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**Original Research Paper** 

**Orthopaedics** 

# ROLE OF DIFFERENT CRITERIA IN OUTCOME ANALYSIS OF MANAGEMENT OF GAP NON-UNION

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**ABSTRACT** Back ground and objectives: Gap or Defect non-union is not uncommon in Orthopaedic practice. Management involves prolonged periods of tedious procedures and decision making. The endpoint of such management does not reveal itself as a well-defined point. Follow ups must include some analysable outcome which should have a standardised criteria-based endpoint. A well-aligned, painless, noninfected, and functional limb is the goal of treatment. The objective of this study is to understand the role of different criterion to understand whether the goal has been reached.

**Summary:** The study is designed as retrospective, prospective observational study. It is conducted in tertiary care hospital (MIOT Hospitals, Chennai). Initial evaluation of all cases were done by Maurizio Catagni's Classification. Type of surgeries, time spent in hospital, union time were calculated. Patients were followed up for a period of 1year. Patients with average defect size of 6.29cm on an average underwent 4.47 procedures and for an overall time of 17.8 weeks with around 83.80 % of individuals were able to return to their preinjury activity level. Analysis of the outcome was done by ASAMI bone criteria, ASAMI functional criteria, Cattneo et al criteria and Karstrom-Olerud's functional evaluation criteria for lower limbs at onset of treatment, 6 months and 1 year of treatment.

# KEYWORDS :Outcome analysis, Gap or Defect nonunion , Catagni, ASAMI,Karlström-Olerud's, Cattneo

# INTRODUCTION

Gap non-union is characterized by loss of segment of long bone. The ends of the fragments may be viable but bone union across the defect is impossible. As time passes the fragments become atrophic. Catagni<sup>(1)</sup> classified Gap Non-union into different categories by length of gaps and presence of infection.

# MAURIZIO CATAGNI'S CLASSIFICATION

- Al- Non infected mobile non-union
- A2-Non infected stiff hypertrophic non-union without deformity
- A3- Non infected Hypertrophic non-union with deformity
- B1- Non infected non-union with bone defect of up to 5 cm.
- B2- Non infected non-union with bone defect exceeding 5 cm.
- B3- Non infected non-union exceeding 10 cm with local scarring
- C1-Infected non-union with atrophy
- C2-Infected non-union with hypertrophy without deformity
- C3-Infected non-union with hypertrophy and deformity
- C4-Infected non-union with bone gap of less than 5 cm.
- C5-Infected non-union with bone gap between 5 and 10 cm.
- C6-Infected non-union with bone gap exceeding 10 cm.

Defect or Gap non-union concerns type B, C3, C4 and C5 and are subject of the study.

# Aim of Study

This study aims to understand the role of different criteria in analysis of outcome of Gap non-union treated by different methods at tertiary level trauma centre.

# Review of Literature

Different criteria were developed at different times for ascertaining whether an outcome is acceptable and to categorise them, separating actual success from the failures.

# Association For The Study And Application Of The Methods Of Ilizarov (ASAMI)<sup>(2).</sup> Table 1

Bone result	Excellent	Union, no infection, deformity<7°,
		limb length discrepancy<2.5 cm
		Union + any two of the following: no infection, deformity<7°, limb length discrepancy<2.5 cm

	Fair	Union +only one of the following: no
		infection, deformity<7°, limb length
		discrepancy<2.5 cm
	Poor	Non-union / refracture / union +
		infection + deformity>7 $^{\circ}$ + limb
		length discrepancy>2.5 cm
Functional	Excellent	Active, no limp, minimum stiffness
results		(loss of <15°knee
		extension/<15°dorsiflexion of ankle),
		no reflex sympathetic dystrophy,
		insignificant pain
	Good	Active with one or two of the
		following: Limp, stiffness, RSD,
		significant pain.
	Fair	Active with three or all the following:
		Limp, stiffness, RSD, significant pain
	Poor	Inactive (unemployment or inability to
		return to daily activities because of
		injury)
	Failure	amputation

As ASAMI protocol does not consider bone union obtained after bone grafting as excellent, patients who had excellent result was considered to have a good result.

#### Cattneo et al scoring system Table 2

Union:	
U0:	Failure to obtain union
UI:	Solid union
Infection:	
I0:	Unchanged infection
I1:	Persistent minimal drainage
I2:	Complete clinical remission
	of infection
Function:	
F0:	Invalid function
F1:	Able to perform all daily
	activity
F2:	Complete recovery

Karlström-Olerud's functional evaluation criteria used.for lower limbs<sup>[3]</sup>Table 3

Parameters	Score	
Pain (6 months)	Severe pain	l point
	Moderate pain	2 points

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	None	3 points
Walking difficulties	Significant / limping	l point
-	Moderate	2 points
	None	3 points
Climbing difficulties	Impossible	l point
-	With supports	2 points
	None	3 points
Difficulties during sport activities	Impossible	l point
	Some sports	2 points
	None	3 points
Working restrictions	Impossible	l point
	Moderate	2 points
	None	3 points
Skin status	Ulcer / fistula	l point
	Skin discoloration	2 points
	Normal	3 points
Deformities	Significant over 7 degrees	l point
	Low up to 7 degrees	2 points
	None	3 points
Muscle atrophy / Tibial circumference	> 2 cm	l point
	1 - 2 cm	2 points
	< 1 cm	3 points
Lower-limb-length difference	> 2 cm	l point
	1 - 2 cm	2 points
	< 1 cm	3 points
Knee-joint motion range limitation	> 20	l point
	10 - 20	2 points
	< 10	3 points
Subtalar –joint motion range limitation	> 20	l point
	10 - 20	2 points
	< 10	3 points
Capacity of full weightbearing	Yes	l point
-	No	2 points

Points are given and added up based on the above criteria.

Results are evaluated as follows. 36 points: excellent, 35-33 points: good, 32-30 points: acceptable, 29-27 points: moderate, and 26-24 points: poor.

#### Materials and Methods

#### **Materials**

- Study design: Retrospective-Prospective Observational Study
- Retrospective cases in different phases of ongoing management i.e. with established gap nonunion or undergoing treatment or in follow-up
- Prospective enrolled at the onset e.g. following RTA, etc.
- Observational- No interventional measures are taken for the sake of the study.

#### Sample size-105

#### Calculation of sample size

Calculation of the sample size was done with nMASTER software with study done by  $Miller^{(4)}$  et al 2010

Hypothesis Testing for Single Proportion Population Proportion Po = .60 Sample Proportion Pa = .46 Power (%) = 80 Alpha Error (%) = 5 Sided = 2

Sample size (n) $= 97$							
Alpha Error(%)	Power(%)	Sample Size(n)					
1	70	119					
	80	145					
	90	185					
5	70	76					
	80	97					
	90	130					
10	70	58					
	80	76					
	90	106					

Setting-tertiary care hospital (MIOT hospitals, Chennai)

Duration of Study-APRIL, 2014 to OCTOBER, 2015.

#### Recruitment of cases

Total number recruited in their follow-up period- 86 patients.

Total number recruited on their treatment period- 19 patients.

# Inclusion Criteria

Allpatients

- in the age range 15 to 60 years
- with segmental gap of bone of more than 1cm.

#### Exclusion Criteria

Patients with

- irregular follow-ups and poor compliance
- distal neuro-vascular deficit
- substance abuse (alcohol, illicit drugs etc.)

#### Follow-up

The follow-up interval was Monthly and as required and follow-up period was l year.

## Methodology

Pre-operative protocol

All recruited cases were classified by Maurizio Catagni's Classification and each surgery recorded and complications documented.

#### Statistics

Data collection techniques

Data was collected from the OPD and IPD.

#### Data analysis plan

Data was tabulated and statistically analysed in MS Excel and SPSS 17 (Chicago, Illinois).

Paired sample "t" test was done to compare the group means and the p value was calculated.

Probability value less than 5% was considered as statistically significant.

#### Observations

Table 4

CATAGNIO TYPE

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	B1	12	11.4	11.4	11.4
	B2	41	39.0	39.0	50.5
	B3	15	14.3	14.3	64.8
	C4	6	5.7	5.7	70.5
	C5	29	27.6	27.6	98.1
	C6	2	1.9	1.9	100.0
	Total	105	100.0	100.0	

Catagnio type B2 e.i. non-infected gap-nonunion with gaps of 5 to 10 cm was the major group with 39 percent of cases. All

type C cases were infected.

# 2% CATAGNIO TYPE

■ B1 ■ B2 ■ B3 ■ C4 ■ C5 ■ C6

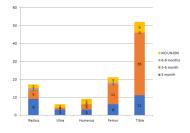
# Figure 1

# Table 5

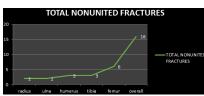
Descriptive Statistics									
	N	Minimum	Maximum	Mean	Std. Deviation				
AGE	105	16	56	30.58	9.281				
LENGTH OF GAP-CM	105	1.80	14.00	6.2905	2.31731				
DEFORMITY- DEGREES	105	0	30	4.81	8.958				
SHORTENING-CM	105	.0	9.0	1.070	2.2316				
TOTAL NUMBER OF PROCEDURES DONE	105	2	10	4.47	1.582				
TOTAL STAY IN HOSPITAL DAYS	105	13	49	27.23	10.054				
UNION TIME- MONTHS	89	3	7	4.15	1.173				
Karlström-Olerud's functional SCORE AT ADMISSION	72	13	16	14.92	1.084				
Karlström-Olerud's functional SCORE 6 MONTHS	72	24	36	31.69	4.161				
Karlström-Olerud's functional SCORE 1 YEAR	72	24	36	32.37	3.747				
Valid N (listwise)	63								

#### Results Table 6

Table 0				
	3 month	3-6 month	6-9 months	No Union
Radius	9	5	1	2
Ulna	3	1	0	2
Humerus	3	3	0	3
Femur	6	11	1	3
Tibia	11	35	0	6



# Figure 2

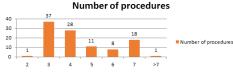


# Figure 3

# Table 6

Number Of Procedures	Number of patients
2	1
3	37
4	28
5	11
6	8
7	18
>7	1

28 percent of the cases underwent procedures 4 times and only one patient underwent more than 7 procedures.





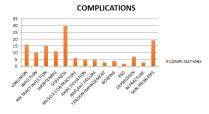
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The average hospital stay was 27.23days, maximum stay being 49 days and minimum being 13 days.



# Figure 5

Stiffness was the commonest complication seen in 30 cases with Reflex sympathetic dystrophy seen in only 2 cases.



# Figure 6

# **Analysis of results**

ASAMI Bone score comparison at Onset , 6 months and 1 year



# Figure 7

# ASAMI BONE SCORE AT ADMISSION \* ASAMI BONE SCORE AT 6 MONTHS Table 7

Crosstat Tota ASAMI BONE SCORE POOR Count 105 100.0% AT ADMISSION % of Tot 17.1% 59.0% 17.1% Tota 105 % of Tot 17.1% 59.0% 5 7% 17.1% 100.0%

# ASAMI BONE SCORE AT ADMISSION \* ASAMI BONE SCORE 1 YEAR Table 8

Crosstab							
ASAMI BONE SCORE 1 YEAR							
	EXCELLENT GOOD FAIR POOR FAILURE						
ASAMI BONE SCORE POOR	Count	21	62	6	15	1	105
AT ADMISSION	% of Total	20.0%	59.0%	5.7%	14.3%	1.0%	100.0%
Total	Count	21	62	6	15	1	105
	% of Total	20.0%	59.0%	5.7%	14.3%	1.0%	100.0%

#### Table 9

#### ASAMI BONE SCORE AT 6 MONTHS \* ASAMI BONE SCORE 1 YEAR Crosstabulation

				ASAMI BONE SCORE 1 YEAR				
			EXCELLENT	GOOD	FAIR	POOR	FAILURE	Total
ASAMI BONE	EXCELLENT	Count	18	0	0	0	0	18
SCORE AT 6		% of Total	17.1%	.0%	.0%	.0%	.0%	17.1%
MONTHS	GOOD	Count	0	62	0	0	0	62
		% of Total	.0%	59.0%	.0%	.0%	.0%	59.0%
	FAIR	Count	0	0	6	0	0	6
		% of Total	.0%	.0%	5.7%	.0%	.0%	5.7%
	POOR	Count	3	0	0	15	0	18
		% of Total	2.9%	.0%	.0%	14.3%	.0%	17.1%
	FAILURE	Count	0	0	0	0	1	1
		% of Total	.0%	.0%	.0%	.0%	1.0%	1.0%
Total		Count	21	62	6	15	1	105
		% of Total	20.0%	59.0%	5.7%	14.3%	1.0%	100.0%

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Table 10

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	390.000ª	16	.000
Likelihood Ratio	218.734	16	.000
Linear-by-Linear Association	77.451	1	.000
N of Valid Cases	105		

a. 20 cells (80.0%) have expected count less than 5. The minimum expected count is .01.

The ASAMI bone score was Excellent in 17.1 % of cases in 6 months and 20 percent of cases in 1 year. As ASAMI does not consider bone grafting as Excellent so many of the cases had to be categorized into Good. Percentage of Good was 62 at both 6 months and 1 year. Values were statistically significant with P value less than 0.05. One case was a failure as it has undergone amputation following recurrence of tumour.

#### ASAMI Functional score comparison at Onset, 6 months and l year



#### Figure 8

#### ASAMI FUNCTIONAL CRITERIA AT ADMISSION \* ASAMI FUNCTIONAL CRITERIA 6 MONTHS and 1 YEAR Table 11 Crosstab

	IAL CRITER	IA 6 MONT	ΉS				
		EXCELLENT	GOOD	FAIR	POOR	FAILURE	Total
ASAMI FUNCTIONAL POOF	Count	56	29	1	18	1	105
CRITERIA AT ADMISSION	% of Tota	53.3%	27.6%	1.0%	17.1%	1.0%	100.0%
Total	Count	56	29	1	18	1	105
	% of Tota	53.3%	27.6%	1.0%	17 1%	1.0%	100.0%

#### ASAMI FUNCTIONAL CRITERIA AT ADMISSION \* ASAMI **FUNCTIONAL CRITERIA 1 YEAR** Table 12

Crosstab

		AS/	ASAMI FUNCTIONAL CRITERIA 1 YEAR					
		EXCELLENT	GOOD	FAIR	POOR	FAILURE	Total	
ASAMI FUNCTIONAL POOR	Count	57	31	1	15	1	105	
CRITERIA AT ADMISSION	% of Total	54.3%	29.5%	1.0%	14.3%	1.0%	100.0%	
Total	Count	57	31	1	15	1	105	
	% of Total	54.3%	29.5%	1.0%	14.3%	1.0%	100.0%	

# Crosstabs

#### Table 13

ASAMI FUNCTIONAL CRITERIA 6 MONTHS \* ASAMI FUNCTIONAL CRITERIA 1 YEAR Crosstabulation

			ASA	MI FUNCTIO	NAL CRITE	RIA 1 YEA	R	
			EXCELLENT	GOOD	FAIR	POOR	FAILURE	Total
ASAMI FUNCTIONAL	EXCELLENT	Count	56	0	0	0	0	56
CRITERIA 6		% of Total	53.3%	.0%	.0%	.0%	.0%	53.3%
MONTHS	GOOD	Count	0	29	0	0	0	29
		% of Tota	.0%	27.6%	.0%	.0%	.0%	27.6%
	FAIR	Count	0	0	1	0	0	1
		% of Tota	.0%	.0%	1.0%	.0%	.0%	1.0%
	POOR	Count	1	2	0	15	0	18
		% of Tota	1.0%	1.9%	.0%	14.3%	.0%	17.1%
	FAILURE	Count	0	0	0	0	1	1
		% of Tota	.0%	.0%	.0%	.0%	1.0%	1.0%
Total		Count	57	31	1	15	1	105
		% of Tota	54.3%	29.5%	1.0%	14.3%	1.0%	100.0%

# Table 14

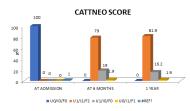
#### Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	394.739ª	16	.000
Likelihood Ratio	202.236	16	.000
Linear-by-Linear Association	91.330	1	.000
N of Valid Cases	105		

a. 18 cells (72.0%) have expected count less than 5. The minimum expected count is .01.

The ASAMI functional score was Excellent in 53.3 % of cases in 6 months and 54.3 percent of cases in 1 year. Percentage of Good was 27.6 and 29.5 at 6 months and 1 year respectively. Cross tabulation values were statistically significant with P value less than 0.05.

# Cattneo comparison at Onset, 6 months and 1 year



# Figure 9

#### Cattneo SCORE AT ADMISSION \* Cattneo SCORE AT 6 MONTHS Table 15

Crosstab

		Cattneo S	Cattneo SCORE AT 6 MONTHS			
		U1/I2/F2	U0/I1/F0	U0/I1/F1	Total	
Cattneo SCORE U0/I0/F	0 Count	83	20	2	105	
AT ADMISSION	% of Total	79.0%	19.0%	1.9%	100.0%	
Total	Count	83	20	2	105	
	% of Total	79.0%	19.0%	1.9%	100.0%	

#### Cattneo SCORE AT ADMISSION \* Cattneo SCORE 1 YEAR Table 16 Crosstab

	Cattneo SCORE 1 YEAR				
		U1/I2/F2	U0/I1/F0	U0/I1/F1	Total
Cattneo SCORE U0/I0/F0	Count	86	17	2	105
AT ADMISSION	% of Total	81.9%	16.2%	1.9%	100.0%
Total	Count	86	17	2	105
	% of Total	81.9%	16.2%	1.9%	100.0%

#### Crosstabs

# Table 17

Cattneo SCORE AT 6 MONTHS \* Cattneo SCORE 1 YEAR Crosstabulation

			Cattne	Cattneo SCORE 1 YEAR					
			U1/I2/F2	U0/I1/F0	U0/I1/F1	Total			
Cattneo SCORE	U1/I2/F2	Count	83	0	0	83			
AT 6 MONTHS		% of Total	79.0%	.0%	.0%	79.0%			
	U0/I1/F0	Count	3	17	0	20			
		% of Total	2.9%	16.2%	.0%	19.0%			
	U0/I1/F1	Count	0	0	2	2			
		% of Total	.0%	.0%	1.9%	1.9%			
Total		Count	86	17	2	105			
		% of Total	81.9%	16.2%	1.9%	100.0%			

#### Table 18

#### Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	191.137ª	4	.000
Likelihood Ratio	95.174	4	.000
Linear-by-Linear Association	90.618	1	.000
N of Valid Cases	105		

a. 6 cells (66.7%) have expected count less than 5. The minimum expected count is .04.

The Cattneo score was U1/I2/F2 (solid union with no infection and full function) was seen in 79 % of cases in 6 months and 81.9% of cases in 1 year. Cross tabulation values were statistically significant with P value less than 0.05.

# Karlström-Olerud's functional evaluation criteria at admission, 6 months and lyear



Figure 10

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Paired	Samples	Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair	Karlström-Olerud's functional SCORE AT ADMISSION	14.92	72	1.084	.128
1	Karlström-Olerud's functional SCORE 6 MONTHS	31.69	72	4.161	.490
Pair	Karlström-Olerud's functional SCORE AT ADMISSION	14.92	72	1.084	.128
2	Karlström-Olerud's functional SCORE 1 YEAR	32.38	72	3.747	.442
Pair	Karlström-Olerud's functional SCORE 6 MONTHS	31.69	72	4.161	.490
3	Karlström-Olerud's functional SCORE 1 YEAR	32.38	72	3.747	.442

#### Table 20

Paired Samples Test

			Paire	d Differenc	xes				
				Std. Error	Interva	nfidence I of the rence			
		Mean	td. Deviation	Mean	Lower	Upper	t	df	Sig. (2-tailed)
Pair 1	Karlström-Olerud's functional SCORE ADMISSION - Karlström-Olerud's functional SCORE MONTHS	-16.778	4.112	.485	-17.744	-15.812	-34.623	71	.000
Pair 2	Karlström-Olerud's functional SCORE ADMISSION - Karlström-Olerud's functional SCORE YEAR	-17.458	3.700	.436	-18.328	-16.589	-40.040	71	.000
Pair 3	Karlström-Olerud's functional SCORE MONTHS - Karlström-Olerud's functional SCORE YEAR	681	2.511	.296	-1.271	091	-2.300	71	.024

Karlström-Olerud's functional evaluation criteria for lower limbs (femur and tibia gaps) score was 14.92 at admission, 31.69 at 6 months and 32.38 at 1 year. Cross tabulation values were statistically significant with P value less than 0.05.

#### Overall return to profession percentage was 83.80% of study population. Table 21

Previous profession	Number	Return to job	Percentage %	
BUSINESSMAN	9	9	100	
CHEF	2	1	50	
CLERK	8	7	87.5	
DOCTOR	1	1	100	
DRIVER	5	4	80	
FARMER	2	2	100	
HOUSEWIFE	4	3	75	
MANUAL WORKER	9	7	77.7	
NURSE	1	0	0	
POLICE	4	3	75	
SALESMAN	5	5	100	
SHOPKEEPER	9	7	77.7	
SOFTWARE	4	3	75	
SOLDIER	5	5	100	
STUDENT	19	17	89.47	
SUPERVISOR	7	6	85.71	

 TEACHER
 6
 5
 83.33

 WHITE COLLAR
 5
 3
 60

# DISCUSSION

According to the Catagnio's classification, among the non infected cases 12(11.4%) patients were B-1, 41(39.0%) were B2 (15.2%) and 15 (14.3%) were B3 nonunions. Among the infected cases 6 (5.7) were C4, 29(27.6) were C5, and 2 (1.9%) was C5.

The bone defect was calculated. The average bone defect was 6.29cm, which is comparable to other reports.

The average time of union in our patients was 4.15 months (Range 3 to 7 months) which was also comparable to other studies.

The treatment goal could be achieved in 89 out of 105 patients (84.76 %).

The ASAMI criteria defines unemployment as poor result.

Majority of our patients (83.8%) were able to join their previous work.

Other studies have highlighted that patient satisfaction is more important than the employment status in functional status assessment. This is not true in case of developing countries like India, where no financial support system exists for the unemployed.

According to final ASAMI scoring, the bone results were Excellent in 21 (20%), Good in 62 (59%), Fair in 6 (5.7% %), and Poor in 15 (14.3%) patients.

Some of the excellent results were considered to be Good because ASAMI does not consider bone grafting as excellent result.

According to final ASAMI scoring, the functional results were Excellent in 57 (54.3%), Good in 31 (29.5%), Fair in 1 (1%), and Poor in 15 (14.3%) patients.

The Cattneo score was U1/I2/F2 (solid union with no infection and full function) was seen in 79 % of cases in 6 months and 81.9% of cases in 1 year.

The lower limb patients were additionally evaluated according to Modified Functional Evaluation System by Karlstrom–Olerud. The score was 14.92 at admission, 31.69 at 6 months and 32.38 at 1 year.

# COMPARISON OF DIFFERENT STUDIES. Table 22

Study	Sample	Bone Results (%)			Functional Results (%)					
	Size	Excellent	good	fair	poor	Excellent	good	fair	poor	Return to work (%)
Dendrinos <sup>[5]</sup> et al 1995	27	50	28	4	18	26	41	15	18	82
Sangkaew C 2004	21	81	14.3	0	4.7	85.7	14.3	0	0	90
Sahibzada <sup>[6]</sup> AS et al 2005	20	60	10	15	15	35	40	20	5	85
Md.Shabir <sup>[7]</sup> et al 2010	32	56	22	6	16	63	19	9	9	72
Our study	105	20	59	5.7	14.3	54.3	29.5	1	14.3	83.80

#### Conclusion

It is essential to use evaluation criteria for outcome analysis of

30 year old presented to the casualty with open injury of leg and ankle.





success or failure of gap nonunion management. Proper analysis of outcome is necessary for completion of treatment.

### CASE PHOTOGRAPHS





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X-ray showed comminution and bone loss



Initial stabilisation was done with ankle spanning Hybrid fixator after debridement





Ring fixator was converted into AO fixator and flap coverage was done.



Segment transport was started with Ring fixator



After 2 months of transport the fixator was removed and regenerate stabilised with Intramedullary nail.



Nail was removed after the union was achieved





Fully functional limb with some stiffness of ankle was achieved in 7 months

# REFERENCES

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