic History	Yes (5), No (55)
Average Follow Up	106 weeks

Table 2

All Patients (60)							
Preoperative	Mean	Range	SD	**Postoperative**	Mean	Range	SD
Coronal Angulation	11.45	(0-49)	8.97	Coronal Angulation	5.1	(0-23)	4.81
Coronal Translation	5.67	(0-28.91)	7.07	Coronal Translation	5.06	(0-17.89)	5.03
Sagittal Angulation	12.1	(1-55)	9.23	Sagittal Angulation	8.52	(0-29)	6.46
Sagittal Translation	5.08	(0-22.98)	5.85	Sagittal Translation	4.12	(0-16.1)	4.5
Axial Rotation	2.6	(-15-25)	6.84	Axial Rotation	0		
Leg Length Discrepancy				Leg Length Discrepancy	(2/60)		
Nonunions (45)							
Varus Deformities	6						
Preoperative	Mean	Range	SD	**Postoperative**	Mean	Range	SD
Coronal Angulation	6.83	(4-14)	3.66	Coronal Angulation	4.33	(2-7)	2.07
Coronal Translation	4.43	(0-11)	5.05	Coronal Translation	6.26	(0-15.54)	6.33
Sagittal Angulation	14.67	(4-29)	11.38	Sagittal Angulation	10.33	(0-18)	6.28
Sagittal Translation	6.64	(0-20)	7.01	Sagittal Translation	5.41	(0-11)	4.08
Axial Rotation	8.17	(0-20)	7.23	Axial Rotation	0		
Leg Length Discrepancy				Leg Length Discrepancy	0		
Valgus Deformities	39						
Preoperative	Mean	Range	SD	**Postoperative**	Mean	Range	SD
Coronal Angulation	12.38	(0-49)	9.99	Coronal Angulation	4.9	(0-23)	5.17
Coronal Translation	6.82	(0-22.98)	7.74	Coronal Translation	5.46	(0-17.89)	5.24
Sagittal Angulation	11.67	(1-55)	9.73	Sagittal Angulation	9.44	(1-29)	6.84
Sagittal Translation	22.98	(0-22.98)	6.02	Sagittal Translation	4.6	(0-16.1)	4.84
Axial Rotation	1.64	(-15-20)	5.71	Axial Rotation	0		
Leg Length Discrepancy				Leg Length Discrepancy	(2/39)		
Malunions (15)							
Varus Deformities	2						
Preoperative	Mean	Range	SD	**Postoperative**	Mean	Range	SD
Coronal Angulation	16	(15-17)	1.41	Coronal Angulation	3.5	(3-4)	0.71
Coronal Translation	0	(0-0)	0	Coronal Translation	2.3	(0-4.6)	3.25
Sagittal Angulation	13	(7-19)	8.49	Sagittal Angulation	7	(5-9)	2.83
Sagittal Translation	0	(0-0)	0	Sagittal Translation	2.52	(0-5.03)	3.56
Axial Rotation	8	(7-9)	1.41	Axial Rotation	0		
Leg Length Discrepancy				Leg Length Discrepancy	0		
Valgus Deformities	13						
Preoperative	Mean	Range	SD	**Postoperative**	Mean	Range	SD
Coronal Angulation	10.08	(1-23)	7.37	Coronal Angulation	4.38	(0-11)	3.36
Coronal Translation	3.63	(0-16.49)	5.51	Coronal Translation	4.48	(0-16.52)	5.26
Sagittal Angulation	11.85	(1-25)	7.43	Sagittal Angulation	8.15	(1-27)	8.15
Sagittal Translation	2.98	(0-14.64)	4.56	Sagittal Translation	2.34	(0-11.4)	3.58
Axial Rotation	2.08	(-10-25)	8.86	Axial Rotation	0		
Leg Length Discrepancy				Leg Length Discrepancy	0		

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Table 3

All Frames (60)	PreOp	Range	SD	PostOp	Range	SD
Angular Deformity	17.96	(2.83-55.73)	10.89	9.68	(2-25.46)	5.33
Translational Deformity	10.75	(0-51.89)	10.96	9.17	(0-31.44)	7.69
Nonunions (45)	**PreOp**			**PostOp**		
Angular Deformity	18.12	2.8-55.73	11.86	10.18	2-25.46	5.63
Translational Deformity	12.42	0-51.89	11.54	7.9	0-31.44	6.92
Malunions (15)	**PreOp**			**PostOp**		
Angular Deformity	17.47	6.4-29.07	7.58	8.16	2-17.12	4.1
Translational Deformity	5.73	0-22.9	7.2	4.77	0-17.5	5.4

Table 4

All Frames (60)							
Preoperative Deformity	**MPTA (mean)**	**Range**	**SD**	**Postoperative Deformity**	**MPTA (mean)**	**Range**	**SD**
MPTA <90 degrees (varus)	90.5	(90-92)	0.76	MPTA <90 degrees (varus)	89.25	(86-94)	2.66
MPTA >90 degrees (valgus)	87.34	(83-90)	1.78	MPTA >90 degrees (valgus)	87.78	(80-95)	2.77
Preoperative Deformity				**Postoperative Deformity**			
LDTA <90 degrees (valgus)	76.74	(47-89)	9.93	LDTA <90 degrees (valgus)	82.89	(67-96)	7.76
LDTA >90 degrees (varus)	101.98	(92-132)	10.7	LDTA >90 degrees (varus)	90.5	(72-106)	6.79
Nonunions							
Preoperative Deformity	**MPTA (mean)**	**Range**	**SD**	**Postoperative Deformity**	**MPTA (mean)**	**Range**	**SD**
MPTA <90 degrees (varus)	90.67	(90-92)	0.82	MPTA <90 degrees (varus)	89.25	(86-94)	3.59
MPTA >90 degrees (valgus)	87.67	(84-90)	1.56	MPTA >90 degrees (valgus)	87.59	(80-92)	2.24
Preoperative Deformity				**Postoperative Deformity**			
LDTA <90 degrees (valgus)	76.5	(47-89)	11.7	LDTA <90 degrees (valgus)	82.52	(67-96)	7.19
LDTA >90 degrees (varus)	102.26	(92-132)	10.1	LDTA >90 degrees (varus)	90.21	(72-106)	7.61
Malunions							
Preoperative Deformity	**LDTA (mean)**	**Range**	**SD**	**Postoperative Deformity**	**LDTA (mean)**	**Range**	**SD**
MPTA <90 degrees (varus)	90	(90-90)	0	MPTA <90 degrees (varus)	90	(88-92)	2.83
MPTA >90 degrees (valgus)	86.38	(83-89)	2.1	MPTA >90 degrees (valgus)	88.43	(81-95)	3.8
Preoperative Deformity				**Postoperative Deformity**			
LDTA <90 degrees (valgus)	77.8	(72-85)	4.97	LDTA <90 degrees (valgus)	85	(73-90)	7.14
LDTA >90 degrees (varus)	101.2	(92-121)	9.94	LDTA >90 degrees (varus)	91.1	(82-103)	6.52

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Figure 1

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.