Improving Global Education and Outcome Evaluation in Orthopaedic Trauma Surgery

Verbetering van mondiaal onderwijs en uitkomstevaluatie voor orthopedische traumachirurgie

(met een samenvatting in het Nederlands)

Proefschrift

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Chapter 1: General Introduction and Thesis Outline

Why is Global Orthopaedics important?

Global surgery has begun to receive more attention as we learn how the poorest third of the world's population only receives 3.5% of worldwide surgical operations.[1] In addition, musculoskeletal trauma is a growing source of morbidity and mortality in developing countries. For example, approximately 4-5 million people die annually from injuries in developing countries – more than HIV/AIDS, tuberculosis and malaria combined.[2,3] Moreover, orthopaedic injuries and disease account for 14% of the world's disability-adjusted life years lost and 9% of the world's mortality per the World Health Organization.[43]

What is the relevance of continuing medical education in Global Orthopaedics?

Continuing medical education (CME) is typically defined as an educational activity that maintains, develops, or increases the knowledge and skill a physician uses to provide services for patients, the public, or the profession once they have completed training.[5,6] The globalization of health has made CME an international concern for both developed and developing countries. Increasingly, international CME is becoming recognized as more than a series of conferences and courses, but as an integrated curriculum that is built on projects in needs assessment, performance evaluation and healthcare outcomes.[5,7] CME is especially important for surgical education as new technology, techniques, and practice patterns can gradually lead to surgeon knowledge and performance gaps.[8]

CME is an important part of capacity building in surgery in the developing world. Learning in CME activities is more likely to lead to change in practice when needs assessment has been implemented.[9] As emphasized in the preceding section, improving education in orthopaedic

trauma, which is one of the essential surgical care needs in the developing world, has become a necessity.

Close attention to competency and skills while promoting capacity building in orthopaedics in the developing world is critical since these efforts are likely to alter surgeon practice and patient satisfaction. However, one challenge in low- and middle-income countries is that post-graduate medical, and especially surgical, education often relies greatly on visiting professors from developed countries to supplement medical knowledge and skills. Organized in-country programs are infrequent, and even when needs assessment is recognized as important, efforts often fail or are made challenging since response rates to paper or online surveys are very poor.[10,11] As a result, improved standardized methods of needs assessment and knowledge delivery are sorely needed. In addition, it remains unclear how structural changes to existing courses can be made and the time span required to observe outcome differences after those interventions. [12-15]

How do we improve outcome evaluation to facilitate better care of orthopaedic trauma patients?

Unsurprisingly, outcomes for musculoskeletal trauma patients are also worse in low-to-middle income countries than in developed, high-resource settings. According to one estimate, 34-38% of all injury deaths could be avoided if trauma in low-resource countries was managed as it is in high-income countries.[16] As a result, many countries have created registries to improve the quality of care delivery to patients. However, the primary outcome tracked by these registries has been in-hospital mortality. But, as trauma care has improved, use of in-hospital mortality as the sole patient outcome variable is less ideal. In response, some trauma registries evolved to incorporate functional status (using patient-reported outcome measures) at discharge or on follow-up. Collection of these measures can vary by geographical and cultural context studies,

and more research is required to better understand methods to make routine inclusion feasible.[17,18]

Improving the collection of patient-reported outcome is important not just for benchmarking care, but also for enabling recent health policy efforts in higher-income countries that have focused on reducing costs and improving quality of medical care using value-based payment strategies, like episode-of-care or bundled payments.[19-21] While it is intuitive that a total hip arthroplasty performed for osteoarthritis, tumor, or fracture is different, the heterogeneity of orthopaedic trauma care is more subtle and established methods for measuring outcomes for elective orthopaedic procedures are unlikely to translate easily. Still, most orthopaedic surgeons recognize that orthopaedic trauma patients present diversely, as there are almost innumerable combinations of injuries from different mechanisms and contexts. As a result, standardized quality measurement has been difficult to implement for this population.[21] However, in order to create effective value-based payment strategies for orthopaedic trauma patients, as well as to guide expectation management and clinical decision making, we need better understanding of not only the cost of care, but also factors associated with outcome.

Outline

The general aim of this thesis is to explore how to improve global education and outcome evaluation in orthopaedic trauma surgery.

The first half of this thesis is focused largely on education. In **Chapter 2**, we profile the delivery of orthopaedic care in a new hospital in Haiti and highlight how this can be used as a low-cost quality improvement method to facilitate needs assessment planning for education. Based on this data, in **Chapter 3**, we use survey methods to explore how and why management of orthopaedic trauma conditions varies by geographical and cultural context. Then, in **Chapters 4 and 5**, we describe a method to perform formalized needs assessment for

management of adult and paediatric orthopaedic conditions. We also investigate the use of electronic audience response systems and incentives in improving survey response. In **Chapter 6**, we assess the effectiveness of international continuing medical education conferences on knowledge-based assessments. Then, in **Chapter 7**, we explore if these methods extend to skills training by examining if similar techniques, and practice on a low-fidelity stimulator, can improve basic arthroscopic skills. Finally, in **Chapter 8**, we explore the effect of including serial needs assessment, problem based learning, and faculty training initiatives to an established continuing medical education course, and estimate the time required to observe improvements in participant evaluation of the usefulness and relevancy of course content and faculty performance.

The second half of this thesis explores collection and evaluation of patient reported outcomes following musculoskeletal trauma. In **Chapter 9**, we investigate the feasibility of routine inclusion of long-term patient reported health-related quality of life in the Dutch National Trauma Database using process related outcomes and we characterize the outcomes of included patients. In Chapter 10, we investigate how injury related factors such as polytrauma and high-energy injuries may be associated with different fracture morphology. In **Chapters 11 and 12**, we extend the results of Chapter 10, and explore how these injury related factors/clinical outcomes may be associated with different patient reported outcomes. Finally, in **Chapter 13**, we perform a systematic review to investigate how injury-related characteristics may differentiate between patient reported outcomes following traumatic musculoskeletal injury.

Aims

This thesis has two focus areas within orthopaedic trauma.

We aim to:

1. Highlight efforts to improve education in global orthopaedic trauma surgery and better understand the timeline and techniques for knowledge and skill transfer.

2. Investigate a framework for understanding variation in longer-term patient reported outcome after musculoskeletal trauma.

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Part 1. Improving Global Education

Chapter 2: Advancing Orthopaedic Surgical Management in Haiti: a partnership in quality improvement

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SUMMARY

Our study is the first to profile the delivery of orthopaedic care in a new state-of-the-art hospital in Haiti, and outlines a low-cost quality improvement method.

BACKGROUND

Global surgery has begun to receive more attention as we learn how the poorest third of the world's population only receives 3.5% of worldwide surgical operations[1]. In addition, approximately 4.5 million people die every year from accidental injuries in developing countries – more than HIV/AIDS, tuberculosis and malaria combined[2]. Orthopaedic injuries and disease account for 14% of the world's disability-adjusted life years lost and 9% of the world's mortality per the World Health Organization[3].

In 2010, the earthquake in Haiti caused an unprecedented orthopaedic catastrophe with the simultaneous destruction of the infrastructure needed to recover. In the process of rebuilding, a new Haitian hospital opened in June 2013 to provide a preferential health care option for the poor. However, even though there is growing interest in global orthopaedics, very little is known about surgical outcomes in new hospitals in low-income countries. Thus, we sought to accurately characterize patterns and outcomes of operative musculoskeletal disease in the first 6 months of the hospital's operation in Haiti. This was a quality improvement project designed to advance database driven changes to improve outcomes, resource utilization, research, primary prevention, and long term management. Our goal was to develop a partnership in orthopaedic quality improvement between Partners in Health/Zanmi Lasante, Harvard Medical School, and HUM.

METHODS

Data was prospectively collected from operative orthopaedic patients who were admitted to HUM from May 31-January 14, 2014 and was retrospectively validated using the operative log, surgical ward registry, and electronic medical record. A 1 week pilot project was performed to successfully validate operative log and surgical ward registry data against ward rounds. Collected data included patient demographics, length of stay, operative interventions and 30-day follow-up completion. Cross-sectional descriptive statistics were calculated quantifying patient characteristics, orthopaedic disease, intervention, and follow-up. Chi-squared and regression analysis were used to analyze follow-up data. All analysis was completed using STATA IC13.

RESULTS

Patient demographics: During this period, 193 patients had orthopaedic operations (23 with multiple procedures). Mean age: 28.48 (2-68) years, 2.78:1 male:female ratio, with homes approximately 30.29 (0-87.2) km away. Average hospital length of stay: 11.14 days (0-56 days) The majority of patients presented from within a 40 km radius seeking acute care with a marked decrease in patients from towns >40 km from HUM (β= -0.1982, R^2=0.20).

Injury data: Major orthopaedic injury classifications included closed fractures (51.78%), open fractures (22.84%), infections (9.14%), soft tissue injuries (4.06%), and dislocations (4.06%). The most common musculoskeletal injuries were long bone fractures of the femur (29.33%), tibia (18.27%), humerus (11.06%), and radius (9.13%). Most common procedures included ORIF (27.5%), IM Nail (17.1%), and External Fixation (9.3%).

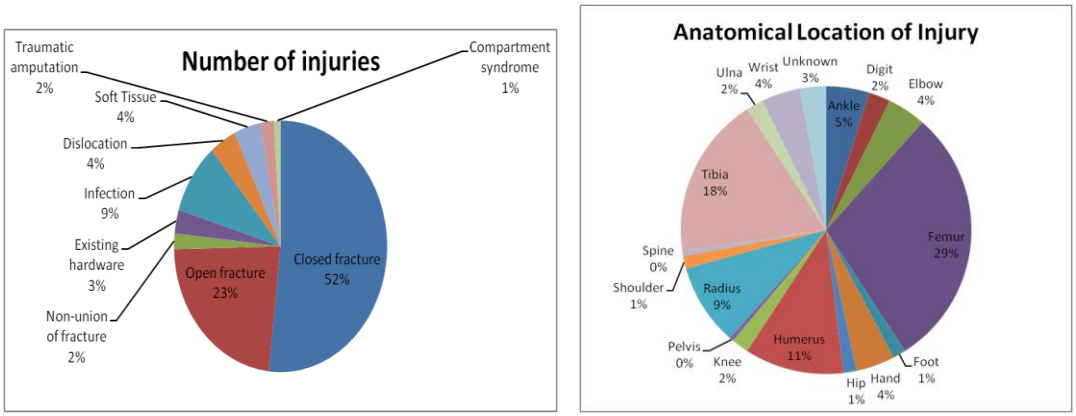

Figure 1: Injury data classification by injury type and anatomical location

Time metrics: ~75% of patients had a time to surgery <3 days, but approximately 15% of patients had clinically significant delays due to lack of blood, OR scheduling/staffing, equipment shortage, or patient medical condition. Considering admitting diagnosis, average hospital stay was 20.3 days for infections, 13.2 days for open fractures, and 9.87 days for closed fractures.

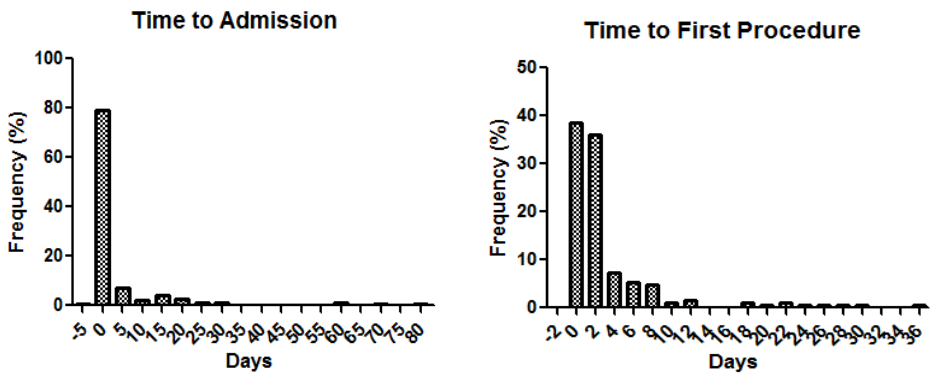

Figure 2: Time metrics for admission and operation (first procedure)

Resource utilization: The ratio of percentage hospitalization duration to percentage injury burden (as a proxy for hospital resource utilization) was highest for infections of joints (2.07) followed by open (1.99) and closed (1.31) fractures of the femur.

Follow-up: 30-day follow-up was 67.5% with significant variance in follow-up by injury type (p=0.014). Follow-up was not different based on age, gender, or location, but patients with more major procedures were more likely to follow-up than those with minor procedures (p=0.14).

DISCUSSION

Our study successfully profiles the delivery of orthopaedic care at HUM in its first 6 months of operation and outlines a low-cost quality improvement method.

Injury data: Our study highlights how long bone fractures of the femur, tibia, humerus and radius account for over 50% of the orthopaedic operative caseload at HUM. And over all procedures, open reduction and internal fixation with a plate or intramedullary nail account for 42% of operations, while external fixation accounts for 9.3%. These findings extend Schulz et al.'s prior work to create an injury surveillance system at the Hopital Albert Schweitzer in rural Central Haiti by collecting data about nearly twice as many patients[4]. In addition, our findings demonstrate that prospective registry implementation is feasible and can be used to provide setting- and resource-specific injury information. Our study also builds upon prior work by Sonshine et al. at the KATH hospital in Ghana since we collected data on all orthopaedic injuries, in addition to femur fractures, to provide a broader scope of operative orthopaedic injury burden[5]. In terms of procedure information, our work also advances prior efforts by the SIGN Foundation to classify intramedullary nail procedures by including more data about the variance in treatment methods for disparate injuries[6]. Finally, our findings are aligned with a recent report about operative caseloads at San Francisco General Hospital and the KATH Hospital that also found that long bone fractures accounted for over 50% of the orthopaedic

operative injury burden. They similarly found that injuries to the lower and upper extremity dominated[7].

Time metrics: At HUM, average time to admission and operation were less than 5 days. For approximately 15% of patients with clinically significant delays, this was due to lack of blood for transfusion, operative room scheduling or staffing challenges, instrumentation delays or the medical condition of the patient. While our findings are limited by the qualitative report of operative delay, these results shed light on the five most common causes of delays in care within a newly operational hospital and are areas for early action. Even so, since HUM provides free care to all patients, we see dramatically lower metrics for time to care in contrast with other hospitals in low-income countries with delays in care ranging from 5-20 days[8]. Interestingly, hospitalization duration was similar at HUM when compared to other hospitals suggesting that the payment structure may influence access to care, but not provision of care once already admitted. At present, our data are limited by unreliable information on patient transport to the hospital and the lack of data on complications to see if delays lead to increased patient morbidity.

Resource utilization: We show how infections, tibia and femur fractures, and elbow dislocations can disproportionately consume hospital resources. As a result, HUM has implemented an open tibia protocol for more effective management and is considering a new protocol for elbow dislocations. Since we lacked true cost data, our findings are limited to using hospitalization duration as a proxy for resource utilization. Future efforts will be directed to using monetary values to more precisely quantify disproportionate usage of hospital resources in terms of staffing and space consumption.

Follow-up: We report a follow-up rate of 67.5% that is much higher than existing estimates of post-surgical follow-up in Haiti. Several prior studies have reported rates between 12.6-29%, and some have troublingly used this as justification to avoid providing operative interventions[9,10]. Our study instead reports follow-up rates that are similar to those in high-income countries. This likely reflects the strength of the community health worker "accompaniment" model that Partners in Health/Zanmi Lasante has advocated for over the last several decades.

In summary, our data demonstrates a robust delivery of care at HUM in its first 6 months of operation. Creation of an orthopaedic operative injury database has allowed for the implementation of targeted quality improvement efforts in open tibia management, new hypothesis driven research in polytrauma and elbow dislocations, and areas of focus for roadside prevention of long bone fractures. This data can be used for medical education and ultimately highlights areas for improvement in local orthopaedic patient care.

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Chapter 3: Variation in Orthopedic Trauma Management between Haitian and American Orthopedic Surgeons

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ABSTRACT

Introduction: The burden of disease from orthopedic trauma is growing in low- and middle-income countries such as Haiti. While orthopedic outcomes differ between Haiti and the United States, it is unknown if these differences are due to variation in surgical training, resource availability, or other factors. The aim of this study was to understand how and why management of orthopedic trauma conditions varies between Haitian and American surgeons.

Methods: Using an audience response system, we surveyed 49 Haitian and 41 American orthopedic attending surgeons and residents to assess management of eight common orthopedic trauma cases: midshaft femur fracture, midshaft tibia fracture, distal femur fracture, posterior acetabular wall fracture, femoral neck fracture in a young patient, femoral neck fracture in an elderly patient, glenoid fracture dislocation, and bimalleolar ankle fracture. Participants selected the one treatment they would choose to manage each case in their hospital from a provided list. Each case management question was followed by a multiple-choice question asking why a proposed management option was not selected. The chi-squared statistic was used to detect differences in response distribution between Haitian and American respondents.

Results: There was no significant difference in management of femoral shaft fractures (p=0.66). Haitians were more likely than Americans to cast a midshaft tibia fracture (49% vs. 13%, p=0.008). The reasons Haitians cited for not using an intramedullary nail were complications (30%) and implant requirements (20%). Haitians were less likely than Americans to use a condylar locking compression plate for a distal femur fracture (49% vs. 87%, p=0.048) due to limited implant availability (50%) and perceived worse functional outcomes (40%). Haitians were less likely than Americans to use open reduction internal fixation for an acetabular fracture (63% vs. 95%, p=0.016) due to low confidence (36%) and resource limitations (43%)

associated with operative intervention. Haitians chose options other than arthroscopy for a glenoid fracture repair due to low confidence (23%) and resource limitations (74%) associated with arthroscopic stabilization.

Discussion/Conclusion: This survey demonstrates that for conditions that are managed differently in Haiti than in the U.S., the treatment rationale in Haiti is context-specific. The management of complex conditions such as acetabular fractures is limited by training, while the management of common conditions such as midshaft tibia fractures is influenced by the prevalence of complications and implant availability. This highlights the need for targeted, context-specific interventions that include resource allocation and associated education around the use of those resources.

INTRODUCTION

Musculoskeletal trauma is a growing source of morbidity and mortality in developing countries. According to a 2002 report, an estimated 5 million people worldwide die annually from injuries, and 90% of those deaths occur in low- and middle-income countries (LMICs)[1]. In part due to rising rates of motor vehicle accidents, this number is likely higher today than in 2002[2]. Orthopedic injury and disease constitute 14% of the world's disability adjusted life-years (DALYs) lost and 9% of the world's mortality, according to WHO estimates[3].

Outcomes for victims of trauma are worse in developing (low and low-to-middle income) countries than in developed, high-resource settings. According to one estimate, 34-38% of all injury deaths could be avoided if trauma in low-resource countries was managed as it is in high-income countries[4]. This discrepancy is likely multifactorial, including severity of injury, patient comorbidities, timing of presentation, physician training, and resource availability. To our knowledge, no prior studies have compared the decision-making process behind management of orthopedic trauma between orthopedic surgeons in low- and high-income countries. An understanding of such differences, along with needs assessments of surgeons in low-income countries, may allow for more targeted resource allocation and thereby improvement in trauma care.

The purpose of this study was to understand how management of eight orthopedic injuries varies between Haitian and American orthopedic surgeons, and to begin to explore the reasons behind that variation. We hypothesized that management variation depends on the case, with resource availability being the primary reason for management variation.

METHODS

We performed a survey of practicing orthopedic surgeons and residents regarding their treatment preferences and decision-making process as it relates to orthopedic injuries. The study protocol was reviewed and approved by the institutional review board at the principle investigator's hospital. A survey was designed to assess management of eight fractures: midshaft femur fracture, midshaft tibia fracture, distal femur fracture, posterior acetabular wall fracture, femoral neck fracture in a 30 year old patient, femoral neck fracture in an 80 year old patient, glenoid fracture dislocation, and bimalleolar ankle fracture. Respondents were asked to choose the one management option that they would use at their hospital, given the particular resource constraints of their practice environment. For each case, relevant demographic information and imaging was provided, and between three and eight answer options were listed. Questions and answer choices were refined with input from two independent fellowship-trained attending American orthopedic surgeons. Each case question was followed by a question to assess the rationale for choosing the previous management option. One management option was chosen as a reference for comparison, and each rationale question asked if the reference option was not chosen, and why. Nine rationale answer choices were provided for each question to include a range of reasons, including level of training, outcome considerations, and resource limitations. Demographic information about respondents, including nationality, age, gender, years in practice, was also collected.

The survey was administered to Haitian and American orthopedic residents and attending surgeons using the TurningPoint audience response system (Turning Technologies). Both resident and attending surgeons were surveyed to increase sample size. American orthopedic residents from the principle investigator's home institution were surveyed. Haitian orthopedic residents and both Haitian and American orthopedic attending surgeons were surveyed at an

annual orthopedic trauma conference in Port-au-Prince, Haiti. Participation was voluntary and anonymous.

Descriptive statistics for demographics of respondents were calculated. Pearson's chi-squared test was used to detect differences in response distributions between Haitian and American respondents. The significance criteria was adjusted for multiple comparisons using the Bonferroni correction to $\alpha<0.0063$. Statistical analysis was performed using Stata 13.1 software.

RESULTS

Survey respondents consisted of 49 Haitian and 41 American orthopedic surgeons, and the survey response rate was 86%. Of the respondents, 80% were orthopedic residents, 82% were male, and 51% had graduated from medical school ≤ 6 years ago (Table 1). Due to the low proportion of attending respondents, we were unable to perform a meaningful subgroup analysis comparing resident to attending responses.

TABLE 1	Demographic characteristics of study participants
	Number (% of total respondents)
Nationality and training	
Haitian attending	7 (8)
Haitian resident	42 (47)
American attending	11 (12)
American resident	30 (33)
Gender	
Male	37 (82)
Female	8 (18)
Years since graduating medical school	
≤2 years	41 (47)
3-6 years	4 (4.5)
≥7 years	43 (49)

The response distribution for the management of each case varied across cases and nationality. Table 2 shows the modal answer for each case and the number of answer choices that were represented by at least one respondent, by nationality.

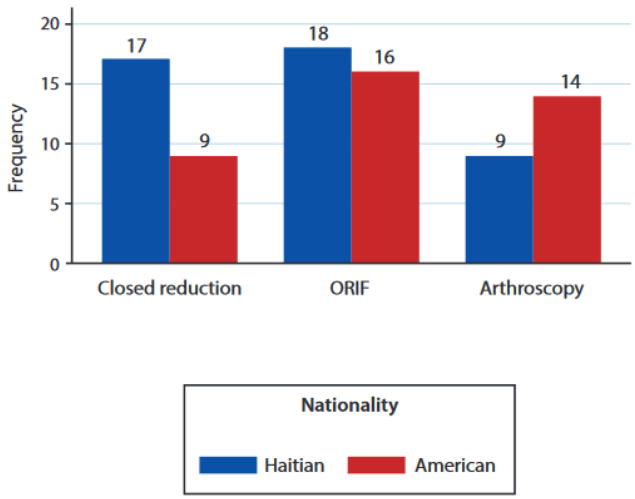
TABLE 2 Fracture management responses by nationality, as demonstrated by percentage of participants who responded with the modal answer and number of answer choices represented

	Haitian participants		American participants		Chi²: p-value*
Question: modal answer	Modal answer (%)	# Choices represented	Modal answer (%)	# Choices represented	
Femur fracture: anterograde nail	86	5	92	3	0.581
Tibia fracture: intramedullary nail	40	5	85	3	0.00 1
Distal femur fracture: locking compression plate	49	5	87	4	0.006
Posterior wall fracture: Kocher-Langenbeck ORIF	63	4	95	2	0.002
Femoral neck, 30 year old: ORIF	79	4	79	2	0.466
Femoral neck, 80 year old: hemiarthroplasty	70	3	38	4	0.012
Glenoid fracture dislocation: ORIF	39	3	39	3	0.334
Bimalleolar fracture: ORIF lateral and medial malleoli	98	2	100	1	0.332

*P-values listed are prior to Bonferroni correction

American orthopedic surgeons in the management of a midshaft femur fracture, in which the most common management choice was an anterograde nail (p = 0.58); femoral neck fracture in a young patient, in which the most common management choice was open reduction internal fixation (ORIF; p = 0.47); femoral neck fracture in an elderly patient, in which the most common management choice was hemiarthroplasty among Haitian respondents and total hip arthroplasty among American respondents (p = 0.01, not significant after adjustment for multiple comparisons); bimalleolar ankle fracture, in which the most common management choice was ORIF of lateral and medial malleoli (p = 0.33); or glenoid fracture dislocation, in which the most common management choice was ORIF (p = 0.33). Regardless of nationality, there was little consensus about the management of a glenoid fracture with associated dislocation, with all three answer choices highly represented (closed reduction, ORIF, and arthroscopic stabilization, Figure 1).

FIGURE 1 Response distribution of management of a glenoid fracture-dislocation, by nationality



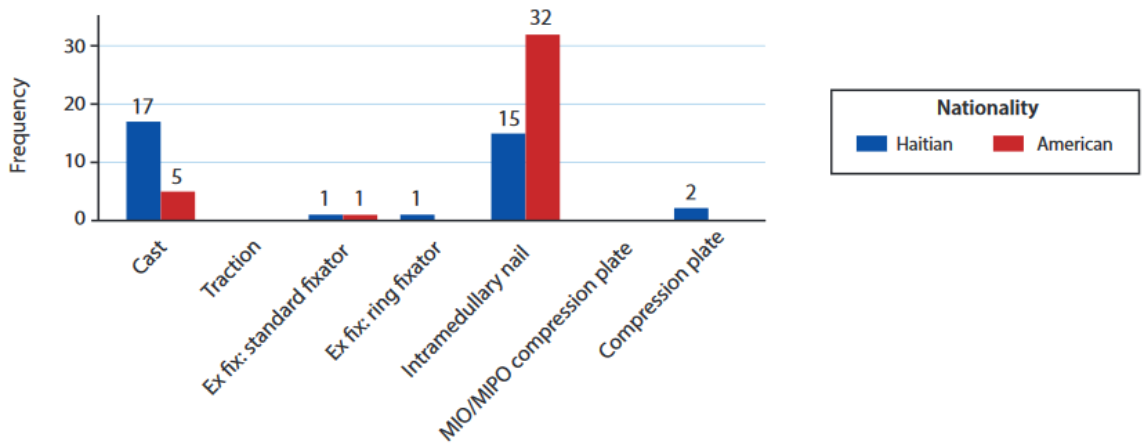
Haitians reported operating room equipment availability (n = 14/46), implant availability (n = 8/46), and confidence performing the operation (n = 7/46) as reasons not to perform arthroscopic stabilization. Americans reported confidence (n = 11/41), functional outcomes (n = 4/41), complications (n = 2/41), time (n = 2/41), and expense (n = 2/41) as the reasons not to perform arthroscopic stabilization (Table 3).

TABLE 3 Rationale for choosing management other than arthroscopic stabilization for glenoid fracture dislocation

Rationale	Haitian respondents (#) of 46 respondents	American respondents (#) of 41 respondents
Confidence	7	11
Functional outcomes	1	4
Complications	0	2
Implants	8	0
OR equipment	14	0
Support staff	1	0
Time	0	2
Expense	0	2

Haitians and Americans reported significantly different management of a midshaft tibia fracture (p = 0.001), with Haitians more likely to cast (n = 17/35) and Americans more likely to use an intramedullary nail (n = 34/40) (Figure 2).

FIGURE 2 Response distribution of management of a closed displaced midshaft tibia fracture, by nationality



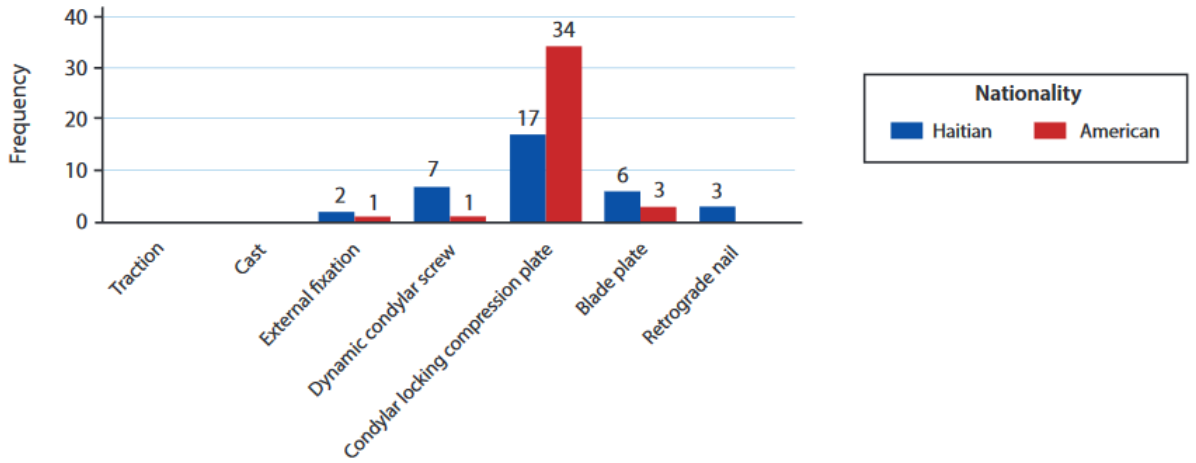
Haitians reported complications (n = 3/35), expense (n = 3/35), and implant availability (n = 2/35), while Americans reported confidence (n = 1/40), complications (n = 5/40), and expense (n = 1/40) as reasons not to use an intramedullary nail for a midshaft tibia fracture (Table 4).

TABLE 4 Rationale for choosing management other than intramedullary nail for a midshaft tibia fracture

Rationale	Haitian respondents (#) of 35 respondents	American respondents (#) of 40 respondents
Confidence	0	1
Functional outcomes	1	0
Complications	3	5
Implants	2	0
Time	1	0
Expense	3	1

Americans were more likely to use a condylar locking compression plate for management of a distal femur fracture (n = 34/39), while condylar locking compression plate (n = 17/33), dynamic condylar screw (n = 7/33), and blade plate (n = 6/33) were highly represented among Haitian orthopedic surgeons (p = 0.006) (Figure 3).

FIGURE 3 Response distribution of management of a closed intra-articular intercondylar fracture of the distal femur, by nationality



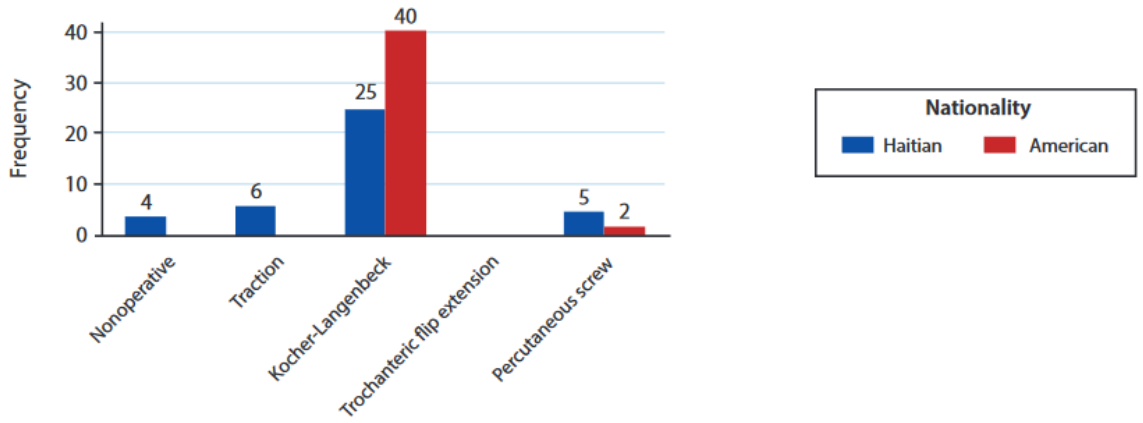
Haitians reported implant availability (n = 5/33) and functional outcomes (n = 4/33), while Americans reported functional outcomes (n = 1/39) and support staff (n = 1/39) as reasons not to use a condylar locking compression plate for a distal femur fracture (Table 5).

TABLE 5 Rationale for choosing management other than condylar locking compression plate for a distal femur fracture

Rationale	Haitian respondents (#) of 33 respondents	American respondents (#) of 39 respondents
Functional outcomes	4	1
Implants	5	0
Support staff	0	1
Expense	1	0

The majority of Americans chose ORIF for the management of a posterior hip dislocation with a displaced fracture of the posterior wall (n = 40/42), while Haitians chose ORIF (n = 25/39), nonoperative management (n = 4/39), or skeletal traction (n = 6/39) (p = 0.002) (Figure 4).

FIGURE 4 Response distribution of management of a posterior hip dislocation with displaced fracture of the posterior wall, by nationality



Haitians reported confidence performing the operation (n = 5), operating room equipment availability (n = 4), and implant availability (n = 2), while Americans reported confidence (n = 2) as reasons not to perform ORIF in this case (Table 6).

TABLE 6 Rationale for choosing management other than Kocher-Langenbeck approach for ORIF of an acetabular posterior wall fracture dislocation

Rationale	Haitian respondents (#) of 39 respondents	American respondents (#) of 42 respondents
Confidence	5	2
Functional outcomes	1	0
Complications	1	0
Implants	2	0
OR equipment	4	0
Time	1	0

DISCUSSION

Regional variation in orthopedic management across the United States has been documented for various conditions [5-8]. Explanations for such variation may include differences in patient population or disease epidemiology; local effect of the environment in which a surgeon trains or practices; reimbursement schemes; or novelty of new technologies. Variation in orthopedic

surgeon decision-making between low- and high-income countries has not previously been explored. In this study, we show that the management of three common orthopedic injuries varies between Haitian and American orthopedic surgeons.

Four of the cases surveyed showed no difference in management, which suggests that many orthopedic trauma cases are managed similarly across countries. Of the three cases with significantly different management strategies, implant availability was a frequently cited reason among Haitian surgeons for not choosing the reference response, which supports known resource constraints and diminished surgical infrastructure in Haiti [9]. While the management options chosen for midshaft tibia fracture and distal femur fracture differed between Haitian and Americans, reported outcomes of the different management options are similar [10-16], suggesting that despite resource limitations, differences in decision may not be clinically significant. While the burden of pelvic and acetabular injury is high in developing countries[17,18], surgery is uncommon in Haiti due to surgical training and equipment availability, such as C-arm, as reflected in this survey. The response to management of a glenoid fracture dislocation confirmed the previously anecdotal belief of reduced access to arthroscopic equipment and training in Haiti.

A recent study comparing orthopedic operative volume between a hospital in Ghana and a hospital in the United States showed a disproportionate burden of trauma, severe fractures, and infections in Ghana as compared to the United States[19]. Therefore, differences in patient demographics and injury severity likely contribute to differences in outcomes. Orthopedic burden in Haiti has similarly high volumes of orthopedic trauma and infections[20], which may influence surgeon decision-making as well as patient outcomes, though this was not evaluated in the current survey and would need to be explored further.

This study has several limitations. First, the survey respondents may not represent orthopedic surgeons as a whole in Haiti and the United States. Respondents were primarily orthopedic surgery residents, with few attending surgeons represented among our respondents. While residents are not ultimately responsible for choosing surgical management, their responses likely reflect the teaching they receive from attendings in their practice environment. Additionally, the American attendings surveyed were those who elected to travel to Haiti, and therefore may not represent U.S. surgeons as a whole; however, as practicing orthopaedic traumatologists, they were experienced in the cases represented in this survey. Second, surgeons were surveyed about hypothetical cases, and their responses may not represent the management choices they would make in practice. A study of injury presentation and management to explore surgical decisions in practice would provide more detailed information about how management decisions differ between countries. Third, previous studies have shown that injury pattern and severity differs between low- and high-income countries[18,19,21]; while these differences are likely to affect surgical management, they were not explored in this survey. Other factors that may influence management decisions, including timing between injury and presentation; patient ability to comply with planned treatment and ability to follow-up; access to specialists, critical care, and anesthesiology; and referral patterns, were not addressed in this survey.

CONCLUSION

These data, while limited by the high representation of residents and the limited scope of the survey design, provide preliminary data to show the difference in management decisions surrounding orthopedic trauma between Haitian and American orthopedic surgeons. In particularly, these data suggest that implant availability and specialized orthopedic trauma

training in pelvic surgery and arthroscopy are current deficits in orthopedic trauma care capacity in Haiti, and may be areas of need for future study and development. As with the introduction of any new equipment, adequate training in its use is necessary to ensure appropriate implementation. Other infrastructure required for advanced trauma care, including general surgery, anesthesiology, radiology, and pharmacy, were not assessed in this survey but may be additional needs that influence surgical management decisions. Future studies should examine management of orthopedic injuries in practice rather than in a survey to better characterize differences. These results could be used improve resource allocation to low-income settings such as Haiti.

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Chapter 4: A Novel Approach for Needs Assessment to Build Global Orthopaedic Surgical Capacity in a Low-Income Country

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ABSTRACT

Objective: Visiting surgical teams are a vital aspect of capacity-building continuing medical education (CME) in low-income countries like Haiti. Imperfect understanding of the genuine needs of local surgeons limit CME initiatives. Previous paper-based needs assessment efforts have been unsuccessful due to low response rates. We explored using an electronic audience response system (ARS) during a Haitian CME conference to improve response rates and better assess needs.

Methods: Data were prospectively collected using an ARS from 78 conference participants (57 Haitian and 21 Foreign) about current and desired knowledge of 7 topic and 8 skill areas using a 5-point Likert scale presented in English and in French. Response rates using ARS versus a similar paper survey were compared using a two-sample test of proportions. Current and desired knowledge levels were compared using paired t-tests. ANOVA and post-hoc unpaired t-tests were used to compare between demographic groups.

Results: Response rates were significantly greater for ARS versus a paper survey (87.7 vs. 63.2%, $p=0.002$). The four areas of least self-confidence for Haitians were pelvic and articular injury, joint dislocation, and osteomyelitis. The four skills of least self-confidence for Haitians were arthroscopy, ORIF-Plate, external fixation, and fasciotomy. Haitians desired improvements in knowledge and management of articular, diaphyseal, and pelvic injury, joint dislocation, and osteomyelitis to a greater extent than foreigners ($p<0.05$). Participants who previously attended the conference on open fractures felt more knowledgeable about open fractures as a topic ($p<0.05$), but not in its management.

Conclusions: We are the first to show that an ARS improves response rates to allow for better characterization of surgeon needs in the developing world. We also demonstrate the importance of

skill building paired with topic area teaching. Lastly, we show how a CME conference is an effective tool to build surgical capacity and increase confidence level.

INTRODUCTION

Continuing Medical Education (CME) is an important part of capacity building in surgery especially in the developing world. Learning in CME activities is more likely to lead to change in practice when needs assessment has been implemented.[1] Orthopaedic trauma, which is one of the essential surgical care needs in the developing world, has become a necessity. In the latest global burden of disease, road traffic injuries are ranked 10th among the leading causes of disability adjusted life years lost, a trend with no sign of slowing down with motorization of the roads in the developing world. These nations account for 90% of this disability-adjusted life years lost.[2]

Close attention to competency and skills while promoting capacity building in orthopaedics in the developing world is critical since these efforts are likely to alter surgeon practice and patient satisfaction.[3] In the developing world, post-graduate medical, and especially surgical, education relies greatly on visiting professors from developed countries to supplement medical knowledge and skills. However, this transfer of knowledge can be very sporadic due to a lack of longitudinal implementation of these visits. Furthermore, the irregularity of these visits may create an imbalance in surgical knowledge even within the same country.

Continuing medical education (CME) is defined as educational activities that serve to maintain, develop, or increase the knowledge, skills, performance, and relationships a physician uses to provide services for patients, the public, or the profession.[4] The Haitian Annual Assembly for Orthopaedic Trauma (HAAOT) is the first orthopaedic-focused CME conference designed for Haitians to provide a platform for post-graduate education. One of the challenges in the design of HAAOT's CME curriculum is the lack of any documented data on the needs of Haitian orthopaedic surgeons and residents. A needs assessment can explore felt needs (what people say they need), expressed needs (expressed in action) normative needs (defined by experts), and comparative needs

(group comparison),[5] but we were interested on "felt needs" as adult learners are best reached when their "felt needs" are addressed.[6] This focus also helps to identify appropriate areas for improvement in skills, knowledge, and attitudes by identifying gaps to be filled.[7]

Even when needs assessment is recognized as important, efforts often fail or are made challenging since response rates to paper or online surveys are very poor.[7,8] Since HAAOT brings all three orthopaedic residency programs and most practicing orthopaedic surgeons in the country together in one place, we sought to determine if the use of an audience response system (ARS) could boost the response rate and provide a more accurate needs assessment. In addition to exploring the use of ARS for needs assessment, the results of our study will help address two main concerns of post-graduate orthopaedic education: (1) the current level of knowledge and skill competency, and (2) self-identified areas for improvement that can be the focus of future CME efforts during conferences and trips by visiting surgeon educators.

MATERIALS AND METHODS

Setting: The Haitian Annual Assembly for Orthopaedic Trauma (HAAOT) was created in 2013 to address a very fundamental need in post-graduate training, continuing education, which at the time did not exist. The conference consists of original research paper presentations, case discussions by Haitian residents and didactic lectures presented by foreign visiting attending surgeons on relevant topics in orthopaedic trauma.

Participants: Survey participants included Haitian and foreign (USA/Ireland) orthopaedic residents and attending surgeons drawn from multiple academic centers within their respective countries. Foreign residents and attendings were volunteers.

Electronic invitations were sent to all aforementioned participants and more specifically to all three orthopaedic residency programs and most of the practicing orthopaedic clinicians in the country. Two of the three programs are located in Port-au-Prince and the other is in Cap-Haitian, which is located about 251 miles (156 km) north of the capital city. Practicing orthopedists came from all over the country to participate. In total, there were 89 participants at the conference when including generalists, family and emergency medicine residents, and physical therapists. Outcomes for these groups are not reported in this study however due to small sample size.

Survey Design: Questions about current and desired competence across key orthopaedic topics and skills were created as Microsoft Office PowerPoint slides that were integrated with an audience response system (TurningPoint ResponseCard RF, Turning Technologies). This system uses radiofrequency to capture anonymous audience responses. Questions were distributed across the day's presentations to prevent "clicker fatigue" and queried in blocks of 5 minutes. A set of 5 demographic questions (gender, attending/resident, post-graduate years, prior HAAOT attendance, and hospital affiliation) was used to train participants in the use of the ARS, and all questions were projected in both English and French to account for the differing language preferences of the audience. These questions allowed us to register each response unit exclusively to a unique individual while maintaining anonymity. No technical difficulties were encountered in the use of the ARS.

The audience was asked to respond to pre-selected topics that were perceived as relevant and crucial to the basic practice of orthopaedic trauma as determined from existing quality information data from multiple hospitals in Haiti (unpublished data). We also sought expert advice on possible extra topics necessary for a well-balanced assessment. The skills and the topics chosen were interrelated

to aid in validation of the answers. We asked the audience to first evaluate their present knowledge on a topic/skill and then followed that question with the desired level they would want to achieve on that same topic/skill using a 5-point Likert scale (expert=1 and novice=5).

Statistical Analysis: ARS response rate was compared to the response rate of a similar paper survey distributed on the same day using a two-sample two-sided test of proportions. Cross-sectional descriptive statistics were calculated quantifying population demographics. Two-sided paired t-tests were used to compare current and desired knowledge levels, while post-hoc unpaired two-sided t-tests following a statistically significant ANOVA were used to compare between demographic groups. All analysis was carried out using STATA IC/13.

Ethical Consideration: Our study was determined to be IRB-exempt by the Brigham and Women's Institutional Review Board (IRB).

RESULTS

Demographics: Seventy-eight orthopaedic surgeons attended HAAOT (57 Haitian, 21 Foreign). Table 1 provides more detailed demographic information. To summarize, among Haitians, 11 were attendings, 12 were residents, and 27 were unassigned at the time of inquiry. Among Foreigners, 13 were attendings, 4 were residents, and none were unassigned.

TABLE 1. Demographic Information About Participants

Characteristics	% of Total Respondents ($n = 67$)
Male	76.7
Haitian	74.6
Resident (% of Haitian)	24
Attending physician (% of Haitian)	22
Unassigned (% of Haitian)	54
Foreign	25.4
Attending physician (% of Foreign)	78.6
Attended HAAOT previously	42.5
Of Haitian residents?	54.5
Of Haitian attending physicians?	63.6
Of Foreign attending physicians?	10.0
Response rate—overall (total attendees = 78)	85.9
Haitian (attendees = 57)	87.7*
Foreign (attendees = 21)	81.0

*p = 0.002. Compared with paper survey (87.7 vs 63.2).

Response rate: Overall response rate using the ARS was 85.9% (87.7% Haitian, 81% Foreign). Response rates were statistically significantly greater for the ARS versus a comparable paper survey (87.7 versus 63.2%, p=0.002).

Baseline Topic: Pelvic injury, articular injury, joint dislocation, and osteomyelitis were the lowest topic areas of self-confidence for Haitian respondents (Figure 1a). Haitian respondents rated their current knowledge as significantly less than that of foreign respondents for joint dislocation ($p<0.01$), but were statistically identical for polytrauma, compartment syndrome, open fracture, and diaphyseal injury. Only for polytrauma did Haitian respondents rate themselves as more confident on average than foreign respondents, although this was not statistically significant. Haitian respondents felt most confident in their baseline knowledge of open fractures and polytrauma. Interestingly, this confidence did not translate into higher levels of confidence in management of complications (osteomyelitis and compartment syndrome, respectively).

When comparing Haitian attendings and residents, areas of discomfort were similar but residents felt much less comfortable managing osteomyelitis ($p<0.05$). When compared to foreign attending physicians, Haitian attendings and residents did not rate themselves as more confident in their knowledge of any topic area (Figure 1b). Curiously, Haitian residents rated themselves as more confident than Haitian attendings in knowledge of open fracture and diaphyseal injury on average, but this was not statistically significant. When compared to foreign attendings, Haitian attendings had similar comfort levels except in management of joint dislocation where they rated themselves as significantly less confident ($p<0.05$).

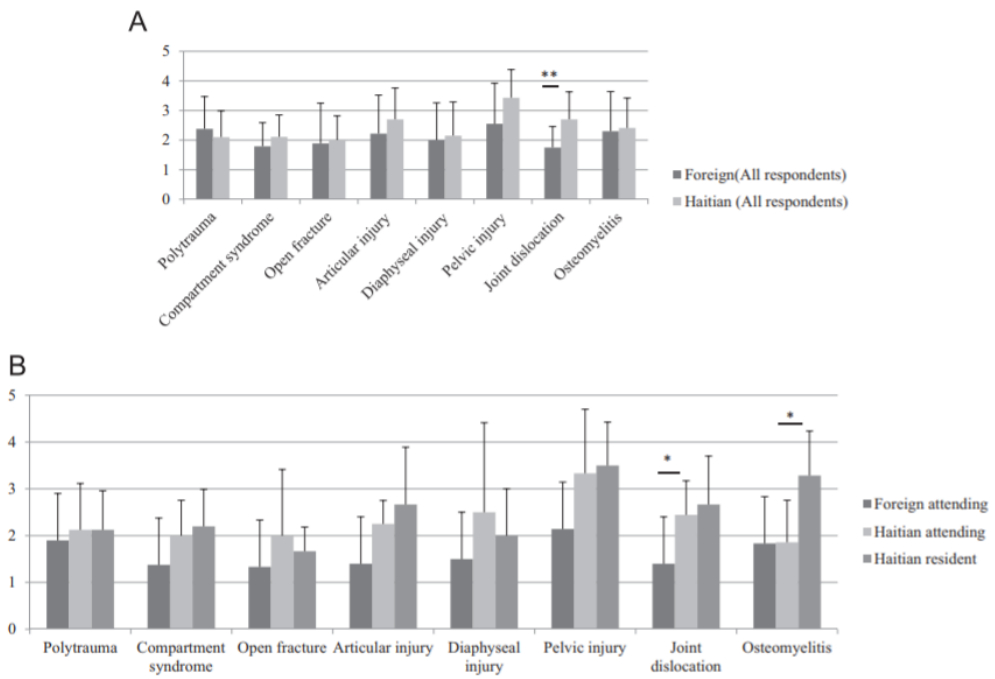

FIGURE 1. Baseline topic self-rating by (A) foreign and Haitian, and (B) foreign attending physician, Haitian attending physician, and Haitian resident; Likert scale: 1 = expert and 5 = novice.

Baseline Skill: Arthroscopy, ORIF-Plate, external fixation, and fasciotomy were the four skills of least confidence for Haitian respondents (Figure 2a). Haitian respondents rated their current skill level as significantly less for external fixation and arthroscopy ($p<0.01$), but were statistically similar for cast/closed reduction, ORIF-Nail, and debridement. Only for ORIF-Nail and debridement did

Haitian respondents rate themselves at a higher self-confidence level than foreign respondents on average.

Haitian attendings and residents had similar areas of perceived skill deficits, but residents were significantly less comfortable with external fixation ($p<0.05$). In all categories, foreign attendings were most confident, followed by Haitian attendings, and then Haitian residents (Figure 2b).

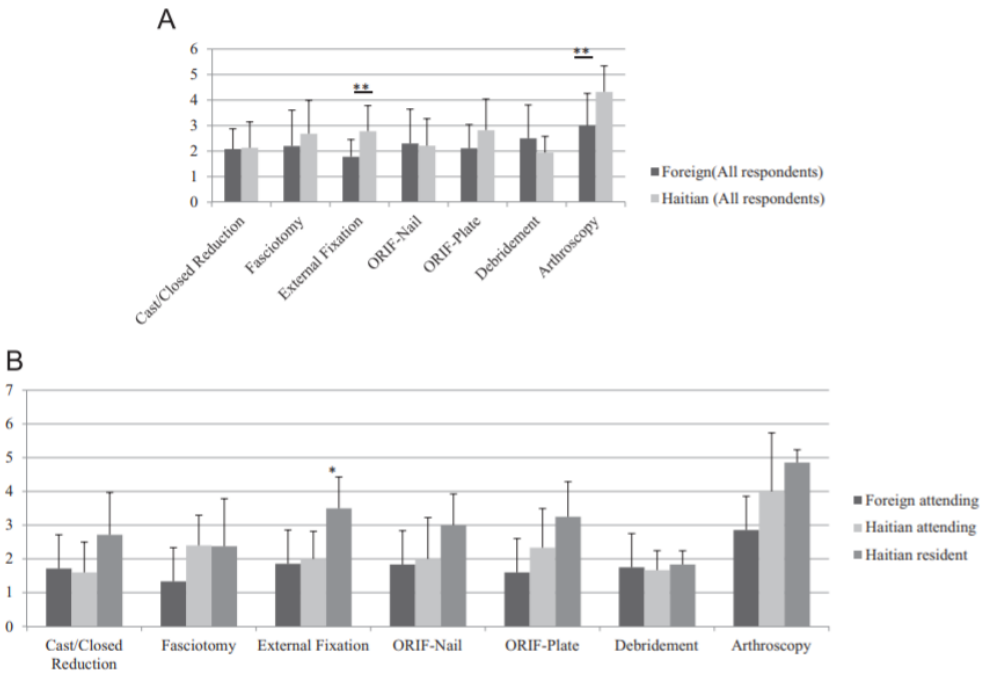

FIGURE 2. Baseline skill self-rating by (A) foreign and Haitian, and (B) foreign attending physician, Haitian attending physician, and Haitian resident; Likert scale: 1 = expert and 5 = novice.

Topic Area Improvement: Haitian respondents desired statistically significant improvements in their knowledge of articular injury, diaphyseal injury, pelvic injury, joint dislocation, and osteomyelitis ($p<0.05$) to a greater extent than foreigners ($p<0.05$). On average, Haitian respondents desired greater improvement in all topic areas than foreign respondents (Figure 3a).

When comparing more closely across demographic categories (Figure 3b), Haitian residents typically desired greater knowledge improvements than Haitian or foreign attendings across topic areas. Notable exceptions were in open fracture management where Haitian residents essentially noted no perceived need for improvement; however, Haitian residents did desire a statistically significantly increase in knowledge of osteomyelitis (a common complication of open fracture) when compared to attendings.

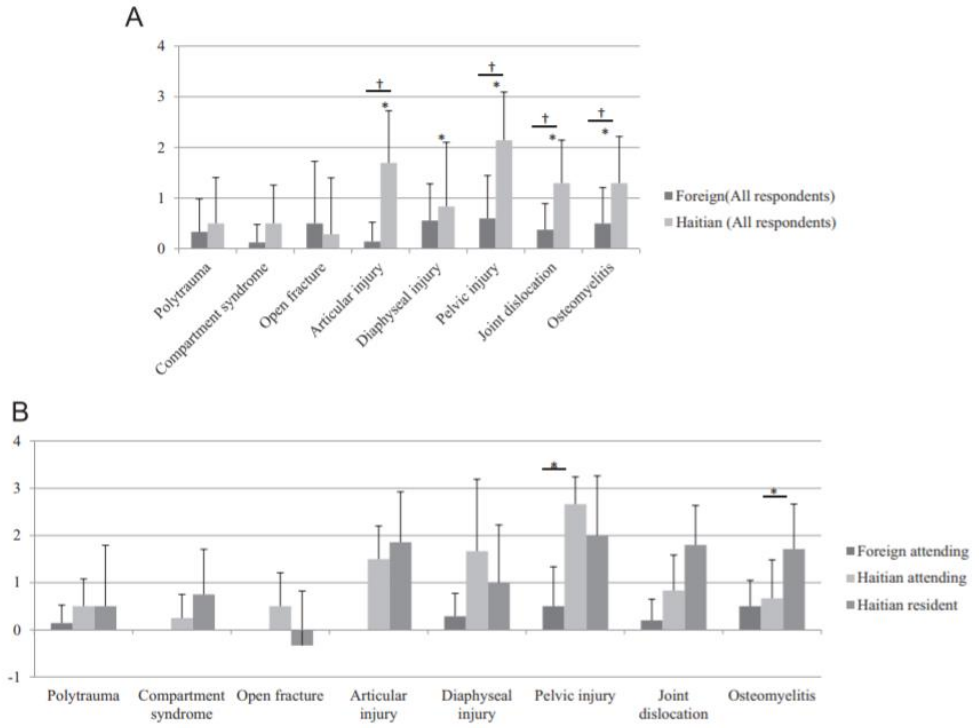

FIGURE 3. Desired topic improvement by (A) foreign and Haitian, and (B) foreign attending physician, Haitian attending physician, and Haitian resident; Likert scale: 1 = expert and 5 = novice.

Skill Area Improvement: Haitian respondents desired statistically significant improvements in the skills of cast/closed reduction, external fixation, ORIF-Nail, ORIF-Plate, debridement, and arthroscopy ($p<0.05$) at levels greater than foreigners ($p<0.05$ for external fixation, ORIF-Plate, and arthroscopy) (Figure 4a). On average, foreign respondents only desired greater improvement than Haitian respondents for cast/closed reduction and ORIF-Nail.

On average, Haitian residents desired greater skill improvements in all categories when compared to Haitian and Foreign attendings (Figure 4b). This was especially evident for external fixation ($p<0.05$). Haitian attendings and residents desired greater skill improvements than foreign attendings at significantly larger magnitudes across all skill areas.

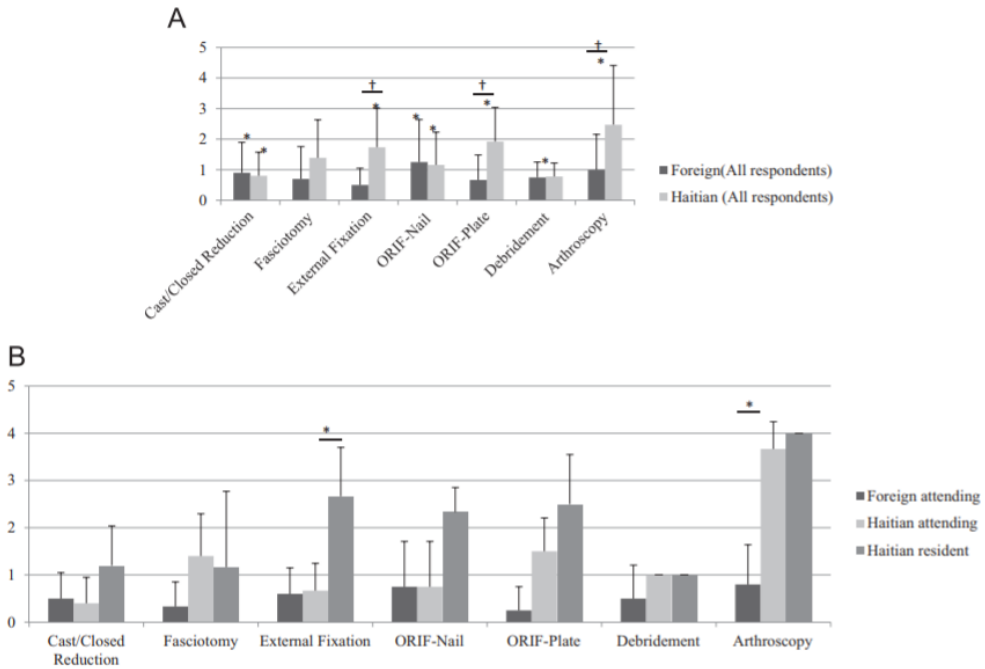

FIGURE 4. Desired skill improvement by (A) foreign and Haitian, and (B) foreign attending physician, Haitian attending physician, and Haitian resident; Likert scale: 1 = expert and 5 = novice.

Effect of Prior HAAOT Attendance: Participants who attended the prior year's HAAOT conference on open fractures felt more comfortable in their knowledge of the open fracture topic area (1.3 versus 2.3, $p<0.05$). However this increased confidence in topic knowledge failed to extend to the management of open fractures (external fixation/ORIF/Debridement) or its complications (osteomyelitis) (Table 2).

TABLE 2. Effect of Attending HAAOT in the Prior Year on Haitians on Current Knowledge of Open Fracture, Management, and Complications

Topic Area	Control	Attended HAAOT
Open fracture	2.33 (0.58)	1.33* (0.52)
Osteomyelitis	2.50 (0.84)	2.50 (1.51)
External fixation	2.86 (0.69)	3.00 (1.55)
ORIF nail	2.71 (1.25)	2.29 (1.11)
ORIF plate	2.60 (1.14)	3.40 (1.14)
Debridement	1.67 (0.58)	1.80 (0.45)

*$p < 0.05$. One-tail (expect improvement in attendees); Likert scale: 1 = expert and 5 = novice.

DISCUSSION

The globalization of health has made CME an international concern for both developed and developing countries. Increasingly, international CME is becoming recognized as more than a series of conferences and courses, but as an integrated curriculum that is built on projects in needs assessment, performance evaluation and healthcare outcomes.[8,9] In Haiti, orthopaedic surgery became acutely sensitive to this challenge after the tragedy of the 2010 earthquake and the orthopaedic injuries it caused. Today, Haitian orthopaedic surgeons still take care of the complications from the 2010 earthquake, but also have renewed focus on the rising burden of orthopaedic disease from injury. A challenge to visiting foreign orthopaedic surgeons is in finding ways to meet the needs of developing countries like Haiti through extended post-graduate training programs.[10] A key result of our study is a basic methodology for needs assessment for CME planning in developing countries to help build orthopaedic surgical capacity. By elucidating the "felt" needs of Haitian surgeons, we can now build assessment criteria internally and externally (e.g. for funding organizations) and create curricula that are learner-centered.[7,9,10]

Our study also sought to tackle the problem of historically poor response rates to needs assessment

by using an audience response system during an existing conference to more compellingly engage participants.[8] When compared to a similar paper survey distributed on the same day, this strategy was significantly more successful.

Lastly, there has been only one reported study on continuing medical education from the Caribbean and relatively sparse data from the rest of the world on how orthopaedic surgeons can impact their global colleagues' efforts at improvement. We sought to explore the difference between topic areas and skills, and show how self-perceived deficiencies in skills are wider than for topic areas. In addition, we show that this desire for improvement extends to both residents and attendings. If surgical capacity is a focus of global surgery, then projects like ours in needs assessment are vital to ensuring that CME can be a functional "effector arm" for complex health care systems in the developing world.[9,11] Our methodology is also unique in that it gives direction to how local level data on CME needs can be captured to avoid inappropriate generalization from national or regional data.

CONCLUSION

A need assessment as shown in our study is a powerful tool to discern an audience's desired areas of improvement during a CME conference. However, care should be taken not to narrow the scope of the conference as meeting normative needs (those defined by external experts) remain important. For instance, our study shows discordance between self-confidence in open fracture management (high) and its common complication of osteomyelitis (low). We have also demonstrated the need for future orthopaedic visiting teams to Haiti to focus on skill building in addition to topic area enhancement. Lastly, using the novel approach of RF-based ARS we were able to circumvent the low yield of needs assessment in a low-income country. This approach has helped us show how a CME

conference can be an effective tool to build surgical capacity and increase confidence level in the developing world.

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Chapter 5: A Self-Reported Needs Assessment Survey of Pediatric Orthopaedic Education in Haiti

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ABSTRACT

Objective: The burden of musculoskeletal disease remains high in low-income countries, with a high rate of pediatric disease. Efforts continue for orthopaedic education, but there is little guidance on local needs and desires. Our aim was to determine the specific content and modalities that would be most useful for pediatric orthopaedic educational programs abroad, and we demonstrate a practical method of identifying country-specific educational deficits through a self-reported needs survey in Haiti.

Design: A cross-sectional survey was administered using an automated response system. We obtained demographic information as well as training and practice patterns, comfort levels with pediatric diagnoses, and desired topics for education using a 5-point Likert Scale.

Setting: Haitian Annual Assembly for Orthopaedic Trauma (HAAOT), the only national, continuing medical education conference for orthopaedic providers in Haiti.

Participants: Of 60 eligible participants, 51 were included in the final analysis.

Results: Time spent on pediatric orthopaedics varied widely, centered at 10-25%. Median comfort level with pediatric orthopaedics was 3 out of 5. Skills with lowest self-reported competence included spica casting, clubfoot casting, and management of supracondylar humerus fractures. Skills with highest self-reported competence were long-leg casting and Salter-Harris classification. Modes of education highly requested included didactics/lectures, hands-on sessions, dedicated rotations, and exchanges with foreign peers/mentors. Diagnoses most encountered were osteomyelitis, trauma, and clubfoot; lowest comfort levels were in neuromuscular, spine, lower extremity deformity, congenital hip, and clubfoot; and most requested for future teaching were congenital hip, neuromuscular, and spine.

Conclusions: Haitian orthopaedic providers express a strong desire and need for ongoing pediatric orthopaedic education. They describe a high prevalence of trauma and infection, but convey a requirement for more comprehensive, multi-modal teaching that also includes congenital deformities/dysplasias, neuromuscular, and spine. Our results demonstrate the importance of assessing country-specific needs and involving local care providers in curriculum development.

INTRODUCTION

The global burden of surgical disease is large and growing, particularly related to orthopaedic problems. An estimated 100 million procedures remain unperformed worldwide for injuries, congenital anomalies, and other musculoskeletal disease alone.[1] Moreover, orthopaedic diagnoses are an increasing cause of global disability-adjusted life years lost, most notably in resource-challenged nations with high rates of childhood disease.[2-4] Numerous individuals and professional societies are focused on pediatric orthopaedics abroad [5], with long-standing efforts established in Uganda [6], Malawi [7, 8], India [9, 10], and Nepal [11] amongst others.

Ranking as the poorest country in the Americas, and one of the poorest in the world, Haiti has also has been the site of numerous orthopaedic efforts since a magnitude 7.0 earthquake in January 2010.[12-15] Orthopaedic training has been established as an important component of improving surgical care in low-resource countries.[16-18] Past efforts have provided proof of concept for continuing medical education (CME) in developing countries including Haiti.[19] In 2013, the first national CME conference for orthopaedics in Haiti since the earthquake was established – the Haitian Annual Assembly of Orthopaedic Trauma (HAAOT).[20] Despite the multiple programs that focus on developing pediatric orthopaedics in developing countries, no study to date has explored educational needs and desires specific to treating children in this context. This has limited the design of any pediatric orthopaedic curriculum abroad including the efforts in the HAAOT. Prior work at this conference

demonstrated the benefits of an audience response tool to allow real-time feedback from attendees regarding self-perceived needs on education topics, but content focused only on trauma in the general (adult) patient setting.[20]

We present a needs assessment survey and analysis of the educational priorities for pediatric orthopaedics in Haiti. We believe this is an important step to guide ongoing pediatric orthopaedic efforts in Haiti and other low-income countries, and an example of incorporating country-specific perspectives into surgical curriculum development abroad.

MATERIALS AND METHODS

The survey was conducted in April 2015 during the Haitian Annual Assembly for Orthopaedic Trauma (HAAOT). This was the third annual conference in Port-au-Prince and featured original research presentations, didactic lectures, and hands-on learning. It has had demonstrable success in education, expanding beyond trauma into multiple sub-specialties.[20, 21] Survey participants included local, Haitian orthopaedic residents and surgeons, as well as a small number of non-orthopaedic physicians and nurses invested in musculoskeletal care. Participation was voluntary and anonymous.

With input from both Haitian and U.S.-based ("foreign") pediatric orthopaedic surgeons, a 28-question survey was designed to assess pediatric orthopaedic educational needs, including training and practice patterns, levels of comfort in this field, perceived clinical burden, and both the form and content desired for ongoing education. We conducted directed interviews with three senior pediatric orthopaedic surgeons, active for many years educating Haitian surgeons, in order to formulate general themes for query. Specific questions and response options were then formulated with two prior conference organizers familiar with demographics of the attendees, and reviewed for content, clarity and language by a U.S-based pediatric orthopaedic surgeon and expert in American resident and fellow education. Questions

were directed towards understanding perceived areas of need, clinical volume, and preferred modes of education in order to objectively guide future conference programming and education.

Responses were collected using a 1 to 5 Likert Scale or by having participants select diagnoses from a list of options - upper extremity (UE) trauma, lower extremity (LE) trauma, spine deformity and trauma, congenital UE, congenital hip, LE deformity, neuromuscular, clubfoot, osteomyelitis and septic arthritis, or compartment syndrome. Demographic information about respondents, including nationality, age, gender, level of training, base hospital, and years in practice was also obtained. Survey questions were collected in real-time using an electronic audience response system (TurningPoint ResponseCard RF, Turning Technologies).[22] Cumulative time to answer all questions was approximately 14 minutes. Each answer was registered exclusively to a unique individual while maintaining anonymity.

Median and mean scores were calculated and ranges presented for all Likert scale questions. Responses of Haitian and U.S.-based orthopedic surgeons were collected but given that the vast majority of foreign participants were not pediatric orthopaedic specialists, foreign comfort levels and current practice patterns are not reported. Given all U.S.-based responses were accounted for, respondents with missing data for nationality (n=18) were recorded as Haitian. Participants not responding to at least 50% of the demographic questions were excluded as these 9 individuals either discontinued participation or had markedly higher nonresponse rate overall (data not shown). Individual question response rates ranged from 47% to 96%. For questions in which more than one answer choice was requested, responses were included if at least one answer choice was provided. Missing data for all questions were excluded from the denominator in percent calculations. Analyses were performed using SAS version 9.4 (SAS Institute, Inc.; Cary, NC, USA).

RESULTS

Demographics

Of the 60 eligible participants, 9 did not complete a majority of the demographic questions, and 51 participants were included in the final analysis. Multiple hospitals around the country were represented, including all centers with orthopaedic residency programs. The majority of participants were male (88%), were orthopaedic residents (67%), and had attended the prior year's conference (61%) (Table 1). The year in training was not available. However, as a proxy, we documented number of years since completing medical school and demonstrate a broad distribution of respondents (Haitian + U.S) by year across residents as well as junior and senior attendings: 8% were <1yr since graduation, 3% 1 yr, 7% 2yrs, 10% 3yrs, 12% 4yrs, 4% 5yrs, 12% 6 yrs, 15% 7-10yrs, 10% 11-20 yrs, and 19% >20 yrs.

TABLE. Demographics of Conference Attendees Participating in Survey ($N = 51$). Missing Responses Indicated as Unspecified and Included in Denominator

Characteristics	Number (%) of Respondents
SEX	
Male	45 (88)
Female	3 (6)
Unspecified	3 (6)
Years since obtaining MD	
0-2	10 (20)
3-4	11 (22)
5-6	8 (16)
7-10	9 (18)
>10	7 (14)
Unspecified	6 (12)
Primary hospital	
HUEH	17 (33)
La Paix	14 (27)
HUJ	6 (12)
Adventist	2 (4)
HSN	2 (4)
Other Haitian	7 (14)
Unspecified	3 (6)
Position	
Orthopedic resident	34 (67)
Orthopedic attending	9 (18)
Nonorthopedic physician	4 (8)
Nurse	2 (4)
Unspecified	2 (4)
Attended HAAOT in prior year	
Yes	31 (61)
No	18 (35)
Unspecified	2 (4)

HSN, Hôpital Saint Nicolas (in Saint-Marc); HUEH, Hôpital de l'Université d'Etat d'Haiti (in Port-au-Prince); HUJ, Hôpital Universitaire Justinien (in Cap-Haïtien); MD, doctor of medicine.

Training and Practice Patterns

Reported percent of training involving pediatric orthopaedics ranged from 0 to greater than 50%, with a broad distribution and median response of 10-25% (Figure 1). Participants indicated a slightly higher percentage of time involving pediatric orthopaedics in their current or expected careers, with a range from 0 to greater than 50%.

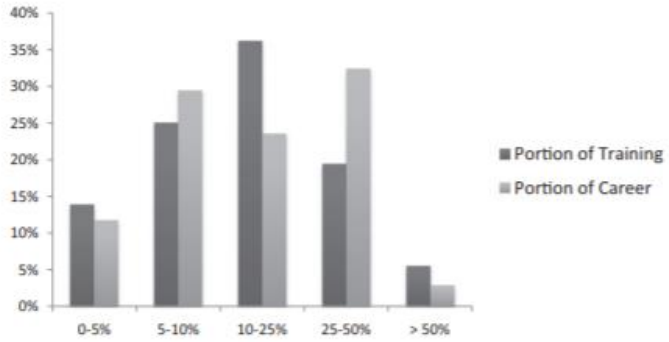

FIGURE 1. Patterns of exposure: percentage of training (dark) or career (light) that involves (or will involve) pediatric orthopedic care. Missing responses for percentage training and career were 15 of 51 and 17 of 51, respectively. Missing respondents excluded from denominator.

Comfort Level with Pediatric Orthopaedics

Reported overall comfort level managing pediatric orthopaedic patients ranged from 1 (least comfortable) to 5 (most comfortable), with median 3 out of 5 (38%) (Figure 2). The median response did not differ between residents and attending surgeons (both 3 out of 5), but the interquartile range for residents was [2, 3] compared to [3, 4.5] for attendings. For selected skills/topics in pediatric orthopaedics, respondents were more comfortable with use of the Salter-Harris classification and long leg (above-knee) casting (median 5 out of 5 for each) than with spica casting for a femur fracture (median 3.5), independent management of a supracondylar humerus fracture (median 3.0), or clubfoot casting (median 3.0). The three latter topics had a wide range of responses, with at least 50% of respondents indicating comfort levels of 3 out of 5 or less. Comfort with clubfoot casting revealed a bimodal distribution with approximately 1/3 of respondents stating 3 out of 5 and 1/3 of respondents stating 5 out of 5.

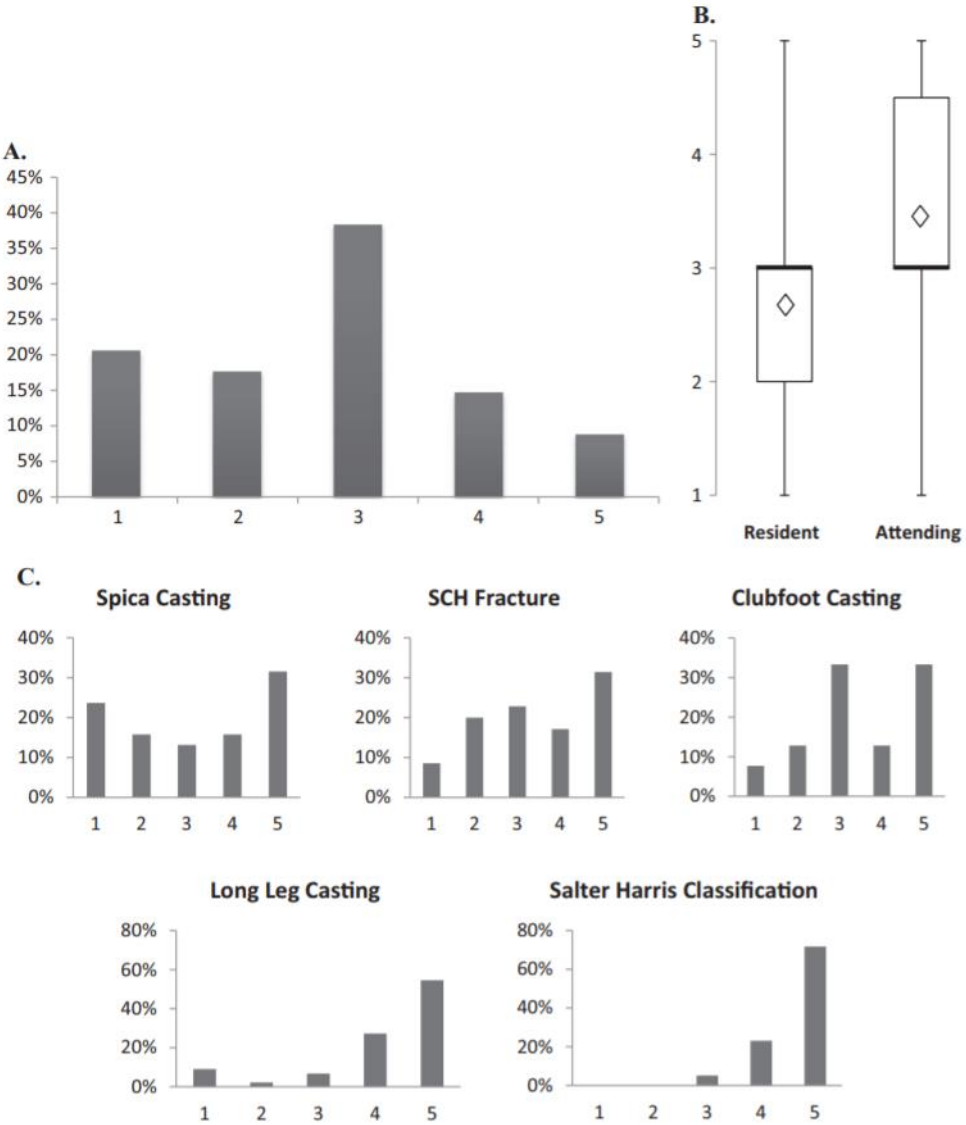

FIGURE 2. Patterns of comfort: self-reported comfort level with pediatric orthopedics (A) in general, (B) by level of training, and (C) by specific pediatric skill. Horizontal dark lines in box-plots represent median, diamonds represent mean, box range indicates 25th to 75th percentile, whiskers extend to minimum and maximum values. Likert scale: 1 = least comfortable, 5 = most comfortable. Missing responses excluded: 17 of 51 for overall comfort, 11 of 23 and 2 of 7 for residents and attendings, respectively, range: 13 of 51 to 20 of 51 for topic areas. SCH, supracondylar humerus.

Educational Needs and Desires

Sixty five percent of respondents rated the importance of pediatric orthopaedic education in Haiti at a 4 or higher out of 5 (5 = most important). The majority of respondents reported 5 out of 5 need (5 = most needed) for pediatric orthopaedic education in the form of more didactics/lectures (69%), hands-on skills workshops (75%), a dedicated rotation (84%), and access to international peers and mentors (86%).

We then examined patterns of need by diagnosis. Attendees selected the top 3 pediatric orthopaedic diagnoses that they: 1) saw the most in Haiti, 2) were least comfortable with, and 3) most wanted to focus on in future teaching programs (Figure 3). Infection (including osteomyelitis and septic arthritis), trauma, and clubfoot were the most commonly encountered. Respondents were least comfortable managing the diagnoses of lower extremity deformity, congenital hip pathology, neuromuscular disease, and spine disorders. Topics with the highest demand for future teaching were congenital hip pathology, neuromuscular disease, and spine disorders. Of the three diagnoses most seen, the topic respondents felt most uncomfortable with was clubfoot, with 29% of people including it as one of the 3 diagnoses they were least comfortable managing.

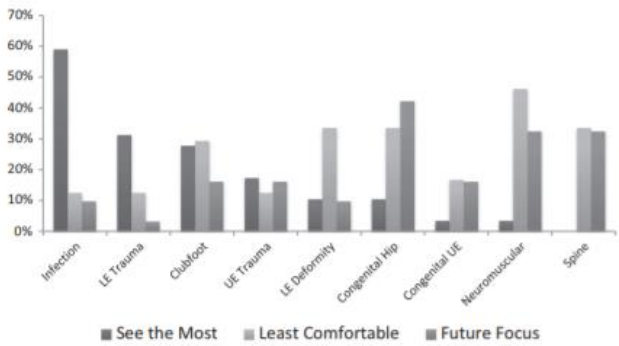

FIGURE 3. Patterns of need and desire. Self-reported rates of pediatric orthopedic diagnoses that Haitian participants see the most, are least comfortable with, and would like future teaching sessions on. Percentages are percentage of individuals who included each diagnosis as 1 of their top 3 choices for each question. Missing rates for each question category ranged from 39% to 53% (considered missing if 0 diagnoses provided). Infection, osteomyelitis and septic arthritis; UE, upper extremity.

DISCUSSION

There is a growing recognition of the importance of orthopaedic surgical education in low-resource settings. Pediatric orthopaedics in particular remains plagued by a lack of specialty training in developing nations despite a disproportionately high rate of pediatric

burden due to a younger population and increased rates of trauma compared to high-income countries.[4] This clinical gap has motivated several bi-directional initiatives such as travel fellowships for foreign orthopaedic surgeons, including Haiti's only two pediatric orthopaedic surgeons, to participate in specialty-specific conferences in the United States.[23] Another approach in this subspecialty has been to organize outreach courses in resource-challenged environments.[5]

Given the considerable time and resources required for global orthopaedic programs, it is important to understand local needs and interests in creating sustainable educational interventions desired by and helpful for in-country care providers. This work presents the first published effort to describe pediatric orthopaedic educational needs in a low-income country. In this study of orthopaedic providers, we found a strong desire and self-reported need for opportunities to better learn pediatric orthopaedics through ongoing lectures and skills workshops, a dedicated rotation during residency, and access to international peers/mentors.

While survey results show that the average time spent on pediatric orthopaedics is roughly concordant between training and practice, the wide range of residency time spent on pediatric care suggests a markedly heterogeneous experience across trainees that may leave some unprepared for eventual career needs. In addition, variation in self-reported comfort levels within pediatric orthopaedics may be a result of inconsistent efficacy of training that is received. These findings suggest that more than simply increasing the quantity of education, programs should focus on improving effectiveness and consistency of education across all trainees. A dedicated pediatric orthopaedic rotation or teaching curriculum during residency may help to standardize trainee experience at least to a minimum level of exposure. Discussions continue in Haiti around such a curriculum, including a central rotation in which all trainees rotate with the few pediatric sub-specialists, which our results would support.

Only moderate (3 out of 5) median levels of comfort are seen with pediatric orthopaedics, a concerning result given the relatively high number of children most practitioners treat. While the distribution of comfort level for attendings was skewed higher than residents, even for attending surgeons all comfort levels were represented, with the same overall median as residents. Particular discomfort with spica cast application, independent management of supracondylar humerus fractures, and clubfoot casting, in combination with high self-reported rates of trauma and clubfoot encountered in Haiti, suggest a need for future workshops and teaching focused on mastery of these basic skills in pediatric care. Of note, even long leg casting, the area in which respondents reported highest levels of confidence, showed less than 60% of participants completely comfortable with this skill, with several individuals reporting comfort level 1 out of 5 (least comfortable), indicating clear room for improvement in this critical skill for pediatric trauma.

Infection, trauma, and clubfoot were perceived to be the most frequent pediatric diagnoses encountered. Of these, clubfoot was reported as the diagnosis with which participants felt least comfortable. However, diagnoses most desired for future educational focus correlated with diagnoses seen least frequently. This may reflect more anxiety and less comfort with areas of less experience. In planning future pediatric orthopaedic curricula in low-income nations, topics of high clinical burden, low comfort level, and high surgeon interest should be considered and delivered appropriately.

Our study has several key limitations. The survey was restricted to self-reported measures of comfort, burden of disease, and educational needs. We believe this is a useful initial approach as it engages local providers by making them the central focus of the study. Moreover, learning in CME programs is more likely to yield change of practice when needs assessments have been implemented [24], and we hope pediatric orthopaedic teaching in Haiti

will have increased acceptance if aligned with local needs and desires. Ultimately, objective measures can be collected to validate the results our study reports.

Our findings are also limited by a number of missing responses. Using our automated response system we had an excellent sampling of conference attendees present at the start of the survey (low total nonresponse), with the overall 76% response rate due mainly to noncoverage via some conference attendees arriving after survey administration. Our main challenge was progressive item nonresponse and partial nonresponse amongst the participants. We believe the primary contributor was survey fatigue as response rate decreased over time (data not shown). In this case, we expect missing data would be randomly distributed and not impact our conclusions based on the "missing completely at random" (MCAR) assumption, however this cannot be confirmed and the risk remains for non-random loss of data.[25] We did utilize deductive imputation where appropriate to minimize missing rates. Our response rate is comparable to other global needs assessment surveys in Haiti [26], but with alternative methods coupling surveys with raffle tickets for textbooks as inducement for participation, our group has found improved participation rates in subsequent surveys (unpublished data). Repeated sampling with improved participation could validate our presently reported results.

Selection or sampling bias is also a possible limitation in our study design surveying attendees at a national conference. However, as HAAOT is the largest gathering of orthopaedic providers in the country, with no dedicated pediatric subspecialty groups, we feel this is the largest feasible sampling of the Haitian orthopaedic community. Furthermore, while the survey was distributed to all Haitian attendees regardless of specialty or focus, pediatric care is distributed broadly across the general orthopaedic community unlike the highly specialized care in developed nations. We do note the majority of survey participants were trainees or attending surgeons in practice for fewer than 10 years but believe this is an appropriate population to help guide interventions in Haiti.

Our study is the first assessment of pediatric orthopaedic educational needs in a developing nation, and our results support the need for a comprehensive pediatric orthopaedic educational effort in Haiti. Prior models exist for pediatric trauma curricula both in developed and developing countries. [27, 28] Based on our findings, however, while topics should continue to include infection and trauma (based on clinical burden), curricula should have a renewed integration of congenital anomalies including clubfoot and congenital hip pathology. Such a program should include a combination of didactic lectures, hands-on skills sessions, and a mechanism for ongoing communication and interaction with visiting pediatric specialists. Efforts are underway for such teaching modules in Haiti through U.S.-based professional societies, and we hope this study can support and guide such work, with a call to integrate the various international pediatric orthopaedic programs into a cohesive educational curriculum based on local provider needs and desires.

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Chapter 6: Short-Term Performance Improvement of a Continuing Medical Education Program in a Low-Income Country

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ABSTRACT

Background: The Haitian Annual Assembly for Orthopaedic Trauma (HAAOT) is a CME conference designed to help Haitian orthopaedic surgeons improve their knowledge and skills. The effectiveness of international CME conferences has not been studied. We hypothesized that HAAOT improves participants' short-term performance on knowledge-based assessments

Methods: Data were prospectively collected from 57 Haitian and 21 foreign orthopaedic surgeons and residents who attended HAAOT using pre- and post-presentation questions. An audience response system was used to capture responses to 40 questions. Five additional demographic questions were used to train participants and to record unique audience member responses. Questions were projected in English and in French. Two-sided paired t-tests were used to compare pre- and post-test scores. ANOVA with post-hoc unpaired t-tests was used to compare among demographic groups.

Results:

Response rate: Median response rate was 77.4% per day (Range: 76.5-85.9% per day).

Pre-test scores: Pre-test scores averaged 21% for Haitians and 39% for foreigners ($p<0.0001$), and were similar among Haitian attendings and residents.

Pre-post differences: Scores improved by 8% for Haitians ($p<0.0001$) and 10% for foreigners ($p<0.01$) after didactic presentations. Among subgroups, Haitian attendings improved on average by 18% compared to 6% for residents ($p<0.0001$). Haitian attending improvement trended toward significance when compared to foreign attendings ($p<0.08$).

Conclusions: Our study is the first to show improved short-term knowledge performance using an audience response system during a CME conference in a low-income country. CME conferences in low-income countries can be an effective tool to increase surgeon knowledge, and audience response systems can help engage participants and track outcomes.

INTRODUCTION

Continuing medical education is known to improve physician knowledge base, competence, and performance in practice, although it is still unknown whether this translates into healthcare outcome improvement [1,2,3]. Didactic lectures derived from learning theory developed in the United States remains the most common approach to CME worldwide, but its implementation has been sporadic and its efficacy unknown in most low- and middle- income countries. Its effectiveness is even less certain given language barriers and the lack of standardized curricula in residency.

CME is traditionally defined as educational activity that maintains, develops, or increases the knowledge, skills, performance and relationships a physician uses to provide services for patients, the public, or the profession [4], yet such activities and forums are non-existent in poor countries like Haiti. The Haitian Annual Assembly for Orthopaedic Trauma (HAAOT) is a CME conference that was started in 2013 through a partnership with Partners in Health, the Haitian Ministry of Health, the SIGN Foundation, Foundation for Orthopaedic Trauma, and American Academy of Orthopaedic Surgeons to bridge this gap. The conference consists of a blend of lectures and case-based presentations by visiting foreign surgeons and local Haitian orthopaedic surgeons and residents. While the response to the conference has been enthusiastic as it is the only orthopaedic-focused conference available to surgeons in Haiti, its short-term and long-term effects on participant knowledge have not been studied until now.

Given recent research that has shown that lecture-based learning is a less effective form of teaching when compared to problem-based learning, we sought to explore if a lecture-based course like HAAOT would still have a tangible positive effect on participants' knowledge base of essential orthopaedics [5,6,7,8]. To increase audience interaction, we also used an audience response system (ARS) instantaneously to gauge audience attentiveness as they answered assessment questions. Since this was the first year an ARS was used in the conference, we evaluated short-term outcomes and hypothesized that HAAOT could improve participant's short-term performance on knowledge-

based assessments.

MATERIALS AND METHODS

Setting: The Haitian Annual Assembly for Orthopaedic Trauma (HAAOT) was created in 2013 to address previously non-existent CME in orthopaedic surgery. The conference consists of original research paper presentations, case discussions by Haitian residents and didactic lectures presented by foreign visiting attending surgeons on relevant topics in orthopaedic trauma. The conference is hosted in Port-au-Prince, the capital city, to facilitate attendance.

Participants: Study participants included Haitian and foreign (United States/Ireland) orthopaedic residents and attending surgeons drawn from multiple academic centers within their respective countries. All orthopaedic attending surgeons had completed residency training in their home country. Foreign orthopaedic surgeons were used as a positive control for comparison with the Haitian participants.

Electronic invitations were sent to all three orthopaedic residency programs and most of the practicing private orthopaedic clinicians in the country. Two of the three programs are located in Port-au-Prince and the other is in Cap-Haitian, which is located about 251 miles (156 km) north of the capital city.

Survey Design: Pre- and post-test questions were designed for each didactic lecture by expert U.S. orthopaedic attending surgeons or extracted from U.S. orthopaedic in-service training exams. The entire test consisted of 40 scored questions (1 minute per question for 30 multiple-choice and 30 seconds per question for 10 true-false) that was designed to have >90% power to detect a difference of 5% between the pre- and post-test. Questions reflected the variety of lectures and were chosen to sample across the scope of key areas in orthopaedic surgery relevant to Haiti (e.g. dislocations, osteomyelitis, etc.).

All questions were created as Microsoft Office PowerPoint slides that were integrated with

an audience response system (TurningPointResponseCard RF, Turning Technologies). This system uses radiofrequency to capture audience responses privately. A set of 5 demographic questions (gender, attending/resident, post-graduate years, prior HAAOT attendance, and hospital affiliation) was used to train participants in the use of the ARS, and all questions were projected in both English and French to account for the differing language preferences of the audience. These questions allowed us to register each response unit to a unique individual while maintaining anonymity.

Determining participant scores was challenging due to the logistics of using an audience response system during a CME conference where participants could miss questions due to momentary absence. We conservatively counted non-answers as incorrect to avoid bias in finding improvement.

Statistical Analysis: Cross-sectional descriptive statistics were calculated to quantify demographics. Two-sided paired t-tests were used to compare pre- and post-test scores. Post-hoc Bonferroni unpaired two-sided t-tests were used following a statistically significant ANOVA to compare among demographic groups.

Ethical Consideration: Our study was determined to be IRB-exempt by our institutional review board and all subjects provided informed consent. There was no inducement or requirement to participate.

Source of Funding: No funding source played a role in this investigation.

RESULTS

Demographics: In total, 85 orthopaedic surgeons attended HAAOT (57 Haitian, 28 foreign). Table 1 provides more detailed demographic information. To summarize, among Haitians, 11 were attending physicians, 12 were residents, and 27 were unreported at the time of inquiry. Half (50%) of all participants had previously attended HAAOT.

Table 1 Demographic Information about participants

Characteristics	Day 1 % of Total	Day 2 % of Total	Day 3 % of Total
Male‡	79.3	85.7	100†
Haitian‡	74.6	66.2	89.6†
Resident (% of Haitian)	17.9	35.4	37.5
Attending (% of Haitian)	16.4	12.3	22.9
Unassigned (% of Haitian)	65.7	52.3	39.6
Foreign	25.4	33.8	10.4
Attended HAAOT previously	42.5	50.0	61.8
Of Haitian residents?	54.5	65.2	66.7
Of Haitian attendings?	63.6	62.5	70.0
Of foreign attendings?	10.0	23.1	33.3

‡ $p < 0.05$ by ANOVA

† $p < 0.05$; t test between Day 2 and Day 3

Response rate: Median response rate using the ARS during the conference was 77.4% (76.5-85.9%), and was similar among Haitian and Foreign respondents reflecting active participation. See Table 2 for more detailed daily information on response rates.

Table 2 Response rate by day among Haitian and Foreign participants

	Response rate % of Total
Day 1 ($N = 78$)	85.9
Haitian ($N = 57$)	87.7
Foreign ($N = 21$)	81.0
Day 2 ($N = 85$)	76.5
Haitian ($N = 57$)	75.4
Foreign ($N = 28$)	78.6
Day 3 ($N = 62$)	77.4
Haitian ($N = 57$)	75.4
Foreign ($N = 5$)	100

Pre-test scores: Pre-test scores averaged 21% for Haitians and 39% for Foreigners ($p<0.0001$) (See Figure 1). Baseline scores were similar among Haitian attendings and residents averaging approximately 20% (See Figure 2a and 2b).

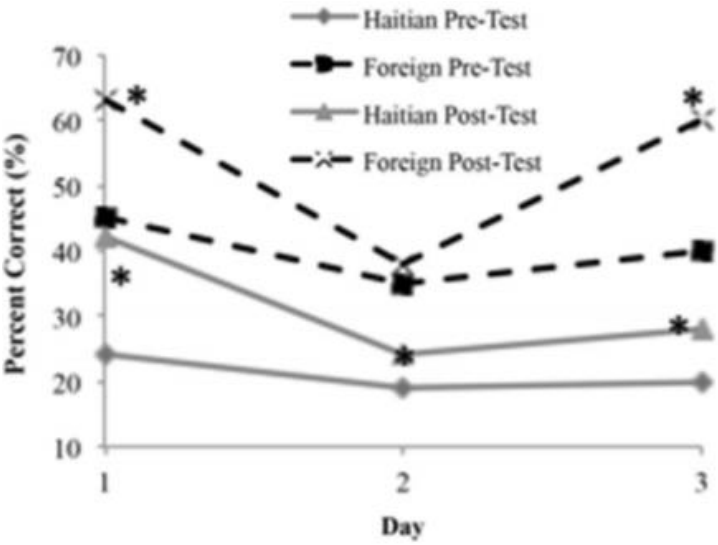

Fig. 1 Pre- and post-test scores among Haitian and Foreign participants for each conference day. $*p < 0.05$ when comparing between pre- and post-test

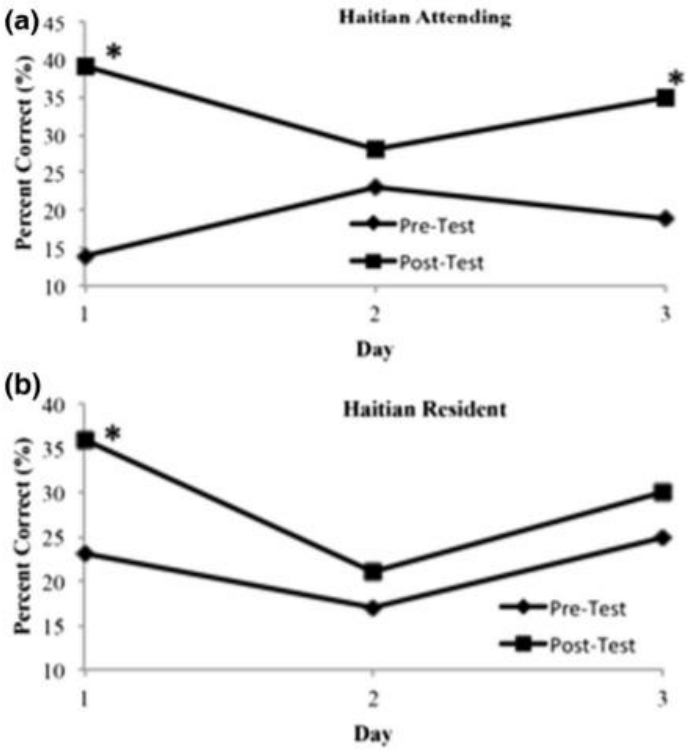

Fig. 2 Pre- and post-test scores for each conference day among Haitian **a** attendings, and **b** residents. $*p < 0.05$ when comparing between pre- and post-test

Pre-post differences: Scores improved by 8% for Haitians (p<0.0001) and 10% for Foreigners (p<0.01) following didactic presentations. Among subgroups, Haitian attendings improved on average by 18% compared to 6% for residents (p<0.0001). Haitian attending improvement trended toward significance when compared to Foreign participants (18 vs. 6%, p<0.08). These trends were consistent over all three-conference days (See Table 3 and Figure 2(a,b)).

Table 3 Score improvements by demographic group

Demographic group	Pre-post difference (%)
Foreign	10 (19)
Haitian	8 (16)
Subgroup analysis‡	
Foreign attending	9 (20)
Haitian attending	18 (19)
Haitian resident*	6 (12)

‡ $p < 0.05$ by ANOVA, * $p < 0.0001$: Haitian attending versus Haitian resident

DISCUSSION

The delivery of surgical care has become an increasingly relevant issue in low-income countries. Beyond simply hosting visiting surgeons or training local surgeons through medical school and residency, all countries are starting to recognize that continuing medical education for established providers and recent trainees is essential to building, maintaining, and improving surgical capacity [9]. At the same time, international CME is also recognized as more than conferences and courses, but as a structured curriculum requiring accreditation and evaluation of surgeon performance and healthcare outcomes [9]. As technology continues to modify the way education is delivered, we also need to continue to provide learner-centered methods that engage participants in CME.

In Haiti, orthopaedic surgery became acutely sensitive to the challenge of orthopaedic surgical delivery after the tragedy of the 2010 earthquake and the orthopaedic injuries it caused. Haitian orthopaedic surgeons still take care of the complications from the 2010 earthquake, but both the Haitian government and local providers have placed a renewed focus on the rising burden of orthopaedic disease from injury. The HAAOT CME conference was designed to build surgical capacity to meet this need, yet while it has been received favorably by the Haitian government and providers, little is known about the true effect of CME courses in low resource settings. Thus, a key result of our study has been to show that an international CME conference hosted in a low-income country improves short-term performance on knowledge-based assessments. We also present a generalized methodology for evaluating CME conferences using pre-post testing with audience response systems. An added benefit of ARS is that it takes advantage of new technology to further engage participants.

Our results in Haiti are relevant in context and scope when compared to prior work in international CME. The most similar international study in current literature is by Ali et al. who found that the implementation of an Advanced Trauma Life Support course in Trinidad and Tobago among untrained providers led to a pre-post improvement in test scores of 22.0% that was sizeable even when compared to Nebraska physicians who were used as a control [10]. They found that all participants improved in terms of total score, cognitive, and attitudinal effects. This effect size was similar to another recent study by Kelly et al. in 2014 who found that a short one-week course in musculoskeletal medicine to 154 students using brief didactic talks, case-based small group work, and physical examination skills demonstration resulted in a 27% improvement in standardized cognitive test scores immediately after the course. After one year, they found that improvement still averaged 21% [11]. Our study represents a novel hybrid approach between existing studies. We found an improvement of 8% among all Haitians, but show that Haitian attendings improve by 18% (relatively in line with the studies previously described) and Haitian residents improve by only 6%.

This dichotomy in improvement may suggest that attending physicians in low-income countries like Haiti, who are more chronologically distant from standardized training (e.g. residency), benefit to a greater extent from CME curricula. Alternatively, this result may occur because residents display a "floor effect" where they lack sufficient knowledge to assimilate information provided in the lectures, and are thus unable to show a change in their understanding on the post-test. Furthermore, our estimates of improvement may be lower than other studies since our investigation explores the differential effect of CME by training level.

In addition to reporting on the outcomes of an international CME course in Haiti, our study also presents a systematic methodology for measuring participant performance using an audience response system. The ARS system also has several advantages; it facilitates audience participation and allows for immediate feedback with higher response rates than would be likely from paper survey. Prior efforts at encouragement of evaluation measurements in workshops have shown adoption rates as low as 28% [12]. The simplicity of our approach with its high participation rate over 70% may allow for greater ease in future adoption of evaluation methods that can help improve the overall quality of global CME efforts.

Limitations: While we show that a CME conference can lead to statistically significant improvements in short-term knowledge based assessments, our study's chief limitations are the lack of long-term performance data and the lack of direct correlation with clinical outcomes. However, there is reason to remain optimistic about our study's findings since prior work has shown sustained improvements in outcomes on knowledge-based assessments [4]. Furthermore, other studies have shown that implementation of systematic education programs improves alignment of surgeon practice with clinical guidelines and lowers annual mortality [13,14].

Although unlikely, given our study setting, it is also possible that participants inadvertently exchanged their personal ARS devices. To account for this possible confounder, we also compared performance using unpaired two-sided t-tests between pre- and post-test among relevant groups.

Our findings remained identical and statistically significant when comparing performance improvement performance among all participants (Haitians and foreigners) ($p<0.05$). Sub-group analysis is not possible in this setting given the new assumption and small sample size.

CONCLUSIONS

Our study is the first to present improved short-term knowledge performance during an orthopaedic CME conference in a low-income country. We also demonstrate how an audience response system can facilitate participant engagement and evaluation measurements. While it is unknown whether these improvements will persist over the long-term or improve patient outcomes, we demonstrate that orthopaedic surgeons in this cohort significantly benefit from CME in the short term, and that these gains are greater among attendings than residents. These findings suggest CME conferences in low-income countries will be an effective tool to build surgical capacity and increase surgeon's knowledge, and that audience response systems are useful to engage participants and track outcomes.

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Chapter 7: A randomized controlled pilot study of educational techniques in teaching basic arthroscopic skills in a low-income country

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ABSTRACT

Object: Little is known about how to introduce complex technologies like arthroscopy into low-income countries. Thus, we compared low- versus high-resource intensive methods of teaching basic arthroscopic skills in a randomized controlled trial in Haiti.

Methods: Forty-eight Haitian orthopaedic surgeons and residents attending an orthopaedic conference in Haiti were block randomized to receive instruction through a composite video (Control) or a composite video plus hands-on teaching with an expert visiting surgeon (Intervention). A low-fidelity surgical simulator tested visualization and triangulation skills. Participants completed a pre- and post-test where the goal was to sequentially tap the most numbers in 2.5 minutes. Outcome metrics included highest tapped number, number of errors, visualization loss, and number of lookdowns. Multivariate linear regression was used to confirm randomization and compare outcomes between groups.

Results: Seventy-five percent of initially randomized attendees participated with similar attrition rates between both groups. All participants who performed a pre-test completed a post-test. In terms of highest tapped number, treatment and control groups significantly improved compared to pre-test scores, with mean improvement of 3.2% ($p=0.007$) and 2.2% ($p=0.03$), respectively. Improvement between treatment and control groups was not statistically different ($p=0.4$). No statistically significant change was seen with regard to other metrics.

Conclusions: We describe a protocol to introduce basic arthroscopic skills in a low-income country using a low-resource intensive teaching method. However, this method of learning may not be optimal given the failure to improve in all outcome measures.

INTRODUCTION

The role of arthroscopy in low-income countries is not well defined. The majority of orthopaedic literature related to surgical intervention in the developing world focuses on the treatment of musculoskeletal trauma with open techniques (1-4). Limited literature conveys the need for arthroscopy in the developing world, yet arthroscopy can be used to diagnose and treat a rising burden of trauma- and sports-related injuries (5, 6). In the future, arthroscopy may be used in these nations as a tool to manage devastating shoulder and knee instability that happen at work and often keep patients out of work (7). These injuries are prevalent in low-income countries and account for significant disability. For example, in countries where arthroscopy is common, it is used as an adjunct to articular fracture care in the knee, wrist, calcaneus and elsewhere (8-12). In addition, arthroscopy may be a useful diagnostic tool for patients in settings where advanced imaging is unobtainable.

Recent literature suggests that arthroscopy may be introduced into low-income countries after methods to control the burden of disease from musculoskeletal injury and infection are established (13). Yet, little is known about how to introduce new surgical technologies into poorer countries like Haiti. The orthopaedic literature does offer principles of appropriate technology transfer to developing countries, but a description of methods for technology transfer is noticeably absent (2, 13).

In addition to patient need, local orthopaedic surgeons are also hopeful for the introduction of arthroscopy. A recent needs assessment conducted in Haiti identified arthroscopy as the skill which local orthopaedic surgeons most wanted to learn (14). Given this interest, we devised a teaching protocol using a previously validated portable simulator to begin introducing basic

arthroscopic skills to Haiti based on the Fundamentals of Arthroscopic Surgery Training (FAST) curriculum (15).

In this randomized controlled pilot study, our aim was to compare two methods (low and high resource) of introducing basic arthroscopic skills training in Haiti. We hypothesized that both standardized lecture/video presentations alone (low-resource intensity) and in combination with expert instruction (high-resource intensity) would improve baseline performance, but teaching transfer from expert instruction would be superior to that from a lecture/video alone.

METHODS

Study type: Prospective randomized controlled trial

Setting: Our study was conducted during the Haitian Annual Assembly for Orthopaedic Trauma (HAAOT) over a single session in April 2015.

Subject enrollment: This study received IRB exemption from our hospital's Institutional Review Board. Eligible subjects were Haitian orthopaedic surgery residents and attending surgeons who attended the conference. Lottery tickets to win a prize were provided as an inducement for participation and improved performance.

Study design (Figure 1): Forty-eight Haitian orthopaedic residents and attending surgeons were block randomized at the start of the conference to receive skills instruction. The random allocation sequence was created and concealed until after intervention was assigned using labelled notecards. The intervention consisted of a 5-minute description of general arthroscopic principles followed by 10 minutes with an expert on the simulator demonstrating appropriate techniques in visualization, triangulation, and hand-eye coordination. The control consisted of a composite teaching video alone. All participants initially received skills instruction through a 10-minute video presentation based on the freely available FAST videos

(http://www.aana.org/FASTProgram/Overview). All participants then completed a pre-test on a previously validated, low-fidelity surgical simulator for basic arthroscopy (Sawbones, Vashon Island, Washington) (15).

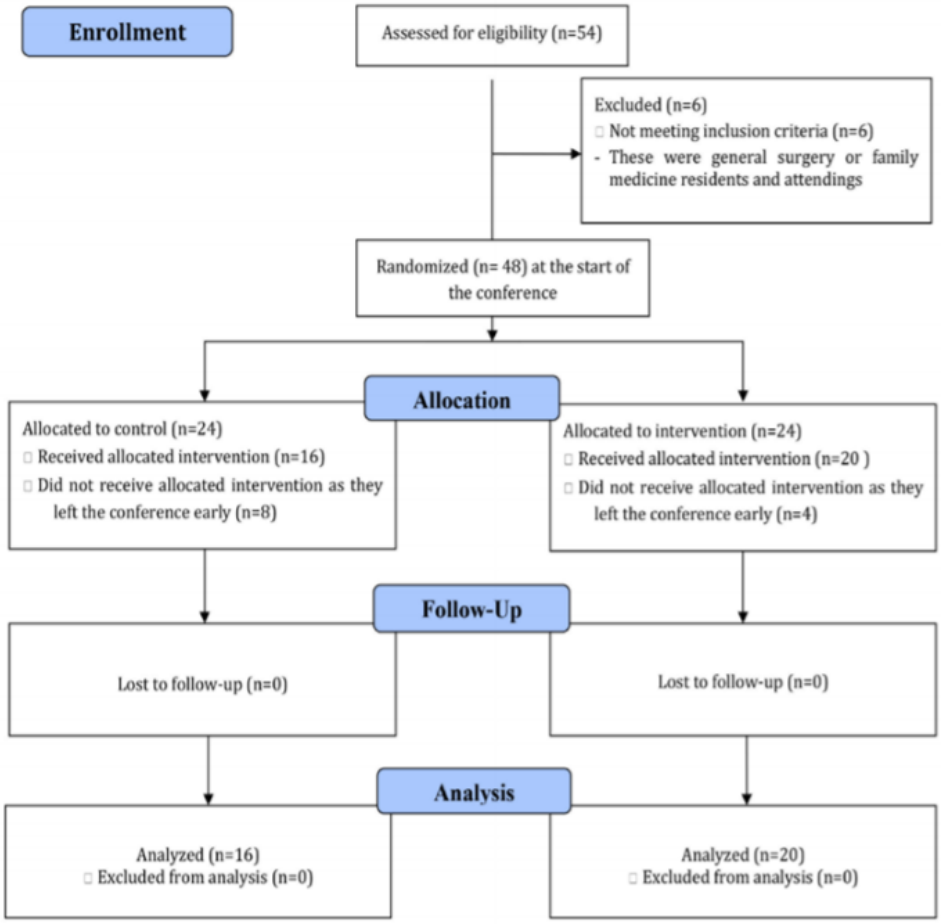

Figure 1. Flow diagram of subject enrollment.

The simulator consists of an arthroscopic camera, computer monitor, arthroscopic probe, and an opaque box covering a construct with numbers arranged randomly from 1 to 21 (Figure 2).

Participants were instructed to sequentially tap the most numbers they could within 2.5 minutes while maintaining visualization of the probe tip to test visualization and triangulation skills.

Following the pre-test, the intervention group received additional hands-on instruction with an expert. Both groups were able to reference the instructional video between their pre- and post-tests. Both groups then completed a post-test.

Figure 2. Arthroscopy simulator module setup.

Outcome measures: Previously validated metrics used for outcome assessment included highest number tapped sequentially, number of errors (unintentionally tapping any areas outside of the numbered tags), visualization loss (number of times probe tip was lost from field of view), and number of look-downs (physically turning eyes away from monitor and looking down at operator's hands) (15-16). Visualization loss and number of look-downs were assessed by a PGY-3 or PGY-4 United States-based orthopaedic surgery resident. Demographic data,

including trainee level, experience with arthroscopy, surgical-handedness, and participation in video game play was also recorded.

Statistical analysis: Data was analyzed using STATA/IC13. Multivariate linear regression was used to compare demographic data between groups to confirm randomization and to compare outcome metrics. A p-value less than 0.05 was considered statistically significant.

RESULTS

Demographics

In total, forty-eight orthopaedic surgeons and residents (100% of eligible participants) consented to participate in this study at the start of the conference and were randomized. Twenty-five percent of subjects who were randomized at the beginning of the conference had left the conference before the study started. All participants who performed a pre-test completed a post-test. Randomization was successful with no significant differences in demographic characteristics (Table 1). To summarize, 80.6% of participants were residents, 22.2% had participated in at least one arthroscopy case before, 91.2% were right-hand dominant, and 52.8% endorsed playing video games. Mean age (+/- standard deviation) was 32.6 +/- 5.7 years.

Table 1. Characteristics of the study sample demonstrating similar distribution between groups [a]

		(%) No./Total	
Characteristics	**Total (n=36)**	**Control (n=16)**	**Intervention (n=20)**
Male sex	34/36 (94.4)	16/16 (100)	18/20 (90)
Resident	29/36 (80.6)	12/16 (75)	17/20 (85)
Prior arthroscopy experience	8/36 (22.2)	6/16 (37.5)	2/20 (10)
Right-hand dominance	33/36 (91.2)	14/16 (87.5)	19/20 (95)
Plays video games	19/36 (52.8)	9/16 (56.2)	10/20 (50)
Age, mean (SD)	32.6 (5.7)	34 (7.3)	31.5 (3.8)

[a] No significant differences between groups were found in any of these characteristics

Highest tapped number

The primary outcome measure was "highest tapped number," defined as the highest number reached by task time completion at 2.5 minutes. When compared to pre-test scores, both intervention and control groups improved on average by 3.2% (p=0.007) and 2.2% (p=0.03), respectively (Figure 3a). Improvement between intervention and control groups was not statistically different (p=0.4).

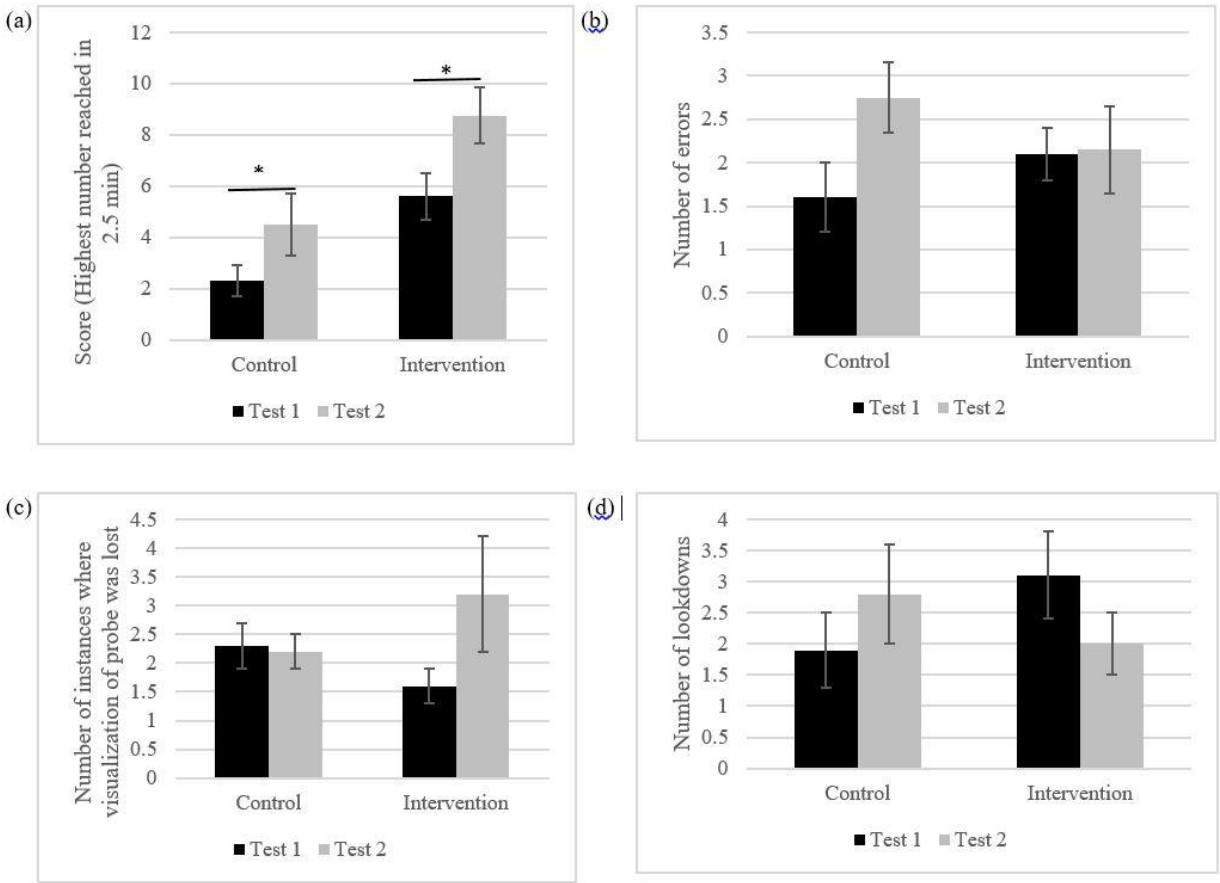

Figure 3: (a) Completion (highest tapped number) comparison between intervention and control groups. Statistically significant improvement (*p<0.05) in both groups, but not different between groups. (b) Number of errors comparison between intervention and control groups. No statistically significant change within or between groups. (c) Visualization loss comparison between intervention and control groups. No statistically significant change within or between groups. (d) Number of lookdowns comparison between intervention and control groups. No statistically significant change within or between groups.

Other outcome measures

No statistically significant change in number of errors, visualization loss, or look-downs was observed within or between treatment and control groups (Figure 3b-d).

Cost analysis of the teaching protocol

We also compared the true budget costs for the low-resource (control) and high-resource (intervention) groups. Ranges in Table 2 are provided for (1), (2) and (3) based on observed price variation at the HAAOT conference over the two previous years. We find that the addition of an expert visiting orthopaedic surgeon traveling to Haiti specifically for an arthroscopic teaching program and working as a volunteer without pay increases the cost of the low-resource teaching protocol by approximately 29-39%; however, this data is specific to the location of our conference and the length of stay. During the time period of our study, this cost was reimbursed by departmental funds or conference funding provided by sponsors.

Table 2. Cost analysis between low-resource (control) and high-resource (intervention) group

	Control	Intervention
FAST Arthroscopy Workstation Bundle	3344.5	3344.48
Miscellaneous supplies (paper, stopwatches, pens)	20	20
FAST videos	0	0
(1) Flight for visiting expert orthopaedic surgeon	---	700-900
(2) Housing for visiting expert orthopaedic surgeon (~$100-150/ night, 2 nights)	---	200-300
(3) Expenses for visiting expert orthopaedic surgeon (~$40-60/day, 2 days)	---	80-120
Total Cost ($)	3364.5	4344.48-4684.48

DISCUSSION

Musculoskeletal trauma is the primary focus of orthopaedic surgical intervention in low-income countries, but efforts exist to introduce arthroscopy (13). In this study, we describe a protocol based on the FAST curriculum to teach basic arthroscopic skills in Haiti. The most important result from our study is that we did not find a statistically significant incremental benefit of high-resource methods (expert instruction) over low-resource methods (video/lecture). However, we also find that low-resource methods may not result in optimal technique. In the pursuit of increasing speed, we observed that many participants did not focus on precision and purposeful movement. Quantitatively, this was reflected in the lack of improvement in three other outcome measures.

More broadly, our study addresses the mechanics of teaching basic skills required to implement and utilize a complex technology like arthroscopy. We also examined two teaching methods that differ in resource intensity and cost, as these are relevant for low-income countries like Haiti which have developed infrastructure for the management of musculoskeletal trauma and infection, but are resource-constrained in expanding orthopaedic capabilities. Using a cost analysis specific to our study location and duration, we demonstrated that a high-resource method can increase costs by 29-39%. This can further increase the difficulty in introducing arthroscopy in low-/middle-income countries. Beyond quantitative outcome measures, our program engendered great excitement for orthopaedic education among participants by meeting their expressed desire to learn basic arthroscopy (14). We believe responding to participant feedback in this manner is critical to sustaining orthopaedic education programs in low-income countries.

Our study fits within the current literature describing the introduction and teaching of new techniques. A similar RCT by Leopold *et al.* examined the process of teaching a simple

surgical task (superolateral knee injection) utilizing a printed manual, video or hands-on instruction (17). Performance improved significantly in all three training groups without a significant difference in improvement between high and low labor-intensive teaching techniques. However, they noted that their study was limited to the teaching of simple surgical tasks, and specifically excluded relevance to techniques like arthroscopy. Our study extends their results by finding similar improvements in basic arthroscopic skills (a complex surgical task) using high and low-labor intensive techniques. Our study's findings of improvement after a short training course are also similar to outcomes from other studies using an endoscopic virtual reality surgical simulator (18).

Limitations

While our study demonstrates equivalent performance improvement on an arthroscopic simulator using both low- and high-resource intensive methods, our study has several limitations. First, while performance improved in terms of highest tapped number, lack of improvement in other outcome measures intended to track triangulation and visualization precision may indicate that participants failed to learn ideal technique. This is relevant, as studies by Strom et al. have shown that it is important to introduce good practices early before negative ones are ingrained (18). In addition, improved performance may not translate to enhanced outcomes on more complex simulators or in operative performance based on the results of prior studies, although this is controversial (16, 19). We also note that our study was aimed at evaluating meaningful, i.e. large, improvements between intervention and control groups but was not powered to detect smaller levels of difference. Further study is needed with larger samples for validation, but given the high cost differential between video and live in-person teaching, only a marginal improvement with in-person teaching may not be financially justified for teaching beginner skills like operating the camera and using an arthroscopic probe.

In addition, low-income countries like Haiti only graduate a small number of residents per year (a maximum of 12 at present), so our study with forty-eight orthopaedic resident and attending surgeons already represents a large population in this context for a single-country study. Lastly, while our study demonstrates initial improvement, it is unclear if this learning persists over the long-term (20).

Conclusion

We describe a potential low-resource intensive protocol using video alone for learning basic arthroscopic skills in Haiti, and we do not find significant incremental benefit of higher resource methods involving hands-on expert instruction.

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Chapter 8: Redesigning an international orthopaedic CME course using problem-based learning and serial needs assessments: the effects on participant engagement over 5 years

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ABSTRACT

Background:

Continuing medical education (CME) remains important in orthopaedic surgical education to keep abreast of new technology, techniques and practice patterns. Successful CME programs require participation and satisfaction to enable learning, competence, and performance, however there is limited information about how long it takes for course changes to have an effect on these factors. We explored the effect of including serial needs assessment, problem-based learning (PBL), and faculty training initiatives to the AO Trauma Masters Courses in Davos on participant evaluation of the usefulness and relevancy of course content, as well as participant perception of faculty performance.

Methods:

We analyzed aggregate course-level data obtained from 1906 participants who attended one of 32 AO Davos Courses over a 5-year period between 2007-2011. The experimental group (Masters Course) consisted of AO Trauma Masters Courses which underwent educational redesign. The control group (Non-Masters Course) consisted of AO Trauma Non-Masters Courses that were targeted toward experienced orthopaedic providers, but which were not directly affected by educational redesign. We also assessed the effect of changes to orthopaedic trauma courses by comparison to veterinary (VET) and craniomaxillofacial (CMF) courses as an additional control group (VET/CMF). After each session during the course, participants were asked to evaluate each presentation using two previously validated questions based on content and faculty performance using a 5-point Likert scale.

Results:

Average scores for the usefulness and relevancy of a course and faculty performance were significantly higher for Masters Courses compared to Non-Masters Courses ($p<0.0001$) and evaluations were significantly improved for both groups in 2011 compared to 2007 ($p<0.001$), after faculty training was formalized in 2009. In 2011, orthopaedic trauma courses had significantly higher evaluations compared to VET/CMF courses ($p<0.0001$).

Discussion:

Introduction of serial needs assessment, problem-based learning, and faculty training initiatives led to significant improvement in participant evaluation of course content and participant perception of faculty performance. However, in some cases, these changes required 4-5 years to become evident.

INTRODUCTION

Continuing medical education (CME) is typically defined as an educational activity that maintains, develops, or increases the knowledge and skill a physician uses to provide services for patients, the public, or the profession once they have completed training.[1,2] Participation in CME activities is one way that physicians commit to continuous learning to provide the best evidence-based care, and CME is known to improve physician knowledge base, competence, and performance in practice.[1,3-5] CME is especially important for surgical education as new technology, techniques, and practice patterns can gradually lead to surgeon knowledge and performance gaps.[6]

The AO Foundation is a medically guided non-profit organization focused on the treatment of trauma and disorders of the musculoskeletal system, and it is one of the leading surgical CME providers for practicing health care professionals in orthopaedic trauma, veterinary, craniomaxillofacial, and spine surgery.[6] To deliver on its educational mission, the AO Foundation annually hosts a CME conference in Davos, Switzerland ("AO Courses Davos"). Within this education program, the AO Trauma Masters Courses in Davos are recognized as the flagship educational program in orthopaedic trauma for the AO Foundation.[7] However, in 2005, AO Trauma Masters Courses were noted to have decreasing enrollment, poor participation and flagging enthusiasm. As a result, beginning in 2005, the AO Trauma Masters Courses underwent a process of structural redesign using the conceptual framework for CME later described by Moore, Green et al.[5,8] First, serial participant needs assessments were introduced,[9] alongside a transition to case-based, problem based learning (PBL).[10-12] Subsequently, efforts to train the course faculty ("train the trainers" concept developed by Lisa Hadfield-Law) in gap analysis and facilitation of PBL for lectures and discussion groups were

formalized (**Table 1**).[7,8,13,14] Although these concepts are now used as a template by the AO, the outcomes of changes to the courses have only been studied in limited fashion.[15,16]

Year	Change(s)
2005-2006	1. AO Learning Assessment Toolkit designed by Joseph Green piloted. (Standardized pre-and post-course needs assessment. Evaluation during the course of presentation relevancy and faculty performance) 2. Transition to problem-based learning
2007	Pilot programs from 2006 are formalized.
2008	"Train the Trainers" approach initiated for AO Masters Courses. Expansion of the AO Learning Assessment Toolkit to other courses begins.
2009-2010	Formalized teacher training and blended online modules introduced for all orthopaedic trauma courses.

Table 1: AO Trauma Masters Course Changes

In addition, changes to the AO Trauma Masters Courses took several years, but there are few long-term studies of educational redesign in surgical CME.[17-22] As a result, we have limited information about how long it takes for course changes to have an effect on participation and student satisfaction (the foundation required for successful CME programs to enable learning, competence and performance).[5,9] Thus, we explored the effect of the redesign of the AO Trauma Masters Courses (Davos) on participant evaluation of the usefulness and relevancy of course content and participant perception of faculty performance over a 5-year period (2007-2011). We hypothesized the course redesign would improve evaluation of course relevancy and evaluation of faculty performance.

METHODS

Ethical Consideration: Our study did not require IRB review as we used only anonymized aggregate course-level data without identifiable information about individuals.

Setting: The AO Davos Courses are an annual education event hosted in Davos, Switzerland in December. This CME conference has multiple courses in orthopaedic trauma, veterinary (VET),

craniomaxillofacial (CMF), and spine surgery. The AO and the AO Davos Courses have been previously studied to understand orthopaedic education in other contexts.[6,15,16,22]

Participants/Courses: Data was collected from surgeons attending the AO Davos Courses, and all responses were anonymized and reported in aggregate at the course level by the AO Foundation.[15] Participant enrollment by course and number of course offerings was recorded each year. In the primary analysis, the experimental group (Masters Course) consisted of AO Trauma Masters Courses which underwent educational redesign. The control group (Non-Masters Course) consisted of other AO Trauma Non-Masters Courses targeted toward experienced orthopaedic providers, but which were not directly affected by educational redesign. We initially excluded courses directed towards trainees (e.g. AO Basic and Advances courses), Non-English language courses, and non-orthopaedic trauma courses (VET, CMF, and Spine). To assess the effects of changes to orthopaedic trauma in comparison to other non-orthopaedic trauma courses, we later included VET and CMF courses as a new control group (VET/CMF). This also allowed us to assess if there were any spillover effects of AO Trauma course changes with VET/CMF courses. We included courses taught at the Davos conference between 2007-2011 and excluded results from pilot years (2006, 2008, and 2010). Each course had a lecture and discussion group component.

Outcome Measures:

Electronic evaluation of course usefulness/relevancy and faculty performance by course participants was carried out in all courses using elements of the AO Learning Assessment Toolkit.[16] After each session during the course, participants were asked to evaluate each presentation (lecture or discussion group) using two previously validated questions based on content ("How useful and relevant was the content presented to your daily practice?") and

faculty performance ("How effective was the faculty in the role that he/she played?") using a 5-point Likert scale (1=not at all useful and relevant/effective, 5= very useful and relevant/effective).[16] Metrics on content and faculty performance were both used as a prior study demonstrated that accurate assessment of curriculum change requires simultaneous analysis of both factors.[16]

Our study analyzed course evaluation data that was aggregated at the course-level to protect data confidentiality concerns of participants and faculty by the AO Foundation. Each course had a lecture and discussion group component that was reported separately. We were provided the course title, number of participants, minimum, mean, and maximum average Likert score for each course in a given year (for lecture and discussion groups).

Statistical Analysis:

Cross-sectional descriptive statistics were calculated to quantify enrollment and participation by year. We performed a pooled analysis using weighted means by course participants to calculate aggregate mean Likert scores for each group (Masters Course, Non-Masters Course, and VET/CMF).[23-25] Response range per group per year was calculated as the minimum average Likert score subtracted from the maximum average Likert score. We estimated the sample standard deviation based on number of participants using previously validated techniques.[23] We performed chi-square tests to assess for differences in response rate and compared differences in mean aggregate Likert score and response range using Welch's unequal variances *t*-test. Pearson correlation coefficient was used to assess correlation between course relevancy and faculty performance evaluation and differences in response range for lectures versus discussion groups. We also assessed changes using course evaluation scores normalized to 2007 responses by respective group (Masters Course, Non-Masters Course, and VET/CMF). We performed a sensitivity analysis using an

alternate standard deviation estimation method and by including the AO Advanced Course within our Non-Masters Course control group (this course accepts advanced trainees/residents so was excluded in our main analysis).[25] The significance criteria to assess for differences between groups was adjusted for multiple comparisons using the Bonferroni correction to $\alpha < 0.0031$. Stata software, version 14 (StataCorp), was used for all analyses.

Source of Funding: No funding source played a role in this investigation.

RESULTS

Course characteristics and participation

We analyzed 1906 participants who attended one of 32 courses between 2007-2011 (Masters Courses 408 participants/6 courses; Non-Masters Courses 951 participants/17 courses; VET/CMF 547/9 courses). Detailed enrollment and number of course offerings by year are presented in **Figure 1**.

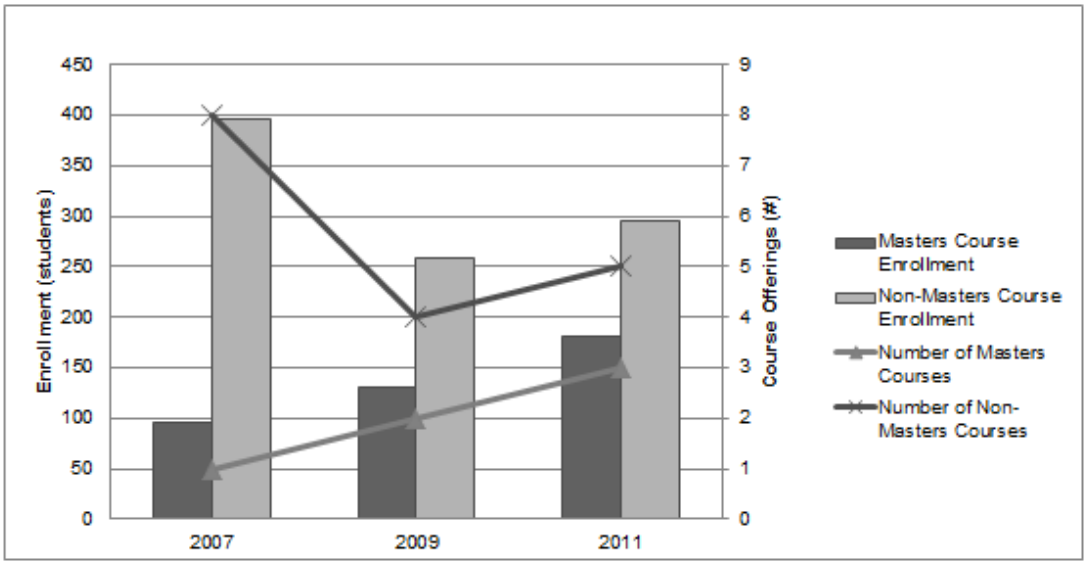
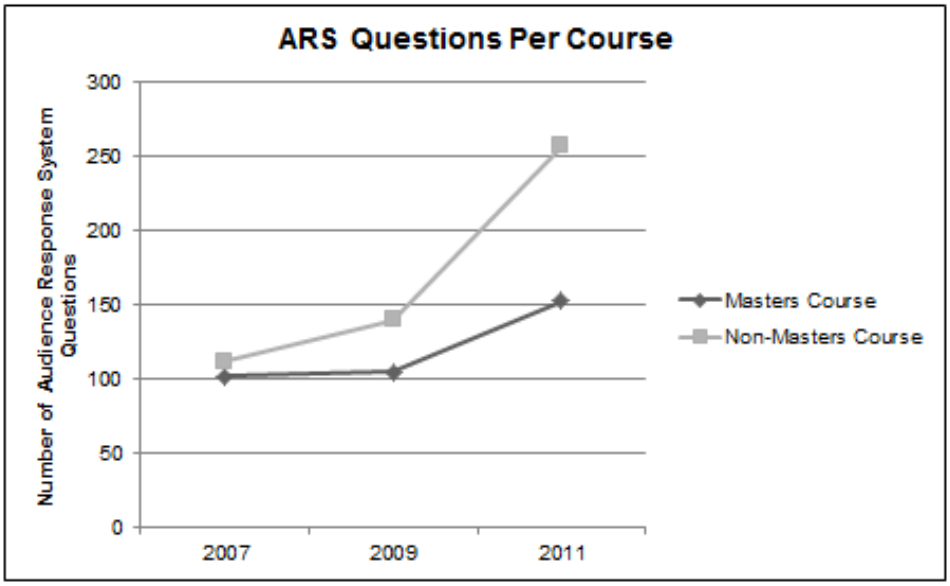


Figure 1: Course Participation

Response characteristics:

Average response rate was 66% (range: 54%-74%). Response rate was similar within groups for 2007-2011, however average response rate was higher for Non-Masters Courses versus Masters Courses in 2007 (74% vs. 60%, p=0.004) and 2011 (73% vs. 54%, p=0.001). Average response range was 1.79 points on the Likert scale (range: 1.04-2.41). Response range for evaluation of course relevancy and faculty performance were correlated (correlation coefficient (r) = 0.88, p=0.021) and similar between Masters and Non-Masters Courses (p=0.24). The number of audience response questions (ARS) increased in both groups over the study period (**Appendix Figure 1**).



Appendix Figure 1: Audience Response System (ARS) Questions per Course

Lecture and Discussion Group Evaluation

For course lectures, average Likert score for lecture relevancy and faculty performance was significantly higher for Masters Courses compared to Non-Masters courses in 2007, 2009, and 2011 (p<0.0001). Lecture evaluations for relevancy and performance for both groups was significantly higher in 2011 as compared to 2007 (p<0.0001, **Figure 2A-B**). There was a very strong correlation between participants' perception of the usefulness and relevancy of the course to their practice and

to their perception of faculty performance for both the Masters Courses (r=0.998, p=0.04) and Non-Masters Courses (r=0.999, p=0.028).

For discussion group, average Likert score for discussion group relevancy and faculty performance was significantly higher for Masters Courses compared to Non-Masters Courses in 2011 (p<0.0001). Evaluations for relevancy and faculty performance were similarly higher for both groups in 2011 compared to 2007 (p<0.0001, **Figure 2C-D)**. There was not a statistically significant correlation between topic relevancy and perception of faculty performance for the discussion groups (Masters Course, r=0.91, p=0.275; Non-Masters Course, r=0.84, p=0.379).

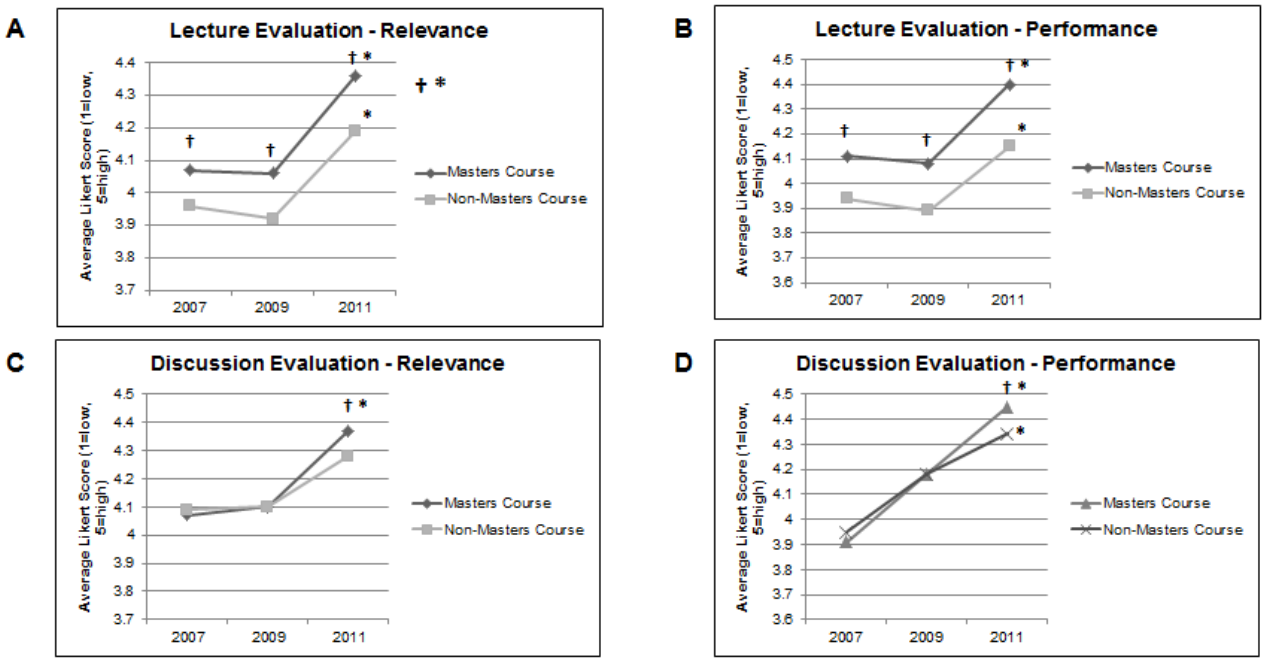


Figure 2: Course Evaluation. (A) Lecture Evaluation – Relevance; (B) Lecture Evaluation – Performance; (C) Discussion Evaluation – Relevance; (D) Discussion Evaluation – Performance; † = p<0.001 (Masters Course vs. Non-Masters Course), *p<0.0001(2011 vs. 2007)

AO Trauma Courses compared to CMF/VET control group

We performed an additional analysis using a CMF/VET control group that was unaffiliated with orthopaedic trauma to further analyze the effects of course redesign. We used normalized scores

(compared to 2007) to adjust for possible baseline demographic differences between orthopaedic and non-orthopaedic trauma student populations. By 2011, we found that orthopaedic trauma courses had significantly higher course evaluations and faculty performance ratings in both lecture and discussion groups compared to VET/CMF courses (p<0.0001) and compared to baseline scores in 2007 (p<0.0001, **Figure 3, Appendix Figure 2**)

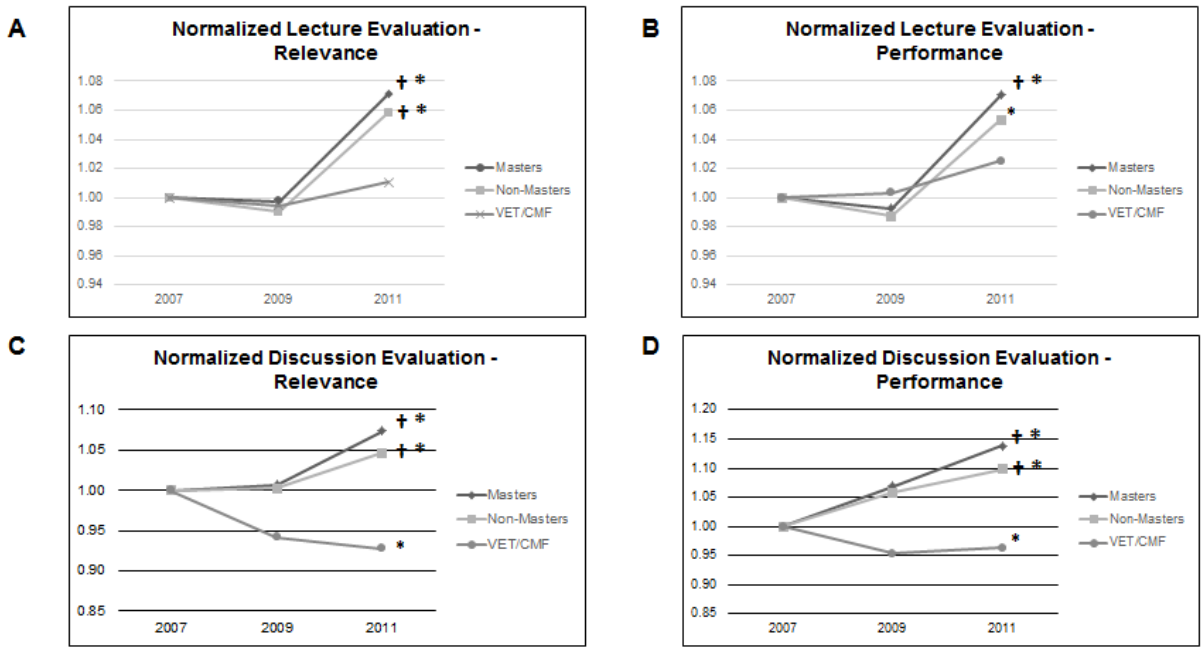
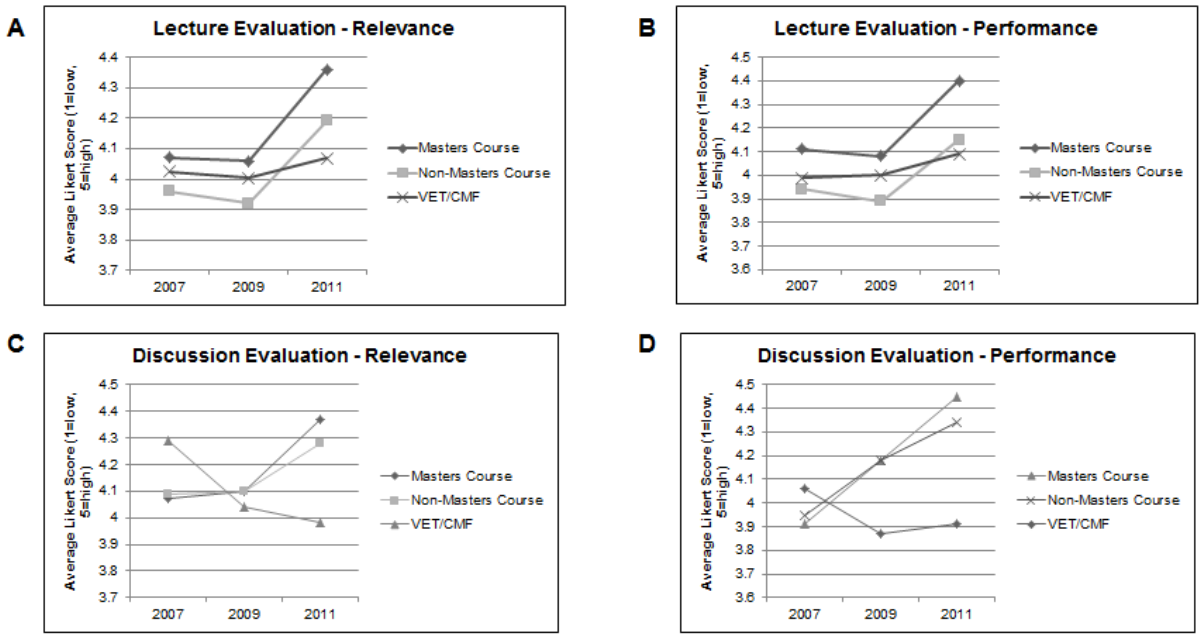


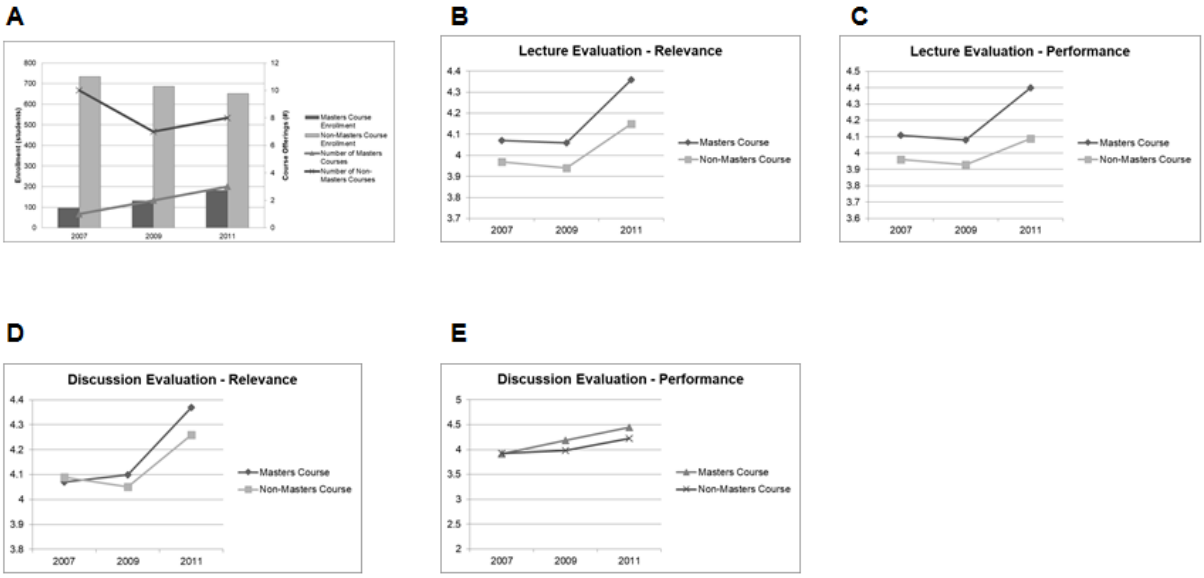
Figure 3: Normalized Course Evaluations. (A) Lecture Evaluation – Relevance; (B) Lecture Evaluation – Performance; (C) Discussion Evaluation – Relevance; (D) Discussion Evaluation – Performance; VET/CMF = Veterinary/Craniomaxillofacial Surgery Courses, † = p<0.001 (Masters Course vs. Non-Masters Course), *p<0.0001(2011 vs. 2007)



Appendix Figure 2: Raw Course Evaluations. (A) Lecture Evaluation – Relevance; (B) Lecture Evaluation – Performance; (C) Discussion Evaluation – Relevance; (D) Discussion Evaluation – Performance; VET/CMF = Veterinary/Craniomaxillofacial Surgery Courses

Sensitivity Analysis

Repeat analysis including Advanced courses with subspecialty courses led to identical results (**Appendix Figure 3)**. Similar statistical results were obtained using a different estimation strategy for the standard deviation.[25]



Appendix Figure 3: Sensitivity Analysis including AO Advanced Courses within Non-Masters Courses. (A) Course Participation; (B) Lecture Evaluation – Relevance; (C) Lecture Evaluation – Performance; (D) Discussion Evaluation – Relevance; (E) Discussion Evaluation – Performance; VET/CMF = Veterinary/Craniomaxillofacial Surgery Courses

DISCUSSION

Most physicians would agree that commitment to continuous learning is the best way to provide evidence-based care, and CME is important in surgical education to remain abreast of new technology, techniques and practice patterns. In orthopaedic surgery, the preferred way to receive education in most countries is by non-industry based courses.[6,26] Successful CME programs require participation and satisfaction to enable learning, but there has been limited literature on how to increase participation and satisfaction within CME courses.[5] In addition, the time span required to observe changes after an intervention is unknown.[17,19,21,22] In this study of the redesign of the AO Trauma Masters Courses, we found that needs assessment, PBL, and faculty training initiatives led to significant improvement in participant evaluation of usefulness and relevancy of course content and participant perception of faculty performance. However, in some cases, these changes required 4-5 years to become evident.

Redesign of the AO Trauma Masters Courses used the conceptual framework, that was later

elaborated upon by Moore et al., where CME development is viewed as a series of overlapping efforts that are part of a continuum linking lectures, discussion groups, and hands-on learning together.[5] Within this framework, three major changes were made to the Masters Courses to enable change (**Figure 4**). First, serial needs assessments were implemented. A needs assessment is a powerful tool to discern an audience's desired areas of improvement and learning in CME activities is more likely to lead to a change in practice when a needs assessment has been implemented.[6,27,28] Second, the course design was switched from lecture-based didactics to PBL in both lectures and discussion groups. Multiple prior studies have demonstrated that interactive techniques using case-based discussions allows for superior performance in improving the medical education environment.[10-12,29] Finally, faculty training initiatives ("train the trainers") were formally implemented to help facilitate learning based on needs analysis and PBL concepts. The marked changes observed in participant perception of usefulness and relevancy of course content and their perception of faculty performance may be the result of synergy between these three elements of curricular redesign.

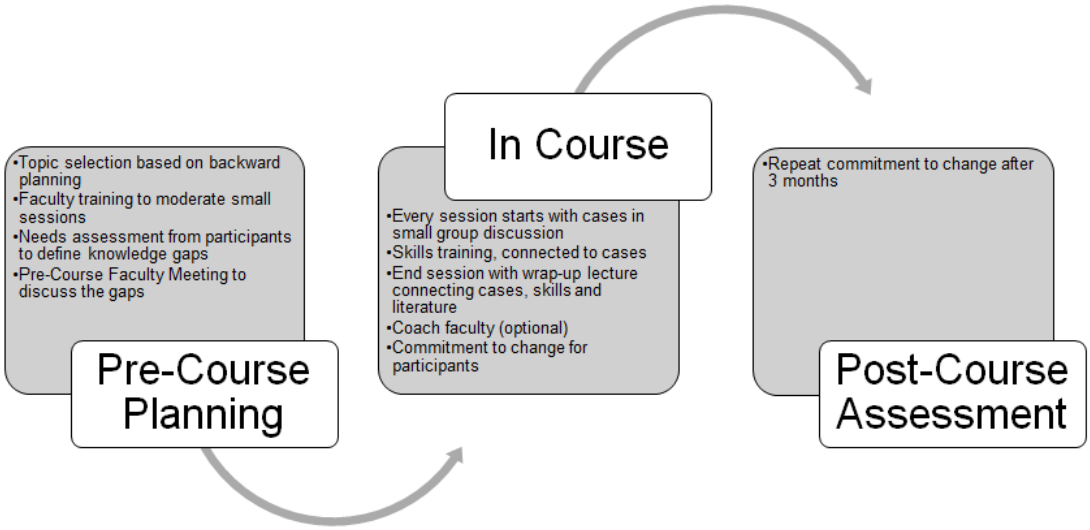


Figure 4: AO Masters Course Redesign Components and Execution

Our results also highlight the importance of faculty training to educational redesign efforts. While

the AO Trauma Masters Course switched to PBL concepts in 2007, improvements in results were most significant in 2011 after faculty training efforts were fully rolled out in 2009. Faculty training was introduced in the United Kingdom by Lisa Hadfield-Law in 1990, started to become international in 2004, but was only formalized by 2009. Prior studies have demonstrated that the primary reason for participants to attend face-to-face courses was for interaction with expert faculty and discussion/feedback from experts, while the majority of course attendants changed their opinion to the correct, evidence-based option after case-based discussion driven by experts.[6,17] Similarly, we saw the largest improvements in participant evaluation after faculty training efforts. In addition, evaluation of course relevancy was strongly correlated with faculty performance. The importance of faculty in enabling learning in CME courses cannot be overemphasized.

Interestingly, we saw a stronger effect of faculty training on orthopaedic trauma courses compared to CMF/VET courses. We did not identify a spillover effect since no difference was seen for CMF/VET courses. Such spillover effects are well-described in other education literature where the introduction of more effective teaching peers resulted in improvements in peer teachers.[30,31] In this setting, there is likely enough difference between AO Trauma faculty and CMF/VET faculty such that spillover effects are unlikely and more active efforts to incorporate faculty training are required.

Finally, multiple prior studies have shown the short-term effects of introduction of new CME conferences or courses, but there has been limited information on expected changes beyond a single course or year.[17,18,21,22] Our results highlight that 3 or more years are sometimes required to see the effects of educational redesign at the course-level. This is especially important at a policy level where funding agencies often expect changes at a much more rapid pace.[32] While the AO Foundation is large and can afford to make changes over longer time spans, changes on this time scale many not be tenable for smaller educational efforts and their funders (e.g. low-middle income

countries).[18,32] As in other settings, our findings emphasize the need for patience to withstand the lag time between change initiation and result observation.[33]

Limitations:

Our study has several limitations. Our analysis was limited to English-language courses at a single site in Europe, although this is the "gold-standard" course for most orthopaedic surgeons. Our response rate to evaluation questions varied between 54-74% allowing for possible response bias. However, this response rate is common for this type of research and is much improved compared to other studies with similar context.[15,18,28] One major limitation of this analysis is that we only assessed participant satisfaction/engagement, which may simply be a "happiness" index, as opposed to a true measure of learning (as with gap analysis). However, student engagement is important to facilitate learning and future studies may focus on the longitudinal effects of curricular change on learning outcomes.[5,9] The minimum significant difference for changes in average Likert scale scores for this context has not previously been defined. However, we considered it significant that average scores increased by 0.2-0.3 points – corresponding to an increase of 5-10% compared to 2007 values or 15-20% of the average response range. Our investigation employed pooled analysis of course-level data given data confidentiality concerns associated with using individual data; however this approach is well-described in current literature. Care should be exercised when employing the results of this study to individuals given the risk of committing the ecological fallacy.[34,35] Finally, in using pooled aggregate data analysis, we estimated the standard deviation for statistical analysis using validated techniques, but it is possible that different results could be obtained when using individual data. However, other studies have used a similar setting and approach.[15,16] Our results were unchanged when using another standard deviation estimation strategy.[25] In addition, others have shown that analysis of summary information yields similar results as when using individual data.[24]

CONCLUSIONS

Our results are of relevance to physicians and educators interested in surgical CME. We demonstrate how introduction of serial needs assessment, problem-based learning, and faculty training initiatives to the flagship AO Trauma Masters Course led to significant improvement in participant evaluation of course content and participant perception of faculty performance. However, in some cases, these changes required 4-5 years to become evident, and the largest changes were only seen after faculty training initiatives. Systematic change to educational programs can improve participant engagement allowing for subsequent development of learning, competence and performance.[5] This philosophy may be able to improve alignment of surgeon practice with evidence-based guidelines that lead to better patient care, but this requires further study.[15,36]

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Part 2. Improving Outcome Evaluation

Chapter 9: Routine Incorporation of Long-Term Patient Reported Outcome Measures into a Dutch Trauma Registry

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ABSTRACT

Importance

Multiple countries routinely collect post-discharge patient reported outcomes measures within trauma registries to benchmark the quality of trauma care. This process is dependent on the geographic and cultural context, but results are lacking regarding the European experience.

Objective

We investigated the feasibility of routine inclusion of long-term patient-reported health-related quality of life (HRQoL) in the Dutch National Trauma Database using process-related outcomes and characterized the outcomes of included patients.

Design

Prospective cohort study.

Setting

Single level 1 trauma center in the Central Netherlands region.

Participants

All adult patients (≥18 years) who presented to our institution for assessment of traumatic injury between January 1, 2015 and December 31, 2016 were included. Deceased patients, mentally impaired patients, patients with no Dutch proficiency and patients residing abroad were excluded.

Main Outcomes and Measures

Primary outcomes were process-related measures of feasibility (response rate, response methods, and reasons for non-response). Response rate was defined as the number of patients that responded to the questionnaire divided by the total amount of patients eligible for follow-up. Secondary outcomes were health-related quality of life measures (EuroQOL 5-Dimensions 3-Level (EQ-5D-3L) with an added cognitive dimension and EuroQOL Visual Analogue Scale (EQ-VAS)).

Results

A total of 2025 unique patients met the initial inclusion criteria, with 1753 patients eligible for follow-up. Within this cohort of eligible patients, 1315 patients participated, leading to a response rate of 75%. Median follow-up was 1.6 years (IQR 1.4 – 2.0, range 1.0 – 3.0). The majority of questionnaires, 990 (75%), were completed on paper, with an additional 326 (25%) completed through telephone interviews. The primary reason for non-response was lack of current contact information (245/438 non-responders; 56%). Median EQ-5D score was 0.81 (IQR 0.68 – 1.00; range -0.33 – 1.00) and median EQ-VAS score was 78 (IQR 65 – 90; range 0 – 100). When compared to a Dutch reference population (mean EQ-5D = 0.87), EQ-5D scores in our population were significantly lower (p <0.001).

Conclusions and Relevance

Routine collection of HRQoL is feasible within European health systems, like in the Netherlands. Further integration of these measures into trauma registries can aid with worldwide benchmarking of the quality of trauma care.

INTRODUCTION

Trauma registries have been created in multiple countries to provide important data for quality assessment and improvement of trauma care at the regional and national level.[1,2] Historically, the primary outcome tracked by these registries has been in-hospital mortality. However, as trauma care improved, in-hospital mortality markedly decreased and its use as the sole patient outcome variable was no longer ideal.[2–5] As a result, trauma registries evolved to incorporate functional status at discharge, but studies have since shown that outcomes collected at discharge do not predict the long-term outcomes valued by patients (i.e. disability and quality of life).[6,7] Given that the vast majority of trauma patients survive their injuries, the most recent iterations of trauma registries have started to incorporate post-discharge, long-term patient-reported outcome measures (PROMs). Incorporating these outcomes into existing trauma registries is necessary for benchmarking institutions, informing clinical decision making, and evaluating and improving overall quality of trauma care.[8,9] In fact, it is now well accepted that systematic outcomes measurement is essential for value improvement, the ultimate goal of trauma registries.[2,10]

Routine, population-based follow-up of adult trauma survivors following hospital discharge was first successfully reported in the Victorian State Trauma Registry (VTSR) in 2006.[11] The data from the VTSR has proven to be a valuable resource for international benchmarking of trauma care and for research into post-trauma PROMs.[12–15] As a result, the methodology of the VTSR has now been adapted for use with trauma registries in the United States, Hong Kong, and New Zealand.[8,13,16] Yet, two recent studies have suggested that routinely including PROMs into trauma registries can vary by cultural context. The FORTE project in the United States demonstrated that incorporation of PROMs was feasible, but that better methods for collection of the data were needed because of low response rates, even when using the original VTSR methodology with additional financial incentives.[8] Similarly, implementation of routine post-

discharge PROMs collection for trauma patients in Hong Kong demonstrated differences in response rate and outcomes compared to patients in Australia.[12] Comparable data is unavailable for the European experience as there has not been a prospective report of the routine collection of post-discharge PROMs in any European country.[7–9,11]

Given the importance of geographical and cultural context emphasized by prior work, we investigated the feasibility of routine inclusion of long-term patient-reported health-related quality of life in the Dutch National Trauma Database (DNTD) using process-related outcomes. Our project was also motivated by the fact that the Dutch Ministry of Health commissioned the National Health Care Institute to carry out the Outcome Information for Joint Decisions program, a program framed to collect outcome information on 50% of the complete burden of disease in the Netherlands.[17] As trauma related injuries account for a large part of this burden, the Dutch National Trauma Database (DNTD) provides an important target area.[18] We hypothesized that incorporating PROMs into the DNTD was possible. As a secondary objective, we sought to characterize the long-term outcomes of Dutch trauma patients after injury.

METHODS

Data Sources and Patient Population

Study Design: Prospective cohort study.

Setting: The University Medical Center Utrecht is a Joint Commission International accredited tertiary care facility with 1000 beds, complying with all requirements defined by the American College of Surgeons' Committee on Trauma.[19] This center is the designated level 1 trauma center of an inclusive trauma system situated in the 2418m^2 Central Netherlands region, serving approximately 1.2 million people in collaboration with nine level II and III centers.[20]

Patient Population: Eligible patients were identified from the Dutch National Trauma Database (DNTD). The DNTD is a prospectively collected database of all admitted trauma patients, continuously monitored by trained data managers and trauma surgeons. Adult patients (≥18 years) who presented to our institution for assessment of traumatic injury between January 1, 2015 and December 31, 2016, were included. Deceased patients, mentally impaired patients, patients with no Dutch proficiency and patients residing abroad were excluded (Figure 1). The vital status was assessed using the municipal personal records database.

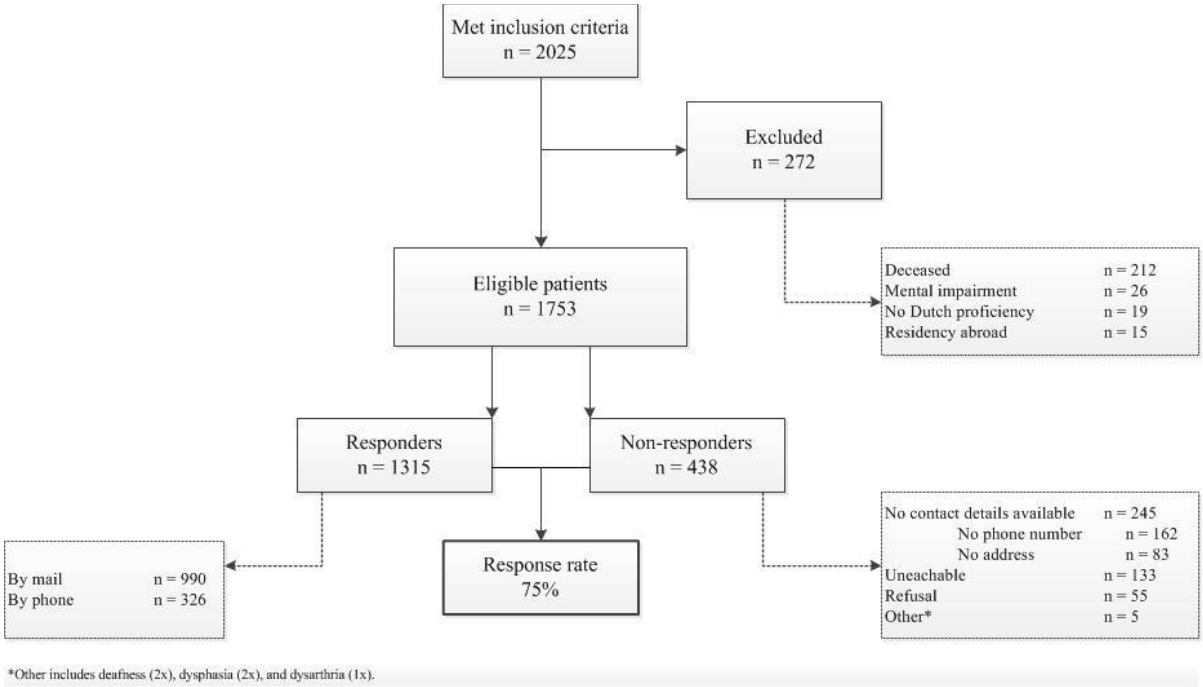

Figure 1. Flowchart of response process.

Patients who were eligible for follow-up were sent a recruitment letter explaining the healthcare evaluation alongside a questionnaire assessing health-related quality of life (HRQoL), and a stamped return envelope. Letters were mailed to the home addresses listed in the electronic medical record (EMR). Patients with multiple trauma admissions during the current study period were approached only once. Recruitment letters were sent in batches four times a year; patients were included in a given batch if they were within approximately three months of one year post-injury. If no response was received within three months after sending out the initial

letter, a reminder letter was sent. The process of sending recruitment and reminder letters was performed by a trained data manager and a secretary. In case of non-response after both letters, patients were contacted by telephone for verbal administration of the questionnaire. Interviews were carried out by a trained medical student and a member of the research team (QV). The timing of the telephone calls was varied in an attempt to maximize response rate.[8] After three failed telephone calls, a patient was deemed a non-responder.

Outcome Measures

Primary outcomes were process-related measures of feasibility (response rate, response methods, and reasons for non-response). Response rate was defined as the number of patients that responded to the questionnaire divided by the total amount of patients eligible for follow-up. Secondary outcomes were HRQoL measures (EuroQOL 5-Dimensions 3-Level (EQ-5D-3L) with an added cognitive dimension (EQ-6D-3L) and EuroQOL Visual Analogue Scale (EQ-VAS)).[21] The EQ-5D-3L covers five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression, and cognition), with three possible levels for all dimensions (no problems, some problems, extreme problems).[22] The EQ-5D scores for the study population were calculated using a scoring algorithm appropriate for a population of Dutch patients, with a possible range from -0.33 – 1.00.[23] The EQ-VAS is an instrument developed for recording an individual's current self-rated health on a scale from 0 to 100. For both the EQ-5D and the EQ-VAS, higher scores represent higher health-related quality of life.[24]

Explanatory Variables

Data on patient demographics, Injury Severity Score (ISS), and injury locations were obtained from the DNTD. Injuries were categorized as severe head, thoracic, or abdominal injury if the Abbreviated Injury Scale (AIS) was greater than 2 in the respective regions. Abrasions and lacerations of the extremities were excluded by only including upper or lower extremity injury with AIS >1.

Statistical analyses

Responses were collected into a Microsoft Office Excel 2010 database. Descriptive statistics were calculated. Categorical variables were reported as numbers with percentages. Continuous variables were reported as medians with interquartile ranges (IQR) after applying Shapiro-Wilk normality tests. Bivariate analyses using chi-squared and Mann-Whitney U tests were performed in order to compare baseline characteristics between responders and non-responders. Multivariable linear regression analyses were conducted to identify demographic and injury-related factors associated with EQ-5D scores. EQ-5D scores of the study population were compared to the norms for a general Dutch population of 0.87 using the Student's t-test.[25] All statistical analyses were performed using STATA® 13.1 (StataCorp LP, TX, USA). A *p*-value of <0.05 was considered statistically significant. This project was approved by the University Medical Center Utrecht Institutional Review Board.

RESULTS

A total of 2025 unique patients met the initial inclusion criteria. Subsequently, 272 patients were excluded as they were found to be deceased (212/272), mentally impaired (26/272), lacked Dutch language proficiency (19/272), or resided outside of the Netherlands (15/272), resulting in 1753 patients eligible for follow-up. Within this cohort of eligible patients, 1315 patients participated, leading to a response rate of 75%. Median follow-up was 1.6 years (IQR 1.4 – 2.0, range 1.0 – 3.0). Figure 1 describes the inclusion and response process of patients. Table 1 describes participants' demographic and clinical characteristics based on inclusion-exclusion criteria.

Table 1. Demographic and clinical characteristics.

	Total cohort (n = 2025)	**Eligible patients (n = 1753)**	**Ineligible patients (n = 272)**
	Median (IQR)	**Median (IQR)**	**Median (IQR)**
Age at injury (years)	54 (34 – 70)	52 (33 – 66)	71 (54 – 83)

Injury Severity Score (n = 1960)	9 (5 – 17)	9 (5 – 16)	10 (5 – 25)
	n (%)	**n (%)**	**n (%)**
Male gender	1336 (66)	1176 (67)	160 (59)
Severe head injury	544 (27)	430 (25)	116 (43)
Severe thoracic injury	366 (18)	312 (18)	57 (21)
Severe abdominal injury	67 (3)	57 (3)	11 (4)
Extremity injury	878 (43)	763 (44)	113 (42)
Upper extremity	473 (23)	410 (23)	60 (22)
Lower extremity	543 (27)	471 (27)	68 (25)
IQR = interquartile range; n = number.			

The majority of questionnaires, 990 (75%), were completed on paper, with an additional 326 (25%) completed through telephone interviews. After sending the initial recruitment letters, questionnaires were returned by 802 patients (802/990 mail responses; 81%). Sending reminder letters yielded 188 (19%) additional returned questionnaires. Of the 326 patients that completed the questionnaire over the telephone, 197 patients were successfully reached after the first attempt (60% of 326), 80 patients were successfully reached after the second attempt (25%), and 41 patients were successfully reached after the third attempt (13%). A record of the number of attempts was missing for 8 patients so they were unclassified (2%).

The primary reason for non-response was lack of current contact information (245/438 non-responders; 56%). Another 133 patients could not be reached after sending two letters and following three phone call attempts (133/438; 30%) and 55 patients (13%) refused to participate (Figure 1).

Table 2 compares the demographic and clinical characteristics of responders and non-responders. These groups were similar in most characteristics, but, on average, responders were of older age (p<0.001) and had higher ISS score (p<0.001) than non-responders.

Table 2. Demographic and clinical characteristics of responders versus non-responders.

	Responders (n = 1315)	**Non-responders (n = 438)**	**p-value**
	Median (IQR)	**Median (IQR)**	
Age at injury (years)	55 (37 – 69)	39 (27 – 56)*	**<0.001**
Injury Severity Score (n = 1960)	9 (5 – 17)	9 (4 – 14)*	**<0.001**

	n (%)	n (%)	
Male gender	879 (67)	297 (68)	0.71
Severe head injury	332 (25)	96 (22)	0.34
Severe thoracic injury	241 (18)	68 (16)	0.57
Severe abdominal injury	43 (3)	13 (3)	0.94
Extremity injury	570 (43)	195 (45)	0.86
Upper extremity	318 (24)	95 (22)	0.17
Lower extremity	351 (27)	124 (28)	0.51

IQR = interquartile range; n = number.
Bold indicates statistically significant difference.

Median EQ-5D score was 0.81 (IQR 0.68 – 1.00; range -0.33 – 1.00) and median EQ-VAS score was 78 (IQR 65 – 90; range 0 – 100). EQ-6D composite and component scores are summarized in Table 2 and the distribution of responses per dimension is presented graphically in Figure 2.

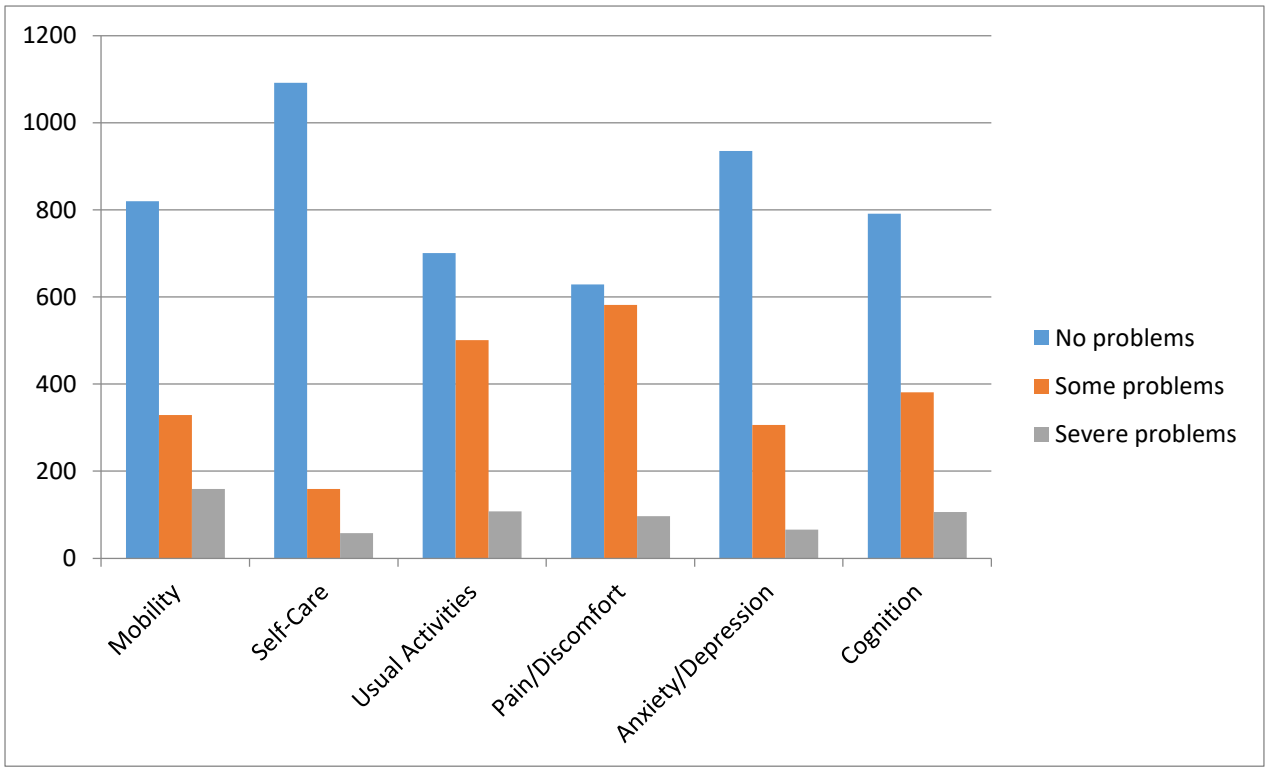

Figure 2. EQ-6D scores.

When compared to a Dutch reference population (EQ-5D = 0.87), EQ-5D scores in our population were significantly lower (p <0.001). For the cognitive dimension, 791 patients (62%) reported no problems, 381 (30%) some problems, and 106 (8%) severe problems.

Using multivariable linear regression analyses, factors independently associated with worse HRQoL (EQ-5D score) were older age at injury (coefficient [95% CI] = -0.002 [-0.003, -0.001]; *p* <0.001), higher ISS (coefficient [95% CI] = -0.004 [-0.006, -0.001]; *p* 0.002), female gender (coefficient [95% CI] = -0.057 [-0.093, -0.020]; *p* 0.003), and lower extremity injury (coefficient [95% CI] = -0.071 [-0.109, -0.032]; *p* <0.001) (Table 3).

Table 3. Regression analyses.

	Regression coefficient*	**95% CI**	***p*-value**
Age at injury	-0.002	-0.003 – -0.001	**<0.001**
Injury Severity Score	-0.004	-0.006 – -0.001	**0.002**
Interval between injury and questionnaire	-0.030	-0.066 – 0.007	0.109
Male gender	0.057	0.020 – 0.093	**0.003**
Severe head injury	0.004	-0.038 – 0.047	0.838
Severe thoracic injury	0.017	-0.029 – 0.063	0.460
Severe abdominal injury	0.038	-0.057 – 0.133	0.435
Upper extremity injury	0.016	-0.024 – 0.055	0.441
Lower extremity injury	-0.071	-0.109 – -0.032	**<0.001**
Model	Multivariable linear		

CI = confidence interval
*Positive regression coefficients denote higher EuroQOL 5-dimensions (EQ-5D) scores.

DISCUSSION

Our study indicates that routine inclusion of long-term patient-reported outcome measures in a Dutch trauma registry is feasible, with a high response rate and little response bias. Health-related quality of life after trauma was comparable to other contexts, but was moderately inferior compared to the general population approximately one year following injury.[8,9,13] Factors independently associated with worse long-term outcome were older age, higher ISS, female gender, and lower extremity injury.

Many prior projects have attempted to assess patient outcomes after a variety of injuries and treatments by focusing on a narrowly defined subset of the population at a particular time period.[9,26,27] However, a drawback to this approach is that many patients are excluded due to study design and data about the quality of a health system is missed.[28,29] This is especially true for trauma patients and trauma systems where it is not uncommon to have high refusal rates

and significant follow-up disparity.[9,28,30,31] As a result, these study designs are not sufficient to evaluate or benchmark the quality of care at the institutional, regional, or national level. Thus, many recent studies have emphasized the routine inclusion of PROMs and HRQoL metrics within trauma registries.[8,13,16] This framework allows for the collection of comprehensive, normative data on the long-term outcomes of patients who sustain trauma, summarizes the care received within health systems, and meets regulatory requests for data collection that can facilitate quality improvement, cost-effectiveness, resource utilization and benchmarking studies.

When we adopted this framework in our health system, we found that routine inclusion of HRQoL in a Dutch trauma registry was feasible, with high follow-up percentage and low response bias. Prospective collection of outcome data likely led to much higher response rates compared to retrospective collection. We also found that outcomes approximately one year after injury were lower compared to the Dutch reference population.[32] Unlike similar studies in the United States or Hong Kong, only a small percentage of patients refused to participate when asked to respond by paper or telephone questionnaire, even when no additional incentive was provided. This findings highlights another scenario where different geographic and cultural context led to variation in practical implementation of the same adapted protocol. [8,13,16] Patients within the Netherlands may have been more eager to participate in order to share information on their health status and thereby contribute to quality improvement programs. Similar to the problems encountered in the efforts of incorporating PROMs into Australian and North American trauma registries, the main reason for non-response in our population was the lack of current contact details.[8,9] Targeting this problem may lead to a higher response rate. Hospitals should be encouraged to document and verify patient contact information, and patients should be instructed to inform the hospital of changes to contact information. With the

advent of EMRs, automatic alerts for providers and staff can be incorporated into the EMR to highlight when a patient has missing or inadequate contact details.

In our study, the majority of questionnaires were completed on paper, and an additional third were administered successfully over the phone. While this led to satisfactory response rates in our setting, future work should investigate the use of other administration modalities, especially since the majority of non-responders were younger patients who may use email or smartphone applications as their primary communication tools.[33] Currently, we are exploring the use of a web-based platform for the distribution of PROMs.

Responders and non-responders differed significantly with respect to age and ISS. Similar age-related differences between responders and non-responders have been identified previously.[8,9] In our catchment area, many young patients may be students who move more frequently and whose contact information changes more often. Higher ISS in non-responders has also been documented in the Victorian State Trauma Registry.[9] As ISS was independently associated with worse quality of life, results of the present study as well as previous studies may underestimate HRQoL in the complete trauma population. A potential explanation for the differences in injury severity is that patients who suffer less severe trauma, with higher odds of returning to pre-injury health status, are less inclined to document their quality of life as they are not confronted with the consequences of their injuries on a daily basis. Differences between responders and non-responders affect generalizability of studies measuring outcomes after trauma, and our study found patterns similar to those observed in other countries.[31]

Due to the unexpected nature of trauma, pre-injury baseline information about patients is often either missing or subject to patient recall bias. This can make it challenging to counsel patients on average expected outcomes or to benchmark across different trauma populations.[13] By routinely incorporating outcomes into trauma registries for all patients, results on average converge to expectations for the general population as the sample size grows. Statistically, this

information can then be used to counsel patients and provide benchmarking information for a cohort of patients on average.[34]

Even though routine inclusion of patient-reported outcome measures in a Dutch trauma registry was deemed feasible, our results were only accomplished with major time investment. Sending out letters, processing returns and conducting telephone interviews created an important time burden for our data managers. In order for the standard incorporation of PROMs to be sustainable, additional financial support and manpower are required. With trauma registries being established to improve care, their contents should be curated to allow for accurate, updated data.

Our study has several limitations. First, the study population was limited to one level 1, tertiary referral center that typically serves severely injured patients and patients with significant comorbidities, which may not be representative of the population. Further validation in other settings will be important, but inclusion of functional outcomes that can be compared to population norms should improve generalizability.[8] Second, for some patients, telephone interviews were performed more than one year after trauma as the protocol for phone interviews was added to the initial protocol to boost response rates. However, we do not believe this significantly altered our outcome results as previous studies have shown that PROMs typically plateau one year after trauma.[35,36] In addition, in our regression analyses, we adjusted for the interval between trauma and completion of the questionnaire. Third, as there is lack of tailored instruments for trauma patients and no consensus on the most optimal tool, making comparisons with similar projects and registries is difficult. We chose to use the EQ-5D and EQ-VAS as they are questionnaires that can discriminate between a wide variety of health states.[24] Keeping our questionnaire simple and short is one reason we believe that our response rate was high.

CONCLUSIONS

Routine collection of HRQoL is feasible within European health systems, like in the Netherlands. Paper and telephone questionnaire methods have high response rate even when no incentive is provided, but lack of response among younger patients highlights the importance of accurate contact information and exploration of electronic communication modalities. In addition, collection of this data demonstrates that trauma patients in the Netherlands continue to report some impairment compared to the general population approximately one year following injury. Further integration of PROMs and HRQoL into trauma registries can aid with worldwide benchmarking of the quality of trauma care and decrease the gap in our understanding of the impact of trauma on both patients and society.

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Chapter 10: Epidemiology of distal radius fractures in polytrauma patients and the influence of high traumatic energy transfer

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ABSTRACT

Introduction

For several extremity fractures differences in morphology, incidence rate and functional outcome were found when polytrauma patients were compared to patients with an isolated injury. This is not proven for distal radius fractures (DRF). Therefore, this study aimed to analyze fracture morphology in relation to energy transfer in both poly- and mono-trauma patients with a DRF.

Methods

This was a retrospective cohort study. All patients aged 16 years and older with a DRF were included. Patients with an Injury Severity Score of 16 or higher were classified as polytrauma patients. Injuries were defined as high or low energy. All DRFs were classified using the AO/OTA fracture classification system.

Results

A total of 830 patients with a DRF were included, 12% were polytrauma. The incidence rate of DRF in polytrauma patients was 3.5%. Ipsilateral upper extremity injury was found in >30% of polytrauma and high-energy monotrauma patients, compared to 5% in low-energy monotrauma patients. More type C DRF were found in polytrauma and high-energy monotrauma patients versus low-energy monotrauma patients. Operative intervention rates for all types of DRF were similar for polytrauma and high-energy monotrauma patients. Non-union rates were higher in polytrauma patients.

Conclusions

Higher energy mechanisms of injury, in polytrauma and high-energy monotrauma patients, were associated with more severe complex articular distal radius fractures and more ipsilateral upper extremity injuries. Polytrauma and high-energy monotrauma patient have a similar

fracture morphology. However, polytrauma patients have in addition to more injured body regions also more non-union related interventions than high-energy monotrauma patients.

INTRODUCTION

The functional outcome of patients with upper extremity fractures in polytrauma is worse compared to patients with similar isolated extremity injuries [1-4]. While it is known that the incidence rate for distal radius fractures (DRF) is up to 17% for patients who sustain it as an isolated injury, the incidence rate for DRF in polytrauma patients is unknown [3,5,6]. In addition, prior studies found that extremity fractures sustained by polytrauma patients are different in the morphology of injury and incidence rate. In polytrauma patients with a displaced clavicle fracture the incidence rate was higher compared to patients with an isolated injury and less displaced fractures were found. In polytrauma patients with hand injuries a high rate of carpal and ligamentous injuries were found as opposed to phalangeal and metacarpal injuries frequently seen in patients with an isolated injury [1,2].

Currently there is sparse data on the epidemiology, fracture pattern and concomitant injuries of distal radius fractures in polytrauma patients. A possible explanation is that most studies exclude polytrauma patients for methodological purposes [7,8]. Despite frequent anecdotes on different fracture patterns seen after high energy impact, little is known about the influence of high energy trauma mechanisms on fracture morphology and the epidemiologically different groups this creates.

Better understanding of the incidence rate and fracture morphology in polytrauma patients would provide insight on the scale and impact of DRF in these patients. Furthermore, it could serve as a basis for future studies on DRF in polytrauma patients. Since the bulk of polytrauma is the result of high energy trauma, we hypothesized that worse fracture morphology (complex articular fractures, type C in the AO-OTA Fracture classification system) was associated with higher energy trauma mechanisms.

Thus, the aim of this study was to determine the prevalence and fracture morphology of distal radius fractures in polytrauma patients in comparison to monotrauma patients. We also

assessed the influence of the trauma mechanism (energy transfer) on fracture morphology and concomitant injuries in patients with distal radius fractures.

METHODS

An institutional review board (IRB) waiver was obtained. A single, level 1 trauma, centre retrospective cohort study was performed. Patients in our region (Central Netherlands) are transported by the Regional Ambulance Service to 1 of the 10 hospitals. The region Central Netherlands consists of 9 level II and level III hospitals and 1 level I trauma center in a 2418-km2 region with a population of 1.2 million people. The University Medical Center Utrecht is designated as a level I trauma center, offering trauma care at the highest level for severely injured patients. The 9 surrounding level II and III hospitals are designed to treat patients without severe injuries. This regional trauma network is based on an inclusive and integrated trauma system [9]. Patients with a DRF who presented at our institution between 2008 and 2015 were identified using ICD-9 codes (International Classification of Diseases). Demographics, type and number of operative interventions, complications from interventions and Gustilo classification, in case of an open fracture, were collected from the electronic medical record.

Interventions were categorized as primary or secondary surgery. Open- and closed reduction and internal fixation or the placement of external fixation were counted as primary surgery. All other procedures were counted as secondary surgery. Removal of hardware was not included in the analysis for secondary surgeries.

Concomitant injuries (fractures and injuries with Abbreviated Injury Scale (AIS)>1, excluding excoriations and lacerations) were collected from the electronic patient documentation. To analyse additional ipsilateral upper extremity injuries, the side was noted. The injuries were subdivided into regions; carpal, metacarpal & phalangeal, elbow & forearm and humeral bone

& shoulder. Additional injuries to the Head, Thorax and Abdominal region were also noted in case of an injury with a AIS of >1.

Radiographic studies were reviewed to confirm the ICD coded diagnosis. Criteria for high-energy trauma were; fall ≥ 3 meters or higher, car accident ≥ 60km/h, motorcycle accident ≥ 30km/h, vehicle shortening ≥ 50cm, vehicle depression passenger side ≥ 30cm, vehicle rollover, passenger thrown from vehicle, fatality in same vehicle, car or motorcycle versus pedestrian or bicyclist ≥ 10km/h, motorcycle or bicycle vs motorcycle or bicycle or stationary object.

All patients aged 16 years and older were included. Polytrauma was defined as an Injury Severity Score (ISS) of 16 or higher, calculated using Abbreviated Injury Scale (AIS) scores [10]. Monotrauma patients were categorized based on the ISS, thus a patient with an ISS of <16 who sustained a high-energy trauma was noted as high-energy monotrauma patients. Due to the extent of the injuries sustained in polytrauma, it can be hypothesized that all polytrauma patients suffered high energy impact, despite this is not classified as such. All polytrauma patients with a low-energy trauma were analyzed to compared differences with high-energy polytrauma and monotrauma patients.

DRF radiographic studies were reviewed by two investigators (SF and QV) and classified as type A, B or C according to the Arbeitsgemeinschaft für Osteosynthesefragen-Orthopaedic Trauma Association (AO/OTA) classification. Type A1; isolated ulnar styloid fractures were excluded, as were epiphysiolysis. Type A; extra articular, type B; partial intraarticular, type C; complete intraarticular with metaphyseal fracture were included. Fractures were classified using both pre- and post-reduction radiographs and computed tomography scans when available. A second assessment by two other investigators (MH and FH) was performed when no consensus was reached. In further subgroup (1, 2 or 3) interpretation, only C3 fractures were

identified because of the limited reliability for extensive subgroup differentiation [11,12].

Statistical Analysis

Continuous variables were presented as mean with standard deviation (SD). Categorical variables were presented as frequencies with percentages. Parametric tests were used for statistical analysis; chi-square test for dichotomous variables, Fisher exact when a cell count of 5 or less was observed, Student-t test and ANOVA for continues variables with dichotomous or categorical variables. For analysis of continuous data with outliers Mann-Whitney test was used. A *p*-value of ≤0.05 was considered significant. Statistical analysis was performed using SPSS version 21 (IBM Corp., Armonk, NY).

RESULTS

A total of 830 patients with a distal radius fracture (DRF) were included and 102 patients (12%) had an ISS of 16 or higher and were considered polytrauma patients. The incidence of DRF in polytrauma patients was 3.5% (102 polytrauma DRF patients/ 2922 polytrauma patients admitted within the studied time period). Of the whole group, 249 patients (30%) suffered additional injuries. The mean age of the entire cohort was 53 years, 34% were males and 6 died due to the trauma. Table 1 depicts the baseline demographics for polytrauma and monotrauma patients after high- and low-energy trauma.

Table 1
Baseline demographics of poly- and monotrauma patients.

	Polytrauma n = 102		Monotrauma High-energy n = 107		Monotrauma Low-energy n = 621		*P*-value
Age in years (SD)	45.7	21	42.6	18	55.4	21	<.001
Male gender	66	65%	69	65%	144	23%	<.001
Injury Severity Score (SD)	25.9	8	9.5	3	7.6	2	<.001
Mechanism of injury							<.001
Fall <3 m	13	13%	2	2%	551	89%	
Fall ≥ 3 m	43	42%	38	36%	2	0.3%	
Bicycle accident	5	5%	8	8%	39	6%	
Car accident	16	16%	25	23%	3	0.5%	
Motorcycle accident	20	20%	30	28%	5	1%	
Pedestrian involved in MVA	2	2%	2	2%	2	0.3%	
Associated head injury AIS > 1	44	43%	2	2%	4	0.6%	<.001
Associated thoracic injury AIS > 1	59	58%	5	5%	1	0.2%	<.001
Associated abdominal injury AIS > 1	35	34%	4	4%	2	0.3%	<.001
HET	82	80%					n.a.
Admitted hospital	100	98%	62	58%	41	6%	<.001
ICU admittance	34	34%	3	5%	0	0%	<.001
ICU days (SD)	3.9	9.8	0.2	1.3	0	0	.001

Number with% unless otherwise indicated, SD; standard deviation, MVA; motor vehicle accident, ICU; Intensive care unit, AIS; Abbreviated injury score, HET; high-energy trauma, n.a.; not applicable, +/−; indicating direction of difference and comparable group, HET and LET (low energy) monotrauma patients with associated head/thorax or abdominal injury sustained only AIS 2 injuries in these regions.

For the entire cohort, type A distal radius fracture (DRF) were the most prevalent with 43% (n= 356), followed by type C, 39% (n=325) and type B 18% (n=149) (Table 2).

Table 2
Distribution of different fracture types in polytrauma patients, monotrauma patients after an high energy trauma (HET) and low energy trauma (LET).

	Total number	Fracture type			Open fractures
		A	B	C	
All patients	830	356 (43%)	149 (18%)	325 (39%)	27 (3%)
Polytrauma	102	23 (22%)	18 (18%)	61 (60%)	9 (9%)
HET monotrauma	107	26 (24%)	23 (22%)	58 (54%)	10 (9%)
LET monotrauma	621	307 (49%)	108 (17%)	206 (34%)	8 (1%)

In polytrauma and high-energy monotrauma patients, a higher ratio of type C (>50%) versus type A DRF was observed compared with low-energy monotrauma patients (p<0.001 and p<0.001). No difference in distribution of type C DRF was observed between polytrauma and high-energy monotrauma patients (p=0.682). Type C3 DRF were identified in 22 polytrauma (22%), 16 high-energy (15%) and 25 low-energy monotrauma patients (4%) (p<0.001). Type C3 DRF were more prevalent after high-energy (n=37, 20%) compared to low-energy trauma (n=26, 4%) mechanisms (p<0.001). Polytrauma and high-energy monotrauma patients had a higher rate of open fractures compared to low-energy monotrauma patients (8.8% and 9.3% versus 1.8%, both p<0.001). The distribution of all types of DRF for different age categories in the 3 groups is shown in Figure 1.

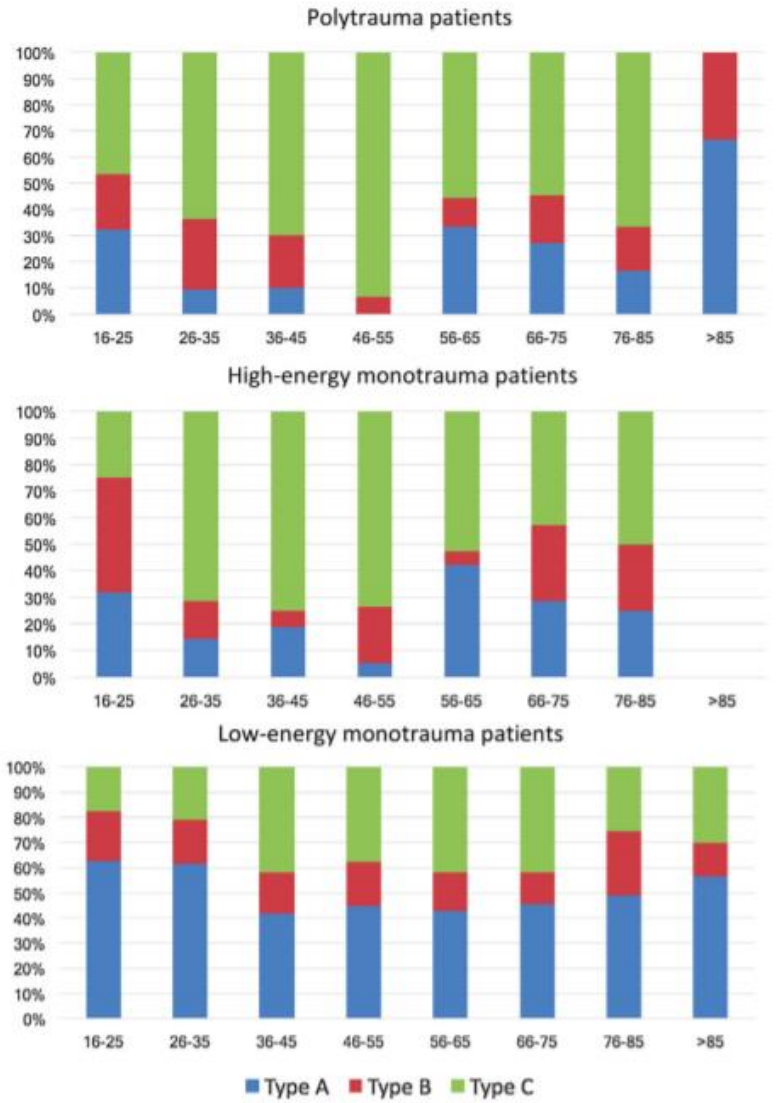

Fig. 1. Distribution per age category of type A, B and C distal radius fractures in polytrauma, high-energy monotrauma and low-energy monotrauma patients.

Both polytrauma and high-energy monotrauma patients received more operative interventions for all types of DRF compared to low-energy monotrauma patients (Table 3). No difference in operative intervention rate between polytrauma and high-energy monotrauma was observed for all fracture types (type A p=0.698, type B p=0.055, type C p=0.438).

Table 3
Details of operative interventions in polytrauma, monotrauma patients after high energy trauma and patients after low energy trauma.

	Polytrauma patients n = 102	High-energy Monotrauma n = 107	Low-energy Monotrauma n = 621	*p*-value
Operation for DRF, n/total (%)	68 (67%)	65 (61%)	176 (28%)	<.001
Type A	11/23 (48%)	11/26 (42%)	53/307 (17%)	<.001
Type B	10/18 (56%)	6/23 (26%)	18/108 (17%)	.001
Type C	47/61 (77%)	48/58 (83%)	105/206 (51%)	<.001
≥2 operations for DRF	26 (38%)	23 (35%)	45 (26%)	.096
≥3 operations for DRF	4 (6%)	6 (9%)	1 (1%)	.003
Time to first operation, d (SD)	6 (5)	5 (5)	9 (5)	<.001
Type of primary operation*				<.001
ORIF	53 (78%)	53 (82%)	163 (93%)	
CRIF	3 (4%)	3 (5%)	10 (6%)	
External fixator	12 (18%)	9 (14%)	2 (1%)	
Secondary surgery				
Nonunion operation	7 (10%)	1 (2%)	1 (1%)	<.001
Revision of osteosynthesis	3 (4%)	2 (3%)	6 (3%)	.905
Removal of osteosynthesis	9 (13%)	12 (19%)	32 (18%)	.624
External fixator to ORIF	8 (67%)	7 (78%)	1 (50%)	.655
Operation for infection	1 (2%)	3 (5%)	1 (1%)	.187
Correction osteotomy radius	2 (3%)	1 (2%)	1 (1%)	.333

DRF; distal radius fracture, SD; standard deviation, d; days*; 1 missing case, ORIF; open reduction and internal fixation, CRIF; closed reduction and internal fixation, +/−; indicating direction of difference and comparable group.

Within the polytrauma group 20 patients (20%) suffered a low-energy trauma. These patients were older than the other 3 groups (mean 66 years, SD 13), had similar admission (98% vs 100%) and ICU admission (34% vs 35%) rates as high-energy polytrauma patients and had a similar head and thoracic injury rates (55% and 40% respectively). The fracture morphology was different than the other 3 groups (40% type A, 20% B and 40% C) and the operative intervention pattern was more similar to low-energy monotrauma patients (more type A DRF interventions but less operative interventions in total compared to high-energy poly- and monotrauma patients, both p<0.001)

Additional ipsilateral upper extremity injuries were observed in 105 patients (13%) (154 sustained injuries). Polytrauma patients and high-energy monotrauma patients had more ipsilateral upper extremity injury compared to low-energy monotrauma patients (38% and 32% versus 5.2% respectively, p<0.001 and p<0.001 respectively). Carpal fractures (n=44, 5.4%), followed by metacarpal & phalangeal injuries (n=34, 4.1%) were the most prevalent (Figure 2). Of the patients with ipsilateral concomitant upper extremity injuries 17 (17/105, 16%) had injuries diagnosed after initial survey.

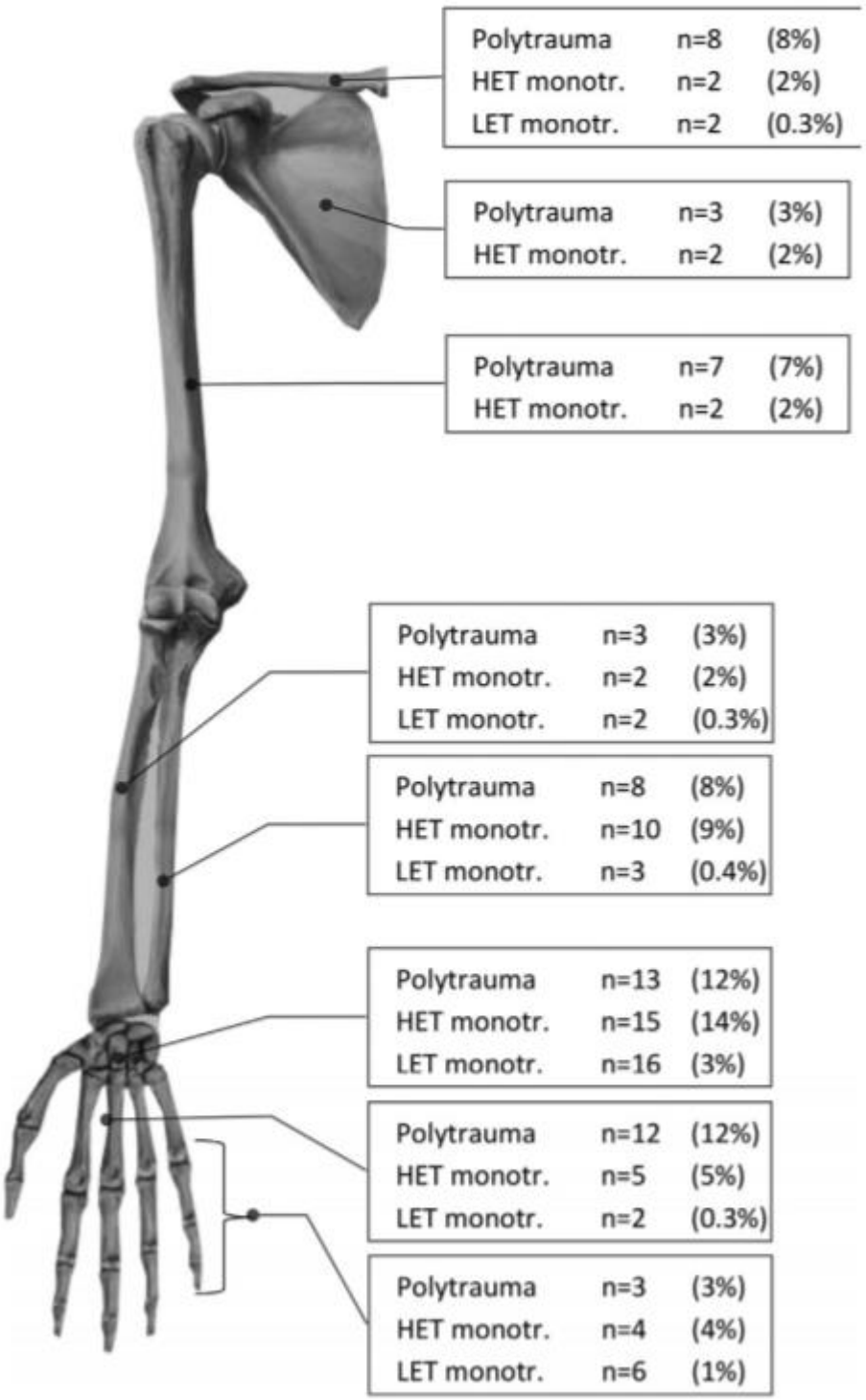

Fig. 2. Distribution of all additional injuries per poly- and monotrauma patients.
HET monotr.; High-energy monotrauma patients.
LET monotr.; Low-energy monotrauma patients.

DISCUSSION

Our study demonstrated fracture morphology in combination with injury mechanism in both polytrauma and monotrauma patients with a DRF. This study found that the fracture morphology and incidence of concomitant soft tissue injuries were associated with the energy impact. High energy monotrauma patients with a DRF demonstrated similar fracture morphology as polytrauma patients. The incidence of concomitant ipsilateral upper extremity injury in polytrauma and high-energy monotrauma patients was high (30%) and 16% of these injuries were found after the initial survey. Although polytrauma and high-energy monotrauma patients sustain similar injuries, differences remain between these groups.

Most importantly, energy of trauma is associated with fracture morphology, concomitant injuries to the ipsilateral upper extremity and other body regions, number of operative interventions and non-union and it thus likely relevant for functional outcome. Therefore, outcome evaluation should be different for polytrauma and high-energy monotrauma versus those who sustain their injury through lower-energy mechanisms.

The incidence of DRF in polytrauma patients (3.5%) is lower compared to patients with an isolated DRF [6]. Furthermore, in polytrauma patients a higher rate of type C and C3 subtype DRF was found, especially in patients aged 20-45 years [6]. The main cause of polytrauma were high-energy trauma accidents, 80% in this study. The remaining 20% polytrauma patients showed a similar head and thoracic injury pattern, similar ISS, and had the same admission and ICU admission rate. These low-energy polytrauma patients were significantly older than the other 3 groups. This likely represents a group of geriatric polytrauma patients in which a low-energy trauma can result in similar injuries as seen in high energy polytrauma patients. Although these patients have multiple injuries, their DRF morphology is somewhat different, but resembles mostly high-energy polytrauma injury, therefore, this group is analysed as one.

Similar DRF classifications were observed in polytrauma and high-energy monotrauma patients. Therefore, we demonstrated that the fracture morphology of DRF depends on the energy transfer during the trauma. High-energy accidents, like fall from heights and high velocity traffic incidents, distribute more energy over a larger area. This could explain the lower incidence but higher severity of DRFs in polytrauma patients. The peak incidence of type C DRF was observed in patients aged 20-45 years old. The higher rate of high-energy traumas in these age categories are probable responsible for this effect. The higher incidence of males, and younger age are known epidemiologic characteristics of patients involved high energy accidents (i.e. fall from height, high velocity traffic accidents) [13]. A study by Flinkkilä et al, examined all DRF in a region in Finland and did not find an association between trauma energy and fracture morphology [14]. However, different, less stringent definitions for high energy trauma and a lower number of high energy trauma patients might be responsible for the lack of association in their study.

Although DRF in polytrauma and high-energy monotrauma patients are radiographically categorized similar to those in low-energy monotrauma, substantial differences were observed. For example, in polytrauma and high-energy monotrauma patients more open fractures, higher rates of C3 fractures, a higher operative intervention rate for all types of DRF, more reoperations and more frequent use of external fixators was seen compared to low-energy monotrauma patients. Although more C3 type DRFs were observed in polytrauma and high-energy monotrauma patients compared to low-energy monotrauma, this only partially describes the injury severity of the fracture in these patients. The increased number of surgeries performed and the higher percentage of external fixation used, suggests an increased injury severity of the fractures that is not reflected by fracture classification. Higher energy transfer causes more additional damage, also to the soft tissues. This was reflected in the higher rate of additional ipsilateral injuries and open fractures. This could explain the higher rate of operative

interventions for the same radiographic types of DRFs in polytrauma and high-energy monotrauma compared to low-energy monotrauma patients.

All patients were treated by the same surgical team. Thus, it is likely that the higher rate of external fixators with delayed definitive internal fixation indicates more severe soft tissue and is not institution or surgeon preference based.

A high rate (>30%) of concomitant ipsilateral upper extremity injuries in both polytrauma and high-energy monotrauma patients was found. This is in line with the observation that high-energy trauma cause more severe DRFs. Sixteen percent of these injuries were found after initial survey. Delayed diagnosed extremity injuries in polytrauma patients are a well-known phenomenon [5]. In this population distal extremity injuries were frequently diagnosed after the primary survey or even after discharge [5]. A challenging aspect in high-energy monotrauma patients, compared to polytrauma patients, is the lower admission rate. This limits the opportunity to re-evaluate the patient for additional injuries. The painful distracting injury of the DRF during the initial survey could lead to missed injuries in these patients [15]. The rate of ipsilateral extremity injuries in DRF patients after a high-energy accident underlines the need for a repeated examination, also in monotrauma patients.

Although polytrauma and high-energy monotrauma patients sustain similar injuries, outcome evaluation should be different. Injuries to other body regions, prioritization of care for life threatening injuries, prolonged sedation and ICU admittance and decreased ability to rehabilitate are all factors that can negatively influence outcome of polytrauma patients. Furthermore, in this study differences were supported by the higher rate of non-union related interventions found in polytrauma patients. This was not observed for high-energy monotrauma patients and therefore might not solely be attributable to energy transfer. It is hypothesized that the systemic inflammatory effects inherent to polytrauma patients play a role in fracture healing. Several animal studies have shown that systemic changes in leucocyte functioning in

polytrauma patients could deteriorate fracture healing [16,17]. This was also found in studies which compared polytrauma patients with and without fracture healing disorders [18]. Interestingly, there are contradictory results on this matter and the influence of polytrauma appears to vary depending on the studied subgroup and bones affected [19-22].

Injuries to other body regions can influence outcome of extremity injury in polytrauma patients. For example traumatic brain injury, severe thoracic injury or a lower extremity injury could dictate treatment priority and influence the ability to rehabilitate after a DRF. Other studies showed that functional outcome of extremity injuries in polytrauma patients was worse compared to (high-energy) monotrauma patients with similar injuries [1,23]. Our results and these studies indicate that outcome in polytrauma patients is multifactorial and therefore polytrauma and high-energy monotrauma patients should be considered as separate groups in outcome analysis.

Our study has several limitations. This study did not report on outcome. Previous studies showed different outcomes for polytrauma patients compared to monotrauma [1,2]. Furthermore, this study lacks information on osteoporosis, vitamin D deficiency and glucocorticoid use. This would have added to the interpretability of the fracture classification, especially in the older age categories [24-26]. Another limitation of this study is the potential of selection bias because the study was performed with data solely from a level 1 trauma center. Inclusion of patients from both level 1 and level 2 centers would have added to the interpretability. However, the large number of low-energy trauma patients included decreases the risk of selection bias. In addition, the patients presented at our level 1 trauma center are not solely polytrauma patients and can be presented by the same route as in level 2 trauma centers. General practitioner referral, patients presenting out of own consideration and ambulance overtriage (not severely injured but allocated to level 1 trauma center because suspected polytrauma) of 30.6% by ambulance personnel in our region are explanations for the presentation of low energy trauma

and high energy monotrauma patients to our facility [9]. This adds to the interpretability and decreases the risk of selection bias. Finally, the classification of fractures was limited to group A, B, C and only type C3 was sub-classified. This latter was based on the large inter-observer variation in the AO classification regarding sub-classifications [11,12]. A prospective design with computed tomography of all included patients could provide further insight in the subgroup division.

CONCLUSION

The incidence of distal radius fractures (DRF) in polytrauma patients was 3.5%, this is low compared to a patients with an isolated DRF. The energy transfer determines fracture morphology and a similar fracture distribution with more type C distal radius fractures was observed in polytrauma and high-energy monotrauma patients. In polytrauma and high-energy monotrauma patients a high rate of ipsilateral upper extremity injury was found. Polytrauma and high-energy monotrauma patient with a DRF are comparable with regard to fracture type and distinctly different in this matter than low-energy monotrauma patients. However, polytrauma patient have in addition to more injured body regions also more non-union related interventions than high-energy monotrauma patients, indicating differences remain. Future studies, especially when focus on outcome measurements, should account for the 3 distinct groups regarding injury pattern in distal radius fractures.

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Chapter 11: Association of Polytrauma and High-Energy Injury Mechanism on Patient-Reported Outcomes after Distal Radius Fracture

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ABSTRACT

Background/Rationale

Patient-reported outcomes (PROs) are increasingly relevant when evaluating the treatment of orthopaedic injuries. Little is known about how outcomes may vary in the setting of polytrauma or secondary to a high-energy injury mechanisms, even for common injuries like distal radius fractures (DRF).

Questions/Purposes (1)

To determine if polytrauma or high-energy injury mechanism are associated with worse longer-term PROs after DRF.

Questions/Purposes (2)

To establish normative data on longer-term PROs after DRFs in the context of monotrauma versus polytrauma and different injury mechanisms.

Methods

This was a retrospective study with follow-up by questionnaire. Patients treated for DRFs at a single level 1 trauma center between 2008 and 2015 were approached for completion of two questionnaires on health-related quality of life (HRQoL) (the EuroQOL five-dimensional questionnaire (EQ-5D-3L) and the EuroQOL Visual Analog Scale (EQ-VAS)) and wrist function (the Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH)). Patients were grouped as polytrauma (Injury Severity Score (ISS) ≥16), monotrauma high-energy (HET) (ISS <16) and monotrauma low-energy (LET) based on ISS score and injury mechanism. A total of 265 patients responded (response rate 77%).

Results for Purpose 1

In multivariable regression analysis, older age and polytrauma were independently associated with decreased HRQoL. Female sex, intra-articular fracture, HET and lower HRQoL scores were independently associated with worse QuickDASH scores.

Results for Purpose 2

Overall, median EQ-5D-3L score was 0.86 (IQR 0.78 – 1.00; range -0.33 – 1.00) and median VAS score was 80 (IQR 70 – 90; range 10 – 100). Between the three groups, EQ-5D-3L scores differed significantly (p = 0.009). Among all patients, median QuickDASH score was 7 (IQR 0 – 23; range 0 – 82). By polytrauma and injury mechanism grouping, median QuickDASH score was 8 for polytrauma (IQR 1 – 25; range 0 – 82), 11 for monotrauma HET (IQR 2 – 26; range 0 – 73) and 5 for monotrauma LET (IQR 0 – 16; range 0 – 68; p = 0.01 for difference between groups).

Conclusions

We found that high-energy injury mechanism and worse HRQoL scores were independently associated with inferior wrist function after distal radius fractures. In addition to relatively well-known demographic and injury characteristics (sex, articular involvement), factors related to injury context (HET) may account for differences in patient-reported wrist function after distal radius fracture. These results highlight the importance of assessing injury context and HRQoL when evaluating region-specific outcomes after orthopaedic trauma.

Level of Evidence

Level III, Prognostic Study

INTRODUCTION

Background

Patient-reported outcomes (PROs) are becoming increasingly important when evaluating the treatment of orthopaedic injuries [13]. While PROs can be helpful for clinical decision making and expectation management in individual patients, they also enable benchmarking between institutions which can aid in the development of quality improvement and bundled payment programs [13, 24, 36].

Part of the challenge in implementing PROs is that outcomes are often context- and patient-dependent [26]. When measuring PROs within highly heterogeneous patient populations, the statistical variance in measured outcomes is often also correspondingly large, making accurate comparison of treatment outcome and cost challenging [25]. To avoid this problem, many existing studies on outcomes after musculoskeletal injury have focused on specific conditions or treatments using well-defined, homogenous patient populations. In this setting, more complicated patient groups, like those who sustain polytrauma or multiple (extremity) injuries, are often excluded [4, 28, 32, 34]. As a result, there is a gap in our understanding of these outcomes in polytrauma patients with orthopaedic injuries and orthopaedic injuries sustained in the context of high-energy injury mechanisms [11]. For example, while it is well known that outcomes following isolated distal radius fractures (DRF) vary by age, sex or articular step-off, similar understanding of the variation in PROs is less known in the setting of multiple or high-energy injuries even though DRFs occur in nearly 3.5% of polytrauma patients [3, 10, 14, 18, 22]. So, while articular step-off and demographic characteristics may still be relevant factors, we do not know if the magnitude of their association is dwarfed by other factors related to a larger burden of injury.

Rationale

We hypothesized that patients who sustain DRFs in the setting of polytrauma or high-energy injury mechanism would have worse general health and wrist-specific PROs compared to patients with isolated, low-energy DRFs. We also aimed to identify risk factors and establish normative data on longer-term PROs after DRF, especially in relation to polytrauma or multiple injuries and to injury mechanism.

METHODS

Study design and setting

In this study, we obtained additional data regarding a patient cohort on which we have previously reported using follow-up questionnaires [10]. Inclusion period for time of injury was January 2008 to December 2015, and follow-up occurred between April to May 2018.

Participants/study subjects

After an institutional review board waiver was obtained, all patients who presented with a traumatic DRF at our American College of Surgeons Level 1 trauma center during the inclusion period were identified using ICD-9 (International Classification of Disease, Ninth Revision) codes. Medical records of all patients ≥16 years at the time of trauma and ≥18 years at the time of follow-up, were reviewed to determine eligibility by assessing medical notes as well as available imaging. Patients who underwent initial treatment at an outside facility and patients with no follow-up beyond primary presentation, were deemed ineligible. Eligible patients were divided into three groups; polytrauma, monotrauma high-energy (monotrauma HET), and monotrauma low-energy (monotrauma LET). Polytrauma was defined as an Injury Severity Score (ISS) ≥16, calculated using Abbreviated Injury Scale (AIS) scores [29]. As a result, all patients with an ISS <16 were categorized as monotrauma. The energy of injury mechanism was defined according to the Advanced Trauma Life Support guidelines [31].

Patients that did not meet the criteria for high-energy trauma (HET) were considered low-energy trauma (LET) patients. Deceased patients, mentally impaired patients, patients with insufficient command of the Dutch language and patients residing outside the Netherlands were excluded for follow-up.

All polytrauma and monotrauma HET patients and a random sample of 200 monotrauma LET patients who sustained a DRF were included and approached for completion of two questionnaires. To all patients eligible for follow-up, a recruitment letter explaining the study, two questionnaires, an informed consent form, and a stamped return envelope were sent. In case of no response within four weeks after sending out the letter, patients were contacted by telephone to obtain verbal informed consent and administer the questionnaires. The timing of the phone calls was varied in an attempt to maximize the response rate [28].

Variables, outcome measures, data sources, and bias

Medical records and imaging were reviewed to obtain the following characteristics: age at trauma, sex, ISS, injury mechanism, AIS codes, bilateral fracture, concomitant ipsilateral upper extremity injury, AO/OTA (Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association) classification, open fracture, and surgical treatment. DRFs were reviewed and classified according to the AO/OTA classification by two investigators (SF and QV) [20]. In case of uncertainty, two attending trauma surgeons (RM and FH) were consulted and group discussions led to consensus. To decrease interobserver variability during analysis, all fractures were then grouped as extra-articular (23.A) or intra-articular (partial articular (23.B) and complete articular (23.C)). Concomitant injuries of the involved upper extremity were recorded and grouped based on anatomical location.

Longer-term patient-reported outcome (>2 years follow-up) was assessed using measures of general health-related quality of life (HRQoL) and wrist function. For patients with bilateral DRFs, the wrist-specific questionnaire was attached twice (one for each side).

HRQoL was assessed using the EuroQOL five-dimensional questionnaire (EQ-5D-3L) and the EuroQOL Visual Analog Scale (EQ-VAS). The EQ-5D-3L is a standardized instrument used to measure general health status based on the level of experienced problems (no problems, some problems, extreme problems) at five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) [33]. Scores were calculated using a scoring algorithm appropriate for a population of Dutch patients [27], with a possible range from -0.33 to 1.00. The EQ-VAS is an instrument developed for recording an individual's current self-rated health on a scale from 0 to 100. For both the EQ-5D and the EQ-VAS, higher scores represent higher health-related quality of life [33]. Patient-reported wrist function was evaluated using the Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH) questionnaire, a questionnaire consisting of 11 items to measure physical function and symptoms in patients with any or multiple musculoskeletal disorders of the upper limb, ranging from 0 to 100, with higher scores indicating worse functionality [2]. Evidence of reliability, validity, and responsiveness of the DASH in a hand and wrist trauma population has been reported, with similar precision of the QuickDASH in comparison to the DASH in patients with upper extremity disorders [7, 15]. More specifically, the DASH has been described to be a valid and reliable patient-reported outcome measure (PROM) to assess function and disability in Dutch patients with displaced DRFs [17].

Demographics, description of study population

Median age at injury for all responders was 50 years (IQR 31 – 63; range 16 – 87), with a median ISS of 9 (IQR 9 – 14; range 4 – 50). In the group of polytrauma and monotrauma HET patients, most were male (69% resp. 60%), while the majority of monotrauma LET patients were female (81%). Demographic and injury characteristics for all responders are reported in **Table 1**.

Table 1. Demographic and injury characteristics.

	All responders	Polytrauma	Monotrauma HET	Monotrauma LET
	n = 265	**n = 65**	**n = 70**	**n = 130**
Age at trauma (median, IQR)	50 (31 – 63)	45 (26 – 60)	44 (30 – 57)	58 (39 – 69)
Male (n, %)	112 (42)	45 (69)	42 (60)	25 (19)
ISS (median, IQR)	9 (9 – 14)	22 (19 – 29)	9 (9 – 10)	9 (4 – 9)
Time between fracture and follow-up (years; median, IQR)	6 (4 – 8)	5 (4 – 7)	6 (4 – 7)	6 (4 – 8)
Mechanism of trauma (n, %)				
Fall <3m	124 (47)	6 (9)	2 (3)	116 (89)
Fall >3m	50 (19)	27 (42)	23 (32)	0 (0)
Bicycle accident	16 (6)	3 (5)	7 (10)	6 (5)
Car accident	22 (8)	7 (11)	14 (20)	1 (1)
Motorcycle accident	41 (15)	18 (28)	21 (30)	2 (2)
Pedestrian involved MVA	4 (2)	2 (3)	1 (1)	1 (1)
Other	8 (3)	2 (3)	2 (3)	4 (3)
Associated head injury AIS >2 (n, %)	25 (9)	24 (37)	1 (1)	0 (0)
Associated thoracic injury AIS >2 (n, %)	38 (14)	37 (57)	1 (1)	0 (0)
Associated abdominal injury AIS >2 (n, %)	30 (11)	25 (38)	4 (6)	1 (1)
Bilateral DRF (n, %)	12 (5)	7 (11)	3 (4)	2 (2)
Concomitant ipsilateral upper extremity injury (n, %)	61 (23)	26 (40)	25 (36)	10 (8)
Metacarpal and phalangeal	18 (7)	9 (14)	7 (10)	2 (2)
Carpal	30 (11)	11 (17)	14 (20)	5 (4)
Distal humerus and elbow	13 (5)	6 (9)	6 (9)	1 (1)
Proximal humerus and shoulder	14 (5)	11 (17)	1 (1)	2 (2)
	n = 277	**n = 72**	**n = 73**	**n = 132**
AO classification (n, %)				
Type A	90 (32)	10 (14)	17 (23)	63 (48)
Type B	52 (19)	14 (19)	14 (19)	24 (18)
Type C	135 (49)	48 (67)	42 (58)	45 (34)
Open fracture (n, %)	12 (4)	6 (8)	6 (8)	0 (0)

HET = high-energy trauma; LET = low-energy trauma; n = number; IQR = interquartile range; ISS = Injury Severity Score; MVA = motor vehicle accident; AIS = Abbreviated Injury Scale; DRF = distal radius fracture; AO = Arbeitsgemeinschaft für Osteosynthesefragen.

Among all DRFs, 145 (52%) were treated operatively (79% of fractures in polytrauma, 80% of fractures in monotrauma HET, and 36% of fractures in monotrauma LET patients). The majority of operatively treated cases underwent open reduction internal fixation (120/145; 83%). Differences in characteristics between responders and non-responders are provided in **Supplementary Table 1**, with the only difference being more severe fractures in polytrauma responders compared to polytrauma non-responders (p = 0.03).

Supplementary Table 1. Comparisons of baseline characteristics between responders and non-responders.

	Polytrauma	Monotrauma HET	Monotrauma LET

	Responders	**Non-responders**	***p*-value**	**Responders**	**Non-responders**	***p*-value**	**Responders**	**Non-responders**	***p*-value**
	n = 65	**n = 22**		**n = 70**	**n = 22**		**n = 130**	**n = 36**	
Age at trauma (median, IQR)	45 (26 – 60)	45 (22 – 63)	0.86	44 (30 – 57)	33 (22 – 52)	0.12	58 (39 – 69)	49 (28 – 66)	0.10
Male (n, %)	45 (69)	14 (64)	0.63	42 (60)	17 (77)	0.14	25 (19)	10 (28)	0.27
ISS (median, IQR)	22 (19 – 29)	27 (21 – 29)	0.54	9 (9 – 10)	10 (9 – 13)	0.48	9 (4 – 9)	9 (9 – 9)	0.35
Mechanism of trauma (n, %)									
Fall <3m	6 (9)	2 (9)	0.47	2 (3)	0 (0)	0.55	116 (89)	33 (92)	0.85
Fall >3m	27 (42)	10 (45)		23 (32)	10 (45)		0 (0)	0 (0)	
Bicycle accident	3 (5)	2 (9)		7 (10)	0 (0)		6 (5)	1 (3)	
Car accident	7 (11)	5 (23)		14 (20)	6 (27)		1 (1)	1 (3)	
Motorcycle accident	18 (28)	2 (9)		21 (30)	6 (27)		2 (2)	0 (0)	
Pedestrian involved MVA	2 (3)	0 (0)		1 (1)	0 (0)		1 (1)	0 (0)	
Other	2 (3)	1 (5)		2 (3)	0 (0)		4 (3)	1 (3)	
Associated head injury AIS >2 (n, %)	24 (37)	10 (45)	0.48	1 (1)	1 (5)	0.38	0 (0)	1 (3)	0.06
Associated thoracic injury AIS >2 (n, %)	37 (57)	14 (64)	0.58	1 (1)	1 (5)	0.38	0 (0)	0 (0)	n/a
Associated abdominal injury AIS >2 (n, %)	25 (38)	5 (23)	0.18	4 (6)	0 (0)	0.25	1 (1)	0 (0)	0.60
Bilateral DRF (n, %)	7 (11)	1 (5)	0.38	3 (4)	1 (5)	0.96	2 (2)	0 (0)	0.45
Concomitant ipsilateral upper extremity injury (n, %)	26 (40)	7 (32)	0.49	25 (36)	6 (27)	0.47	10 (8)	0 (0)	0.09
Metacarpal and phalangeal	9 (14)	5 (23)	0.33	7 (10)	4 (18)	0.30	2 (2)	0 (0)	0.45
Carpal	11 (17)	1 (5)	0.15	14 (20)	1 (5)	0.09	5 (4)	0 (0)	0.23
Distal humerus and elbow	6 (9)	4 (18)	0.26	6 (9)	3 (14)	0.49	1 (1)	0 (0)	0.60
Proximal humerus and shoulder	11 (17)	1 (5)	0.15	1 (1)	0 (0)	0.57	2 (2)	0 (0)	0.45
	n = 72	**n = 23**		**n = 73**	**n = 23**		**n = 132**	**n = 36**	
AO classification (n, %)									
Type A	10 (14)	9 (39)	**0.03**	17 (23)	8 (35)	0.45	63 (48)	16 (44)	0.66
Type B	14 (19)	2 (9)		14 (19)	5 (22)		24 (18)	5 (14)	
Type C	48 (67)	12 (52)		42 (58)	10 (43)		45 (34)	15 (42)	
Open fracture (n, %)	6 (8)	2 (9)	0.96	6 (8)	2 (9)	0.94	0 (0)	0 (0)	n/a

HET = high-energy trauma; LET = low-energy trauma; n = number; IQR = interquartile range; ISS = Injury Severity Score; MVA = motor vehicle accident; AIS = Abbreviated Injury Scale; DRF = distal radius fracture; AO = Arbeitsgemeinschaft für Osteosynthesefragen; n/a = not applicable. **Bold** indicates statistically significant difference.

Accounting for all patients/study subjects

A total of 830 patients were identified initially. After random selection of 200 monotrauma LET patients and application of exclusion criteria for follow-up, 345 patients were approached for follow-up by questionnaire. Questionnaires were completed by 265 patients for 277 fractures (12 patients sustained bilateral DRFs), leading to a response rate of 77% (**Figure 1**).

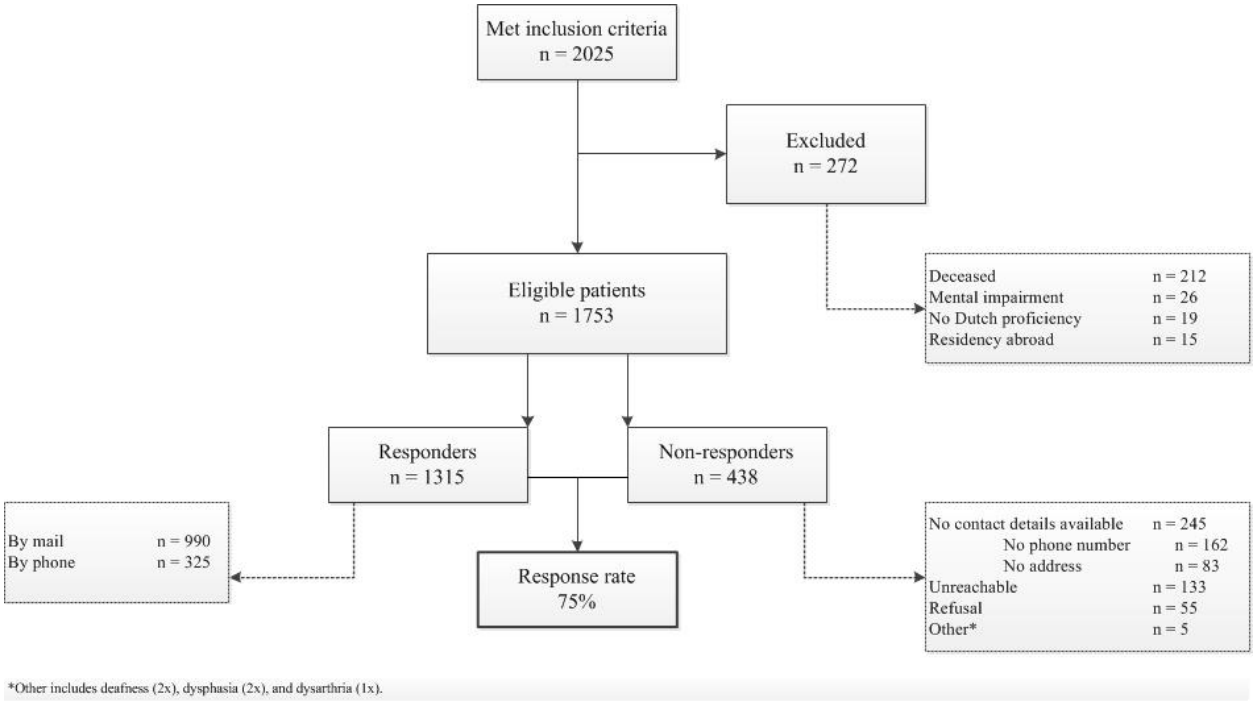

Figure 1. The flowchart shows the inclusion and response process.

Statistical analysis, study size

Baseline characteristics were calculated as medians and interquartile ranges (IQR) for continuous variables and absolute numbers with percentages for categorical variables. Baseline characteristics between responders and non-responders in the four groups of interest were compared using Chi-squared and Mann-Whitney tests. Differences in functional outcomes between the groups, were calculated using Kruskal-Wallis tests. The strength of correlations between the three different outcome measures was assessed using Pearson's correlation coefficient. Associations between individual predictors and the patient-reported outcomes of interest were first determined by simple bivariate linear regression (**Supplementary Table 2**).

Supplementary Table 2. Bivariate linear regression analyses.

	EQ-5D			**QuickDASH**		
	β regression coefficient*	**95% CI**	***p*-value**	**β regression coefficient***	**95% CI**	***p*-value**
Age at trauma	-0.001	-0.003 – 0.0003	0.11	0.1	0.02 – 0.2	**0.02**
Time to follow-up	0.001	-0.01 – 0.01	0.88	-0.5	-1.5 – 0.5	0.36
Male	-0.004	-0.06 – 0.05	0.89	-5.4	-9.7 – -1.1	**0.01**
Polytrauma	-0.11	-0.17 – -0.04	**0.001**	3.3	-1.5 – 8.2	0.18
High-energy trauma	-0.06	-0.11 – 0.002	0.06	5.7	1.5 – 9.9	**0.01**
Associated head injury AIS >2	-0.04	-0.14 – 0.05	0.39	1.1	-6.0 – 8.2	0.76
Associated thoracic injury AIS >2	-0.14	-0.22 – -0.06	**0.001**	2.4	-3.6 – 8.3	0.43
Associated abdominal injury AIS >2	-0.04	-0.13 – 0.05	0.34	1.5	-5.2 – 8.3	0.66
Bilateral DRF	-0.02	-0.16 – 0.12	0.77	5.2	-2.4 – 12.7	0.18
Concomitant ipsilateral upper extremity injury	-0.03	-0.10 – 0.04	0.41	2.4	-2.5 – 7.4	0.34
Intra-articular DRF	-0.03	-0.09 – 0.03	0.40	3.7	-0.9 – 8.2	0.11

EQ-5D = EuroQOL 5-Dimensions; QuickDASH = Quick Disabilities of the Arm, Shoulder, and Hand; CI = confidence interval; AIS = Abbreviated Injury Scale; DRF = distal radius fracture.
*Positive regression coefficients denote higher outcome scores (indicating better health-related quality of life according to the EQ-5D and worse wrist function according to the QuickDASH).
Bold indicates statistically significant difference.

The final models were selected by forward stepwise regression modeling to avoid overfitting. In this approach, predictors associated with the outcome by bivariate analysis were included in the multivariable regression model. Predictors no longer associated with the outcome were omitted only if doing so did not increase the deviance of the model. Predictors excluded at the bivariate analysis state were reincorporated only if doing so reduced the overall deviance of the model [30]. Interaction terms were applied to the analyses. All statistical analyses were performed using STATA® 13.1 (StataCorp LP, TX, USA). A p-value of <0.05 was considered statistically significant.

RESULTS

Questionnaires were completed after a median of 6 years since injury (IQR 4 – 8 years; range 2 – 10 years). Overall, median EQ-5D-3L score was 0.86 (IQR 0.78 – 1.00; range -0.33

– 1.00) and median VAS score was 80 (IQR 70 – 90; range 10 – 100). Between the three groups, EQ-5D-3L scores differed significantly (p = 0.009), but EQ-VAS scores did not (p = 0.22, **Figure 2**). Among all patients, median QuickDASH score was 7 (IQR 0 – 23; range 0 – 82). By polytrauma and injury mechanism grouping, median QuickDASH score was 8 (IQR 1 – 25; range 0 – 82) for polytrauma, 11 (IQR 2 – 26; range 0 – 73) for monotrauma HET and 5 (IQR 0 – 16; range 0 – 68) for monotrauma LET (p = 0.01 for difference between groups). All three outcome metrics were correlated: EQ-5D and EQ-VAS (correlation coefficient=0.60, p <0.001), QuickDASH and EQ-5D (correlation coefficient = -0.45, p <0.001), and QuickDASH and EQ-VAS (correlation coefficient = -0.40, p <0.001). In general, worse HRQoL metrics (EQ-5D and EQ-VAS) were inversely proportional to QuickDASH scores.

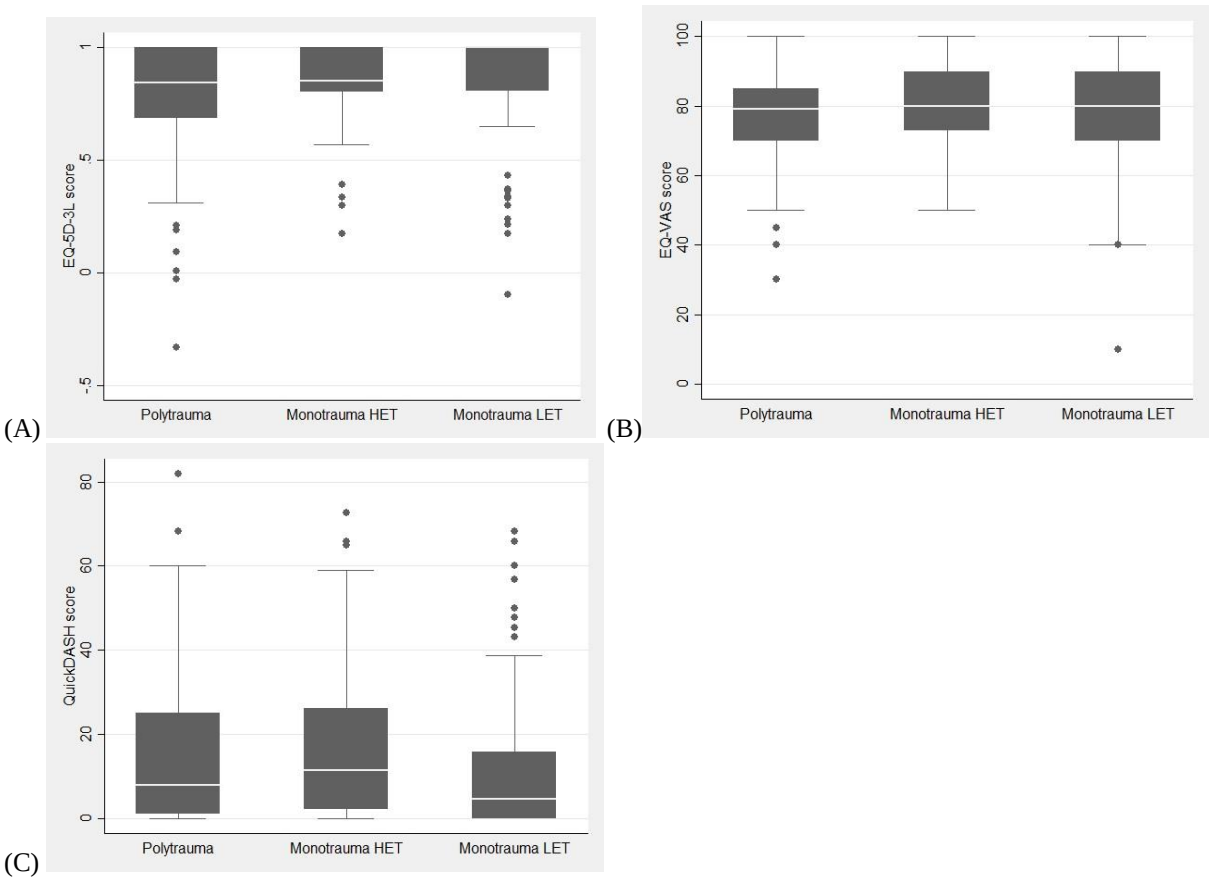

Figure 2: (A) The graph shows EQ-5D-3L scores for polytrauma, monotrauma HET, and monotrauma LET patients. Higher scores represent better HRQoL; (B) The graph shows EQ-VAS scores for polytrauma, monotrauma HET, and monotrauma LET patients. Higher scores represent better HRQoL; (C) The graph shows QuickDASH scores for polytrauma, monotrauma HET, and monotrauma LET patients. Higher scores represent worse wrist function.

In multivariable regression analysis, older age and polytrauma were independently associated with lower HRQoL as measured by EQ-5D scores, but articular involvement was not. However, female sex, intra-articular fracture, HET, and lower EQ-5D or EQ-VAS scores were independently associated with worse QuickDASH scores (**Table 2 and Supplementary Table 3**). Polytrauma tended to be associated with worse QuickDASH scores but this was not statistically significant after adjusting for EQ-5D and EQ-VAS scores.

Table 2. Multivariable regression analyses.

	EQ-5D			**QuickDASH**		
	β regression coefficient*	**95% CI**	***p*-value**	**β regression coefficient***	**95% CI**	***p*-value**
Age at injury	-0.002	-0.003 – -0.0001	**0.04**	0.1	0.0 – 0.2	0.16
Male sex	0.02	-0.04 – 0.09	0.45	-8.6	-13.0 – -4.2	**<0.001**
Injury description						
Monotrauma LET, extra-articular	Reference			Reference		
Monotrauma LET, intra-articular	0.03	-0.05 – 0.11	0.44	3.5	-1.9 – 8.9	0.21
Monotrauma HET, extra-articular	0.07	-0.06 – 0.19	0.30	8.5	-0.1 – 17.1	0.05
Monotrauma HET, intra-articular	-0.03	-0.12 – 0.06	0.46	12.6	6.6 – 18.6	**<0.001**
Polytrauma, extra-articular	-0.16	-0.32 – -0.01	**0.04**	8.8	-1.8 – 19.4	0.11
Polytrauma, intra-articular	-0.11	-0.20 – -0.02	**0.01**	8.9	2.8 – 15.0	**0.004**
EQ-5D index	---	---	---	-32.6	-40.7 – -24.4	**<0.001**
Model	Multivariable linear			Multivariable linear		

EQ-5D = EuroQOL 5-Dimensions; QuickDASH = Quick Disabilities of the Arm, Shoulder, and Hand; CI = confidence interval; LET = low-energy trauma; HET = high-energy trauma; EQ-VAS = EuroQOL Visual Analogue Scale.
*Positive regression coefficients denote higher outcome scores (indicating better health-related quality of life according to the EQ-5D and worse wrist function according to the QuickDASH).
Bold indicates statistical significance.

Supplementary Table 3. Multivariable regression analyses using EQ-VAS.

	QuickDASH		
	β regression coefficient*	**95% CI**	***p*-value**
Age at injury	0.1	-0.1 – 0.2	0.33
Male sex	-8.3	-12.8 – -3.8	**<0.001**
Injury description			
Monotrauma LET, extra-articular	Reference		
Monotrauma LET, intra-articular	3.4	-2.2 – 8.9	0.24
Monotrauma HET, extra-articular	8.3	-0.6 – 17.1	0.07
Monotrauma HET, intra-articular	13.4	7.3 – 19.6	**<0.001**
Polytrauma, extra-articular	10.7	-0.2 – 21.6	0.05
Polytrauma, intra-articular	10.6	4.4 – 16.8	**0.001**
EQ-VAS score	-0.5	-0.6 – -0.3	**<0.001**
Model	Multivariable linear		

EQ-VAS = EuroQOL Visual Analogue Scale; QuickDASH = Quick Disabilities of the Arm, Shoulder, and Hand; CI = confidence interval; LET = low-energy trauma; HET = high-energy trauma.

*Positive regression coefficients denote higher outcome scores (indicating worse wrist function according to the QuickDASH).
Bold indicates statistical significance.

DISCUSSION

Background and rationale

Patient-reported outcomes are increasingly important for patients, physicians, and healthcare policymakers. However, there is limited information about PROs for extremity fractures in polytrauma patients and fractures resulting from high-energy injury mechanisms. In this study, we assessed the relationship between PROs, polytrauma, and injury mechanism in patients who sustained a DRF. We observed that older age and polytrauma were associated with worse general HRQoL, but intra-articular fracture involvement was not. High-energy mechanism next to intra-articular involvement and lower HRQoL were strongly correlated with worse QuickDASH wrist function scores.

Limitations

This study has several limitations. First, this study was subject to response bias, however we did have relatively high response rate of 77% for this type of study [28], and we identified no important differences in demographic characteristics between responders and non-responders. Second, questionnaires were completed at various lengths of follow-up. Outcome scores change over time but have also been described to plateau after one year (especially HRQoL after trauma) [1, 12] and no questionnaires in the present study were completed before this point. Furthermore, follow-up duration was added to the regression analyses, but was omitted in final multivariable regression because of a lack of association as described in our statistical methods. Third, as this was a retrospective study, not all potential predictors could be assessed. For example, functioning prior to the injury and patient psychological factors such as depression or self-efficacy may have influenced the outcome measures [16], but these measures could not be retrieved retrospectively. Therefore, factors identified to be associated with

HRQoL and wrist function in the present study, should not be seen as the only factors of influence. Fourth, since this study was conducted in a tertiary referral center, many patients did not receive routine follow-up at our institution. Therefore, long-term postoperative imaging assessing factors such as posttraumatic arthritis were not available for the majority of patients and limited our ability to incorporate these clinical factors into the analyses. Fifth, as patients included in the present study were treated over a relatively large time span, technique-related and surgeon-related changes may have influenced the outcome measures. However, follow-up duration, indicative of the period of treatment, was not associated with outcome measures.

Findings

In this study, we assessed for injury-related factors that may drive differences in PROs following DRF, in addition to typical factors like articular involvement or sex, especially among patients who sustain polytrauma or high-energy trauma. First, we assessed differences in general HRQoL and observed significant differences in outcome between polytrauma patients and monotrauma patients, regardless of articular involvement or the energy associated with the injury mechanism. Other studies have similarly demonstrated differences between polytrauma patients and monotrauma patients and our findings are aligned with that literature [14, 35, 37]. Polytraumatized patients often suffer from persistent pain and global disabilities that impact their long-term HRQoL, and since the scope of injuries for monotrauma patients is smaller, the difference is not surprising [9, 10, 22]. In addition, it is likely that we do not see an effect of intra-articular involvement or injury mechanism because their contribution to general HRQoL is proportionally much smaller to that of polytrauma.

Interestingly, when we adjusted for general health status, we observed that longer-term wrist function was associated with injury mechanism, intra-articular involvement, and sex. Data on the influence of energy transfer during trauma on injury is relatively sparse. Our finding that higher energy injuries were associated with worse QuickDASH scores, even in

absence of polytrauma, may be a reflection of the soft tissue damage associated with fractures resulting from HET. During traumatic injury, while the bony injury is evident by the resulting fracture, the damaging effects of energy dissipation into surrounding soft tissues is less obvious [21]. Similar findings have previously been reported for calcaneal fractures [37].

The importance of articular surface involvement has been known since Knirk and Jupiter's classic paper,[18] but the role of sex on PROs is less clear [5, 19, 23, 38]. We found that female sex was associated with worse wrist function. Differences in levels of functioning, coping attempts, and pain behavior between men and women may play a role, but future study is needed to investigate these differences [8, 19].

A previous study has suggested that general health function may significantly influence region-specific PROs [35]. We also found that EQ-5D and EQ-VAS scores were strongly correlated with patient-reported wrist function using the QuickDASH. The finding that EQ-VAS scores were correlated with wrist functioning implies that even a single question on self-reported health status can improve outcome measurement. Our results highlight the importance of obtaining general and region specific measures of HRQoL when evaluating PROs after injury. Without adjusting for general health measures, nearly all patients who sustain DRFs in a polytrauma setting would be judged to have worse wrist function when compared to a control group of patients with isolated DRF. Determining the importance of context on injuries will only increase in importance as health systems transition to value-based payment models based on the quality of delivered care, especially since musculoskeletal injuries are the fastest and largest drivers of US Medicare spending [6, 11, 39].

Conclusions

We found that high-energy injury mechanism and worse HRQoL scores were independently associated with inferior wrist function after distal radius fractures. In addition to relatively well-

known demographic and injury characteristics (sex, articular involvement), factors related to injury context (high-energy trauma) may account for differences in patient-reported wrist function after distal radius fracture. We also illustrate the importance of using both region-specific and general health outcome measures to measure outcomes after DRFs. Future research may address this concept for other fractures. Awareness of factors associated with poorer clinical outcome measures can be used to guide patient expectations and maximize overall recovery. From a health systems perspective, this information may guide quality improvement, enable benchmarking, guide processes of reimbursement decisions and aid in the development of bundled payments.

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Chapter 12: Association of Patient-Reported Outcomes with Clinical Outcomes after Distal Humerus Fracture Treatment

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ABSTRACT

Background

PROMIS scores are increasingly being used to evaluate patient-reported outcomes (PRO) following treatment for upper extremity injuries. Previous studies have demonstrated associations between legacy outcome scores and clinical outcomes after elbow trauma, but it is unclear if this relationship persists when using PROMIS instruments. In this study, we assessed the PRO of distal humerus fracture treatment using PROMIS or QuickDASH scores and explored the association between PRO and clinical outcomes.

Methods

We performed a retrospective cohort study of 76 consecutive adult patients who sustained an acute distal humerus fracture between 2016-2018. Starting in January 2016, collection of patient reported outcome measures (PROMs) was standardized in our orthopaedic clinics and 53 patients completed at least one PROM used to assess physical function/upper extremity disability (69.7% response rate) with an average follow-up of 10.3 months. Patients completed the PROMIS Physical Function (PF) 10a CAT, PROMIS Upper Extremity (UE) 10a CAT, and/or the QuickDASH to assess physical function and upper extremity disability on an electronic device. . In addition, the PROMIS Global CAT (Mental) subscale score was used as a measure of self-rated mental health. To assess clinical outcomes, we measured radiographic union, Broberg and Morrey Arthrosis grade, range of motion, and postoperative complications. Multivariable linear regression was used to assess the relationship between clinical outcomes and PRO.

Results

Most fractures were intra-articular (67.9%), and nearly all patients were treated surgically (84.9%). After treatment, 98.1% of fractures united radiographically and the majority of patients had grade 0-1 arthrosis (84.9%). By final follow-up, average flexion contracture was 18 degrees, terminal flexion was 122 degrees, and the average arc of flexion-extension was 105 degrees. Average (±SD) PROMIS PF and UE scores were 41.7 ± 11.1 and 40.8 ± 12.4, respectively. The average Quick DASH score was 39.4 ± 26.5. The arc of flexion-extension and PROMIS Global (Mental) score were independently associated with PROMIS PF and PROMIS UE scores.

Discussion

In this study, we present data about the clinical and patient-reported outcomes following treatment of distal humerus fractures. We found that the arc of flexion-extension and the PROMIS Global (Mental) score were independently associated with PROMIS measures of physical function. This data can be used to contextualize patient outcomes and guide patient expectations.

Level of Evidence: Level III, Retrospective Cohort Study (Outcomes)

INTRODUCTION

Fractures of the distal humerus account for 2% of fractures in the adult population and comprise approximately 30% of all humeral fractures.[2,11,24] An increase in the annual incidence of distal humeral fractures has been reported, likely due to a growing older population.[21,22] In general, these injuries are treated operatively with open reduction and internal fixation (ORIF), but some patients may still be managed with nonsurgical treatment.[2]

While several studies have evaluated clinical outcomes of distal humeral fractures, fewer studies have explored the association between clinical and patient-reported outcomes.[19,30] Moreover, a recent systematic review identified 109 articles assessing the outcomes of acute distal humeral fracture, but found that clinical and patient-reported outcomes (PROs) were not consistently reported, making accurate comparison of treatment effectiveness difficult.[32] In addition, the review found that general health surveys were rarely reported and comparisons using Patient-Reported Outcomes Measurement Information System (PROMIS) instruments were not possible.[32]

PROMIS instruments are increasingly being used to evaluate PRO for upper extremity injuries as they can be administered and scored in a standardized manner allowing for quality assessment across medical and surgical fields.[4,17] In addition, several studies have demonstrated that PROMIS scores correlate with legacy instruments used to measure the PRO of orthopedic upper extremity trauma patients.[6,9,20] Few studies have assessed the association between PRO and clinical outcomes, but it is unclear if similar findings are relevant when using PROMIS instruments or shortened disability questionnaires (e.g. QuickDASH).[16,29] In addition, the extent to which variation in PROMIS scores is explained by clinical outcomes is unknown. Therefore, in this study, we assessed the PRO of distal humerus fracture treatment

using PROMIS or QuickDASH scores and explored the association between PRO and clinical outcomes.

MATERIALS AND METHODS

Study Design

This study was approved by our institutional review board. We performed a retrospective cohort study of 85 consecutive adult patients (>18 years old) who received treatment at one of two American College of Surgeons Level 1 Trauma Centers from January 2016 to February 2018 for an acute distal humerus fracture. Starting in January 2016, collection of patient reported outcome measures (PROMs) was standardized in the orthopaedic clinics at both hospitals. Patients were excluded if their injury was initially treated at an outside hospital, or if they had a pathologic or periprosthetic fracture. Patients who had zero follow-up visits (5 patients) or were in hospice care (1 patient) were also excluded, as were patients treated with total elbow arthroplasty (3 patients). From the 76 eligible patients, 53 patients completed at least one PROM used to assess physical function/upper extremity disability (69.7% response rate) with an average follow-up of 10.3 months (**Table 1**).

Patient-reported Outcome Measures

Patients completed the PROMIS Physical Function (PF) 10a CAT, PROMIS Upper Extremity (UE) 10a CAT, and the QuickDASH to assess physical function and upper extremity disability on an electronic device as part of their routine follow-up visit.[4,6,7,9,12] In addition, the PROMIS Global CAT was completed and the PROMIS Global (Mental) subscale score was used as a measure of self-rate mental health.[26] The PROMIS instruments range from 0 to 100 with a mean score of 50 for the general population of the United States (standard deviation of 10).[4] The QuickDASH is an 11-item questionnaire that measures upper extremity-specific disability

with higher scores reflecting more severe disability (range of 0 to 100) and a mean of 11 points reflecting the general US population average.[4]

Clinical Outcomes

To assess clinical outcomes, we measured radiographic union, Broberg and Morrey Arthrosis grade, range of motion, complications (symptomatic implants, heterotopic ossification, infection), and unplanned return to the operating room. The most recently available anteroposterior and lateral radiographs were evaluated to assess for radiographic union and arthrosis. Arthrosis of the ulnohumeral joint was rated using the system of Broberg and Morrey, as grade 0 (normal), grade 1 (slight joint-space narrowing with minimum osteophyte formation), grade 2 (moderate joint-space narrowing with moderate osteophyte formation), or grade 3 (severe degenerative changes with gross destruction of the joint).[3] To improve the reliability of arthrosis grading, a binary measure of arthrosis was used for statistical analysis.[1,15] Range of motion was assessed in terms of flexion contracture (i.e. terminal extension), terminal flexion, and the total arc of flexion-extension. Patients were deemed to have a functional range of motion if their flexion extension arc was at least 30 to 130 degrees.[33]

Independent Variables

Detailed sociodemographic and clinical data were identified for each patient using our institutions' Enterprise Data Warehouse and the electronic medical record (**Table 1**). Median income for each patient was abstracted for each patient using the ZIP code of residence based on census data.[23] Primary health insurance was divided into 3 categories (Private, Medicaid, Medicare).[25] Injuries were classified using the AO-OTA fracture classification.[18] To decrease interobserver variability during analysis, all fractures were then grouped as extra-articular (13.A) or intra-articular (partial articular (13.B) and complete articular (13.C)). The energy of

injury mechanism was defined according to the Advanced Trauma Life Support guidelines.[27] Patients that did not meet the criteria for high-energy trauma (HET) were considered low-energy trauma (LET) patients. Procedures were grouped as closed treatment, ORIF, or ORIF with ulnar nerve transposition (subcutaneous versus submuscular).

Statistical Analysis

Baseline characteristics and clinical results between responders and non-responders were compared using Fisher's exact test for categorical variables and t-test/ANOVA for continuous variables to assess for response bias. Multivariable linear regression modeling was used to assess the relationship between PROMs and clinical results of distal humerus fracture treatment. To adjust for factors that may confound the relationship between PROMIS Physical Function/PROMIS Upper Extremity/QuickDASH and clinical outcomes, we used forward stepwise selection to include those patient sociodemographic and clinical variables that were significant at an alpha level of 0.10.[29] All models were constrained to include arc of flexion-extension, arthrosis grade and complications as relevant, independent, non-collinear clinical outcomes. We also assessed the relationship between PROMIS Physical Function, PROMIS Upper Extremity, and Quick DASH using simple linear regression to validate our data against prior studies.[4,6,12] P-values <0.05 were considered statistically significant. Stata software, version 13.1 (StataCorp), was used for all analyses.

RESULTS

Characteristics of Patient Population

In this cohort of 53 patients who underwent treatment for a distal humerus fracture and completed PROMs about upper extremity function, the majority of patients were female (67.9%) and white (83%). Most patients carried private (56.6%) or Medicare (37.7%)

insurance. Among all injuries, 13.2% were the result of high-energy trauma, 5.7% were open, and 17% of patients sustained multiple injuries. The majority of injuries were intra-articular (67.9%) and nearly all patients were treated surgically (84.9%). Approximately 45% of patients were treated by an upper-extremity specialist (Hand or Shoulder/Elbow fellowship trained), 58.5% of injuries were treated as inpatient procedures, and only 11.3% of patients were discharged to rehab. Responders and non-responders were similar in almost all characteristics, except non-responders were younger, more likely to be on Medicare/Medicaid, and had shorter follow-up (**Table 1**).

Table 1: Sociodemographic and Clinical Characteristics of responders versus non-responders; *Median income from ZIP code of residence based on 2016 census data

	Responders	**Non-responders**	
N	53	23	
Percent of total patients (N=76)	69.7	20.3	
	No. of Patients (%) or Mean ± SD	No. of Patients (%) or Mean ± SD	p-value
Sociodemographic Characteristics			
Age at injury (years)	54.5 ± 20.4	65.1 ± 19.4	**0.038**
Male	17 (32.1)	8 (34.5)	0.509
White race	44 (83.0)	15 (65.2)	0.081
Median income ($)*	93,600 ± 30,600	83,600 ± 30,900	0.200
Marital Status			0.15
Single	25 (48.1)	5 (23.8)	
Married	22 (42.3)	11 (52.4)	
Widowed	4 (7.7)	3 (14.3)	
Divorced	1 (1.9)	2 (9.5)	
Insurance Type			**0.025**
Private	30 (56.6)	6 (26.1)	
Medicaid	3(5.7)	5 (21.7)	
Medicare	20 (37.7)	12 (52.2)	
Injury-related Characteristics			
High-energy trauma	7 (13.2)	3 (13.0)	0.648
Open fracture	3 (5.7)	4 (17.4)	0.119
Multiple injuries	9 (17.0)	3 (13.0)	0.477
AO/OTA Fracture Classification			0.550
A (Extra-articular)	17 (32.1)	10 (43.5)	
B (Partial-articular)	12 (22.6)	53(13.0)	
C (Complete articular)	24 (45.3)	10 (43.5)	
Procedure-related Characteristics			
Procedure			0.133
Closed treatment	8 (15.1)	3 (13.0)	
ORIF	22 (41.5)	16 (69.6)	
ORIF + subcutaneous ulnar nerve transposition	8 (15.1)	2 (8.7)	
ORIF + submuscular ulnar nerve transposition	15 (28.3)	2 (8.7)	
Upper-extremity specialist	24 (45.3)	9 (39.1)	0.405
Inpatient surgery	31 (58.5)	15 (65.2)	0.387
Post-Procedure Characteristics			
Length of stay (days)	2.3 ± 2.3	2.3 ± 1.8	0.933
Discharge to Rehab	6 (11.3)	5 (21.7)	0.200
Follow-up time (months)	10.3 ± 7.1	5.8 ± 4.2	**0.001**

Clinical Results

After treatment, 98.1% of patients demonstrated radiographic healing of their distal humerus fracture and the majority of patients had grade 0-1 arthrosis (84.9%). By final follow-up, average flexion contracture was 18 degrees, terminal flexion was 122 degrees, and the average arc of flexion-extension was 105 degrees; 52.8% of patients had at least 30-130 degree flexion-

extension arc of motion. Among all patients, 28.3% of patients sustained at least one complication (**Table 2**). The most common complications were symptomatic hardware (7 patients), HO (4 patients), and infection (3 patients). Clinical results were similar between responders and non-responders.

Table 2: Clinical outcomes of responders versus non-responders and patient-reported functional outcome of responders

	Responders	**Non-responders**	
	No. of Patients (%) or Mean ± SD	No. of Patients (%) or Mean ± SD	p-value
Clinical Outcomes			
Radiographic Union	52 (98.1)	23 (100)	0.697
Broberg and Morrey Arthrosis Grade			0.730
Grade 0 (Normal)	23 (43.4)	13 (56.5)	
Grade 1 (Slight joint space narrowing with minimum osteophyte formation)	22 (41.5)	7 (30.4)	
Grade 2 (Moderate joint-space narrowing with moderate osteophyte formation)	7 (13.2)	3 (13.1)	
Grade 3 (Severe degenerative changes with gross destruction of the joint)	1 (1.9)	0 (0)	
Flexion contracture (degrees)	18 ± 21	19 ± 12	0.756
Terminal Flexion (degrees)	122 ± 15	118 ± 16	0.331
Arc of flexion-extension	105 ± 30	99 ± 23	0.422
Functional arc of motion (30-130 degree)	28 (52.8)	9 (40.9)	0.247
Complication	15 (28.3)	3 (13.0)	0.125
Unplanned return to the OR	10 (18.9)	3 (13.0)	0.398
Patient Reported Functional Outcomes			
PROMIS Physical Function 10a	41.7 ± 11.1	---	
PROMIS Global (Physical)	44.7 ± 11.6	---	
PROMIS Global (Mental)	52.2 ± 10.4	---	
PROMIS Upper Extremity 16a	40.8 ± 12.4	---	
QuickDASH	39.4 ± 26.5	---	

Patient-reported Functional Outcome Measures

Average (±SD) PROMIS PF and UE scores were 41.7 ± 11.1 and 40.8 ± 12.4, respectively. The average Quick DASH score was 39.4 ± 26.5 (**Table 2**). As in previous studies, PROMIS Physical Function scores were associated with PROMIS Upper Extremity scores ($r=0.84$, $p<0.001$) and Quick DASH scores ($r=-0.55$, $p=0.012$).[6,9,12,20] In addition, PROMIS Upper Extremity scores were associated with Quick DASH scores ($r=0.87$, $p<0.001$).

Association of Clinical Results with Patient-reported Outcome Measures

After controlling for likely confounding variables using multivariable analysis, the arc of flexion and extension (coefficient [95%CI] = 0.11 [0.04, 0.18], p=0.002) and PROMIS Global (Mental) score (coefficient [95%CI] = 0.77 [0.55, 0.98], p<0.001) were independently associated with PROMIS Physical Function scores. Similar results were observed for PROMIS Upper Extremity and Quick DASH scores (**Table 3, Figures 1-2**).

Table 3: Multivariable analysis of the association between clinical outcomes and patient-reported functional outcomes, adjusted for sociodemographic and clinical factors

PROMIS Physical Function 10a (n=40)	Coefficient	95% CI		p-value	Adjusted R^2
Arc of Flexion-Extension	0.12	0.06	0.18	<0.001	0.740
Arthrosis	-2.96	-6.87	0.96	0.134	
Complication	-0.02	-4.77	4.74	0.994	
PROMIS Global (Mental)	0.76	0.56	0.97	<0.001	

PROMIS Upper Extremity 16a (n=40)	Coefficient	95% CI		p-value	Adjusted R^2
Arc of Flexion-Extension	0.14	0.03	0.26	0.013	0.477
Arthrosis	0.37	-6.22	6.95	0.911	
Complication	-2.64	-9.89	4.60	0.464	
PROMIS Global (Mental)	0.68	0.35	1.004	<0.001	

Quick DASH (n=33)	Coefficient	95% CI		p-value	Adjusted R^2
Arc of Flexion-Extension	-0.10	-0.37	0.17	0.457	0.289
Arthrosis	-10.10	-28.8	8.55	0.277	
Complication	8.84	-10.10	27.77	0.347	
PROMIS Global (Mental)	-1.28	-2.01	-0.55	<0.001	

DISCUSSION

Historically, clinical outcomes have been used to measure surgical treatment effectiveness and quality as they are easily obtained from administrative and clinical records, are easily quantified, and have high face validity.[28] Yet, clinical outcomes do not capture the full patient perspective and multiple recent studies have demonstrated how PROMIS scores can be used to better describe aspects of health status that are reported directly from patients following upper extremity trauma.[4,28] In this study, we present data about the clinical and patient reported outcomes following treatment of distal humerus fractures. Our findings demonstrate the PROs are associated with clinical outcomes, but each of these sets of metrics has features that are

unique and important when evaluating treatment effectiveness. This study also highlights the utility of routine collection of PROMs.

While PROs capture benefits of surgical treatment beyond survival and physiologic markers, the extent to which PROs are affected by traditionally measured clinical outcomes has remained unclear, especially when using PROMIS scores, abbreviated functional outcome measures (e.g. QuickDASH), or for specific clinical conditions.[28] In this cohort of distal humerus fractures, the only clinical outcome independently associated with PROs was the arc of motion (**Figure 1**).

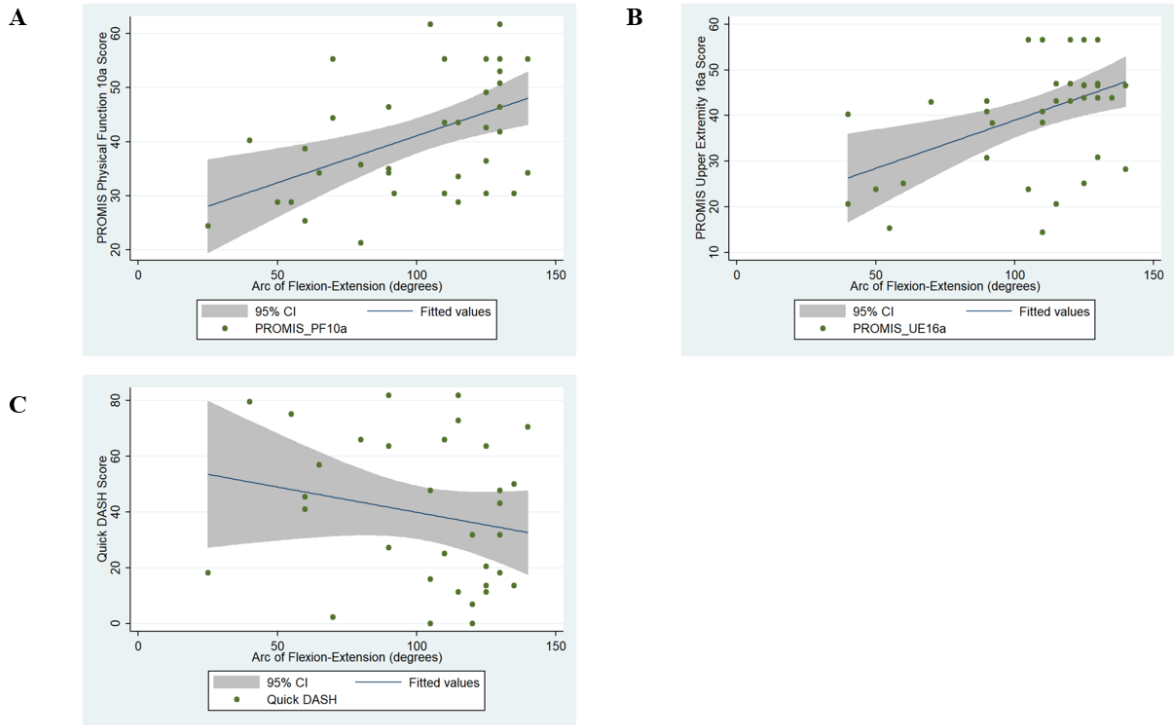

Figure 1: Association between Functional Outcome Scores and Elbow Range of Motion (Flexion-Extension Arc); (A) PROMIS Physical Function, (B) PROMIS Upper Extremity, (C) QuickDASH

On average, an improvement in the arc of flexion-extension of 70-80 degrees was associated with an improvement of 8-9 points on the PROMIS instruments.[8] This finding is comparable

to prior studies which have shown that the arc of motion was related to DASH scores after elbow/wrist trauma.[16,31] We also found that the presence of arthrosis did not correlate with disability or function.[5] Compared to a recent study in bariatric surgery, we similarly observed that long-term outcomes (e.g. final arc of motion) were more strongly associated with PROs then perioperative complications. These findings lend further support to the notion that patients are often satisfied despite adverse or unexpected events, and that PROs likely reflect the durability of clinical outcomes.[29] Finally, not all of the variation in PROs could be explained by clinical outcomes suggesting that these measures are capturing a unique aspect of surgical quality. These results support a comprehensive approach to surgical quality that incorporates both clinical events and self-reported measures of health status.

We also found that the PROMIS Global (Mental) subscale was independently associated with all measures of physical or upper-extremity-specific function **(Figure 2)**. On average, improvement in PROMIS Global (Mental) subscale scores of 10-12 points were associated with 8-9 point improvements on PROMIS PF or UE measures.[8] This result is supported by multiple prior studies that have demonstrated how patient mindset is an important driver of self-reported outcomes.[13,26] The importance of patient mental health in the measurement of PROMs presents a plausible explanation for why PROMs are not fully determined by clinical outcomes and, in part, emphasizes the importance of collecting "patient independent" outcome measures. Unlike findings in other settings, sociodemographic or injury-related characteristics were not independently associated with PROMs.[4,13,26]

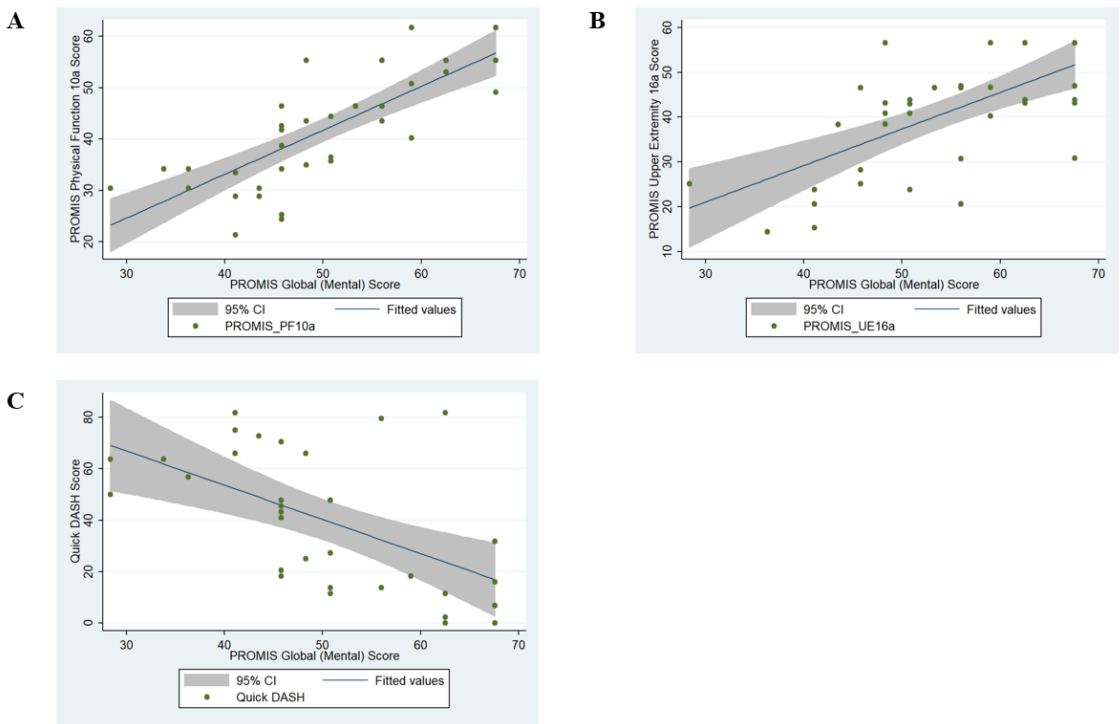

Figure 2: Association between Functional Outcome Scores and PROMIS Global (Mental Health) Subscale Score; (A) PROMIS Physical Function, (B) PROMIS Upper Extremity, (C) QuickDASH

To further assess if clinical outcomes are measuring different features of treatment outcome we performed a similar analysis assessing for factors associated with clinical outcome. Interestingly, intra-articular injuries were independently and strongly associated with the presence of arthrosis (grade 1-3 vs. no arthrosis).[15] Older age was also associated with increased likelihood of arthrosis and decreased final arc of flexion-extension (**Appendix Table 1**). The importance of articular surface involvement in the development of radiographic arthrosis is well-known and our study recapitulates that finding.[14] These results also provide additional evidence that injury-related variation is important and can have a differential effect on relevant outcomes (e.g. patient self-reported health status).

Appendix Table 1: Multivariable analysis of the association between clinical outcomes with sociodemographic and clinical factors

Presence of Arthrosis (Broberg and Morrey Arthrosis Grade > 0, n=76)	OR	95% CI		p-value
Intra-articular	4.49	1.53	13.14	0.006
Age	1.03	1.003	1.06	0.025
Male	2.79	0.88	8.74	0.081

Arc of Flexion-Extension (n=75)	Coefficient	95% CI		p-value
Age	-0.34	-0.64	-0.03	0.031

Limitations

This study has several limitations. There is a potential for response bias since only 69.7% of eligible patients completed an upper extremity patient reported outcome measure; however, our response rate is similar to other comparable studies and patient/injury characteristics of responders and non-responders were similar (**Table 1**).[6,12] Given the retrospective nature of the study, patients had various endpoints of follow-up although the effect of this is unclear. Follow-up duration was added to our regression analyses, but was omitted in final multivariable regression models because of the lack of statistically significant association. In addition, not all potential predictors could be assessed. For example, physical function prior to the injury or other patient psychological factors (e.g. PROMIS Pain Interference) may have influenced outcome measures, but these could not be retrieved retrospectively.[10] Finally, some of the lack of influence of clinical outcomes on PROMs may be a limitation of our follow-up. We focused on shorter-term PROMs in this study but future studies should assess this in the long-term, ideally in prospective fashion. Nevertheless, it is reassuring that our analysis recapitulates findings from multiple prior studies.[6,9,12,16,20]

CONCLUSIONS

This study highlights the importance of measuring both clinical and patient-reported outcome measures when evaluating distal humerus fracture treatment effectiveness. Given the paucity

of data regarding typical PROMIS or QuickDASH scores after distal humerus fracture treatment, our study also provides benchmark data that can be used for future comparison.[17,32] Finally, awareness of factors associated with poorer patient-reported and clinical outcome measures can be used to guide patient expectations and maximize overall recovery.

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Chapter 13: Injury-Related Variation in Patient-Reported Outcome after Musculoskeletal Trauma: A Systematic Review

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ABSTRACT

Background

A better understanding of the factors related to patient reported outcome is needed to create effective value-based payment strategies for orthopaedic trauma patients. The purpose of this study was to explore injury-related characteristics that differentiate patient-reported outcomes (PROs) following traumatic musculoskeletal injury.

Methods

A systematic review of the literature was performed and we searched for English-language articles in PubMed/MEDLINE, Google Scholar, and the Cochrane Database of Systematic Reviews (January 1995 - September 2018). We included studies that compared PROs of musculoskeletal trauma based on injury characteristics, and excluded studies related to development or validation of outcome tools without implementation, measurement, or comparison. Study quality was assessed using the modified Oxford Center for Evidence-based Medicine rating system.

Results

A total of 21 studies that reported on a total of 10,186 patients were included (5 were prospective cohort studies, 8 were matched control retrospective cohort studies, and 8 were retrospective cohort studies). Median minimum follow-up was 3 years (range 0.5-10 years). Injury-related factors associated with worse PROs were polytrauma or multiple injuries (10 studies), neurotrauma (11 studies), and high-energy injury mechanism (7 studies). Among all studies, 32 different outcome metrics were used (17 general health status metrics and 15 limb-specific metrics) making meta-analysis infeasible.

Conclusions

Based on the results of the included studies, we propose a framework where musculoskeletal injures occur in one of 4 scenarios that is associated with a different, context-dependent

outcome: (1) Polytrauma with neurotrauma, (2) Polytrauma without neurotrauma, (3) High-energy monotrauma, (4) Low-energy monotrauma. We propose future studies should measure at least two types of PROs: (1) a health-related quality of life metric to assess global disability, and (2) a limb-specific instrument.

Level of Evidence: Prognostic, Level III

INTRODUCTION

Recent health policy efforts have focused on reducing costs and improving quality of medical care using value-based payment strategies, like episode-of-care or bundled payments.[1-3] In general, value-based care models have been targeted toward high cost episode-of-care conditions such as cardiovascular treatment or arthroplasty for end-stage osteoarthritis.[3,4] Given that the cost of care for musculoskeletal injuries accounts for 6.1% of total Medicare spending and affects almost a quarter of significantly injured patients, the next area for broad implementation of value-based payment strategies may be orthopaedic trauma.[4-6] Most orthopaedic surgeons recognize that orthopaedic trauma patients present diversely, as there are almost innumerable combinations of injuries from different mechanisms and contexts. As a result, standardized quality measurement has been difficult to implement for this population.[3]

While it is intuitive that a total hip arthroplasty performed for osteoarthritis, tumor, or fracture is different, the heterogeneity in orthopaedic trauma care is more subtle and established methods for measuring outcomes for elective orthopaedic procedures are unlikely to translate easily.[3,5] For example, a common framework for judging post-intervention patient-reported outcome (PRO) for elective procedures is presented in **Figure 1**: post-operative function is compared to pre-operative function in the same patient (essentially a paired analysis). But because the pre-injury status for trauma patients is less clear and subject to recall bias, this framework is difficult to apply without additional assumptions that vary by patient and injury context. As a result, these factors make implementation of value-based care models for trauma patients particularly challenging. For instance, recent studies demonstrated that if bundled payment strategies designed for a total joint population were applied with minimal allowance for trauma patient heterogeneity, short-term outcome, and post-operative complication rate, value-based payment strategies would likely fail to cut costs or improve outcomes.[3,7] In

addition, since almost two-thirds of trauma patients are uninsured or on Medicare/Medicaid, increased cost-sharing without consideration of patient heterogeneity would leave hospitals and physicians underfunded while simultaneously increasing the personal financial burden of patients.[8] Yet, it is still possible that appropriately designed value-based payment models may help to stem rapid increases in healthcare costs.[4,9]

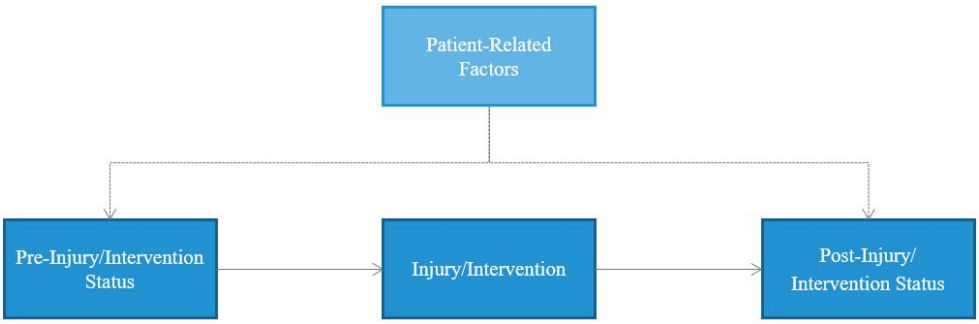

Figure 1: Current framework for assessment of outcomes after injury or intervention. Patient-related factors can affect both pre- and post-states (dotted line), but are controlled when comparing within the same patient

In this context, while many studies have investigated cost control, less is known about outcome measures and quality when evaluating trauma care.[6,7] This is partly because acutely injured patients enter the medical system in a completely different manner than elective patients due to the unexpected nature of trauma.[7] In order to create effective value-based payment strategies for (orthopaedic) trauma patients, as well as to guide expectation management and clinical decision making, we need better understanding of not only the cost of care, but also factors associated with outcome. Thus, in this review we explore the effects of injury-related characteristics on PROs following traumatic musculoskeletal injury. While other factors like patient demographics and socioeconomics are related to outcome, we focus on injury-related factors in this review because current clinical care and financial billing are injury-based and injury type is known to be correlated with the cost of care.[3,5,7,10] Our goal is to present a

conceptual framework that helps patients and physicians understand what injury-related factors result in patient-reported outcome differences following traumatic injury and illustrate why this differentiation is important when transitioning to value- or incentive-based care, as supported by available literature.[11]

METHODS

A literature search of PubMed/MEDLINE, Google Scholar, and the Cochrane Database of Systematic Reviews through September 1, 2018, using search terms and synonyms for *injuries, trauma,* and *patient outcome assessment*. Non-English language articles, studies related to development or validation of outcome tools without implementation or measurement, and articles published before January 1995, were excluded. Bibliographies of retrieved studies were reviewed for inclusion of other relevant studies. Articles were reviewed for their ability to contribute to current understanding of injury-related factors that differentiate between patient reported outcomes following traumatic musculoskeletal injury. Priority was given to clinical trials, large longitudinal observational studies, and more recently published articles. Study quality of included articles was independently assessed by 2 reviewers (ARB and QMJV) using the modified Oxford Center for Evidence-based Medicine rating system.[12] Disagreements were resolved by discussion with a third independent reviewer (RMH).

RESULTS

Search:

The electronic searches yielded 880 articles. After removing duplicates, 686 articles were screened on title and abstract. A total of 41 possible relevant studies from the initial search were assessed using the full-text for eligibility and references were checked for suitable related citations. Of this group, 20 articles were excluded (4 were clinical summaries, 10 compared to a non-trauma population or had no comparison to other injuries, and 6 did not measure any

PROs). In total, 21 studies could be included for analysis. Of all included studies, 5 were prospective cohort studies, 8 were matched control retrospective cohort studies, and 8 were retrospective cohort studies. The search results, reasons for exclusion, and selection process are summarized in the flowchart in **Figure 2**.

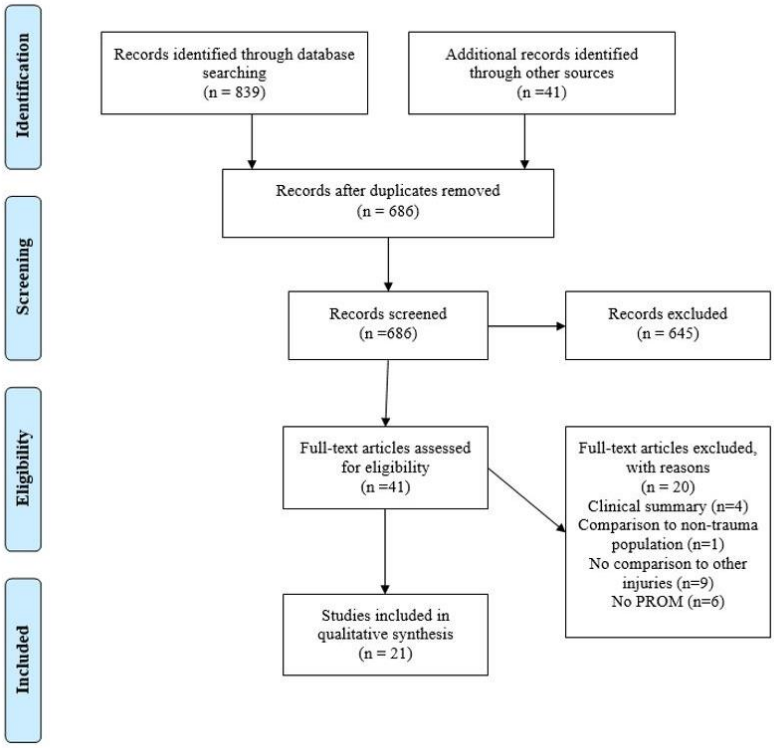

Figure 2: Flowchart of the articles included in the systematic review of injury-related factors associated with patient-reported outcomes following musculoskeletal injury

Quality Assessment:

Tables 1-2 briefly summarize the study population, outcomes, and quality assessment across all included articles. All prospective studies had a modified Oxford Center for Evidence-based Medicine rating of 2, while all retrospective case-control and cohort studies had a rating of 3.

Table 1: Prospective cohort studies examining injury-related factors in outcomes after trauma; *Rating 1-5 based on modified Oxford Centre for Evidence-based Medicine rating system

Source	Study Population	Outcome Instruments [Follow-up]	Findings	Quality Rating*
Prospective Cohort Study				
Gross et al, 2012[38]	45 polytrauma patients with TBI compared to 66 polytrauma patients	GOS, EQ-5D, EQ-VAS, SF-36, NHP, TOP [2 years]	Both groups had markedly reduced functional outcome and QoL compared with pre-injury status (p<0.05)	2
Holtslag et al, 2007[39]	359 adult trauma patients with ISS≥16	GOS, EQ-5D [1-2 years]	Neurotrauma was associated with GOS<5 (p<0.05) Neurotrauma and lower extremity injuries were associated with decreased EQ-5D scores (p<0.01)	2
Turchin et al, 1999[13]	28 multiply injured patients with foot injuries were matched to 28 multiply injured patients without foot injuries	SF-36, WOMAC, BCH Grade [>2 years]	SF-36 scores were worse for patients who had foot injuries (49 vs 66, p=0.008) WOMAC and BCH grades for lower extremity function were worse in the patients with foot injuries (p<0.001) There was strong correlation between SF-36 scores and WOMAC/BCH-Grade in patients with and without foot injuries (r=0.71-0.88)	2
Holbrook et al, 1999[40]	1048 trauma patients	QWB [1.5 years]	The majority of patients (80%) at the 18-month follow-up continued to have QWB scores below the healthy norm of 0.800. Serious extremity injury was a significant predictor of QWB outcome (p<0.05)	2
Holbrook et al, 1998[41]	1048 trauma patients	QWB, ADL [>0.5 years]	After major trauma, QWB scores at discharge showed a significant degree of functional limitation (mean, 0.401 +/- 0.045). At 6-month follow-up, QWB scores continued to show high levels of functional limitation (mean, 0.633 +/- 0.122) Injury to the extremities was significantly and negatively associated with 6-month QWB scores (p<0.05)	2

Abbreviations:
TBI =Traumatic Brain Injury, ISS = Injury Severity Score, QoL=Quality of Life

General Health Status Measures
GOS=Glasgow Outcome Scale, SF-36=Short Form (36), EQ-5D=EuroQoL 5-dimensional questionnaire, EQ-VAS=EuroQoL visual analog scale, TOP=Trauma Outcome Profile, QWB=Quality of Well Being scale, ADL=Activities of Daily Living Scale, NHP=Nottingham Health Profile

Region-specific Outcome Measures
WOMAC=Western Ontario and McMaster Universities Osteoarthritis Index, BCH Grade=Boston Children's Hospital Grading System, AAOS Global Foot and Ankle Scale

Table 2: Retrospective Matched-control and cohort studies examining injury related factors in outcomes after trauma; *Rating 1-5 based on modified Oxford Centre for Evidence-based Medicine rating system

Source	Study Population	Outcome Instruments [Follow-up]	Findings	Quality Rating*
Matched Control Cohort Study				
Macke et al, 2017[42]	307 multiply-injured patients with upper extremity injury were compared to 322 patients without upper extremity injury	HASPOC, SF-12, Employment status [>10 years]	No significant differences between the two groups Patients with a brachial plexus injury had worse HASPOC score (p<0.05)	3
Andruszkow et al, 2013[43]	229 patients with upper extremity	HASPOC, SF-12,	Additional TBI in multiple trauma patients led to reduced function (HASPOC, GOS; p<0.05)	3

	injury/no TBI vs 32 patients with upper extremity injury/TBI vs 20 patients with TBI/no upper extremity injury	GOS [>10 years]		
von Ruden et al, 2013[44]	88 patients with severe polytrauma (ISS≥50) were compared to 1347 polytrauma patients with ISS<50	GOS, SF-36, Quality of life index, TOP [6 years]	ISS≥50 polytrauma patients had higher incidence of severe neurotrauma and extremity injuries (p<0.05) Long term outcomes of severely injured trauma patients was worse than for patients with ISS<50 (p<0.05) More distal extremity injuries had greater functional disability that affect daily life	3
Zeckey et al, 2011[45]	125 polytrauma patients with head injury were compared to 125 polytrauma patients without head injury	HASPOC, SF-12, GOS	Significant difference was shown for the GOS only (GOS head injury 4.3 ± 0.3 vs no head injury 4.9 ± 0.2, p = 0.01)	3
Steel et al, 2010[46]	398 multiply injured patients with TBI were compared to 222 multiply injured patients without TBI	SF-12 [>10 years]	Patients with TBI had significantly worse SF-12 scores (psychological subscale, p<0.05), but no difference in standardized physical subscale score	
Tran et al, 2002[47]	14 polytrauma patients with foot injuries were compared to 14 polytrauma patients without foot injury	SF-36, AAOS Global Foot and Ankle Scale, Shoe Comfort	SF-36 scores were worse for patients with foot injuries (p<0.05) Region-specific scores were also worse for patients with foot injuries (p<0.05)	3
Michaels et al, 2001[48]	100 trauma patients with orthopaedic injuries compared to 65 patients without orthopaedic injuries	SF-36, SIPw [0.5-1 year]	After controlling for ISS, patients with orthopaedic injuries had worse scores 6 months after injury on the SF-36 bodily pain, physical function, and role-physical domains (p<0.05). By 12 months after injury, orthopaedic patients had relatively worse scores on the SIPw score and six of eight SF36 domains (bodily pain, physical function, role-physical, mental health, role-emotional, and social function, p<0.05)	3
Gallay et al, 1998[49]	12 polytrauma patients with a displaced acromioclavicular (AC) joint injury were matched to two groups (12 patients with isolated AC injury and 12 polytrauma patients without AC injury)	SF-36, SPADI, SSRS, SST, SSI, M-ASES, Return to work [~2-4 years]	Shoulder function in polytrauma patients with AC injury was inferior to patients with an isolated AC injury and polytrauma patients without AC injury General health status (SF-36) was worst for polytrauma patients with AC injury, followed by polytrauma patients without AC injury, then patients with isolated AC injury (p<0.05) 100% of isolated AC patients returned to work, but only 67% of polytrauma patients returned to work	3
Retrospective Cohort Study				
van der Vliet et al, 2018Van[50]	84 patients who underwent subtalar arthrodesis for posttraumatic arthritis after a calcaneal fracture	PROMIS PF, EQ-5D, EQ-VAS, FAAM, MFS [4-12 years]	Quality of life was significantly lower when compared to a reference population (p=0.001) High-energy injury mechanism was associated with worse region-specific outcome measures (FAAM/MFS, p<0.01). Additional ipsilateral injury was associated with worse general health status/quality of life (EQ-5D/EQ-VAS, p<0.05)	3
Hatamabadi et al, 2017[51]	1471 patients hospitalized for a road traffic injury	Mortality, GOS [1 year]	79% of patients fully recovered Injury-related factors associated with worse outcome were neurotrauma (p=0.002), multiple trauma (p=0.01), and higher energy mechanism/ISS (p<0.001)	3
Ferree et al, 2017[16]	2046 polytrauma patients; 72 had a hand injury	QDASH, PRWHE	Patients with concomitant upper extremity injury (p=0.002) and those with higher ISS scores (p=0.034) had the worse outcome scores	3

		[1-6 years]	Worst outcomes in patients with neurotrauma (spine/brachial plexus/TBI)	
Ferree et al, 2017[15]	152 patients with a displaced midshaft clavicle fracture (71 polytrauma)	QDASH [~4 years]	Polytrauma patients had worse QDASH score compared to monotrauma patients (12 vs. 5, p=0.002) Polytrauma patients were more likely to have high-energy trauma (52% vs. 19%, p<0.001) and to have sustained neurotrauma (55%)	3
Pape et al, 2010[52]	637 adult patients with ISS>16	SF-12, HASPOC [>10 years]	Traumatic amputation and presence of a severe spine injury were associated with worse outcome (p<0.01) Poorer physical functioning was reported by patients who had suffered a lower extremity vs upper extremity injury(p<0.05) Two or more articular injuries or a combination shaft and articular injury resulted in unfavorable outcome scores (p<0.05)	3
Livingston et al, 2009[53]	241 trauma patients admitted for ≥10 days to the ICU	GOS, FIM [~3 years]	70% of patients considered themselves to be less active and only ~50% had returned to work or school Severe neurotrauma (p=0.06) and extremity injury (p=0.01) were associated with decreased FIM	3
Zelle et al, 2005[29]	389 polytrauma patients with lower extremity fracture	HASPOC, SF-12, TAS, Inability to work, modified KO score, Lysholm score [>10 years]	Lower extremity functional status of patients with below-knee injuries was worse than those with above knee injuries (modified KO, Lysholm, p<0.05) Lower extremity functional status of combined injuries was worse than isolated injuries (p<0.05) HASPOC, SF-12, TAS, and inability to work was worse for patients with injuries below the knee joint (p<0.05)	3
Mkandawire et al, 2002[54]	158 patients with a musculoskeletal injury and ISS>15	Bull Disability Scale [5 years]	Patients with multiple extremity injuries or combinations of pelvic and lower extremity or shoulder girdle and upper extremity injuries were much more likely to have continuing disability compared with those sustaining single bone injuries of that limb	3

Abbreviations:

General Health Status Measures

GOS=Glasgow Outcome Scale, SF-36=Short Form (36), SF-12=Short Form (12), PROMIS PF=Patient-Reported Outcomes Measurement System Physical Function, EQ-5D=EuroQol 5-dimensional questionnaire, EQ-VAS=EuroQoL visual analog scale, FIM=modified Functional Independence Measure, Quality of Life Index, TOP=Trauma Outcome Profile, Bull Disability scale, HASPOC=Hannover Score for Polytrauma Outcome, Employment Status/Inability to work, TAS=Tegner Activity Score, QWB=Quality of Well Being scale, ADL=Activities of Daily Living Scale, SIPw=Sickness Impact Profile work scale, NHP=Nottingham Health Profile

Region-specific Outcome Measures

Upper Extremity: QDASH=Quick Disability of Arm, Shoulder and hand questionnaire, PRWHE=Patient-Rated Wrist/Hand Evaluation, SPADI=Shoulder Pain and Disability Index, SSRS=Subjective Shoulder Rating Scale, SST=Simple Shoulder Test, SSI=Shoulder Severity Index, M-ASES=Modified Shoulder and Elbow Surgeons Form

Lower Extremity: FAAM=Foot and Ankle Ability Measure, MFS=Maryland Foot Score, WOMAC=Western Ontario and McMaster Universities Osteoarthritis Index, BCH Grade=Boston Children's Hospital Grading System, AAOS Global Foot and Ankle Scale, Shoe Comfort, Karlstom-Olerud score, Lysholm score

Study Population:

Among all studies, the outcomes of 10,186 patients were assessed. Median minimum follow-up was 3 years (range 0.5-10 years). All 21 studies included patients who sustained

musculoskeletal injuries; 5 studies were focused on upper extremity injuries, 4 studies considered only lower extremity injuries, 2 studies considered combinations of injuries, and 10 studies examined the effect of musculoskeletal injuries in patients with polytrauma (Injury Severity Scale score ≥ 16). Only five studies explicitly considered extremity injuries in different contexts as the primary analysis.

Outcome Metrics:

Among all studies, 32 different outcome metrics were implemented (17 general health status metrics and 15 region-specific metrics). Seven different patient reported outcome measures (PROMs) were used for upper extremity function, while eight different PROMs were used for lower extremity function. Overall, the median number of PROMs per study was two (range 1-7). The most common PROMs used for general health status were the Short Form-36/12 (SF-36/SF-12, 12 studies), Glasgow Outcome Scale (GOS, 7 studies), and the Hannover Score for Polytrauma Outcome (HASPOC, 5 studies).

Fourteen articles only measured general health status and two articles only measured condition-specific PROMs. Five studies measured both general health and condition-specific PROMs. Of these, one article compared the correlation between general health and condition-specific outcomes, and reported close correlation between them.[13]

Injury-Related Factors Associated with Outcomes:

Musculoskeletal injuries sustained in the context of polytrauma or multiple (orthopaedic and non-orthopaedic) injuries (10 studies), neurotrauma (traumatic brain injury, spinal cord/plexus injury; 11 studies), and high-energy injury mechanism (7 studies) were associated with worse PRO. Polytrauma/multiple injuries and neurotrauma tended to be associated with worse general

health outcome measures, while high-energy trauma was typically associated with worse limb-specific function. We highlight relevant studies and areas of overlap in **Figure 3**.

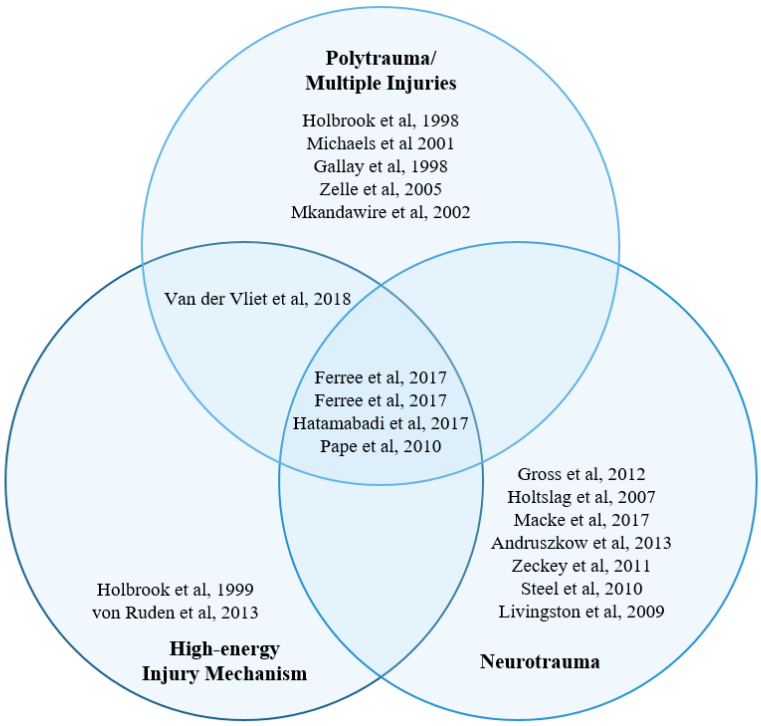

Figure 3: Grouping of injury-related factors identified in included studies that were associated with different patient-reported outcome for musculoskeletal injury (including areas of overlap as illustrated in a Venn diagram)

DISCUSSION

Injury-related factors associated with patient-reported outcome after musculoskeletal trauma were largely related to injury mechanism and associated injuries (**Figure 3**). In our framework, based on the presented literature review and clinical experience, we identified 4 broad injury scenarios where outcomes of musculoskeletal extremity injuries varied: (1) Polytrauma/multiple injuries with neurotrauma, (2) Polytrauma/multiple injuries without neurotrauma, (3) High-energy monotrauma, and (4) Low-energy monotrauma (**Figure 4**). Polytrauma/multiply injured patients were significantly different than patients who sustained isolated injuries in terms of injuries sustained, and polytraumatized patients often reported persistent pain and global disabilities that affected limb-specific PRO.[13,14] In addition, energy

transfer was associated with different injury mechanisms that resulted in different types of extremity injuries with disparate morphologic features and PROs.[15-17] As nearly all polytrauma/multiply injured patients had higher energy injuries based on the extent of the injuries sustained, energy transfer was not used to further categorize these patients. The included studies also suggest that analysis of PROs of extremity injury treatment without considering injury context, such as concomitant injury, can lead to significantly different expected results of treatment.

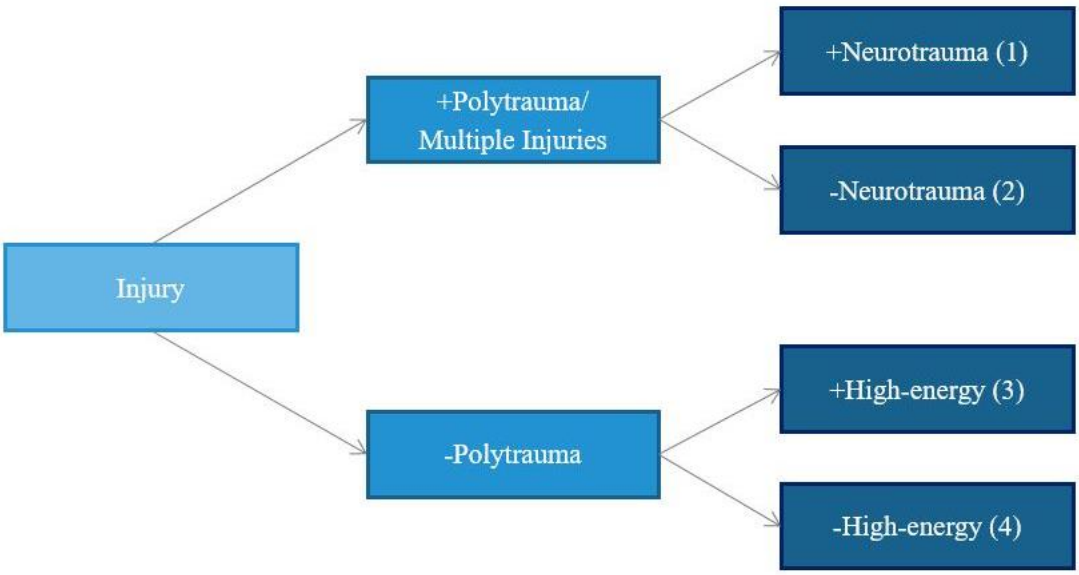

Figure 4: Four broad groups of injury scenarios where outcomes of musculoskeletal extremity injuries widely vary: (1) Polytrauma with neurotrauma, (2) Polytrauma without neurotrauma, (3) High-energy monotrauma, (4) Low-energy monotrauma

Caring for patients with significant injuries, like polytrauma, is inherently different when the primary goal of treatment is to focus on life- and limb-preservation first, and subsequently focus on less significant extremity injuries.[21,22] This prioritizing of initial care may cause a delay in diagnosis, treatment, and/or rehabilitation that affects PROs. These factors must be considered when transitioning away from fee-for-service standards to bundled payments tied

to quality, otherwise institutions which care for more severely injured patients will artificially appear to have poorer outcomes when compared to less complex cases.[7] In addition, this may result in unfair reimbursements for centers caring for (severely) injured patients.[8]

Understanding the basis for injury-related variation in PROs is especially important as value-based insurance models become more prevalent in orthopaedic trauma surgery. Given that musculoskeletal injuries occur frequently and are the fastest and largest drivers of Medicare spending, changes to payment models by incorporating episode of care or bundled payments is reasonable if such changes can be balanced with accurate quality metrics.[4,5,7] Yet, trauma patients are different than other orthopaedic surgical patients and evaluation of pre- and post-intervention outcome evaluation is difficult due to the unexpected nature of trauma. Pre-injury information about patients is often either missing/unavailable or subject to patient recall bias making it challenging to assess outcomes using pre-injury status as a baseline. As a result, counseling patients on average expected outcomes or benchmarking across different trauma populations is not easy.[18] One strategy to overcome this hurdle is to collect pre-injury baseline information by proxy or directly from the patient, and future study is needed to see if this can be feasibly introduced into current trauma outcome measurement pathways.[19,20] However, this strategy faces important challenges. Recall bias as well as limited possibilities of obtaining adequate information in patients with altered mental status (for example due to neurotrauma or substance abuse) decreases the likelihood of consistent usefulness. A different strategy, that may be feasible, is to compare an individual's reported outcome to a group of similar patients based on injury mechanism, concomitant injury and polytrauma as proposed by our framework (**Figure 4**). For example, a patient who sustained a distal radius fracture in the context of polytrauma without neurotrauma would be compared to a similar cohort (category (2) in **Figure 4**).

Trauma patients and the injuries they sustain are typically heterogeneous. In line with the framework presented in our study, others have also shown that long-term outcomes are distinct for patients with neurotrauma, polytrauma/multiple injuries, or isolated orthopedic injury.[23,24] Our hope is that by grouping these patients into these 4 general categories, better estimates of benchmark and expected outcome data can be obtained (**Figure 4**).[6,7] Much of the current literature on incorporating value-based care has focused on cost containment, but it will also be important to better characterize how outcome measures vary, and our study represents one step in that direction.[6] Future studies will be required to determine which specific quality measures to institutionalize, how to modify them for different injury contexts, and then how to incorporate them into new payment models (e.g. Surgical Hip and Femur Fracture Treatment bundle or other new voluntary bundles).[6]

Our review also highlights how the multiplicity of PROMs used makes comparison between and within studies exceedingly challenging. Out of 21 included studies, 32 different metrics were used. This was the primary reason we were unable to complete a quantitative meta-analysis, and this has been described in other contexts.[14,25,26] The reason for this variation has historical roots. Traditionally, mortality was the only outcome of interest when evaluating treatment of trauma patients.[27,28] As greater numbers of patients survive after trauma, there is increasing interest in functional patient-reported outcome data.[22] Yet, there is also a lack of tailored instruments and consensus opinion on the most optimal tool for trauma patients. Consistent with our framework, we suggest that contemporary measurement of PROs following musculoskeletal injury should have at least two components: (1) a health-related quality of life metric (HRQoL, e.g. EQ-5D, SF-36, PROMIS Global) to assess global disability, and (2) a condition-specific instrument (e.g. QuickDASH for distal radius fractures). While this strategy has been proposed for polytrauma patients, we suggest broader application to all musculoskeletal injuries to allow for more accurate assessment of injury-related outcome

contingent on context.[29] In addition, identification of injury patterns known to perform poorly may help improve relevant long-term outcomes through changes to management and approach.[30,31] Patient-related factors undoubtedly have a strong influence on PRO and this should be a focus of future research.[32,33] Finally, when optimizing knowledge on PROs and their use, the use of physician-based outcomes should also be considered.

Limitations

Our study has several limitations. Many of the included studies are older and use legacy PROM instruments that are now known to have significant floor- or ceiling-effects.[34-37] In addition, there were very few direct comparative studies by injury mechanism or associated injuries. Combined with the plethora of PROM metrics used, this made it infeasible to conduct a pooled meta-analysis in reasonable fashion, although we did attempt to illustrate general patterns. Definitions for polytrauma in the included studies varied. As a result, comparisons between studies and generalizability of the results may be subject to differences between the studied cohorts. Various types of neurotrauma were grouped together. However, as neurologic injuries have a wide range of severity, results of the included studies as well as our framework may not be generalizable to all these possible injuries. Finally, many factors other than anatomical injury are known to affect functional outcomes following trauma, but we focused on injury-related factors as a first step in understanding variation in PROM after musculoskeletal injury. Future studies should explore the contribution of demographic, injury specific, and socioeconomic influences.[10]

Conclusion

In this review, we explored injury-related characteristics that can be used to differentiate between PROs following traumatic musculoskeletal injuries. Based on the results of the included studies, we propose a framework where musculoskeletal injuries occur in one of 4

scenarios that are associated with different, context-dependent outcomes. We also propose that measurement of PROs should include at least one measure for HRQoL and another for condition-specific outcome. Understanding injury variation is important when transitioning to value- or incentive-based care that does not simply cut costs, but also improves the quality of care.

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Part 3. Summary and General Discussion

Chapter 14: General Discussion

This thesis explores how to improve continuing medical education (especially in low-income countries) in global orthopaedics and better evaluate variations in outcome following orthopaedic trauma.

Education for Global Orthopaedic Trauma

The value of assessing injury burden, variation in practice patterns, and needs assessment

The globalization of health has made continuing medical education (CME) an international concern. In particular, given the growing burden of injury-related orthopaedic trauma, there is a growing recognition of the importance of orthopaedic surgical education in low-resource settings and CME is an important part of capacity building. Increasingly, international CME is being recognized as an integrated curriculum that is ideally built on projects in needs assessment, performance evaluation and healthcare outcomes.[1,2] Given the considerable time and resources required to build effective global orthopaedic programs, it is important to understand local needs and interests in order to create sustainable educational interventions that are desired by and helpful for in-country care providers.

For example, creation of orthopaedic operative injury databases allowed for the implementation of targeted quality improvement efforts in open tibia management, new hypothesis driven research in polytrauma and elbow dislocations, and areas of focus for roadside prevention of long bone fractures. Such data could be used for medical education and highlights areas for improvement in local orthopaedic patient care. In addition, educational needs can also be identified by studying differences in care. For example, we showed that the management of three common orthopedic injuries varied between Haitian and American orthopedic surgeons. We found that this discrepancy is likely multifactorial, including severity

of injury, patient comorbidities, timing of presentation, physician training, and resource availability. The key take-home point from this work was that for conditions that are managed differently in Haiti than in the U.S., the treatment rationale in Haiti was context-specific. Specifically, the management of complex conditions such as acetabular fractures was limited by training, while the management of common conditions such as midshaft tibia fractures was influenced by the prevalence of complications and implant availability. This work highlights the need for targeted, context-specific interventions that include resource allocation and associated education, especially since previous studies have shown that injury pattern and severity differs between low- and high-income countries.[3-5]

A challenge to visiting foreign orthopaedic surgeons interested in orthopaedic trauma education is in finding ways to meet the needs of participants through extended post-graduate training programs.[6] A key result of our work is to present a basic methodology for needs assessment for CME planning in developing countries that may help build orthopaedic surgical capacity. By elucidating the "felt" needs of surgeons, we will be able to build assessment criteria internally and externally (e.g. for funding organizations) and create curricula that are learner-centered.[6-8] If surgical capacity is a focus of global surgery, then projects like ours in needs assessment are essential to ensuring that CME can be a functional "effector arm" for health care systems in both high-, middle-, and low-income countries.[8,9] Our methodology is also unique in that it gives direction to how local level data on CME needs can be captured to avoid inappropriate generalization from national or regional data.

Finally, we addressed challenges of implementation (i.e. historically poor response rates to needs assessment) by using an audience response system (ARS) during an existing national conference to more compellingly engage participants.[2] When compared to a similar paper surveys, this strategy

was significantly more successful.

Highlighting the role of continuing medical education programs in low-income countries and applicability to both knowledge and skill transfer

Beyond simply hosting visiting surgeons or training local surgeons through medical school and residency, all countries are starting to recognize that CME for established providers and recent trainees is essential to building, maintaining, and improving surgical capacity.[8] While many groups have established courses to build surgical capacity with the aid of governments, non-profits, or healthcare systems, objective data about educational outcomes of CME courses in low resource settings was limited. Thus, a key result of some of our work has been to show that an international CME conference hosted in a low-income country significantly improves short-term performance on knowledge-based assessments.

We also present a generalized methodology for evaluating CME conferences using pre-post testing with audience response systems. An added benefit of ARS is that it takes advantage of new technology to further engage participants. For example, prior efforts at encouragement of evaluation measurements in workshops have shown adoption rates as low as 28%.[10] Yet, using an ARS allowed for high participation rates (over 70%). Such strategies may facilitate more robust and easier adoption of evaluation methods that can help improve the overall quality of global CME efforts. Our results contribute to the general belief that CME conferences in low-income countries can be an effective tool to build surgical capacity and increase surgeon knowledge.

Similarly, little is known about how to introduce complex technologies and skills like arthroscopy into low-income countries. Thus, we compared low- versus high-resource

intensive methods of teaching basic arthroscopic skills in a randomized controlled trial in Haiti. The most important result from our study was that we did not find a statistically significant incremental benefit of high-resource methods (expert instruction) over low-resource methods (video/lecture). However, we also found that low-resource methods may not have resulted in optimal technique. More broadly, our study addresses the mechanics of teaching basic skills required to implement and utilize a complex technology like arthroscopy, and our findings are similar to those from studies in other contexts.[11] Beyond quantitative outcome measures, introduction of skills training to surgeons can engender great excitement for orthopaedic education among participants by meeting their expressed desire to learn new techniques like basic arthroscopy.[12] We believe responding to participant feedback in this manner is critical to sustaining orthopaedic education programs in low-income countries. Lastly, while our work demonstrates initial improvement, it is unclear if this learning persists over the long-term.[13]

Understanding important course features and the timelines required to make changes in established continuing medical education programs

Successful CME programs require participation and satisfaction to enable learning, competence, and performance, but there has been limited literature on how to increase participation and satisfaction within CME courses and the outcomes of changes to the courses had only been studied in limited fashion.[14,15] In addition, the time span required to observe changes after an intervention was also largely unknown.[16-19] In this thesis, we found that implementation of needs assessment, problem-based learning, and faculty training initiatives led to significant improvement in AO Masters Course participation, participant evaluation of usefulness and relevancy of course content, and participant perception of faculty performance. Our results also highlighted the importance of faculty training to educational redesign efforts. In addition, we found that 3 or more years are sometimes required to see the effects of educational redesign. This is especially important from a

policy perspective because funding agencies often expect changes at a much more rapid pace.[20] As in other settings, our findings emphasized the need for patience to withstand the lag time between change initiation and result observation.[21]

Systematic change to educational programs can improve participant engagement allowing for learning, competency and improved performance.[22] In totality, this philosophy may improve efforts to align surgeon practice with evidence-based guidelines that facilitate better patient care worldwide.[14,23]

Improving Outcome Evaluation

Routine inclusion of long-term follow-up is possible

In addition to education, collection and evaluation of patient reported outcomes following musculoskeletal trauma is important for improving the quality of global orthopaedics. Many prior projects have attempted to assess patient outcomes after a variety of injuries and treatments by focusing on a narrowly defined subset of the population at a particular time period.[24-26] However, a drawback to this approach is that many patients are excluded due to study design and data about the quality of a health system is missed.[27,28] In contrast, we found that routine inclusion of long-term patient-reported outcome measures in a Dutch trauma registry was feasible, with a high response rate and little response bias. This framework allowed for the collection of comprehensive, normative data on the long-term outcomes of patients who sustain trauma, summarized the care received within health systems, and met regulatory requests for data collection that facilitates quality improvement, cost-effectiveness, resource utilization and benchmarking studies. However, even though routine inclusion of patient-reported outcome measures was deemed feasible, this was only accomplished with major time

investment. In order for the standard incorporation of patient reported outcomes to be sustainable and scalable, additional financial support and manpower will be required.

Context matters: not all fractures are the same

As we continue to follow our patients with patient reported outcomes, we are also realizing that injury context matters both for the types of injuries sustained and in the outcomes following acute fracture management. We found that worse health related quality of life scores and high-energy injury mechanism were independently associated with inferior wrist function after distal radius fractures. In addition to relatively well-known demographic and injury characteristics (sex, articular involvement), factors related to injury context (polytrauma, injury mechanism) may also account for differences in patient-reported wrist function after distal radius fracture. Finally, our results highlighted the importance of obtaining general and region specific measures of health-related quality of life when evaluating region-based patient-reported outcomes after injury. For example, without adjusting for general health measures, nearly all patients who sustain distal radius fractures in a polytrauma setting would be judged to have worse wrist function when compared to a control group of patients with an isolated distal radius fracture. Determining the importance of context on injuries will only increase in importance as health systems transition to value-based payment models based on the quality of delivered care, especially since musculoskeletal injuries are the fastest and largest drivers of US Medicare spending.[29-31] Awareness of factors associated with poorer clinical outcome measures can be used to guide patient expectations and maximize overall recovery. From a health systems perspective, this information may enhance quality improvement efforts, enable benchmarking, guide processes of reimbursement and aid in the development of bundled payments.

A new framework for measuring outcomes after orthopaedic trauma and its importance in the era of value-based care

Finally, most orthopaedic surgeons recognize that orthopaedic trauma patients present diversely, as there are almost innumerable combinations of injuries from different mechanisms and contexts. As a result, standardized quality measurement has been difficult to implement for this population.[32] This is especially important when designing value-based payment models to stem rapid increases in healthcare costs by shifting financial incentives away from volume and toward quality.[31,33] Yet, since less is known about outcome measures and quality metrics for trauma patients, most studies have investigated cost control, resulting in a gap in our understanding. [30,34] When we investigated this topic in our systematic review, we found that injury-related factors associated with patient-reported outcome after musculoskeletal trauma were largely related to injury mechanism and associated injuries. In our framework, we identified 4 broad injury scenarios where outcomes of musculoskeletal extremity injuries varied: (1) Polytrauma/multiple injuries with neurotrauma, (2) Polytrauma/multiple injuries without neurotrauma, (3) High-energy monotrauma, and (4) Low-energy monotrauma. The included studies also suggested that analysis of patient reported outcomes of extremity injury treatment without considering injury context, such as concomitant injury, could lead to significantly different expected results of treatment. We also highlighted how the multiplicity of patient reported outcome measures used in existing studies makes comparison between and within studies exceedingly challenging. For example, out of 21 included studies in our review, 32 different metrics were used. Consistent with our framework, we suggest that contemporary measurement of patient reported outcomes following musculoskeletal injury should have two components: (1) a health-related quality of life metric (HRQoL, e.g. EQ-5D, SF-36, PROMIS Global) to assess global disability, and (2) a condition-specific instrument (e.g. QuickDASH for distal radius fractures). While this strategy has been proposed for polytrauma patients, we

suggest broader application to all musculoskeletal injuries to allow for more accurate assessment of injury-related outcome contingent on context.[35]

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Chapter 15: Summary

This thesis explored how to improve global education and outcome evaluation in orthopaedic trauma. In **Chapter 1**, the importance of global orthopaedics and relevancy of education and outcome evaluation were described. The aims of this thesis were to:

1. Highlight efforts to improve education in global orthopaedic trauma surgery and better understand the timeline and techniques for knowledge and skill transfer.
2. Investigate a framework for understanding injury-related variation in longer-term patient reported outcome after musculoskeletal trauma.

In the first part of this thesis, we focused on education in global orthopaedic trauma. First, we highlighted the value of assessing injury burden and variations in practice patterns, and illustrated how this relates to performing needs assessments in a low-income country. **Chapter 2** profiled the delivery of orthopaedic care in a new state-of-the-art hospital in Haiti, and outlined a low-cost quality improvement method that could be used for medical education by highlighting areas for improvement in local orthopaedic patient care. In **Chapter 3,** we used a survey to demonstrate that for conditions that are managed differently in Haiti than in the U.S., the treatment rationale in Haiti is context-specific. The management of complex conditions such as acetabular fractures was limited by training, while the management of common conditions such as midshaft tibia fractures was influenced by the prevalence of complications and implant availability. This highlighted the need for targeted, context-specific interventions that include resource allocation and associated education around the use of those resources. Next, in **Chapters 4 and 5**, we demonstrated how an audience response system and incentive scheme could improve needs assessment response rates for adult and pediatric orthopaedic patients. This allowed for better characterization of surgeon needs in the developing world. We also demonstrated the importance of skill building paired with topic area teaching, and

illustrated how a continuing medical education (CME) conference is an effective tool to build surgical capacity and increase confidence level.

Then, we described the role of continuing medical education programs in low-income countries and applicability to both knowledge and skill transfer. In **Chapter 6**, we showed improved short-term knowledge performance using an audience response system during a CME conference in a low-income country. This finding highlighted how CME conferences in low-income countries can be an effective tool to increase surgeon knowledge, and audience response systems can help engage participants and track outcomes. In **Chapter 7**, we showed that the methods from **Chapter 6** could be extended to skills training. We described a protocol to introduce basic arthroscopic skills in a low-income country using a low-resource intensive teaching method. However, we also cautioned that this method of learning may not be optimal given the failure to improve in all outcome measures. Finally, in **Chapter 8**, we illustrated important course features and the timelines required to make changes in established continuing medical education programs like the AO Masters Courses.

In the second part of this thesis, we focused on improving outcome evaluation in orthopaedic trauma patients. First, in **Chapter 9**, we highlighted how routine inclusion of long-term patient reported outcome measures in routine follow-up is possible and we emphasized how further integration of these measures into trauma registries can aid with worldwide benchmarking of the quality of trauma care. Then, we showed how not all fractures are the same, and emphasized the importance of context. In **Chapter 10**, we illustrated that higher energy mechanisms of injury in polytrauma and high-energy monotrauma patients were associated with more severe complex articular distal radius fractures and more ipsilateral upper extremity injuries. We also found that polytrauma and high-energy monotrauma patients had a similar fracture

morphology. Then, in **Chapters 11 and 12**, we showed that factors related to injury context (polytrauma and injury mechanism), health-related quality of life (HRQoL), clinical outcomes, and mental health were associated with limb-specific patient-reported outcome in distal radius and distal humerus fractures, respectively. These findings highlighted the importance of assessing HRQoL when evaluating region-specific outcomes after orthopaedic trauma. Finally, in **Chapter 13**, we performed a systematic review of injury-related characteristics that differentiate between patient-reported outcomes (PROs) following traumatic musculoskeletal injury. Based on the results of the included studies, we proposed a framework where musculoskeletal injures occur in one of 4 scenarios that is associated with a different, context-dependent outcome: (1) Polytrauma with neurotrauma, (2) Polytrauma without neurotrauma, (3) High-energy monotrauma, (4) Low-energy monotrauma. In addition, we suggested that future studies should measure two types of PROs: (1) a health-related quality of life metric to assess global disability, and (2) a limb-specific instrument.

Chapter 16: Addendum – Acknowledgements, Curriculum Vitae, Review Committee

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Curriculum Vitae

Abhiram R. Bhashyam was born on May 25th, 1988 in Providence, Rhode Island, USA. He attended high school at Bethel Park High School in Pittsburgh, PA where he graduated as valedictorian. Subsequently, Abhiram completed a B.S. in Biomedical Engineering and Applied Mathematics and Statistics at The Johns Hopkins University in Baltimore, MD. For his graduate studies, Abhiram earned his MD from the Harvard-MIT Health Sciences and Technology Program at Harvard Medical School, as well as an MPP from the Harvard Kennedy School (Public Policy). Since 2015, he has been a resident in the Harvard Combined Orthopaedic Residency Program in Boston, MA. Following residency, he plans to complete a fellowship in Hand/Upper Extremity Surgery.

Abhiram has been interested in research since 2003 (when he built a homemade fuel cell after purchasing materials from the internet and a local hardware store). This passion has continued throughout his formal education, and his recent work has resulted in this dissertation under the supervision of professor dr. L.P.H. Leenen, dr. R.M. Houwert, and dr. G.S.M. Dyer.

Abhiram currently lives in Boston with his amazing wife Hemali. In his free time, he enjoys watching Pittsburgh sports teams (especially the Steelers), scuba diving, reading and running.

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