The Economics of Treating Tibia Fractures

The Cost of Delayed Unions

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Abstract

The tibia, being the most commonly fractured long bone, is associated with a high incidence of delayed union and nonunion. A previously published prospective, randomized, double-blind and placebo-controlled tibia study demonstrated that pulsed, low-intensity ultrasound shortened the time to a healed fracture and significantly reduced the incidence of delayed union. The economics of treating tibia fractures has never been calculated. We have reviewed the literature pertaining to the tibia, the results of the above published tibia study, and stratified the data from that study for those patient and fracture co-morbidity factors that can influence healing of tibia fractures.

Three economic models are presented with the total costs of treating a pool of 1,000 patients with tibial shaft fractures divided into two treatment paths — operative and conservative. These costs include surgery and recovery, outpatient costs, and Workers' Compensation costs for both the primary and secondary procedures, and emergency room and disability costs. The first model does not use low-intensity ultrasound and provides a summary of the costs associated with fracture treatment for each treatment path. The second model uses low-intensity ultrasound adjunctively with the conservatively treated group while the third model uses ultrasound adjunctively in both the operative and conservative groups. When comparing the conservative treatment path of Model 2 to Model 1 a cost savings of over $15,000 per case (40%) is realized by dramatically lowering secondary procedures and Workers' Compensation costs when pulsed low-intensity ultrasound is used adjunctively with conservative treatment. A similar savings of over $13,000 per case results from the use of ultrasound in the operative treatment path of Model 3 when compared with the standard operative care of Model 1. The total savings realized is over $14.6 million when adjunctively using low-intensity ultrasound in both the conservative and operative treatment paths.

These analyses demonstrate that reduced healing time could yield substantial cost savings for third party payors, employers, and government agencies by lessening the need for secondary procedures and reducing the amount of Workers' Compensation payments.

The tibia is the most commonly fractured long bone and is probably fractured more often than any other bone in the lower extremity.[1-3] Tibia fractures are also associated with a high incidence of delayed union and nonunion.[1,3,4-7] They account for 35% to 65% of all nonunions.[4,8] There is also evidence that the incidence of tibia nonunions as a percentage of all long-bone nonunions appears to have increased over the past two decades.[9,10]

There is no universal consensus on the best method of managing tibial shaft fractures. Furthermore, based on a thorough search of the clinical literature, the total cost of treating tibia fractures, from initial fracture to union, has never been calculated. Bondurant and colleagues,[11] for example, have reviewed the economic impact of delayed versus primary amputations following severe open fractures of the lower extremity. Beck and associates[12] have estimated inpatient charges associated with treating adult femoral neck fractures. (In fact, the hip appears to be the most studied bone in the health economics literature.)

Intuitively, the longer the delay in the union of fractured tibias, the greater the cost will be to treat the fracture to the

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Table 1 Contributing Factors to Delayed Union of Tibial Fractures — Incidence Rates

Factor	Nicoll[6]	Darder[5]
Initial displacement (moderate to severe)	36%	33%
Comminution	30%	14%
Non-infected wound	37%	N/A
Severe comminution/wound	39%	N/A
Severe displacement/wound	55%	75%
Severe displacement/comminution	31%	54%
Severe displacement/comminution/wound	39%	79%
Fractured fibula	29%	48%

time of union. Re-operations, secondary, and tertiary procedures, and prolonged physical therapy add to the clinical costs of treating delayed unions. Our working hypothesis is that delays in fracture healing cost more money than early intervention to shorten the time of fracture healing.

This paper seeks to fill a gap in the literature in quantifying the cost of treating fractures that become delayed unions.

Defining Delayed Unions

For purposes of this study, delayed unions of the tibia are defined as tibial fractures that have not achieved union at 150 days post-fracture. Many fracture and patient characteristics contribute to delayed unions. Rockwood and coworkers[13] list age, gender, hormonal effects, bone necrosis, infection, percent pre-reduction displacement, fracture location, fracture type, and fracture gap as contributing factors. Nicoll,[6] Weissman,[7] Darder,[5] and Moore[3] have also identified the incidence of factors that inhibit fracture healing and lead to delayed union. Table 1 details the findings of Nicoll[6] and Darder,[5] which include initial displacement, comminution, presence of wound, and fibula fracture. Many studies have determined time to union for certain patient populations with tibial fractures. The average time to union reported in the literature ranges from 105 to 210 days (15 to over 30 weeks). Table 2 summarizes some of the results from these studies.[3,6,7,14-16] Where late delayed union or nonunion is evident, secondary procedures, done on an inpatient basis, are usually performed. These include but are not limited to bone grafting, intramedullary nailing, and internal fixation with plates and screws.

The Economic Model

Our working hypothesis is that it costs less money to pro-actively and adjunctively treat a population of tibia fractures with pulsed low-intensity ultrasound therapy when compared to a matching patient population of tibia fracture patients treated by standard methods alone. To test this hypothesis, we developed an economic model

Table 2 Time to Union for Tibial Fractures: Summary of the Literature

Authors	Type of Fracture	Time to Union (Days)*	Incidence of Delayed/Nonunion
Weissman[7]	Closed	140 patients > 15 years of age 152 days to healing patients > 15 years of age 12% delayed unions	12%
Nicoll[6]	Closed	674 fractures 17% delayed union (> 140 days) 5% non-union (35 fractures) Mean time to union = 111 days	22%
Jackson[14]	Closed	368 cases 14% non-union 16% union in 90 days 62% union by 182 days	38% (100%-62%)
Moore[3]	Closed (closed reduction & casted)	141 cases 20% healed in 150 days (40 cases) 21% required secondary procedures (29 cases)	21%
Oni, Hui and Gregg[15]	Closed	100 fractures 19% non-union as of 140 days	19%
Heckman[16]	Closed/ Grade I	67 fractures (33 Active w/ultrasound; 34 Placebo)	36%†
Average Incidence Delayed/Nonunion			**25%**

*Where a study indicates time in months, we have calculated days to facilitate comparison across studies.
†Incidence of delayed union is in placebo group

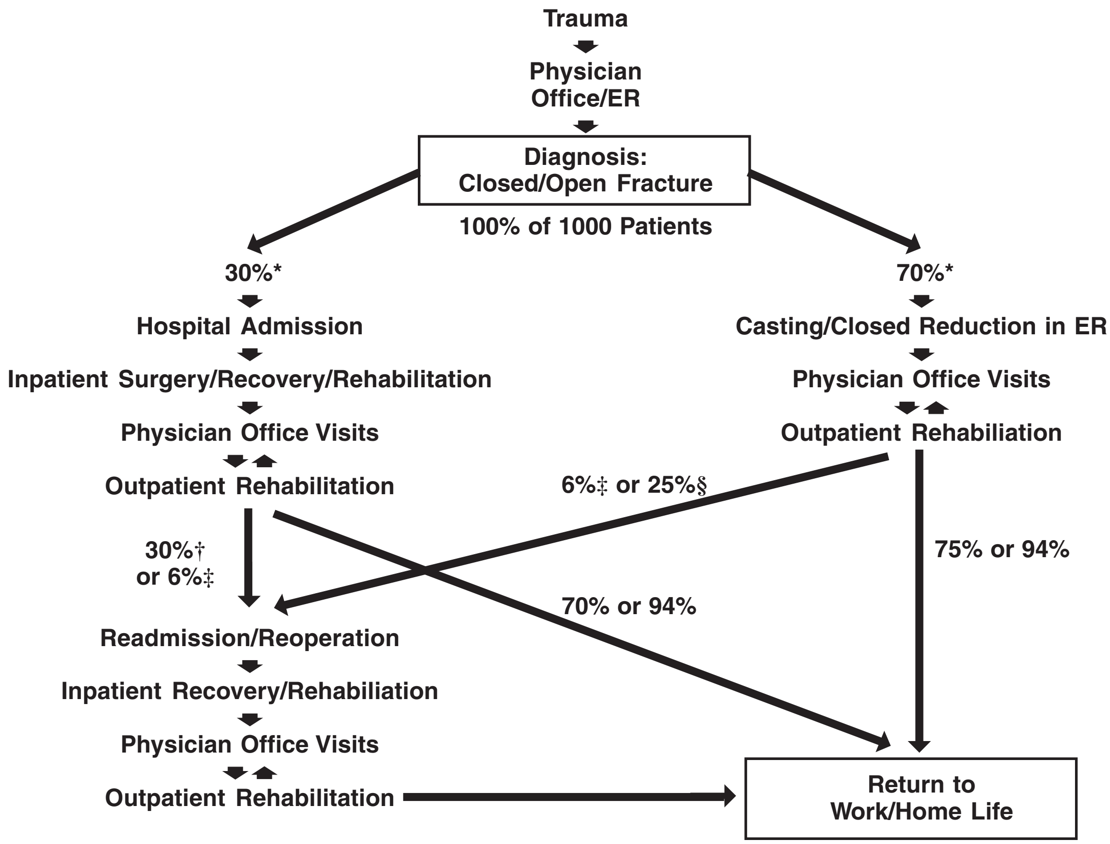

Figure 1 Tibial fracture treatment pathways — closed and Grade 1 open fractures.*Estimate based on clinical experience; †Riemer[21]; ‡6% reoperation rate from active population in Heckman[16]; §25% average of references in Table 3.

based on the life cycle of treating closed and Grade I open tibial fractures (Gustilo[17]). Figure 1 is a graphic representation of the economic model. We first developed this model in a previous paper, *Measuring the Costs of Treating Tibial Fractures.*[18] That model analyzed the costs of tibial fractures from initial trauma to union and included all fracture types (i.e., closed, open Grade I, Grade II, and Grade III). In the present paper, we are using three models and have adjusted each to reflect the study population of closed and open Grade I fractures; we assume two treatment paths within each model as described below. The treatment paths are generically diagrammed in Figure 1. These models are based on the following three categories of assumptions (Table 3).

Patient Characteristics

A pool of 1,000 patients with closed and open Grade I tibial diaphysis fractures is assumed for each model.

Treatment Models

The first model assumes that only standard conservative or operative orthopaedic management is used for treating the 1,000 closed or open Grade I fractures. Model 2 provides early intervention in the form of pulsed, low-intensity ultrasound to promote early fracture healing in the conservatively (non-operative) treated patient pool. The third model employs early intervention with ultrasound for both the conservative (non-operative) and the operative (IM rod) patient pools.

Treatment Paths

Treatment paths consistent with current clinical protocols for treating closed and open Grade I fractures were developed. Although closed reduction with cast immobilization remains the treatment of choice for closed or Grade I fractures, the use of intramedullary rods (IM rod) is increasing for these fractures with an estimated present use of 30%. This division of conservative and operative management is shown in Figure 1. The treatment paths (conservative and operative) "drive" the costs in the economic model. Patients were divided into the treatment paths with the following assumptions:

1. Conservatively treated (Group 1): In this group 70% of the 1,000 patient pool present to the emergency room and are treated through closed reduction and cast immobilization. In Model 2 and 3, this patient pool receives early intervention in the form of pulsed, low-intensity ultrasound to promote early fracture healing as reported by Heckman.[16] As a result of receiving ultrasound, this popula-

Table 3 Tibial Fracture Economic Model — Assumptions

Patient Characteristics	
Closed and Open I Tibial Diaphysis Fractures	100%
Total tibial fracture population	1,000
Treatment Model	
Model 1 — Standard Conservative or Operative Treatment (No ultrasound therapy in either clinical pathway)	
Model 2 — Standard Conservative Treatment with Adjunctive Ultrasound and Operative Treatment without Ultrasound Therapy	
Model 3 — Both Standard Conservative and Operative Treatment with Adjunctive Ultrasound Therapy	
Treatment Paths	
Patient pools:	
Conservatively Treated (non-operative)	
Casting/Closed Reduction in Emergency Room	70%
Secondary Surgery Rate (without ultrasound)	25%
Secondary Surgery Rate (with ultrasound)	6%
Operative Treated (IM Rod)	
Primary Surgery (IM Rod)	30%
Re-operation Rate	30%
Economic Assumptions	
Wage and fringe benefits per day out of work*	$123
Disability days (operative — Table 5)	154
Disability days (conservative without ultrasound — Table 5)	176
Disability days (conservative with ultrasound†)	96
Disability days (Operative with ultrasound‡)	122
Disability non-hospital costs per case§	$716

*Average hourly wage for nonagricultural nonsupervisory job, 1989 = $9.66 (plus 30% benefits). Adjusted for general consumer price inflation as follows: 1990@4.6%, 1991@4.2%, 1992@3.0%, 1993@3.0%, 1994@2.6%, 1995@2.8%. 1996 adjusted hourly wage and benefits = $15.32 per hour including 30% benefits. Assuming an 8-hour workday, daily wage = $123.
†Disability days with ultrasound are based on results of the average time to a healed fracture in research reported by Heckman.
‡Disability days obtained from ultrasound registry of general orthopaedic prescription use for IM rodded tibial shaft fractures
§Workers' compensation non-hospital cost per case based on Miller. 1992 data calculated as $640 worth of non-hospital costs per case, adjusted for general consumer price inflation as detailed above to $716. Non-hospital costs per case include administrative costs such as claims, case management, and managed care plan expenses. Sources: Ted Miller, et al: *The Costs of Occupational Traumatic and Cumulative Injuries,* The Urban Institute, 1991. U.S. Bureau of Labor Statistics.

tion is assumed to have an average time to a healed fracture of 96 days.[16] Based on Heckman's[16] work, for Group 1, 6% of the active ultrasound-treated patients result in delayed unions and require secondary operative procedures to achieve union. In Model 1, conservative treatment without ultrasound, the work days lost to disability is 176 based on the average of the four conservative treatment studies shown in Table 4.[1,16,19,20] The percent of conservatively treated fractures reaching delayed union status and requiring secondary operative procedures is 25% based on the studies shown in Table 2.

2. Operatively treated (Group 2, IM rod): In Model 1 and 2, 30% of the 1,000 patient pool present to the emergency room and their surgeons admit them to the hospital for surgical intervention with an intramedullary rod. Due to delayed union or other complications, 30% of these patients will require re-operation (Riemer and colleagues[21]). Work days lost due to disability are assumed at an average of 154 days based on Puno's[1] operative IM group (Table 4). For Group 2 in Model 3, data is available for disability days (122 days) and re-operation rate (2%) from the low-intensity ultrasound registry of general orthopaedic prescription use for IM rodded tibial shaft fractures.

Costs

Unit costs for each treatment component and encounter along the treatment path were developed from the authors' survey of applicable costs and current national U.S. average cost estimates.[22] These are detailed in Table 5. We use clinical data gathered during our previously controlled study[16] into ultrasound's accelerated healing effect in tibial diaphysis fractures to validate assumptions made in the economic model.

Methodology

The previously referenced clinical study was prospective, randomized, double-blind, placebo-controlled, and multicenter. All skeletally mature men and non-pregnant women, age seventy-five or younger, with a closed or Grade I open, transverse, short oblique, or short spiral tibial diaphysis fracture, that could be treated effectively with closed reduction and immobilization in a cast, were

Table 4 Disability Days Until Return to Work in Tibial Fracture Populations — Comparison of Four Studies

Study	Year	Treatment Type Conservative	Operative
Dehne[19]*	1961	150 days	-
Haines[20]†	1984	217 days	-
Heckman[16]‡	1994	154 days	-
Puno[1]§	1986	181 days	154 days
Average disability days =		176 days	

*Early weightbearing with cast. †Conservative with cast. ‡Conservative with cast; return to work assumed to be time to a healed fracture [clinically and radiographically healed (three cortices bridged)] for placebo patients. §Operative/intramedullary rod.

given the opportunity to participate in the study. The pulsed low-intensity ultrasound therapy device for both the active and placebo groups was identical in all respects except no ultrasound was emanated by the placebo device. The device was used for one continuous 20 minute treatment per day until the site investigator judged the fracture sufficiently healed to discontinue therapy. The end-point of the study was a healed fracture [clinically healed (no pain or motion on gentle stress and no pain on weightbearing), and radiographically healed (3 of 4 cortices bridged)].

Clinical Results

Discussions and Implications of Stratification Data

The overall results of the study have been presented in Heckman and colleagues,[16] and demonstrated that the randomization process produced comparable active and placebo groups for all fracture and patient characteristics. The result demonstrated the efficacy of low-intensity ultrasound stimulation in the acceleration of the normal fracture-repair process. The mean fracture healing time for the active device group overall was 96 ± 5 days while a mean healing time of 154 ± 14 days was observed among placebo users ($p < 0.0001$). Clinical healing time was reduced from 114 ± 10.4 days for the placebo group to only 86 ± 5.8 days for the active group ($p < 0.01$). In addition, the mean time to discontinuation of the cast was 94 ± 5.5 days for the active group compared with 120 ± 9.1 days for the placebo group ($p < 0.008$).

Data generated by this study were available to assess the effect on the time to a healed fracture for different strata associated with fracture characteristics such as fracture type, location, gap size, percent displacement at fracture, associated fibula fracture, and patient characteristics such as age, gender, and smoking history. Each personal and fracture characteristic stratum was analyzed for this report by analysis of variance (ANOVA) for the time to a healed fracture's mean, standard error of the mean (SEM), and significance level. Each stratum was also assessed for treatment effect and stratum-by-treatment interaction. Table 6 details the results of the analy-

Table 5 Tibia Fracture Economic Model Clinical Cost Assumptions

Assumption			Cost per Case
Surgery/Recovery			$20,575
OR/Recovery (90 min. @ $30/min)	$2700	(2)	
Anesthesia supplies	$250	(2)	
Professional fees-Surgeon	$3000	(2)	
Professional fees-Anesthesiologist	$1200	(2)	
Radiology	$2000	(2)	
Laboratory/Diagnostic	$3000	(2)	
Pharmacy	$1700	(2)	
Supplies (ultrasound not included)	$1100	(2)	
Hospital Charges/Recovery (ALOS)	$3750	(2)	
Professional fees	$1875	(2)	
Re-operation (second phase)			$20,575
Same as Above			
Outpatient (first or second phase)			$4,317
Physical Therapy visits	$3083	(3)	
Radiology	$308	(4)	
Laboratory/Diagnostic	$156	(5)	
Pharmacy	$330	(6)	
Physicians visits	$440	(7)	
Emergency Room			$825
Visit	$150		
Professional fees-Initial Consult	$200		
Initial Casting	$75		
Supplies	$50		
Laboratory/Diagnostic	$250		
Pharmacy	$100		
Disability Cost per Case		(1)	$716
Workers Compensation per day		(1)	$123
Pulsed Low-intensity Ultrasound		(8)	$2,950

(1) Average hourly wage for nonagricultural non-supervisory job, 1989 = $9.66 (plus 30% benefits). Adjusted for general consumer price inflation as follows: 1990 @ 4.6%, 1991 @ 4.2%, 1992 @ 3.0%, 1993 @ 3.0%, 1994 @ 2.6%, 1995 @ 2.8%. 1993 hourly wage and benefits adjusted = $15.32 per hour including 30% benefits. Assuming an 8 hour day, daily wage = $123. Workers compensation non-hospital cost per case based on Miller (1992 data calculated $640 worth of non-hospital costs per case). Data is adjusted to reflect 1996 dollars based on CPI rates as detailed above. Non-hospital costs per case include administrative costs such as claims, case management and managed care plan expenses.

(2) Surgery includes all procedures required during an inpatient stay, such as: open reduction, debridement, stabilization, fixation, IM nailing, and bone grafting. Charges are based on unit cost times appropriate LOS, minutes in surgery, number of PT visits, etc.

(3) Physical Therapy visits are calculated at rate of 1 visit per every 3 days prior to bone healing.

(4) Radiology encounters calculated at rate of every 30 days prior to bone healing.

(5) Lab/diagnostic encounters are calculated at rate of 1 per every 30 days prior to bone healing.

(6) Pharmacy costs calculated at rate of 1 order per every 14 days prior to bone healing.

(7) Physician visits calculated at rate of 1 every per every 21 days prior to return to work/home.

(8) Exogen Pulsed Low-intensity Ultrasound System (SAFHS®)

Sources: HCIA, Fracture Cost Breakdown, 1992 Discharges, ICD-9 823.xx-Tibia and Fibula Fractures[22]; and authors' survey.

Table 6 Time to a Healed Fracture (Days Post-Fracture) to Assess Treatment Effect Within Strata

Strata	Active Mean ± SEM	(N)	Placebo Mean ± SEM	(N)	ANOVA P-Value <	% Acceleration
Gender:						
Female	89 ± 8	8	180 ± 32	5	0.005	50%
Male	98 ± 6	25	149 ± 15	28	0.001	34%
Age:						
≤ 30	84 ± 4	12	126 ± 12	18	0.02	33%
≥ 30	103 ± 8	21	187 ± 18	15	0.0001	45%
Percent Pre-Reduction Displacement:						
0-24	85 ± 6	13	146 ± 26	10	0.01	41%
≥ 25	103 ± 7	20	158 ± 17	22	0.002	35%
Fracture Location:						
Distal	106 ± 8	17	178 ± 25	16	0.0004	41%
Middle	85 ± 5	15	128 ± 10	14	0.03	33%
Proximal	89 ± NC*	1	149 ± 46	3	NC*	40%
Fracture Type:						
Oblique	91 ± 5	17	168 ± 29	14	0.0004	46%
Spiral	101 ± 11	11	152 ± 16	11	0.03	33%
Transverse	101 ± 17	5	132 ± 15	8	0.19	23%
Fracture Gap (mm):						
0-3	90 ± 6	17	127 ± 10	18	0.03	29%
≥ 4	102 ± 8	16	187 ± 26	15	0.0001	45%
Fibula Fracture:						
No	77 ± 4.0	9	182 ± 51	4	0.002	58%
Yes	103 ± 6.1	24	150 ± 14	29	0.003	31%

*Not calculated due to insufficient sample size.

ses for the time to a healed fracture within each stratum. All stratum showed a statistically significant difference in favor of the active group with the exception of the transverse stratum in fracture type where active was superior to placebo with only a trend toward statistical significance. Large differences between active and placebo are especially noted for females, the older age group, distal fracture location, oblique fracture type, larger fracture gap, and the presence of a fibular fracture. All strata had no covariate by treatment interaction effect, and with the exception of age, no covariate effect. In Table 6, the ANOVA of the data stratified to the two age groups suggested an age effect with patients 30 years and under with $p < 0.006$.

The study data also allowed an assessment of the incidence of delayed union (≥ 150 days post fracture) in both active and placebo treatment groups (Fisher's Exact Test). Thirty-six percent of the placebo group experienced delayed unions as compared to only 6% in the active group ($p < 0.003$). The stratification of these data assessing the incidence of delayed union by strata is summarized in Table 7 and demonstrates the effect of comorbidity factors on the incidence of delayed unions.

Smoking and Delayed Union

Smoking has been found to delay bone union of tibial shaft fractures, as well as other types of fractures.[23-25] Schmitz and colleagues,[23] showed clinical evidence that smoking may be implicated in nonunions of diaphyseal fractures resulting from trauma. In 1993, they treated 200 consecutive closed and Grade I open tibial shaft fractures in smokers and nonsmokers with either cast immobilization, IM nails, or external fixation. They demonstrated that smoking may delay healing. Radiography revealed a 43% delay in healing in the smoking group, and the average time to complete union was 70% longer in smokers compared to nonsmokers. Kwiatkowski and associates[24] reviewed the body of knowledge on cigarette smoking and its ramifications in the field of orthopedic surgery, confirming the findings of the above authors. Our research suggests that ultrasound helps to neutralize smoking's negative impact on fracture healing. In a retrospective study on the impact of smoking on the Heckman tibia study population and a parallel study in distal radius metaphysis fractures, Cook and associates[25] stated that, "The use of the active ultrasound device accelerates cortical and cancellous bone fracture healing, substantially mitigates the delayed healing effects of smoking, speeds the return to normal activity, and reduces the long-term complication of delayed union."

Results and Discussion of the Economic Model

Based on the assumptions in the economic models, significant cost savings were achieved by the early inter-

Table 7 Effect of Comorbidity Patient and Fracture Characteristics on the Incidence of Delayed Union (Fracture Percentage ≥ 150 Days Post-Fracture)

I. Without stratification treatment effect:	Active		Placebo		P-Value <
	6.1%	(2/33)	36.4%	(12/33)	0.003
II. Strata	**Active**		**Placebo**		**P-Value <**
Gender:					
Female	0.0%	(0/8)	60.0%	(3/5)	0.04
Male	8.0%	(2/25)	32.1%	(9/28)	0.03
Age:					
≤ 30	0.0%	(0/12)	22.2%	(4/18)	0.1
≥ 31	9.5%	(2/21)	53.3%	(8/15)	0.006
Percent Pre-Reduction Displacement:					
0-24	0.0%	(0/13)	30.0%	(3/10)	0.07
≥ 25	10.0%	(2/20)	40.9%	(9/22)	0.03
Fracture Location:					
Distal	11.8%	(2/17)	50.0%	(8/16)	0.02
Middle	0.0%	(0/15)	21.4%	(3/14)	0.1
Proximal	0.0%	(0/1)	33.3%	(1/3)	NC*
Fracture Type:					
Oblique	0.0%	(0/17)	35.7%	(5/14)	0.01
Spiral	9.1%	(1/11)	45.5%	(5/11)	0.07
Transverse	20.0%	(1/5)	25.0%	(2/8)	0.7
Fracture Gap (mm):					
0-3	5.9%	(1/17)	16.7%	(3/18)	0.3
≥4	6.3%	(1/16)	60.0%	(9/15)	0.002
Fibula Fracture:					
No	0.0%	(0/9)	50.0%	(2/4)	0.08
Yes	8.3%	(2/24)	34.5%	(10/29)	0.02

*Not calculated due to insufficient sample size.

vention of applying pulsed, low-intensity ultrasound in a tibia fracture population. The results of the economic models appear in Tables 8, 9, and 10. These tables demonstrate that the application of ultrasound to shorten the time of fracture healing yields substantial economic benefits in three areas:

1. In the surgical costs of re-operation required due to delayed fracture healing,
2. In the reduction of Workers' Compensation costs due to significantly reduced healing time, and
3. In the outpatient care requirements in the second phase of fracture healing.

Significant Cost Savings

When comparing the treatment costs of the 1,000 patients in each of Model 1 (no ultrasound in either treatment path) and Model 2 (ultrasound used pro-actively in only the conservative treatment path), a significant cost savings of 24% (over $10.6 million or $10,650 per case) is realized. The cost difference, resulting from the adjunctive use of low-intensity ultrasound, is even more substantial when one compares only the conservatively treated Group 1 of Model 1 (*see* Table 8) and Group 1 of Model 2 (*see* Table 9). A per case savings of over $15,000 or 40% is realized with the adjunctive use of low-intensity ultrasound in this 700 patient subset.

Model 3 incorporates adjunctive low-intensity ultrasound into both clinical pathways. The cost savings realized increases to $14,630 per case or over $14.6 million. This equates to a 33% savings for the total 1,000 patient fracture pool (*see* Tables 8 and 10). These savings are more dramatic if the effect of delayed healing due to smoking as reported in Schmitz[24] and Cook[25] is factored into the analyses. For smokers, Model 2 (ultrasound in the conservative path) produces a savings of over $20.6 million (33%) when compared to Model 1 (no ultrasound in either treatment path). Model 3 (ultrasound in both treatment paths) versus Model 1 realizes a savings of over $30.8 million (50%).

When one analyzes the resource consumption/cost analysis (Table 11) for the cost savings relative to the low-intensity ultrasound device cost, the resulting return on the ultrasound therapy investment in both cases is over 450% for both the conservatively treated and operatively treated groups with and without ultrasound.

The shortening of the time to union and a substantial reduction in secondary procedures when using low-intensity ultrasound translates into cost savings for all treatment following the initial treatment of the fracture. Components of fracture management costs that are reduced include outpatient and ambulatory care, re-operation costs, workers compensation, and disability costs.

Other Economic Benefits

There are other costs which are not easily quantified in an economic model, but yield economic benefit nonetheless and should therefore be noted. Our clinical data indicate that the application of ultrasound to accelerate fracture healing neutralizes several factors that typically compromise fracture healing. The stratification data demonstrates the effect of patient and fracture comorbidity factors on the healing time in tibia fractures. Table 2 demonstrates the incidence of delayed union in tibia fractures as reported in the literature. Thirty-six percent of all of the placebo fractures in the study by Heckman[16] were delayed unions as previously reported. These delayed unions reflect the influence of comorbidity factors: all had pre-reduction displacements of greater than 20% and fracture gaps of 3 mm or more; 92% were in the mid or distal tibia; and 83% were oblique or spiral fractures. The models presented in this paper do not attempt to quantify the cost savings and benefits that would accrue for patients with the more severe of these fracture healing comorbidity factors. In addition, the real economic impact of the injured worker's lost household productivity and quality of life are not quantified in these models.

Table 8 Model 1: Standard Conservative or Operative Treatment (No Ultrasound in Either Clinical Pathway)

Assumptions		Clinical Pathway Group 1* Conservatively Treated		Group 2† Operative	
Patient pool — 1,000 cases		70%		30%	
Treatment groups		700		300	
Disability days		176‡		154‡	
Rate of re-operation		25%§		30%§	
	Cost Per Case	Closed Reduction/Cast	Secondary Surgery	Primary Surgery	Re-operation
Emergency Room	$825	$577,500		$247,500	
Surgery/Recovery (First phase)	$20,575			$6,172,500	
Re-operation (Second phase)	$20,575		$3,600,625		$1,851,750
Outpatient (First phase)	$4,317	$3,021,900		$1,295,100	
Outpatient (Second phase)	$4,317		$755,475		$388,530
Workers' Compensation (First phase)	$123/day	$15,153,600		$5,682,600	
Workers' Compensation (Second phase)	$123/day		$3,314,850		$1,704,780
Disability costs (administrative)	$716	$501,200		$214,800	
Subtotal		$19,254,200	$7,670,950	$13,612,500	$3,945,060
Total			**$26,925,150**		**$17,557,560**
Cost per Patient		**700 Cases =**	**$38,465**	**300 Cases =**	**$58,525**
Grand Total		**1,000 Cases =**			**$44,482,710**
Overall Cost per Patient		**1,000 Cases =**			**$44,483**

*Clinical pathway: Conservative treated/cast closed reduction. No ultrasound. †Clinical pathway: IM rod/surgery. No ultrasound. ‡Table 5: Conservative = 176 days; Operative = 154 days. §Group 1: Table 2; Group 2: Reimer[21]

Table 9 Model 2: Standard Conservative Treatment with Adjunctive Ultrasound and Operative Treatment without Ultrasound

Assumptions		Clinical Pathway Group 1* Conservatively Treated		Group 2† Operative	
Patient pool — 1,000 cases		70%		30%	
Treatment groups		700		300	
Disability days (First phase)		96‡		154§	
Disability days (Second phase)		154§		154§	
Rate of re-operation		6%‡		30%¶	
	Cost Per Case	Closed Reduction/Cast	Secondary Surgery	Primary Surgery	Re-operation
Emergency Room	$825	$577,500		$247,500	
Low-Intensity Ultrasound Device	$2,950	$2,065,000			
Surgery/Recovery (First phase)	$20,575			$6,172,500	
Re-operation (Second phase)	$20,575		$864,150		$1,851,750
Outpatient (First phase)	$4,317	$3,021,900		$1,295,100	
Outpatient (Second phase)	$4,317		$181,314		$388,530
Workers' Compensation (First phase)	$123/day	$8,265,600		$5,682,600	
Workers' Compensation (Second phase)	$123/day		$795,564		$1,704,780
Disability costs (administrative)	$716	$501,200		$214,800	
Subtotal		$14,431,200	$1,841,028	$13,612,500	$3,945,060
Total			**$16,272,228**		**$17,557,560**
Cost per Patient		**700 Cases =**	**$23,246**	**300 Cases =**	**$58,525**
Grand Total		**1,000 Cases =**			**$33,829,788**
Overall Cost per Patient		**1,000 Cases =**			**$33,830**

*Clinical pathway: Conservative treated/cast closed reduction and ultrasound. †Clinical pathway: IM rod/surgery. No ultrasound. ‡Disability days and re-operation rate with ultrasound based on Heckman.[16] §Table 5 - from Puno[1] operative disability days. ¶Reoperation rate based on Reimer.[21]

Table 10 Model 3: Both Standard Conservative and Operative Treatment with Adjunctive Ultrasound Therapy

Assumptions		Clinical Pathway: Group 1* Conservatively Treated		Group 2† Operative	
Patient pool — 1,000 cases		70%		30%	
Treatment groups		700		300	
Disability days (First phase)		96‡		122§	
Disability days (Second phase)		154¶		154¶	
Rate of re-operation		6%‡		2%§	
	Cost Per Case	Closed Reduction/Cast	Secondary Surgery	Primary Surgery	Re-operation
Emergency Room	$825	$577,500		$247,500	
Low-Intensity Ultrasound Device	$2,950	$2,065,000		$885,000	
Surgery/Recovery (First phase)	$20,575			$6,172,500	
Re-operation (Second phase)	$20,575		$864,150		$123,450
Outpatient (First phase)	$4,317	$3,021,900		$1,295,100	
Outpatient (Second phase)	$4,317		$181,314		$25,902
Workers' Compensation (First phase)	$123/day	$8,265,600		$4,501,800	
Workers' Compensation (Second phase)	$123/day		$795,564		$113,652
Disability costs (administrative)	$716	$501,200		$214,800	
Subtotal		$14,431,200	$1,841,028	$13,316,700	$263,004
Total			**$16,272,228**		**$13,579,704**
Cost per Patient		**700 Cases =**	**$23,246**	**300 Cases =**	**$45,266**
Grand Total		**1,000 Cases =**			**$29,851,932**
Overall Cost per Patient		**1,000 Cases =**			**$29,852**

*Clinical pathway: Conservative treated/cast closed reduction and ultrasound. †Clinical pathway: IM rod/surgery and ultrasound. ‡Disability days and re-operation rate with ultrasound based on Heckman.[16] §Disability days and re-operation rate based on results of low-intensity ultrasound prescription use registry. ¶Reoperative disability days from Puno[1] (Table 5).

Discussion and Implications

The impact of various strata characteristics on delayed healing can be neutralized by using low-intensity ultrasound early in fracture patients. It is clear that ultrasound accelerated fracture healing for patients in every comorbidity strata. The incidence of delayed union was significantly reduced by the early use of ultrasound (36% in placebo non-treated patients versus only 6% in active ultrasound-treated patients) and provided more predictable healing in this challenging fracture type.

In April 1995, the American Academy of Orthopaedic Surgeons[26] reported that 21% of patients treated by orthopaedic surgeons were covered by managed care plans. Those managed care organizations that must integrate clinical care with financial risk can benefit from the application of ultrasound for predictable healing for fractures with significant comorbidity factors. Increasingly, patients and health care plans are becoming attuned to patient satisfaction and quality of life issues, which can have an impact on the retention of members within the plan.

In 1994, there were 33.2 million elderly Americans (aged 65 or older), one-eighth of the country's total population. The "oldest old" population (persons aged 85 and over) is expected to double in size by 2020, reaching 7 million by that year. Health care costs for this segment will place a tremendous burden on the nation's health care budget — and current forecasts for the Medicare trust fund indicate that before the year 2000 a fiscal crisis could occur in the Medicare program. Based on our analyses of the comorbidity strata, the use of ultrasound was even more effective in the older adult; it reduced the healing time, thereby allowing for early rehabilitation in this difficult fracture population. The use of ultrasound for fracture care in the older person can have a positive impact on the costs to the nation's health care system.

Conclusions

Low-intensity pulsed ultrasound significantly reduces the time to a healed fracture, the time to clinical healing, and the time to cast removal. Reduced time to healing trans-

Table 11 Per Case Resource Consumption/Cost Analyses

	Conservatively Treated (700 Cases)	Operatively Treated (300 Cases)
Without ultrasound	$38,465	$58,525
With ultrasound	$23,246	$45,266
Cost reduction with ultrasound	$15,219	$13,259

lates into cost savings for health plans, employers, government agencies, as well as patients by reducing the requirements for secondary procedures due to delayed union, Workers' Compensation costs, and complications exacerbated by delayed healing. The cost savings from the use of low-intensity ultrasound for both conservatively and operatively treated cases when low-intensity ultrasound is used proactively is over $15,000 per case in the conservative pathway and over $13,000 per case in the operative pathway. Thus, health care providers and payors should consider how early application of ultrasound in the treatment of tibia fractures, especially when comorbidity factors are present, can save resources and provide more predictable healing for fracture patients.

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