Proximal Tibial Metaphyseal Fractures with Severe Soft Tissue Injury

Clinical and Functional Results at 2 Years

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Received: 11 May 2009 / Accepted: 9 October 2009 / Published online: 28 October 2009
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Abstract

Background Controversy exists regarding management of proximal tibial metaphyseal fractures with severe soft tissue injury. It is unclear whether limb salvage or early amputation results in the best functional and clinical outcomes.

Questions/Purpose We hypothesized that in this group of patients, there is no difference in functional outcomes, complication rates, clinical outcomes, or objective physical function related to the treatment approach.

Methods We used the LEAP study database to perform a retrospective comparative review of a subset of patients with proximal tibial metaphyseal fractures (AO/OTA 41A, B, and C) with associated severe soft tissue injuries

comparing the outcomes of patients who were treated with either limb salvage or amputation.

Results Although there were major differences in clinical and functional outcomes based on patients' sociodemographics at 2 years, no differences in clinical or functional outcomes were detected regardless of whether amputation or limb salvage was performed. Severity of soft tissue injury was more predictive of outcome than the surgical approach used.

Conclusions Sociodemographics and soft tissue injury severity are more important than treatment approach for predicting clinical and functional outcomes at 2 years in patients with proximal tibia metaphyseal fractures with severe soft tissue injury.

Level of Evidence Level III, retrospective comparative study. See Guidelines for Authors for a complete description of levels of evidence.

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One or more of the authors (RCC, MJB, EJM) received funding from NIH-NIAMS (RO1-AR42659).

Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

This work was performed at Carolinas Medical Center, Charlotte, NC, USA, with study data collected from eight institutions.

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Introduction

Proximal tibial metaphyseal fractures (AO/OTA classification 41), including extraarticular (41A) and intraarticular fractures (41B, C) associated with severe soft tissue injury (Gustilo-Anderson Grades IIIA, B, C), pose a treatment dilemma for the surgeon and a high incidence of complications for the patient [17, 19]. Specifically, a decision must be made regarding whether to pursue early amputation or to attempt limb salvage [5, 8, 10, 14].

Two prospective studies of treatment of extremity fractures below the distal femur with associated severe soft tissue injury have suggested that for these patients, long-term functional outcomes are relatively similar for amputation and limb salvage [3, 12]. However, no previous study specifically has evaluated the treatment outcomes

of proximal tibial metaphyseal fractures with associated severe soft tissue injuries, and controversy remains regarding whether amputation or salvage produces better long-term clinical and functional outcomes [11].

Among patients undergoing limb salvage, additional controversy exists regarding the importance of obtaining a precise anatomic articular reduction and whether different methods of stabilization (ie, external fixation versus plate fixation) result in superior clinical and functional outcomes or a reduced complication rate [18]. Commonly encountered complications include infection, range of motion (ROM) deficits, malunion, loss of fixation, and soft tissue compromise. In some cases, these may lead to delayed amputation and considerable additional morbidity for the patient.

The Lower Extremity Assessment Project (LEAP) is a multicenter, prospective outcomes study that includes patients who sustained a high-energy lower extremity injury [2]. The study relies on existing variations in treatment of severe limb-threatening injuries across eight Level I trauma centers to examine differences in treatment decisions and outcomes [11]. The LEAP study database offers an opportunity for a retrospective comparative review of a subset of patients with proximal tibial metaphyseal fractures (AO/OTA 41A, B, and C) with associated severe soft tissue injuries.

The primary aim of our study was to determine whether salvage or amputation results in superior clinical and functional outcomes 2 years after treatment in patients with severe soft tissue injuries associated with a proximal tibial metaphyseal fracture. We hypothesized that salvage and amputation would result in equivalent outcomes with respect to long-term functional outcomes (Sickness Impact Profile [SIP] scores, return to work), complications (reoperation, infection, nonunion, osteomyelitis), clinical outcomes (time to union, procedures to union, bone grafts, total procedures), and objective physical function (strength, ROM, timed walking distance test). Our second aim was to determine whether external fixation or plate fixation (among patients who undergo salvage) results in a lower complication rate (infection, nonunion, osteomyelitis) and better clinical outcomes (time to fracture union, procedures to union). We hypothesized there is no difference in these outcomes as a result of the chosen fixation method.

Patients and Methods

The LEAP Study consists of eight Level I trauma centers that prospectively enrolled 656 patients aged 18 to 69 years with severe soft tissue injuries associated with lower extremity fractures between 1994 and 1997 [3]. Patients were excluded if they had a Glasgow Coma Score less than 15 at 21 days postinjury, a spinal cord deficit, prior

amputation, presented more than 24 hours after injury, did not speak English or Spanish, had a documented psychiatric disorder, or were on active military duty. The study was approved by the Institutional Review Board at the coordinating center and at each study site. Informed written consent was obtained from all study participants.

Our study is a retrospective cross-sectional comparison of two subsets of patients originally enrolled by the LEAP Study. Five hundred sixty-nine of the originally enrolled patients were available for review at 24 months followup. In this group, there were 38 patients with proximal tibial fractures who met the AO/OTA classification for proximal end segment fractures with open soft tissue injury (3A = 10, 3B = 20, 3C = 8) who completed a limb salvage protocol (SAL). Among this subset 29 patients had intraarticular (41B, C) and nine had extraarticular (41A) fractures. An additional 22 patients with proximal end segment fractures (17 intraarticular [41B, C] and five extraarticular [41A]) with open soft tissue injury (3A = 0, 3B = 14, 3C = 8) underwent early amputation (AMP), which was defined as any amputation occurring within the first 3 months of the initial injury. There were five below-knee amputations, five through-knee amputations, and 12 above-knee amputations.

Prospective examinations of all patients at 3, 6, 12, and 24 months were completed. To assess functional outcomes, a record was made of whether the patient had returned to work (RTW), and SIP scores were calculated. This included the physical SIP, psychosocial SIP, and overall SIP. The SIP is a multidimensional measure of self-reported health status and consists of 136 statements about limitations in 12 categories of function: ambulation, mobility, body care and movement, social interaction, alertness, emotional behavior, communication, sleep and rest, eating, work, home management, and recreation [1]. Scores are computed for each of the 12 categories and two overall categories, physical and psychosocial health. These outcome measures have been well validated, and it is known that a score of 2 to 3 indicates meaningful limitations in function with scores greater than 10 indicating severe disability [6, 9, 13, 15]. To assess complications, a record was made of any infections, nonunion, osteomyelitis, or reoperations. Clinical measures were recorded, including time to union, number of procedures to attain union, number of bone grafts required, and total procedures completed during the study period. Finally, objective measurements of physical function included an assessment of ROM, strength of the affected extremity, and a timed walking distance test.

Basic sociodemographic characteristics were obtained and compared for the AMP and SAL groups, including age, gender, insurance status, education level, poverty status, and ethnicity. Injury characteristics likewise were compared, including Gustilo and Anderson grade of soft tissue injury, amount of bone loss, degree of muscle damage, skin defect

circumference, injury severity score (ISS), degree of wound contamination, presence or absence of nerve injury, and presence or absence of compartment syndrome. Treatment characteristics for both study groups also were recorded. For the AMP group, amputation level and myodesis or myoplasty were noted. For the SAL group, final fracture stabilization method and time to bone grafting were recorded. None of the patients in the SAL group progressed to amputation during the study period. Finally, for both groups, the following were recorded: number of débridements, soft tissue coverage type, need for vascular repair, need for fasciotomy, time to first débridement, and time to soft tissue coverage.

For each sociodemographic, injury, and treatment characteristic, the average physical SIP was calculated along with the percent with major complications and percent RTW. A major complication was defined as those requiring an additional admission to the hospital. A multivariate regression analysis statistical technique was used to identify any statistically significant differences between the groups with significance defined as $p \leq 0.05$.

Next, 2-year outcome data were assessed according to treatment group (SAL, AMP). Two-year functional outcomes included the overall SIP, the physical SIP, the psychosocial SIP, and percent RTW. Two-year treatment complications were compared based on percent with major complications, percent with nonunion, percent with

osteomyelitis, and percent with infections. Two-year clinical outcomes were compared, including time to fracture union, number of procedures required to achieve union, number of bone grafts required, and number of surgeries completed during followup (24 months). Finally, 2-year physical therapist-reported outcomes were compared between groups, including percent of patients with walking speed greater than 4 feet per second, American Medical Association (AMA) percent impairment of strength, and AMA percent impairment of ROM. Statistical comparisons were completed with significance defined as $p \leq 0.05$.

In the SAL group, an additional analysis was completed to compare outcomes with external fixation and plate fixation. Specific variables compared included overall complications (infections, nonunions, osteomyelitis), time to fracture union, and number of procedures to achieve union. Statistical significance was defined by $p \leq 0.05$.

Results

There were no major differences in the distribution of patients' ages, gender, insurance status, education level, poverty status, or ethnicity between the study populations; however, several sociodemographics were significantly related to outcomes (Table 1). For SAL, physical SIP

Table 1. Sociodemographic characteristics of the study population

Demographic factor	Salvage (N = 38)				Amputation (N = 22)			
	Number	Physical Sickness Impact Profile	Percent with major complications	Percent return to work	Number	Physical Sickness Impact Profile	Percent with major complications	Percent return to work
Age (years)								
< 34	17	6.8*	41	62	8	10.1	13	57
> 35	21	12.6*	48	65	14	16.0	29	64
Gender								
Male	32	9.5	47	55	19	13.5	26	46
Female	6	14.0	33	100	3	11.5	0	100
Insurance status								
None/public	23	11.6	44	50	14	15.9	21	50
Private	15	7.8	47	75	8	9.2	25	50
Education								
No college	26	12.2*	46	40 [†]	13	17.6	25	25 [†]
Some college	12	5.5*	42	91 [†]	9	9.4	23	83 [†]
Poverty status								
Nonpoor	26	8.7	54	58	15	9.5*	27	46
Poor	12	13.7	25	71	7	20.8*	14	67
Race/ethnicity								
White	27	7.8	44	65	17	11.1	29	50
Nonwhite	11	15.0	45	50	5	19.2	0	50

* $p \leq 0.05$, Student's t-test, [†] $p \leq 0.05$, chi square test.

scores were lower in patients 34 years and younger versus 35 years and older ($p = 0.05$). Patients in the SAL group with a college education had lower physical SIP scores ($p = 0.031$) as did patients in the AMP group who were scored as nonpoor ($p = 0.018$). In both groups, there was a significant difference in percent RTW based on education level with patients with a college education more likely to return to work ($p = 0.004$, $p = 0.008$). Both groups had similar results with respect to each injury category, and the only statistically significant difference was a higher physical SIP among amputees with an ISS greater than 13 ($p = 0.05$) (Table 2). With respect to the treatment characteristics of the AMP group, myoplasty ($p = 0.018$) and fasciotomy ($p = 0.037$) were associated with a significantly higher physical SIP but no difference in major complications or RTW (Table 3). Amputation level, number of débridements, soft tissue coverage, vascular repair, time to first débridement, and time to soft tissue coverage

were not significantly associated with physical SIP, major complications, or RTW. For the SAL group, final fracture stabilization method, débridements, soft tissue coverage, vascular repair, fasciotomy, time to first débridement, time to soft tissue coverage, and timing of bone graft had no significant association to physical SIP, major complications, or RTW (Table 4).

Two-year outcomes data showed no major differences between AMP and SAL. There were no statistical differences among the functional outcomes, including overall SIP, physical SIP, psychosocial SIP indices, and percent RTW (Table 5). Complications during the 2-year period were prevalent in both treatment groups with no significant differences between SAL and AMP, although there was a trend toward more major complications and nonunions in the SAL group ($p = 0.088$, $p = 0.055$) (Table 6). Among clinical outcomes, patients in the SAL group underwent significantly more bone graft and overall procedures than

Table 2. Injury characteristics of the study population

Injury characteristic	Salvages				Amputees			
	Number	Physical Sickness Impact Profile	Percent with major complications	Percent return to work	Number	Physical Sickness Impact Profile	Percent with major complications	Percent return to work
Gustilo & Anderson grade								
IIIA	10	5.3	50	55	0	—	—	—
IIIB	20	13.8	40	69	14	13.5	14	40
IIIC	8	6.2	50	50	8	12.7	38	75
Bone loss								
2 cm or less	27	10.4	44	58	11	14.8	27	63
Greater than 2 cm	11	9.5	45	71	11	11.5	18	33
Muscle damage								
None or AO MT 1-4	34	10.5	44	56	12	11.9	33	55
AO MT 5	4	7.5	50	100	10	14.4	10	40
Skin defect circumference								
Less than half	19	8.5	37	58	4	8.7	0	50
Greater than half	19	12.1	52	64	18	13.6	28	50
Injury Severity Score								
Less than 13	26	9.5	36	55	15	11.0*	27	50
Greater than 13	12	11.5	58	83	7	17.7*	14	50
Contamination								
None/single	23	9.1	57	64	4	17.7	25	75
Multiple/massive	15	11.7	27	58	18	12.9	22	40
Nerve injury								
None/minimal	35	10.5	49	63	13	13.5	31	25
Moderate/severe	3	5.8	0	50	9	13.0	11	83
Compartment syndrome								
Absent	11	6.6	36	71	4	14.5	0	0
Present	27	11.7	48	58	18	13.1	28	63

* $p \leq 0.05$, Student's t-test.

Table 3. Treatment characteristics of the amputation population

Treatment characteristic	Number of amputees	Physical Sickness Impact Profile	Percent with major complications	Percent return to work
Amputation level				
Below the knee	5	14.5	0	33
TKA	5	16.5	20	75
Above the knee	12	11.5	33	43
Myodesis				
Myodesis	5	1.9*	20	33
Myoplasty	14	14.6*	7	44
Débridements				
1–2	17	13.0	24	40
3–4	5	13.8	20	50
Soft tissue coverage				
Standard coverage	3	23.3	100	100
Rotational flap	12	8.8	0	33
Free flap	7	15.0	29	50
Required vascular repair				
No	16	13.3	25	50
Yes	6	12.9	17	50
Fasciotomy required				
No	17	11.4*	29	50
Yes	5	20.9*	0	50
Time to first débridement				
Less than 6 hours	12	13.5	41	56
Greater than 6 hours	10	12.8	0	40
Time to soft tissue coverage				
Less than 3 days	21	13.3	19	50
Greater than 3 days	1	—	100	0

* $p \leq 0.05$.

patients in the AMP group during the followup period ($p = 0.0003$, $p = 0.0005$) (Table 7). Finally, comparing physical therapist-reported outcomes, the SAL group was able to walk faster than the AMP group ($p = 0.039$) (Table 8).

Comparing different fixation methods among patients undergoing SAL (external fixation to plate stabilization), no significant differences were noted. It appeared the percent nonunion rate was less with plate fixation ($p < 0.15$), although the plate fixation group had a slightly higher infection rate. The only other apparent trend was the number of procedures to achieve union, which was less for plate fixation compared with external fixation ($p < 0.15$).

Table 4. Treatment characteristics of the salvage proximal tibia population

Treatment characteristic	Number of salvages	Physical Sickness Impact Profile	Percent with major complications	Percent return to work
Final fracture stabilization				
Nail	3	9.0	0	50
External fixator	19	9.9	53	69
Plate	16	10.5	44	55
Débridements				
1–2	26	9.4	46	61
3–4	12	11.5	42	63
Soft tissue coverage				
Standard coverage	18	7.8	50	42
Rotational flap	11	13.2	36	88
Free flap	9	10.9	44	67
Required vascular repair				
No	31	11.1	42	70
Yes	7	6.1	57	33
Fasciotomy required				
No	30	10.6	50	60
Yes	8	8.4	25	67
Time to first débridement				
Less than 6 hours	16	9.1	50	42
Greater than 6 hours	22	10.9	41	79
Time to soft tissue coverage				
Less than 3 days	17	10.5	53	55
Greater than 3 days	22	9.9	38	67
Timing of bone graft				
No bone graft	21	11.6	38	64
Bone graft by 3 months	10	6.2	50	63
Bone graft greater than 3 months	7	11.2	50	50

* $p \leq 0.05$.

Discussion

Controversy persists regarding whether amputation or salvage produces a better outcome for patients with proximal end segment tibial metaphyseal fractures with severe soft tissue injury [4, 5, 7, 8, 16]. We hypothesized that for this subset of patients, functional outcomes, complications, clinical outcomes, and objective functional outcomes are equivalent for salvage and amputation. Furthermore, it was hypothesized that outcomes for salvaged limbs are not

Table 5. Two-year functional outcomes according to treatment group

Treatment group	Number	Overall Sickness Impact Profile	Physical Sickness Impact Profile	Psychosocial Sickness Impact Profile	Percent return to work
Proximal tibia amputations	22	14.0	13.3	9.3	50.0
Proximal tibia salvages	38	12.7	10.1	11.7	61.5

* $p \leq 0.05$, chi square test.

Table 6. Treatment complications over 2 years according to treatment group

Treatment group	Number	Percent with major complications	Percent with nonunion	Percent with osteomyelitis	Percent with infections
Proximal tibia amputations	22	22.7	4.5	4.5	13.6
Proximal tibia salvages	38	44.7	23.7	15.8	28.9

* $p \leq 0.05$, chi square test.

Table 7. Two-year clinical outcomes according to treatment group

Treatment group	Number	Time to fracture union	Procedures to achieve union	Number of bone grafts	Surgeries during followup
Proximal tibia amputations	22	NA	NA	0.0	0.32
Proximal tibia salvages	38	46.1	0.32	0.50*	1.74*

* $p \leq 0.05$, Student's t-test; NA = not applicable.

Table 8. Two-year physical therapist-reported outcomes according to treatment group

Treatment group	Number	Percent with walking speed greater than 4 feet per second	AMA percent impairment strength	AMA percent impairment range of motion
Proximal tibia amputations	22	33.3	NA	NA
Proximal tibia salvages	38	61.2*	36.9	22.2

* $p \leq 0.05$, Student's t-test; AMA = American Medical Association; NA = not applicable.

significantly affected based on the choice between plate fixation and external fixation.

Our study has important limitations that must be acknowledged. As noted, our patients were not assigned randomly to either amputation or salvage, and therefore, it is possible some bias resulted from individual surgeons choosing the treatment plan. The AMP group had more patients with substantial wound contamination and a higher percent of patients with Gustilo and Anderson Grades IIIB and IIIC soft tissue injuries. The statistical methods we used attempted to minimize this factor; however, the possibility of a residual bias cannot be ignored. In addition, it is unclear whether these results would be generalizable beyond a Level I trauma center, because the individual expertise of the surgeons at Level I centers in treating these injuries may not match the skill set of the general community orthopaedic surgeon. Finally, outcomes at 24 months postinjury are presented in this study, and

although related studies suggest this is a valid measurement of long-term (5+ year) outcomes for this population [12], it remains possible that salvage may have better 5- or 10-year outcomes as compared with amputation or vice versa.

Although there were significant differences in clinical and functional outcomes based on patients' sociodemographics at 2 years, our results were consistent with our hypothesis that clinical and functional outcomes from these injuries are equivalent in most respects regardless of the treatment approach. A previous meta-analysis of 1300 patients after Grades IIIB and IIIC injuries of the tibia showed a 64% RTW rate for patients who had a salvage procedure and a 73% RTW rate for patients who had an amputation [16]. In our study, similar results were observed with only 50% to 60% of patients returning to work during the followup period in both groups. Patients in both treatment groups in the current study also had similar residual functional limitations at 2 years postinjury as well based on

SIP data. This was consistent with the conclusions reached by the original LEAP study, which included a more general population with limb-threatening traumatic injuries below the distal femur [3]. Additional followup from the patients in that study showed clinical and functional results did not significantly improve with time beyond the 2-year followup. In fact, average functional outcomes for patients who had salvage procedures and patients who had amputations continued to deteriorate between 24 and 84 months [12]. Therefore it may be inferred that similar limitations are faced by the current study population. The remaining differences between SAL and AMP in the current cohort echoed previously reported results as well with a clear trend toward more complications and more overall procedures in patients who had limb salvage [4].

Our analysis of method of fixation for the salvage group was limited by the relatively small number of subjects but did not show any significant differences between external fixation and plate fixation. There was a trend toward increased risk of infection with plate fixation compared with external fixation, but also a lower risk of nonunion and the need for additional procedures ($p < 0.15$). These findings may be worthy of additional study in a larger patient population.

It is concluded from this review of severe soft tissue injuries associated with proximal, tibial end segment fractures (AO/OTA 41) that there are no significant differences between functional and clinical outcomes of salvage and early amputation at 2 years postinjury; however, overall function and objective outcomes generally are below normal levels.

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