A Cost-Utility Analysis of Amputation versus Salvage for Gustilo IIIB and IIIC Open Tibial Fractures

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Abstract

Background: Lower extremity trauma is common. Despite an abundance of literature on severe injuries that can be treated with salvage or amputation, the appropriate management of these injuries remains uncertain. In this situation, a cost-utility analysis is an important tool in providing evidence-based practice an approach to guide treatment decisions.

Methods: Costs following amputation and salvage were derived from data presented in a study that emerged from the Lower Extremity Assessment Project. We extracted relevant data on projected lifetime costs and analyzed them to include discounting and sensitivity analysis for consider patient age. The utilities for the various health states (amputation or salvage, including possible complications) were previously measured using the standard gamble method and a decision tree simulation to determine quality-adjusted life years (QALYs).

Results: Amputation is more expensive than salvage independent of varied ongoing prosthesis needs, discount rate, and patient age at presentation. Moreover, amputation yields fewer QALYs than salvage. Salvage is deemed the dominant, cost-saving strategy.

Conclusions: Unless the injury is so severe that salvage is not a possibility, based on this economic model, surgeons should consider limb salvage, which will yield lower costs and higher utility when compared to amputation.

Keywords

Cost-utility analysis; lower leg trauma; utility; amputation; salvage; reconstruction

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Lower extremity trauma is common. Epidemiology studies have shown that open long bone fractures occur at a rate of 11.5 per 100,000 persons per year, and many of these are open tibial shaft fractures[1-3]. Type III open fractures are the most severe, involving extensive soft tissue trauma and complex fracture patterns[4].

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Many of these injuries can be managed with salvage involving either local muscle flaps or microvascular free tissue transfer for wound coverage. The alternative to reconstruction for such injuries is amputation. Over the past decades, many studies have sought to delineate the advantages and disadvantages of these two principal options for managing severe lower extremity trauma. A recent systematic review of all available literature demonstrated that, despite the abundance of evidence, neither option is superior with respect to clinical outcomes[5].

Because microvascular reconstruction is technically demanding, time-consuming, and fraught with substantial risk of complications, we must look beyond clinical outcomes to evaluate the costs and utilities afforded to patients by this option. Studies have shown that even with successful limb salvage, many patients are still not ambulatory after two years; persistent pain and disability are not uncommon after this type of injury[6, 7]. Despite the residual problems with reconstruction, however, some studies suggest that patients with salvaged lower limbs have a better quality of life and impose lower costs on the health care system[8-10].

As surgeons, we want the best for our patients, but as stewards of modern medicine who work with limited healthcare resources, we are also charged with making evidence-based, fiscally-sound decisions. When dealing with complex operations of uncertain effectiveness, cost-utility analyses can help provide the scientific evidence upon which these decisions can be based. Although costs[10] and utilities[11] have been measured, a detailed cost-utility analysis with robust sensitivity analysis, which is needed to consider the wide-range of assumptions in clinical decision-making, has not been conducted. This study presents a cost-utility analysis for management of severe open tibial fractures, and will serve to guide surgeons and patients in deciding between the two competing management options.

Materials and Methods

Cost is typically measured in currency, and it should reflect the present value of total future expenditures that would be incurred by making a certain decision. Utilities are typically measured in quality-adjusted life years (QALYs). A QALY is used to account for the morbidity of a health state, based on the assumption that a year of life with morbidity is not equal to a year of life without morbidity. For example, if a year of life with blindness is only three-fourths as valuable to patients as a year with perfect vision, each year of life with blindness will equal 0.75 QALYs. The value of a year with morbidity, referred to as the "utility weight," can be determined through validated surveys including the standard gamble method, the time-tradeoff method, or the Short Form-36, among others[12].

Cost-utility ratios are normalized values that reveal how much money (cost) must be paid for a single extra QALY (utility). Thus, if making Decision 1 costs $200,000 and yields an extra 3 QALYs, it costs $66,667 per QALY ($200,000 / 3 QALYs). When deciding between two management options, one should consider the incremental cost for the incremental gain of QALYs. This ratio, the incremental cost-effectiveness ratio, is calculated as $(\text{Cost}_1 - \text{Cost}_2) / (\text{QALY}_1 - \text{QALY}_2)$ and is only useful when Decision 1 costs more but yields increased QALYs. If one of the interventions costs less and yields increased QALYs, that decision is "cost-saving" and "dominates" the other decision.

To calculate the cost-utility ratios for salvage and amputation following IIIB and IIIC tibial fractures, we combined the authors' previous work on utility, based on a survey of reconstructive microsurgeons and physical medicine and rehabilitation (PM&R) physicians, [11] with reworked cost data from the Lower Extremity Assessment Project (LEAP) study[10].

Costs

The costs following amputation and salvage were derived from the data presented in an outcome study from the LEAP study. LEAP is the largest primary analysis of limb-threatening injuries. The project is a prospective, longitudinal, multicenter study funded by the National Institutes of Health, and it has resulted in numerous publications[7, 13, 14][6, 10, 15-25]. The authors of the cost study estimate two-year costs and lifetime costs for amputation and salvage. For secondary amputation, data on amputations performed within three months of injury were aggregated in the amputation group. Data for amputations performed after three months were aggregated in the salvage group. Two-year costs include initial hospitalization, all re-hospitalizations for acute care related to the limb injury, inpatient rehabilitation, outpatient doctor visits, outpatient physical and occupational therapy, and the purchases and maintenance of prosthetic devices. Projected lifetime costs include ongoing clinical needs, such as clinic visits and prosthetic needs. To better reflect true cost of care, billed rates are multiplied by Medicare cost-to-charge ratios or cost-recovery ratios as appropriate. All dollar amounts are inflated to 2002 US dollars using the medical service Cost Price Index[10].

By correcting only for inflation, the LEAP study ignores the time value of money (i.e., the fact that a dollar tomorrow is worth less than a dollar today even after adjusting for inflation). Discounting takes this value into account and is necessary in order to compare the actual or true values of the alternative interventions. This is an essential practice when alternative interventions have different costs occurring at different times over the remaining life of the patient. Procedures that involve a large fraction of long-term expenses, such as ongoing prosthetic needs, are likely to be more overstated in past studies that do not discount. Discounting reduces the costs of these interventions because of the process of compounding, year after year. To obtain estimates of the true costs of salvage versus amputation, we have discounted the costs by the risk-free rate. The risk-free rate is the minimum discount rate and can be used because it is assumed that the costs of the medical interventions are perfectly predictable. Because costs are likely to change in the future, the estimates in this study should be regarded as a conservative estimate of the effects of discounting.

The risk-free rate, R_f, used to discount future cash flows that are certain, is typically the 20-year U.S. Treasury rate. Because the study has already accounted for inflation, we need to employ a rate of return that has been normalized for inflation. The nominal rate can be normalized to account for inflation by subtracting the inflation rate, i. The newly obtained value, $R_f - i$, is called the real risk-free rate. Real Treasury bill rates have been reported since 2004. Since that time, the real risk-free rate has ranged from 1.58% to 3.35%[26].

For discounting purposes, two-year costs were simplified by assuming that they take place at the beginning of year one. This is a reasonable assumption for two reasons. First, 60-80% of the two-year costs result from the initial hospitalization. Second, discounting at relatively low risk-free rates will only have a clinically meaningful effect over a period of time much longer than two years.

Annual lifetime costs were extracted from the available cost data from the LEAP study [10]. Prosthetic device costs, based on a frequency of purchase of every 2.3 years and annual maintenance costs of 20% of the prosthetic cost, as noted in the study, were annualized by taking into account the time value of money and then added to ongoing lifetime costs.

The LEAP study did not account for non-medical costs. A robust assessment of the true cost difference between two interventions must account for all costs that vary between the two options. According to a systematic review of all available literature, loss of income with these injuries can be severe: only two-thirds of patients return to work, and this is only after an average delay of 14 months[5]. However, the percent of patients returning to work and the

average delay until return to work did not differ significantly between salvage and amputation patients. Therefore, although these costs are important in determining the true cost of an intervention, they will not affect the comparison of salvage with amputation. For this reason, we exclude these costs in our comparison of these two interventions.

Utility

In 2008, we conducted a survey of randomly selected physicians from the American Society for Reconstructive Microsurgery (ASRM) and Physical Medicine and Rehabilitation (PM&R) physicians from the authors' home institution[11]. In this study, a web-based survey was deployed based on our prior experiences with utility surveys[27, 28], using the standard gamble method. The standard gamble is based on von Neumann and Morgenstern's utility theory, and involves a survey in which participants are asked to compare specific outcomes with a probability of certain death. From this, we are able to determine how much "death" one is willing to risk in order to avoid a morbid health state. For example, if someone would rather risk a 25% chance of death than be blind with 100% certainty, then the utility of being blind is 75% (100% - 25%), and a year of this morbid life would be worth 0.75 QALYs. To avoid double counting, survey takers in the utility study are explicitly asked to ignore any financial burdens when comparing outcomes.

Quality-adjusted life years are calculated from the utility values in the standard fashion[29, 30]. The utilities of the different outcomes following salvage (no complications, secondary amputation, osteomyelitis, etc.) and those following below-the-knee amputation (no complications, secondary revision, etc.) are combined by weighting each of the utilities with the rates of occurrence as determined by a systematic review of the literature[5]. This yields the utility weights of each of the two management options. By multiplying the utility weights by the expected lifespan of a patient, we derive the total QALYs remaining following salvage or amputation.

Sensitivity Analyses

Sensitivity analyses were performed by varying the assumptions of costs, discount rates, utilities, and expected patient lifespan. Performing sensitivity analyses is integral in any economic analysis model in an effort to consider extreme values of the initial assumptions. The stability of a conclusion is predicated on the sensitivity analyses in order to understand whether changing values can affect the results. As in the LEAP cost study, the need to purchase a new prosthetic device was varied from once every 2.3 years to once every 5 years, and annual device maintenance costs were varied from 20% to 10% of the device cost. Because real discount rates have historically varied from 1.58% to 3.35%, we performed our calculations over a range of 1% to 4%. For illustrative purposes, we also included a 0% discount rate to show the problems that arise when discounting is not taken into consideration. Additionally, we varied expected patient lifespan to account for patients of all ages. Resultant values were correlated with patients' ages based on the 2003 US Life Expectancy Table[31]. Finally, as in the original utility study, we also employed a range of utilities based on sensitivities on the complication rates used to calculate utility.

Results

Costs

Ongoing annual costs for salvage were calculated as follows. Total average lifetime costs for reconstruction patients are reported to be $163,282[10]. Because costs for the first two years following injury are $81,316, this leaves $81,966 in medical costs after year 2. The average LEAP patient age is 35.2[6] and 76.7% of the patients included in the cost study were male. Combining these data with the 2003 US Life Expectancy Table used in the cost study, the

weighted average of expected years of life remaining for each patient is 42.8 years. Distributing the $81,966 over the remaining years of life after year 2 yields a yearly average, ongoing medical cost of $1913 per patient. Ongoing costs after year 2 are discounted at 2% and combined with initial two year costs. In total, lifetime cost of salvage for a patient with 40 years of life remaining is $133,704.

The total average lifetime costs for amputation patients are reported as $509,275[10]. Because costs for the first two years following injury are reported as $91,105, this leaves $418,170 in medical costs for year 3 onward. Assuming 42.8 years of remaining life, and a frequency of prosthetic purchase of every 2.3 years after year 2, yields an expected purchase of 17.4 prosthetics. The weighted average prosthetic cost is $10,232, so total prosthetic device costs after year 2 are $181,500. The annual prosthetic maintenance costs are assumed to be 20% of the prosthetic cost, for a total of $83,490 after year 2. Therefore, non-prosthesis-related medical costs after year 2 are $153,181, which amounts to annual ongoing costs of $3,754. These non-prosthetic-related costs are then added to the appropriately discounted prosthetic costs to calculate the lifetime cost. Ongoing costs after year 2 are discounted at 2% and combined with initial two year costs. In total, lifetime cost of amputation for a patient with 40 years of life remaining is $350,465.

Utility

Mean utility values for each major clinical outcome from the utility study are shown in Table 1. After running a simulation to incorporate the probabilities of complication, we determine the overall utility weights to be 0.954 for amputation and 0.969 for salvage. The result is that for every year of life left, salvage patients enjoy an extra 0.016 QALYs.

Sensitivity Analyses

To ensure our results are robust, we performed the various sensitivity analyses. First, ongoing prosthesis needs were decreased by reducing both the frequency of purchase from every 2.3 years to every 5 years and by reducing the annual maintenance cost from 20% to 10% of the cost of the prosthetic. This reduces the cost difference between amputation and salvage, especially for younger patients (Table 2). Despite this decrease, however, amputation remains the more expensive option.

To assess whether varying patient ages or discounting rates changed our result, we recalculated the cost of each intervention for patients with 10 to 60 years of life remaining at discount rates ranging from 1% to 4% (Tables 3 and 4) (Figures 1 and 2). For reference, according to the 2003 US Life Expectancy Table, a person with 60 years of life remaining is approximately 18 years old, a person with 40 years of life remaining is approximately 40 years old, and a person with 20 years of life remaining is approximately 63 years old. Therefore, at a 2% discount rate, the medical costs of salvage and amputation, respectively, are $147,870 and $427,457 for an 18-year-old patient, $133,704 and $350,465 for a 40-year-old patient, and $112,654 and $236,059 for a 63-year-old patient.

Discounting appropriately decreases the difference between the true cost of salvage and amputation. This is because the more expensive option, amputation, is associated with higher ongoing costs, and these long-term costs are impacted more substantially by discounting. Because amputation is also associated with higher short-term costs, however, it remains more expensive across all sensitivities. As expected, the long-term expenses have more impact for younger patients, making amputation even more relatively expensive for this group. (Table 5) (Figure 3) The difference between the two treatment options is diminished with age, and it would not be surprising to find that the burden of attempted salvage could be too high in a much older patient.

Complication rates are used in calculating utility rates. These rates were varied in order to find a point at which the utility of amputation is greater than that of reconstruction. However, even under the most extreme conditions – when the complication rate of reconstruction is assumed to be 100% and the complication rate of amputation is expected to be 0% – reconstruction continues to yield higher utility than amputation[11].

Discussion

Our analysis shows that amputation is more expensive independent of ongoing prosthesis needs, discounting effect, and years of life remaining. For example, even under the most favorable prosthesis maintenance conditions, amputation will cost a 40-year-old patient at least $93,606 (assuming a 4% real discount rate) and up to $154,636 (assuming a 1% real discount rate) *more* than limb salvage. Furthermore, we found that utility is increased with salvage; a similar patient with an estimated 40 years of life remaining will enjoy an additional 0.63 QALYs after undergoing salvage instead of amputation. The cost and utility differences between these two interventions are even more pronounced for younger patients.

Salvage is the dominating strategy – it is less expensive and provides higher utility. Therefore, surgeons should select limb salvage more aggressively in patients where amputation is not absolutely necessary, especially those patients with higher life expectancies. This policy should, of course, be followed up to a point, because more aggressive salvage of more severe cases will eventually lead to decreased utility for the patient and increased costs. This will happen as more severe cases will require increased healthcare resources and lead to healthcare utilities that are lower than the current expectations included in our measurement of utility.

This study has several limitations. Most notably, we face many of the same limitations of the original articles. Because cost estimates were based partly on patient surveys, they are subject to recall bias. Furthermore, although we have accounted for costs related to loss of income, we have not accounted for other costs such as the possible need for institutional care, residential adaptations, and pharmacy-related costs. Given the relative magnitude of these expenditures, however, we do not expect that these factors would meaningfully change the cost figures we employed in our analysis. Furthermore, even if these expenditures were greater, we do not expect that they would substantially impact one group more than the other. Therefore, our conclusion regarding the comparison of these two groups is still valid.

Furthermore, because not all data were presented in the LEAP cost study, we made certain assumptions with respect to ongoing medical costs of each intervention. Specifically, by asserting that the average annual cost per patient is equal to the average lifetime cost divided by average lifespan, we assume that ongoing annual costs and age at presentation are statistically independent. Even though it is likely that age at presentation has some effect on ongoing medical costs, our assumptions yield data consistent with the LEAP study's data. Therefore, any effect is likely to be clinically negligible. By discounting prostheses at the real rate of inflation, we assume that prosthetic costs will grow at the same rate as inflation. However, if the costs outpace inflation, our results are conservative and underestimate the cost of amputation. Alternatively, if the costs rise more slowly than inflation, amputation will still remain more expensive because of the higher non-prosthetic annual costs.

Our study assumes that life expectancy following IIIB and IIIC tibial fractures is similar to life expectancy of the normal population. By performing sensitivities across years of remaining life, however, we were able to confirm our results independent of remaining years of life. Therefore, even if life expectancy differs, as long as the differences in life expectancy are similar between salvage and amputation, our conclusion still stands. Unfortunately, long-term data to answer this question are currently lacking. Finally, because our data are based on

observational studies, it is possible that patients who underwent amputation inherently have more severe injuries that would require more costly treatment and lead to decreased utility if salvage would have been attempted. It is for this reason that our recommendations for surgeons are targeted only at borderline patients.

Despite these limitations, this unique economic analysis paper can help guide surgeons' decisions for patients with open tibial fractures. Our comprehensive modeling and robust sensitivity analyses reveal a consistent result, which strengthens and supports the generalizability our conclusion. Furthermore, because we have stratified our results by patient age, surgeons will be able to make evidence-based decisions that are more patient-specific.

With the nation's increasing focus on healthcare costs, it is even more important that the conclusion of this study be brought to the forefront of discussion. We have found that, across a range of robust sensitivities, salvage currently dominates amputation as a strategy for the management of IIIB and IIIC tibial fractures. We therefore recommend that surgeons become more aggressive in their attempts to save limbs in patients whose management choice is unclear. For these borderline patients, we will continue to incur higher costs and provide less utility by routinely taking recourse to amputation.

Acknowledgments

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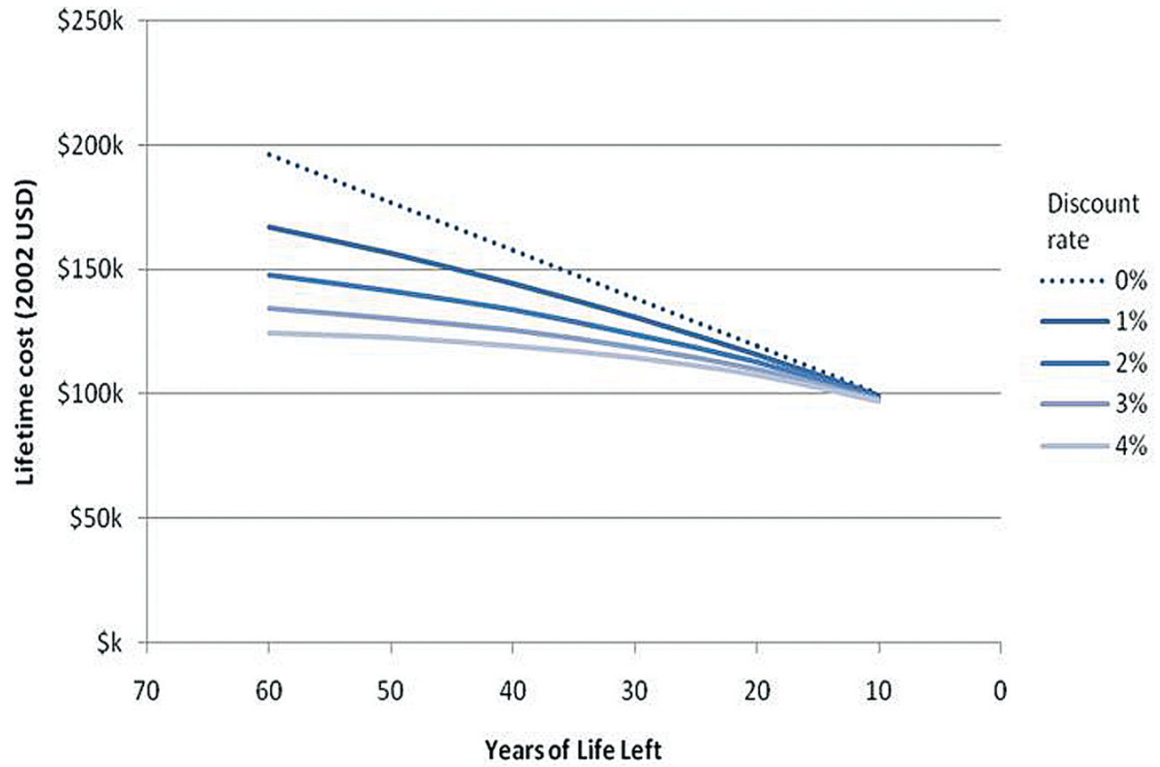
Figure 1.
Lifetime Costs of Salvage Based on Years of Life Remaining. Both higher discount rates and
lower life expectancy reduce lifetime cost of reconstruction.

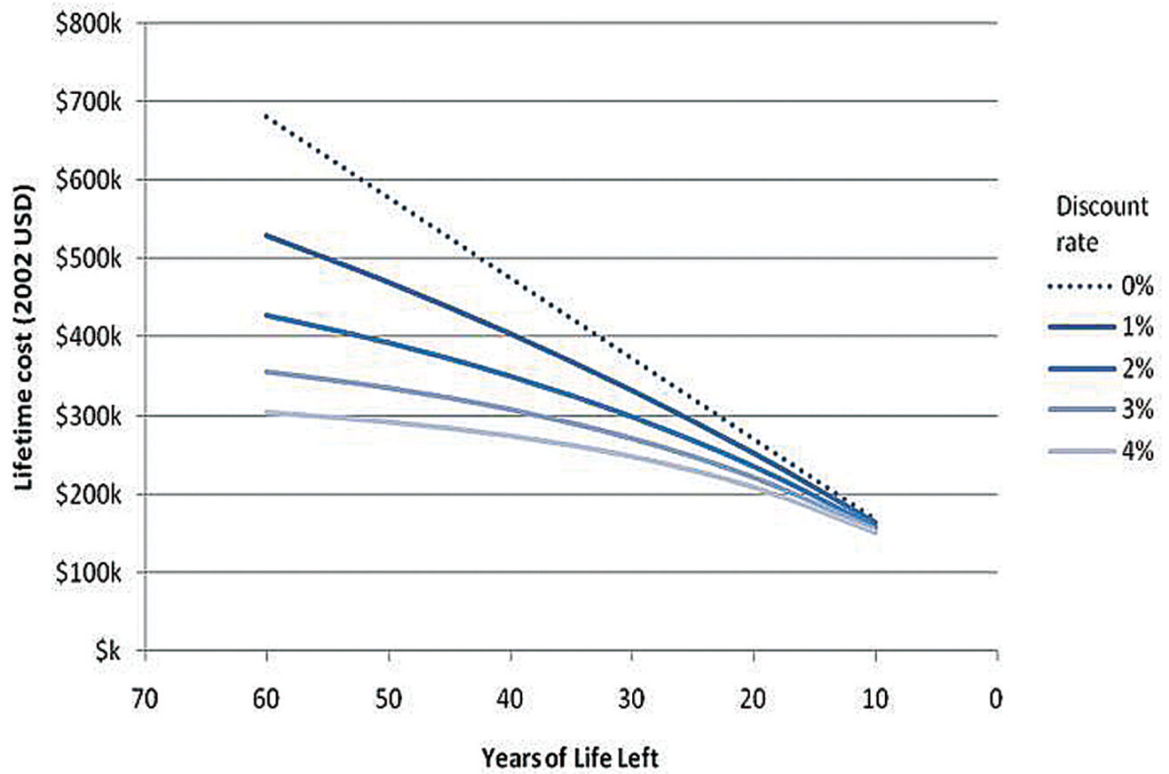## Lifetime Costs of Amputation Based on Years of Life Left

Figure 2.
Lifetime Costs of Amputation Based on Years of Life Remaining. Higher discount rates and lower life expectancy reduce lifetime cost of amputation. Discount rate has a larger effect on amputation because of the high long-term costs associated with prosthetic purchase and maintenance. This figure also illustrates the importance of discounting. By not taking into account the time value of money (the dotted line, "0%"), the true present value of treatment is overestimated.
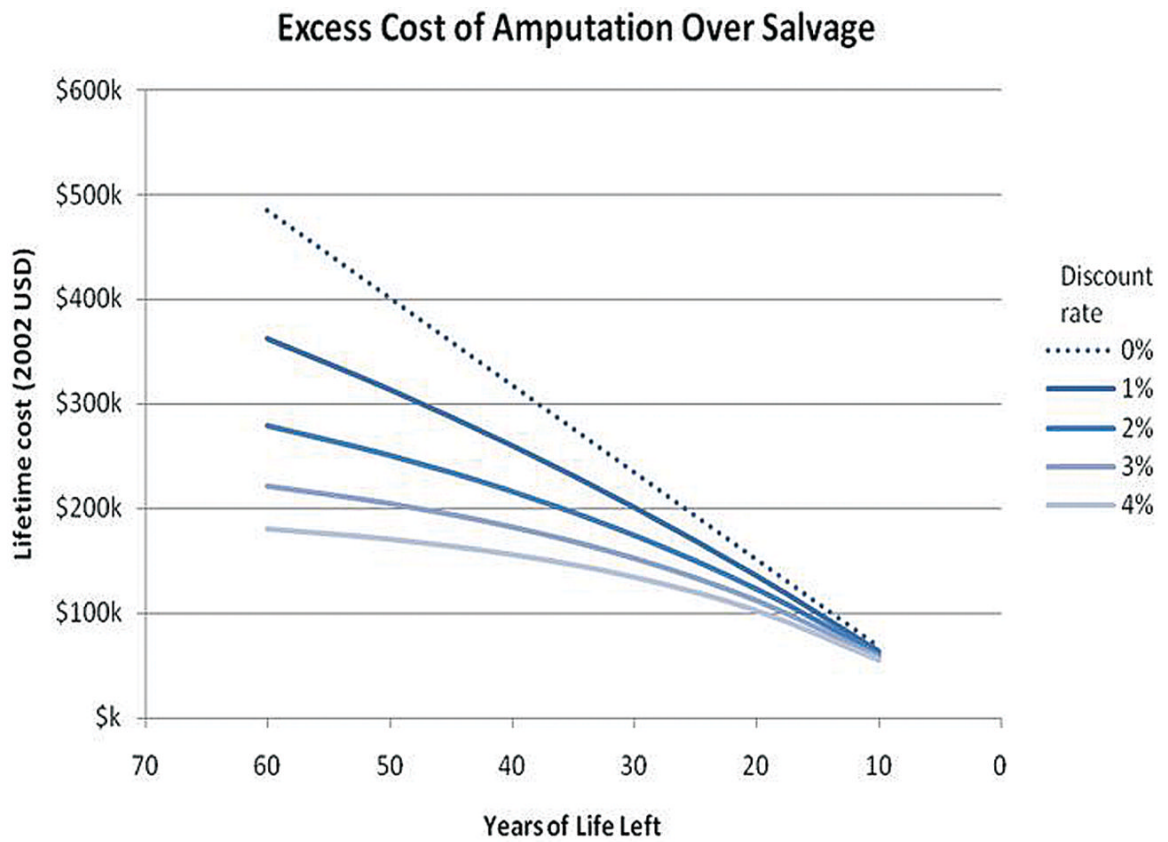
Excess Cost of Amputation Over Salvage

Figure 3.
Excess Lifetime Cost of Amputation over Salvage. Because amputation is more expensive even in the short term, it remains more expensive than salvage through the entire range. The difference is less exaggerated when we account for discounting and when we consider patients with fewer remaining years to live.

Table 1

Mean Utility Values Following Salvage and Amputation of IIIB and IIIC Tibial Fractures

Clinical outcome	Utility
Reconstruction without complications	0.975
Reconstruction with secondary amputation	0.907
Reconstruction with osteomyelitis	0.971
Reconstruction with nonunion	0.976
Reconstruction with flap failure	0.968
Amputation without complications	0.963
Amputation with secondary revision	0.967
Amputation with osteomyelitis	0.850

The standard gamble method was employed to assess utility values for major clinical outcomes. Values were calculated by assessing users' willingness to avoid them in exchange for risking known probabilities of certain death.

Table 2

Sensitivity Analysis for Prosthesis Maintenance Needs

	Expected Prosthesis Need	Lower Prosthesis Need
Varied values		
Frequency of Purchase (Years)	2.3	5
Cost of Annual Maintenance	20%	10%
Excess cost of amputation with 2% discount rate		
18-year-old patient	$279,586	$166,413
40-year-old patient	$216,761	$129,124
63-year-old patient	$123,405	$73,714

Lower ongoing prosthesis need (i.e., reduced frequency of purchase from every 2.3 years to every 5 years and reduced annual maintenance cost from 20% to 10% of the cost of the prosthesis) reduces the cost difference between reconstruction and amputation, especially for younger patients.

Table 3

Lifetime Costs of Limb Salvage Following IIIB and IIIC Fractures.

Years Remaining	Real discount rate ($R_f - i$)				
	0%	1%	2%	3%	4%
60	$ 196,039	$ 166,894	$ 147,036	$ 133,131	$ 123,122
50	$ 176,910	$ 155,878	$ 140,652	$ 129,409	$ 120,939
40	$ 157,780	$ 143,709	$ 132,870	$ 124,407	$ 117,707
30	$ 138,651	$ 130,267	$ 123,384	$ 117,684	$ 112,923
20	$ 119,522	$ 115,418	$ 111,820	$ 108,649	$ 105,842
10	$ 100,393	$ 99,017	$ 97,724	$ 96,507	$ 95,360

Both higher discount rates and lower life expectancy reduce lifetime cost of reconstruction.

Table 4

Lifetime Costs of Amputation Following IIIB and IIIC Fractures

Years Remaining	Real discount rate ($R_f - i$)				
	0%	1%	2%	3%	4%
60	$ 680,701	$ 529,540	$ 426,611	$ 354,740	$ 303,269
50	$ 578,209	$ 470,092	$ 391,914	$ 334,365	$ 291,233
40	$ 475,716	$ 404,424	$ 349,619	$ 306,984	$ 273,418
30	$ 373,223	$ 331,885	$ 298,062	$ 270,186	$ 247,047
20	$ 270,731	$ 251,758	$ 235,214	$ 220,733	$ 208,011
10	$ 168,238	$ 163,248	$ 158,602	$ 154,271	$ 150,228

Higher discount rates and lower life expectancy reduce lifetime cost of amputation. Discount rate has a larger effect on amputation because of the high long-term costs associated with prosthetic purchase and maintenance.

Table 5

Excess Lifetime Costs of Amputation over Salvage Following IIIB and IIIC Fractures.

Years Remaining	Real discount rate $(R_f - i)$				
	0%	1%	2%	3%	4%
60	$ 484,663	$ 362,646	$ 279,575	$ 221,609	$ 180,147
50	$ 401,299	$ 314,214	$ 251,262	$ 204,957	$ 170,295
40	$ 317,936	$ 260,715	$ 216,749	$ 182,578	$ 155,711
30	$ 234,572	$ 201,619	$ 174,678	$ 152,502	$ 134,123
20	$ 151,209	$ 136,340	$ 123,394	$ 112,083	$ 102,169
10	$ 67,846	$ 64,231	$ 60,878	$ 57,764	$ 54,868

Because amputation is associated with higher short-term costs, it remains more expensive across all sensitivities. As expected, the long-term expenses have more impact for younger patients, making amputation even more relatively expensive for this group.