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Socioeconomic impact of orthopaedic trauma

Studies on measuring outcomes, estimating effects, and identifying recovery priorities in the United States, Canada, and Uganda

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Socioeconomic Impact of Orthopaedic Trauma

**Studies on Measuring Outcomes, Estimating
Effects, and Identifying Recovery Priorities in
the United States, Canada, and Uganda**

Nathan N. O'Hara

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**Studies on Measuring Outcomes, Estimating Effects, and
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Canada, and Uganda**

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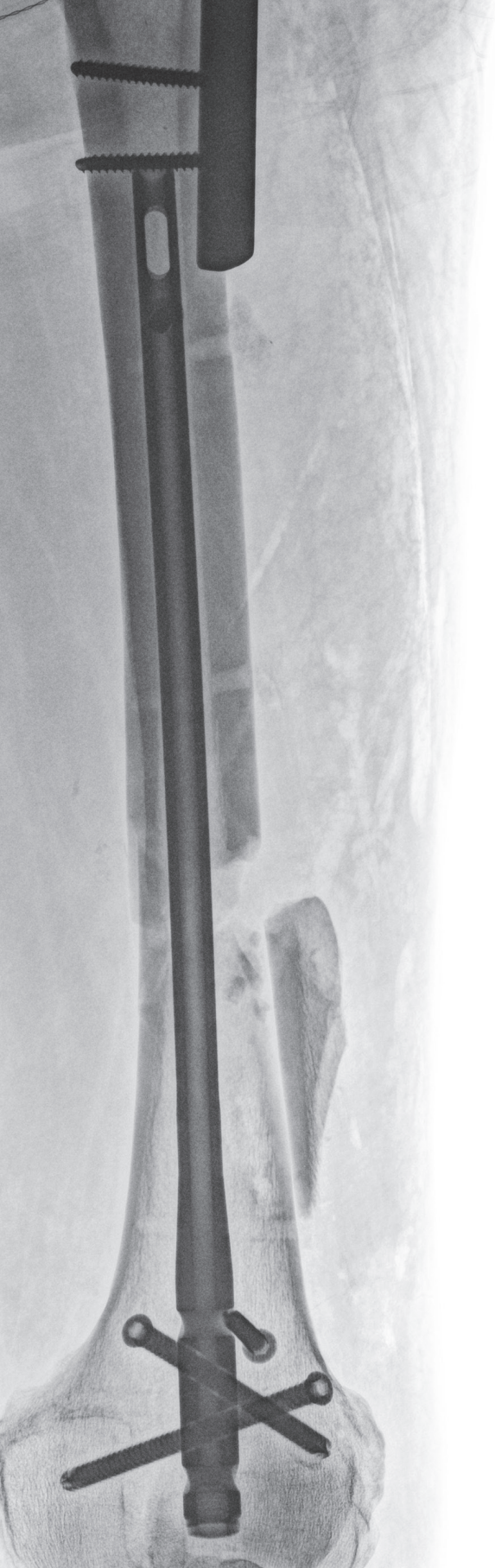
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General Introduction and Outline of the Thesis

BACKGROUND AND CURRENT KNOWLEDGE

The Global Burden of Orthopaedic Trauma is Substantial

Orthopaedic injury represents a substantial healthcare burden.¹ Globally, over 130 million people sustain a fracture each year.¹ Road traffic collisions and falls remain the leading cause of these injuries.¹ The rates of road traffic injuries are higher in low-income countries (1209 per 100,000 person-years) than in high-income countries (735 per 100,000 person-years).² In both high- and low-income countries, road traffic injuries account for approximately 2% of the total disease burden and the majority of that burden is borne by working-age adults.^{2,3}

Socioeconomic Risk Factors for Fractures

Socioeconomic factors, such as physical labor employment and lower incomes, are risk factors for traumatic injury. The odds of a fracture are three-times higher for individuals living in high deprivation areas compared to low deprivation areas.⁴ Fracture risk is negatively correlated with education and income.⁵ Data from the United States reports that 17% of all fractures are work-related.⁶ Those with physical labor jobs are more likely to sustain a fracture and also more likely to have a delayed return to work. Low pre-injury socioeconomic status also increases the risk of infection and other severe complications.^{7,8}

Serious Socioeconomic Consequences

The physical impairment from orthopaedic trauma is often compounded by socioeconomic hardships. One-quarter of surgically treated fracture patients will incur financial catastrophe as a result of seeking care.⁹ The burden of catastrophic expenditure for surgery is highest in low- and lower-middle-income countries and, within any country, lays most heavily on patients on the left tail of the income distribution.⁹ In their 2009 study, Himmelstein et al estimated that 62% of bankruptcies in the United States were attributable to medical conditions.¹⁰ Orthopaedic injury was determined to be a contributing factor for over half of these medically-attributable bankruptcies.¹¹ More than three-quarters of debtors had health insurance coverage when they filed for bankruptcy, and 80% reported that it was the income loss from their medical condition that caused them to file for bankruptcy.¹¹ A comparable study in Canada reported similar findings.¹² Even with Canada's universal health coverage, medical conditions were the second leading cause of bankruptcy filing. The authors suggest this is primarily due to the job loss attributed to medical conditions. Morrison et al added that pre-injury financial fragility exasperates the economic effects of an injury.¹³

The hospitalization costs associated with a post-fracture complication have been widely reported.¹⁴⁻¹⁸ However, the impact of post-fracture complications likely has

broader societal costs. Precise estimates of the societal costs attributable to post-fracture complications are limited. Using single center data, Whitehouse et al reported a post-fracture infection increased median indirect costs within one-year of injury by USD 10,000.¹⁴ The study limited their indirect cost estimates to out-of-pocket hospital-related expenses. It did not capture costs related to work incapacity that would typically be factored into societal cost estimates.

Inconsistent Measurement of Socioeconomic Impacts

While many orthopaedic studies include a socioeconomic outcome, there is inconsistency in the definition and application of these measures. *Return to work* and *days absent from work* are two common outcomes in fracture research, each with inherent limitations. Both outcomes are only relevant for individuals working prior to their injury, and neither measure captures productivity impairment upon resuming employment. More nuanced measures, such as the Work Productivity and Activity Impairment questionnaire, are more broadly applicable and have demonstrable validity and reproducibility,¹⁹ yet remain under-utilized in fracture research.

Limited High-Quality Research on Socioeconomic Effects of Fractures

There is a paucity of high-quality data investigating the socioeconomic effects of a fracture. Using California administrative data from 2000 through 2012, Dobkin et al (2018) estimated that non-maternity hospitalizations were associated with a USD 9000 loss in annual income.²⁰ Social insurance covered less than 10% of lost earnings. Dobkin et al estimated that hospitalizations increased the probability of bankruptcy by 1.4%.²⁰ Using national panel data from the US, Charles reported that income loss attributable to new physical impairment persisted for at least ten years after the initial injury.²¹ While these studies substantially improve the understanding of an injury's socioeconomic impact, neither is specific to the fracture population.

Fracture-specific estimates of socioeconomic consequences are limited. Several studies capture estimates of the orthopaedic injury's financial effects using primary data collection but have less than two years of follow up.²² Prior data suggest the economic effects of injury may persist for a number of years after injury and studies of two years or less will underestimate true effects.^{20,21} National and regional databases present an opportunity to capture long-term economic data but integrating this information with health data requires common identifiers and the navigation of data-access restraints. These privacy and security concerns pose a barrier to precise, long-term estimates on the economic implications of injury.

In addition to quantifying the economic losses associated with a fracture, more research on the mechanisms that may prevent socioeconomic hardships after injury is needed.

There is evidence that the expansion of social insurance coverage may prevent economic loss after catastrophic health events.^{23,24} However, the forms of insurance coverage vary tremendously from country to country. Optimizing the utilization of financial protection policies and services can be informed through behavioral economics methods.

Understanding Patient Recovery Priorities

There is a common adage in management science, “What gets measured, gets managed.” The post-treatment management of a fracture includes a series of physical assessments. Socioeconomic outcomes are rarely included in these routine assessments. The measurement of recovery priorities is even less frequent.

A better understanding of patient recovery priorities aligns with value-based care and shared decision principals. Further, the routine measurement of patients’ recovery priorities would inform clinicians on how to direct patients’ care plans to be consistent with patient priorities. Value-based reimbursement structures may also incentivize clinicians to offer social interventions as part of routine care. Examples of social intervention include assistance in finding and retaining employment, peer support programs, and stable housing support. Several small-scale studies suggest social intervention may be effective in preventing hospital readmission.^{25,26} Understanding the psychological forces that optimize patient utilization of these social interventions through behavioral economic research is critical to scaling effective programs. Recent advances in stated preference research through methods, such as discrete choice experiments and best-worst scaling, provides an instrument to capture patient recovery priorities.

Clinical Interventions with Socioeconomic Benefits

The availability of effective health services is a pre-requisite to prevent downstream economic implications of the injury. Despite the varying availability of surgical resources worldwide, only 15% of fractures receive surgical treatment.¹ The timely treatment of open fractures was identified as one of three bellwether procedures, along with caesarean delivery and laparotomy, by the Lancet Commission on Global Surgery.⁹ Even with an adequate supply of health services, financial barriers to treatment can exist. Half of the United States’ Medicare beneficiaries report considerable financial hardship in paying medical bills.²⁷

In addition to physical impairment, traumatic fractures are also associated with significant mental health challenges. A recent meta-analysis identified that one-third of orthopaedic trauma patients endure depressive symptoms, and one-quarter experience post-traumatic stress disorder symptoms following their injury.²⁸ Access to post-injury mental health services can be more challenging than obtaining surgical care.

Alignment of Healthcare and Social Welfare

Even with dramatic improvements in clinical therapeutics and patient safety, the socioeconomic consequences of injury will likely remain. A responsive social welfare system is required to support socioeconomic incapacity after an injury.²⁹ The integration of healthcare and social care systems within a country is vital to preventing coverage gaps for individuals.³⁰ However, even in countries with some integration of these systems, cross-sector data sharing is uncommon.³¹ A lack of data sharing increases the administrative burden for social welfare applicants leading to delays or an absence of support during times of immense financial distress.³² The absence of post-injury financial protection may also increase the prevalence of psychological distress, compounding the injury's societal costs.^{33,34}

AIMS OF THE THESIS

There is a paucity of research quantifying the socioeconomic consequences of orthopaedic trauma. The overarching objective of this thesis is to advance the evidence on the socioeconomic impact of orthopaedic trauma. This objective is to be achieved through three specific aims. Firstly, I aim to describe and evaluate the currently available options for measuring the socioeconomic outcomes after orthopaedic injury. The second aim is to estimate the socioeconomic effects of fractures in three distinct geographic settings (Uganda, Canada, and the United States), each with distinct healthcare and social welfare systems. Finally, we aim to identify the socioeconomic recovery priorities of fracture patients.

OUTLINE OF THE THESIS

In this thesis, a series of research questions are asked to address major knowledge gaps related to the quantification of socioeconomic effects after injury. Various methods are employed to answer these questions, including difference-in-difference models, inverse probability weighting, and two choice experiments. Administrative databases in Canada and the United States, and a prospectively enrolled cohort in Uganda were used to estimate the socioeconomic effects of injuries in those countries. The research topics divided into three sections and accompanying study designs are listed below. All studies were performed between October 2013 and August 2020.

Section	Topic	Study Design
1	Measuring Socioeconomic Outcomes	
	Description of socioeconomic outcome measures in orthopaedic trauma	Systematic review and meta-analysis
	PROMIS architecture for patient-reported outcomes	Narrative review
2	Estimating Socioeconomic Effects	
	Weighting patient-reported outcomes	Best-worst scaling experiment
	Socioeconomic effects of hip fractures in non-elderly patients (British Columbia, Canada)	Retrospective population-based case series
	Socioeconomic effects of tibia and femur fractures from road traffic injuries (Uganda)	Prospective case-series
	Economic effects of extremity fractures (Maryland, United States)	Difference-in-differences analysis
3	Identifying Patients' Socioeconomic Recovery Priorities	
	Economic effects of a post-fracture infection (Maryland, United States)	Target trial emulation using inverse probability weighting
	Post-fracture physical and socioeconomic recovery priorities (Maryland, United States)	Longitudinal discrete choice experiment

SETTINGS

The studies in Sections II and III utilize data from three distinct settings – Uganda's national referral hospital, province-wide data from British Columbia, Canada, and data from the state-mandated trauma center in Maryland, United States. The healthcare systems, income distributions, and social welfare systems differ greatly between the three countries.

The United States, Canada, and Uganda health system have stark differences in their structure and expenditures. The United States dramatically exceeds all other countries in the total health expenditure (public and private) per capita (USD 11,072).³⁵ The United States' healthcare system is a patchwork of systems that provide redundant coverage to millions of Americans while leaving millions more uninsured. A recent Lancet report estimates the United States has 82% universal health coverage – lower than most high-income countries.³⁶ In contrast, Canada implemented a universal healthcare system in 1961. Although, pharmaceuticals and dental care remain a notable omission to the plan. Its total health expenditure per capita is USD 5418 and it has 90% universal health coverage.^{35,36} Uganda has a national public health system that is supplemented by non-governmental organization and private healthcare services. The health expenditure per capita in Uganda is USD 121 and universal health coverage is 53%.^{36,37}

Despite differences in the size of their economies, the United States and Uganda are similarly challenged by income inequality. The mean wage in the United States of USD 65,836 is among the highest in the world.³⁵ However, among OECD countries, the United States has one of the highest Gini coefficients (0.39) – a measure of inequality that compares the cumulative proportions of the population against cumulative proportions of income they receive.³⁵ The Gini coefficient ranges from 0 in the case of perfect equality and 1 in the case of perfect inequality. In Uganda, the mean income is USD 3908, and the Gini coefficient is 0.43.^{38,39} Canada has less inequality than the United States and Uganda, with a Gini coefficient of 0.31.³⁵ Canada's average wage earnings is USD 53,198.³⁵

The social welfare systems of all three countries differ considerably. One year after work incapacity, unemployment insurance in the United States covers a mean of 8% of one's previous income.³⁵ In Canada, unemployment benefits cover an average of 31% of previous work income one year after work incapacity.³⁵ Canada, along with only the United States and Japan, has no federal sick leave policy. However, one Canadian province (Ontario) does have a policy for mandatory paid sick leave and nine other provinces and territories have provisions for unpaid sick leave. The United States and Canada's public spending on incapacity, including sickness, disability, and occupational injury, amounts to only 1.3% and 0.8% of the gross domestic product (GDP), respectively.³⁵ Uganda does not have a government-sponsored unemployment insurance program, and less than 1% of the population are contributors to the National Social Security Fund and Public Services Pension Scheme.⁴⁰

METHODS

Apart from a systematic review and meta-analyses, the thesis incorporates choice modeling techniques, causal inference methods, and Bayesian hierarchical modeling to address its three aims.

Choice models estimate the preferences of individuals for competing products, services, or outcomes. The approach was pioneered by Daniel McFadden in 1974 and was the basis for his Nobel Prize in Economic Sciences awarded in 2000.⁴¹ The method is based on Lancaster's Theory of Demand whereby the total utility gained from a product or service is the sum of the individual utilities provided by the attributes of that good.⁴² In a choice experiment, respondents are presented a series of hypothetical comparisons where by a product, service, or outcome is described by several attributes. The response data can be used to calculate the utility derived from the included attributes and the relative importance of the presented outcomes. Two variants of choice models, discrete choice experiments and best-worst scaling, were used in Chapters 3 and 8.

Two studies in the thesis used two different causal inference methods – difference-in-differences and inverse probability of treatment weighting. The critical step in any causal inference analysis is estimating the counterfactual, defined as a prediction of what would have happened in the absence of the exposure.⁴³ Difference-in-difference analysis requires longitudinal data and a sudden change, such as a new policy or for our study a traumatic injury, that affects the exposure group and not a comparable control group. Given these parameters one can estimate the average treatment effect of the treated. In Chapter 7, we used inverse probability of treatment weighting to simultaneously balance a large number of covariates to improve the exchangeability between fracture patients the sustained a post-fracture infection and those who did not.

In Chapter 3 and 8, the best-worst scaling and discrete choice experiment data were analyzed using Bayesian hierarchical models. Bayesian hierarchical models offer several advantageous over the more commonly used method for analyzing choice experiments, multinomial logit models. Most notably, hierarchical Bayesian models account for both the observed response patterns of individual respondents and the sequence of scenarios presented to the respondents when calculating the model estimates. In addition, the models treat missing response values as unique parameters and utilizes the distributions of the observed responses to form posterior estimates for the full sample conditioned these missing values

STRUCTURE OF THE THESIS

The thesis chapters are organized into three sections pertaining to measuring outcomes, estimating effects, and identifying recovery priorities. Following the presentation of the chapters, the thesis discusses the key findings, provides reflections on the methods, and presents applications of the findings to practice and policy.

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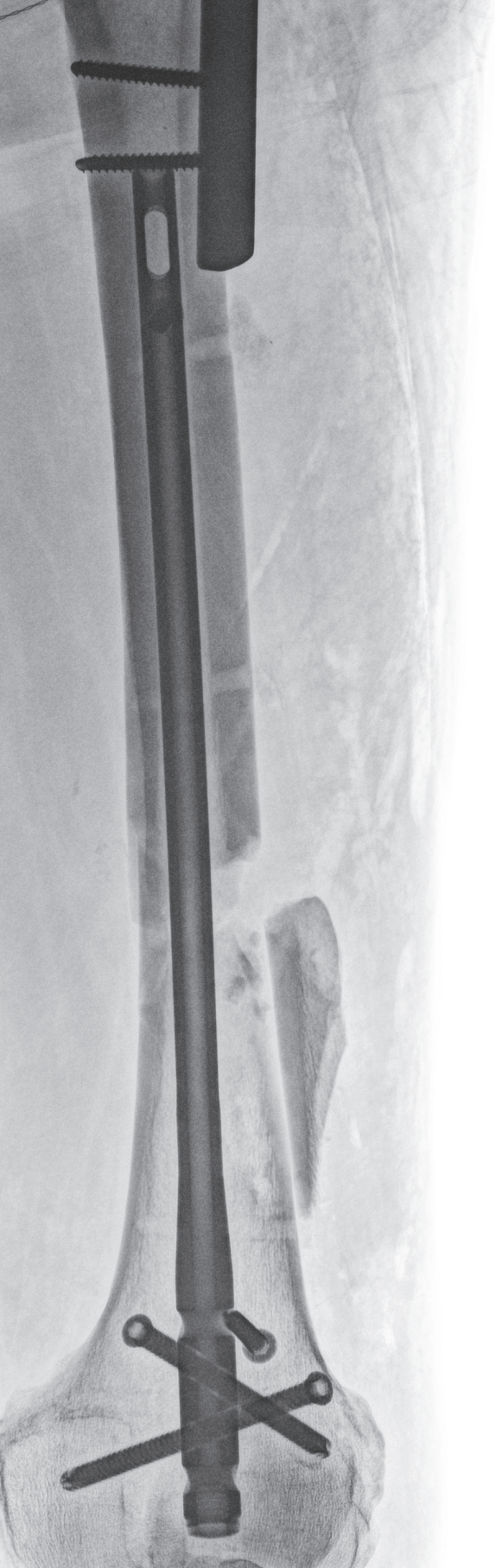
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Section I

Measuring socioeconomic
outcomes



1

The Socioeconomic Impact of Orthopaedic Trauma: A Systematic Review and Meta-Analysis

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ABSTRACT

The overall objective of this study was to determine the patient-level socioeconomic impact resulting from orthopaedic trauma in the available literature. The MEDLINE, Embase, and Scopus databases were searched in December 2019. Studies were eligible for inclusion if more than 75% of the study population sustained an appendicular fracture due to an acute trauma, the mean age was 18 through 65 years, and the study included a socioeconomic outcome, defined as a measure of income, employment status, or educational status. Two independent reviewers performed data extraction and quality assessment. Pooled estimates of the socioeconomic outcome measures were calculated using random-effects models with inverse variance weighting. Two-hundred-five studies met the eligibility criteria. These studies utilized five different socioeconomic outcomes, including *return to work* (n=119), *absenteeism days from work* (n=104), *productivity loss* (n=11), *income loss* (n=11), and *new unemployment* (n=10). Pooled estimates for return to work remained relatively consistent across the 6-, 12-, and 24-month timepoint estimates of 58.7%, 67.7%, and 60.9%, respectively. The pooled estimate for mean days absent from work was 102.3 days (95% CI: 94.8 – 109.8). Thirteen-percent had lost employment at one-year post-injury (95% CI: 4.8 – 30.7). Tremendous heterogeneity ($I^2 > 89\%$) was observed for all pooled socioeconomic outcomes. These results suggest that orthopaedic injury can have a substantial impact on the patient's socioeconomic well-being, which may negatively affect a person's psychological wellbeing and happiness. However, socioeconomic recovery following injury can be very nuanced, and using only a single socioeconomic outcome yields inherent bias. Informative and accurate socioeconomic outcome assessment requires a multifaceted approach and further standardization.

INTRODUCTION

Orthopaedic trauma is a common reason for ongoing pain and significant disability [1,2]. The resumption of work activities following injury has been demonstrated to be a reliable marker of healing and is significantly associated with increased patient satisfaction [3,4]. For these reasons, outcomes, such as return to work and absenteeism days from work, are important dimensions in determining value-based healthcare [5].

Socioeconomic outcomes can be broadly defined as events related to income, employment, and education [6]. It has been suggested that efforts to mitigate income loss have the potential to reduce the severity and costs of major diseases more than traditional medical advances [7]. Socioeconomic measures are particularly relevant for extremity fracture patients, as the injuries commonly afflict the working age population and the injuries themselves are frequently work-related [8]. A better understanding of the socioeconomic consequences of fractures will aid in advocating for the necessary resources and reimbursements to appropriately manage these injuries and mitigate negative socioeconomic outcomes.

The overall objective of this study was to determine the socioeconomic impact of orthopaedic trauma in the available literature. We aimed to achieve this objective by defining the various socioeconomic outcome measures and calculating pooled socioeconomic outcomes for extremity fracture patients at commonly reported time points. Finally, the study aimed to identify common limitations in the use of socioeconomic outcome measures for extremity fracture research.

MATERIALS AND METHODS

The systematic review protocol was developed based on the Preferred Reporting Items for Systematic Review and Meta-analysis guidelines (PRISMA) and registered in PROSPERO (CRD42018093622) [9].

Eligibility Criteria

Studies were eligible for inclusion if more than 75% of the study population sustained an appendicular fracture due to an acute trauma, the mean age of the study population was between 18 and 65 years of age, and the study included a socioeconomic outcome, defined as a measure of income, employment status, or educational status. Studies were excluded if over half of the study population was greater than 65 years of age, had pathologic fractures (osteoporotic, osteomyelitis), had a spinal injury or traumatic brain injury, or a traumatic amputation. In addition, we excluded case series of less than ten study participants, as well as expert opinion and narrative papers.

Identification of Studies

An experienced academic research librarian conducted searches in MEDLINE (Ovid), Embase (Elsevier), and Scopus on December 3, 2019, without restrictions on publication date or language (see **S1** for complete strategy). Searches comprised of two concepts: socioeconomic consequences and orthopaedic trauma. Keywords were used in combination with database-specific terminology. The reference lists of the included studies were examined for additional papers.

Screening and Assessment of Eligibility and Data Extraction

DistillerSR (Evidence Partners, Ottawa, ON), an online reference management system for systematic reviews, was utilized for screening and study selection. All screening forms were pre-designed and piloted. Two reviewers independently reviewed the titles and abstracts of articles identified in the literature search. All conflicts were included in the full-text screening. The remaining full-text articles were reviewed in a similar independent and duplicate fashion with two reviewers to determine final inclusion. Any disagreements were resolved through a consensus meeting. When English versions of the articles were unavailable, *Google Translate* (Mountain View, CA) was used to translate the article text into English. Articles that met the full inclusion criteria were used for data extraction. Study characteristics and the demographics, injury characteristics, and socioeconomic outcomes of the study participants were recorded for each included study. As the duration from injury to the socioeconomic assessment was often provided for multiple time points, the outcome and time point were extracted in tandem.

Quality Assessment

The quality of the included studies was assessed following four criteria from the *Users' Guides to the Medical Literature* to evaluate the risk of bias [10]. The criteria included, 1) the duration of follow-up, 2) the proportion of enrolled patients that completed full follow up, 3) a well-described and consistently applied assessment of the socioeconomic outcome, and 4) a study sample with broad eligibility criteria to be considered representative of the fracture population of study. Two reviewers independently assessed the risk of bias. Articles were considered to have a low risk of bias if the study included a representative population, a well-defined socioeconomic outcome, and more than 80% follow-up at least 12-months from injury. Studies were categorized as a high-risk of bias with non-representative samples, ill-defined socioeconomic outcomes, and follow-up rates of less than 70%.

Data Synthesis and Analysis

The characteristics of the included studies, the study participants, and the socioeconomic outcomes were described using counts and proportions. The types of fractures were defined using the Arbeitsgemeinschaft für Osteosynthesefragen (AO)/ Orthopaedic

Trauma Association (OTA) Fracture and Dislocation Classification Compendium, 2018 [11]. When possible, socioeconomic outcomes were pooled using the inverse variance method and summarize with point estimates with 95% confidence intervals. Given the tremendous heterogeneity in the pooled data ($I^2 > 80\%$), random-effects meta-analyses were performed. Multiple imputations were used to calculate the variance for absenteeism days from work in studies with no measure of variance reported. Cost data were converted from the reported currency to US dollars (USD) based on the market exchange rate on January 1 in the year of publication.

RESULTS

Study Characteristics

A total of 3,404 titles and abstracts, and subsequently, 972 full-text articles were screened; 205 met our eligibility criteria and were included in the review (**Fig 1**). The included studies predominately comprised of retrospective cohort studies (35.6%) and case series (31.7%) (**Table 1**). The majority of the studies were performed at a single site (78.0%) with a median sample size of 62 patients (IQR: 34 – 145), and over half were conducted in either Europe (37.6%) or North America (27.3%). In the included prospective studies, the median follow-up was 12 months (IQR: 6 – 24 months). Retrospective studies had a median follow-up of 18 months (IQR: 12 – 25). Fractures of the tibia (31.2%) and hand (31.2%) were the most commonly studied. While calcaneus (n=30), scaphoid (n=24), and malleolus (n=18) were the most frequently included fracture locations in the included studies. Over 80% of the included studies were published from 2000 through 2019.

Participant Characteristics

The 205 studies included 273,618 patients. The mean age of the study participants was 39.8 years (95% CI: 38.1 – 41.5), and 73.3% were male (95% CI: 71.0 – 75.4) (**Table 2**). In the studies that reported the mechanism of injury (n=115), 75.0% (95% CI: 71.3 – 78.3) of the study participants had high-energy injuries. The majority of the patients in the included studies were employed at the time of injury (95.0%, 95% CI: 93.9 – 95.9).

Socioeconomic Outcome Measure

Five common socioeconomic outcomes were identified in the included studies (**Table 3**). The most common outcome measure was return to work (n=119), closely followed by absenteeism days from work (n=104). Productivity loss (n=11), income loss (n=11), and unemployed due to injury (n=10) appeared less frequently.

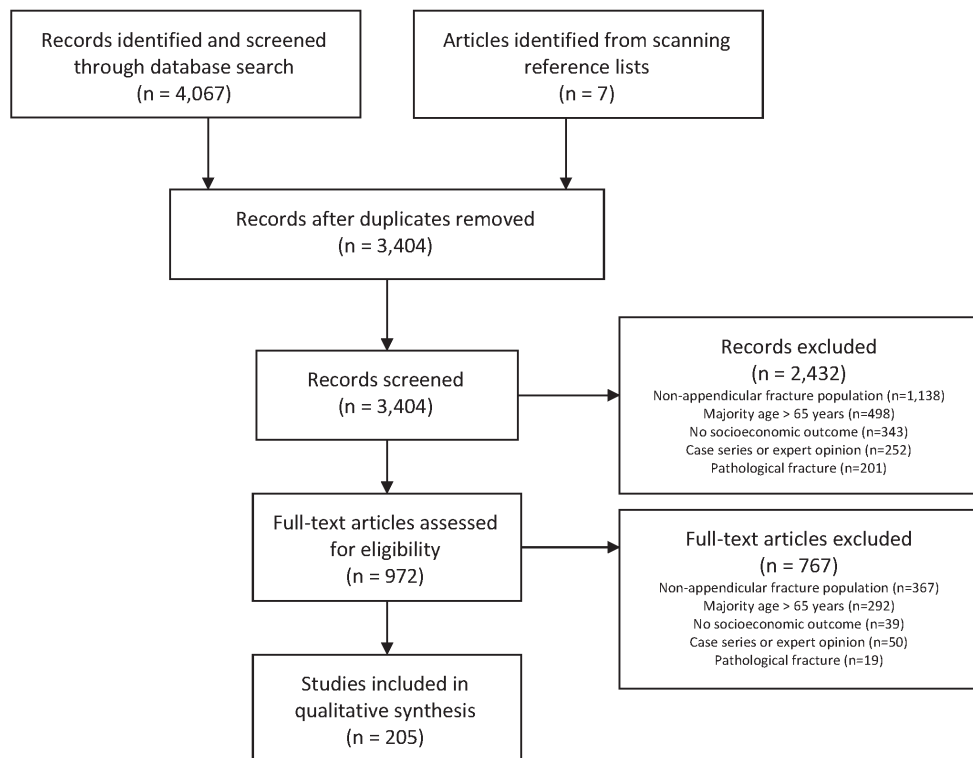


Fig 1. PRISMA Flow Chart.

Table 1. Summary of Study Characteristics (n=205).

Study Characteristic	No. (%)
Study type	
Randomized Controlled Trial	25 (12.2)
Prospective Cohort	32 (15.6)
Retrospective Cohort	73 (35.6)
Case-Control	2 (1.0)
Case Series	65 (31.7)
Other ^a	8 (3.9)
Fracture location of study ^b	
Humerus	41 (20.0)
Forearm	36 (17.6)
Femur	31 (15.2)
Tibia	64 (31.2)
Pelvis	24 (11.7)
Hand	64 (31.2)
Foot	59 (28.8)
Continent ^c	
Europe	77 (37.6)
North America	56 (27.3)
Asia	39 (19.0)
Australia/New Zealand	22 (10.7)
Africa	6 (2.9)
South America	4 (2.0)
Multi-continent	1 (0.05)

Number of study sites	Single Site	160 (78.0)	
	Multisite	32 (15.6)	
	Payer Database	13 (6.3)	
Study sample size	11 – 50	80 (39.0)	
	51 – 100	59 (28.8)	
	101 – 250	34 (16.6)	
	251 – 500	12 (5.9)	
	> 500	20 (9.8)	
Duration of enrollment	Prospective Studies	< 1 year	9 (15.7)
		1 – 3 years	19 (33.3)
		4 – 5 years	9 (15.7)
		> 5 years	4 (7.0)
		Not reported	16 (28.1)
	Retrospective Studies	< 1 year	12 (8.1)
		1 – 3 years	19 (12.8)
		4 – 5 years	39 (26.4)
		> 5 years	57 (38.5)
		Not reported	21 (14.2)
Length of follow-up, months, median (range)	Prospective Studies	0 – 6 months	17 (29.8)
		7 – 12 months	23 (40.4)
		13 – 24 months	12 (21.1)
		25 – 60 months	0 (0)
		> 60 months	4 (7.0)
	Retrospective Studies	Not reported	1 (1.8)
		0 – 6 months	16 (10.8)
		7 – 12 months	40 (27.0)
		13 – 24 months	42 (28.4)
		25 – 60 months	27 (18.2)
> 60 months	6 (4.1)		
Not reported	17 (11.5)		
Year of publication	1960 – 1969	3 (1.5)	
	1970 – 1979	2 (1.0)	
	1980 – 1989	7 (3.4)	
	1990 – 1999	28 (13.7)	
	2000 – 2010	73 (35.6)	
	2010 – 2017	92 (44.9)	

^a Other study types included four quasi-experimental studies, two longitudinal studies, and two cost-effectiveness studies.

^b Cumulative total is greater than 100% as 37 studies included more than one fracture location.

^c Continent refers to where the study was conducted; if not reported explicitly, the location of the corresponding author's institution was used as a proxy.

Table 2. Summary of Patient Characteristics from Included Studies (n=273,618).

Characteristic	No. (%)
% Male	
0 - 49.9	16 (7.8)
50 - 74.9	74 (36.1)
75 - 100	90 (43.9)
Not reported	21 (10.2)
Age, mean, years	
18 - 29	23 (11.2)
30 - 39	83 (40.5)
40 - 49	61 (29.8)
50 - 65	8 (3.9)
Not reported	27 (13.2)
% Mechanism of injury	
> 50% high energy	92 (44.9)
> 50% low energy	22 (11.2)
Not reported	90 (43.9)
% Employed at baseline	
0 - 49	6 (2.9)
50 - 74	23 (11.2)
75 - 89	30 (14.6)
90 - 100	123 (60.0)
Not reported	23 (11.2)

Table 3. Summary of Socioeconomic Outcome Measures from the Included Studies. The outcomes are described by follow-up time frames commonly associated with various socioeconomic measures, and the practices employed for collecting socioeconomic metrics.

Outcome	Return to work (duty)	Absenteeism days from work	Productivity loss	Income loss (USD)	Injury-related unemployment
No. of studies	119 [12-130]	104 [19, 20, 26, 28, 37, 38, 40, 44, 46, 47, 55, 60, 62, 66, 73, 74, 77, 79, 83, 94, 100, 103, 106, 110, 112, 114, 119, 118, 131 - 206]	11 [51, 60, 73, 79, 89, 116, 134, 141, 207 - 209]	11 [19, 37, 47, 51, 89, 135, 143, 163, 186, 210, 211]	10 [16, 60, 62, 72, 73, 77, 107, 186, 211, 212]
No. of patients					
11 - 50	49 (41.1)	46 (44.2)	1 (9.1)	3 (27.3)	3 (30.0)
51 - 100	34 (28.6)	29 (27.9)	3 (27.3)	3 (27.3)	3 (30.0)
101 - 250	15 (12.6)	20 (19.2)	2 (18.2)	4 (36.4)	1 (10.0)
251 - 500	11 (9.2)	2 (1.9)	1 (9.1)	0 (0)	2 (20.0)
> 500	10 (8.4)	7 (6.7)	4 (36.4)	1 (9.1)	1 (10.0)
No. of studies where the socioeconomic measure was the primary outcome	32 (26.9)	11(10.6)	3 (27.3)	1 (9.1)	0 (0)

No. of studies that included each time point*					
0 - 6 months	29 (24.5)	-	1 (9.1)	1 (9.1)	1 (10.0)
7 - 12 months	31 (26.1)	-	-	1 (9.1)	2 (20.0)
13 -24 months	20 (16.8)	-	-	1 (9.1)	1 (10.0)
> 24 months	3 (2.5)	-	-	-	1 (10.0)
Undefined	54 (45.4)	-	10 (90.9)	8 (72.7)	5 (50.0)
Point estimate for each time point					
6 months	58.8% (48.8 – 68.1) ^a	-		\$96.0 (-)	46.2%
12 months	67.7% (61.0 – 73.7) ^b	-	No consistent measure used for productivity loss	\$1,823.0 (-)	40.5% (8.4 – 83.4) ^e
24 months	60.9% (51.8 – 69.3) ^c	-		\$14,621.0 (-)	42.2%
Undefined	102.3 days (94.8 – 109.8) ^d	-		\$3,611 (1,617 – 5,605)	13.1% (4.8 – 30.7) ^f
Data collection methods					
Primary	95 (79.8)	90 (86.5)	4 (36.4)	4 (36.4)	8 (80.0)
Database	18 (15.1)	13 (12.5)	4 (36.4)	7 (63.6)	2 (20.0)
Not specified	6 (5.0)	1 (1.0)	3 (27.3)	0 (0)	0 (0)
Risk of bias					
High	12 (10.1)	8 (7.7)	1 (9.1)	0 (0)	1 (10.0)
Moderate	96 (80.7)	87 (83.7)	9 (81.8)	9 (81.8)	7 (70.0)
Low	12 (9.2)	9 (8.7)	1 (9.1)	2 (18.2)	2 (20.0)

^a I² = 97.0% (95% CI: 96.2 – 97.6)

^b I² = 95.1% (95% CI: 93.9 – 96.1)

^c I² = 97.5% (95% CI: 96.8 – 98.0)

^d I² = 99.9% (95% CI: 99.9 – 99.9)

^e I² = 97.9% (95% CI: 94.9 – 99.1)

^f I² = 89.1% (95% CI: 77.2 – 94.8)

* Many studies collected and reported outcome data at multiple time points.

USD = US dollars. Non-US currencies were converted to US dollars based on the exchange rate on January 1 in the publication year. Costs remain nominal for the publication year and were not adjusted for inflation.

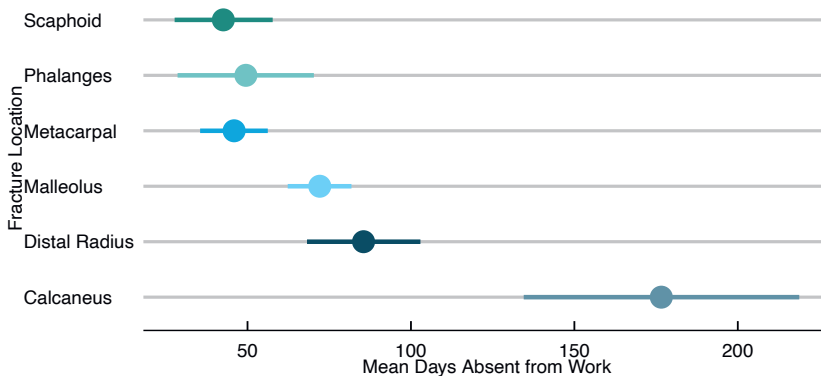


Fig 2. Mean Absenteeism Days by Fracture Location.

Return to Work

Based on the included literature, return to work measures the proportion of study participants that return to employment at a defined time interval or within the duration of the study. Several studies broadened the definition to include return to work or participation in an education program. Studies of military populations typically refer to return to duty. Return to work within six months of injury (24.5%) or 12 months of injury (26.1%) were the most common time intervals utilized by the included studies. However, nearly half of the studies did not define a specific time interval for measuring the return to work. Few studies specified if there were any changes in the employer or the work duties for the study participant upon returning to work. These data were mostly obtained using primary data collection (79.8%). Pooled estimates for return to work remained relatively consistent across the 6-, 12-, and 24-month reporting point estimates of 58.7%, 67.7%, and 60.9%, respectively. Thirty-two studies used return to work as the primary outcome.

Absenteeism Days from Work

Absenteeism days from work was the second most common socioeconomic outcome in the reviewed studies (n=104). This outcome was synonymously reported as days lost, time to return to work, temporary disability days, and sick leave. Eleven studies used absenteeism days from work as the primary outcome, and data were predominantly obtained through primary data collection (86.5%). The pooled estimate for mean days absent was 102.3 days (95% CI: 94.8 – 109.8). Six fracture locations (distal radius, scaphoid, metacarpal, phalanges, malleolus, and calcaneus) had more than five studies that used absenteeism days from work as an outcome, enabling a comparison in the heterogeneity of days absent from employment across those fracture locations. As highlighted in **Fig 2**, we observed substantially more absenteeism days for study participants with calcaneus fractures than what was observed for study participants with other fracture locations.

Productivity Loss

Of the five main socioeconomic measure, the calculation and reporting of productivity loss had the greatest variation. Several studies used techniques to estimate a monetary value for lost productivity. MacKenzie et al. used the Work Limitations Questionnaire [73], and another study applied an actuarial assessment of impairment due to injury to their study population [79]. Other studies qualitatively assessed lost productivity. Of the 11 studies that assessed productivity loss, three used the metric as their primary outcome. Only one study defined a time interval for their assessment and over a third of the studies collected these data from an existing database.

Income Loss

Income loss was used as a socioeconomic outcome in 11 of the included studies. The outcome was commonly calculated as days absent multiplied by average wage rates in the jurisdiction or the wage cost using public insurance databases [47, 135]. The majority (72.7%) did not specify a time interval for this outcome. The mean lost income for 6-, 12-, and 24-months post-injury was \$96, \$1,823, and \$14,621, respectively. For studies with undefined time intervals, the pooled mean income loss was \$3,611 (95% CI: 1,617 - 5,606). One of the included studies used income loss as their primary outcome.

Injury-Related Unemployment

Ten of the included studies used injury-related unemployment, or lost employment, as a study outcome. Injury-related unemployment was often described as a level of disability resulting in a withdrawal from the workforce. This measure was predominately determined through primary data collection, and half of the studies did not specify a time interval for the outcome. The pooled proportion of patients that were employed prior to injury but no longer employed at 12-months post-injury was 40.5% (95% CI: 8.4 - 83.4). For included studies with an undefined time interval, the pooled proportion of lost employment following injury was 13.1% (95% CI: 4.8 - 30.7).

Other Socioeconomic Outcomes

Several other socioeconomic outcome measures were described in the included literature, such as the Sickness Impact Profile, or the Olerud and Molander Score [78, 116]. The accumulation of debt and accessing social assistance were also reported in the literature [118, 211]. Ioannou et al. measured financial worry relative to physical and mental recovery after injury [129]. Finally, Hou et al. integrated health-related quality of life with sick leave days to create a novel measure of health-adjusted leave days [160].

Risk of Bias

Based on our defined criteria, the methodological safeguards against the risk of bias were limited among the included studies. Eighteen of the included studies (8.9%) were categorized as a high risk of bias, while 171 studies were considered to be at moderate risk of bias (83.4%) (**Table 4**). The main factors leading to an elevated risk of bias were due to inconsistent or lacking definitions of the socioeconomic outcome (71.2%), narrow eligibility criteria (41.0%), and six months or less of follow-up (12.2%). Sixteen of the included studies (7.8%) were deemed to be at low risk of bias.

Table 4. Risk of Bias Assessment for the Included Studies.

Assessment Criteria	Bias Risk	No. (%)
Duration of follow up		
0 – 6 months	High	33 (16.1)
7 – 12 months	Moderate	48 (23.4)
13 – 24 months	Low	48 (23.4)
> 24 months	Low	85 (41.5)
Proportion of sample that completed full follow-up		
> 90% follow up	Low	116 (56.6)
80 – 90% follow up	Low	28 (13.7)
70 – 80% follow up	Moderate	11 (5.4)
< 70% follow up	High	33 (16.1)
Not reported	High	17 (8.3)
Described and consistently applied definition of socioeconomic outcome		
Well-described, consistently applied	Low	59 (28.7)
Inconsistent or lacking description	High	146 (71.2)
Sample representative of studied fracture population		
Broad eligibility criteria	Low	121 (59.0)
Narrow eligibility criteria	High	84 (41.0)

DISCUSSION

Orthopaedic trauma can have a profound socioeconomic impact on patients, particularly within a year of injury. Based on the included studies, one-third of patients had not returned to work at one-year post-injury and, on average, patients missed over 100 days of work following their fracture. Data on the long-term socioeconomic impact of orthopaedic trauma is limited but suggests that 13% of fracture patients may lose employment due to injury.

Various measures have been used to quantify the economic impact of orthopaedic trauma. Return to work and absenteeism days from work were the most commonly used socioeconomic outcomes. Productivity loss, income loss, and lost employment were used with much less frequency. Primary data collection was used to capture the socioeconomic outcomes in over three-quarters of the included studies. The majority of the included prospective studies calculated their socioeconomic measures at one year or less from injury. However, even in retrospective studies, over one-third measured their

socioeconomic outcomes within one-year of injury. The bias assessment concluded that the methods for measuring the socioeconomic outcomes were vague or lacking entirely in three-quarters of the included studies. Tremendous heterogeneity was observed in the pooled socioeconomic outcomes.

The increased availability of large registry data presents an opportunity for long-term, population-level estimates of the socioeconomic effects of fractures. However, to realize this opportunity, socioeconomic data must be routinely and reliably collected in health data registries, or health registry data must include identifiers that can be linked to available socioeconomic data.

The results of this review identified opportunities to improve the societal relevance of orthopaedic trauma research by demonstrating the limitations in the current approaches of commonly used socioeconomic outcomes. Socioeconomic recovery following injury can be very nuanced and applying only a single measure of socioeconomic recovery yields inherent bias. Absenteeism days from work fails to describe study participants that do not return to work or return with impairment. Return to work rarely accounts for changes in the employment situation or productivity of the study participants [36]. Productivity loss is difficult to compare across study participants and can be confounded by baseline productivity. Income loss is largely dependent on the pre-injury income distribution of the study population. As study duration increases, new unemployment tends to be a rare outcome for most types of fractures and is easily confounded by the type of pre-injury employment.

Many of the included studies highlight practical approaches to measuring socioeconomic impact. Several of the included studies, such as those by MacKenzie et al. and Gardner et al. [73, 155], utilized a multifaceted approach to assessing the socioeconomic outcomes for the study population. Mortelmans et al. combine absenteeism days from work and an estimate of impairment for a detailed understanding of the socioeconomic outcomes following an intraarticular calcaneus fracture [79]. However, the specific method for quantifying impairment lacks description. Nusser et al. added a minimum duration of work absence to their socioeconomic outcome reporting [86]. Several other studies specifically characterized the sustained absence from work into categories such as retired, unemployed, undergoing rehabilitation, recipient of disability payments, in school, never working, or retraining for a different job [85, 115]. Prognostic modeling and stratified analysis included in five studies highlight several common confounders, such as the physical demands of the pre-injury employment [77, 79, 139, 148, 18, 95]. Additionally, the association between study participant age and return to work as well as the association between having dependents and return to work were identified and should be investigated as confounders in future studies on the socioeconomic consequences of extremity fractures [66, 93].

The systematic review and meta-analysis included a broad range of extremity fracture research from 40 countries and strictly adhered to the PRISMA guideline for conduct and reporting. However, despite these strengths, there were several limitations. Socioeconomic outcomes were reported at inconsistent time intervals in the included studies, therefore limiting our ability for both pooled and subgroup analyses. Other subgroup analyses were not possible due to inconsistent reporting of potential confounders, such as the severity of the injury, patient comorbidities, the type of pre-injury employment, and legal adjudication for compensation. All of these factors are likely to affect the patient's post-injury economic well-being. The assessment of study generalizability and a consistent socioeconomic outcome definition used in our risk of bias assessment carries a level of subjectivity. However, the appraisal was performed in duplicate. Finally, the described socioeconomic measure does not represent a fully inclusive list; rather, it includes those socioeconomic outcomes currently being utilized in orthopaedic trauma research. There are likely other socioeconomic outcomes, such as the Work Productivity and Activity Impairment questionnaire [213], that are available but were not utilized by the included studies.

Determining the effect of orthopaedic trauma on the economic well-being of the patient is essential for designing value-based care programs. In addition, these data inform surgeon-patient communication on recovery expectations, support the prioritization of health policies, and inform the design of future therapeutic studies aimed at mitigating the socioeconomic consequences of injury. The findings of this meta-analysis suggest that orthopaedic trauma can have a substantial socioeconomic impact on patients, and therefore also affect a person's psychological well-being and happiness. However, the current techniques to measure socioeconomic outcomes following orthopaedic trauma are widely varied in both design and implementation. Informative and accurate socioeconomic outcome assessment requires a multifaceted approach and further standardization.

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SUPPORTING INFORMATION

Detailed Search Strategies

MEDLINE (Ovid)

((socioeconomic OR financial OR economic).ab,ti ADJ1 (impact OR consequence* OR burden OR stress).ab,ti) OR employment.ab,ti OR unemployment.ab,ti OR unemployed.ab,ti OR loss of work.ab,ti OR missed work.ab,ti OR return to work.ab,ti OR sickness absence.ab,ti OR income.ab,ti OR cost of illness/ OR return to work/ OR absenteeism/ OR income/) **AND**

((hip OR leg OR knee OR arm OR upper extremity OR lower extremity OR limb OR bone OR orthopaedic OR orthopedic) ADJ2 (trauma OR injur* OR fracture*).ab,ti. OR dislocation.ab,ti. OR orthopaedic surgery.ab,ti. OR orthopedic surgery.ab,ti. OR orthopedics/ OR orthopedic procedures/ OR fractures, bone/ OR hip injuries/ OR leg injuries/ OR knee injuries/ OR arm injuries/)

Embase

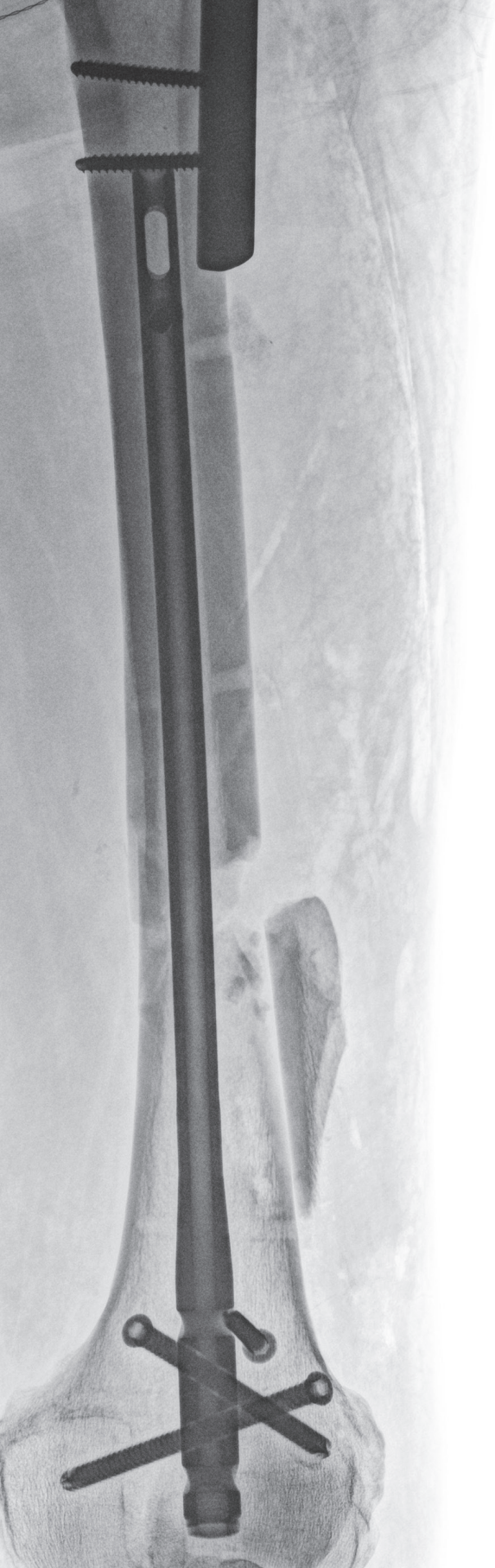
((socioeconomic OR financial OR economic) NEXT/1 (impact OR consequence* OR burden OR stress)):ab,ti OR employment:ab,ti OR unemployment:de,ab,ti OR unemployed:ab,ti OR "loss of work":ab,ti OR "missed work":ab,ti OR "return to work":de,ab,ti OR "sickness absence":ab,ti OR income:ab,ti OR "financial deficit"/de OR "employment status"/de OR "income"/de) **AND**

((hip OR leg OR knee OR arm OR "upper extremity" OR "lower extremity" OR limb OR bone OR orthopaedic OR orthopedic) NEAR/2 (trauma OR injur* OR fracture*)):ab,ti OR dislocation:ab,ti OR "orthopaedic surgery":ab,ti OR "orthopedic surgery":ab,ti OR orthopedics/de OR "joint fracture"/exp OR "limb fracture"/exp OR "pelvic fracture"/exp OR "hip injury"/exp OR "hip fracture"/exp OR "leg fracture"/exp OR "knee injury"/exp OR "arm fracture"/exp)

Scopus - TITLE-ABS-KEY

((socioeconomic OR financial OR economic) Pre/1 (impact OR consequence* OR burden OR stress) OR employment OR unemployment OR unemployed OR "loss of work" OR "missed work" OR "return to work" OR "sickness absence" OR income) **AND**

((hip OR knee OR leg OR arm OR "upper extremity" OR "lower extremity" OR limb OR bone OR orthopaedic OR orthopedic) W/2 (trauma OR injur* OR fracture*) OR dislocation OR "orthopaedic surgery" OR "orthopedic surgery")



2

Is PROMIS the New Standard for Patient-Reported Outcomes Measures in Orthopaedic Trauma Research?

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ABSTRACT

This review describes some of the benefits of the Patient-Reported Outcomes Measurement Information System (PROMIS) architecture, determined how frequently PROMIS measures were used in the current orthopaedic trauma literature, and compared the features of PROMIS instruments with other frequently used patient-reported outcomes measures (PROMs). PROMIS instruments have several unique elements to their architecture, such as item response theory, computerized adaptive testing options, and scaling using T-scores, that differentiate the instruments from many other PROMs. Over the past five years, 108 different PROMs were reported in 319 studies published in high-impact orthopaedic journals. PROMIS measures, including PROMIS Physical Function, Pain Interference, and Upper Extremity Function, were only used in seven studies (2%). PROMIS measures were found to be comparable to other more common PROMs with respect to respondent burden, administration options, and psychometric assessments specific to fracture patients. Likely, the limited familiarity and interpretability of PROMIS measures in the fracture population remain the most substantial barriers to broader adoption in orthopaedic trauma research.

INTRODUCTION

Patient-Reported Outcome Measures (PROMs) are designed to quantify the patient's health, quality of life, or functional status, and are directly reported by the patient without interpretation of the patient's response by a clinician or researcher [1]. PROMs are commonly measured in absolute terms but can be used to monitor relative changes in patient health following a treatment or over the course of a disease. In addition to the value PROMs provide to clinical research, PROMs can be integrated into the regular clinical management of patients to support patient and provider assessment [2,3].

The Patient-Reported Outcomes Measurement Information System (PROMIS) was initiated in 2004 and funded by the United States' National Institutes of Health [4]. The PROMIS initiative was led by Northwestern University, in partnership with six other American academic institutions, with an objective to build and validate a common, accessible item bank to measure key symptoms and health domains applicable to a range of chronic conditions [4,5]. Achieving this objective would enable efficient and interpretable clinical research and clinical practice applications of PROMs.

A symposium at the 2013 Orthopaedic Trauma Association's Annual Meeting featured the PROMIS toolkit and its benefits to orthopaedic trauma research [6]. In 2016, the American Academy of Orthopaedic Surgeons Board of Directors approved the recommendation of their Quality Outcomes Data Work Group for the use of the PROMIS Global Health instrument to measure the general quality of life of orthopaedic patients [7]. Despite this attention among the orthopaedic community, PROMIS' role as the new standard in orthopaedic trauma PROMs remains uncertain.

The purpose of this review was to describe the design and properties that differentiate PROMIS measures from other PROMs. Secondly, we aimed to review the current orthopaedic trauma literature to determine the most commonly used PROMs, and specifically, determine the proportion of publications that used PROMIS measures relative to other PROMs. Finally, we compared the utility of PROMIS measures for orthopaedic trauma research as compared to other common orthopaedic trauma PROMs using a framework developed for the Organisation of Economic Cooperation and Development's (OECD) Patient-Reported Outcomes Indicators Survey (PaRIS) program that facilitates international comparability of PROMs [8].

PROMIS: THE DESIGN AND PROPERTIES

Domains and Item Banks

PROMIS has developed multiple item banks for a variety of different domains. Domains are defined as the feeling, function, or perception that one wishes to measure [3]. The domains cut across various diseases and symptoms, such as physical function and feelings of depression. Item banks are a collection of items that each measure the same domain. Item banks are used to create different measure types, all producing a score on the same domain. PROMIS domains can be profiled into physical health (e.g., pain interference, physical function), mental health (e.g., anxiety, depression), and social health (e.g., ability to participate in social roles and activities, social isolation). The PROMIS profiles are small collections of short forms that serve to measure multiple, different domains at once. PROMIS also has a Global Health item bank which includes elements of the physical health, mental health, and social health profiles.

PROMIS measures can be deployed in three different ways. Short form measures use a subset of a domain's item bank. Most PROMIS domains have at least one short form measure, and some domains have multiple short form options. Short form measures typically include 4 – 10 items. Alternatively, there are computerized adaptive testing (CAT) options for many PROMIS domains. PROMIS measures can also be delivered as a profile option, where respondents complete all items available in the specific domains.

PROMIS Architecture

Three elements of the PROMIS architecture differentiate the instruments from many other PROMs. These elements include item response theory, CAT, and T-scores.

Item Response Theory

Item response theory relies on two assumptions. First, that a single trait determines how people respond to items. The second assumption is that there is little association between a response to two items beyond that accounted for by the underlying trait. For example, item response theory would conclude that the respondent's physical function will predict the probability of a response for each item in the PROMIS Physical Function item bank. This is a logical assumption if the instrument has domain validity; in other words, the instrument measures the construct it intended to measure.

Computerized Adaptive Testing

Computerized Adaptive Tests (CATs) aims to reduce the respondent burden by limiting the number of questions required when surveying the study participant on a single domain. The first item administered in a CAT is usually one in the middle of the range of function or symptom severity. After the first response, an estimated score is calculated.

Depending on the estimated score, the CAT algorithm then selects the best item for refining the estimated score using item response theory. This process is repeated until a specific level of measurement precision is obtained, or a specified maximum number of items are administered. In addition to reducing respondent burden, this process typically improves precision and minimizes the administration of redundant or irrelevant questions to the respondent. For example, a physical function survey may first ask if the respondent can run or jog one mile. Depending on the first response, the next question will ask the respondent if they can run or jog an increased or shortened distance. **Figure 1** illustrates one question in PROMIS' physical function survey.

Assessment Center

Are you able to do chores such as vacuuming or yard work?

- Without any difficulty
- With a little difficulty
- With some difficulty
- With much difficulty
- Unable to do

Previous Next Exit

Figure 1. A screenshot of a question included in the PROMIS Physical Function item bank as administered using the PROMIS computerized adaptive testing platform, Assessment Center.

T-Scores

PROMIS measures use a T-score metric in which scores are scaled to which 50 is the mean of a relevant reference population, and the standard deviation of that population is 10. PROMIS maintains a web service called *Health Measures* to calculate T-scores based on the study participant responses (**Figure 2**) [5]. In addition, there are built-in scoring systems available for CAT-administered measures in REDCap, Epic, and proprietary computer-based and tablet-based platforms. The use of T-scores can be useful in avoiding the floor and ceiling effects observed in other PROMs [9]. For example, the Disabilities of the Arm, Shoulder, and Hand (DASH) instrument has been reported to have 5% ceiling effect and 1% floor effect in hand and upper extremity fracture patients [10].

Your score on the Physical Function CAT is 37. The average score is 50.

Your score indicates that your level of Physical Function is higher (better) than:

- **14 percent of people in the general population**
 - **10 percent of people age 35-45**
 - **11 percent of males**
-

Figure 2. An example of the computerize adaptive testing report produced for a single respondent.

NARRATIVE REVIEW OF PATIENT-REPORTED OUTCOMES IN ORTHOPAEDIC TRAUMA LITERATURE

Search Strategy

To determine the frequency to which PROMs, and specifically PROMIS measures, are used in orthopaedic trauma research, we searched the abstracts of all original research articles published by five orthopaedic journals between January 1, 2014 to December 31, 2018. The journals included *Injury*, the *Journal of Orthopaedic Trauma*, *Clinical Orthopaedics and Related Research*, the *Bone and Joint Journal*, and the *Journal of Bone and Joint Surgery*. Studies were eligible for the review if the study population sustained a fracture and a PROM was used in the outcome assessment of the study. There were no age restrictions on the study population for the included studies.

Table 1. The ten most common patient-reported outcomes in orthopaedic trauma literature in 319 studies published in 2014-2018

Patient Reported Outcome	N	%
DASH or <i>Quick</i> -DASH	77	24.1
Pain Numerical Rating Scale	73	22.9
Short Form-36	55	17.2
EuroQoI-5D	41	12.9
(Short) Musculoskeletal Functional Assessment	32	10.0
Constant-Murley Score	31	9.7
Harris Hip Score	30	9.4
American Orthopaedic Foot & Ankle Society Ankle Hindfoot Score	28	8.8
Short Form-12	27	8.5
Olerud-Molander Ankle Score	17	5.3

Review Findings

In the 319 studies that met our eligibility criteria, 108 different PROMs were used to quantify patient outcomes. The most commonly used PROM was the DASH or *Quick-DASH* score (n=77, 24%) followed by the Pain Numerical Rating Scale (NRS) (n=73, 23%). The Short Form-36 (SF-36) was the most commonly used health-related quality of life PROM (n=55, 17%). By comparison, PROMIS measures were only used in seven studies (2%). All of these seven studies used domain-specific PROMIS measures. Three studies with PROMIS outcomes were published in 2018 [15-17]. One study that used PROMIS measures was published in 2017 [14], another in 2016 [13], and two 2015 [11,12].

Of the seven studies which used PROMIS measures, the most commonly used instrument was PROMIS Physical Function (n=7, 100%) [11-17], followed by PROMIS Pain Interference (n=3, 43%) (**Table 2**) [13,15,16]. All of the studies that utilized PROMIS measures were conducted in the United States, and included the CAT feature for at least one of their PROMIS instruments.

Table 2. PROMIS measures used in recent orthopaedic trauma literature published in 2014-2018

Author	PubMed ID	Journal, Year	PROMIS domain	Study Injury	Study Location	Other PROs in study
Morgan et al [11]	26001348	JOT, 2015	Physical Function - CAT	Proximal humerus fractures	United States	DASH, SMFA, Constant-Murley Score
Stuart et al [12]	26192378	JOT, 2015	Physical Function - CAT	Any surgically treatment fracture	United States	None
Kim et al [13]	27380397	JOT, 2016	Physical Function – CAT, Pain Interference - CAT	Lower extremity fracture	United States	Time to Brake
Kaat et al [14]	28938284	JOT, 2017	Upper Extremity – CAT, Physical Function – Short Form (8-item), Physical Function – Short Form (10-item)	Upper extremity fracture	United States	SF-36, QuickDASH, SMFA, Dysfunction Index
Vikus et al [15]	29920192	JOT, 2018	Physical Function - CAT, Pain Interference - CAT	Bicondylar tibial plateau fracture	United States	None
Cavallero et al [16]	29738401	JOT, 2018	Physical Function - CAT, Pain Interference - CAT	Bicondylar tibial plateau fracture	United States	None
Vincent et al [17]	30130305	JOT, 2018	Physical Function – CAT, Psychosocial Illness Impact-Positive – CAT, Satisfaction with Social Roles and Activities - CAT	Any surgical treated fracture	United States	Beck Depression Inventory – II, State-Trait Anxiety Inventory

JOT = Journal of Orthopaedic Trauma; CAT = Computerized Adaptive Testing; DASH = Disabilities of the Arm, Shoulder and Hand; SMFA = Short Musculoskeletal Function Assessment

COMPARISON OF PROMIS WITH OTHER COMMON PROMS

Comparison Framework

The OECD's PaRIS Initiative facilitates the international comparability of PROMs-based performance [8]. One area of focus for the OECD's PaRIS Initiative, in collaboration with the Canadian Institutes for Health Information (CIHI), is on the comparability of PROMs for patients that have undergone hip or knee surgery. Using the framework developed by the PaRIS Initiative, we have compared frequently-used orthopaedic trauma PROMs with their PROMIS counterpart.

The review framework includes the mode of administration, the respondent burden, the operational elements of the PROMs, and whether the psychometric properties of the PROM have been assessed in an orthopaedic trauma population. The Consensus-based Standard for the Selection of Health Measurement Instruments (COSMIN) recommends that PROMs be evaluated on at least the following four psychometric properties; reliability, validity, responsiveness, and interpretability [18]. In our assessment, we did not evaluate the psychometric performance of each PROM in our comparison, but merely cited relevant psychometric assessments of the PROM for a fracture population. Our comparisons on the mode of administration compared the availability of paper versus computer-based versus phone-based administration. We also assessed the available language options for each instrument. Our review of operational elements included licensing approval requirements, fees, and support services available for administration and scoring. The respondent burden was assessed based on the number of items in the instrument. The comparison included measures of physical function, pain interference, upper extremity function, and health-related quality of life (**Table 3**).

Physical Function Measures

The PROMIS Physical Function measure has a larger item bank than the Musculoskeletal Function Assessment (MFA), with short form versions of PROMIS Physical Function having fewer items than the Short Musculoskeletal Function Assessment (SMFA). The SMFA has several studies assessing its psychometric properties in fracture patients [20-23], compared to two psychometric assessments of the PROMIS Physical Function measure in fracture patients [14,19]. Both instruments are available without a fee or approval requirements. The SMFA has substantially more language options, but the PROMIS Physical Function a CAT option.

Pain Measures

The PROMIS Pain Interference measure has a larger item bank than the full version of the Brief Pain Inventory (BPI), and fewer items in the short form version of the BPI. However, with a single question, the Pain Numerical Rating Scale (NRS) has the least respondent

Table 3. Comparison of common PROMIS measures with other patient-reported outcomes that are commonly used in orthopaedic trauma research

Instrument	Scoring Scale	Number of Items	Psychometric Properties for Fracture Population	Mode of Administration	Language Options	Licensing, Costs	Support Services
Physical Function							
PROMIS Physical Function	0 – 100 (better function)	165-items (v2.0), 4-item, 6-item, 8-item, 10-item, 20-item	Validity, reliability, and responsiveness assessed [14, 19]	Paper, CAT	English, Spanish	No fee or approval required	Scoring service available
Short Musculoskeletal Function Assessment	0 – 100 (poorer function)	46-item (Short), 101-item (Full)	Validity, reliability, and responsiveness assessed [20-23]	Paper	Dutch, German, Chinese, Swedish, Korean, Japanese	No fee or approval required	Scoring manuals available
Pain							
PROMIS Pain Interference	0 – 100 (more pain)	40-items (v1.1), 4-item, 6-item, 8-item	Validity assessed [19]	Paper, CAT	English, Spanish	No fee or approval required	Scoring service available
Pain Numerical Rating Scale	0 – 10 (more pain)	1	Not assessed in the fracture population	Paper, Phone	English, French, Chinese, Spanish, Italian (at least 18-languages in total)	No fee or approval required	No scoring services required
Brief Pain Inventory	0 – 10 (more pain)	9-item (Short), 32-item (Full)	Not assessed in the fracture population	Paper	English, French, Chinese, Spanish, Italian (24-languages in total)	Approval required, fees may apply	Scoring manuals available
Upper Extremity							
PROMIS Upper Extremity	0 – 100 (more function)	34-item (Full, v2.0)	Validity, reliability, and responsiveness assessed [14,19]	Paper, CAT	English	No fee or approval required	Scoring service available
DASH	0 – 100 (more disability)	11-item (QuickDASH), 30-item (DASH)	Validity, reliability, and responsiveness assessed [24-29]	Paper	English, French, Chinese, Spanish (27-languages in total)	Approval required, fees may apply	Scoring manuals and service available
Constant-Murley Score	0 – 100 (more function)	10-item	Validity, reliability, and responsiveness assessed [27, 30]	Paper, Computer	English, French, Chinese, Spanish (More than 10 languages in total)	No fee or approval required	Scoring manuals available

Table 3. Continued

Instrument	Scoring Scale	Number of Items	Psychometric Properties for Fracture Population	Mode of Administration	Language Options	Licensing, Costs	Support Services
Overall Health							
PROMIS Global Health	0 – 100 (better health), reports separate Global Mental and Global Physical score	10-item	Not assessed in the fracture population	Paper, Computer	English, Spanish	No fee or approval required	Scoring service available
Short Form-36	0 – 100 (better health), reports separate physical component and mental component score	36-item	Validity, reliability, and responsiveness assessed [21,23,31-33]	Paper, Computer	English, French, Chinese, Spanish (22-languages in total)	Version 1- No fee or approval required; Version 2 - Approval required, fees apply	Scoring manual available
Short Form-12	0 – 100 (better health), reports separate physical component and mental component score	12-item	Not assessed in fracture population	Paper, Computer	English, French, Chinese, Spanish (at least 13-languages in total)	Approval required, fees apply	Scoring manual available
EuroQol-5D	0 – 100 (better health)	5-item	Validity, reliability, and responsiveness assessed [32-34]	Paper, Computer	English, French, Chinese, Spanish (170-languages in total)	Approval required, fee may apply	Value sets available for 32 different countries

burden of the three instruments. The validity of the PROMIS Pain Interference measure has been assessed in upper extremity fracture patients [19]. The psychometric properties of the NRS and BPI have not been specifically evaluated in the fracture population. The NRS and BPI have substantial more language options than the PROMIS Pain Interference measure, but again, the PROMIS Pain Interference has a CAT option.

Upper Extremity Measures

With 34-items, the PROMIS Upper Extremity measure has a larger item bank than the DASH or Constant-Murley Score. However, the PROMIS Upper Extremity measure does not have a short form version similar to the *Quick*-DASH or the 10-item Constant-Murley Score but does have a CAT version. The psychometric properties of all three measures have been tested in fracture populations [14,19,24-30]. The DASH and Constant-Murley have substantially more language options.

Health-Related Quality of Life Measures

For health-related quality of life measures, the respondent burden of commonly used PROMs ranges from the 5-item Euro-Qol-5D (EQ-5D) to the 36-item Short Form-36 (SF-36). The psychometric properties of the SF-36 and EQ-5D have been extensively assessed in fracture populations [21, 23, 31-34]. However, this population-specific psychometric evaluation is lacking for the Short Form-12 (SF-12) and PROMIS Global Health measure. All measures are available for administration by paper or computer. Unlike other PROMIS instruments, there is no CAT version available for the PROMIS Global Health measure. This is likely because it is only ten items and covers several domains. Depending on the application, approvals and fees may be required for the use of the SF-36 and SF-12, whereas EQ-5D can in principle be used free of charge. All three have many language and administration options.

CONCLUSIONS

PROMIS measures have several attractive elements to their architecture, including item response theory, CAT, and scoring based on the T-score metric. Despite these elements, our review of the recent literature found no evidence that PROMIS measures are the new standard for orthopaedic trauma research. Among the most common PROMs used in orthopaedic trauma research over the past five years, legacy instruments such as the DASH, NRS, SF-36, and EQ-5D continue to be the most frequently used. The slow adoption of PROMIS measures in orthopaedic trauma is likely multifactorial.

Potential barriers to the adoption of PROMIS measures in orthopaedic trauma research include a lack of familiarity with the instruments and limited comparisons of PROMIS measures to other legacy PROMs. PROMIS, through its PROsetta Stone initiative [35], aims to improve its comparability of PROMIS with legacy PROMs using crosswalk algorithms. Crosswalk tools are currently available for PROMIS measures and PROMs, such as the SF-36, DASH, and *Quick-DASH*, and the BPI. Even with these compatibility tools, interpretability of the PROMIS scores which are unfamiliar to orthopaedic trauma community impedes adoption. Some researchers may also be hesitant to rely on CAT scores due to concerns about the comparisons of study participants that have responded to different items in the item bank of a domain. However, research has demonstrated high test-retest reliability when using CATs, as well as a high correlation between PROMIS CAT scores and legacy measures [36,37].

In addition to the efforts by the PaRIS Initiative, the International Consortium for Health Outcomes Measurement (ICHOM) defines international standard sets of outcome measures for value-based healthcare [38]. However, similar to the PaRIS Initiative, ICHOM has not included fracture patients in their standard sets to date. ICHOM's standard sets for musculoskeletal conditions currently include low back pain, hip and knee osteoarthritis, and inflammatory arthritis. For these three musculoskeletal conditions, ICHOM's standard sets include the EQ-5D, SF-12, and NRS, but do not include any of the PROMIS measures.

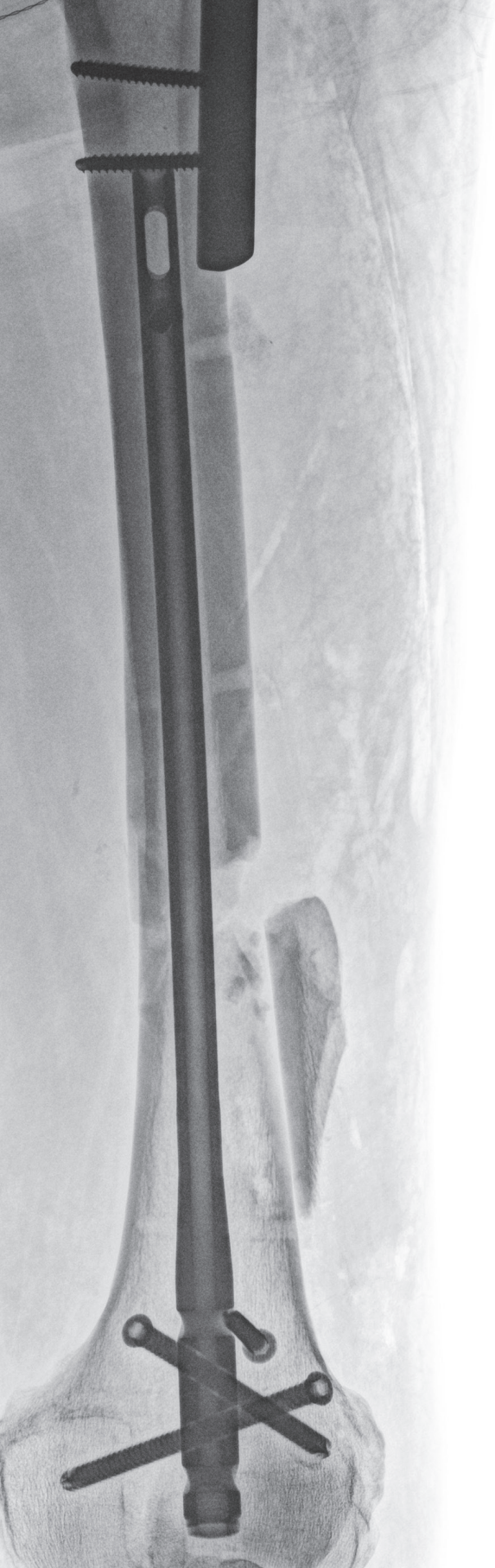
PROMIS measures, such as the Global Health, Physical Function, and Pain Interference measures, are seemingly well-suited for orthopaedic trauma research. However, to date, the use of PROMIS measures in orthopaedic trauma research has been limited, at best. The technical benefits of the PROMIS architecture, its large item banks, and the availability of PROMIS instruments without fees or pre-approvals add to the appeal of PROMIS. While PROMIS instruments are used far less frequently in orthopaedic trauma research compared to other legacy measures, PROMIS instruments may just be in the early stages of the adoption life cycle and require more time to improve the familiarity and interpretability of the measures among this study population.

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3

A Patient-Centered Composite Endpoint Weighting Technique for Orthopaedic Trauma Research

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ABSTRACT

Background: This study aimed to address the current limitations of the use of composite endpoints in orthopaedic trauma research by quantifying the relative importance of clinical outcomes common to orthopaedic trauma patients and use those values to develop a patient-centered composite endpoint weighting technique.

Methods: A Best-Worst Scaling choice experiment was administered to 396 adult surgically-treated fracture patients. Respondents were presented with ten choice sets, each consisting of three out of ten plausible clinical outcomes. Hierarchical Bayesian modeling was used to determine the utilities associated with the outcomes.

Results: Death was the outcome of greatest importance (mean utility = -8.91), followed by above knee amputation (-7.66), below knee amputation (-6.97), severe pain (-5.90), deep surgical site infection (SSI) (-5.69), bone healing complications (-5.20), and moderate pain (-4.59). Mild pain (-3.30) and superficial SSI (-3.29), on the other hand, were the outcomes of least importance to respondents.

Conclusion: This study revealed that patients' relative importance towards clinical outcomes followed a logical gradient, with distinct and quantifiable preferences for each possible component outcome. These findings are incorporated into a novel composite endpoint weighting technique.

BACKGROUND

A commonly used definition of a composite endpoint in clinical research is the occurrence of any one of several study events of interest [1]. Incorporating multiple endpoints into a single metric increases the number of observed events, can avoid issues pertaining to multiplicity, and thus, may increase statistical power [1,2,3]. Composite endpoints also enable the inclusion of rare, but clinically important, outcomes; therefore, providing a broader interpretation of the net clinical benefit of a treatment [1].

Composite endpoints have several limitations [4-7]. The treatment effect of an outcome of high importance but low frequency, such as death, may be muted by the inclusion of more common outcomes of lesser importance, such as a superficial infection [4]. Additionally, in studies that analyze composite endpoints using a traditional time to first event analysis or other analyses of frequency that only consider the first event, each study participant can have only one event; therefore, censoring subsequent events biases treatment effects to earlier outcomes. Efforts to address these limitations have included weighting techniques such as those utilizing the Delphi method [8], disability-adjusted life years [9,10], or hierarchical and global ranking systems [11- 14]. However, weighting methods which incorporated patient values specific to the target patient population are lacking [15,16].

Composite endpoints are becoming increasingly common in orthopaedic trauma research. The objective of this study was to address the limitations related to the use of composite endpoints in orthopaedic trauma research. The primary aim was to quantify the utility and heterogeneity of utility of clinical outcomes common to orthopaedic trauma patients using a Best-Worst Scaling experiment. The secondary aims were to use the patient values derived from the Best-Worst Scaling experiment to develop a patient-centered composite endpoint weighting technique that accounts for multiple events per patient. Finally, we provide one hypothetical clinical trial example and several options for how the weights may be applied in practice.

METHODS

Study design

A Best-Worst Scaling experiment was used to determine the relative importance of common clinical outcomes to orthopaedic trauma patients. Best-Worst Scaling experiments are a type of choice experiment that were first devised for marketing research but have been more recently applied to healthcare research [17,18]. Choice experiments assume that any product or service, such as a healthcare treatment or

clinical outcome, can be described by its characteristics, or attributes [19]. In a Best-Worst Scaling experiment, respondents are presented with a set of three or more attribute levels and then asked to select the best and worst attribute level in each choice set. The utility of each attribute level is then determined based on the probability of respondents choosing one attribute level over others [20]. The mean utility of each attribute level is then reported relative to a single, common reference level. In this study, the calculated utilities were used to produce a weighting technique accounting for the patient-reported importance of orthopaedic clinical outcomes.

Attribute development and survey design

The study was performed at a single Level-1 trauma center in Baltimore and followed the International Society for Pharmacoeconomics and Outcomes Research conjoint analysis practice guidelines [21]. The attributes used in this study were selected through a combination of quantitative and qualitative methods. A literature review identified common components of composite endpoints used in orthopaedic trauma research [22-25]. Expert consensus was elicited from orthopaedic trauma surgeons at the study location. Finally, semi-structured interviews were conducted with three orthopaedic trauma patients for additional perspective on plausible clinical outcomes. Information gathered from this work informed the final selection of the included attributes and levels deemed most important by our patient and clinician stakeholders. Orthopaedic trauma patient-partners then participated in the development of patient-oriented descriptions of each attribute level. **Figure 1** lists the attributes included in the final Best-Worst Scaling experiment questionnaire. The MaxDiff Design platform in JMP Pro Version 13 (Cary, NC) was used to create a Best-Worst Scaling questionnaire. The respondent burden was reduced using a blocked, balanced, fractional factorial design, based on optimal D-efficiency [26]. The final design included four versions of the questionnaire, each consisting of 10 choice sets. The choice experiment was pilot tested on orthopaedic trauma patients in an outpatient setting to validate respondent comprehension and study feasibility before the final administration.

Prior to completing the Best-Worst Scaling questionnaire, respondents answered several demographic questions and indicated which orthopaedic complications they had experienced during their post-operative clinical course. This process served to familiarize patients with the description of each attribute level prior to the choice experiment. To ensure face validity for the attribute descriptions, a chart review was performed to compare each patient's reported post-surgical complications with any complications noted in the electronic medical records. Each choice set included a brief clinical scenario designed to establish a common context in which the post-surgical complications included in the choice sets could occur. Each choice set presented the respondent with three possible attribute levels (clinical outcomes) (see **Figure 2** for

Attribute	Description
Death	Death
Above knee amputation	Amputation above the knee
Below knee amputation	Amputation below the knee
Severe pain or discomfort	Severe pain or discomfort, most of the time
Moderate pain or discomfort	Moderate pain or discomfort, most of the time
Mild pain or discomfort	Mild pain or discomfort, most of the time
Nonunion / Malunion / Removal of Hardware	Bone healing issue needing another surgery
Deep Surgical Site Infection	Bone infection needing one or more operation(s) to clean out infection, followed by 6 weeks of antibiotics
Superficial Surgical Site Infection	Skin infection needing antibiotic pills for 2 weeks
Perfect Health	Perfect Health

Figure 1. Description of the attribute levels used in the Best-Worst Scaling questionnaire

Please select the **BEST** (most preferred) complication and the **WORST** (least preferred) complication from options provided.

Best (most preferred)		Worst (least preferred)
	Skin infection needing antibiotic pills for 2 weeks	
	Mild pain or discomfort most of the time	
	Amputation <i>below</i> the knee	

Figure 2. Example of a Best-Worst Scaling experiment choice set used in this study

a sample choice set), and the respondents were asked to select the best and worst attribute level based on their personal preferences. This process was then repeated for the remaining choice sets (n=10), with each subsequent choice set containing a different combination of the attribute levels.

Eligibility criteria

The Best-Worst Scaling questionnaire was administered to English-speaking patients, 18 years of age or older with a surgically treated appendicular fracture from November 2017 to March 2018. Patients were enrolled in the study at an outpatient follow-up appointment, at which time they provided written informed consent and completed the written questionnaires. Electronic medical records were reviewed to assess respondent injuries, treatments, and complications. To ensure adequate statistical power for an a priori defined subgroup analysis by injury location, study participants were purposely sampled to ensure at least 50 participants with each of the following fractures: hand/wrist; upper extremity (proximal to distal $\frac{1}{4}$ radius/ulna); hip (pelvis, acetabulum, femoral neck, and greater/lesser trochanter), tibia/femur (distal to lesser trochanter and proximal to ankle fractures), and foot/ankle.

Statistical analysis of BWS data

There is no consensus on the appropriate sample size calculation for choice experiments; however, previous research recommends a minimum of 50 respondents in each subgroup included in the analysis [27]. Ten sub-groups with hypothesized divergent outcome preferences were monitored to ensure adequate representation in the sample.

The BWS statistical analyses were performed using JMP Pro Version 13 (Cary, NC). Patient demographic and clinical characteristics were described using means and standard deviations for continuous variables, and frequencies and proportions described categorical variables. A hierarchical Bayesian multinomial logit model was used to estimate the utility for each of the included clinical outcomes. This technique derives posterior estimates of the respondent's utility based on the distribution of coefficients across the study sample and the individual respondent's utility coefficients. Model parameters were calculated iteratively using Gibbs sampling. We ran 10,000 iterations, including 5,000 burn-in iterations. The respondent-level covariates are estimated based on the algorithm described by Train, which incorporates Adaptive Bayes and Metropolis-Hastings approaches [28]. The likelihood function for the utility parameters for a given respondent is based on a model for each subject's preference within a choice set, given the attributes in the choice set [29]. The parameters for each attribute level represent the mean of these iterations, and the utility of each included outcome estimates the strength and direction of the respondents' preference towards a given outcome. The utility estimates for a specific outcome derived in the model have no

direct interpretation, and can only be interpreted relative to another utility estimate in the model. We set the mean utility at zero for perfect health; all other possible outcomes are then presented as negative utilities.

To test heterogeneity in respondents' utility for each included clinical outcome, ten demographic and injury-specific covariates were independently tested as interaction terms in the primary model. To adjust for ten statistical tests, we set the level of significance for the interaction terms at $\alpha = 0.05/10 = 0.005$. Only covariates with a significant independent interaction were jointly tested with a $\alpha = 0.005$ level of significance. If a significant interaction was observed in the joint testing, a stratified analysis was performed for covariate and outcomes using a one-way analysis of variance (ANOVA) test. Significant associations between the covariates and a specific outcome at $\alpha = 0.05$ in the ANOVA test were further tested using a Tukey-Kramer post hoc test [30,31]. To determine if experiencing a clinical outcome is associated with a different utility for that outcome, we stratified respondents by those who had and had not experienced the outcome. The respondent-level utilities for the outcome of interest were then compared using a Student's t-test.

Derivation of composite outcome weights

An orthopaedic trauma composite endpoint weighting technique based on the mean utilities of the component outcomes and a modified version of the conditional logit formula described by McFadden [23] is provided below:

$$W_a = \frac{e^{u_b} + e^{u_i}}{e^{u_a} + e^{u_b} + e^{u_i}}$$

The weight (W) is calculated separately for each included outcome a where u is the mean utility of each included outcome. b and i note the component outcomes included in the composite. A weight calculator, with sub-group adjustment, is included in the **Supplementary Appendix A**.

A hypothetical pilon fracture trial was used to illustrate the application of the proposed weighting technique (**Table 1**). In this hypothetical trial, 1000 patients are randomized to hypothetical Treatment A ($n=498$) or Treatment B ($n=502$). Three components (deep surgical site infection, bone healing complication, and superficial surgical site infection) were included in the hypothetical trial's primary composite endpoint. The effect of Treatment A versus Treatment B on the composite endpoint was then calculated using several unweight methods, including a Fisher's Exact Test, time to first event analysis, and a random effects model. For comparison, the treatment effect was also calculated

using several methods that accounted for the proposed component weights, including a Wilcoxon Rank Sums test, time to event allowing for weighted repeated events, and a random effects model that accounted for component weights [32]. The effect size for the random effects models are reported as odds ratios, and hazard ratios are used for the time to event models [33]. The Probability Index was used to report the treatment effect for the Wilcoxon Rank Sums test [32-34]. These analyses were performed using R Version 3.6.1 (Vienna, Austria). All of the data and code for the models are included in **Supplementary Appendix B and C**. However, for simplicity, only the unweighted and weighted time to event analysis are reported in the results section.

Table 1. Summary of events in a hypothetical pilon fracture trial

Outcomes	Utility	Weight	Treatment A	Treatment B (n=502)
			(n=498)	
			Number of Events	Number of Events
Deep SSI	-5.69	0.93	61	91
Bone healing complication	-5.20	0.88	30	55
Superficial SSI	-3.29	0.20	98	42
Total			168	174

SSI, surgical site infection

RESULTS

Sample characteristics

A total of 428 patients consented for the Best-Worst Scaling questionnaire at their scheduled follow up visits. Of those, 32 patients (7.5%) did not clearly indicate best and worst outcomes in the Best-Worst Scaling choice sets and were omitted from the analysis. The sociodemographic and fracture characteristics of the survey respondents are shown in **Table 2**. The mean age of the respondents was 48.7 years, and the respondents were more commonly male (58.3%) and white (66.4%). The median time from initial orthopaedic injury to survey completion was four months (IQR: 2-12 months). Nearly half (47.5%) of respondents had a tibia or femur fracture below the lesser trochanter. The most commonly experienced post-surgical outcome was 'severe pain or discomfort' (42.2%) followed by 'bone healing complication' (31.3%), and 'moderate pain or discomfort' (29.3%).

Utilities of the clinical outcomes

The mean utility for each of the included clinical outcomes was scaled relative to "perfect health" (referenced at zero) (**Table 3**). Of the ten included clinical outcomes,

Table 2. Characteristics of study participants

Characteristic	n=396
Age, mean (SD)	48.7 (17.5)
Sex, Male, n (%)	231 (58.3)
Ethnicity, n (%)	
White	263 (66.4)
African-American	98 (24.7)
Asian/South Asian	10 (2.5)
American Indian/Alaskan Native	10 (2.5)
Hispanic/Latino	9 (2.3)
Other	6 (1.5)
Marital Status, n (%)	
Single	158 (39.9)
Married	144 (36.4)
Divorced/Widowed/Separated	94 (23.7)
Education, n (%)	
Less than high school	50 (12.6)
High school diploma	132 (33.3)
Some college	96 (24.2)
Degree	75 (18.9)
Graduate/Professional degree	40 (10.1)
Annual Income, n (%)	
Less than \$10,000	114 (28.8)
\$10,000 - \$34,999	94 (23.7)
\$35,000 - \$49,999	54 (13.6)
\$50,000 - \$74,999	57 (14.4)
\$75,000 - \$100,000	26 (6.6)
More than \$100,000	32 (8.1)
Not reported	19 (4.8)
Health Insurance, n (%)	
Medicare/Medicaid/TRICARE	207 (52.2)
Private	175 (44.2)
No insurance	14 (3.6)
Injury Location, n (%)*	
Tibia/Femur (below lesser trochanter)	188 (47.5)
Foot and ankle	107 (27.0)
Femoral neck/pelvis/acetabulum	80 (20.2)
Upper extremity (proximal to carpals)	53 (13.4)
Hand	55 (13.8)
Complications, n (%)#	
Severe pain	167 (42.2)
Bone healing complication	124 (31.3)
Moderate pain	116 (29.3)
Mild pain	98 (24.7)
Deep surgical site infection	57 (14.4)
Superficial surgical site infection	35 (8.8)
Below knee amputation	11 (2.8)
Above knee amputation	3 (0.8)

*Proportions exceed 100% as 73 patients had fractures in multiple anatomical locations.

Proportions exceed 100% as 173 patients suffered from multiple complications.

Table 3. Utility estimates for all of the included clinical outcomes

Outcome	Mean Utility	Lower 95%	Upper 95%
Death	-8.91	-9.23	-8.65
Amputation [above knee]	-7.66	-7.83	-7.48
Amputation [below knee]	-6.97	-7.14	-6.85
Severe pain	-5.90	-6.00	-5.80
Deep surgical site infection	-5.69	-5.81	-5.60
Bone healing complication	-5.20	-5.31	-5.09
Moderate pain	-4.59	-4.69	-4.57
Mild pain	-3.30	-3.46	-3.13
Superficial surgical site infection	-3.29	-3.39	-3.16
Perfect health	0.00	-0.37	0.44

Model Statistics	
Total iterations	10,000
Burn-in iterations	5,000
Number of respondents	396

the greatest importance was associated with death (mean utility = -8.91, 95% CI -9.23 - -8.65), followed by an above knee amputation (AKA) (-7.66, 95% CI -7.83 - -7.48]). Mild pain (-3.30, 95% CI -3.46 - -3.13) and a superficial surgical site infection (-3.29, 95% CI -3.39 to -3.16) were determined to be the outcomes of least importance to the respondents. There was no overlap in the confidence intervals of the clinical outcomes, except for those of superficial surgical site infection and mild pain, where considerable overlap in their utilities was observed.

Heterogeneity in utilities of clinical outcomes

Ten covariates were independently tested as interaction terms in the primary model. There was no heterogeneity in the respondent' mean utility of the component outcomes based on sex, time since treatment, the location of their injury, or specifically an open tibia fracture. Statistically significant interactions based on age, race, education level, income level, and health insurance status were observed. The association between these five covariates and the respondent's utilities for the included clinical outcomes was further tested using a stratified analysis with the findings reported in **Table 4**.

For each included clinical outcome, the respondent-level utilities for that specific outcome were compared between respondents that had experienced that particular outcome versus those that had not experienced the outcome. Of the 72 comparisons, only seven comparisons demonstrated significantly different mean utilities. Respondents

Table 4. Heterogeneity in the importance of clinical outcomes by patient characteristics

Characteristic	N	Death		Above knee amputation		Severe pain		Deep SSI		Moderate pain		Superficial SSI	
		Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	
Age													
18-64	320			-7.70 (0.17)**									
>=65	76			-7.75 (0.11)									
Race													
White	263			-7.68 (0.14)***		-5.92 (0.25)*				-4.61 (0.23)**			-3.18 (1.13)*
Non-white	133			-7.61 (0.17)		-5.86 (0.26)				-4.55 (0.22)			-3.48 (1.21)
Education													
High school or less	182			-7.63 (0.12)**		-5.85 (0.25)***				-4.56 (0.23)*			-3.51 (1.21)**
Some college	96			-7.69 (0.14)		-5.91 (0.26)				-4.59 (0.21)			-3.10 (1.16)
Degree or higher	115			-7.68 (0.14)		-5.97 (0.26)				-4.63 (0.22)			-3.06 (1.02)
Income Level													
Less than \$10,000	114					-5.86 (0.27)*				-5.70 (0.12)*			-3.41 (1.07)**
\$10,000 - \$34,999	94					-5.88 (0.25)				-5.70 (0.11)			-3.51 (1.37)
\$35,000 - \$74,999	111					-5.92 (0.24)				-5.69 (0.12)			-3.17 (1.08)
\$75,000 or more	58					-5.98 (0.28)				-5.65 (0.09)			-2.87 (1.09)
Health Insurance													
Medicare/Medicaid/TRICARE	205			-8.83 (0.76)**						-5.70 (0.11)*			
Private	175			-9.01 (0.61)						-5.68 (0.11)			

Level of significance as determined by ANOVA test. * $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$
 SSI = surgical site infection

with bone healing complications were less averse to an amputation above the knee (-7.63 vs. -7.67, $P = 0.02$) compared to other respondents. Respondents with an above knee amputation were more averse to death (-9.50 vs. -8.91, $P < 0.01$), but less averse to a superficial surgical site infection (-2.07 vs. -3.29, $P < 0.01$). Respondents with a below knee amputation placed less importance on mild pain (-3.49 vs. -3.30, $P = 0.02$) and superficial surgical site infection (-2.66 vs. -3.30, $P < 0.01$) but a greater importance on severe pain (-6.07 vs. 5.90, $P = 0.04$) compared to the other respondents. Respondents who experienced a superficial surgical site infection had a greater aversion to severe pain (-5.99 vs. 5.89, $P = 0.04$).

Composite outcome weighting: An example

For the hypothetical pilon fracture trial, the results with the unweighted composite endpoint using a time to first event analysis would have determined that there was no difference between the two treatments (hazard ratio (HR): 1.02, 95% CI 0.83 – 1.27, $P = 0.83$) (**Figure 3**). When weights are applied to the included component outcomes, and the analysis allows for patients to have more than one event, Treatment A is superior (HR: 0.72, 95% CI 0.57 – 0.90, $P < 0.01$). A similar difference in effect size was observed when the data were analyzed using unweighted and weighted random effects models (**Supplementary Appendix C**). However, the treatment effect was not statistically significant when the weights were applied using a global rank approach, and treatment groups were compared using a Wilcoxon Rank Sums test and Probability Index Model.

DISCUSSION

This study presents a novel composite endpoint weighting technique that includes ten, commonly-reported, orthopaedic trauma clinical outcomes. Hierarchical Bayesian modeling was used to calculate the importance, and heterogeneity in the importance of these outcomes in a cohort of nearly 400 orthopaedic trauma patients. Patients consistently ranked clinical outcomes according to a logical gradient ranging, from perfect health to death. Some heterogeneity in importance was observed based on respondent age, race, education level, income level, and health insurance provider. We did not observe heterogeneity in responses based on the location of the fracture or time since the initial treatment, suggesting the observed utility estimates and weighting technique has face validity across multiple fracture types and clinical experiences.

To our knowledge, this is the first study to incorporate patient preferences derived from a choice experiment into a composite endpoint weighting technique for orthopaedic outcomes. Other efforts at weighting composite endpoints have included assigning weights based on clinical and research experience [1,8,12], hierarchical ranking of

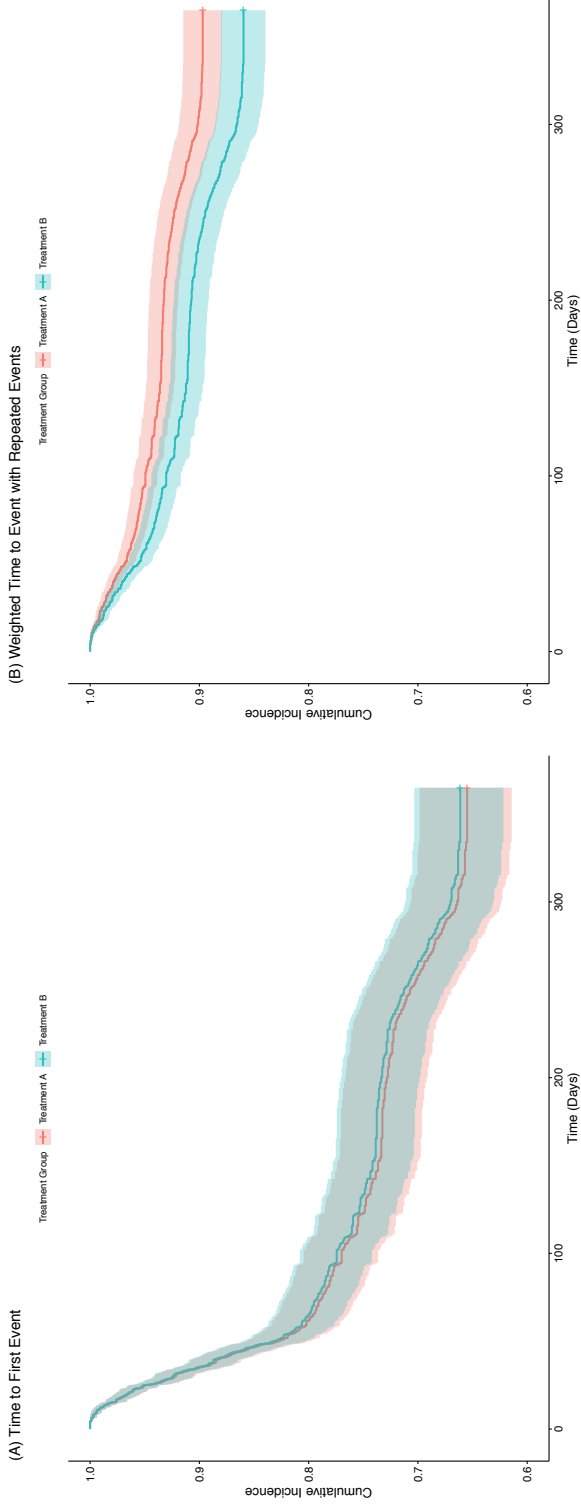


Figure 3. Survival curves of an unweighted time to first event analysis (A) and a weighted time to event analysis that allowed for repeated events (B) using the hypothetical pilon fracture data

outcomes for an entire cohort of patients in a trial [11,14], and the inclusion of a measure of “importance to patients” assigned by clinical experts [8,13,14]. Outside of cardiovascular research, patient surveys on the relative value of component outcomes of composite endpoints have not been incorporated into weighing techniques [15,16,35,36].

This study's patient-centered composite endpoint weighting technique represents an improvement on previous weighted composite endpoint techniques. This work advances patient-centered outcomes research by weighting study outcomes using responses derived from the study population of interest. For the orthopaedic community, the technique provides a set of ten common clinical outcomes researchers may incorporate into future composites endpoints. The limited heterogeneity in observed preferences suggests a common value gradient for clinical outcomes that is not altered by the type of fracture, or the time since injury, and only a small variation based on outcomes experienced. Weightings may be adjusted to reflect the relative importance of an outcome of interest for specific subpopulations, when heterogeneity in that subpopulation exists on a specific outcome, such as an above knee amputation among patients over the age of 65.

Additionally, the technique addresses an important limitation of traditional composite outcomes. The weighting formula can be easily applied to several different statistical methods, including time to event analysis, multivariate modeling, or a global rank test [33,34]. Multiple events can be included for a single patient in any of the three methods. Furthermore, multiple events per patient could be used in a time-to-event analysis enabling a comparison of the trajectory of clinical outcomes subsequent to treatment [37]. The confidence intervals associated with the mean utility of each clinical outcomes allows for a sensitivity analysis of treatment effect based on the distribution of the weightings. In the weighting formula, the weights adjust relative to the components that are included in the composite. The precision of the weights is useful in distinguishing order in a global rank test with several components of similar weight [32,33].

Despite the strengths of this study, several limitations must be considered. This study enrolled patients from a single trauma center. While the trauma center has a statewide catchment, sample populations from other regions may vary in their relative importance for the included outcomes. Although respondents may have had a different understanding of clinical outcomes described in the survey, a comparison of patient-reported outcomes with the medical records found 96% accuracy in reporting, suggesting an adequate comprehension of the included clinical outcomes. The questionnaire's brief descriptions of the clinical outcomes may have not adequately conveyed the magnitude of such an event for a patient and are open to subjective interpretation. However, the overall homogeneity in the importance of the clinical outcomes suggests a consistent

understanding by the respondents. Finally, the list of clinical outcomes included in the study is not exhaustive. While there are many other clinical outcomes commonly reported in orthopaedic trauma research, the identification of outcomes included in this analysis was based on a synthesis of the literature and conducted in collaboration with clinical experts and orthopaedic patient trauma survivors who confirmed the proposed outcomes were both commonly used and relevant to patients. This weighting technique could be easily expanded to other outcomes and replicated in other health conditions. However, at present, the application of this weighting technique is limited to studies with component outcomes included in our model.

CONCLUSION

Based on prospectively collected preference data from nearly 400 orthopaedic trauma patients, the study proposes a novel composite endpoint weighting technique. The findings suggest an overall homogeneity among orthopaedic trauma patients in their importance towards clinical outcomes. This composite endpoint technique applies weights to the component outcomes based on orthopaedic trauma patient preferences and can be applied to several types of statistical comparisons to estimate the clinical benefit of a treatment.

ABBREVIATIONS

ANOVA	Analysis of Variance
AKA	Above knee amputation
SSI	Surgical Site Infection

ACKNOWLEDGMENTS

The authors would like to thank the study participants who participated in the survey.

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Supplementary Appendix A. Composite Weighting Calculator

<https://www.dropbox.com/sh/i09nscykuhfo8fw/AAAPOKv9zG2dBEeJcspCGvRja?dl=0>

Supplementary Appendix B. Data for Hypothetical Pilon Trial in Long and Wide Format

<https://www.dropbox.com/sh/sgtaxtyhqfhz3r/AADsiS8Arei4lsJDLg-X2i8va?dl=0>

Supplementary Appendix C. Plausible unweighted and weighted methods of analyses for counts, time to event, and multivariate analysis.

1. BIVARIATE TESTS

Unweighted - Fisher's Exact Test

A participant with any one of the three component outcomes is counted as having an event for the analysis.

Treatment A (n, %): 168 (34%)

Treatment B (n, %): 174 (35%)

Treatment Effect: Odds Ratio, 0.96 (95% CI: 0.73 – 1.26, p=0.79)

R Code:

```
TAB <- table(wide$Treatment, wide$Event)
fisher.test(TAB, conf.int = TRUE)
```

Weighted – Wilcoxon Rank Sums Tests

Similar to a global rank analysis, the component weights are multiplied by each outcome event and summed for each study participant. The rank sums of each Treatment group are compared using the Wilcoxon Rank Sums test with the effect determined using a Probability Index Model.

Treatment A (mean weight, sd): 0.21 (0.38)

Treatment B (mean weight, sd): 0.28 (0.44)

Probability of Treatment Benefit (A vs. B): 6% (95% CI: 5 – 19%), p=0.26

R Code:

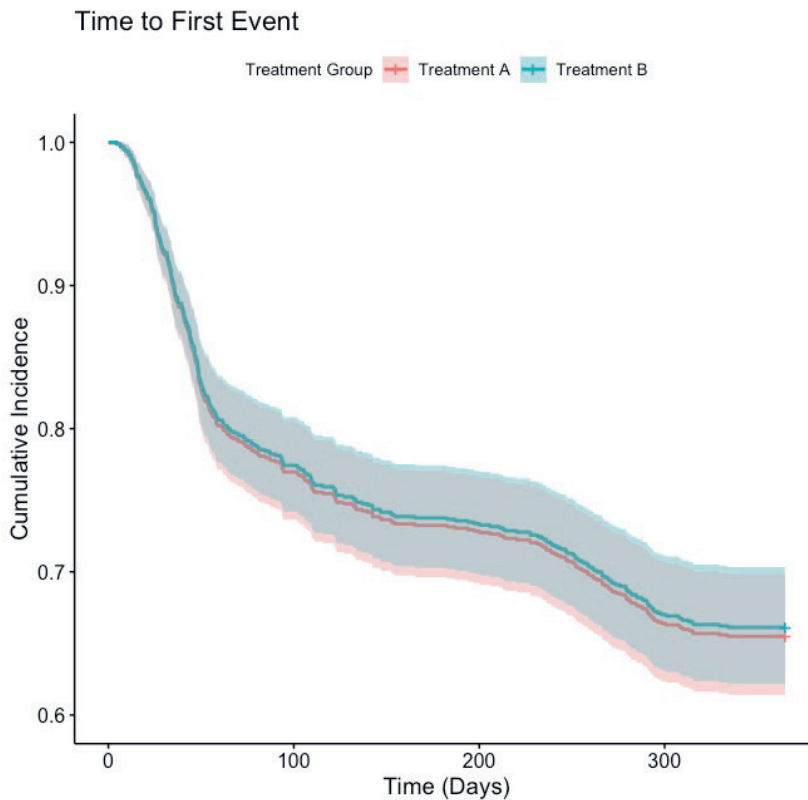
```
library("pim")
wilcox.test(wide$WeightEvent ~ wide$Treatment, conf.int = TRUE)
pim1 <- pim(WeightEvent ~ Treatment, data = wide)
summary(pim1)
confint(pim1)
```


2. TIME TO EVENT ANALYSIS

Unweighted - Time to Event Analysis

A Cox Proportional Hazard model was fit to the data. Only the first component event to occur was accounted for in the time to event analysis.

Treatment Effect: Hazard Ratio, 1.02 (95% CI: 0.83 – 1.27, $p=0.83$)



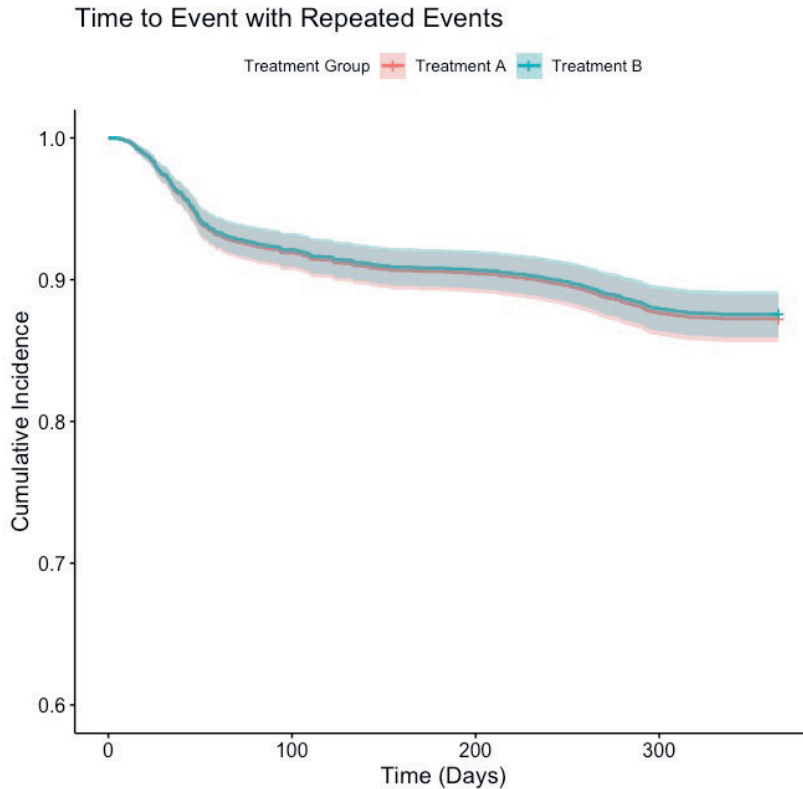
R Code:

```
library("survival")  
fit3 <- coxph(Surv(EventDays, Event) ~ Treatment, data = wide)  
summary(fit3)
```

Unweighted - Time to Event Analysis with Repeated Events

In this second, unweighted Cox Proportional Hazard model, multiple events were allowed in the model.

Treatment Effect: Hazard Ratio, 1.02 (95% CI: 0.84 – 1.24, p=0.80)



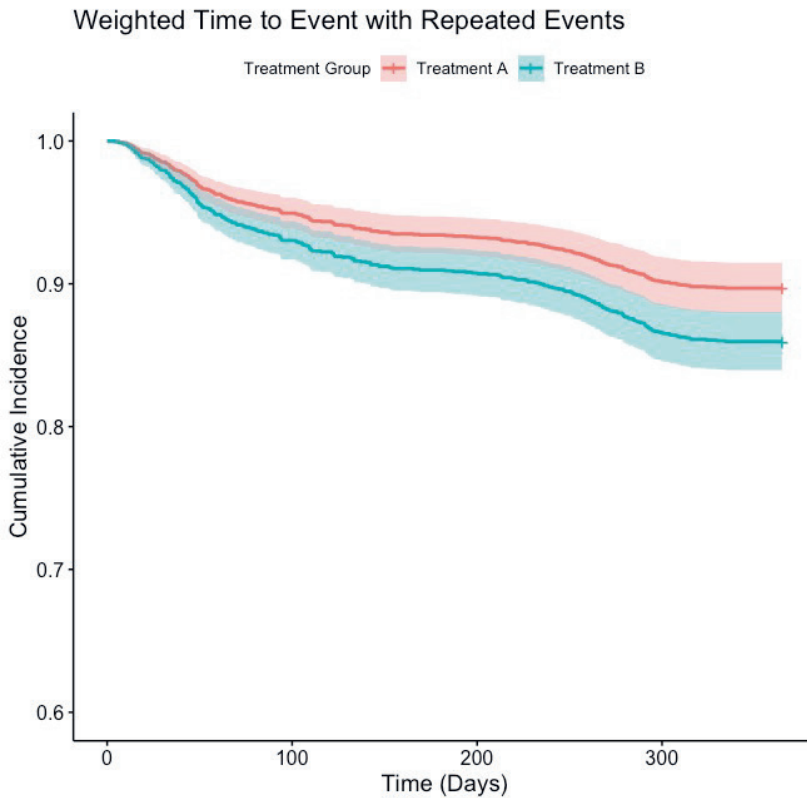
R Code:

```
library("survival")
fit1 <- coxph(Surv(TimetoEvent, Event) ~ Treatment + cluster (ID), data=long)
summary(fit1)
```

Weighted - Time to Event Analysis with Repeated Events

The third time to event model weighted the Cox Proportional Hazard model, and multiple events were allowed.

Treatment Effect: Hazard Ratio, 0.72 (95% CI: 0.57 – 0.90, $p < 0.01$)



R Code:

```
library("survival")
fit2 <- coxph(Surv(TimetoEvent, Event) ~ Treatment + cluster (ID), weights = EventWeight,
data=long)
summary(fit2)
```

3. MULTIVARIATE METHODS

Unweighted - Random Effects Model

The data was fit with a binomial generalized linear model that allowed for repeated events by including a random intercept for the subject ID.

Treatment Effect: Odds Ratio, 1.01 (95% CI: 0.81 – 1.25, $p=0.93$)

R Code:

```
library("lme4")
library("broom.mixed")
fit4<-glmer(Event ~ Treatment + (1|ID), family = binomial, data=long, nAGQ = 9)
summary(fit4)
tidy(fit4,conf.int=TRUE, exponentiate = TRUE, effects="fixed")
```

Weighted - Random Effects Model

The data was fit with a binomial generalized linear model that allowed for repeated events by including a random intercept for the subject ID.

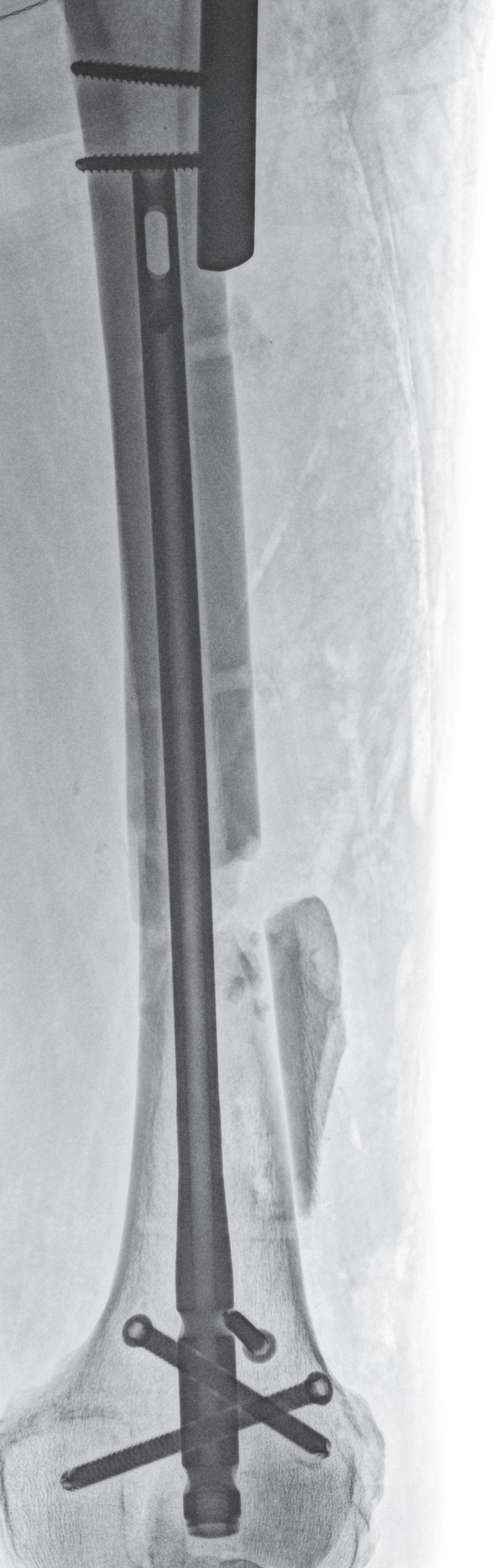
Treatment Effect: Odds Ratio, 0.70 (95% CI: 0.53 – 0.91, $p<0.01$)

R Code:

```
library("lme4")
library("broom.mixed")
fit5<-glmer(Event ~ Treatment + (1|ID), family = binomial, weights = EventWeight,
data=long, nAGQ = 9)
summary(fit5)
tidy(fit5,conf.int=TRUE, exponentiate = TRUE, effects="fixed")
```


Section II

Estimating socioeconomic
effects





**The Socioeconomic Impact of a Femoral Neck
Fracture on Patients Aged 18-50:
A Population-Based Study**

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Niek S. Klazinga

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ABSTRACT

Background: By linking health and census data, the objective of this study was to determine the effect of a femoral neck fracture on the household income of non-elderly patients.

Methods: All individuals aged 18 to 50 who underwent internal fixation for a femoral neck fracture during the years 2006 to 2012 in the Canadian Province of British Columbia were included in the study. Patient-level hospital data was linked with patient's after-tax household income decile, as estimated by Statistics Canada Postal Code Conversion Files. The primary endpoint was a decline of ≥ 2 income deciles following the index fracture. Kaplan-Meier analysis was performed to estimate the probability of income decline during the study period. A Cox regression model was used to study the association between a ≥ 2 income decline and patient age, sex, reoperation, and pre-injury income decile.

Results: Of the 391 femoral neck fracture patients included, the majority of patients were male (61.6%), with a median age of 43 years (IQR: 35-48), and a pre-injury median income in the fifth decile (IQR: decile 3-8). 27.0% of patients sustained a decline of ≥ 2 income deciles during the study period, with 16.3% declining ≥ 2 income deciles within 2-years of injury. A pre-injury household income in the top 4 deciles (mean of deciles: \$57,000-170,500) was associated with an increased likelihood of a ≥ 2 drop in household income (HR: 1.38, 95% CI: 1.06-1.79, $p=0.02$).

Discussion: Over a quarter of the femoral neck fracture patients in this study sustained a decline of ≥ 2 deciles in their household income following their injury. The income decline was disproportionately absorbed by patients with baseline incomes in the 6th decile or higher. This suggests that the available incapacity programs are limited in providing income protection to patients with higher incomes.

INTRODUCTION

Sudden health events, such as myocardial infarction, a cancer diagnosis, or a femur fracture, bear substantial medical costs. A principal objective of healthcare insurance is to pool the risk of these health events among individuals, and therefore providing financial protection for the patient against a catastrophic health expenditure [1]. In Canada, and as in most countries of the Organisation for Economic Co-operation and Development (OECD), health systems and financial risk-pooling mechanisms have been developed to protect patients from catastrophic health expenditures [1]. However, less attention is directed towards the economic impact of these health conditions beyond direct healthcare expenditures.

Following recommendations by the National Academy of Sciences in 1966 that stated trauma should be recognized as an important public health issue [2], trauma systems in OECD countries have observed rapid advances in improving access and quality of care [3]. Financial protection against emergency medical costs is generally included in countries with universal health insurance coverage or supported through additional forms of protection such as the Emergency Medical Treatment and Active Labor Act in the United States [4]. The coverage of post-acute medical costs can vary substantially among countries. Protecting individuals from employment income loss following a medical condition may include private disability protection, workers compensation for work-related injuries, or incapacity protection by a government welfare system that may consist of employment insurance and disability coverage [5].

Resuming economic activities after an injury is important to patients and predictive of future health [6,7]. However, there is a paucity of data on the long-term economic impact of an orthopaedic injury or the effectiveness of post-acute financial protection in mitigating economic loss. A recent study in Italy estimated that patients with a pelvis or acetabular fracture lost over 17,000 euros in income due to lost productivity [8]. This estimate was calculated as the monetary value of one lost working day multiplied by the gross domestic product of the country per day. However, the study failed to account for any long-term impairment in productivity or modifications in occupation. Rotondi et al investigated the impact on fragility fractures on return to work and work productivity in a Canadian cohort and found 86% of the sample returned to work within 6-months with no work modifications [9].

Understanding the long-term economic impact of orthopaedic injuries is essential to developing effective health and welfare policies that provide long-term financial protection to patients and their families. Knowledge of the economic consequences of injury is also of value to the treating surgeon, to not only prepare fracture patients for

the financial challenges they may face during recovery but also to refer their patients to other services or programs equipped to support the patient's socioeconomic recovery.

Among orthopaedic injuries, femoral neck fractures in non-elderly adults are known to be associated with substantial healthcare costs [10]. These fractures often are the result of high-energy trauma, and successful treatment is challenging due to difficulty in preserving the native hip joint [11-14]. Complications rates for femoral neck fractures in non-elderly adults likely exceed 20% and can substantially impact physical function [14-17]. Given the challenges in treating femoral neck fractures and high rate of complications for this injury, it is a valuable benchmark for future post-injury financial protection policy.

By linking health and census data, this study aimed to describe the associated effect of a femoral neck fracture on the household income of non-elderly patients. The secondary objective was to determine the independent associations between post-fracture income decline and patient sex, age, pre-injury income, and reoperation for bone-healing complications. Furthermore, we investigated if income loss within the first two-years of injury was sustained.

METHODS AND MATERIALS

Study Design

This longitudinal cohort study linked patient-level hospital billing data from the Canadian Province of British Columbia with the patient's after-tax household income decile, as estimated by Statistics Canada Postal Code Conversion Files. The data linkage was performed by Population Data BC, a multi-university, data, and education resource facilitating interdisciplinary research on the determinants of human health, well-being, and development of British Columbia's 4.6 million citizens. The data sources from this study included the Medical Services Plan (MSP) Payment Information Files that capture data on medically necessary services provided by physicians to individuals covered by MSP, the province's universal insurance program [18]; the Discharge Abstracts Database (DAD) which contains demographic, administrative, and clinical data for all patients discharged from acute-care hospitals in British Columbia [19]; and Statistics Canada Postal Code Conversion Files that contain basic demographic information including geocoding that indicates location of residence [20]. These databases are held securely in a linked, de-identified format with Population Data BC (www.popdata.bc.ca). Clinical Research Ethics Board at the University of British Columbia approved by the study (H14-03413).

Study Participants

All individuals aged 18 to 50 who underwent internal fixation for a femoral neck fracture (MSP code 55751 for closed reduction internal fixation and 55755 for open reduction internal fixation) between January 1, 2006 to December 31, 2012 in British Columbia were included in the study. Patients who concomitantly experienced femoral shaft fractures (MSP codes 55782, 55783, and 55785) were also included; however, those that had a pelvic or acetabular fracture (MSP code 55741, 55745, or 55746) were excluded. This type of fracture was selected as the injury of interest because of its relatively high complication rate, but its potential for good long-term functional recovery in the non-elderly population. Patients were also excluded if they moved out-of-province after their index surgery (identified by the Province of Patient code from the DAD). All patients had a minimum of 1-year follow-up.

Primary Endpoint

Income mobility has an absolute and relative component [21]. Absolute mobility measures the change in income of an individual relative to their previous income. Whereas, relative mobility depends on both the income of the individual in question and the incomes of others within a given region or jurisdiction. The primary endpoint for the study was a decline of ≥ 2 income deciles following index fracture and is a measure of relative income mobility. Despite this being an individual patient-level analysis, the income level, as reported by the Statistics Canada Postal Code Conversion Files was determined by the adjusted mean after-tax family income for the patient's geographic code. The Statistics Canada Postal Code Conversion Files are based on enumeration areas with relatively homogeneous economic and social living conditions and has been previously validated [22,23]. Adjusted family after-tax income is defined as the sum of after-tax income earned by all family members in a household divided by the square root of the family size. All dollar figures were converted into 2006 constant dollars. For the 2006 census year, mean incomes ranged from \$9,000 in the lowest decile to \$170,500 in the highest decile.

Study Variables

In addition to income data, several additional variables of interest were included in our analysis. Age and sex variables were obtained from the DAD. Baseline income was determined based on the year prior to the index fracture. Reoperation was defined as a composite of procedures performed after the index surgery, including: hardware removal (MSP code 55415 or 55420), proximal femur osteotomy (55603), bone grafting (MSP code 55651), non-union fixation (MSP code 55633), hip hemiarthroplasty (55662), and total hip arthroplasty (MSP code 55663).

Statistical Analysis

Patient characteristics were described using medians with interquartile ranges for continuous variables and frequencies and proportions for categorical data. Kaplan-Meier analysis was performed to determine the incidence of income decline during the study period. Patients that did not experience the primary endpoint were censored at the end of the study period. A Cox proportional-hazards regression model was used to study the associations between a ≥ 2 income decline and patient age, sex, any reoperation, and pre-injury income decile in a bivariate analysis. Covariates with an association of $p < 0.2$ were included in a multivariable model. Finally, the proportion of annual income mobility between years 2-7 post-injury was compared between patients with income decline within 2-years to those without an income decline in 2-years using a Chi-squared test. All statistical analysis was performed with SPSS Version 24 (Chicago, IL).

RESULTS

Three hundred ninety-one femoral neck fracture patients were treated with internal fixation from 2006 to 2012, and included for analysis in this study. The majority of the patients were male (61.6%), with a median age of 43 years (IQR: 35-48), and a pre-injury median income in the 5th decile (mean income for 5th decile: \$46,000; IQR: decile 3-8 (\$28,000-\$83,600)) (**Table 1**).

Table 1. Patient characteristics (n=391)

Characteristic	
Age, median (IQR)	43 (35-48)
Sex, male, n (%)	244 (61.6)
Income decile at injury, median (IRQ)	5 (3-8)

Twenty-seven percent (SE: 4.2) of the cohort sustained a decline of ≥ 2 income deciles during the study period, with 16.3% (SE: 2.5) of the cohort declining ≥ 2 income deciles within 2-years of injury (**Fig 1**). There was significant variation in the proportion of the sample with a ≥ 2 income decile reduction in income when stratified by income decline at baseline ($p < 0.01$) (**Table 2**). A pre-injury household income in the top 4 deciles (mean of deciles: \$57,000-170,500) was associated with an increased likelihood of ≥ 2 decile drop in household income (HR: 1.38, 95% CI: 1.06-1.79, $p=0.02$) (**Table 3**). Patient age (HR: 1.00, 95% CI: 0.97-1.02, $p=0.65$), sex (HR: 0.99, 95% CI: 0.62 – 1.59, $p=0.96$), or requiring a reoperation (HR: 0.94, 95% CI: 0.71-1.20, $p=0.63$) were not associated with a decline in household income following injury in our bivariate or multivariable analysis.

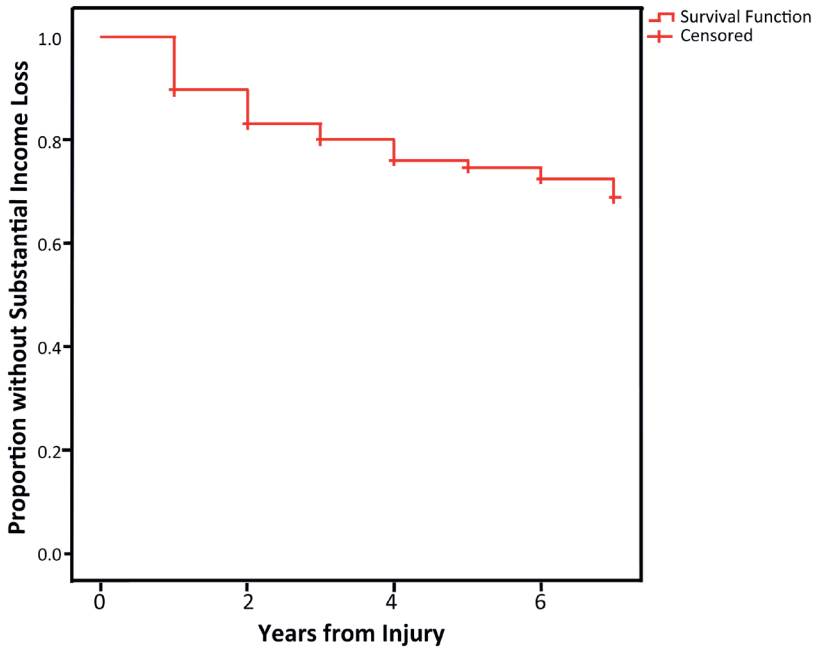


Figure 1. Kaplan Meier curve representing the proportion of the sample that did not experience substantial income loss. Substantial income loss is defined as a ≥ 2 decile decline in income following their index fracture.

Table 2. Canadian income statistics by after-tax income decile

Income Decile	Mean Income (2006)	Proportion at Time of Injury	Proportion with Income ≥ 2 decile Decline
Lowest decile	9,000	12.5	0
Second decile	20,100	9.2	0
Third decile	28,800	12.0	6.4
Fourth decile	37,600	10.0	25.6
Fifth decile	46,600	8.7	20.6
Sixth decile	57,000	12.0	29.8
Seventh decile	68,600	8.7	20.6
Eighth decile	83,600	11.3	34.1
Ninth decile	104,700	9.0	28.6
Highest decile	170,500	6.6	26.9

Table 3. Association between a ≥ 2 decile decline in income and patient age, sex, baseline income, and a reoperation

	Bivariate			Multivariable		
	HR	95% CI	P-value	HR	95% CI	P-value
Reoperation	1.40	0.87 – 2.25	0.17	0.94	0.71 – 1.20	0.63
Sex, Male	0.99	0.62 – 1.59	0.96	-		
Age (continuous)	0.98	0.96 – 1.01	0.16	1.00	0.97 – 1.02	0.65
Baseline Income						
Decile (3-5)		Reference (1.00)			Reference (1.00)	
Decile (6-10)	1.40	1.08 – 1.80	0.01	1.38	1.06 – 1.79	0.02

Table 4. Comparison in the change in annual income decile, stratifying the cohort between patients that had a ≥ 2 decline in income within the first 2-years from injury with those patients that did not experience a ≥ 2 decline in income within the first 2-years from injury

Years Post-Injury	N	≥ 2 Decile Decline within 2-Years of Injury			No ≥ 2 Decile Decline within 2-Years of Injury				P Value
		Income Decrease	No Change	Income Increase	N	Income Decrease	No Change	Income Increase	
Year 2-3	61	11 (18)	43 (70)	7 (11)	164	16 (10)	130 (79)	18 (11)	0.22
Year 3-4	46	11 (24)	27 (59)	8 (17)	139	6 (4)	119 (86)	14 (10)	<0.001
Year 4-5	36	8 (22)	24 (67)	4 (11)	108	9 (5)	92 (85)	7 (6)	0.04
Year 5-6	24	2 (8)	18 (75)	4 (17)	69	7 (4)	60 (87)	2 (3)	0.06
Year 6-7	18	2 (11)	15 (83)	1 (6)	37	3 (2)	31(84)	3 (8)	0.89

Note: Income decrease refers to ≥ 1 income decile decline. Income increase refers to a ≥ 1 income decile increase.

The income deciles remained relatively stable for both patients that experienced a ≥ 2 income decile decline in income within 2-years of their fracture, with 59-83% of the sub-group experiencing no change in annual income in the subsequent years (**Table 4**). Of those with the initial income decline, 8-24% declined further in the subsequent years. By contrast, 6-17% experience an annual increase in their incomes. Of the sub-group of patients that did not experience income decline within 2-years of injury, 79-87% did not experience a change in income in the subsequent years. No evidence of substantial economic recovery was observed in patients that experienced a ≥ 2 income decile decline in income within 2-years of their fracture. Moreover, we observed higher rates of income decline in years 3-5 for patients with income decline within two-years compared to those patients with no initial decline.

DISCUSSION

Over a quarter of non-elderly femoral neck fractures in British Columbia injured between 2006-2012 sustained a decline ≥ 2 deciles in their household income following their injury. Depending on the pre-injury income decile of the patient (**Table 2**), a 2 decile decline in income translates to a 32-69% absolute reduction in annual income. Patients with a pre-injury household income in the top 4 income deciles were 38% more likely to experience this level of income decline. Age, sex, or a reoperation due to a bone-healing complication were not associated with post-injury income decline. Minimal income recovery was observed in the 5-years following injury in those patients that experienced a decline of ≥ 2 income deciles within 2-years of injury.

The findings suggest that while a hip fracture has substantial economic consequences to patients ages 18-50, the available social safety nets mitigate catastrophic income decline for patients on the lower end of the income spectrum. Current employment insurance protection in Canada provides income support up to a maximum of \$51,300 [24], which is the 5th decile in 2006 dollars. Our findings suggest that this support effectively protects British Columbians with a baseline income in the 5th decile or lower from substantial income decline following injury. Expanding the income limits of welfare protection programs may guard fracture patients with higher incomes from their high rate of income decline following injury. Furthermore, additional financial protection and rehabilitation support may assist in long-term financial recovery for those patients that experienced substantial income loss within 2-years of injury.

There is limited data on the long-term economic impact of orthopaedic injuries. Given the severity of these fractures, it is reasonable to assume the injury would impair short-term employment productivity. However, our data suggest that income loss in femoral neck fracture patients is sustained beyond two years. There are several possible explanations for this observed effect. Campenfeldt et al demonstrated that the majority of patients ages 20 – 69 years with healed femoral neck fractures due to return to their pre-injury physical function at 2 years from injury [25]. This persistent physical impairment is likely associated with some of the post-injury economic decline. Rogmark et al suggest that low bone mineral density is a common risk factor for non-elderly hip fractures regardless of the trauma mechanism [26]. This reduced bone strength may impede many patient's recovery to pre-injury levels of economic productivity. The sustained income loss observed in this study may also be linked with concomitant post-injury mental health challenges. A study by Whooley et al noted that depressive symptoms were associated with a significant loss in family income and higher rates of unemployment [27]. A recent meta-analysis estimated that over 30% of orthopaedic trauma patients have depressive symptoms, and over 25% demonstrate a moderate

to severe post-traumatic stress disorder [28]. These data suggest that, in addition to physical impairment, the post-fracture mental health condition of a patient may play a role in long-term income decline.

Research by Zhang et al provides detailed information on income mobility in Canada during our study period [29]. Their paper details how income growth between 1982 - 2012 was mainly concentrated in individuals aged 25-44, highlighting the particular importance of this age group on the province's economic growth and the downward economic strain associated these fractures. Additionally, Zhang's paper reports individuals in income deciles 6-10 having the most substantial proportion transitioning downward in their income. This finding suggests that economic factors outside of an individual's fracture likely contributes to the income decline we observed in our cohort.

The strengths of this study include its province-wide data and substantial follow-up. Canada's government health expenditures, federally supported incapacity programs, and employment protection laws are similar to many other OECD countries, including the United Kingdom, Australia, and New Zealand [30-32], and similar effects may be observed under these similar parameters. Previous studies on the economic impact of health conditions commonly use a human capital method, which only investigates the income loss of the individual. This study's use of geocoded zone income data is considerably more inclusive of the effect of other household members who may reduce their labor productivity to support the care of the patient. The methods used to link the administrative data and analyze economic impact can be easily replicated for other fracture types and in other countries.

Despite these strengths, the findings must be interpreted within the context of the study design, which presents several limitations. Firstly, the income data is based on the mean after-tax adjusted family income of the geocoded zone for that individual. While this has been demonstrated as a reliable estimate in previous research [23], it lacks the precision of individual-level data. Income mobility, under these parameters, would be the result of a change in mean income for the geocoded zone or the individual relocating to a different geocode zone. Furthermore, given the limited variables available through the administrative database, we were restricted in our analysis of factors associated with income decline. The absence of data on the post-acute medical disposition of patients is particularly limiting, and further study should investigate post-acute care as a possible pathway to divergent economic outcomes. While a composite covariate for reoperation was not found to be a factor associated with an increased risk of income loss, the effect of components of that covariate, such as a non-union or avascular necrosis, may have been attenuated by the inclusion of hardware removals.

CONCLUSIONS

In this study, we observed substantial downward income mobility by over a quarter for the study patients. This economic hardship was compounded by a period of relative income rigidity following the initial decline in income after the injury. The income decline was disproportionately absorbed by patients with baseline incomes in the 6th decile or higher, suggesting that current incapacity programs in British Columbia have their limits in providing financial protection for fracture patients with higher incomes. With an understanding of these economic implications of femoral neck fractures in non-elderly patients, surgeons can better prepare their patients for these challenges during their recovery, as well as advocate for the necessary resources and reimbursements to manage these injuries and mitigate these negative socioeconomic outcomes. Further study on an individual level that includes pre-injury occupation and work history might help to identify policies that could help this specific category of fracture patients to cope, not only with the short-term but also the long term, socioeconomic consequences of a femoral neck fracture.

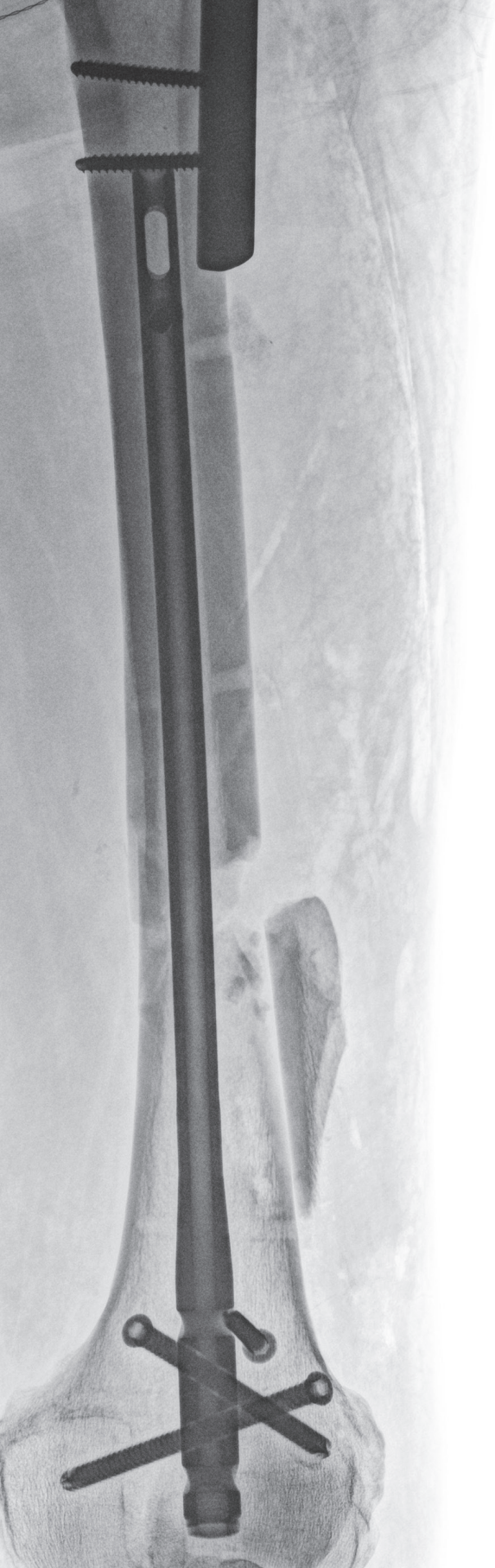
ACKNOWLEDGMENTS

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5

The Socioeconomic Implications of Isolated Tibia and Femur Fractures from Road Traffic Injuries in Uganda

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ABSTRACT

Background: The purpose of this study was to determine the socioeconomic implications of isolated tibia and femur fractures caused by a road traffic injury in Uganda.

Methods: This prospective longitudinal study included adult patients admitted to Uganda's national referral hospital with an isolated tibia or femur fracture. The primary outcome was the time to recovery following injury. We assessed recovery using four domains: income, employment status, health-related quality of life (HRQoL) recovery, and the school attendance of the patient's dependents.

Results: The majority of the study participants were employed (83%) and the main income earner for their household (74.0%) at the time of injury, earning a mean annual income of \$2,375 USD. All patients were admitted with the intention of surgical treatment, however, due to resource constraints, only 56% received operative treatment.

By two-years post-injury, only 63% of the participants had returned to work and 34% had returned to their previous income level. Overall, the mean monthly income was 62% less than pre-injury earnings and participants had accumulated \$1069 USD in debt since injury. 41% of the participants had regained HRQoL scores near their baseline. 62% of school-aged dependents, enrolled at the time of injury, were in school at two-years post-injury.

Conclusion: At two-years post-injury, only 12% of our cohort of Ugandan patients who sustained an isolated tibia or femur fracture from a road traffic injury had recovered both economically and physically.

INTRODUCTION

Road traffic injuries (RTIs) are a leading cause of death worldwide and are projected to increase, particularly in low- and middle-income countries (LMICs) [1,2]. It is estimated that for every death due to injury, there are 10-50 times as many left permanently disabled [3,4]. Timely access to life- and limb-saving interventions would dramatically reduce these staggering figures. However, the Lancet Commission on Global Surgery concluded that 5 billion people worldwide do not have access to safe surgical care [5,6].

In high-income countries, patients with isolated tibia and femur fractures treated with timely surgical treatment are expected to return to full function within one-year of the injury [7-10]. Along with functional recovery, previous studies report that a high proportion of injured patients regain employment and income near pre-injury levels in less than a year [10,11]. Given the tremendous incidence of fractures in low-income countries (LICs), and a disproportional lack of surgical resources to manage these injuries, similar recovery timeframes in LICs are unlikely.

The objective of this study was to determine the socioeconomic implications of post-fracture recovery in Uganda, given currently available fracture treatment options. The 12-month findings of this research have been previously reported [12]. Given the limited recovery of our cohort at 12-months, we extended the follow-up by an additional year to better understand the recovery process in this patient population. Our hypothesis was that the majority of patients with isolated tibia and femur fractures due to RTIs would regain previous levels of employment, income, and quality of life at two-years post-injury.

METHODS AND MATERIALS

This prospective longitudinal study investigated time to socioeconomic and health-related quality of life (HRQoL) recovery following an isolated tibia or femur fracture caused by RTIs in Uganda. Adult patients injured in RTIs and admitted to Mulago National Referral Hospital in October 2013 with an acute, single long-bone lower extremity fracture were recruited. Patients with multiple fractures, abdominal trauma, or head trauma were excluded. Ethical approval was obtained by the Mulago Hospital Research Ethics Committee and the University of British Columbia Clinical Research Ethics Board. The study location was a publicly funded tertiary referral and teaching hospital with 10 attending orthopaedic surgeons in practice during the study period.

Data Collection

Within 48-hours of admission and following informed consent, a baseline survey was administered to study participants by a local research team to capture demographic, injury, and economic data. Economic questions were derived from the Uganda National Panel Survey. The HRQoL data was derived using the EuroQol-5D-3L (EQ-5D) instrument [14-16]. Additional clinical information was obtained from the patient's chart. After baseline, participants were interviewed at 6-months, 12-month, and 24-months after their injury. Patients were asked to recall specific dates for regaining employment, income, and the return to school of their school-aged dependents. The patient's phone number and at least two additional contact numbers were collected at enrollment to minimize loss to follow-up. Patients were contacted by a local research assistant with a phone call one-week and one-day prior to each follow-up appointment to remind the patient of their appointment with the research team. If the research team was unable to reach the patient, the additional contact numbers were called several times in an effort to contact the patient. A local surgeon was available at each follow-up visit to answer the patient's medical questions. After attending each follow-up appointment, patients were reimbursed for their transportation expenses. The lead author, a local surgeon, and two local research assistants that were fluent in most common local languages were present at each follow-up visit.

Outcome Variables

The primary outcome was the time to recovery following injury. We assessed recovery using four domains: income, employment status, HRQoL recovery, and the school attendance of the patient's dependents. Income recovery was defined as earning, at minimum, 90% of the patient's pre-injury monthly income. Employment status measured return to work, in any capacity. Based on previous research, physical recovery was defined as achieving a HRQoL score within 20% of the patient's pre-injury assessment [17]. To capture the socioeconomic impact of injury on a patient's family, at the time of injury patients were asked how many of their school-aged dependents were in school prior to the injury. At each follow-up interview the patient was asked about each of their dependents, if they were absent from school for any extended period of time, and if so, when they resumed their schooling.

Secondary outcomes measures included the proportion of income lost, as well as the change in employment status, HRQoL, and the number of dependents attending school in the two-years following the injury. While all patients were admitted for surgical treatment, only 56% received surgical treatment due to resource constraints. Those that received surgical treatment had a median wait time of 18 days (IRQ: 5.5 – 34.5) from their time of injury. As an exploratory observational analysis, we investigated the association between surgical treatment and the patient's monthly income, post-injury debt, employment status, HRQoL, and the number of dependents in school.

Statistical Analysis

Baseline characteristics of the patients were assessed using descriptive statistics. Survival analysis was used to determine the time to recovery on the four outcome variables of interest. Those patients that did not recover, as per the definitions above, were censored at two-years post-injury and not included in our mean time to recovery analysis. Outcome variables were summarized using means with 95% confidence intervals and compared with previous recovery time points of the patients using matched pairs t-tests. The association between surgical treatment and selected outcome variables were estimated using logistic regression and presented as unadjusted parameter estimates and parameter estimates that adjust for pre-injury levels of the given outcome, the location of injury (femur vs. tibia), and the severity of injury (open vs. closed). All statistical analyses were performed using JMP Pro Version 13 (Cary, NC).

Source of Funding

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RESULTS

A total of 57 patients met our eligibility criteria during the study period. All eligible patients were enrolled, and 54 (94.7%) participants successfully completed two-years of follow-up. The baseline characteristics of the participant are shown in **Table 1**. Study participants were predominately male (88.9%) and had a median age of 33.7 years (IQR: 26.6 – 45.0). The majority of the study participants were employed (83.3%) and the main income earner for their household (74.0%) at the time of injury, earning a mean annual income of \$2,375 USD (95% CI: \$1,276 - \$3,475). The patient sample comprised of 36 diaphyseal fractures and 18 articular fractures. The fracture classification and type of treatment for each patient is listed in **Table 2**.

At two-years after injury only 31.5% of participants regained a monthly income of at least 90% of their pre-injury monthly earnings (Figure 1). Of those that returned to their previous income level, the mean time was 0.97 years (95% CI: 0.76 – 1.18) following the injury. Overall, the participants' monthly income 24-months after injury was 62% less than their pre-injury monthly earnings (mean difference: \$117.50; 95% CI: \$34 - \$201) (Figure 2). 63% of the participants had returned to work at two-years post-injury, and 48% remained the main income earner for their household. Those that regained employment did so in an average of 1.01 years (95% CI: 0.82 – 1.20) (**Figure 1**) and the most common occupations were working as a shop vendor (n=12, 35%) or in agriculture (n=10, 29%). Additionally, participants accumulated \$1069 USD in debt (95% CI: \$673 - \$1466) in the 24-months post-injury or the equivalent to 45% of the mean pre-injury annual income.

Table 1. Characteristics of patients at the time of injury (n=54)

Characteristic	Baseline
Sex, Male, n (%)	48 (88.9)
Age, median (IQR)	33.7 (26.6 – 45.0)
Fracture type, n (%)	
Tibia	14 (25.9)
Femur	40 (74.1)
Injury severity, Open Fracture, n (%)	19 (36.5)
Employed, n (%)	45 (83.3)
Shop Vendor	18 (40.0)
Driver	12 (26.7)
Agriculture	7 (15.7)
Other	8 (17.8)
Main Income Earner, n (%)	40 (74.0)
Annual Income (\$USD), mean (95% CI)	\$2375 (\$1276 – \$3475)
HRQoL, mean (95% CI)	0.93 (0.88 – 0.98)
Dependents in school, mean (95% CI)	3.6 (3.0 – 4.2)

IQR = interquartile range; \$USD = United State dollars; HRQoL = health-related quality of life; CI = confidence interval

Table 2. AO/OTA fracture classification as stratified by treatment type and whether the fracture was open versus closed. The proportions are based on row totals.

Treatment	Open Fracture						Closed Fracture				
	IM Nail	Ex-Fix	Plates/Screws	Plaster	Traction	Hemi	IM Nail	Plates/Screws	Plaster	Traction	
AO/OTA Fracture and Dislocation Classification	Total (N)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
31-A	5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)	1 (20)	0 (0)	3 (60)
31-B	5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	4 (80)	0 (0)	0 (0)	0 (0)	1 (20)
32-A	11	1 (9)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	6 (55)	0 (0)	1 (9)	2 (18)
32-B	8	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)	0 (0)	5 (63)	0 (0)	0 (0)	2 (25)
32-C	6	0 (0)	0 (0)	0 (0)	1 (17)	1 (17)	0 (0)	1 (17)	0 (0)	1 (17)	2 (33)
33-A	2	0 (0)	1 (50)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
33-B	2	0 (0)	0 (0)	1 (50)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
33-C	1	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
41-A	2	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)
42-A	5	0 (0)	2 (40)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)	1 (20)	1 (20)	0 (0)
42-B	4	0 (0)	2 (50)	1 (25)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (25)	0 (0)
42-C	2	0 (0)	0 (0)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
43-C	1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)
All	54	1 (2)	7 (13)	3 (6)	5 (9)	3 (6)	4 (7)	13 (24)	2 (4)	6 (11)	20 (19)

Note: IM = intramedullary; Ex-Fix = external fixation; Hemi = hemiarthroplasty

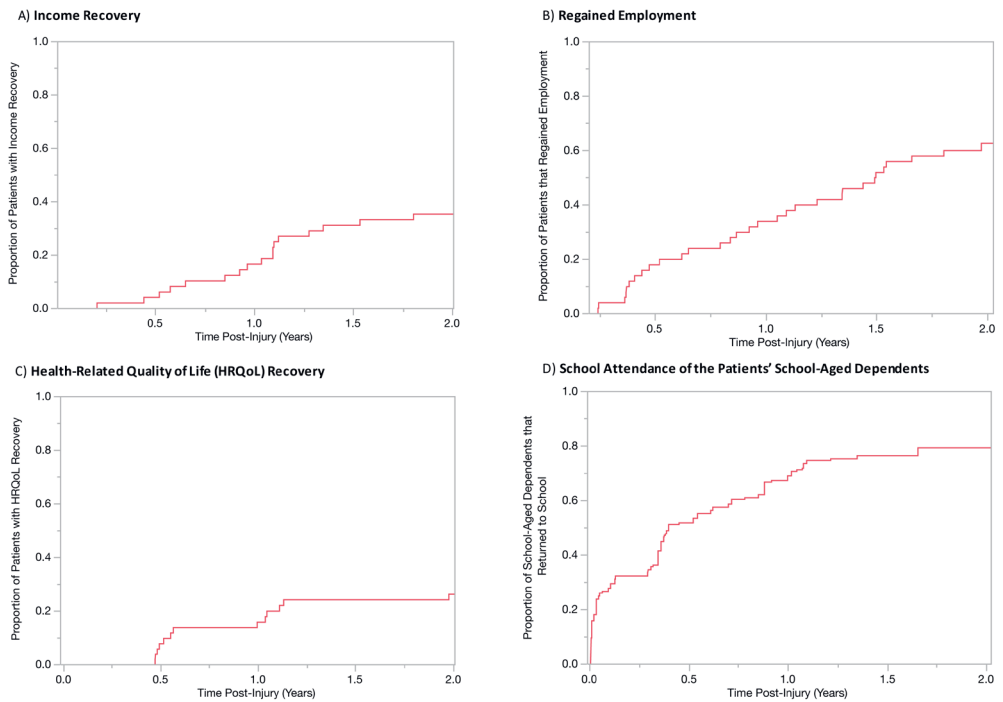


Figure 1. Mean time to recovery based on income, employment, health-related quality of life (HRQoL), and school attendance of the patient’s dependents.

Prior to injury, study participants were near perfect health (Mean HRQoL: 0.93; 95% CI: 0.88 – 0.98) but declined significantly six-months after their injury (Mean HRQoL: 0.37; 95% CI: 0.25-0.48) (Figure 2). Participants’ health gradually improved after six-months. However, at two-years post-injury only 40.7% of participants had HRQoL scores that recovered to near baseline level (**Figure 1**). The overall sample remained significantly lower than pre-injury HRQoL levels (Mean difference: -0.30; 95% CI: -0.40 - -0.20).

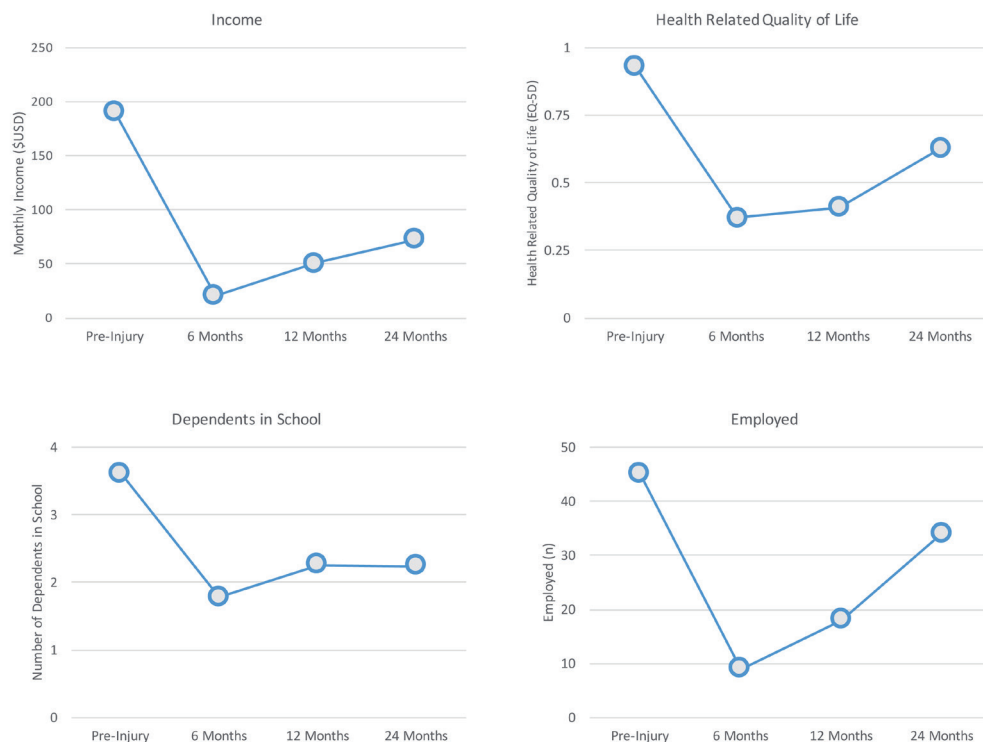


Figure 2. Mean levels of monthly income, health-related quality of life, number of dependents in school, and employment following injury. The time points are just prior to injury, and 6-, 12-, and 24-months after injury.

At the time of injury, study participants had 3.61 dependents attending school (95% CI: 3.04 – 4.18). Half of these dependents were not attending school 6 months after the injury (Mean: 1.78; 95% CI: 1.27 – 2.29) (**Figure 2**). 79% of school-aged dependents enrolled at the time of injury maintained or resumed their enrollment in school during the two years post-injury with a mean time of 0.42 years (95% CI: 0.35 -0.50) to resume their schooling (**Figure 1**). While nearly 80% of the previously enrolled dependents initially resumed their schooling within two years of the patient’s injury, many of these dependents subsequently withdrew during that time due to the family’s financial hardships. Our interviews at two years after the injury determined that only 62% of the participants’ dependents were still attending school (Mean difference: -0.91; 95% CI: -1.58 - -0.24).

We found no association between surgical treatment received and monthly income, debt, employment, or dependents in school two-years after their injury in our

unadjusted or adjusted analyses (**Table 3**). The association between surgical treatment and an increased HRQoL at two-years post-injury (0.13; 95% CI: -0.05 – 0.31) was near statistical significance in our adjusted analyses. Furthermore, HRQoL at two-years had the strongest association with income at 24-months when adjusting for sex, age, severity of fracture, pre-injury HRQoL, and pre-injury income.

Table 3. The effect of surgical treatment on recovery outcomes (monthly income, monthly debt, employment, health-related quality of life, and school attendance of dependents). The beta coefficients estimate the incremental change in a given outcome when the patient's fracture is surgically treated relative to non-operative treated patients.

	Unadjusted			Adjusted (per note)		
	β	95% CI	P-Value	β	95% CI	P-Value
Monthly Income (\$USD)	13.6	-46.4 – 73.6	0.65	18.2	-43.8 – 80.1	0.56
Monthly Debt (\$USD)	4.1	-17.6 – 64.7	0.26	15.6	-28.6 – 59.91	0.48
Employment	0.09	-0.48 – 0.66	0.76	0.09	-0.55 – 0.73	0.79
HRQoL	0.17	-0.002 – 0.33	0.05	0.13	-0.05 – 0.31	0.15
Dependents in School	0.02	-1.17 – 1.20	0.98	-0.22	-1.46 – 1.03	0.73

Note: Adjustments were made to the regression analyses based on the location of injury (femur vs. tibia), and severity of injury (open vs closed), and the pre-injury value for the given outcome. The beta coefficients for monthly income and monthly debt are presented as the incremental dollars in the 24th month post-injury associated with surgical treatment. The employment beta coefficients are presented as the additional likelihood (9%) of employment 24 months after injury associated with surgical treatment. The HRQoL beta coefficients are presented as the incremental gain in EQ-5D score associated with surgical treatment. The dependents in school beta coefficients are presented as the incremental change in the number of average number of dependents in school at 24 months post-injury that is associated with surgical treatment for the patient's fracture.

\$USD = United State dollars; HRQoL = health-related quality of life; CI = confidence interval

DISCUSSION

At two-years post-injury, only 12% of Ugandan patients who sustained an isolated tibia or femur fracture from RTIs had recovered both economically and physically. Patients were, on average, earning less than half of their pre-injury income level, nearly a third had not re-entered the workforce, and the majority remained with a considerable physical disability. As a result of these economic hardships, one-third of the school-aged dependents of the patients were no longer in school two-years after the injury.

In contrast to our findings, a study of orthopaedic poly-trauma patients reported that treatment in Denmark had considerably higher mean EQ-5D scores (0.60 vs.0.41) [18], and a much lower proportion were unable to return to work at 12-months post-injury (18% vs 60% in Uganda). Additionally, the HRQoL of patients in a US-based study increased by 7% from six- to 12-months post-injury and 4% from 12- to 18-months

post-injury [19]. In comparison, the HRQoL of the Ugandan cohort improved by 11% between six- to 12-months post-injury and by 54% between 12- and 24-months post-injury. This impressive gain in HRQoL after 12-month post-injury far exceeds marginal improvements after one-year reported in a US study [20].

Consistent with other research from LICs, our findings confirm that RTIs in this region predominately affect males at the height of their income earning potential [21-23]. Prior to injury, our participants were slightly above the average income in country and predominately employed [24]. An isolated tibia or femur fracture had devastating socioeconomic implications for these patients, bringing the mean income at two-years post-injury close to the \$2/day global poverty line [25]. The hardship caused by lack of income was further compounded by excessive debt. Given the incidence of isolated tibia and femur fractures due to RTIs in Uganda [26,27], the national economic impact of these injuries is estimated to be at least \$32 million USD per year.

Within the two years after injury nearly 80% of the dependents had returned to school. However, the number of students returning to school between 1-2 years post-injury was offset by 33% of the patients having to withdraw their children from school due to their mounting financial burdens. Patients routinely mentioned alternating years of enrollment for children to cope with the financial stress of school fees under limited income. Other patients noted a difficult decision to select only some of their children to continue with their education.

All of the patients in our study were admitted with the intention of surgical treatment for their fracture. While it is assumed that high quality surgical treatment - particularly within a day or two of injury - would have a positive effect on their recovery, we were unable to detect an association between surgical treatment over those treated conservatively with regards to our socioeconomic outcomes. There was a trend towards association between surgical treatment received and HRQoL ($p=0.15$). Our cohort included a variety of fracture patterns and the decision for, and type of, surgical treatment was based on a multitude of factors. Therefore, while an association between surgical treatment and socioeconomic outcomes was not observed, we caution these analyses were exploratory. Expanding pre-hospital and surgical services may increase timely and effective surgical treatment for injured individuals, and subsequently improve physical recovery. However, labour market barriers may remain prohibitive to socioeconomic recovery in this economic landscape.

The strengths of the study include two years of follow-up with a high follow-up rate, and a broad dataset with socioeconomic information that is pertinent to decision-makers. However, the results of this study must be interpreted within the context of the study

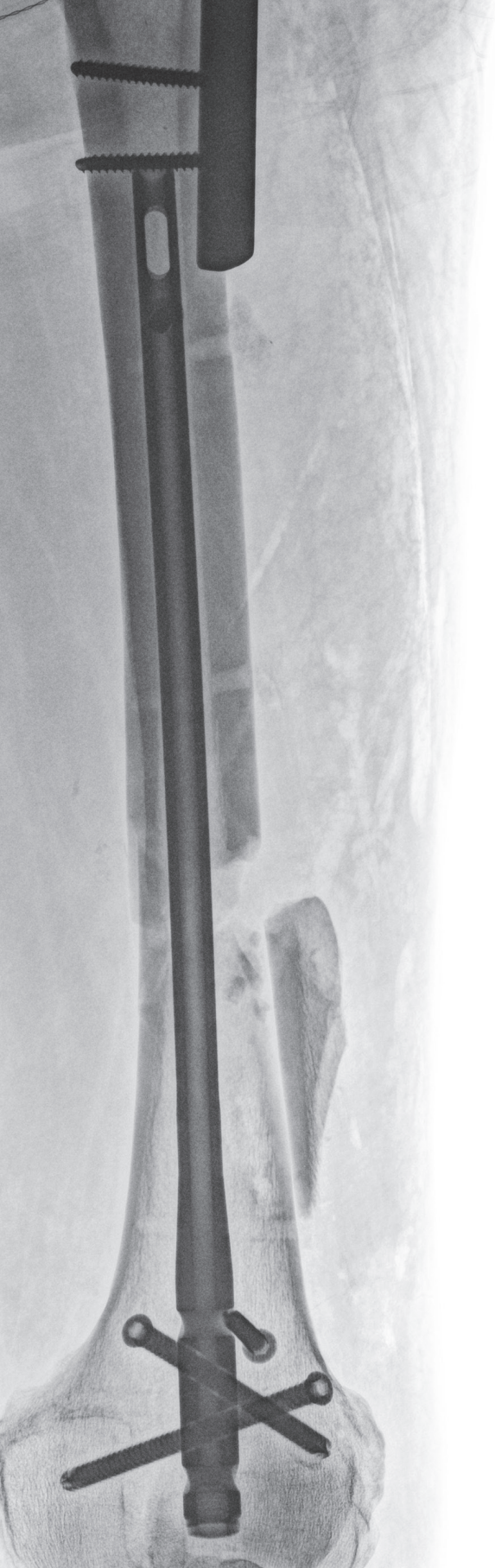
design. The study was conducted at a single center and, while the patient characteristics are similar to what has been reported in other sub-Saharan African studies [21-23], the findings may be limited in their generalizability due to the variation in the availability of resources to manage fractures. At the time of admission, patients were requested to complete the EQ-5D questionnaire based on their HRQoL a week prior to their injury. This may present a possible recall bias, however, a previous study noted this to be minimal within our timeframe [28]. Finally, we recognize that income earned through informal labour agreements is inconsistent by definition and therefore used a validated survey that included a series of income- and labour-related questions to ensure our economic estimates are accurate [13].

Despite injury prevention measures, the number of musculoskeletal injuries from RTIs are predicted to increase in the coming decades, particularly in LICs [1,2]. Our findings provide detail on the socioeconomic implications for injured patients in a LIC that can inform decision-makers for effective resource allocation, health workforce planning, and further prevention strategies. The recovery for a patient with an isolated tibia or femur fracture in Uganda is currently much different than what would be expected in a high-income country. Reducing this gap will require innovative health delivery strategies, and further research should seek to identify interventions to mitigate the current socioeconomic burden of these fractures in resource-limited settings.

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6

Analysis of Patient Income in the Five Years Following a Fracture Treated Surgically

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ABSTRACT

Importance: Orthopaedic injury is assumed to bear negative socioeconomic consequences. However, the magnitude and duration of a fracture's impact on patient income and social insurance benefits remain poorly quantified.

Objective: To characterize the association between orthopaedic injury and patient income using state tax records.

Design, Setting, Participants: This cohort study included adult patients who were surgically treated for an orthopaedic fracture at an academic trauma center from January 1, 2003 through December 31, 2014. Hospital data were linked to individual-level state tax records and analyzed using a difference-in-differences analysis performed from November 2019 through August 2020. The control group comprised of data resampled from fracture patients at least six years prior to injury.

Exposure: An operatively treated fracture of the appendicular skeleton.

Main Outcomes and Measures: The primary outcome was individual annual earnings up to five years post-injury. Secondary outcomes included annual household income and social security benefits for five years post-injury, and catastrophic wage loss within two years of injury.

Results: A total of 9997 fracture patients (mean age: 44.6 [18.9] years; 67.3% men) to 34 570 pre-fracture control participants (mean age: 40.0 [20.5] years; 62.7% men). The median pre-injury wage earnings was \$16 847 (IQR: \$0 to \$52 221). The mean annual decline in individual earnings during the five years post-injury was \$9865 (95% CI: -\$10 686 to -\$8862). Annual household income declined by \$5259 (95% CI: -\$6337 to -\$4181) over the same period. A fracture was associated with a \$206 (95% CI: \$147 to \$265) mean annual increase in Social Security benefits in the five years after injury. An injury increased the risk of catastrophic wage loss by 11.6% (95% CI, 10.5% to 12.7%). Substantial relative income loss was observed in patients with pre-injury earnings in the top three quartiles, but changes in income were negligible for patients with pre-injury earnings in the bottom quartile (19%; 95% CI, -4% to 48%).

Conclusions and Relevance: Fractures were associated with substantial individual and household income loss up to five years after injury, with one in five patients sustained catastrophic income loss in the two years after fracture. Gains in Social Security benefits offset less than 10% of annual income losses.

INTRODUCTION

Orthopaedic injury often has negative socioeconomic consequences for the patient.¹ A 2020 meta-analysis suggests that patients remain absent from work an average of 102 days after their fracture, and one-third of fracture patients do not return to work within 12 months of injury.² The magnitude and duration of a fracture's impact on patient income remain unclear. Prior research has not accounted for the correlation between the injury and pre-injury financial conditions and rarely distinguishes between individual and household effects.³

Negative wealth shocks and job displacement have health consequences across the socioeconomic spectrum.^{4,5} Further, adverse health events can affect the patient's economic well-being.^{6,7} Protection against the financial effects of injury is a major rationale for health and social welfare policy. However, little is known about the impact of sudden health events, such as a fracture, on the magnitude and duration of income loss.

The objectives of this study were to: (1) determine the magnitude and duration of a fracture's association with the incomes of patients and their households; (2) assess if the available social insurance mechanism offset this income deficit; and (3) identify policy-relevant subgroups, particularly at risk of income loss after injury.

METHODS

Study Design

We performed a retrospective cohort study with non-equivalent controls using a difference-in-differences analysis that linked data from a single academic trauma center to state tax records. The study was approved by the University of Maryland institutional review board under a waiver of consent. Data linkage was performed in a secure data enclave by the Comptroller of Maryland data warehouse team. Individual tax records remained masked to research team members not affiliated with the Comptroller of Maryland.

Study Participants

We identified all adult patients with an appendicular fracture treated surgically, based on *Current Procedural Terminology* (CPT) codes, at a state-legislated primary adult resource center for trauma from January 1, 2003 through December 31, 2016. Social Security numbers were obtained through hospital billing records and individually linked to state tax records from 2000 through 2018. We excluded patients without recorded social

security numbers, patients with a subsequent fracture admission during the study period, and patients with a severe concomitant traumatic brain injury or spinal cord injury defined as an Abbreviated Injury Scale score of five or greater.^{8,9}

Main Exposure

The exposure was a surgically treated fracture of the appendicular skeleton. The primary assumption of a difference-in-differences analysis is that the trends observed in the controls are a valid counterfactual for what would have occurred in the exposure group if the fracture was not sustained.¹⁰ Fractures are not randomly distributed.^{11,12} Certain risk-taking behaviors and environmental hazards place specific subpopulations at an increased fracture risk. To comply with the parallel-trends assumption, this study's control group was developed using exposed patients in the years before their index exposure. The tax year in which the fracture occurred for patients in the exposed group was used to anchor the covariate construction of the control group. For example, the tax data of patients who suffered a fracture in 2003 were compared with the 2003 tax data of patients who sustained a fracture between 2009 through 2016. Time zero was defined as the calendar year of injury for the exposure group.

Study Outcomes

Tax-reported income was evaluated up to five years after injury. The primary outcome was individual earnings, obtained from pre-tax wages and salary reported on W-2 tax forms. Secondary outcomes included household income, Social Security benefits, and catastrophic wage loss. Household income was estimated using the federal adjusted gross income of the patient's household and includes wage earnings, Social Security benefits, unemployment compensation, workers' compensation, disability insurance, and most legal settlements. Social Security benefits were reported at the individual level and included Supplementary Security Income, Disability Insurance, and Social Security Retirement Income. Catastrophic wage loss was defined as a ratio of less than 0.5 when dividing the sum of the mean wage earnings in the year of the injury plus two years post-injury by the sum of the mean wage earnings in the two years prior to injury.^{13,14} We adjusted incomes for inflation using the Consumer Price Index and reported in 2018 US dollars. We recoded the earnings of individuals with negative incomes or non-filers to zero, consistent with the methods previously used by Chetty et al.¹⁵⁻¹⁷

Covariates

Demographic and injury characteristics were obtained from patient medical records and tax data. Demographic data included age, sex, race, and type of health insurance. Clinical data included the mechanism of injury, AIS scores for all body regions, location of the fracture, and the number of surgical procedures associated with the index injury. Comorbidity data included tobacco use, hypertension, depression, diabetes, alcohol use,

and drug use. Each individual was assigned an Area Deprivation Index (ADI) value based on their tax return address in the year before time zero. ADI measures neighborhood deprivation based on income, education, employment, and housing quality indicators from the 2011-2015 American Community Survey.^{18,19}

Statistical Analysis

Data analysis was conducted between November 19, 2019 and August 13, 2020. We used an equivalence test to evaluate the parallel-trends assumption for individual income, household income, and Social Security benefits.²⁰ Pre-fracture income trends were similar between the fracture and control groups (**eTable 1 in Supplement 1**). We detected a difference in the pre-fracture Social Security trends, yet the equivalence margin was within \$200.

We fit mixed-effects regression models for patient income as a function of exposure group status, the pre- or post-injury period, and their interaction. The interaction term is the difference-in-differences estimate. Two exogenous effects were of concern during the estimation. First, after years of real wage growth in the early 2000s, the US has experienced a stagnation in wages, most pronounced in low- and middle-income earners, from the mid-2000s until present.²¹ Secondly, rapid real wage growth experienced by individuals in their 20s and 30s attenuates in one's 40s and 50s.²² We included a dummy variable for the calendar year and conditioned our estimates based on the patient's age at time zero to account for these exogenous forces. We assumed that other patient factors associated with injuries and patient income would be similar over the duration of the study. All effect estimates were reported as average absolute differences and relative effects from the year of the fracture to one- to -five years after injury as calculated using longitudinal models. For the estimates of relative effects, outcomes were transformed with a natural log plus one for modeling and then reported after subtracting the exponentiated coefficient from one.²³ In all models, standard errors were clustered by individual to account for the resampling of the controls. The association between a fracture and catastrophic wage loss was estimated using logistic regression.

We estimated subgroup differences in individual earnings and Social Security benefits using a difference-in-difference-in-differences model. Subgroups that were analyzed included the wage income quartile in the year prior to time zero, patient age (<65 years vs. ≥65 years), sex, race (White vs. racial minority group), fracture severity (open vs. closed fracture), fracture region (proximal vs. distal), health insurance status, and neighborhood deprivation, measured as the ADI quartile in the year before time zero. Further, the primary income models were replicated within subsets based on the anatomical location of the fractures, including humerus, radius or ulna, femur, tibia,

pelvis, hand, or foot. We did not adjust for multiple testing, and all subgroup estimates should be considered exploratory. Estimates are reported as multiplicative effects and can be interpreted as the increase or decrease in income relative to counterfactual gains in earnings after time zero.

Missing covariate data were imputed using multiple imputations.²⁴ We performed a sensitivity analysis for the catastrophic wage loss model with alternative definitions of catastrophic wage loss, ranging from 25% to 75%, and varying the time horizon from two to five years post-injury. A two-sided *P* value of less than 0.05 was considered statistically significant for models. All statistical analyses were performed using R Version 3.6.1 (R Project for Statistical Computing).

RESULTS

Sample Characteristics

In total, we compared 9997 patients with fractures (mean [SD] age: 44.6 [18.9] years; 6725 [67.3%] men) to 34 570 pre-fracture control participants (mean [SD] age: 40.0 years; 21 666 [62.7%] men) (**Table 1, eFigure 1**). The final sample included 40 438 person-years of patient income for the fracture group, and 126 495 person-years for the control group. In the year before injury, the median individual income of tax filers was \$16 847 (IQR: \$0 to \$52 221), and the mean earnings were \$38 501 (SD: 84 551).

Individual Income

The mean five-year reduction in annual individual earnings associated with a fracture was \$9865 (95% CI, -\$10 686 to -\$8862; *P* < 0.001) (**Table 2, Figure 1**). Fracture patients lost 81% (95% CI, -82% to -80%; *P* < 0.001) of counterfactual earnings growth in five years post-injury. The \$9000 difference in adjusted annual individual earnings loss associated with the fracture remained consistent from one to five years after injury.

Household Income

Fractures were associated with a \$5259 reduction (95% CI, -\$6337 to -\$4181; *P* < 0.001) in annual household income over five years post-injury (**Table 2, Figure 1**). Fracture patient households suffered a 64% reduction (95% CI, -65% to -62%; *P* < 0.001) in counterfactual income growth after injury. The magnitude of the absolute and relative income loss increased slightly from one to five years post-injury.

Table 1. Patient Characteristics (continued)

Characteristic	Fracture (n = 9997)	Control (n=34,570)	Standardized Difference
Age, mean (SD), y	44.6 (18.9)	40.0 (20.5) ^a	0.23
Sex, male, No. (%)	6725 (67.3%)	21,666 (62.7%)	0.10
Race, No. (%)			
White	6686 (66.9%)	22,654 (65.5%)	0.15
African-American	2626 (26.3%)	9660 (27.9%)	
Hispanic	141 (1.4%)	128 (0.4%)	
Other	544 (5.4%)	2128 (6.2%)	
Mechanism of injury, No. (%)			
Motor vehicle accident	6046 (60.5%)	18,358 (53.1%) ^b	0.182
Fall	2563 (25.6%)	11,259 (32.6%) ^b	
Firearm	446 (4.5%)	1732 (5.0%) ^b	
Struck	292 (2.9%)	910 (2.6%) ^b	
Cyclist	266 (2.7%)	636 (1.8%) ^b	
Machinery	156 (1.6%)	783 (2.3%) ^b	
Other	228 (2.3%)	92 (2.6%) ^b	
Abbreviated Injury Scale, mean (SD)			
Lower extremity	1.9 (1.1)	1.7 (1.1) ^b	0.12
Upper extremity	1.0 (1.1)	0.9 (1.0) ^b	0.13
Abdomen	0.4 (0.9)	0.4 (0.9) ^b	0.04
Face	0.4 (0.6)	0.3 (0.6) ^b	0.11
Head	0.7 (1.0)	0.6 (1.0) ^b	0.14
Neck	0.1 (0.4)	0.1 (0.4) ^b	0.02
Spine	0.4 (0.8)	0.4 (0.8) ^b	0.05
Thorax	0.7 (1.2)	0.7 (1.1) ^b	0.04
Co-morbidities, No. (%)			
Alcohol dependence	914 (9.1%)	1871 (5.4%) ^c	0.14
Depression	665 (6.7%)	2471 (7.1%) ^c	0.02
Diabetes	911 (9.1%)	3931 (11.4%) ^c	0.08
IV drug use	162 (1.6%)	625 (1.8%) ^c	0.01
Non-IV drug use	788 (7.9%)	2590 (7.5%) ^c	0.02
Hypertension	2292 (22.9%)	9798 (28.3%) ^c	0.12
Smoker	3049 (30.5%)	9859 (28.5%) ^c	0.04
Fracture Location, No. (%)			
Humerus, clavicle, scapula	1259 (12.6%)	5024 (14.5%) ^b	0.06
Radius or ulna	2392 (23.9%)	7628 (22.1%) ^b	0.04
Femur	2347 (23.5%)	10,178 (29.5%) ^b	0.14
Tibia or fibula	3653 (36.5%)	11,778 (34.1%) ^b	0.05
Pelvis or acetabulum	1776 (17.8%)	4047 (11.8%) ^b	0.17
Hand	1031 (10.3%)	3451 (10.0%) ^b	0.01
Foot	869 (8.7%)	3299 (9.5%) ^b	0.03
Open Fracture, No. (%)	2887 (28.9%)	10,269 (29.7%) ^b	0.02
No. of Surgical Procedures, median (IQR)	4.0 (5.1)	4.5 (6.0) ^b	0.10
Health Insurance Status, No. (%)			
Private employer-based	3618 (36.2%)	9306 (26.9%) ^d	0.23
Medicare	2011 (20.1%)	7691 (22.2%) ^d	
Medicaid	1789 (17.9%)	6942 (20.1%) ^d	
Uninsured	1264 (12.6%)	4877 (14.1%) ^d	
Direct purchase	975 (9.8%)	3916 (11.3%) ^d	
Other public	193 (1.9%)	1460 (4.2%) ^d	
Tricare/VA/Champ-VA	147 (1.5%)	378 (1.1%) ^d	

^a Age for the control group is the age of the patient at the time of the match with the fracture group.

^b Characteristics of the future fracture for the control group patient.

^c Co-morbidities present at the time of the fracture admission and may not have been present at the time of the match with the fracture group.

^d Health insurance status at the time of the fracture admission and may differ at the time of the match with the fracture group.

Table 2. Difference-in-Difference in Individual Earnings, Household Income, and Social Security Benefits^a

Outcome	Years from Injury	Fracture Group Mean (SD)	Control Group Mean (SD)	Adjusted Annual Difference (95% CI)	Adjusted Relative Difference (95% CI)	P Value
Individual Earnings						
	Year prior to injury	19,730 (63,510)	13,328 (63,818)	-	-	-
	1	\$18,575 (44,520)	\$22,089 (89,517)	-\$8492 (-\$9620 to -\$7364)	-70% (-72% to -68%)	<0.001
	2	\$18,784 (44,068)	\$22,061 (89,315)	-\$9142 (-\$10,178 to -\$8106)	-75% (-77% to -73%)	<0.001
	3	\$18,699 (45,164)	\$22,128 (90,724)	-\$9505 (-\$10,500 to -\$8510)	-77% (-79% to -76%)	<0.001
	4	\$18,661 (46,191)	\$22,304 (90,776)	-\$9766 (-\$10,724 to -\$8807)	-79% (-80% to -78%)	<0.001
	5	\$18,100 (175,519)	\$21,297 (68,643)	-\$9865 (-\$10,686 to -\$8862)	-81% (-82% to -80%)	<0.001
Household Income						
	Year prior to injury	30,704 (72,301)	\$30,899 (124,716)	-	-	-
	1	\$25,599 (57,702)	\$32,213 (129,712)	-\$4586 (-\$5909 to -\$3263)	-45% (-58% to -42%)	<0.001
	2	\$26,299 (59,860)	\$32,414 (129,335)	-\$4974 (-\$6134 to -\$3814)	-51% (-54% to -49%)	<0.001
	3	\$26,756 (79,716)	\$32,467 (127,137)	-\$5067 (-\$6157 to -\$3977)	-56% (-58% to -54%)	<0.001
	4	\$26,370 (89,419)	\$32,139 (115,073)	-\$5135 (-\$6172 to -\$4098)	-59% (-61% to -57%)	<0.001
	5	\$24,545 (182,042)	\$30,792 (100,422)	-\$5259 (-\$6337 to -\$4181)	-64% (-65% to -62%)	<0.001
Social Security Benefits						
	Year prior to injury	707 (4166)	207 (2361)	-	-	-
	1	\$1146 (5373)	\$387 (3273)	\$314 (\$259 to \$369)	17.4% (14.7% to 20.1%)	<0.001
	2	\$1346 (5957)	\$562 (3890)	\$347 (\$292 to \$402)	17.9% (15.4% to 20.6%)	<0.001
	3	\$1557 (6508)	\$798 (4565)	\$356 (\$301 to \$411)	17.1% (14.6% to 19.7%)	<0.001
	4	\$1600 (6592)	\$1097 (5324)	\$311 (\$254 to \$368)	14.0% (11.4% to 16.6%)	<0.001
	5	\$1462 (6307)	\$1410 (5972)	\$206 (\$147 to \$265)	8.0% (5.5% to 10.6%)	<0.001

^aAdjusted annual difference and adjusted relative difference are the difference-in-difference estimates from the year of injury to the year indicated.

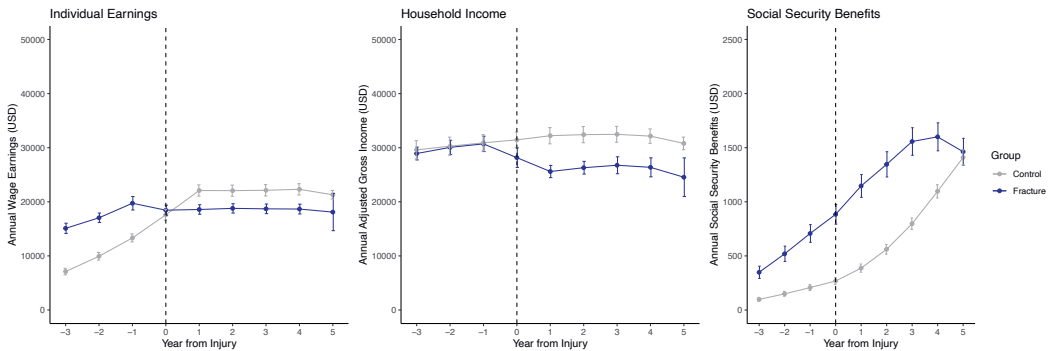


Figure 1. Annual Individual Earnings, Household Income, and Social Security Benefits from Three Years Prior to Injury to Five Years After Injury

Social Security Benefits

Fractures were associated with an increase in mean annual Social Security benefits in all five time periods (**Table 2, Figure 1**). The mean difference in annual Social Security benefits compared with pre-injury benefits was most substantial in the three years after injury (difference, \$356; 95% CI, \$301 to \$411; $P < 0.001$). The relative increase in Social Security benefits received post-fracture compared with pre-injury benefits was consistent, at approximately 17% higher, in years one to three. However, the relative annual difference in Social Security benefits received post-fracture compared with pre-fracture attenuated to 14.0% (95% CI, 11.4% to 16.6%) in the four years after injury, and 8.0% (95% CI, 5.5% to 10.6%) in the five years post-injury.

Catastrophic Loss in Individual Income

Fractures increased the risk of catastrophic wage loss in the two years after injury by 11.6% (95% CI, 10.5 to 12.7%; $P < 0.001$) (**eTable 2 in Supplement 1**). The risk of catastrophic wage loss attributable to a fracture remained similar when we expanded the catastrophic wage loss window from two to five years after injury (adjusted difference, 11.9%; 95% CI, 10.8% to 13.0%; $P < 0.001$). Nearly one in ten patients treated for fractures had a 75% or more decline in individual income in the two years after injury.

Heterogeneity of Treatment Effects

We observed significant heterogeneity in post-fracture individual income loss based on patient age, health insurance status, pre-injury income, fracture region, and fracture location (**Figure 2**). Patients with fractures aged 65 years or older sustained less relative income loss (-77%; 95% CI, -80% to -73%) than fracture patients under 65 years of age (-93%; 95% CI, -94% to -92%). We did not observe relative income loss for patients in the lowest income quartile (19%; 95% CI, -4% to 48%). Patients with distal fractures (-93%; 95% CI, -94% to -92%) had greater relative income loss than patients

with proximal fractures (-87%; 95% CI, -88% to -86%). The magnitude of relative income loss was marginally lower for patients with hand fractures (-85%; 95% CI, -89% to -81%) or patients with femur fractures (-76%; 95% CI, -80% to -72%) compared with other patients.

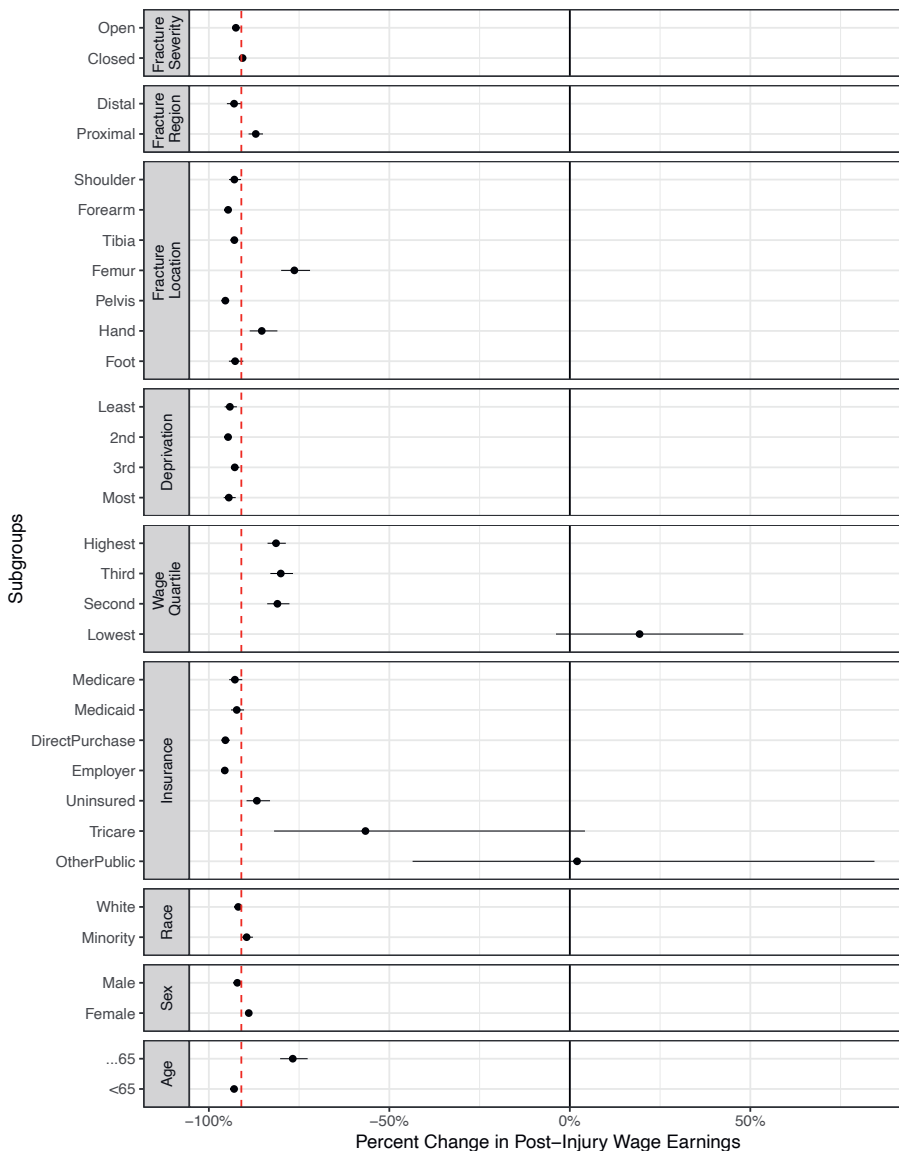


Figure 2. Relative Difference from Counterfactual Individual Earnings Associated with a Fracture^a

^aThe red dotted line represents the mean percent change in post-injury wage earnings for the overall sample.

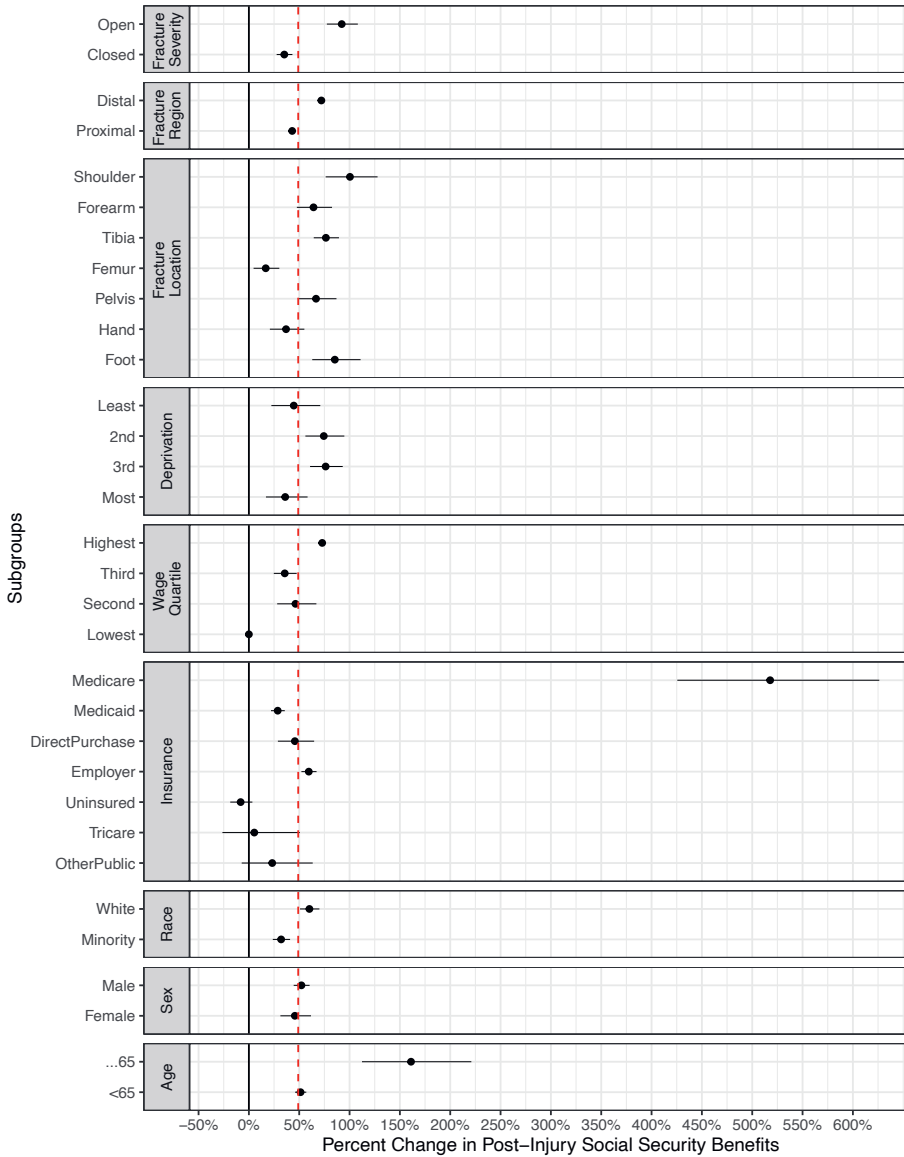


Figure 3. Relative Difference from Counterfactual Social Security Benefits Associated with a Fracture^a

^aThe red dotted line represents the mean percent change in post-injury social security benefits for the overall sample.

Medicare beneficiaries were significantly more likely to receive increased Social Security benefits (518%; 95% CI, 426% to 626%) than patients with other health insurance coverage (**Figure 3**). Patients with fractures aged 65 years or older had a greater increase

in Social Security benefits (161%; 95% CI, 112% to 221%) than patients under the age of 65 years (51%; 95% CI, 46% to 57%). Patients living in neighborhoods grouped in the middle quartiles of deprivation had greater increases in Social Security benefits (2nd quartile, 74%; 95% CI, 56% to 95%; 3rd quartile, 76%; 95% CI, 61% to 93%) than the changes observed for patients living in neighborhoods with the least deprivation (45%; 95% CI, 29% to 65%) and most deprivation (36%; 95% CI, 17% to 58%). Patients with distal fractures (72%; 95% CI, 68% to 74%) had a greater relative increase in Social Security benefits than patients with proximal fractures (43%; 95% CI, 40% to 46%). Of the fracture types, patients with femur fractures (17%; 95% CI, 5% to 30%) and patients with hand fractures (37%; 95% CI, 21% to 55%) had the smallest gains in Social Security benefits.

DISCUSSION

In this study, we used newly available state tax data to obtain precise and comprehensive estimates of an orthopaedic injury's impact on patient income. Fractures were associated with a \$9000 decline in annual individual earnings and a \$5000 reduction in yearly household income. The mean annual loss in earnings remained consistent for at least five years after injury. Nearly one in five patients had a 50% loss in individual earnings within two years of the injury. Fractures were associated with a 17% increase in social security benefits in the three years after injury, but benefits diminished in years four and five. Patients in the highest income quartile experienced a greater relative earnings loss than patients with lower pre-injury earnings yet received more social welfare.

Substantial Income Loss After Injury

Our analyses yielded four major conclusions. First, the loss in earnings after injury was substantial and persisted for at least five years after injury. Nearly half of the sample sustained their injury during the ages of peak income growth. While the decline did not reduce earnings below pre-injury levels, early wage stagnation was observed. Our estimated magnitude and duration of relative earnings loss was consistent with previous research on the economic effects of hospital admissions and physical impairment.^{25,26} However, the persistent income loss observed five years after injury has not been previously reported in the fracture literature. Understanding the expected duration of income loss is important for guiding clinical care and designing health and social policies.

The loss in household earnings was less than the individual income loss. This suggests a natural smoothing effect where other household members increase their workforce participation to offset the patient's income decline. Increased income from workers'

compensation or legal settlements, which were included in estimates of household income but not individual income, may also explain part of the observed discrepancy. Financial hardships are often associated with emotional and psychological distress, are an impediment to supporting dependents, and may possibly lead to intergenerational economic effects.^{14,27}

Limited Access to Social Welfare

Our second conclusion was that Social Security benefits significantly increased after the injury but offset less than 10% of lost income in any given year. Similar levels of Social Security protection were reported in a California-based study of hospitalized patients.²⁷ Over one-quarter of tax-filing patients treated for fractures reported individual incomes of \$0. Lacking formal employment precludes the contributory requirements of many social insurance benefits in the US, such as sick leave, unemployment insurance, and long-term disability benefits. By contrast, research from Denmark suggests that various social programs insured almost 50% of post-hospitalization earnings decline.²⁸

The US has weaker employment protections than other Organisation of Economic Cooperation and Development (OECD) countries.²⁹ It is one of three OECD countries that does not provide universal access to paid sick leave.³⁰ A lack of such social insurance policies likely contributes to the significant financial loss observed after injury. Employer-based health insurance was the most common form of coverage in the study population. Physical impairment that prevents patients from returning to work exposes individuals to further liability for downstream healthcare expenses. Increasing employment protections for sudden health events and passing legislation for mandatory sick pay benefits and the expansion of social welfare programs may reduce the financial implications of orthopaedic injury.

Catastrophic Income Loss

Our third conclusion was that fractures were associated with an 11.6% increase in the risk of catastrophic wage loss in the two years post-injury. One in ten patients treated for fractures experienced catastrophic wage loss under a more restrictive definition of a 75% reduction in income. Our estimates of catastrophic wage loss observed in the control group were similar to previous national estimates.¹³ Dobkin et al estimated an 11% decline in the probability of being employed three years after hospitalization, which was consistent with these findings.²⁶

Variations in Income Loss and Social Welfare Benefits

Our fourth conclusion was that pre-injury income, age, neighborhood deprivation, fracture region, and the location of injury modified the financial implications of injury. Although the subgroup analysis failed to identify characteristics associated with greater

income loss, we observed several factors protective against income loss. With low-income quartile patients reporting no formal pre-injury income, it was mathematically impossible for those individuals to sustain income loss. The overall estimates were driven by income losses of individuals from quartiles two through four. Patients aged 65 years or older sustained less relative income loss than patients under 65 years of age. This difference likely results from older patients receiving a higher proportion of their income from fixed, passive sources.³¹ Patients with fractures of the hand and femur were also associated with less relative income loss. The reduced income loss due to a hand fracture may be explained by shorter healing times for that fracture type, the importance of preserved mobility for resuming work, and the ability to perform many work tasks with a fractured hand. Of the included fracture types, femur fractures had the highest correlation with those over 65 years of age.

Access to social welfare after injury varied. The increase in social spending on older adults compared with working-age adults has been previously reported.³² This research has shown a U-shaped association between neighborhood deprivation and Social Security benefits. Specifically, patients living in the least and most deprived neighborhoods received significantly less benefits than patients residing in the mid-level deprivation quartiles. These differences may reflect coverage gaps or variations in benefit demands. Medicare beneficiaries and elderly patients had a considerable change in Social Security benefits. A 2018 study reported a similar finding attributed to Social Security Retirement Income eligibility and the higher upper limit for retirement benefits compared with other Social Security benefits.²⁶ Open fractures, a common marker of more severe injury, had a significant increase in Social Security benefits compared with less severe fractures. Patients with femur and hand fractures received less Social Security benefits than other fracture types, which plausibly can be associated with less relative income loss.

Limitations

This study had several limitations. The primary outcome was obtained from W-2 reported data, which does not include self-employment income, tips, or earnings from jobs that paid less than \$1800 a year, all likely important sources of earnings for this population. Certain covariates previously associated with economic loss after injury, such as occupation, were not available within our data. Although the proportion of non-filers in our sample was similar to previous studies and IRS reporting, we cannot completely discount the endogenous effects of non-filing.^{15,16,33} We do not have specific data on workers' compensation or legal compensation received by the patients. In most cases, these sources of income would be included as federal adjusted gross income that comprises our household income endpoint. Our heterogeneity of treatment effect analysis did not control for familywise type I error, and should be considered exploratory, not confirmatory. Given the potential challenges of heterogeneity of treatment effect

analysis in observational data leading to false positive and false negative conclusions, we adopted a descriptive approach. Despite these limitations, we believe the administrative data used in the study is a profound improvement over the self-reported data used in previous studies. Finally, the study sample was obtained from a single trauma center, and tax data was specific to one state, which enhances internal validity but may limit the generalizability of the findings to other hospitals and states.

CONCLUSIONS

The findings of this study suggest that fractures significantly reduced patient earnings for up to five years after injury. Gains in social welfare payments were limited, covering less than 10% of annual income losses. Patients aged 18 to 65 years and patients with pre-injury incomes in the upper quartiles suffered the greatest loss in earnings. Increases in Social Security benefits were most profound in patients older than 65 years at the time of injury.

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SUPPLEMENTAL MATERIAL

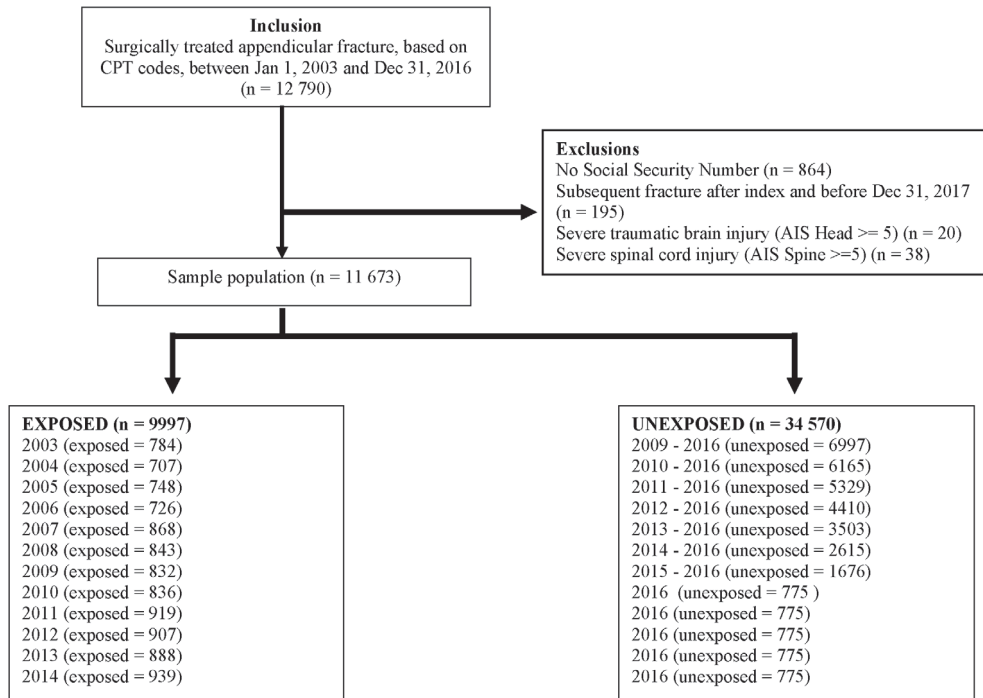
eTable 1. Parallel Trends Test for Pre-Injury Treatment Group Comparisons^a

	Annual Mean Difference (SE)	Value	Equivalence Margin	Equivalence P Value
Individual Earnings	-\$792 (469)	0.09	\$2000	0.005
Household Income	\$241 (1032)	0.82	\$2000	0.044
Social Security Benefits	\$125 (20)	<0.01	\$200	<0.001

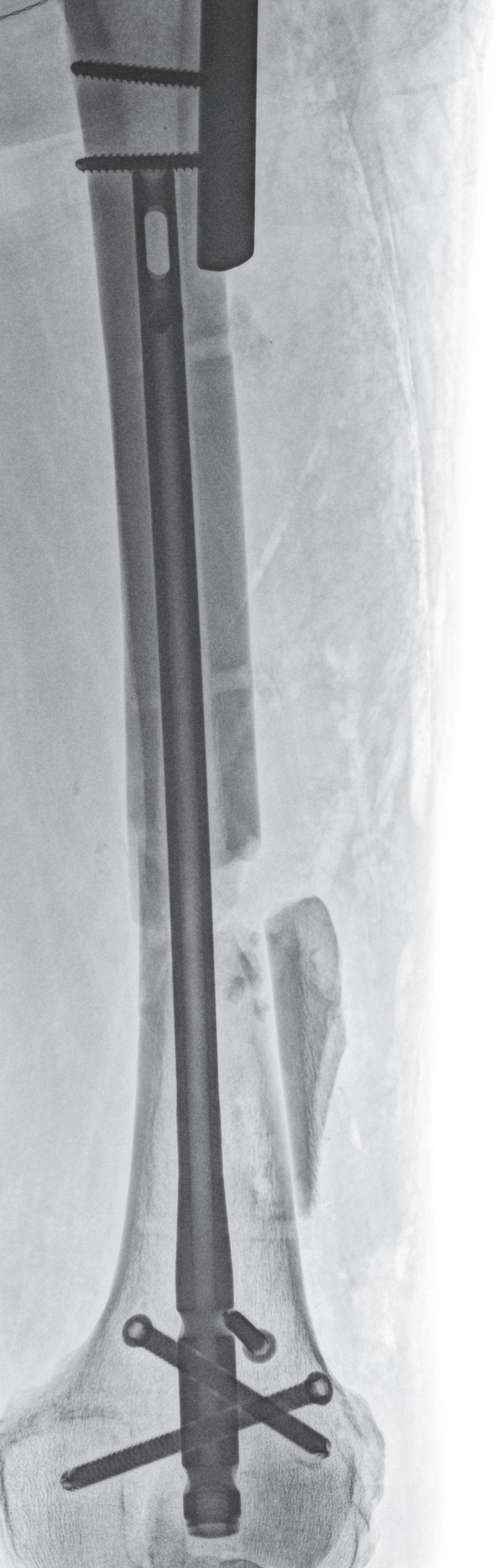
^a Adjusted for patient age and year of injury.

eTable 2. Risk of Risk of Catastrophic Wage Loss After Injury

Level of Catastrophic Wage Loss	Years Post-Injury	Fracture (n = 9997)	Control (n = 28 785)	Adjusted Mean Difference (95% CI)	P Value
25%	2 years	2989 (29.9%)	3857 (13.4%)	18.7% (17.3%–20.1%)	<0.001
	5 years	2899 (29.0%)	4318 (15.0%)	17.6% (16.3%–18.9%)	<0.001
50%	2 years	1789 (17.9%)	2245 (7.8%)	11.6% (10.5%–12.7%)	<0.001
	5 years	1809 (18.1%)	2418 (8.4%)	11.9% (10.8%–13.0%)	<0.001
75%	2 years	950 (9.5%)	1267 (4.4%)	6.0% (5.1%–6.8%)	<0.001
	5 years	1000 (10.0%)	1267 (4.4%)	6.8% (5.9%–7.6%)	<0.001



eFigure 1. Patient Selection



7

Long-Term Income Among Adults with Post-Operative Infections After Fractures

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ABSTRACT

Importance: Post-operative infections after a fracture exert tremendous costs on the healthcare system. However, the patient economic burden attributable to a post-operative infection is unclear.

Objective: To determine the association between a post-operative infection and long-term income among patients with surgically-treated fractures.

Design: Retrospective cohort study using inverse probability of treatment weighting to estimate between-group differences.

Setting: Academic trauma center in Maryland linked to State tax records.

Participants: The study included adult patients who underwent surgery to treat fractures of the extremities or pelvis between 2003-2016.

Exposure: A post-operative infection within one year of injury.

Main Outcomes and Measures: The primary outcome was the annual household income up to six years after injury. Household income incorporates multiple types of income, including wage earnings, taxable social security benefits, workers' compensation, and disability benefits. Secondary outcomes included individual earnings, social security benefits, unemployment benefits, and catastrophic income loss.

Results: We included 11,673 patients (mean age: 45.2 years [SD: 19.2]; 7756 males [66.4%]) with a mean pre-injury household income of \$30,505 (SD: 89,030). Four hundred and three patients (3.5%) had a post-operative infection. Post-operative infections were associated with a \$6080 annual decrease (95% CI: -\$12,114 to -\$47, p=0.048) in household income over the six years post-injury. Post-operative infections increased the risk of catastrophic wage loss by 6.6% (95% CI: 4.9% to 8.3%, p<0.001) and increased the odds of receiving social security benefits by 45% (OR, 1.45; 95% CI: 1.25 to 1.68, p<0.001). However, incurring a post-operative infection did not increase the value of the social security benefits received.

Conclusions and Relevance: Post-operative infections have significant and sustained income-related implications for fracture patients. Current social security mechanisms do not offset the decreased income.

INTRODUCTION

Post-operative infections exert a tremendous cost and resource burden on the healthcare system.¹⁻³ Infected patients require additional treatment, more diagnostic testing, readmission to hospital or prolonged hospital stay, and other additional uses of scarce healthcare resources.^{4,5} The impact of post-operative infections also likely manifests more broadly in the economy through lost capacity and productivity of patients and their caregivers.^{6,7} Many post-operative infections can be systematically prevented through improved healthcare quality and infection prevention policies.^{8,9} Previous studies have demonstrated that the cost of infection prevention is typically much lower than the cost of treating the complication.^{3,4,8-10} However, there is a clear gap in knowledge on the long-term effects of a post-operative infection on the patient's economic well-being.⁹

Post-operative infections are common after the surgical treatment of a fracture. Soft tissue damage adjacent to the fracture and a systematic inflammatory response from the trauma contribute to a post-operative infection risk that ranges from 2-5% for most closed fractures to over 20% for some types of open fractures.¹¹⁻¹³ Fractures commonly affect individuals during their most economically productive years and are associated with significant income loss.^{6,7,12,14,15} Adverse events following a fracture likely bear further economic consequences to the patient and society.

Tax records provide precise annual financial data to estimate the economic impact of medical conditions, treatments, and complications on patients. Yet, health researchers rarely use tax records for medical research given strict privacy restrictions. The granularity of tax data enables the estimation of changes in the composition of earnings and social welfare benefits associated with a medical episode.

With unique access to State tax records, we aimed to estimate the association between a post-operative infection and the long-term incomes of patients who sustained a fracture. We hypothesized that a post-operative infection would decrease patients' overall household income and increase social security benefits. Secondly, we explored variation in the relative effects of post-operative infection on patient income based on policy-relevant subgroups. We hypothesized that a post-operative infection would be associated with greater relative income loss for fracture patients who were more severely injured, lacked health insurance, and lived in an area of high deprivation.

METHODS

Study Design

In this retrospective cohort study, we linked longitudinal data from annual State of Maryland tax records to individual-level hospital data from an academic trauma center in Baltimore, Maryland. The study used the target trial emulation approach, which included inverse probability of treatment weighting, for inference in observational research.¹⁶ The target trial emulation approach is particularly applicable for research questions, such as this, where the exposure of interest cannot ethically be randomly assigned. The approach requires precise specification of the exposure groups to ensure positivity (all patients could have the exposure) and analytical techniques for conditional exchangeability (independence between the exposure and outcome).¹⁷ The University of Maryland Baltimore institutional review board approved the study, including a waiver of informed consent (HP-00079745). This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

Study Participants

We used *Current Procedural Terminology* (CPT) codes to identify adult patients who underwent surgery to treat a fracture of the extremities or pelvis between January 1, 2003 and December 31, 2016. We excluded patients admitted for a subsequent fracture during the study period, and patients with a severe traumatic brain injury or spinal cord injury, defined as an Abbreviated Injury Scale score of five or more in those body regions.^{18,19} Patients without social security numbers recorded in their hospital billing records were also excluded.

Using the social security numbers obtained from hospital billing records, we linked hospital data with the patient's State tax filings from 2000 through 2018. All eligible patients were matched to at least one tax record during the study period. However, the proportion of individuals who filed taxes varied over time (**eFigure 1**).²⁰

Assessment of Exposure

The primary exposure was a post-operative infection defined using the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network criteria for a deep or organ space surgical site infection.²¹ Deep or organ space surgical site infections are more severe than superficial incisional surgical site infections and typically require additional surgical treatment. We modified the CDC's 90-day window to include infections that occurred up to 12-months post-surgery. This modification was based on evidence that nearly half of fracture-related infections occur more than 90-days from the index procedure and is commonly applied in fracture research.²²⁻²⁴ We also included infections that occurred at the site of amputation. All suspected infections were identified using

CPT and International Classification of Diseases, 9th Revision (ICD-9) and 10th Revision (ICD-10) codes (eTable 1). The medical record of each patient suspected of a post-operative infection was independently reviewed by a certified infection preventionist to confirm the diagnosis at the fracture location.

Study Outcomes

The primary outcome was household earnings up to six years after injury calculated as tax-reported annual adjusted federal gross income. Adjusted gross income incorporates multiple types of income, including wage earnings, tax-exempt interest income, taxable social security benefits, workers' compensation, and disability benefits. Consistent with the methods of Chetty et al,²⁵⁻²⁷ we recoded non-tax filers and patients with negative incomes as having zero income for that specific year. Several components of household income were analyzed as secondary outcomes, including individual earnings and social security benefits. Social security benefits included Retirement Income, Disability Insurance, and Supplemental Security Income. Receipt of social security benefits or unemployment insurance were binary secondary endpoints. Catastrophic income loss was also included as a secondary outcome. Consistent with prior research, we defined catastrophic income loss as mean wage earnings in the year of the injury plus two years post-injury that was 50% less than the mean wage earnings in the two years before injury.²⁸ All income values were adjusted to 2018 US Dollars using the Consumer Price Index (CPI). The CPI adjustment mitigates macroeconomic effects, such as the 2009 economic recession. Time zero was defined as the calendar year of the index fracture admission.

Statistical Analysis

Patient characteristics were described using counts with proportions and means with standard deviations. We compared categorical data between the post-operative infection group and the control group using χ^2 tests. Continuous data were compared using t-tests.

We used inverse probability of treatment weights derived from the hospital and tax data to account for potential imbalance in factors prognostic of the exposure. Inverse probability of treatment weights form a pseudo-population based on the conditional probability of a post-operative infection given the observed sociodemographic, economic, and medical data.^{17,29} We created the pseudo-population by weighting each patient by the inverse of the conditional probability of receiving the exposure they did receive. Under this approach, the models estimate the average difference between the potential outcomes if all patients did and did not have a post-operative infection. Demographic data used for the conditional probabilities included age, sex, race, the type of health insurance based on the National Health Interview Survey coding, and the Area

Deprivation Index as a neighborhood-based measure of socioeconomic status at the time of injury.^{30,31} Clinical data included the mechanism of injury, location of the fracture, the number of surgical procedures associated with the index injury, and the Abbreviated Injury Scale scores, an anatomically-based injury severity scoring system, for all body regions. Comorbidity data included tobacco use, obesity, hypertension, diabetes, alcohol use, drug use, and renal disease. In addition, we included the components of the tax-reported earnings for the three years prior to injury to account for pre-injury earning trends, and the calendar year of injury to control for macroeconomic changes.

Inverse probability of treatment weighted mixed-effects models were used to estimate the difference in income and catastrophic income loss associated with a post-operative infection. We fit distinct models censored at one-year post-injury until the proportion of tax-filers was less than 50% of pre-injury levels to determine the duration of any observed differences. We observed this level of tax-filing attrition at six-years post-injury (**eFigure 1**). The estimated differences in the models were interpreted as the annual mean difference in income during the censored time period. As a sensitivity analysis for the catastrophic income loss endpoint, we varied the threshold for wage loss from 25% to 75% of pre-injury income and the window for wage loss from two to five years.

We analyzed heterogeneity in the association between a post-operative infection and household income and if the patient received social security benefits at two- and five-years after the fracture within several clinical- and policy-important subgroups. The subgroups included age (≥ 65 years vs. < 65 years), sex, race (white vs. minority), pre-injury income quartile, neighborhood deprivation quartile, fracture severity (open vs. closed fracture), fracture location, and health insurance status (uninsured vs. some form of insurance). Neighborhood deprivation was calculated based on the Area Deprivation Index of the patient's tax filing address in the year prior to injury. For the subgroup analyses, household income was transformed with logarithm plus one to account for the right-skewed distribution and modeled using mixed-effects regression. The estimates can be interpreted as the post-operative infection's relative effect on household earnings within two and five years after injury. We estimated a post-operative infection's relative effect on obtaining social security benefits with generalized linear regression models with a binomial distribution reported as odds ratios at two- and five-years post-injury. All subgroup analyses utilized inverse probability weighting.

Missing covariate data were imputed using multiple imputations (**eTable 2**).³² A two-sided significance level of 0.05 was used for all analyses. Due to the increased potential for type I error with multiple comparisons, the estimates for secondary outcomes and the subgroup analyses should be interpreted as exploratory. R Version 4.0.0 (R Foundation for Statistical Computing) was used for all statistical analyses.

RESULTS

The study included 11,673 patients (mean age: 45.2 years [SD: 19.2]; 7756 males [66.4%]) treated surgically for a fracture of the extremities or pelvis from January 1, 2003 through December 31, 2016 (**Table 1, eFigure 2**). In the year prior to injury, the patients' mean household income was \$30,505 (SD: 89,030). Nine percent of patients received social security benefits in the year before injury, and 3% received unemployment insurance. Four-hundred-three patients (3.5%) in the sample had a surgical site infection within one year of their index fracture fixation. There were notable differences between patients that developed a post-operative infection and the uninfected control patients. Specifically, the patients with a post-operative infection were younger (mean age, 41.4 years [SD, 14.4] vs. 45.3 years [SD, 19.3], $p < 0.001$), more likely to be male ($n = 310$ [76.9%] vs. $n = 7446$ [66.1%], $p < 0.001$), and have an open fracture ($n = 321$ [79.7%] vs. $n = 3119$ [27.7%], $p < 0.001$).

Household Income

Post-operative infections significantly reduced the annual household incomes of fracture patients from one- through six years after injury (**Figure 1, Table 2**). Within one-year of injury, post-operative infections were associated with a \$3160 loss (95% CI -\$5141 to -\$1178, $p = 0.002$) in household incomes. In the six years after the fracture, a post-operative infection reduced fracture patients' household incomes by \$6080 per year (95% CI -\$12,114 to -\$47, $p = 0.048$). Post-operative infections after a fracture were associated with a 56.5% relative decrease (95% CI -93.1% to -19.9%, $p < 0.001$) in household earnings within two-years of injury and 53.4% relative decrease (95% CI -85.6% to -21.2%, $p < 0.001$) in household earnings within five years of injury.

The relative effects of a post-operative infection on household incomes varied based on the pre-injury income quartile and neighborhood deprivation of the patient (**Figure 2**). Specifically, the relative change in household income associated with a post-operative infection was significantly greater for patients in the lowest pre-injury income quartile (difference=-82.4%, 95% CI -196.2% to 31.3%)) than in the highest pre-injury income quartile (difference=-33.1%, 95% CI -64.0% to -2.3%) within two-years ($p = 0.001$) and five-years of injury ($p = 0.04$). Secondly, patients in the most deprived neighborhoods quartile had a significantly greater loss in household income attributable to a post-operative infection within two-years of injury (difference=-83.7%, 95% CI -99.5% to -67.9%) than patients living neighborhoods in the least deprived neighborhood quartile (difference=-34.4%, 95% CI -117.3% to 48.3%, interaction $p = 0.03$).

Individual Earnings

Post-operative infections reduced annual individual incomes by approximately \$4,000

Table 1. Patient characteristics (n=11,673)

	Post-Operative Infection (n=403)	Uninfected Control (n=11,270)	Overall (n=11,673)	P-Value
Age , mean (SD)	41.4 (14.4)	45.3 (19.3)	45.2 (19.2)	<0.001
Male , n (%)	310 (76.9%)	7446 (66.1%)	7756 (66.4%)	<0.001
Race , n (%)				
White	254 (63.0%)	7496 (66.5%)	7750 (66.4%)	0.70
African-American	121 (30.0%)	3005 (26.7%)	3126 (26.8%)	
Hispanic	6 (1.5%)	135 (1.2%)	141 (1.2%)	
Other or unknown	22 (5.5%)	634 (5.6%)	656 (5.6%)	
Neighborhood deprivation , n (%)				
Least deprivation quartile (ADI, 1-3)	81 (20.1%)	2284 (20.3%)	2365 (20.3%)	0.88
Second quartile (ADI, 4-6)	76 (18.9%)	2289 (20.3%)	2365 (20.3%)	
Third quartile (ADI, 7-8)	86 (21.3%)	2279 (20.2%)	2365 (20.3%)	
Most deprivation quartile (ADI, 9-10)	83 (20.6%)	2281 (20.2%)	2364 (20.3%)	
Missing	77 (19.1%)	2137 (19.0%)	2214 (19.0%)	
Mechanism of injury , n (%)				
Motor vehicle accident	283 (70.2%)	6627 (58.8%)	6910 (59.2%)	<0.001
Fall	65 (16.1%)	3059 (27.1%)	3124 (26.8%)	
Firearm	15 (3.7%)	536 (4.8%)	551 (4.7%)	
Struck	7 (1.7%)	323 (2.9%)	330 (2.8%)	
Cyclist	10 (2.5%)	272 (2.4%)	282 (2.4%)	
Machinery	10 (2.5%)	198 (1.8%)	208 (1.8%)	
Other	13 (3.2%)	255 (2.3%)	268 (2.3%)	
Injury type , n (%)				
Blunt	365 (90.6%)	10452 (92.7%)	10817 (92.7%)	<0.001
Penetrating	22 (5.5%)	648 (5.7%)	670 (5.7%)	
Crush	16 (4.0%)	156 (1.4%)	172 (1.5%)	
Other	0 (0%)	14 (0.1%)	14 (0.1%)	
Glasgow Comma Score , Mean (SD)	12.7 (4.04)	14.2 (2.45)	14.1 (2.54)	<0.001
Health insurance , n (%)				
Private Employer Based	140 (34.7%)	3863 (34.3%)	4003 (34.3%)	<0.001
Medicare	88 (21.8%)	2298 (20.4%)	2386 (20.4%)	
Medicaid	101 (25.1%)	2058 (18.3%)	2159 (18.5%)	
Uninsured	29 (7.2%)	1447 (12.8%)	1476 (12.6%)	
Direct Purchase	21 (5.2%)	1160 (10.3%)	1181 (10.1%)	
Other Public Insurance	18 (4.5%)	285 (2.5%)	303 (2.6%)	
Tricare/VA/Champ	6 (1.5%)	159 (1.4%)	165 (1.4%)	
Abbreviated Injury Scale				
Lower extremity, mean (SD)	1.98 (0.930)	1.85 (1.08)	1.86 (1.07)	<0.01
Upper extremity, mean (SD)	0.94 (1.08)	0.98 (1.07)	0.975 (1.07)	0.51
Abdominal, mean (SD)	0.74 (1.13)	0.42 (0.87)	0.427 (0.88)	<0.001
Face, mean (SD)	0.36 (0.63)	0.36 (0.62)	0.361 (0.62)	0.97
Head, mean (SD)	0.90 (1.19)	0.67 (1.01)	0.674 (1.02)	<0.001
Neck, mean (SD)	0.11 (0.50)	0.08 (0.43)	0.0810 (0.43)	0.29
Spine, mean (SD)	0.55 (0.93)	0.40 (0.85)	0.408 (0.85)	0.01
Chest, mean (SD)	0.96 (1.38)	0.69 (1.22)	0.698 (1.23)	<0.001
Comorbidities				
Alcohol dependence, n (%)	39 (9.7%)	940 (8.3%)	979 (8.4%)	0.34
Cancer, n (%)	6 (1.5%)	357 (3.2%)	363 (3.1%)	0.06
Depression, n (%)	29 (7.2%)	755 (6.7%)	784 (6.7%)	0.70
Diabetes, n (%)	40 (9.9%)	1075 (9.5%)	1115 (9.6%)	0.80
IV drug use, n (%)	8 (2.0%)	185 (1.6%)	193 (1.7%)	0.60
Non-IV drug use, n (%)	33 (8.2%)	872 (7.7%)	905 (7.8%)	0.74
Hypertension, n (%)	67 (16.6%)	2710 (24.0%)	2777 (23.8%)	<0.001
Tobacco use, n (%)	109 (27.0%)	3433 (30.5%)	3542 (30.3%)	0.14

	Post-Operative Infection (n=403)	Uninfected Control (n=11,270)	Overall (n=11,673)	P-Value
Fracture location				
Humerus, clavicle, scapula, n (%)	57 (14.1%)	1487 (13.2%)	1544 (13.2%)	0.58
Radius or ulna, n (%)	89 (22.1%)	2622 (23.3%)	2711 (23.2%)	0.58
Femur, n (%)	134 (33.3%)	2785 (24.7%)	2919 (25.0%)	<0.001
Tibia or fibula, n (%)	242 (60.0%)	3976 (35.3%)	4218 (36.1%)	<0.001
Pelvis or acetabulum, n (%)	97 (24.1%)	1842 (16.3%)	1939 (16.6%)	<0.001
Hand, n (%)	54 (13.4%)	1162 (10.3%)	1216 (10.4%)	0.046
Foot, n (%)	56 (13.9%)	998 (8.9%)	1054 (9.0%)	<0.001
Open fracture, n (%)	321 (79.7%)	3119 (27.7%)	3440 (29.5%)	<0.001

Notes: ADI, Area Deprivation Index; VA, Veterans Affairs; IV, intravenous.

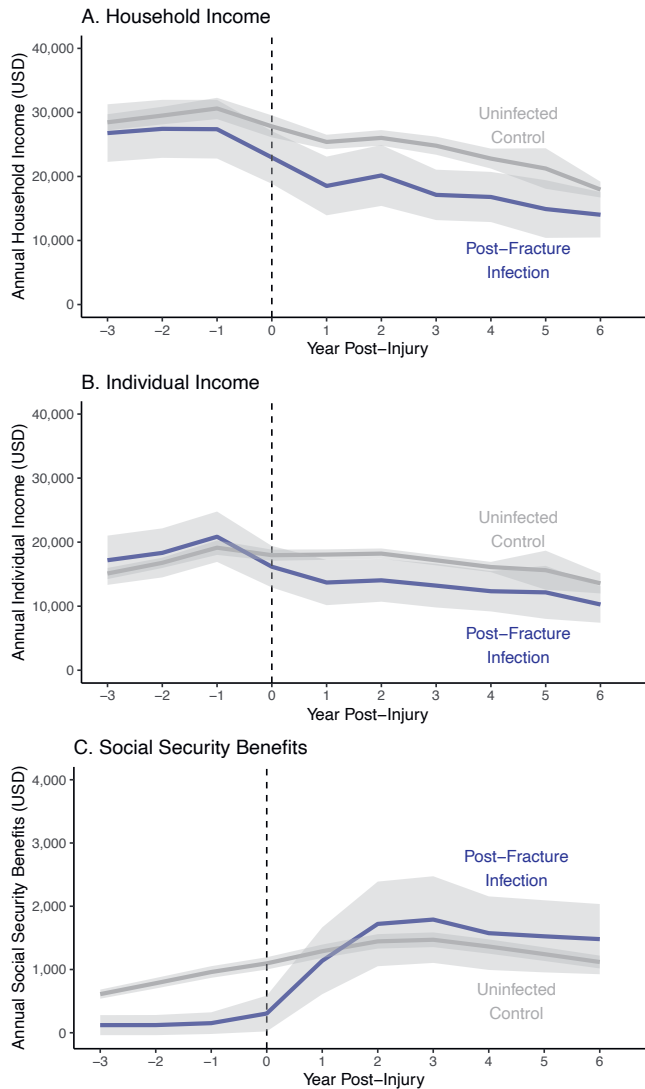


Figure 1. Association between a post-operative infection and a) household income, b) individual income, and c) social security benefits.

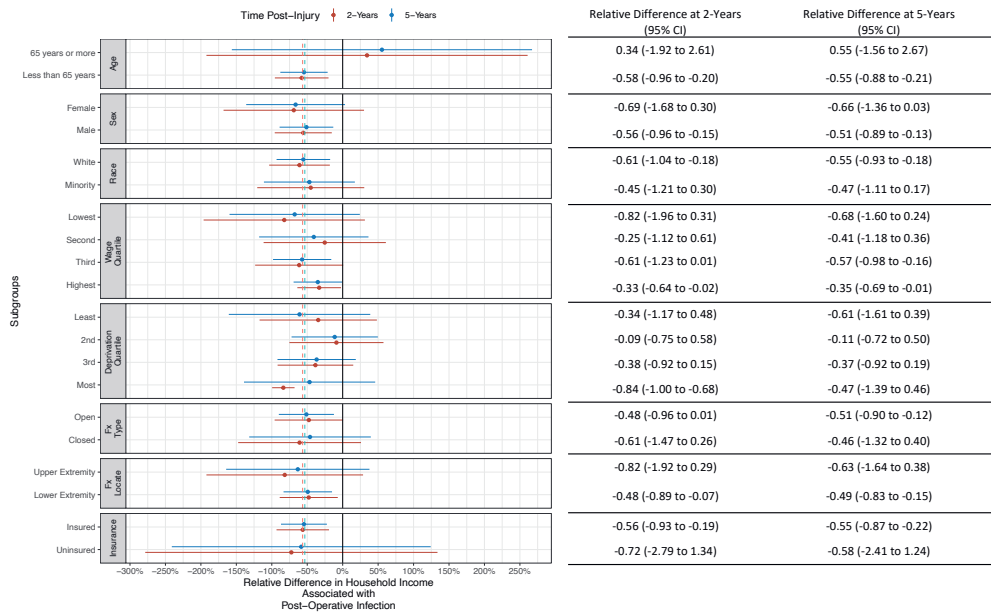


Figure 2. Relative household income associated with a post-operative infection within subgroups and evaluated at two- and five-years post-fracture. The dashed vertical lines represent sample mean estimates of the relative change in household income associated with a post-operative infection at two-years (red) and five-years (blue) post-fracture.

Note: The median incomes for the pre-injury wage quartiles are as follows: lowest quartile (\$0), second quartile (\$5257), third quartile (\$31,686), and highest quartile (\$91,749).

for up to six years post-injury (**Figure 1, Table 2**). However, the reductions in annual individual income attributable to a post-operative infection were only statistically significant within two, three, and four years after the injury.

Social Security and Unemployment Benefits

Post-operative infections were associated with less social security benefits (difference, -\$288, 95% CI -\$477 to -\$98, $p < 0.001$) in the year after injury (**Figure 1, Table 2**). In the following years, we did not observe a significant association between a post-operative infection and the value of social security benefits received. However, a post-operative infection was associated with an increased odds of receiving social security benefits at two years post-fracture (OR=1.74, 95% CI 1.51 to 2.02, $p < 0.001$) and five-years after injury (OR=1.45; 95% CI 1.25 to 1.68, $p < 0.001$) (**eFigure 3**). Post-operative infections were not associated with receiving unemployment insurance at two-years (OR=0.94, 95% CI 0.72 to 1.21, $p = 0.62$), but were associated with a three-fold increase in the odds of receiving unemployment insurance at five-years post-injury (OR=3.45, 95% CI 2.82 to 4.23, $p < 0.001$) (**eFigure 4**).

Table 2. Adjusted annual mean differences in household income, individual income, and social security benefits estimated in models censored from one- to six-years post-injury.

Outcome Timeframe	Post-Operative Infection Mean (SE)	Uninfected Control Mean (SE)	Adjusted Annual Mean Difference (95% CI)	P-Value
Household Income				
Pre-injury	\$27,379 (2339)	\$30,617 (849)	NA	NA
1-year	\$18,516 (2338)	\$25,390 (575)	-\$3160 (-\$5141 to -\$1178)	0.002
2-year	\$20,156 (2426)	\$26,022 (622)	-\$6368 (-\$12,252 to -\$483)	0.03
3-year	\$17,123 (2009)	\$24,801 (720)	-\$6790 (-\$12,262 to -\$1317)	0.02
4-year	\$16,797 (1999)	\$22,791 (795)	-\$6582 (-\$12,020 to -\$1143)	0.02
5-year	\$14,912 (2300)	\$21,239 (1615)	-\$6520 (-\$12,502 to -\$538)	0.03
6-year	\$14,022 (1811)	\$17,953 (631)	-\$6080 (-\$12,114 to -\$47)	0.048
Individual Income				
Pre-injury	\$20,846 (2007)	\$19,137 (579)	NA	NA
1-year	\$13,695 (1805)	\$18,054 (416)	-\$4359 (-\$8727 to \$10)	0.051
2-year	\$14,042 (1705)	\$18,208 (412)	-\$4274 (-\$8348 to -\$200)	0.04
3-year	\$13,210 (1741)	\$17,164 (408)	-\$4167 (-\$8147 to -\$187)	0.04
4-year	\$12,333 (1609)	\$16,112 (411)	-\$4067 (-\$7975 to -\$159)	0.04
5-year	\$12,157 (2113)	\$15,620 (1557)	-\$3972 (-\$8367 to \$423)	0.08
6-year	\$10,265 (1455)	\$13,565 (805)	-\$3844 (-\$8430 to \$743)	0.10
Social Security Benefits				
Pre-injury	\$152 (87)	\$960 (47)	NA	NA
1-year	\$1138 (270)	\$1289 (54)	-\$288 (-\$477 to -\$98)	0.002
2-year	\$1721 (341)	\$1445 (58)	\$56 (-\$459 to \$571)	0.83
3-year	\$1789 (350)	\$1470 (60)	\$134 (-\$374 to \$641)	0.61
4-year	\$1574 (297)	\$1363 (58)	\$150 (-\$344 to \$643)	0.55
5-year	\$1525 (291)	\$1243 (55)	\$174 (-\$301 to \$649)	0.48
6-year	\$1480 (283)	\$1118 (52)	\$203 (-\$250 to \$656)	0.38

Note: Pre-injury levels were based on the tax year prior to injury.

The odds of receiving social security benefits after a post-operative infection varied by sex ($p < 0.001$), race ($p < 0.001$), fracture severity ($p = 0.03$), pre-injury income quartile ($p < 0.001$), and neighborhood deprivation ($p < 0.001$) (**Figure 3**). Male patients had greater odds of receiving social security benefits after a post-operative infection than female patients at two-years (Male, OR=2.50, 95% CI 2.13 to 2.95; Female, OR=0.39, 95% CI 0.26 to 0.56) and five-years post-injury (Male, OR=1.60, 95% CI 1.36 to 1.89; Female, OR=0.92, 95% CI 0.65 to 1.29). White patients were more likely to receive social security benefits after a post-operative infection than minority patients two years (White, OR=1.72, 95% CI 1.47 to 2.01; Minority, OR=0.93, 95% CI 0.57 to 1.46) and five years after injury (White, OR=1.65, 95% CI 0.40 to 1.94; Minority, OR=0.66, 95% CI 0.43 to 1.00). Closed fracture patients that sustained a post-operative infection (OR=2.01,

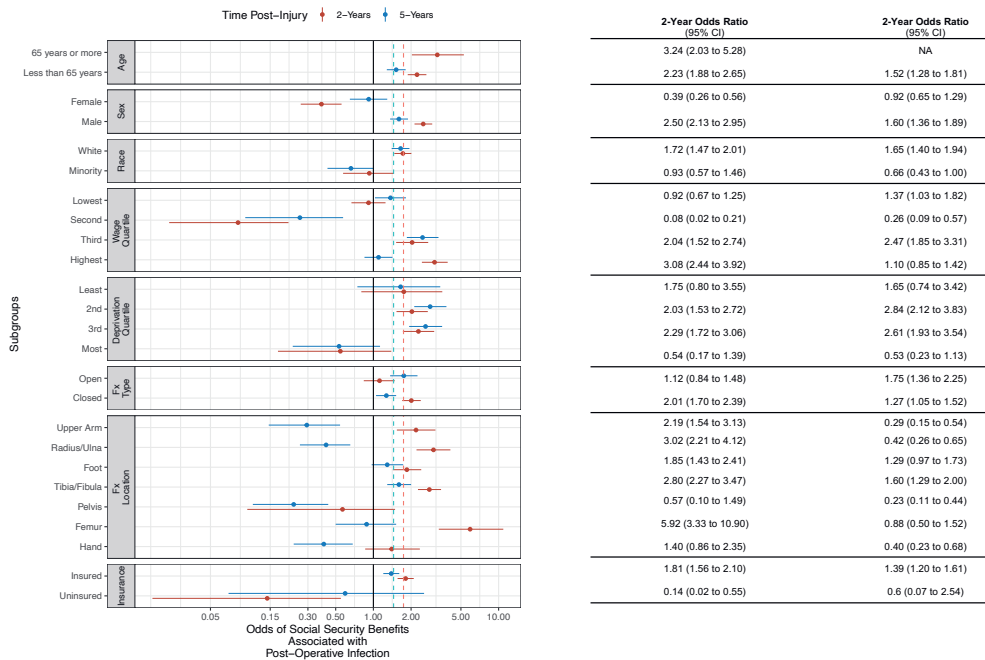


Figure 3. Odds of receiving social security benefits associated with a post-operative infection within subgroups and evaluated at two- and five-years post-fracture. The dashed vertical lines represent sample mean odds of receiving social security benefits associated with a post-operative infection at two-years (red) and five-years (blue) post-fracture.

Note: All post-operative infection that occurred in patients ≥ 65 years at the time of injury reported receiving social security benefits five years after their injury. The median incomes for the pre-injury wage quartiles are as follows: lowest quartile (\$0), second quartile (\$5257), third quartile (\$31,686), and highest quartile (\$91,749).

95% CI 1.70 to 2.39) were more likely than open fracture patients that sustained a post-operative infection (OR=1.12, 95% CI 0.84 to 1.48) to receive social security benefits within two years of injury. Conversely, open fracture patients that developed a post-operative infection had greater odds of receiving social security benefits five years after injury (OR=1.75, 95% CI 1.36 to 2.25) than closed fracture patients (OR=1.27, 95% CI 1.05 to 1.52). Two years after injury, patients in the highest (OR=3.08, 95% CI 2.44 to 3.92) and second-highest pre-injury income quartile (OR=2.04, 95% CI 1.52 to 2.74) had greater odds of receiving social security benefits after a post-operative infection than patients in the lowest (OR=0.92, 95% CI 0.67 to 1.25) and second-lowest income quartile (OR=0.08, 95% CI 0.02 to 0.21). Five years after injury, patients in the lowest (OR=1.37, 95% CI 1.03 to 1.82) and second-highest pre-injury income quartile (OR=2.47, 95% CI 1.85 to 3.31) had the greater odds of receiving social security benefits after a post-operative infection than patients in the highest income quartile (OR=1.10, 95% CI 0.85 to 1.42). Among patients living in neighborhoods with mid-levels of deprivation,

a post-operative infection doubled the odds of receiving social security benefits (2nd lowest quartile, OR=2.03, 95% CI 1.53 to 2.72; 3rd lowest quartile, OR=2.29, 95% CI 1.72 to 3.06) two years after injury.

Catastrophic Wage Loss

Post-operative infections were associated with a 6.6% increase in the risk of catastrophic wage loss within two-years of the fracture (95% CI 4.9% to 8.3%, $p<0.001$) (**eTable 3**). This estimate was robust when we increased the post-injury window to five years. When we restricted the catastrophic wage loss definition to a 75% reduction in annual wage earnings, a post-operative infection increased the risk of catastrophic wage loss by 7.5% (95% CI: 6.1% to 9.0%, $p<0.001$). When we softened the catastrophic wage loss definition to a 25% loss in mean wages, a post-operative infection was associated with a 4.3% increase in the risk of catastrophic wage loss (95% CI 2.3% to 6.2%, $p<0.001$).

DISCUSSION

Our findings suggest that among patients with a fracture, a post-operative infection is associated with a \$6,000 reduction in annual household income. The income loss attributable to post-operative infections represents roughly 20% of pre-injury earnings, and the income loss persisted for at least six years after injury. Post-operative infections also increased the risk of catastrophic wage loss within two-years of injury by 7% and increased the odds of receiving social security benefits by 45%. However, incurring a post-operative infection did not increase the amount of social security benefits received. Patients in the lowest pre-injury income quartile suffered the greatest relative income loss yet had decreased odds of receiving social security benefits within two-years of injury.

Clinical interventions and hospital policies to reduce hospital-associated infections are considered to be essential, but the economic impact of these infections remains understudied. Prior research suggests the average hospitalization costs in the US to treat a post-operative infection in a fracture patient exceeds \$20,000.^{33,34} The present value of \$6000 in lost annual income over six years, discounted with a 2% inflation rate, is \$34,281. There are approximately 1 million patients that sustain an operatively treated fracture in the US each year.³⁵ Assuming 3.5% of fracture patients have a post-operative infection, as observed in this study, the lost earnings attributable to these complications exceeds \$1 billion per year. Reducing the incidence of post-operative infections in fracture patients by 1% would prevent over \$300 million in lost earnings annually.

Alternative payment models to incentivize patient safety, such as Centers for Medicare and Medicaid Services' Hospital Readmissions Reduction Program, have demonstrated positive effects.³⁶⁻³⁸ However, current readmission penalties are based on treating costs and fail to account for the indirect costs measured in this study. Further, most current reimbursement programs do not apply to fracture patients, and most post-operative infections in fracture patients occur beyond the 30-day penalty window, implying the treating institution's patient safety responsibility should be extended.³⁹

The costs of preventing post-operative infections are diffused within and between hospitals. The benefits of patient safety are also diffused at the hospital level but concentrated at the patient level. Circumstances with diffused costs and concentrated benefits at the individual-level are typically favorable for advancing policy.⁴⁰ However, the low socioeconomic status of many trauma patients suggests this patient population has limited political capital to direct additional resources towards patient safety.

The pre-injury household income levels of the sample were less than half the State's median. This difference highlights the profound socioeconomic deprivation faced by many orthopaedic trauma patients prior to their injury. The low reported earnings imply that many fracture patients were without formal employment prior to their injury.⁴¹ This lack of workforce participation would negate the patient's eligibility to obtain sick leave benefits, unemployment insurance, and Social Security Disability Insurance. The early access to social security benefits in this study was realized by patients who were male, white, and in the top income quartile. This allocation inequity questions the distributional fairness of social insurance programs. The distributions observed in the study provide further evidence of limited social welfare for historically disenfranchised subpopulations.

Despite the frequency and associated socioeconomic impacts, surgical site infections that occur after fracture surgery are not currently included in the National Healthcare Safety Network's Surgical Care Improvement Project. Therefore, they are not captured in the Agency for Healthcare Research and Quality's National Scorecard of Hospital-Acquired Conditions.¹⁰ Given the profound societal costs, surgical site infections that occur after fracture surgery should be included in this national healthcare quality surveillance program.^{42,43} The financial implications of post-operative infections on patients should be included in evaluating infection prevention interventions and used to assess the marginal value of public investments in patient safety.^{44,45} Finally, the study highlights the disconnect between healthcare and social insurance programs supporting the need for further integrations of these domains.⁴⁶

Study Limitations

The study had several limitations. Post-operative infections were retrospectively identified in fracture patients using *CPT* codes, and therefore, the potential for misclassification exists. However, a certified infection preventionist independently reviewed the medical records of each suspected case. The economic effects were estimated solely based on tax-reported earnings. We observed greater attrition in tax filing for post-operative infection patients and cannot completely discount the endogenous effects of non-filing in both groups. Prior studies suggest that an annual income lower than the Internal Revenue Service (IRS) age-dependent thresholds of roughly \$20,000 is the most common reason for non-filing.⁴⁷ Further, data on incurred debt and consumption effects were not included in our estimates. The inclusion of these effects would likely amplify the societal costs of post-operative infections further. The study data did not report the components of social security income separately and, therefore, we were unable to assess the association between post-operative infections and means tested (e.g., Supplementary Security Income) versus event conditioned (e.g., Disability Insurance or Retirement Income) social security programs. We did not have data on pre-injury occupations, which would have likely explained some of the observed variances. The study data was collected from a single trauma center, and tax records were obtained from a single State, limiting the generalizability of the findings. However, obtaining a precise estimate of the financial consequences of a post-operative infection using tax data represents a substantial advancement over prior estimates.^{5-7,33} Further, the analytical framework for calculating the economic effects of post-operative infections is transportable to other health conditions and underscores the value of expanded use of administrative data for health outcomes research and the improvement of the safety of health care delivery.

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CONCLUSIONS

This study utilized a novel approach of linking hospital data with tax records to determine reliable and precise estimates of the financial impact of post-operative infections on fracture patients in Maryland. We know that an operatively treated fracture substantially reduces patient income.¹⁵ The data from this study suggest post-operative infections have a significant and sustained effect on patient income that is in excess of the loss attributable to the fracture. The current social insurance mechanisms do not offset the decreased earnings. Given the long-term economic effects of a post-operative infection, healthcare providers should be incentivized to continue seeking high-return investments in patient safety.⁸ Substantial economic benefits can be achieved through incremental improvements in infection prevention.

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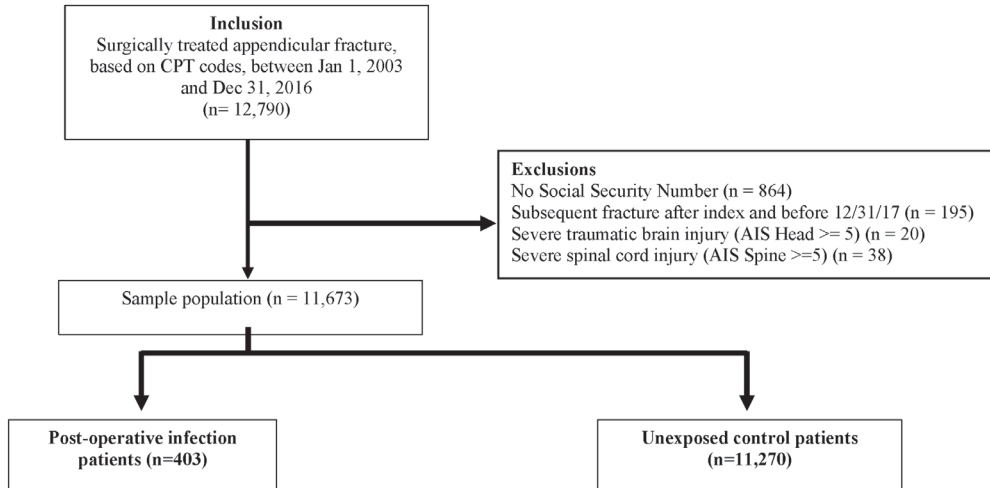
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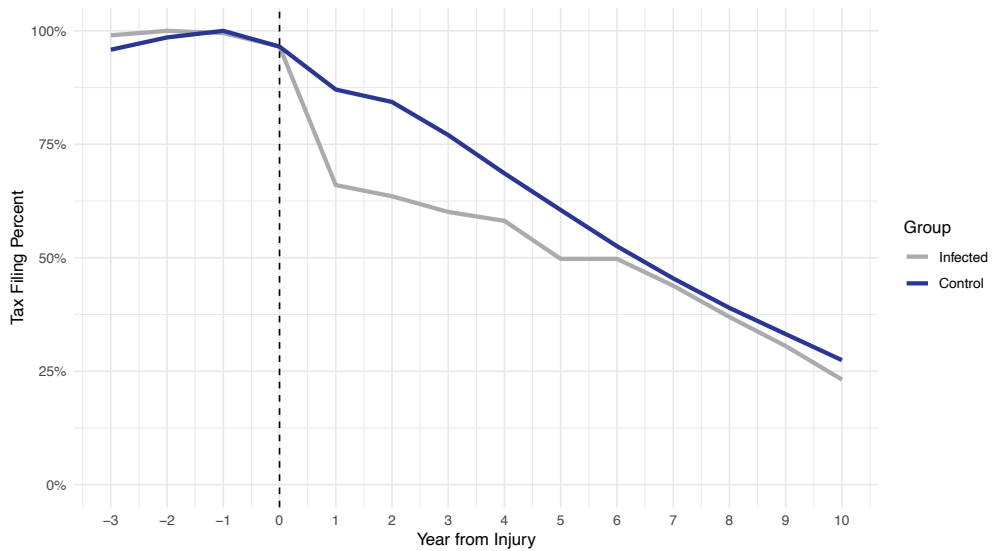
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SUPPLEMENTAL INFORMATION



eFigure 1. Flow chart.



eFigure 2. Attrition in tax filing.

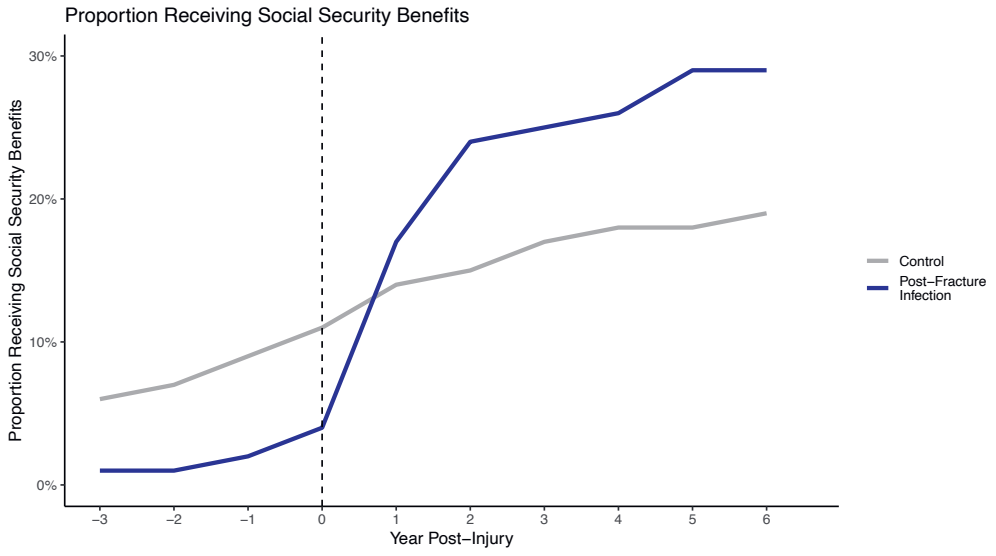


Figure 3. Proportion of patients receiving social security benefits.

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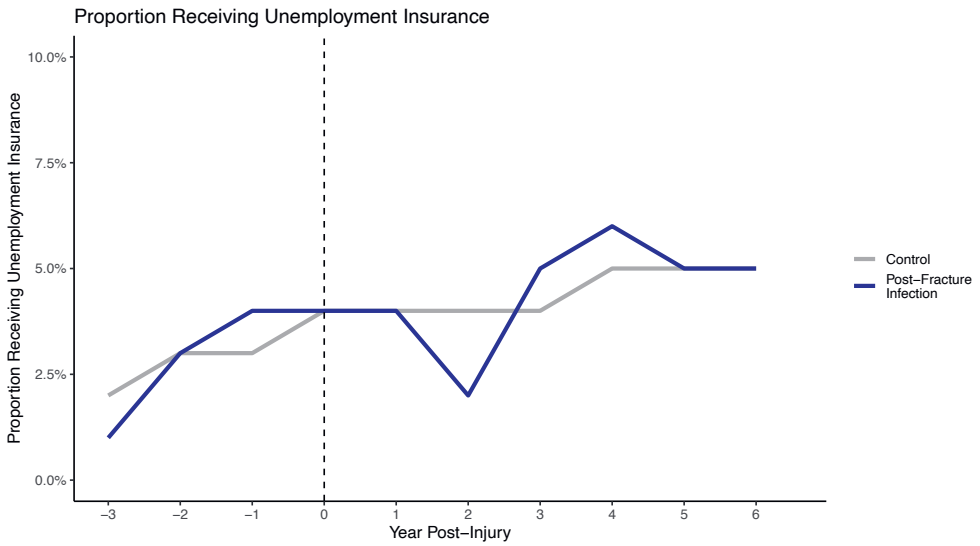


Figure 4. Proportion of patients receiving unemployment insurance.

eTable 1. *Current Procedural Terminology (CPT), International Classification of Diseases, 9th Revision (ICD-9), and 10th Revision (ICD-10) codes used to identify patients with a suspected post-operative infection.*

Code	Description
ICD-9	
730.2	Unspecified osteomyelitis
730.20	Unspecified osteomyelitis site unspecified
730.21	Unspecified osteomyelitis involving shoulder region
730.22	Unspecified osteomyelitis involving upper arm
730.23	Unspecified osteomyelitis involving forearm
730.24	Unspecified osteomyelitis involving hand
730.25	Unspecified osteomyelitis involving pelvic region and thigh
730.26	Unspecified osteomyelitis involving lower leg
730.27	Unspecified osteomyelitis involving ankle and foot
730.28	Unspecified osteomyelitis involving other specified sites
730.29	Unspecified osteomyelitis involving multiple sites
998.5	Postoperative infection not elsewhere classified
996.67	Infection and inflammatory reaction due to other internal orthopedic device implant and graft
ICD-10	
T81.3	Disruption of wound, not elsewhere classified
T81.30	Disruption of wound, unspecified
T81.31	Disruption of external operation (surgical) wound, not elsewhere classified
T81.32	Disruption of internal operation (surgical) wound, not elsewhere classified
T81.33	Disruption of traumatic injury wound repair
T81.4	Code for Infection following a procedure
T81.40	Code for Infection following a procedure, unspecified
T81.41	Infection following a procedure, superficial incisional surgical site
T81.42	Infection following a procedure, deep incisional surgical site
T81.43	Infection following a procedure, organ and space surgical site
T81.44	Sepsis following a procedure
T81.49	Infection following a procedure, other surgical site
T84.5	Infection and inflammatory reaction due to internal joint prosthesis
T84.51	Infection and inflammatory reaction due to internal right hip prosthesis
T84.52	Infection and inflammatory reaction due to internal left hip prosthesis
T84.53	Infection and inflammatory reaction due to internal right knee prosthesis
T84.54	Infection and inflammatory reaction due to internal left knee prosthesis
T84.59	Infection and inflammatory reaction due to other internal joint prosthesis
T84.6	Infection and inflammatory reaction due to internal fixation device
T84.60	Infection and inflammatory reaction due to internal fixation device of unspecified site
T84.61	Infection and inflammatory reaction due to internal fixation device of arm
T84.62	Infection and inflammatory reaction due to internal fixation device of leg
T84.63	Code for Infection and inflammatory reaction due to internal fixation device of spine
T84.69	Infection and inflammatory reaction due to internal fixation device of other site

T84.7	Infection and inflammatory reaction due to other internal orthopedic prosthetic devices, implants and grafts
T84.7XXA	Infection and inflammatory reaction due to other internal orthopedic prosthetic devices, implants and grafts, initial encounter
T84.7XXD	Infection and inflammatory reaction due to other internal orthopedic prosthetic devices, implants and grafts, initial encounter
T84.7XXS	Infection and inflammatory reaction due to other internal orthopedic prosthetic devices, implants and grafts, sequela
M86.9	Osteomyelitis, unspecified

CPT Codes

11011	Debridement including removal of foreign material associated with open fracture(s) and/or dislocation(s)
11012	Debridement including removal of foreign material associated with open fracture(s) and/or dislocation(s)
11043	Under Debridement Procedures on the Skin
11044	Under Debridement Procedures on the Skin
10180	Under Incision and Drainage Procedures on the Skin, Subcutaneous and Accessory Structures
27360	Under Excision Procedures on the Femur (Thigh Region) and Knee Joint
27640	Under Excision Procedures on the Leg (Tibia and Fibula) and Ankle Joint
28120	Under Excision Procedures on the Foot and Toes
28122	Under Excision Procedures on the Foot and Toes

eTable 2. Summary of missing data and methods of imputations.

Covariate	Missing Data (n=11,673)	Imputation Method
Age , n (%)	0 (0%)	NA
Male , n (%)	0 (0%)	NA
Race , n (%)	133 (1.1%)	Polytomous logistic regression
Area Deprivation Index , n (%)	2214 (19.0%)	Predictive mean matching
Mechanism of injury , n (%)	0 (0%)	NA
Injury type , n (%)	0 (0%)	NA
Glasgow Comma Score , n (%)	0 (0%)	NA
Health insurance , n (%)	0 (0%)	NA
Abbreviated Injury Scale		NA
Lower extremity, n (%)	0 (0%)	NA
Upper extremity, n (%)	0 (0%)	NA
Abdominal, n (%)	0 (0%)	NA
Face, n (%)	0 (0%)	NA
Head, n (%)	0 (0%)	NA
Neck, n (%)	0 (0%)	NA
Spine, n (%)	0 (0%)	NA
Chest, n (%)	0 (0%)	NA
Comorbidities		NA
Alcohol dependence, n (%)	0 (0%)	NA
Cancer, n (%)	0 (0%)	NA
Depression, n (%)	0 (0%)	NA
Diabetes, n (%)	0 (0%)	NA
IV drug use, n (%)	0 (0%)	NA
Non-IV drug use, n (%)	0 (0%)	NA
Hypertension, n (%)	0 (0%)	NA
Tobacco use, n (%)	0 (0%)	NA
Fracture location , n (%)	0 (0%)	NA
Open fracture , n (%)	0 (0%)	NA

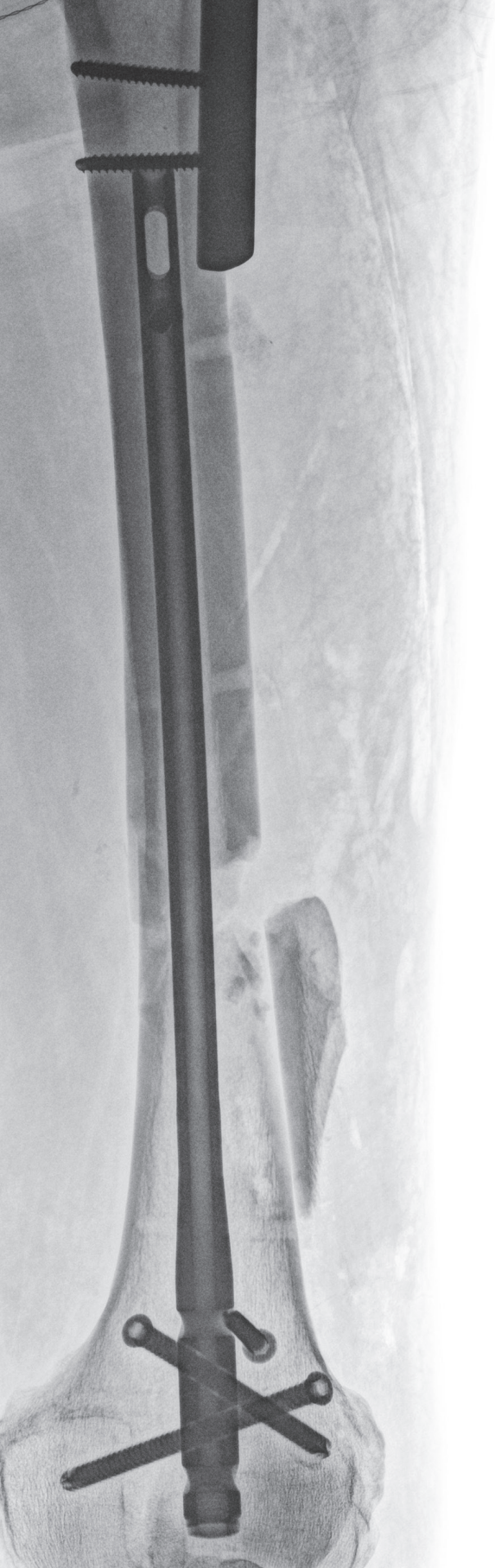
eTable 3. Sensitivity analysis for catastrophic wage loss after a post-operative infection.

Level of Catastrophic Wage Loss	Years Post-Injury	Post-Operative Infection (n=160)	Unexposed Control (n=4597)	Adjusted Mean Difference (95% CI)	P-Value
50%	2 years	46 (28.8%)	833 (18.1%)	6.6% (4.9 to 8.3)	<0.001
	5 years	53 (31.5%)	861 (18.1%)	6.8% (5.1 to 8.6)	<0.001
25%	2 years	68 (42.5%)	1384 (30.1%)	4.3% (2.3 to 6.2)	<0.001
	5 years	70 (41.7%)	1382 (29.1%)	4.4% (2.5 to 6.3)	<0.001
75%	2 years	23 (14.4%)	456 (9.9%)	7.5% (6.1 to 9.0)	<0.001
	5 years	27 (16.1%)	490 (10.3%)	6.4% (5.0 to 7.8)	<0.001

Note: Mean differences were adjusted using inverse probability of treatment weighting.

Section III

Identifying patients;
socioeconomic recovery
priorities





Patients Place More of an Emphasis on Physical Recovery Than Return to Work or Financial Recovery

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ABSTRACT

Background: Value-based healthcare models aim to incentivize healthcare providers to offer interventions that address determinants of health. Understanding patient priorities for physical and socioeconomic recovery after injury can help determine which services and resources are most useful to patients.

Questions/purposes: (1) Do trauma patients consistently identify a specific aspect/domain of recovery as being most important at 6 weeks, 6 months, and 12 months after an injury? (2) Does the relative importance of those domains change within the first year after injury? (3) Are differences in priorities greater between patients than for a given patient over time? (4) Are different recovery priorities associated with identifiable biopsychosocial factors?

Methods: Between June 2018 and December 2018, the study site surgically treated 504 adult patients with fractures of the extremities or pelvis. For this prospective longitudinal study, we purposively sampled patients from six of the 12 orthopaedic attendings' postoperative clinics. The participating surgeons surgically treated 243 adult patients with fractures of the extremities or pelvis. Five percent (11 of 243) of patients met inclusion criteria but missed their appointments during the 6-week recruitment window and could not be consented. We excluded 4% (9) of patients with a traumatic brain injury, 1% (2) of patients with a spinal cord injury, and 5% (12) of non-English-speaking patients (4%, Spanish speaking [10]; 1% other languages [2]). Eighty-six percent of eligible patients (209 of 243) were approached for consent and 5% of those patients (11 of 209) refused to participate. All remaining 198 patients consented and completed the baseline survey, 83% (164 of 198 patients) completed at least 6 months of follow-up, and 68% (134 of 198 patients) completed the 12-month assessment. The study participants' mean age was 44 ± 17 years, and 63% (125 of 198) were men. The primary outcome was the patient's recovery priorities, assessed at 6 weeks, 6 months, and 12 months after fracture using a discrete choice experiment. Discrete choice experiments are a well-established method for eliciting decisional preferences. In this technique, respondents are presented with a series of hypothetical scenarios, described by a set of plausible attributes or outcomes, and asked to select their preferred scenario. We used hierarchical Bayesian modeling to calculate individual-level estimates of the relative importance of physical recovery, work-related recovery, and disability benefits, based on the discrete choice experiment responses. The hierarchical Bayesian model improves upon more commonly used regression techniques by accounting for the observed response patterns of individual patients and the sequence of scenarios presented in the discrete choice experiment when calculating the model estimates. We computed the coefficient of variation for the three recovery domains and compared the between-patient versus within-patient differences using asymptotic tests. Separate prognostic models were fit for each of the study's three recovery domains to assess marginal

changes in the importance of the recovery domain based on patient characteristics and factors that remained constant over the study (such as sex or preinjury work status) and patient characteristics and factors that varied over the study (including current work status or patient-reported health status). We previously published the 6-week results. This paper expands upon the prior publication to evaluate longitudinal changes in patient recovery priorities.

Results: Physical recovery was the respondents' main priority at all three timepoints, representing $60\% \pm 9\%$ of their overall concern. Work-related recovery and access to disability benefits were of secondary importance and were associated with $27\% \pm 6\%$ and $13\% \pm 7\%$ of the patients' concern, respectively. The patients' concern for physical recovery was 6% (95% CrI 4% to 7%) higher at 12 months after fracture than at 6-weeks postfracture. The mean concern for work-related recovery increased by 7% (95% CrI 6% to 8%) from 6 weeks to 6 months after injury. The mean importance of disability benefits increased by 2% (95% CrI 1% to 4%) from 6 weeks to 6 months and remained 2% higher (95% CrI 0% to 3%) at 12 months after the injury. Differences in priorities were greater within a given patient over time than between patients as measured using the coefficient of variation (physical recovery [245% versus 7%; $p < 0.001$], work-related recovery [678% versus 12%; $p < 0.001$], and disability benefits [620% versus 33%; $p < 0.001$]). There was limited evidence that biopsychosocial factors were associated with variation in recovery priorities. Patients' concern for physical recovery was 2% higher for every 10-point increase in their Patient-reported Outcome Measure Information Systems physical health status score (95% CrI 1% to 3%). A 10-point increase in the patient's Patient-reported Outcome Measure Information Systems mental health status score was associated with a 1% increase in concern for work-related recovery (95% CrI 0% to 2%).

Conclusion: Work-related recovery and accessing disability benefits were a secondary concern compared to physical recovery in the 12 months after injury for patients with fractures. However, the importance of work-related recovery was elevated after the subacute phase. Priorities were highly variable within a given patient in the year after injury compared to between-patient differences. Given this variation, orthopaedic surgeons should consider assessing and reassessing the socioeconomic well-being of their patients throughout their continuum of care.

INTRODUCTION

Fractures are associated with physical and socioeconomic impairment, which may be temporary or permanent [2, 7, 22]. This loss of function may result in loss of ability to work, earn an income, or other disruptions to activities of daily living [15, 20, 23, 28]. Clinicians, such as orthopaedic surgeons, focus on physiologic and biologic healing of fractures and emphasize the patient's physical recovery. However, other aspects of recovery, such as return to work and financial security, are often not addressed with such a focus [9, 11, 12, 27].

The economic distress experienced by patients after trauma has been well-documented [2, 20, 22]. Consequently, all states administer some form of workers compensation, and many employers augment this insurance with sick leave programs or unpaid job-protection under the Family and Medical Leave Act [3]. Previous work has demonstrated that social interventions, such as assistance in finding and retaining employment, peer support programs, and stable housing support, can reduce hospital readmissions [1, 12]. However, the availability of social interventions in the clinical environment and access to social welfare vary substantially across health systems and jurisdictions in the United States [18]. In addition, perverse incentives often exist, where highly compensated services are often more readily available than less lucrative but potentially more effective interventions [5, 18]. Without knowing what patients' value most over their continuum of care, the appropriate allocation of services and resources is impossible and efficacious programs will be underutilized.

We, therefore, asked the following in a group of patients who had fracture surgery: (1) Do trauma patients consistently identify a specific aspect/domain of recovery as being most important at 6 weeks, 6 months, and 12 months after injury? (2) Does the relative importance of those domains change within the first year of injury? (3) Are differences in priorities greater between patients than for a given patient over time? (4) Are different recovery priorities associated with identifiable biopsychosocial factors?

PATIENTS AND METHODS

Study Design and Setting

In this prospective study, we assessed patient recovery priorities at 6 weeks, 6 months, and 12 months after fracture. Patient recovery priorities were measured using a discrete choice experiment, a technique pioneered by McFadden in 1974 for which he was awarded the Nobel Memorial Prize in Economic Sciences in 2000 [17]. Discrete choice experiments are a powerful analytic method used to estimate the probability

of individuals making a particular choice from presented alternatives. The technique has served as a valuable tool for designing health policies and health services, such as Medicare Part D [10]. All patients were recruited for participation between June 2018 and November 2018 from a single Level 1 trauma center in Maryland. The 6-week survey data reported in this study have been previously published [21]. The prior publication was considered pilot and feasibility work. The questions posed within this paper were unanswerable with initial data from a single timepoint and required the repeated measures of this longitudinal study. The University of Maryland's institutional review board approved the study. Informed consent was obtained from all patients.

Study Participants

Between June 2018 and November 2018, 504 patients with fractures of the extremities or pelvis underwent surgery at the study site (**Fig. 1**). Given our limited research staff, we purposefully sampled patients from 6 of the 12 orthopaedic attendings' postoperative clinics. Under this restriction, 243 patients met the inclusion criteria. Five percent of patients (11 of 243) met the inclusion criteria but missed their clinical appointments during the 6-week recruitment window and could not be consented. We excluded 9 (4%) patients with a traumatic brain injury, 2 (1%) patients with a spinal cord injury, and 12 (5%) non-English-speaking patients (Spanish speaking, n=10 (4%); other languages, n=2 (1%)). All patients were enrolled after their surgical treatment but within 6 weeks of their fracture and were provided with a USD 20 gift card for each completed study assessment. Of the 209 patients who met the eligibility criteria, 198 patients consented and completed the baseline survey, 83% (164 of 198 patients) completed at least 6 months of follow-up, and 68% (134 of 198 patients) completed the 12-month assessment. One-hundred thirty of 198 patients (66%) completed all three surveys. One patient (1%) consented and completed the baseline assessment but died before completing the 6-month survey. The mean age of the respondents was 44 ± 17 years, 63% (125 of 198) were men, and 37% (74 of 198) were of a racial minority (**Table 1**). Sixty-nine percent of the patients (137 of 198) were employed at the time of injury, and the median annual household income was USD 35,000 (IQR USD 15,000 to USD 57,500). Seventy-five percent (149 of 198) of the respondents had a lower extremity fracture, 9% (18 of 198) of the patients had fractures in more than one anatomical region, and 31% (61 of 198) of the fractures were open. The patients who failed to complete 12 months of follow-up differed from patients who completed 12 months of follow-up in three measured characteristics (**Appendix Table 1**; supplemental materials are available with the online version of *CORR*). Patients who were lost to follow-up differed in their health insurance coverage, most notably in the proportion who were uninsured (22% versus 9%; $p = 0.03$). Male patients were also less likely to complete the 12-month assessment (75% versus 58%; $p = 0.02$). Foot and ankle fracture patients were more likely to complete the 12-months of follow-up (31% versus 17%; $p = 0.05$). Twenty percent (40

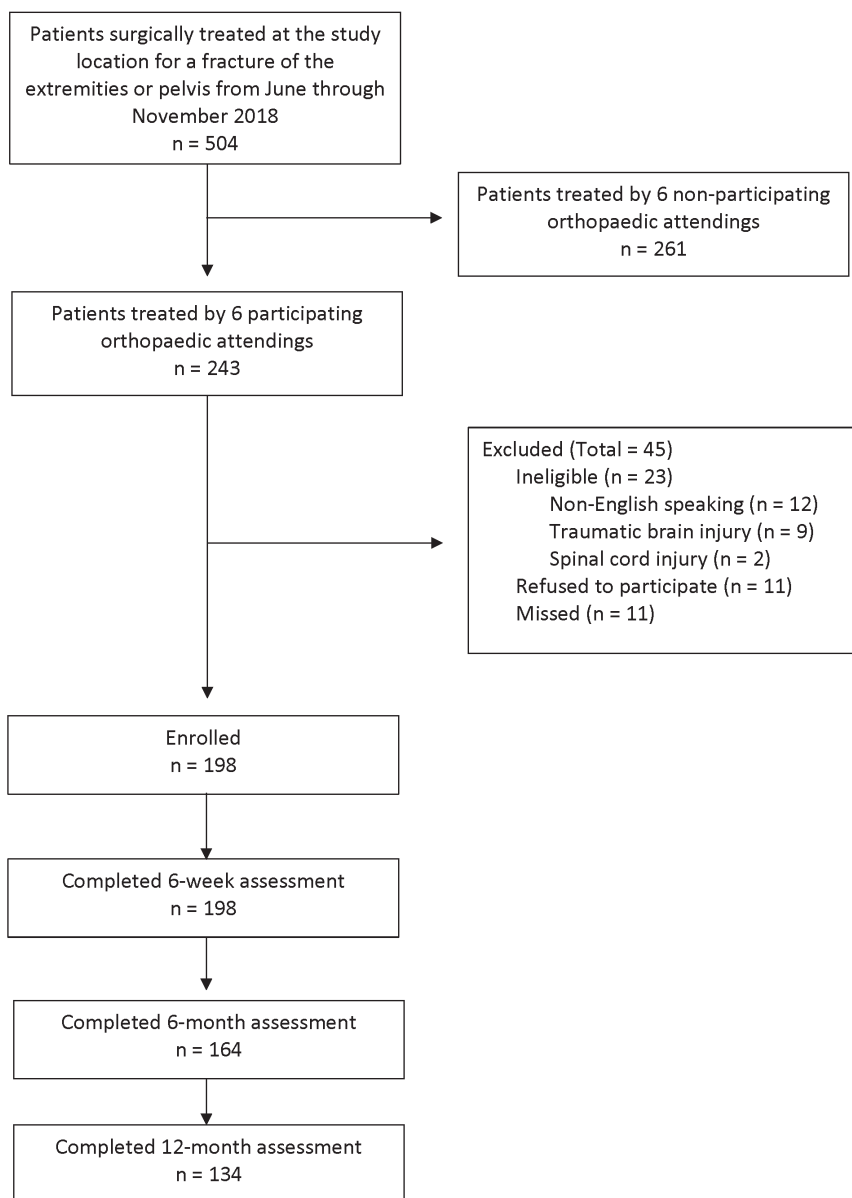


Figure 1. This diagram shows in the patients included in the study, reasons for exclusions, and follow up at 6 week, 6 months, and 12 months after injury.

of 198 patients) had a reoperation or readmission within 1 year of injury (**Table 2**). Of those patients, the median time to the first reoperation or readmission was 150 days (IQR 72 to 233 days). Three percent (5 of 198 patients) had more than one complication. The most common medical complications were a deep surgical site infection (7% [13 of

Table 1. Patient characteristics and associated factors (n = 198).

Patient characteristics and factors	All patients (n=198)
Age in years, mean \pm SD	43.8 \pm 16.7
Men, % (n)	63 (125)
Racial minority, % (n)	37 (74)
Education level, % (n)	
High school or less	48 (94)
Some college or associate's degree	25 (50)
Bachelor's or graduate degree	27 (54)
Dependents, yes, % (n)	36 (71)
Working before injury, % (n)	69 (137)
Employment involving physical labor, % (n)	18 (36)
Annual household income in USD, median (IQR)	35,000 (15,000-57,500)
Area Deprivation Index, median (IQR)	28 (17-46)
Health insurance, % (n)	
Private (employer-based, direct purchase)	42 (83)
Public (Medicare, Medicaid, Tricare)	45 (89)
Uninsured	13 (26)
Fracture location, % (n) ^a	
Foot or ankle	26 (52)
Tibia or femur	49 (97)
Pelvis or acetabulum	11 (22)
Upper extremity	23 (46)
Open fracture, % (n)	31 (61)
Pre-injury PROMIS physical status, median (IQR)	50.3 (42.9-56.0)
Pre-injury PROMIS mental status, median (IQR)	52.7 (47.7-58.2)

^a19 patients had fractures in more than one anatomical regions.
 PROMIS, Patient-Reported Outcome Measurement Information System

198]) and symptomatic hardware removal (6% [12 of 198]). Sixty-five percent (71 of 110) of patients who were working before their injury resumed working in the year after their injury (**Table 3**). These patients were absent from work for a median of 7 months (IQR 5-11). Of those who returned to work, 76% (54 of 71) returned to the same employer, 69% (49 of 71) returned to the same or higher incomes, and 68% (48 of 71) returned to the same duties. At 12 months after injury, 25% of the patients (41 of 164) were unable to work because of their injury, 16% (27 of 164) were searching for employment, and 5% (9 of 164) were on sick leave. Eighteen percent (29 of 164) of the patients received some form of disability compensation. Forty-five percent (74 of 164) of the sample reported accumulating debt because of their injury. The median debt accumulated was USD 6000 and ranged from USD 640 to USD 130,000.

Table 2. Major medical complications resulting in readmission or reoperation (n = 198)

Complication	% (n)	Median time to complication in days (IQR)
All complications ^a	20 (40)	150 (72-233)
Deep surgical site infection	7 (13)	146 (33-195)
Symptomatic hardware removal	6 (12)	235 (146-362)
Nonunion	5 (10)	148 (83-244)
Amputation	2 (3)	83 (4-84)
Conversion to arthroplasty	2 (3)	151 (34-215)
Pulmonary embolism	1 (1)	70
Manipulation under anesthesia	1 (1)	271
Wound dehiscence	1 (1)	20

^aFive patients had more than one major medical complication.

Table 3. Economic impact of injury based on a minimum of 6 months follow-up

Economic outcomes	% (n)
Returned to work, % (n)	65 (71 of 110)
Absenteeism from work in months, median (IQR)	7 (5-11)
Return to same employer, % (n)	76 (54 of 71)
Return to same income or higher income, % (n)	69 (49 of 71)
Return to same duties, % (n)	68 (48 of 71)
Productivity level at the last follow-up visit, ^a median (IQR)	9 (8-10)
Work status at the last follow-up visit, % (n)	
Working	43 (71 of 164)
Unable to work	25 (41 of 164)
Searching or training for work	16 (27 of 164)
Sick leave	5 (9 of 164)
Retired	4 (6 of 164)
Other	6 (10 of 164)
Disability compensation, % (n)	
None	82 (135 of 164)
Disability benefits from employer	5 (9 of 164)
Disability benefits from government	5 (9 of 164)
Workers compensation	4 (7 of 164)
Disability benefits from other sources	2 (4 of 164)
Accumulated debt, % (n)	45 (74 of 164)
Estimated debt from injury in USD, median (range) ^b	6000 (640-130,000)
Debt to income ratio, median (range) ^b	0.18 (0.01-4.0)

^aSubjective assessment on a scale of 1 to 10.

^bIncludes only the 74 participants who incurred debt.

Measured Outcomes and Variables

The primary endpoint was the patients' subjective recovery priorities. The priorities were calculated using a discrete choice experiment and are reported as their importance on a scale of 0% to 100%. Discrete choice experiments are an established method to estimate decisional preferences between two or more discrete alternatives, such as the choice of health insurance coverage options [10, 13, 24, 25]. Using this approach, we created 48 hypothetical comparisons, called choice sets. Each choice set included two potential recovery scenarios described by several attributes. The attributes included whether the patient experienced a complication or had a complication-free physical recovery; whether they would return to work with the same employer, duties, and income; and whether disability benefits were received. We used focus groups and semistructured interviews with clinicians and patients who had experienced one or more fractures to inform the attributes and description of the attributes included in the choice sets. Specifically, we held two focus groups with 14 peer support members of the Trauma Survivors Network. Eight semistructured interviews were performed with three patients, two orthopaedic surgeons, two nurse practitioners, and one registered nurse. The 48 choice sets were based on a blocked orthogonally design that allocated the choice sets into four versions of the survey (12 choice sets per survey) with the goal of optimizing the number of hypothetical comparisons while minimizing each respondent's burden. Having multiple versions of the survey also mitigated any question order bias that may arise with a single survey. We also randomly reordered the choice sets for each subsequent assessment. Each patient was randomly assigned to complete one version of the survey at each study timepoint. When completing the survey, patients were asked to select their preferred outcome for each choice set. If the patient presented to the clinic for a follow-up appointment, the surveys were administered in person. Otherwise, the survey was sent to the patient by email and completed in the Research Electronic Data Capture (REDCap) survey platform (Nashville, TN, USA). All choice sets presented in the surveys are available as supplemental materials available with the online version of *CORR*[®]. Details on the development of the attributes and attribute levels for the study have been described [21].

The study also included several measures of economic well-being and major medical complications resulting in readmission or reoperation. The economic impact of the fracture was measured as days absent from work, return to work, disability compensation, and accumulated debt. The major medical complications included amputation, conversion to arthroplasty, bone healing nonunion, symptomatic hardware removal, manipulation under anesthesia, pulmonary embolism, deep surgical site infection, and wound dehiscence.

We recorded a number of patient characteristics and associated factors at baseline and at each follow-up evaluation as potential factors prognostic of patient recovery priorities. Time-constant covariates included age at the time of injury, sex, race, educational attainment, number of dependents at baseline, work status at the time of injury, and a preinjury occupation that involved physical labor. Time-varying covariates included a major medical complication as previously defined, postinjury debt, work status, a change in residence, and physical and mental health status as measured using the Patient-reported Outcomes Measurement Information System global health item bank [6].

Statistical Analysis

The target sample size for the study was 200 patients. This sample would provide 90% power to detect a 10% difference in the importance of a given recovery priority, assuming at least a 60% response rate at each follow-up visit, an SD of 0.15, three measurements, a correlation between measurements of 0.8, and a two-sided alpha of 0.05. The study sample did not have adequate statistical power to assess the association between biopsychosocial factors and the study outcomes. These comparisons should be considered exploratory.

Patient characteristics, economic outcomes, and medical complications are described using proportions with counts for categorical data and medians with IQRs or ranges for continuous data. We compared the characteristics of patients who completed the full follow-up with those who did not using χ^2 tests for categorical data, t-tests for normally distributed continuous data, and Wilcoxon rank sums test for non-normal continuous data. We used hierarchical Bayesian modeling to calculate individual-level estimates of the importance of physical recovery, work-related recovery, and disability benefits, based on the discrete choice experiment responses. Bayesian models differ from the more commonly used frequentist models by using prior probabilities and updating those probabilities with the observations from the study data to calculate effect estimates, known as posterior probabilities. Our particular models were hierarchical versions of this approach. For this study, the hierarchical, also called multilevel, models clustered responses by each study participants and version of the survey, incorporating the information gained from each previous question in the survey and previous surveys administered to a given respondent to form prior probabilities, thus deriving more precise estimates of patient priorities. Three models were initially created for three different aspects of work-related recovery (employer, duties, and income). The model that included income, along with clinical recovery and access to disability benefits, provided the best model fit, based on the average log-likelihood function across the three timepoints, and was used for the final analysis. We computed the coefficient of variation for the three recovery domains and compared between-patient and within-

patient differences using asymptotic tests. The coefficient of variation is a unitless measure of dispersion calculated by dividing the SD of a sample by the mean. The change in the importance of recovery domains across the study timepoints were estimated using hierarchical Bayesian models to account for the correlation between repeated responses from a single patient. We developed a separate prognostic model for each of the study's three recovery domains. All models assessed marginal changes in the importance of the recovery domain based on biopsychosocial factors that remained constant over the study period (for example, sex or pre-injury work status) and biopsychosocial factors that varied over the study period (such as, work status or physical and mental health status). We used weak priors for all Bayesian models with 1000 warmup iterations, four Markov chains, and 10,000 iterations per chain. We report all estimates as the absolute mean difference with 95% credible intervals (CrI).

The discrete choice experiment surveys were developed, and the responses were modeled, using JMP version 14 (Cary, NC, USA). All other statistical analyses were performed with R version 4.0.0 (Vienna, Austria). Missing Patient-reported Outcomes Measurement Information System assessment data at 6- and 12-months were imputed using multiple imputations [4]. Missing response data were assumed to be missing at random.

RESULTS

Do Trauma Patients Consistently Identify a Specific Aspect/Domain of Recovery as Being Most Important at 6 Weeks, 6 Months, and 12 Months after Injury?

Trauma patients consistently identified physical recovery as the most important domain of recovery. The typical patient reported that physical recovery represented $60\% \pm 9\%$ of their overall concern across the three study timepoints (**Fig. 2**). Work-related recovery was consistently the second most important recovery domain at 6 weeks, 6 months, and 12 months after injury, and represented $27\% \pm 6\%$ of their overall concern. Access to disability benefits remained the least important among the included recovery domains and was associated with $13\% \pm 7\%$ of the overall concern within a year of injury.

Does the Relative Importance of Those Domains Change Within the First Year?

The relative importance of each domain changed within the first year after injury, but the overall hierarchy of the domains did not change at any timepoint (**Table 4**). The mean concern for physical recovery remained similar from 6 weeks to 6 months after injury but increased by 6% (95% CrI, 4% to 7%) at 12 months after fracture compared

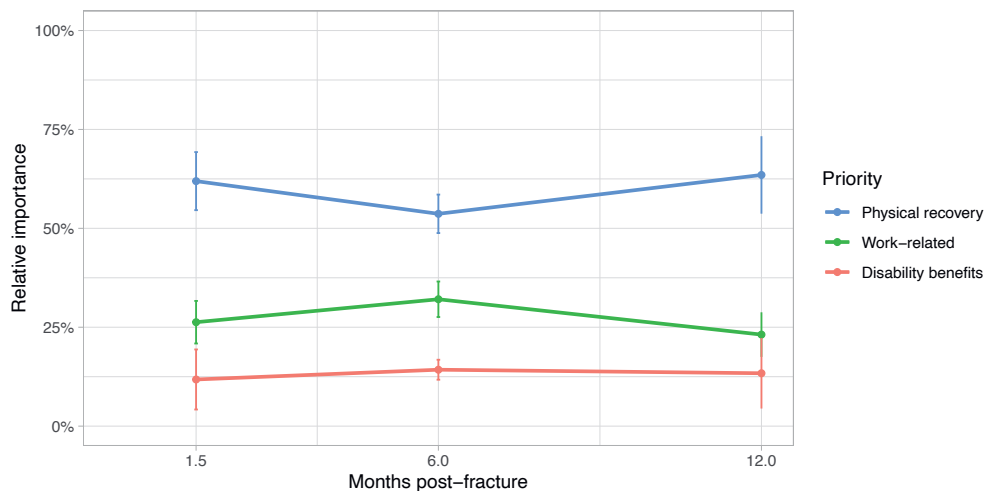


Figure 2. This graph shows crude estimates of the importance of recovery priorities after fractures.

Table 4. Change in the relative importance of recovery domains across study timepoints using hierarchical Bayesian models.

Domain	Time	Absolute difference (95% CI)
Physical recovery	6 weeks	Ref (0.0)
	6 months	0.1% (0.0-0.3)
	12 months	5.8% (4.4-7.2)
Work-related recovery	6 weeks	Ref (0.0)
	6 months	7.4% (6.4-8.4)
	12 months	0.1% (0.0-0.3)
Disability benefits	6 weeks	Ref (0.0)
	6 months	2.4% (1.2-3.8)
	12 months	1.7% (0.4-2.9)

with the 6-week estimates. The mean concern for work-related recovery increased by 7% (95% CrI, 6% to 8%) from 6 weeks to 6 months after injury. However, the prioritization of work-related recovery at 12 months after injury was similar to 6-week estimates (0% [95% CrI 0% to 0%]). The mean importance of disability benefits increased by 2% (95% CrI 1% to 4%) at 6 months and by 2% (95% CrI 0% to 3%) at 12 months compared with 6-week estimates.

Are Differences in Priorities Greater Between Patients Than for a Given Patient Over Time?

Differences in priorities were greater within a given patient over time than between patients. The within-patient variation, as measured by the coefficient of variation, was greater than the between-patient variation for physical recovery (245% versus 7%; $p < 0.001$), work-related recovery (678% versus 12%; $p < 0.001$), and disability benefits (620% versus 33%; $p < 0.001$).

Are Different Recovery Priorities Associated with Identifiable Biopsychosocial Factors?

We found limited evidence that biopsychosocial factors were associated with variations in recovery priorities (Fig. 3). A 10-point increase in Patient-reported Outcomes Measurement Information System physical health status score was associated with a 2% increase (95% CrI 1% to 3%) in the importance of physical recovery. A higher Patient-reported Outcomes Measurement Information System mental health status score (1% per 10 points; 95% CrI 0% to 2%) was associated with an increased prioritization of work-related recovery.

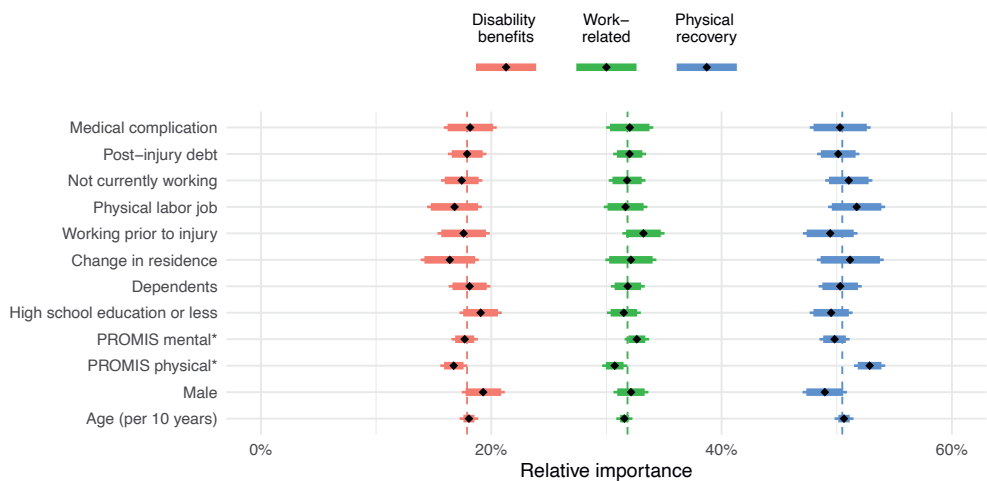


Figure 3. This graph shows heterogeneity in the importance of fracture recovery priorities associated with biopsychosocial factors.

DISCUSSION

Value-based payment models aim to incentivize healthcare providers to offer services and resources that address the socioeconomic determinants impacting health outcomes. However, it is impossible to align services and resources for optimal use without first establishing patients' priorities for physical, work-related, and financial recovery. The findings of this study substantially expand upon our prior publication providing clinicians, policy makers, and the research community a nuanced understanding of the variation in patients' recovery priorities within one-year of injury [21]. We observed the patients' concern for physical recovery exceeds their concern for work-related recovery and access to disability benefits in the year after injury. Patients' concern for work-related recovery was heightened 6 months after injury but did not displace physical recovery as the patients' paramount concern. Patient recovery priorities varied more within a given patient over the study duration than between patients. We were unable to identify biopsychosocial factors that meaningfully predicted patient recovery priorities.

Limitations

This study has several limitations. Discrete choice experiments measure stated preferences, which may differ from revealed preferences. Patient comprehension of a survey is always a concern. To mitigate comprehension issues, all patients completed their first survey in the presence of a research staff member, who was available to answer questions during the survey and assess the respondent's understanding after completing the initial survey. In addition, patients completed the survey at three distinct timepoints, improving their familiarity with the discrete choice experiment structure. Many other recovery domains were not included in the discrete choice experiment. However, we believe we included the most relevant priorities because our selection process was informed by focus groups and semistructured interviews with clinicians and patients that sustained a fracture [21]. Although the recovery priorities may be correlated [29], the discrete choice experiment is an effective method to disentangle the independent effects of correlated outcomes.

The study setting and eligibility criteria may limit the generalizability of the findings. The study was conducted at a single level 1 trauma center. We only included patients who underwent surgery, and patients with spinal cord or traumatic brain injuries were excluded. Therefore, our results may not generalize to fracture patients treated without surgery, those treated at a community hospital, or those with spinal cord or brain injuries. The respondents' priorities may also be influenced by the socioeconomic situation and social welfare policies in Maryland, thus limiting the findings' generalizability to other jurisdictions. The survey's English-speaking requirement excluded 5% of the eligible

patients. The socioeconomic circumstances and priorities of non-English speaking patients may differ from the patients included in the study.

As 32% of the enrolled patients failed to complete their 12-month survey, attrition bias is a concern. Although this attrition level is far from ideal, it exceeds the 60% survey response rate threshold established in prior literature [14]. The minimal differences in baseline characteristics between patients who responded at 12-months to those who did not complete their 12-month survey suggest the effects of this bias may be minimal. Further, our estimates were derived using hierarchical Bayesian models. One advantage of this type of model is that it treats missing response values as unique parameters and uses the distributions of the observed responses to form posterior estimates for the full sample conditioned these missing values.

Do Trauma Patients Consistently Identify a Specific Aspect/domain of Recovery as Being Most Important at 6 Weeks, 6 Months, and 12 Months after Injury?

Patients with trauma consistently identified physical recovery as the most important domain of recovery at all three timepoints. The observed hierarchy of priorities is consistent with prior research [26, 29] and may be explained by prospect theory [8]. Developed by Kahneman and Tversky [8], prospect theory posits that individuals place greater importance on losses than on a comparable gain. The common shared experience among the cohort was a traumatic injury. The loss of physical function was immediate, profound, and for many patients, persisted for months, if not longer. More than 30% of the sample were not working before their injury, and a lack of workforce participation would understandably decrease one's concerns for work-related recovery.

Does the Relative Importance of Those Domains Change Within the First Year?

The relative importance of each domain remained constant throughout the study, but the importance of work-related recovery and disability benefits increased slightly at the 6- and 12-month timepoints. The trend of an increase concern for socioeconomic well-being after injury was consistent with research by Zatzick et al. [29]. The Family and Medical Leave Act covers most employees in Maryland with 12 weeks of unpaid job protection [3]. The 12 weeks of job protection prevent job loss for many patients and may reduce the prioritization of work-related recovery within 6 weeks after an injury. Work incapacity that exceeds 12 weeks likely increases the patient's concern for work-related recovery and disability benefits. Due to delays in hospital billing, the patient may also not be fully aware of the financial implications of their injury at the 6-week survey.

Are Differences in Priorities Greater Between Patients Than for a Given Patient Over Time?

The time from injury was associated with more substantial variation in patient recovery priorities for a given patient than the observed variability between patients. Two studies have evaluated patient recovery priorities at a single timepoint [7, 26]. Few studies assessed the stability of preferences over some duration using repeated assessment of the same individuals [19, 29]. To our knowledge, only one study has compared within-person versus between-person preferences over time [19]. Although the study population was very different, a comparable pattern was observed. Mueller et al. [19] found fertility preferences to be unstable within individuals over time but consistent between individuals of similar ages.

Are Different Recovery Priorities Associated with Identifiable Biopsychosocial Factors?

We found little evidence to associate biopsychosocial factors with variations in recovery priorities. Prior research suggests that patients lacking preinjury employment and with lower education levels have increased socioeconomic hardship after injury [7, 16]. Although our point estimates are consistent with these studies, our estimated effects are close to null and the overall hierarchy of priorities remain unchanged. Of note, a major medical complication leading to readmissions or reoperations was not associated with variation in recovery priorities. Our review of the patients' medical records highlights the limitations of a medical complication to serve as a proxy for physical recovery challenges. A patient may be free of a major medical complication but experience dramatic physical disruptions. Patients often have pain, superficial wound complications, or bone healing challenges that inhibit activities of daily living but do not lead to readmission or reoperation. Factors, such as comorbidities and injury severity, were not included in the study and may influence patient recovery priorities. Finally, there may be other external policy factors that influence recovery priorities but were not explicitly captured in the analysis, such as labor market conditions and access to social insurance.

CONCLUSION

Physical recovery remained the primary recovery concern for patients with fractures during the 12 months after injury. However, the importance of work-related recovery and disability benefits was elevated after the subacute phase of injury. We were unable to identify patient characteristics that clearly predicted recovery priorities but did observe greater variation in recovery priorities within a given patient than between patients. As such, clinicians should routinely assess and reassess the socioeconomic

well-being of all trauma patients. A clear understanding of patient recovery priorities can align available social interventions and resources with the patient's preferences and social circumstances. However, determining which social interventions and resources are most effective in mitigating the socioeconomic effects of injury and improving health outcomes requires further research. Future studies should also investigate the factors associated with within-patient variation in priorities.

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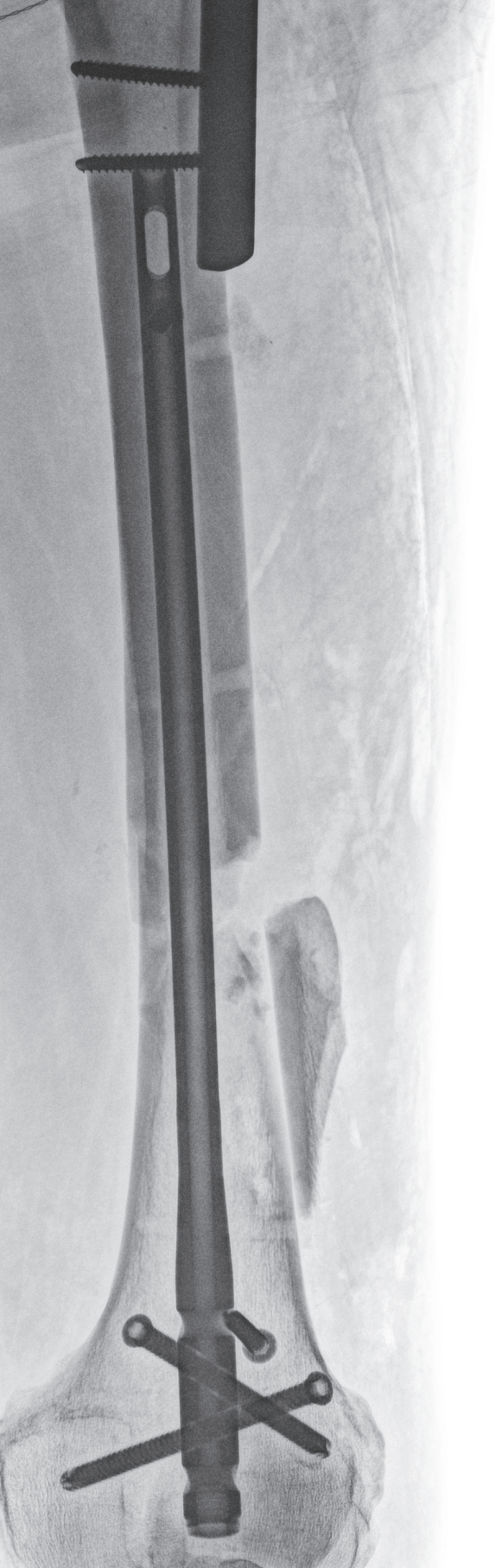
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Appendix Table. Patient characteristics of those that completed 12-month follow up (n=134) compared to patients that did not complete 12-month follow up (n=64)

Patient Characteristic	Enrolled (n=198)	Completed 12-Month Follow Up (n=134)	Did Not Complete 12-Month Follow Up (n=64)	P-Value
Age, y, mean (SD)	43.8 (16.7)	44.5 (15.9)	42.2 (18.4)	0.38
Sex, male, % (n)	63 (125)	58 (77)	75 (48)	0.02
Racial minority, % (n)	37 (74)	34 (45)	45 (29)	0.11
Education, % (n)				
High school or less	48 (94)	44 (59)	55 (35)	0.34
Some college or Associate's degree	25 (50)	28 (37)	20 (13)	
Bachelor or Graduate degree	27 (54)	28 (38)	25 (15)	
Dependents, yes, % (n)	36 (71)	38 (51)	31 (20)	0.35
Working prior to injury, % (n)	69 (137)	71 (95)	66 (42)	0.45
Physical labor employment, % (n)	18 (36)	16 (21)	23 (15)	0.19
Annual household income, median (IQR)	\$35,000 (\$15,000 - \$57,500)	\$35,000 (\$22,500 - \$65,000)	\$35,000 (\$15,000 - \$55,000)	0.41
Area Deprivation Index, median (IQR)	28 (17 - 46)	28 (17 - 47)	28 (16 - 44)	0.85
Health insurance, % (n)				
Private (Employer- based, Direct purchase)	42 (83)	46 (62)	33 (21)	0.03
Public (Medicare, Medicaid, Tricare)	45 (89)	45 (60)	45 (29)	
Uninsured	13 (26)	9 (12)	22 (14)	
Fracture location, % (n)				
Foot or ankle	26 (52)	31 (41)	17 (11)	0.045
Tibia or femur	49 (97)	47 (63)	53 (34)	0.42
Pelvis or acetabulum	11 (22)	12 (16)	9 (6)	0.59
Upper extremity	23 (46)	23 (31)	23 (15)	0.96
Open fracture, % (n)	31 (61)	31 (42)	30 (19)	0.81
Pre-Injury, Physical Status, median (IQR)	50.3 (42.9 - 56.0)	50.3 (44.3 - 56.0)	49.2 (41.0 - 63.3)	0.46
Pre-Injury Mental Status, median (IQR)	52.7 (47.7 - 58.2)	52.7 (47.7 - 58.2)	52.7 (44.1 - 58.2)	0.24

Note: Categorical data were compared using Pearson's χ^2 test. Normally distributed continuous data were compared using t-tests. Non-normal continuous data were compared using Wilcoxon rank sums tests.



General Discussion

MAIN FINDINGS

The overarching objective of this thesis was to advance the evidence on the socioeconomic impact of orthopaedic trauma. The thesis endeavored to achieve this objective through three specific aims. The aims were: 1) to describe and evaluate the currently available options for measuring socioeconomic outcomes after orthopaedic injury; 2) to estimate the socioeconomic effects of fractures in three countries with unique healthcare and social welfare systems; and 3) to identify the socioeconomic recovery priorities of fracture patients.

Section I – Measuring Socioeconomic Outcomes

Socioeconomic outcomes are important to orthopaedic trauma patients and providers.^{1,2} In this section, we determined what socioeconomic measures are most commonly used in fracture research.³ We calculated pooled estimates of those socioeconomic outcomes across the prior literature. Using a narrative review,⁴ we commented on the adoption of the PROMIS architecture for measuring outcomes in orthopaedic trauma. Finally, we surveyed over 200 patients to calculate patient-centered weights for common orthopaedic outcomes.⁵

Our systematic review and meta-analysis (**Chapter 1**) included 205 studies.³ *Return to work* (n=119) and *absenteeism days from work* (n=104) were the most frequently used socioeconomic measures. Most of the included studies had less than two years of follow-up, and less than 20% of the studies utilized administrative databases. Four of the 205 studies employed a multifaceted approach to measuring socioeconomic effects. The meta-analysis findings suggest that 33% of fracture patients have not returned to work 12 months after injury, and patients were absent from work for a mean of 102 days.

We described the architecture and uptake of Patient-Reported Outcomes Measurement Information System (PROMIS) items in fracture research (**Chapter 2**).⁴ There are several aspects of the PROMIS instruments, including item-response theory, computerized adaptive testing options, and the T-score scale, which provide psychometric improvements over other commonly reported patient-reported outcome measures. However, our narrative review identified that only 2% of the fracture studies that used patient-reported outcomes measures and were published between 2014 through 2018 in five of the leading orthopaedic journals used a PROMIS instrument. We surmised that a limited familiarity of PROMIS measures among the orthopaedic community and comparability challenges with legacy instruments led to the under-utilization of the PROMIS items despite their architectural advantages.

Our study described in **Chapter 3** administered a best-worst scaling choice experiment to 396 patients who underwent surgical treatment for a fracture.⁵ The study aimed to assess the feasibility of using patient preferences to weight composite endpoints. The study revealed that the hierarchy of potential outcomes was consistent across patients. We suggest several options for weighting the components of a composite endpoint based on the relative importance of the outcomes to patients.

Section II – Estimating Socioeconomic Effects

We estimated the socioeconomic effects of fractures in Uganda,⁶ Canada,⁷ and the United States,⁸ and post-fracture complications in the United States.⁹ Patients were prospectively enrolled in Uganda. The research in Canada and the United States linked administrative data. Prior research on the socioeconomic effects of orthopaedic injuries is limited, particularly in low-income countries. The studies from Canada and the United States represent some of the most extensive socioeconomic studies in fracture patients to date.

By linking province-wide hospitalization data from the Canadian province of British Columbia with national census data, we estimated the effect of a hip fracture on the household incomes of patients aged 18 to 50 years (**Chapter 4**). The study included 391 patients with a median age of 43 years, and 62% were male. The patients' median household income at the time of injury was CDN 46,600, which was approximately CDN 6000 less than the provincial median. Twenty-seven percent of the cohort sustained a two or more decile drop in income within two-years of injury. A pre-injury household income in the upper deciles was associated with a 40% increase in the risk of significant income decline compared to patients with pre-injury incomes in deciles three through five.

Our study in Uganda enrolled a prospective cohort of 57 patients admitted to the national referral hospital with an isolated tibia or femur fracture caused by a road traffic injury (**Chapter 5**). The majority of the patients were employed (83%) and the primary income earner for their household (74%) at the time of injury. The mean annual income at the time of injury was USD 2375. Two years after injury, only 63% of the patients had returned to work, and the mean monthly incomes had declined by 62% compared to pre-injury earning. Among those who returned to work, the mean time out of the workforce was 12 months. Patients accumulated an average of USD 1069 in debt over the 24-months post-injury. At the time of injury, patients had a median of four dependents attending school. Two years after the injury, 38% of the dependents in school prior to the injury were no longer in school due to the financial hardships.

To determine the financial implications of an orthopaedic injury in the United States, we linked 14 years of hospital data with tax records in the state of Maryland (**Chapter 6**). Using 166,933 person-years of state tax records, we used a difference-in-difference model to estimate that a fracture reduced annual individual incomes by USD 9865 and annual household incomes by USD 5259 in the five years post-injury. Fractures were associated with a 10% increase in the risk of catastrophic income loss, defined as a 50% decline in wages in the two years after injury compared to mean earnings in the two years before the injury. The gains in social security benefits attributable to the fracture failed to account for less than 10% of the lost income.

Using the linked hospital and United States tax records, we aimed to characterize the association between a post-fracture infection and long-term patient income (**Chapter 7**). Of the 11,673 fracture patients included in the study, 403 (3.5%) had a post-fracture infection. We used inverse-probability weighted random-effects models to estimate that post-fracture infections reduced annual household incomes by USD 6080 compared to uninfected fracture patients in the six-years post-injury. Post-fracture infections increase the risk of catastrophic wage loss by 7% and the odds of receiving social security benefits by 45%. However, post-fracture infections were not associated with an increase in the value of the social security benefits received, thus failing to offset lost earnings.

Section III – Identifying Patients’ Socioeconomic Recovery Priorities

The widespread adoption of value-based healthcare encourages health providers to apply more holistic therapeutic services. Social interventions, including peer support programs, employment assistance services, and housing support, may effectively mitigate the socioeconomic consequences of injury.^{10,11} A clearer understanding of patient recovery concerns may optimize the design of programs and services aimed to improve socioeconomic well-being after injury. We enrolled 198 adult fracture patients from a single trauma hospital in the United States to ascertain patient priorities for physical and socioeconomic recovery at six weeks, six months, and 12 months post-injury (**Chapter 8**).¹² Fracture patients consistently identified physical recovery as the most important domain of recovery at all three time points. Work-related recovery and access to disability benefits were given significantly less priority. Although, the relative importance of work-related recovery did increase at the six-month assessment. Within-patients variation was substantially greater than the observed differences between patients.

METHODOLOGICAL REFLECTIONS

Section I – Measuring Socioeconomic Outcomes Through Novel Approaches

The systematic review and meta-analyses (**Chapter 1**) had robust internal and external validity.³ The study was pre-registered in PROSPERO, and the methods adhered to the PRISMA guidelines.¹³ The review included 205 studies from six continents, and nearly half were published after 2010. The heterogeneity of the pooled study results was accounted for using random effect models. The strength of the findings was limited by the high proportion of low-quality studies included in the study.

Our narrative review (**Chapter 2**) provides a contemporary evaluation of PROMIS in fracture research.⁴ The literature search was performed in tandem and identified articles in five high-impact orthopaedic journals. The findings reflect the current utilization of PROMIS measures for fracture research. However, this topic is evolving, and our conclusions regarding the utilization of PROMIS in orthopaedic trauma research may not persist five or ten years in the future.

Our study to develop a patient-centered composite outcome weighting technique had a number of methodological strengths (**Chapter 3**).⁵ We used the best-worst scaling method – a well-validated technique for eliciting patient preferences. The weights were derived through a survey of nearly 400 orthopaedic trauma patients, and precise estimates of the weights were calculated using hierarchical Bayesian models. The study presented several options for applying the technique to analyze trial outcomes. An example of this application on a recent trial has already been published.¹⁴ Despite these strengths, the study was performed at a single center, and the derived weights may not generalize to other centers. The study was specifically designed for fracture patients, but the approach could be expanded to other health conditions.

Section II – Estimating Socioeconomic Effects with Primary and Administrative Data

All four studies in Section II reported a substantial and sustained economic loss after a fracture.^{6–9} The eligibility criteria and definition of outcomes differed between the studies, limiting a direct comparison of effects.

The Canadian study (**Chapter 4**) included a province-wide sample and data spanning seven years. However, we had limited data on the characteristics of the included patients, which constrained our inferences and evaluation of variation in effects. Further, the primary outcome of income was reported as income deciles and, therefore, lacked the optimal granularity for more precise estimates of income changes.

The study in Uganda (**Chapter 5**) prospectively enrolled a cohort of patients with isolated fractures of the tibia and femur. Patients were followed for two years post-injury with 95% follow up. The study's prospective design allowed us to collect very detailed sociodemographic information from the patients at the time of injury, and at six-months, 12-months, and 24-months after injury. We also conducted in-depth qualitative interviews with thirty-five of the patients during their initial hospital admission to gain further context for the primary study.¹⁵ Despite these strengths, our sample was small, with only 57 patients. The research was performed at a single center, Mulago Hospital. Mulago Hospital is the national-referral hospital serving the country of over 40 million people, and our sample did include patients from most regions of the country. However, the majority of the patients lived in the greater Kampala area, and their pre-injury economic conditions may not be representative of the entire country.

The two United States-based studies (**Chapters 6 and 7**) benefited from unique access to state tax records. Few prior studies have managed to link United States tax records to health data.¹⁶ The use of tax data allowed for precise longitudinal estimates of patient income. Patient income was reported as household income, individual income, social security benefits, and unemployment insurance. The studies also utilized two causal inferences techniques – difference-in-differences (**Chapter 6**) and inverse probability of treatment weighting (**Chapter 7**). The primary exposure in Chapter 7 was a post-operative infection, and the diagnosis was confirmed by a medical record review by a certified infection preventionist.

The two United States-based studies shared several common limitations. The patient hospital records were obtained from a single trauma center. Although the trauma center is the state-mandated primary trauma center, and the samples included referral patients from over 100 hospitals, the generalizability to other hospitals and other states may be limited. In addition, we observed inconsistency in the tax filings among the included patients. This inconsistency in tax filing on adults in the United States has been previously reported and is more common in adults with incomes less than USD 20,000.¹⁷ We followed methods used by Chetty et al and recoded non-filer incomes to zero to address this limitation.^{16,18,19}

The studies from the United States and Canada highlight the advantages of linking large administrative databases. In the private sector, it is common for companies to use large datasets to improve products and services. Privacy regulations often inhibit researcher access to health, employment, and income data from public entities. However, these data provide a tremendously valuable and cost-effective approach to obtaining precise estimates of the socioeconomic effects of health conditions. The panel structure of many of these data enables a longitudinal assessment and the ability to evaluate

variation in effects based on time-constant or time-varying covariates. Among the three countries, Canada has the most advanced data infrastructure and central agencies to facilitate data access and data linkage. As the research questions in this section cannot be answered through experimentation, analyzing variations within these administrative data through causal inference and quasi-experimental designs present the next best alternative.

The study settings likely influence the socioeconomic effect estimates presented in Section II. Health insurance and other forms of social insurance can protect against catastrophic income loss after a sudden health event.^{20–22} The coverage for health and work incapacity insurance varies greatly between the three study locations and limits the transportability of these estimates to other settings.^{23,24} Except for the Uganda study, we did not have measures of education and pre-injury occupation available for analyses. Prior research suggests education and occupation affect post-hospitalization incomes.²⁵ However, we were unable to investigate these differences in our larger sample studies.

Section III – Identifying Patients’ Socioeconomic Recovery Priorities Using a Longitudinal Discrete Choice Experiment

We used a discrete choice experiment to identify patients’ socioeconomic recovery priorities at six weeks, six months, and 12 months after injury (**Chapter 8**). Discrete choice experiments are a robust quantitative technique to elicit preferred outcomes when presented with several plausible alternatives.^{26–29} There are likely other patient recovery priorities that were not included in the study. However, we used a series of focus groups and semi-structured interviews with patients and clinicians to define and describe the included priorities. The repeated measurement of preferences is unique and enabled us to evaluate between- and within-patient variation in priorities over the 12 months after injury.

A secondary objective of the study was to evaluate variation in patient recovery priorities based on time-constant and time-dependent patient characteristics. With 198 respondents, our sample had limited power for these analyses, and our estimates should be considered exploratory. However, we did use hierarchical Bayesian models to derive the estimates, which reduces the likelihood of overestimating treatment effects.

The Bayesian models were also advantageous for modeling missing response data. Only 68% of respondents completed the 12-month follow up. The hierarchical Bayesian models treat missing response values as unique parameters and utilizes the distributions of the observed responses to form posterior estimates for the full sample conditioned on these missing values.

Several aspects of the study design limit the generalizability of the findings. The study was performed at a single Level 1 trauma center in Maryland. Patients admitted for treatment in other jurisdictions or other hospitals may vary in their recovery priorities. In addition, we only included patients who underwent surgical treatment of their fracture. Patients with fractures treated non-operatively may have different recovery concerns.

IMPLICATIONS FOR POLICY AND PRACTICE

Section I – Measuring Socioeconomic Outcomes with Repeated Multidimensional Item Banks

Studies within this section confirm that socioeconomic measurement in fracture research is primarily limited to *return to work* and *days absent from work* outcomes.³ Most studies use a single-item measurement. However, as indicated throughout the thesis, socioeconomic effects are multi-dimensional, and the accurate quantification of effects requires multi-item measures.

There is an opportunity to develop standardized multi-item socioeconomic measurement sets. Novel measurements should utilize modern survey architecture, such as the item-response theory and computerized adaptive testing techniques used by the Patient-Reported Outcome Measurement Information System (PROMIS).³⁰ In addition to the psychometric benefits of these architectural attributes, incorporating these advantages improves the integrability of measures into electronic health records for routine clinical capture and feedback to patients and clinicians.

There are several benefits to including socioeconomic outcomes with routinely measured functional outcomes. Clinicians can use the pooled data to set realistic socioeconomic expectations for their patients. The data would also be invaluable to researchers as we continue to explore the longitudinal correlations between functional outcomes and socioeconomic outcomes.

The section also suggests opportunities to weigh patient outcomes used in clinical research based on patient preferences. These analytic options would allow for repeated, time-varying components within a single analysis of effects. Further, the developed technique can be integrated into a socioeconomic composite score – weighted based on pre-injury socioeconomic conditions.

Section II – Estimating Socioeconomic Effects and Policies to Protect Against Income Loss

Section II provides evidence that a significant proportion of fracture patients will face persistent socioeconomic impairment after injury. A post-operative infection further increases the magnitude of impairment. The proportion of patients who suffer substantial economic loss after a fracture appears to vary by country. The socioeconomic effects of a fracture are clearly the most substantial in Uganda, where 66% of isolated tibia or femur fracture patients suffer catastrophic income loss within two years of injury.⁶ The comparison between the United States and Canada is less clear. Sixteen percent of Canadian non-elderly patients with hip fracture had a two decile decline in income within two years of injury.⁷ Hip fractures are rare in non-elderly patients, and we expect the physical impairment of this type of fracture to be very debilitating.^{31–33} The inclusion criteria for our United States' studies were much broader.^{8,9} Both studies included adult patients with surgically treated fractures of the extremities, including hand fractures, and the pelvis. With these broad inclusion criteria, the data suggests that 12% of all adult fracture patients in Maryland sustain catastrophic income loss within two-years of injury. Our definition of catastrophic income loss was a 50% or more decline in income in the two years after injury compared to the average income in the two years prior to injury. The proportion of fracture patients that face catastrophic income loss, increased by an additional 7% after a surgical site infection.

To transpose the definition of catastrophic income loss used in the United States' studies to the Canadian data, most Canadian patients would have to decline four deciles in their incomes. Patients with pre-injury incomes in the top decile would only have to decline one decile for catastrophic income loss. Patients with a pre-injury income in the lowest fourth and third decile would have to decline two deciles, the second lowest would only need to decrease one decile, and the lowest decile earners cannot reduce further. This suggests the socioeconomic effects of a fracture are greater in the United States than in Canada.

Our findings on the magnitude and duration of income loss after a fracture are consistent with prior research. Dobkin et al estimated that hospitalization in California was associated with a USD 9000 loss in annual income that persisted for five years.²⁵ Our Maryland data estimated a USD 9865 income loss that was sustained for at least five years. Similarly, Charles reported that job loss due to physical impairment had long-term effects.³⁴ Both our United States and Canadian data support Charles' conclusion. Our Uganda data was limited to two years, but there was no indication of socioeconomic improvement for patients at two years post-injury once they had sustained catastrophic income loss. Meara et al (2015) estimated that, globally, one-quarter of fracture patients sustain catastrophic income loss due to injury.³⁵ Our results suggest American

and Canadian patients face a lower risk of considerable income loss. The risk borne by Ugandan patients is almost three times higher than the Meara et al estimate.

Some of the differences in the socioeconomic outcomes of fracture patients between the three countries are likely attributable to the overall wealth of the nations. The Uganda health care system is heavily under-funded and spends only USD 121 per citizen on healthcare.³⁶ The lack of resources in the healthcare system inhibits timely access to appropriate surgical treatments. Orthopaedic surgery requires substantial infrastructure and disposables.³⁷ The scarcity of both components of care in Uganda likely affects patients' socioeconomic outcomes in Uganda.³⁸ The socioeconomic consequences of injury are less likely due to access to the initial treatments in the United States and Canada. All Canadians have access to fracture care and clinical follow up services through the country's universal health coverage. United States hospitals are required to treat all patients regardless of health insurance coverage under the Emergency Medical Treatment and Active Labor Act.³⁹ However, access to post-treatment care in the United States requires some form of insurance coverage or out-of-pocket expenditure.

One of the main benefits of health insurance is the protection it provides its beneficiaries from catastrophic health expenditures.²⁰⁻²² In the Oregon Health Experiment, the state's Medicaid health insurance expansion was randomly allocated.²⁰ While the study's evaluation of the experimental effects of health insurance expansion found no improvement in short-term health outcomes, gaining health insurance reduced out-of-pocket spending, bankruptcies, and collections.^{20,40} The expansion of health insurance coverage in the United States may not be welcomed by United States-based trauma hospitals. Although these hospitals are required by law to treat all emergencies regardless of the patient's insurance status, the hospitals are commonly reimbursed for these treatments from state funds that pay a higher rate for the services than most public and private insurers.⁴¹

The majority of Americans receive their health insurance through private employer-based plans.⁴² This arrangement produces a number of negative effects. If the fracture patients lose their job after the injury, individuals do have the option to maintain their coverage but would have to pay the premium personally. Most newly unemployed Americans cannot afford the premiums after job loss and lose their health insurance while recovering from their injury.⁴³

Uganda does have a national health insurance scheme, but its coverage is limited.⁴⁴ Patient out-of-pocket payments account for more than 50% of overall health expenditures.⁴⁵ Private health insurance options are available within the country but provide coverage to only 1% of the population.⁴⁶ The magnitude of health insurance

expansion required to provide adequate universal coverage to its citizens would face many challenges. Without compulsion, adverse selection will negatively skew the risk pool.^{47,48} The collection of even modest premiums through payroll charges to employees and employers as less than 10% of the population is formally employed.⁴⁴ Further, many Ugandans remain unwilling to join available Community Health Insurance schemes due to concerns of government corruption and mistrust of public institutions.⁴⁹ However, if adequate universal coverage were enacted, the positive externalities of universal coverage would improve public health and likely have a tremendous boost to the economy.

The thesis studies affirm the majority of fracture patients are economically disadvantaged prior to injury. The median pre-injury household income for the United States' cohort was USD 5000 below its poverty line.⁵⁰ The median pre-injury income of the Ugandan sample was slightly more than the World Bank's international poverty line threshold of USD 1.90 per day.^{51,52} Approximately 40% of the Canadian cohort had a pre-injury household income below the national poverty line.⁵²

The income distribution of fracture patients provides further context to possible post-fracture socioeconomic challenges. The United States and Canada both have tax rebate programs for low-income individuals. However, the benefits are dispersed as an annual payment that is not necessarily liquid at the time of need. There is also evidence that many citizens eligible for social benefits do not utilize the available programs.⁵³ To combat this social welfare access gap, Canada is considering automatic tax filing for low-income individuals to reduce the administrative burden of accessing these benefits.^{54,58}

Given gaps in health insurance coverage and the pre-injury financial position of many fracture patients, other forms of social insurance are critical in protecting against socioeconomic consequences. Canada and the United States are two of only three OECD countries that do not have a federally-mandated sick leave program.⁵⁵ There is strong evidence that these programs improve social welfare with no evidence of free-ridership.⁵⁶

The evidence to support the expansion of other forms of social insurance, like disability insurance programs, is less robust. United States data from the 1970s showed that less than half of rejected disability insurance applicants returned to any form of employment.⁵⁷ An extensive literature followed with a general consensus that increasing the generosity of disability insurance has small to negligible reductions in the labor supply.^{58,59} Research from Norway suggests that a spouse's increased labor activity is one of the most effective mechanisms to protect against disability shock.⁶⁰ This finding may explain why the individual income loss after a fracture was more substantial than

the household income loss. In our research on the effects of a post-operation infection on income, the caregiving demands of a post-fracture complication may prevent the spouse's increased labor activity. We acknowledge there are potential positive spillover effects from the increased labor activity of other members of the household after an injury. Given the various compositions of households, policies should be anchored on the injured individual and not the household.

The socioeconomic effects of a fracture likely extend beyond the individual patient. In our Uganda study, we examined the effect of a fracture on the school attendance of the patient's dependents. The results suggest that fractures have an intergenerational effect. A study in Norway found that obtaining disability insurance increased the probability of the beneficiary's children receiving disability insurance.⁶¹ The mechanism for this correlation is unclear. Generous social insurance programs may create a culture of welfare. An alternative explanation is that social welfare programs are too frugal and increases income inequality, which persists intergenerationally.

The appropriate level of generosity for social insurance programs is debatable. The need for governments to administer many of these programs is clear. Hendren et al (2017) thoroughly outline how the principles of adverse selection make a private market for unemployment insurance unpalatable.⁶² Most United States welfare programs are tied to employment, which creates a noticeable gap in the safety net.

Universal basic income is a promising social welfare option that addresses many pitfalls of current programs.⁶³⁻⁶⁵ Its automaticity would have efficiency benefits and provide similar peace of mind to universal health coverage. The major criticism against universal basic income is the cost of the program and access determination.⁶⁵ Would the program only be available to citizens, or would new immigrants also be eligible for the service? Many current means-tested programs, like Social Security Supplementary Income in the United States, is more generous to qualifying individuals than an underfunded universal basic income program would be. Another salient argument against universal basic income focuses on the intangible benefits and the sense of purpose one receives from employment.⁶⁶

Work can also be a source of satisfaction and meaning for many people. The inability to work reduces income. Reduced income leads to reduced consumption, increased debt, or both. The inability to work can also have mental health consequences. Some of which may present a comparable barrier to resuming employment as the initial physical impairment. As Amartya Sen stated, sickness reduces capabilities.⁶⁷

Personal circumstances, such as one's financial resources, educational background,

and social capital, greatly influence the patient's socioeconomic outcomes.^{68,69} In some cases, injury may be precluded by income stagnation or decline. Income also affects health outcomes.^{16,70} In the United States, there is a strong correlation between income and life expectancy.¹⁶ This correlation is present in other countries, like Norway, even with less income inequality.⁷⁰

The studies presented in this section conclude that a substantial proportion of patients endure significant financial hardship after a fracture. The socioeconomic effects persist for many years after injury. However, the socioeconomic effects are not uniformly distributed. This evidence must be combined with an understanding of patient socioeconomic recovery priorities to mitigate the socioeconomic effects of injury.

Section III – Identifying Patient Socioeconomic Recovery Priorities Through Behavioral Economic Concepts

The hierarchy of priorities and variation in the importance of the outcomes reported in Section III may be explained through three economic concepts: prospect theory, transaction costs, and agency.⁷¹⁻⁷³ Developed by Tversky and Kahneman,⁷² prospect theory posits that individuals place greater importance on losses than a comparable gain. The common shared experience among the cohort was a traumatic injury. The loss in physical function was immediate, profound, and in many cases, persisted for months, if not more. Over 30% of the sample was not working prior to their injury, and a lack of workforce participation would understandably decrease the mean prioritization of work-related recovery. While the United States does not have a national sick leave policy, the State of Maryland legislates most employees with 12 weeks of unpaid job-protection.⁷⁴ The 12 weeks of job protection prevents job loss for many patients and may reduce the prioritization of work-related recovery within 6-week post-injury. For patients already receiving benefits prior to injury, whether disability, social security, or otherwise, it is unlikely a fracture would decrease those benefits' disbursement. Thus, prospect theory would suggest that the receipt of disability benefits to be of lesser importance.

The patient perceptions of their transaction costs and agency are likely also incorporated into patient recovery concerns. The transaction costs in this study would be the investment required by the patient to improve a given recovery domain.⁷¹ Agency describes the capacity of the individual to affect a given situation.⁷³ A transaction cost for physical recovery would be the time and financial investment in a rehabilitation program. Disability benefits are encumbered with many eligibility conditions and a multitude of paperwork - or transaction costs. As such, less than 20% of the sample accessed some form of disability benefits in the 12-months post-injury. The reality of limited access to disability benefits may have contributed to the lower prioritization of

these benefits in the study.⁷⁵ By contrast, returning to work may have limited transaction costs but requires more agency.

Depending on one's pre-injury employment status, the patient may have minimal agency to gain employment after injury. Similarly, the multitude of work requirements and other conditions that must be met to receive disability benefits limits many patients' agency in this domain. Agency is likely the highest for the physical recovery domain.

Adequate financial and social support aid physical recovery.⁷⁶⁻⁷⁸ This study's findings suggest that the demand for social interventions was heightened after the 6-week subacute recovery phase. Clinicians should assess and reassess the socioeconomic well-being of their patients routinely following the subacute phase. Our prognostic modeling suggests that particular attention should be directed to patients working before injury, with higher mental health scores, high school education or less, or of a male gender given their increased demand for socioeconomic resources. A prior study noted that patients are often forced to return to work before physically recovering due to financial pressures.⁷⁹ The early return to work may hamper productivity and compromise a full recovery. Clinicians must advocate for their patient's social welfare and may seek to use disability benefits as a therapeutic intervention.⁸⁰ At a minimum, providing resources to simplify the access to disability benefits may increase agency and lower transaction costs.

Given the primary concern for physical recovery over socioeconomic recovery, it is unclear whether patients utilize social services and benefits if available. A study of proximal humerus fracture patients in Canada reported that physical recovery was the primary concern of patients.⁸¹ This finding was consistent with our qualitative research in Uganda.¹⁵ Despite the profound socioeconomic effects of injury for patients in Uganda, the majority were unwilling to access interest-free loans to offset their financial hardship.⁸²

Social interventions should borrow from behavioral economic principles to nudge fracture patients towards economic protection.⁷³ Prior research suggests that automatic enrollment with opt-out features is more effective than programs where people have to opt-in.⁸³⁻⁸⁶ Our data suggest that patients' inattention to socioeconomic concerns will lead to imperfect optimization of programs. Present bias blinds patients from recognizing the cumulative socioeconomic effects of their injury and their downstream economic consequences.⁸⁷ Programs must be designed to ensure salience.

Given the profound socioeconomic effects of injury and concerns toward the imperfect optimization of social services by patients, policies to increase the hospital's

responsibility for socioeconomic outcomes could be implemented. Even under bundled payments and other value-based reimbursement models, the hospital's responsible rarely extends beyond 30 days from treatment. Including socioeconomic outcomes and extending the window for reimbursement penalties would shift more responsibility to the health systems. This approach would also incentivize the integration of health and social services.

RELEVANCE TO THE NETHERLANDS

As this doctoral thesis was undertaken through the University of Amsterdam, we evaluated the comparability of the findings of the thesis to research and policies in the Netherlands. The epidemiology of fractures in the Netherlands is similar to other high-income countries,⁸⁸⁻⁹⁰ including the United States and Canada.^{91,92} Similar to the studies reported in this thesis, lower socioeconomic status increases the fracture risk of individuals in the Netherlands.⁹³ Socioeconomic status has also been correlated with worse functional outcomes after a fracture, potentially due to limited access to rehabilitation services.⁹⁴

To our knowledge, there are no estimates on the magnitude and duration of income loss associated with a fracture in the Netherlands. However, several studies estimate the socioeconomic effects using return to work and days absent from work. An analysis of patients with ankle fractures reported a median of 79 days absent from work, with all 81 patients returning to work within one year.⁹⁵ Two case series of ankle fracture patients reported that, among severely injured patients, 74% returned to work and most within 13 months of injury.^{96,97} Those that did not return to work did receive disability benefits.⁹⁶ Among less severely injured ankle fracture patients, 89% return to work with a mean of 90 days absent from work.⁹⁷ Similarly, all patients in the study who were unable to work did receive disability benefits. A metacarpal trial reported that 94% of fracture patients returned to work within six weeks of injury, and all patients were back to work within 12 weeks of injury.⁹⁸ Of the 59 calcaneus fracture patients included in a case series, 90% returned to work within one year of injury.⁹⁹ A cohort study of 109 olecranon fracture patients determined that all patients working before injury returned to full employment.¹⁰⁰ A retrospective cohort study of 278 clavicle fracture patients described 21 days of mean work absenteeism and a significant correlation between work absenteeism and patient care dissatisfaction.¹⁰¹

This prior research suggests that Dutch fracture patients have better socioeconomic outcomes than the mean estimates reported in our systematic review and meta-analysis. The social insurance system in the Netherlands is particularly robust compared

to other OECD countries.²⁴ There are several unique aspects of the Dutch system that may explain the reduction in socioeconomic effects after injury.

The Dutch Healthcare Insurance Act makes health insurance compulsory for all residents 18 years of age or older with subsidies for individuals with low incomes. A recent study ranks the country's effective universal health coverage on par with Canada.²³ Further, enrollment in health insurance is not related to your employment or receipt of disability benefits, as in the United States.

The Netherlands also has several mechanisms, such as the Invalidity Insurance Act and the Illness Benefit Act, to provide financial support to individuals who cannot work due to their injury. Compared to other OECD countries, the policies are generous, covering 68% of prior earnings two years after the initial claim.²⁴ As such, the Netherlands spends a higher proportion of their gross domestic product on social incapacity programs (3.4% of GDP) than nearly all other OECD countries.²⁴

The Disability Insurance program in the Netherlands has two unique features that may be related to the higher rates of socioeconomic recovery among fracture patients.¹⁰² The program does not have work history requirements as observed in the United States system and other countries. The Netherlands also does not have a waiting period to receive the benefits after injury. Reforms to the program in the early 2000s increased gatekeeper protocols through employer incentives.¹⁰³ Evaluations on the effect of these reforms on worker reactivation are inconclusive.^{102,103} However, research by Garcia-Gomez and Gielen suggests the disability benefit access restrictions also have adverse health effects, specifically for females with low pre-disability earnings.¹⁰⁴

Prior fracture research and reviews of the Dutch disability insurance programs suggest comparatively high work reactivation among fracture patients in the Netherlands. Further comparative analysis between the Netherlands and other OECD countries would be valuable to ascertain the extent to which these social insurance programs also protect against income loss. Understanding these programs' specific effects on patients with post-operative infections would be valuable for future program reforms.

Future Research

The findings of the thesis present several opportunities for future research. The measurement of socioeconomic outcomes could be substantially improved. The development of a standard set using item-response theory and other PROMIS architecture benefits would be of tremendous value.

There is a paucity of data on effective interventions to prevent the socioeconomic effects of injury. Bergman et al (2019) present the compelling effects of assigning housing voucher recipients a navigator who assists with the housing selection process.¹⁰⁵ A similar model may be transportable to mitigate the socioeconomic consequences of fracture.

A reevaluation of who qualifies for social insurance mechanisms and the timing of access in all three countries of study would be informative for program optimization. Research on the Supplemental Nutrition Assistance Program in the United States demonstrated substantial gains in optimization through modest changes in the process for assigning case reviewers.¹⁰⁶ Further, Hendren et al's (2020) marginal value of public funds framework provides an objective approach to ascertaining which of the available interventions give the highest yield.¹⁰⁷

Finally, using default social interventions may improve the optimization of available programs. In general, the evidence supports that a default enrollment increases service utilization.⁸³⁻⁸⁶ However, the application of this approach to fracture research is lacking and requires further research.

CONCLUSIONS

The first major conclusion is that prior socioeconomic outcome research in fracture patients is predominately measured on a single dimension, most commonly *return to work* or *absentee days from work*. While there has been substantial advancement in patient-report measurement architecture, these improvements have not been applied to socioeconomic measures. Increased access to big administrative datasets would improve the efficiency and precision of socioeconomic research in fracture patients.

The second major conclusion is that fractures have a substantial and sustained effect on patient income. The magnitude of effect was higher in our Uganda research than data from Canada and the United States. However, in all three countries, at least one in ten fracture patients suffered catastrophic income loss within two years of injury. The studies suggest the socioeconomic effects persist for at least two years and, potentially, more than five years from injury.^{25,34}

The third major conclusion is that a post-operative infection after a fracture significantly increases the magnitude of income loss beyond the average effects observed in uninfected fracture patients. Household income loss is greater than individual income

loss, suggesting the post-operative complication adds a substantial caregiver burden and prevents spouses from increasing their labor supply to offset the patient's lost earnings.¹⁰⁸⁻¹¹⁰

Fourth, the concern for socioeconomic recovery among fracture patients was substantial within one-year of injury but secondary to the relative importance of physical recovery.^{2,111}The results provide new information on the substantial variability of recovery priorities within patients, suggesting the importance of reevaluating patient priorities throughout the care continuum.

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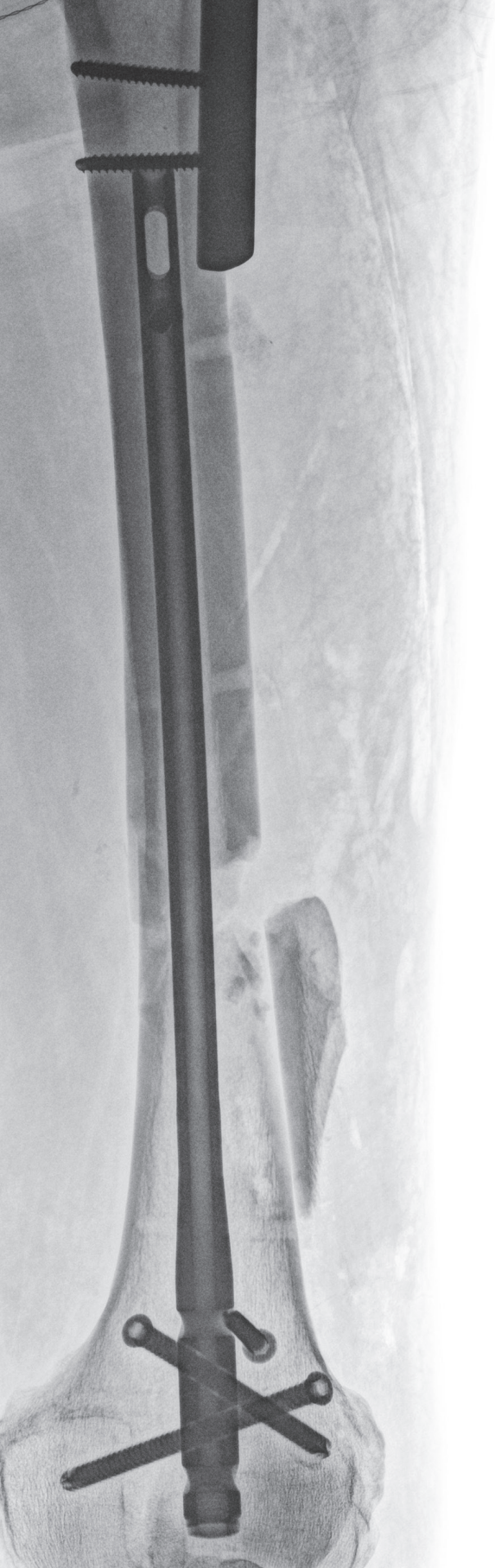
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Appendices

SUMMARY

Fractures are common, globally affecting 130 million people each year. The burden of injury falls disproportionately on working age individuals, with many injuries occurring at the workplace. The demographics of fracture patients suggest many are the primary income earner for their household. An injury and any subsequent disability may impact the socioeconomic well-being of the individual and their dependents.

Socioeconomic well-being after injury is a patient-important measure used to evaluate the effects of treatments and policies. Measures, such as return to work and days absent from work, are frequently used as outcomes in fracture research. Research has investigated the magnitude and duration of socioeconomic effects after a hospitalization. However, few studies have aimed to precisely measure the long-term socioeconomic impact of a fracture.

The overarching objective of this thesis was to advance the evidence on the socioeconomic impact of orthopaedic trauma. The thesis endeavored to achieve this objective through three specific aims. The aims were:

- 1) to describe and evaluate the currently available options for measuring socioeconomic outcomes after orthopaedic injury;
- 2) to estimate the socioeconomic effects of fractures in three countries with unique healthcare and social welfare systems; and
- 3) to identify the socioeconomic recovery priorities of fracture patients.

The thesis includes a systematic review and meta-analysis, a narrative review, and a methods paper incorporating the responses of nearly 400 fracture patients to describe and evaluate the currently available options for measuring socioeconomic outcomes after orthopaedic injury (**Section I, Chapters 1-3**).

To our knowledge, the thesis' systematic review and meta-analysis (**Chapter 1**) is the first to pool the available data to estimate the socioeconomic effect of fractures. The review included 205 studies and estimated that fracture patients remain absent from work an average of 102 days after injury. Only two-thirds of patients return to work within 12 months of injury. Return to work and days absent from work were the most commonly reported socioeconomic outcomes, but the socioeconomic effects were predominately reported on only a single dimension with follow-up limited to 12-months or less. The findings highlight the profound socioeconomic impact of fractures and the need for multidimensional measures of socioeconomic well-being.

Chapter 2 was a narrative review that evaluated the use of PROMIS measures in fracture research. The study presents the benefits of the PROMIS architecture, including item-response theory, computerized adaptive testing, and T-score scaling. However, PROMIS measures are rarely used in fracture research, potentially due to unfamiliarity within the field and the legacy effects of other measures. The architectural benefits of PROMIS could be applied to the development of improved socioeconomic measures.

Our best-worst scaling experiment of 396 fracture patients measured patient preferences for plausible clinical outcomes (**Chapter 3**). Patient preferences followed a clear gradient and were used to devise a method to weight components of composite endpoints. This approach has several analytical advantages, such as the ability to evaluate changes in outcome states and offers a broader view of overall treatment benefit.

The thesis includes four studies (**Section II, Chapters 4-7**) that estimate the socioeconomic effects of fractures in three countries (Canada, Uganda, and the United States), each with unique healthcare and social welfare systems.

Chapter 4 used population data (n=391) from the Canadian Province of British Columbia to determine the association between a hip fracture in non-elderly adults and income decline. One in four hip fracture patients sustained a substantial income reduction by two years after injury. The risk of substantial income decline was 40% higher in patients with high pre-injury incomes. This subgroup difference suggests current social insurance mechanisms are protective for low- and middle-income earners but provide less income loss protection for higher income earners.

A prospective longitudinal study enrolled 57 patients in Uganda with an isolated tibia or femur fracture (**Chapter 5**). Two years after injury, 37% had not returned to work, 66% had suffered catastrophic income loss, and 62% of school-aged dependents who attended school prior to injury were no longer in school. The low rates of socioeconomic recovery after injury suggest tremendous opportunities for improvement in healthcare delivery and social protection in this population.

We linked hospital data from 9997 fracture patients with state tax records to estimate the effect of a fracture on long-term income in the State of Maryland (**Chapter 6**). Fractures were associated with a \$9865 reduction in annual income during the five years after injury, but only a \$206 annual increase in social security benefits. The findings suggest that a fracture is associated with significant and sustained income loss for patients in Maryland. There is limited social welfare support to offset these losses.

Chapter 6 data were also used to determine the effect of a post-operative infection on long-term income among fracture patients (**Chapter 7**). Among 11,673 fracture patients, post-operative infections were associated with a \$6080 decrease in annual household incomes six years after injury. Post-operative infections increased the odds of receiving social security benefits by 45% but did not increase the overall value of the benefits received. Household income loss was greater than the loss in individual earnings suggesting an additional burden on household caregivers due to the infection that was not observed in the Chapter 6 findings. Given the incidence of fractures and the post-operative infection rate in this population, the social cost of post-fracture infections likely exceeds \$1 billion in the United States alone.

The final chapter (**Section III, Chapter 8**) reports a longitudinal discrete choice experiment used to identify the socioeconomic recovery priorities of fracture patients. The study enrolled 198 patients after injury and evaluated their physical and socioeconomic recovery priorities at 6-weeks, 6-months, and 12-months after injury. Physical recovery was the primary concern at all three time points. Work-related recovery was a secondary priority, which was elevated in importance 6-months after injury. Interestingly, within-patient variation in priorities was greater than between-patient variation. These findings suggest clinicians should continually reassess patient recovery priorities and ensure fracture patients are aware of social interventions and services, particularly between 6 weeks and 6 months post-injury.

Conclusion

In conclusion, fractures have a substantial and sustained impact on the socioeconomic well-being of patients. The effects appear to vary by country and are likely correlated with the availability of health and social insurance programs. Common socioeconomic measures are insufficient for evaluating socioeconomic effects, and innovation for quantifying socioeconomic well-being is required. Understanding patient recovery priorities is essential for optimizing current care pathways and policies to improve value-based care. The failure to mitigate the socioeconomic consequences of injury will not only affect the patient's socioeconomic well-being but may also negatively affect future health.

SAMENVATTING

Botbreuken komen vaak voor en treffen wereldwijd jaarlijks 130 miljoen mensen. De last van een fractuurletsel valt onevenredig zwaar op de schouders van personen in de werkende leeftijd, mede omdat veel letsel op de werkplek plaats vindt. Demografische kenmerken van fractuurpatiënten suggereren dat het veelal de belangrijkste kostwinner van het huishouden is. Een letsel en een eventuele daaropvolgende handicap kunnen van invloed zijn op het sociaaleconomische welzijn van het individu en hun gezinsleden.

Sociaaleconomisch welzijn na letsel is een voor de patiënt belangrijke maatstaf welke wordt gebruikt om de effecten van behandelingen en beleid te evalueren. Werkhervatting en verzuimdagen worden vaak als uitkomstmaten gebruikt bij onderzoek naar fracturen. De omvang en duur van sociaaleconomische effecten na een ziekenhuisopname is eerder onderzocht. Er zijn echter maar weinig studies uitgevoerd, gericht op het nauwkeurig meten van de sociaaleconomische impact van een fractuur op de lange termijn.

Het doel van dit proefschrift is kennis te genereren over de sociaaleconomische impact van orthopedisch trauma. Het proefschrift tracht dit doel te bereiken door middel van drie specifieke doelstellingen:

- 1) het beschrijven en evalueren van de beschikbare opties voor het meten van sociaaleconomische uitkomsten na orthopedisch letsel;
- 2) inschatten van de sociaaleconomische effecten van fracturen in drie landen met unieke systemen voor gezondheidszorg en sociale zekerheid; en
- 3) het identificeren van de sociaaleconomische herstellprioriteiten van fractuurpatiënten.

Het proefschrift omvat een systematisch literatuuronderzoek en een meta-analyse, een narratieve review en een methodologisch artikel met de reacties van bijna 400 fractuurpatiënten om de momenteel beschikbare opties voor het meten van sociaaleconomische uitkomsten na orthopedisch letsel te beschrijven en te evalueren (**Sectie I, Hoofdstukken 1-3**).

Voor zover wij weten, is het systematische literatuuronderzoek en de meta-analyse van dit proefschrift (**Hoofdstuk 1**) de eerste studie welke de beschikbare gegevens samenvoegt om het sociaaleconomische effect van orthopedisch trauma te schatten. Het literatuuronderzoek omvatte 205 studies en schatte dat fractuurpatiënten gemiddeld 102 dagen na letsel afwezig blijven op het werk. Slechts twee derde van de patiënten gaat binnen 12 maanden na verwonding weer aan het werk. Terugkeer naar het werk en dagen afwezigheid van het werk waren de meest gerapporteerde sociaaleconomische uitkomstmaten, maar de sociaaleconomische effecten werden

voornamelijk gerapporteerd op slechts een enkele dimensie, waarbij de follow-up tijd beperkt was tot 12 maanden of minder. De bevindingen benadrukken de grote sociaaleconomische impact van fracturen en de behoefte aan een breder scala aan uitkomstmaten voor sociaaleconomisch welzijn.

Hoofdstuk 2 was een narratieve review waarin het gebruik van 'Patient-Reported Outcomes Measurement Information System' (PROMIS)-metingen in fractuuronderzoek werd geëvalueerd. De studie presenteert de voordelen van de PROMIS-architectuur, inclusief item-responstheorie, geautomatiseerd adaptief testen en T-score-schaling. PROMIS-maatregelen worden echter zelden gebruikt in fractuuronderzoek, mogelijk vanwege onbekendheid binnen het veld en de vertrouwdsheid met andere maten. De voordelen van de PROMIS architectuur kunnen worden benut voor de ontwikkeling van verbeterde sociaaleconomische effectmaten.

Ons 'best-worst scaling'-experiment met 396 fractuurpatiënten onderzocht de voorkeuren van patiënten voor mogelijke klinische resultaten (**Hoofdstuk 3**). Patiëntvoorkeuren volgden een duidelijk verloop en werden gebruikt om een methode te bedenken om onderdelen van samengestelde eindmaten van een wegingsfactor te voorzien. Deze aanpak heeft verschillende analytische voordelen, zoals de mogelijkheid om veranderingen in de waardering van uitkomsten te evalueren en biedt een breder beeld van de opbrengsten van de behandeling.

Het proefschrift omvat vier studies (**Sectie II, Hoofdstukken 4-7**) die de sociaaleconomische effecten van orthopedisch trauma in drie landen (Canada, Oeganda en de Verenigde Staten) schatten, elk land met een uniek gezondheidszorg- en sociaal welzijnssysteem.

Hoofdstuk 4 gebruikte populatiegegevens (n = 391) uit de Canadese provincie British Columbia om de associatie tussen een heupfractuur bij niet-oudere volwassenen en inkomensdaling te bepalen. Bij één op de vier patiënten met een heupfractuur was het inkomen twee jaar na het letsel aanzienlijk gedaald. Het risico op substantiële inkomensdaling was 40% hoger bij patiënten met een hoog inkomen vóór het letsel. Dit verschil in subgroepen suggereert dat de huidige sociale verzekeringsmechanismen in British Columbia beschermend zijn voor mensen met een laag en gemiddeld inkomen, maar minder bescherming bieden tegen inkomensverlies voor mensen met een hoger inkomen.

We hebben een prospectieve longitudinale studie uitgevoerd waar 57 patiënten in Oeganda aan deelnamen met een geïsoleerde tibia- of femurfractuur (**Hoofdstuk 5**). Twee jaar na het letsel was 37% niet terug aan het werk gegaan, 66% had een

catastrofaal inkomensverlies geleden en 62% van de schoolgaande kinderen die vóór de verwonding naar school gingen, zat niet meer op school. Het lage sociaaleconomische herstel na letsel suggereert enorme kansen voor verbetering van de gezondheidszorg en sociale bescherming bij deze groep in Oeganda.

Om het effect van een fractuur op het inkomen op lange termijn in de staat Maryland te schatten, koppelden we ziekenhuisgegevens van 9997 fractuurpatiënten aan staatsbelastinggegevens (**Hoofdstuk 6**). Breuken werden in verband gebracht met een verlaging van het jaarinkomen van \$ 9865 gedurende vijf jaar na het letsel, en slechts een jaarlijkse verhoging van \$ 206 door sociale uitkeringen. De bevindingen suggereren dat een fractuur geassocieerd is met een aanzienlijk en aanhoudend inkomensverlies voor patiënten in Maryland. Er is slechts een beperkte sociale bijstand om deze verliezen te compenseren.

De gegevens uit hoofdstuk 6 werden ook gebruikt om het effect van een postoperatieve infectie op het inkomen op lange termijn bij fractuurpatiënten te bepalen (**Hoofdstuk 7**). Onder 11.673 fractuurpatiënten werden postoperatieve infecties geassocieerd met een daling van \$ 6080 in het jaarlijkse gezinsinkomen zes jaar na verwonding. Postoperatieve infecties verhoogden de kans op het ontvangen van socialezekerheidsuitkeringen met 45%, maar verhoogden de totale waarde van de ontvangen uitkeringen niet. Het inkomensverlies van huishoudens was groter dan het verlies in individueel inkomen, wat duidt op een extra last voor de mantelzorgers als gevolg van de infectie, welke niet werd waargenomen in de bevindingen van Hoofdstuk 6. Gezien de incidentie van fracturen en het postoperatieve infectiepercentage in deze populatie, bedragen de maatschappelijke kosten van post-fractuurinfecties waarschijnlijk alleen al in de Verenigde Staten meer dan \$ 1 miljard.

Het laatste hoofdstuk (**Sectie III, Hoofdstuk 8**) beschrijft een longitudinaal discrete keuze-experiment dat werd gebruikt om de sociaaleconomische herstellprioriteiten van fractuurpatiënten te identificeren. Aan het onderzoek namen 198 patiënten deel na het doormaken van een orthopedisch letsel. Geëvalueerd werd hun fysieke en sociaaleconomische herstellprioriteiten na 6 weken, 6 maanden en 12 maanden. Lichamelijk herstel was de eerste prioriteit op alle drie de tijdstippen. Werk gerelateerd herstel was een secundaire prioriteit, welke zes maanden na letsel in belang toenam. Interessant genoeg was de variatie in prioriteiten van individuele patiënten groter dan de variatie tussen patiënten. Deze bevindingen suggereren dat klinici de herstellprioriteiten van de patiënt voortdurend opnieuw moeten beoordelen en ervoor moeten zorgen dat fractuurpatiënten op de hoogte zijn van sociale interventies en diensten, met name tussen 6 weken en 6 maanden na het letsel.

Conclusie

Op basis van dit proefschrift kunnen we concluderen dat fractures een substantiële en aanhoudende impact hebben op het sociaaleconomische welzijn van patiënten. De effecten lijken per land te verschillen en houden waarschijnlijk verband met de beschikbaarheid van gezondheids- en sociale verzekeringsprogramma's. De gebruikelijke sociaaleconomische maten zijn onvoldoende om sociaaleconomische effecten volledig te evalueren, en nieuwe methoden voor het kwantificeren van sociaaleconomisch welzijn zijn nodig. Inzicht in de prioriteiten voor het herstel van de patiënt is essentieel voor het optimaliseren van zorgtrajecten en beleid ter verbetering van op waarde gebaseerde zorg. Indien de sociaaleconomische gevolgen van letsel niet verkleind worden, zal dit niet alleen het sociaaleconomische welzijn van de patiënt aantasten, maar kan het ook een negatieve invloed hebben op de toekomstige gezondheid.

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Gerard Slobogean, thank you for challenging me to pursue a career in research, for inspiring me to ask important questions, and to strive to answer those questions with the utmost rigor. And most importantly, thank you for your friendship and support.

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Thank you to the patients that participated in this work for allowing me to learn from your experiences.

Thank you to our ever-growing family, Aly and Andrew, Hailey and Fin, Thomas and Jess, Sarah and Ryan, Mike and Donna. You made marginal gains feel extraordinary.

Mom and Dad, thank you for instilling a love of learning in all your children. You taught us that success should not be determined by the end result but by the honest pursuit of an aim bigger than yourself.

Grace Leighton, Elyse Harper, and Emmett Alder, you ensure that I keep things in perspective, pursue endeavors with joyful participation, and remind me to always "do my best".

And finally, Lyndsay O'Hara, thank you for your love, companionship, encouragement, and unwavering support along this journey. Without you, none of this is possible.

ABOUT THE AUTHOR

Nathan O'Hara was born on March 10, 1983 in Peace River, Canada. After a childhood of hockey, mountain biking, and skiing in the Canadian Rocky Mountains, he began an undergraduate Bachelor of Arts degree at the University of Alberta in 2002. The following year, he transferred to the Bachelor of Commerce program at the University of British Columbia in Vancouver. He completed his undergraduate degree in 2006, including one semester at the ESADE business school in Barcelona, Spain.

After graduation, he went to Rusinga Island, Kenya where he worked with a local leader to establish a charitable organization designed to provide secondary school scholarships to promising, young female students. After 10 years of international support, the organization transitioned to a locally supported and managed entity. The organization has supported more than 50 female students in their educational pursuits.

Nathan returned to Vancouver, Canada in 2007 and began working with the Department of Orthopaedics at the University of British Columbia to establish a collaboration with Makerere University to reduce the burden of neglected orthopaedic trauma in Uganda. His work in Uganda highlighted the profound socioeconomic impact that injuries had on patients on their families. This awareness inspired him to enroll in the Master of Health Administration program at the University of British Columbia in 2011 with a focus on health economics under the supervision of Professor Carlo Marra. He completed the program in 2013 and his thesis evaluated healthcare worker preferences for active tuberculosis case-finding programs in South Africa.

In 2015, Nathan was recruited to the University of Maryland Baltimore to manage the orthopaedic department's clinical research program. Under the leadership of Dr. Bob O'Toole and Dr. Gerard Slobogean, the department secured funding to launch the two largest multicenter clinical trials in the field, PREVENT CLOT (12,200 patients) and PREP-IT (10,000 patients). The department also supported the author to develop an independent research program. He began his doctorate work at the Department of Public and Occupational Health at the Academic Medical Centre of the University of Amsterdam (the Netherlands) under the supervision and mentorship of Professor Niek Klazinga and Assistant Professor Dionne Kringos in 2018.

Nathan currently lives with his wife, Lyndsay, two daughters, Grace and Elyse, and son, Emmett, in Ellicott City, Maryland.

PHD PORTFOLIO

Name PhD student: Nathan N. O'Hara
Name PhD supervisor: prof. dr. N.S. Klazinga and dr. D.S. Kringos
PhD period: February 2018 – June 2021

1. PhD training	Year	Workload (ECTS)
<i>Specific courses</i>		
Longitudinal Data Analysis Using R (Statistical Horizons)	2018	0.6
Conceptual Foundation of Epidemiological Study Design (Erasmus Summer Programme)	2018	0.5
Methods of Health Services Research (Erasmus Summer Programme)	2018	0.5
Propensity Score Analysis (Statistical Horizons)	2018	0.6
Application of propensity scores and inverse probability weighting for estimating policy-relevant effects in epidemiology (Society of Epidemiological Research)	2019	0.1
Survival Analysis (Statistical Horizons)	2019	0.6
Multilevel Modelling (Statistical Horizons)	2019	0.6
Markers and Prediction Research (Erasmus Summer Programme)	2019	1.4
Workflow of Data Analysis (Vanderbilt University)	2020	0.1
Advanced Topics in Biostatistics (UvA)	2020	2.1
(Inter)national conferences		
<i>Presentations</i>		
Canadian Orthopaedic Association Annual Meeting. Victoria, BC, Canada.	2018	1.0
American Academy of Orthopaedic Surgeons Annual Meeting. Las Vegas, NV, USA.	2019	1.2
Academy Health Annual Meeting. Washington, DC, USA.	2019	0.9
American Academy of Orthopaedic Surgeons Annual Meeting. Orlando, FL (Virtual due to COVID-19).	2020	0.6
Orthopaedic Trauma Association Annual Meeting. Nashville, TN (Virtual due to COVID-19).	2020	0.4

Attended conferences without presentation

International Society of Pharmacoeconomics and Outcomes Research, Baltimore, MD, USA	2018	0.9
Academy Health National Health Policy Conference, Washington, DC, USA	2019	0.6
Orthopaedic Trauma Association Annual Meeting, Denver, CO, USA	2019	1.3
Canadian Orthopaedic Association Annual Meeting, Halifax, NS (Virtual due to COVID-19).	2020	0.4

2. Teaching

Lecturing

METRC Emerging Investigators Workshop –Baltimore, MD	2018	0.4
Introduction to JMP, University of Maryland Orthopaedic Residents, Baltimore, MD	2018	0.1
Curso de Investigaciones Clinicas, Havana, Cuba	2018	0.6
PROMIS – The New Standard? Osteosynthesis and Trauma Care Foundation – Hot Topics Research Course, Toronto, Ontario	2018	0.6
METRC Emerging Investigators Workshop –Baltimore, MD	2019	0.4
AO PEER Principles of Clinical Research Course – Online	2020	0.4
Erasmus Summer Programme – Health Services Research Course – Guest Lecture	2020	0.1

Supervising

Medical students	2018 - 2020	8.0
Graduate students	2018 - 2020	3.2
Orthopaedic resident research projects	2018 - 2019	4.0
Clinical fellow research projects	2018 - 2020	4.3

3. Parameters of Esteem

Funded grants related to thesis

Osteosynthesis and Trauma Care Foundation – Research 2019 – 2021

Grant Psychosocial Recovery After Injury: Determining the Optimal Timing and Subgroups for Interventions

Role: Principal Investigator

Total Costs: \$50,000 USD

Agency for Healthcare Research and Quality (1R03HS027218-01A1) 2020 – 2022

The Effect of Traumatic Extremity Fractures on Patients Long-Term Household Income

Role: Principal Investigator

Total Costs: \$100,000 USD

Funded grants unrelated to thesis

OTA Research Award

Can Soft Tissue Perfusion Measured by Real-time Laser 2018 -2019

Assisted Indocyanine Green Angiography Predict Post-Operative Wound Complications in High Risk Tibial Plafond and Plateau Fractures?

Role: Co-Investigator

Total Costs: \$80,000 USD

OTA/AOTNA Research Award 2018 - 2019

Biofilm detection for early diagnosis after treatment of open fractures: A nested cohort within the PREP-IT Trials

Role: Co-Investigator

Total Costs: \$100,000 USD

US Department of Defense (W81XWH1910848) 2019 – 2023

Novel Topical Antibiotic Therapy to Reduce Infection After Operative Treatment of Fractures at High Risk of Infection: TOBRA-A Multicenter RCT

Role: Co-Investigator

Total Costs: \$2,992,023 USD

US Department of Defense (OR 190099) 2020 - 2024

Can Preoperative Skin Perfusion Predict Wound Healing Complications in High- Risk Peri-Articular Tibial Fracture Fixation

Role: Co-Investigator

Total Cost: \$1,190,352 USD

National Institutes of Health (1R01AR07715701) 2020 – 2025

Real-time fluorescence-based measurement of bone perfusion in post-traumatic infection

Role: Co-Investigator

Total Cost: \$2,882,636

Grants submitted but not funded

AHRQ R03 Proposal, The Effect of Traumatic Extremity Fractures on Patients Long-Term Household Income Role: Principal Investigator	February 2018
Orthopaedic Research and Education Foundation The Effect of Isolated Extremity Fractures on Economic Well-Being Role: Principal Investigator	January 2019
AHRQ R03 Proposal The Economic Impact of Avoidable Healthcare Associated Infections on Traumatic Extremity Fracture Patients Role: Principal Investigator	February 2019
Bill & Melinda Gates Foundation – Voices for Economic Opportunity Rebuilding Economic Opportunity After Injury Role: Principal Investigator	November 2019
Total (28 hrs = 1 ECTS)	36.5

LIST OF PUBLICATIONS

Articles included in this dissertation

O'Hara NN, Isaac M, Slobogean GP, Klazinga NS. The socioeconomic impact of orthopaedic trauma: A systematic review and meta-analysis. *PLoS One*. 2020;15(1):e0227907.

O'Hara NN, Richards JT, Overmann A, Slobogean GP, Klazinga NS. Is PROMIS the new standard for patient-reported outcomes measures in orthopaedic trauma research? *Injury*. 2020 May;51 Suppl 2:S43–50.

Udogwu UN, Howe A, Frey K, Isaac M, Connelly D, Marinos D, Baker M, Castillo RC, Slobogean GP, O'Toole RV, **O'Hara NN**. A patient-centered composite endpoint weighting technique for orthopaedic trauma research. *BMC Med Res Methodol*. 2019 Dec 26;19(1):242.

O'Hara NN, Slobogean GP, Stockton DJ, Stewart CC, Klazinga NS. The socioeconomic impact of a femoral neck fracture on patients aged 18-50: A population-based study. *Injury*. 2019 Jul;50(7):1353–7.

O'Hara NN, Mugarura R, Potter J, Stephens T, Rehavi MM, Francois P, Blachut PA, O'Brien PJ, Mezei A, Beyeza T, Slobogean GP. The Socioeconomic Implications of Isolated Tibial and Femoral Fractures from Road Traffic Injuries in Uganda. *J Bone Joint Surg Am*. 2018 Apr 4;100(7):e43.

O'Hara NN, Slobogean GP, Klazinga NS, Kringos DS. Analysis of patient income in the five years following a fracture treated surgically. *JAMA Netw Open*. 2021 Feb 1;4(2):e2034898.

O'Hara NN, Mullins CD, Slobogean GP, Harris AD, Kringos DS, Klazinga NS. Association of Postoperative Infections After Fractures With Long-term Income Among Adults. *JAMA Netw Open*. 2021 Apr;4(4): e216673.

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Selection of articles not included in this dissertation

Lin CA, **O'Hara NN**, Sprague S, O'Toole RV, Joshi M, Harris AD, Warner SJ, Johal H, Natoli RM, Hagen JE, Jeray KJ, Fowler JT, Phelps KD, Pilson HT, Gitajn IL, Bhandari M, Slobogean GP; PREP-IT Investigators. Low Adherence to Recommended Guidelines for Open Fracture Antibiotic Prophylaxis. *J Bone Joint Surg Am*. 2021 Apr 7;103(7):609-617.

Stennett CA, **O'Hara NN**, Sprague S, Petrisor B, Jeray KJ, Leekha S, et al. Effect of Extended Prophylactic Antibiotic Duration in the Treatment of Open Fracture Wounds Differs by Level of Contamination. *J Orthop Trauma*. 2020 Mar;34(3):113–20.

Sepehri A, **O'Hara NN**, Slobogean GP. Do standardized hip fracture care programs decrease mortality in geriatric hip fracture patients? *Injury*. 2021 Mar;52(3):541-547.

O'Hara NN, Slobogean GP, O'Halloran K, Castillo R, Sprague S, Bhandari M, et al. Predicting tibia shaft nonunions at initial fixation: An external validation of the Nonunion Risk Determination (NURD) score in the SPRINT trial data. *Injury*. 2020 Oct;51(10):2302–8.

Haac BE, **O'Hara NN**, Manson TT, Slobogean GP, Castillo RC, O'Toole RV, et al. Aspirin versus low-molecular-weight heparin for venous thromboembolism prophylaxis in orthopaedic trauma patients: A patient-centered randomized controlled trial. *PLoS One*. 2020;15(8):e0235628.

Afaq S, **O'Hara NN**, Schemitsch EH, Bzovsky S, Sprague S, Poolman RW, et al. Arthroplasty Versus Internal Fixation for the Treatment of Undisplaced Femoral Neck Fractures: A Retrospective Cohort Study. *J Orthop Trauma*. 2020 Nov;34 Suppl 3:S9–14.

Parikh HR, **O'Hara N**, Levy JF, Cunningham BP. Value Denominator: The Fundamentals of Costing for Orthopaedic Surgeons. *J Orthop Trauma*. 2019 Nov;33 Suppl 7:S56–61.

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O'Hara NN, Degani Y, Marvel D, Wells D, Mullins CD, Wegener S, et al. Which orthopaedic trauma patients are likely to refuse to participate in a clinical trial? A latent class analysis. *BMJ Open*. 2019 Oct 11;9(10):e032631.

Kwok AK, **O'Hara NN**, Pollak AN, O'Hara LM, Herman A, Welsh CJ, et al. Are injured workers with higher rehabilitation service utilization less likely to be persistent opioid users? A cross-sectional study. *BMC Health Serv Res*. 2019 Jan 14;19(1):32.

Kisitu DK, Stockton DJ, **O'Hara NN**, Slobogean GP, Howe AL, Marinos D, et al. The Feasibility of a Randomized Controlled Trial for Open Tibial Fractures at a Regional Hospital in Uganda. *J Bone Joint Surg Am*. 2019 May 15;101(10):e44.

O'Hara NN, Pollak AN, Welsh CJ, O'Hara LM, Kwok AK, Herman A, et al. Factors Associated With Persistent Opioid Use Among Injured Workers' Compensation Claimants. *JAMA Netw Open*. 2018 Oct 5;1(6):e184050.

Nichols E, **O'Hara NN**, Degani Y, Sprague SA, Adachi JD, Bhandari M, et al. Patient preferences for nutritional supplementation to improve fracture healing: a discrete choice experiment. *BMJ Open*. 2018 Apr 12;8(4):e019685.

