**Official Title:**

Orthosis of Acute Traumatic Rib Fractures via RibFx Belt for Pain Alleviation and Improved Pulmonary Function: A Pre-Post Interventional Trial for Quality Improvement

**NCT Number:**

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The University of Vermont

# Human Subjects Research Protocol

The Common Human Subjects Protocol Cover Form **must** be completed and accompany this form. This Protocol form should be completed for any human subjects research proposal that does not have a specific "protocol," such as a grant application. This form must be submitted along with a copy of the complete grant proposal and all the information in this form **must** be consistent with that proposal. This protocol form, once IRB approved, will be the working protocol for that research. **When completing this document, do not refer to page numbers within your grant.** If revisions are necessary during the course of the research, amendments should refer to this protocol form, not the grant proposal. Enter responses for all sections. Check N/A if the section does not apply. All materials must be submitted electronically to the IRB via InfoEd. Proper security access is needed to make electronic submissions. Visit the InfoEd Resource Materials page for more information.

## PROTOCOL SUMMARY

| Project Title: | Protocol Version Date: |
|---|---|
| **Orthosis of Acute Traumatic Rib Fractures via RibFx Belt for Pain Alleviation and Improved Pulmonary Function: A Pre-Post Interventional Trial for Quality Improvement** | 10 03 2019 |

Principal Investigator: Ajai Malhotra, MD FACS

Grant Sponsor: N/A Grant Number: N/A

(For grants routed through UVM, indicate the OSP Proposal ID # located at the top of the OSP Routing Form)

***Lay Language Summary:*** *(Please use non-technical language that would be understood by nonscientific IRB members to summarize the proposed research project. The information must include: (1) a brief statement of the problem and related theory supporting the intent of the study, and (2) a brief but specific description of the procedure(s) involving the human subjects. Please do not exceed one single-spaced 8 ½ X 11" page.)*

Acute traumatic rib fractures are a common issue for patients of trauma surgeons. They inflict substantial morbidity, the most dreaded and consequential of which are pulmonary complications. While these fractures are often treated non-operatively, there is a continued need for effective adjuvant treatments to improve rib fracture pain and outcomes. Prior studies have evaluated outcome measures for traumatic rib fractures that include respiratory failure, tracheostomy requirement, ICU length of stay, hospital length of stay, narcotic requirement, daily maximum incentive spirometry volume, pneumonia, and mortality [1]. Other studies have evaluated range of motion, kinesiophobia (as evaluated by the Tampa Score), the Respiratory Measurement Movement Index (RMMI), Spirometry, and Pain assessment (Continuous vs. Intermittent) [2].

Rib belts, which have been present since at least 1945, have long been used to provide pain relief via chest wall stabilization [3]. However there is an extreme paucity of literature regarding their clinical efficacy, and their use has largely been abandoned due to concerns that they may have been overly constricting and resulted in poorer respiratory (pulmonary/breathing) outcomes. Newer generation rib belts are more elastic and theoretically less constricting than their earlier generation predecessors, however their clinical efficacy has not been yet demonstrated. We will therefore plan to perform a prospective trial to determine if these rib strapping devices are effective clinical tools in the traumatic rib fracture population. The goal of the study is institutional quality improvement, to determine if we see benefit of these devices for the pain management of our trauma population. We will also conduct this as a pilot trial for hopeful future research applications, however the overall goal is institutional improvement.

Patients determined to be eligible for the study by the patient's clinical provider (and per our previously defined criteria) will be recruited to enroll in the project within the first 24 hours of their hospital admission (i.e. 24 hours following the documented H&P Note). They will be offered the opportunity to consent to enrollment in the study and will be assigned by the study team into either the intervention (RibFx belt +current standard of care) (n=35 subjects) or control (current standard of care) arm (n=15 subjects) in a quasi-experimental prospective design: untreated control group with dependent pretest and posttest samples. In this manner, the intervention arm will be both compared to themselves (pretest vs. posttests) as well as to a control group not exposed to the intervention.

Patients upon enrollment in the study will undergo an initial assessment that will include their baseline pain scores, narcotic

consumption, incentive spirometry scores, and the subjective self-reported results of their questionnaire (the pre-test questionnaire- see attached). Patients will continue to be scored on objective (incentive spirometry results, opioid pain medicine consumption) and subjective variables (pain scores) during their hospital course. Between 24-48 hours after enrollment, they will be prompted to again complete a similar 2nd questionnaire post-test (if they are discharged from the hospital at this point in the time course, they will be sent home with the questionnaire and prompted to complete it at home, or asked for an agreed upon time and day for study staff to call the patient to complete the questionnaire over the phone). At their follow up appointment in trauma clinic (which will be coordinated by the research team to be as close as possible to 3 weeks post injury), they will have the opportunity to again voluntarily complete a final short questionnaires (post-test) that assess their pain control and respiratory function over the last 3 weeks. If the patient does not plan to follow up in trauma clinic (or is not asked to), we will ask the patient for an agreeable time and day to call the patient and administer the questionnaire over the phone. At this point, their involvement in the trial will be complete.

All aspects of data collection will be performed only by approved members of Key Personnel.

Patients themselves will play an active role in data collection during the trial, and will be instructed and prompted in how to do so. One key change from the prior iteration of the protocol was that before, UVM staff nurses would collect research data while the patient was inpatient. Because they are not research personnel, we will no longer ask them to do so. Patients will be expected to fill out a worksheet on a daily basis, both while inpatient and after discharge, on their daily incentive spirometry scores as well as their minimum and maximum pain scale scores. This will be used to supplement the survey or questionnaire data, as well as the objective data from the EMR.

We will ultimately compare groups using a quasi-experimental design as follows: Untreated control group with dependent pretest and posttest samples. This will allow for a direct comparison of patient to patient within the intervention arm (patient pretest result serving as control compared to posttest result) (n=35 patients). To observe for temporal variability, we will have a control group with no intervention as well (no rib belt worn) (n=15), however the principle aim of the study is the comparison of patients to themselves in a pre-test, post-test fashion.

## PURPOSE AND OBJECTIVES

***Purpose:*** *The importance of the research and the potential knowledge to be gained should be explained in detail. Give background information.*

The purpose of this study is to ascertain whether the use of next generation rib orthosis belts (such as the RibFx) can improve patient outcomes following traumatic rib fractures within our population, whether it be by improving pain control, decreased respiratory complications, or increased patient satisfaction. We hypothesize that the use of elastic rib belts will improve rib fracture pain control without compromising pulmonary function (statistically significant improvement in pain control without significant impairment in respiratory function or increase in respiratory complication). We feel as though answering this question can help us as providers to improve the quality of care to our patients in our department.

Rib fractures are a common traumatic injury, and can cause substantial morbidity and mortality in the trauma population. As rib fractures most often are not treated with surgical intervention, there is demand for non-operative strategies to promote healing, pain control, and mechanical/musculoskeletal support. This can also help decrease the administration of potentially harmful pain medications such as opioid or narcotic pain medication. Further, as rib fracture pain can often be long lasting, this can truly increase quality of life for patients as they recover from these injuries.

***References****. Include references to prior human or animal research and references that are relevant to the design and conduct of the study.*

1. Butts, CA, Brady, JJ, Wilhelm, S, and Castor, L (2017). Do simple beside lung function tests predict morbidity after rib fractures? The American Journal of Surgery. 213: 473-477

2. Olsén, MF, Slobo, M, and Klarin, L (2016). Physical function and pain after surgical or conservative management of multiple rib fractures–a follow-up study. … Journal of Trauma.

3. Quick, G (1990). A randomized clinical trial of rib belts for simple fractures. The American Journal of Emergency Medicine.

4. Brasel, KJ, Moore, EE, and Albrecht, RA (2017). Western Trauma Association Critical Decisions in Trauma: Management of rib fractures. Journal of Trauma Acute Care Surgery 82 (1): 200-203.

5. Lazcano, A, Dougherty, JM, and Kruger, M (1989). Use of rib belts in acute rib fractures. The American Journal of Emergency Medicine. 7(1): 97-100.

6. Fabricant L, Ham B, Mullins R., Mayberry J. (2013) Prolonged pain and disability are common after rib fractures. Am Journal Surgery 205 (5): 511-516.

7. Bugaev N, Breeze JL, Alhazmi M, et al. Magnitude of Rib Fracture Displacement Predicts Opioid Requirements. J Trauma Acute Care Surg 2016. 81 (4): 699-704.

***Objectives:*** *Clearly state the primary and secondary objective(s) of the study.*

The objectives of the clinical trial are to determine if rib orthosis via the use of the RibFx belt can improve patients after traumatic rib fractures by improving pain control without compromise of respiratory function or increase respiratory complications of rib fracture.

Primary objective: Compare pain control in patients with non-operatively managed traumatic rib fractures via subjective/qualitative self-reporting of pain control via pain scores and questionnaires, as well as narcotic consumption requirements.

Secondary objectives: Compare pulmonary hygiene and function amongst patients with non-operatively managed traumatic rib fractures via incentive spirometry scores and incidence of post-traumatic pneumonia and radiological evidence of atelectasis incidence

## METHODS AND PROCEDURES

***Study Design:*** *Describe the research design, including a description of any new methodology and its advantage over existing methodologies.*

Per Jeffords Institute for Quality Data, there were 190 patients admitted the to Acute Care Surgery (Trauma) service at the University of Vermont Medical Center during the year 2016. Assuming that these numbers remain fairly static overtime as they have in the past, we would expect approximately 16 patient admissions per month with the diagnosis of rib fracture (seasonal fluctuations do exist with more traumatic admissions during the summer months). The goal time period for the trial would be to conduct this trial during the summer, with a goal of 50 total patients. We would therefore expect an enrollment period (data collection phase) of approximately 3 months.

During the study (following appropriate IRB approval), appropriate patients will be recruited both to the control arm of the study and the intervention/comparison arm in a specified / non-randomized sequence as seen in the schematic below (First 5 patients control, next five patients intervention, next five patients control, next five patients intervention, next five patients control, final 25 patients intervention). Control arm will include 15 total patients. All will be consented to the study upon admission (first 24 hours of index hospitalization for injury) with full knowledge that they will either be undergoing no intervention other than receiving the current standard of care for rib fracture care per our institution's standard, and if assigned to the rib belt group, expected to wear the rib belt during their recovery.

The current standard of care for rib fractures at our institution is as follows: includes oral and IV analgesia and other multimodal pain control as appropriate, including muscle relaxants such as methocarbamol (robaxin) unless there is a contraindication, pulmonary hygiene/toilet and respiratory care (including frequent evaluations by physicians, respiratory therapists, and nursing staff, early mobilization, and monitoring for pulmonary complication (via vital signs, pulse oximetry, oxygen requirement, chest imaging if appropriate).

All patients will undergo initial "Pre-test" testing which will include baseline pain scores (1-10 traditional pain scale), initial narcotic consumption (in MME) for first 24 hours of hospitalization, maximum incentive spirometry score for first 24 hours of hospitalization, and pre-test questionnaire result (see attached questionnaire #1). As the study continues their relevant data will be collected, including both objective (incentive spirometry scores, opioid pain medication consumption, incidence of atelectasis and pneumonia) and subjective (pain scores, survey result) clinical data. Concurrently, we will complete the trial with the intervention (RibFx belt) phase in which participants will be enrolled in the interventional arm of the study. The objective and subjective data will be collected in an identical fashion- the only difference between groups will be that this group will have been fitted with the RibFx belt for their hospital course and discharge.

The participants (both in the control and interventional groups) will again be asked to complete essentially the same brief surveys in a post-test fashion at two set time points: between 24-48 hours after initial enrollment in the study (Questionnaire #2)(if patient has been discharged at this point, they will be sent home with this survey and instructed when to complete, or facilitated completion by calling the patient at this time), and at 3 weeks post-injury (this will be done at their clinic visit, assuming they are not still admitted to the hospital at this time point).

Patients will also be sent home with a work-book to record their incentive spirometry scores and pain scores (all patients will be sent home with an incentive spirometer, and all patients in the interventional group will be sent home with their Ribfx belt).

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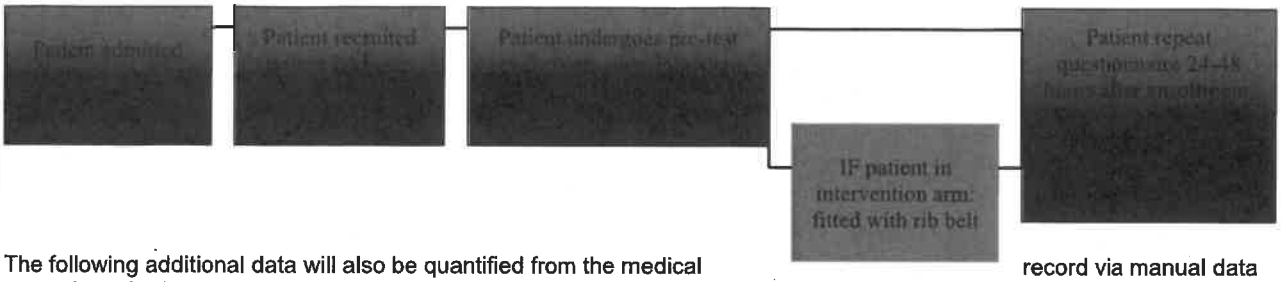
**The following schematic will be used for enrollment group assignment in the study (n=50 total participants):**

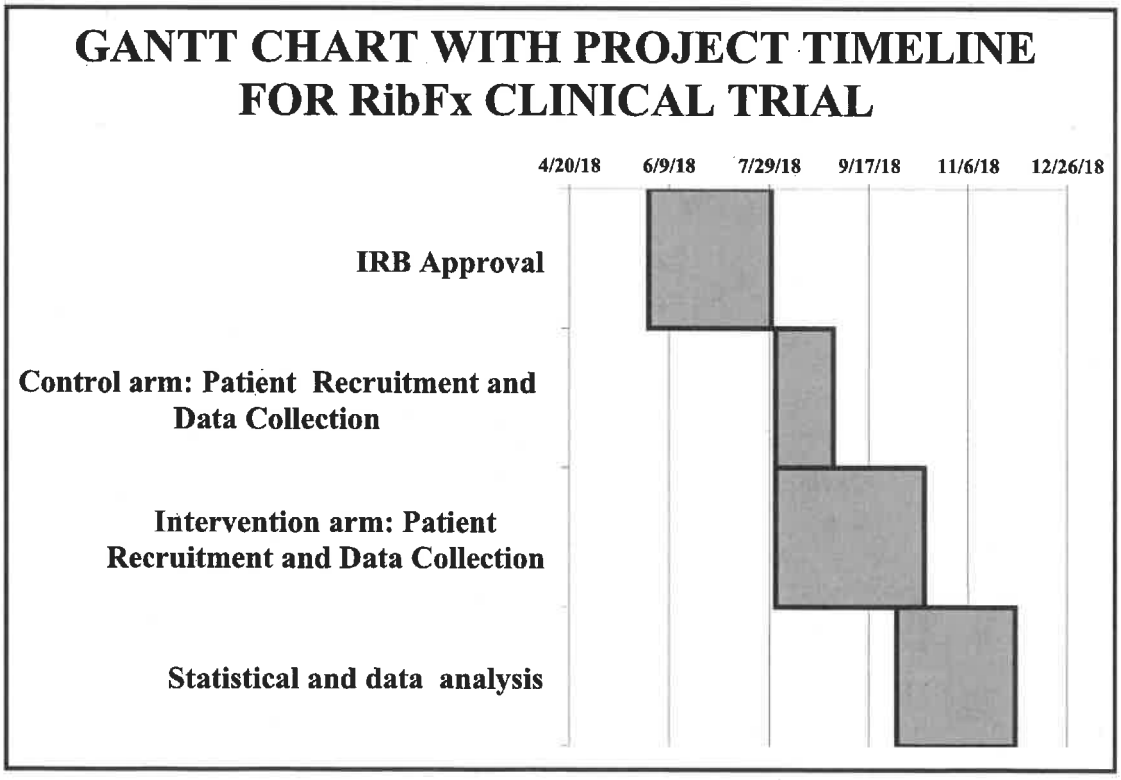

During the chart review portion of the study, patients who have authorized to have their medical records reviewed will have their post-traumatic records reviewed for the following diagnoses or conditions: respiratory failure, tracheostomy requirement, pneumonia, tube thoracostomy (chest tube), epidural use, intubation rates, hospital length of stay, and mortality.

**The following schematic represents the patient/subject trial course:**




The following additional data will also be quantified from the medical record via manual data extraction: ICU length of stay, hospital length of stay, pulse oximetry and respiratory rate scores (taken from already collected vital signs every four hours), body mass index (BMI), bronchodilator (such as albuterol or other inhaled beta agonist) use, age, sex/gender, tobacco history/pack years, days on mechanical ventilator, narcotic requirement (in mean morphine equivalents or morphine equianalgesic dose per day).

In addition, an independent radiology physician will analyze the chest x-rays, CT chests of the patients enrolled in the study and grade them in a blinded fashion) on a scale for the following characteristics: Degree and quantity of rib fracture, presence and degree of atelectasis, presence of COPD/emphysematous change or other parenchymal lung disease, presence and degree of pneumothorax, bilateral vs. unilateral disease, presence of intrapleural fluid, evidence of "flail chest" segment, and presence of pulmonary contusion and other noted pathology (see the attached Radiology Grading Form document). We will measure the degree of radiological severity and compare the control and interventional group to determine what differences in initial disease severity exist (so they can be accounted for).




***Procedures:*** *Describe all procedures (sequentially) to which human participants will be subjected. Identify all procedures that are considered experimental and/or procedures performed exclusively for research purposes. Describe the types, frequency and duration of tests, study visits, interviews, questionnaires, etc. Include required screening procedures performed before enrollment and while on study. Please provide in table, list or outline format for ease of review. (describe and attach all instruments)*

*Note: A clinical research protocol may involve interventions that are strictly experimental or it may involve some aspect of research (e.g., randomization among standard treatments for collection and analysis of routine clinical data for research*

*purposes). It is important for this section to distinguish between interventions that are experimental and/or carried out for research purposes versus those procedures that are considered standard therapy. In addition, routine procedures performed solely for research purposes (e.g., additional diagnostic/follow-up tests) should be identified.*

Each patient in the interventional arm will be fitted with a RibFx orthosis belt, which is to be worn during the majority of their day (excluding showering/bathing). It will be encouraged (though not mandatory) to wear at night. Patients in both the control and interventional arm will be expected to participate in pulmonary hygiene / toilet exercises with guided and independent incentive spirometry as per our normal routine and standard of care. There are no other interventions or procedures that the patients will be subjected to for the research trial- other procedures/interventions will be performed only if the clinical care team feels they are indicated.

***For research involving survey, questionnaires, etc.:*** *Describe the setting and the mode of administering the instrument and the provisions for maintaining privacy and confidentiality. Include the duration, intervals of administration, and overall length of participation. (describe and attach all instruments)*

☐ ***Not applicable***

Patients will be assessed with three short questionnaires in a pretest , posttest fashion at both the onset of the study, 24-48 hours after enrollment, and at their follow-up appointment 3 weeks after (2 post test questionnaires). The initial evaluation will occur on initial assessment prior to placement of the rib belt (or, for the control/ non-intervention group, at the onset/first 24 hours of the study).

Each of the questionnaires is essentially the same with only brief modifications made in the first two questions to make them appropriate for the timing during the clinical course. However these are all attached (see Questionnaire 1,2,and 3). Questionnaires 2 and 3 may be facilitated over the phone if the patient is discharged before the defined time frames are met.

Patients in both the intervention and control arms will present in post-admission follow up at a time period of 3 weeks post injury (range, 2-4 weeks) following their hospital admission, and will be asked to fill out a brief survey regarding their respiratory function and pain control. This survey will also inquire into compliance with the use of incentive spirometer, and compliance with the use of the RibFx belt (for patients in the intervention arm). If patients are not asked to present to trauma clinic for follow up, or if a patient does not intend to follow up, we will aim to complete this questionnaire over the phone in the same time frame.

The surveys are a novel series of questionnaires using previously validated tools such as the COPD Assessment Test or CAT (Jones PW, Harding G, Berry P et al 2009) and the Brief Pain Inventory (BPI) in order to subjectively assess each patient's own breathing/ respiratory and pain symptoms. The surveys also have additional questions gaging their pain medication usage, compliance with their treatment therapies (including IS and rib belt usage, when applicable). The survey is designed to be completed in ten minutes. The survey was constructed with the assistance of a professor psychologist who specializes survey construction (Author ACB). There will be no financial compensation for survey completions.

All surveys will be adapted to apply to the unique population being surveyed- the post-trauma population. This may involve removal of some questions that are not applicable to the rib fracture patients. There are several questions on the questionnaire that might not be applicable to the control group- they are simply instructed to not complete those four questions.

The surveys have been modified in order to be more easily comprehended to the average patient, and to require minimal additional instruction (so that the patient can complete them independently with no additional prompting).

The surveys that will be utilized are attached to the research protocol (see supplemental documents- Questionnaires 1,2, and 3).

***Statistical Considerations:*** *Delineate the precise outcomes to be measured and analyzed. Describe how these results will be measured and statistically analyzed. Delineate methods used to estimate the required number of subjects. Describe power calculations if the study involves comparisons. Perform this analysis on each of the primary and secondary objectives, if possible.*

In this study, we will utilize a quasi-experimental design to compare 35 subjects to themselves in a pre-test, post-test fashion. In addition, we will have an additional 15 non-interventional control patients to observe for temporal changes in patient's symptoms not secondary to the intervention itself. However, it is important to note that the study is not powered to detect differences between the control group and the intervention group. The purpose of the control group is to observe for differences that occur in this population over time regardless of intervention (it should be assumed that pain will improve as time increases from the set injury point, regardless of intervention). Further, this preliminary data could potentially be used to calculate an accurate power calculation for a definitive randomized controlled trial.

Groups will be compared by demographical and clinical data to determine what potentially confounding differences exist between the arms of the study. Relevant objective data that will be used to determine group differences include (but not limited to): age, sex, tobacco use status (active/former/none), presence of asthma, presence of COPD, or presence of restrictive lung

disease, home oxygen use, obstructive sleep apnea/ CPAP use, chronic pain incidence, narcotic/opioid medication consumption, obesity/ BMI. We will also measure relevant variables of their clinical course such as regional block/anesthesia/epidural administration. Radiological appearance of presenting imaging (either CT Chest or chest X-ray) will be compared by a dedicated and blinded radiologist who will grade the initial imaging based on severity including the following variables: number of fractures, bilateral vs. unilateral, degree of displacement, presence of lung contusion, presence of pneumothorax, presence of intrinsic lung disease, pleural effusion or blood.

Survey results (both pretest and posttests) will be compared using the appropriate statistical methods depending on the questions construct: with Chi squared performed for categorical variables (such as multiple choice) and unpaired t test for continuous variables (such as likert scale rankings).

We have performed a power calculation to determine if the following hypothesis can be reasonably answered with the trial of this size: We hypothesize that the RibFx belt can improve pain control in the post-rib fracture setting for patients without impeding pulmonary functioning. We anticipate seeing an improvement in pain scores and/or narcotic consumption within the rib belt group, without seeing significant differences in pulmonary function (although do expect a nonsignfiicant trend toward improved pulmonary function).

In order to perform our power function we reviewed the literature to determine prior similar samples to our expected cohort. We performed our power calculation with the goal of 80% power (with 2-sided alpha= 0.05). We anticipate based on prior studies (Fabricant et al that the baseline chest wall pain score (MPQ PPI and MPQ PRI) were a median of 3 (range 0-5) and a mean of 28 +/- 16 (range 0-70) respectively[1]. Looking at a study for Bugaev et al, we can also anticipate pain medicine requirements in the form of Mean Equianalgesic Dose (MED) of opioid pain medication. In this study, the MED for rib fracture patients was found to be 135.8 (IQR 50.83-440.0). Finally, Butts CA et al [3] studied incentive spirometry volume (ISV) scores in this population of patients and found their median ISV (in ml) was 1250 (IQR 750-1250).

For a one-group pre-post design, a sample size of 30 subjects would provide 83% power to detect a 20% decrease in MPQ PRI, assuming a within subject correlation of 0.8 for MPQ PRI scores and using a two-sided type I error rate of 0.05. A sample size of 35 (the planned size of the intervention group), provides an 88% power to detect a 20% decrease.

**[1] Butts CA et al. Do simple bedside lung function tests predict morbidity after rib fractures? Am J Surg 2017. 213: 473-477.**
**[6] Fabricant L, Ham B, Mullins R, Mayberry J. Prolonged pain and disability are common after rib fractures. Am J Surg 2013. 205 (5): 511-5.**
**[7] Bugaev N, Breeze JL, Alhazmi M, et al. Magnitude of Rib Fracture Displacement Predicts Opioid Requirements. J Trauma Acute Care Surg 2016. 81 (4): 699-704.**

***Risks/Benefits:*** *Describe any potential or known risks. This includes physical, psychological, social, legal or other risks. Estimate the probability that given risk may occur, its severity and potential reversibility. If the study involves a placebo or washout period, the risks related to these must be addressed in both the protocol and consent. Describe the planned procedures for protecting against or minimizing potential risks and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to the subjects are reasonable in relation to the anticipated benefits to subjects and others. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research and why the risks are reasonable in relation to the knowledge that reasonably may result. If there are no benefits state so.*

Theoretical risks to the use of the RibFx belt include worsening of pain or respiratory status. Risks are expected to be very low based on available clinical data regarding prior use of rib belts, and these devices are considered low risk by the FDA (class I device).

There is also a small potential risk given the nature of the study that a patient's protected health information (PHI) may be compromised during the study process, resulting in loss of confidentiality. For this reason we have implemented protocols to safeguard patient data to the maximum extent possible (see Data and Safety Monitoring, below).

***Therapeutic Alternatives:*** *List the therapeutic alternatives that are reasonably available that may be of benefit to the potential subject and include in the consent form as well.*

☐ ***Not Applicable***

Therapeutic alternatives include pharmacological pain management (including narcotic and non-narcotic pain medications), local nerve blocks (including intercostal and epidural injections/catheters), and operative intervention (rib fixation).

Importantly, patients who receive our current intervention will receive all current therapeutic alternatives in addition (as the current modalities represent the standard of care, which they will still receive during the trial). The intervention planned (RibFx belt) will therefore be in addition to (rather than in lieu of) current therapeutic alternatives.

Patients deemed to be candidates for operative intervention (open rib fixation with or without thoracotomy/decortication), for reasons already stated elsewhere in the protocol, will not be including within the trial.

***Data Safety and Monitoring:*** *The specific design of a Data and Safety Monitoring Plan (DSMP) for a protocol may vary extensively depending on the potential risks, size, and complexity of the research study. For a minimal risk study, a DSMP could be as simple as a description of the Principal Investigator's plan for monitoring the data and performance of safety reviews or it could be as complex as the initiation of an external, independent Data Safety and Monitoring Board (DSMB). The UVM/UVM Medical Center process for review of adverse events should be included in the DSMP.*

Data safety and monitoring will be the responsibility of the entire research team, however ultimate responsibility for safeguarding the patient's data will fall on the primary investigator. While 100% security of such data is never fully possible, the research team commits to taking all necessary and reasonable steps toward protecting patient data from HIPAA violation.

All the patient data will be kept in secure locations. When electronic, this involves storing the files only on secure servers with password protection. When in physical/paper copies, this involves use of lock-and-key filing cabinets and offices. All aggregate data will be coded to remove patient identifiers, as able, to safeguard the security of their identifiable data.

***Adverse Event and Unanticipated Problem (UAP) Reporting:*** *Describe how events and UAPs will be evaluated and reported to the IRB. All protocols should specify that, in the absence of more stringent reporting requirements, the guidelines established in the Committees on Human Research "Adverse Event and Unanticipated Problems Reporting Policy" will be followed. The UVM/UVM Medical Center process for review of adverse events and UAPs to subjects or others should be included in the DSMP.*

Adverse events will be reported as soon as they are identified to the research protections office and will be subject to thorough review. The affected patients, if applicable, will be notified regarding this adverse event. If needed, the clinical care team will provide any medical care related to this adverse event. Necessary changes to prevent the recurrence of such an event will be implemented with the assistance of the review board, and if necessary (for serious adverse events) the trial may be terminated early for patient safety.

***Withdrawal Procedures:*** *Define the precise criteria for withdrawing subjects from the study. Include a description of study requirements for when a subject withdraws him or herself from the study (if applicable).*

Patients will be eligible to withdraw from the study at any time if they chose to. This includes participants in both the control and intervention arms of the trial. Subjects will be asked to provide a reason for withdrawal (such as intolerance or difficulty with the rib belt, worsened pain associated with the rib belt, personal preference, difficulty complying with study rules, etc.), but patients are also free to withdraw without providing a reason.

A patient may be deemed no longer eligible for inclusion in the trial by the research team (such as if the patient undergoes rib fixation surgery). These patients will be removed from the trial and will be notified of the reason for their removal.

***Sources of Materials:*** *Identify sources of research material obtained from individually identifiable human subjects in the form of specimens, records or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data.*

Sources of materials will principally be derived from studies, images, tests that the patient is already undergoing as part of the standard of care for rib fracture treatment. The only additional test obtained solely for research purposes is are the pre-test and post-test questionnaires. X-rays and imaging tests analyzed will be obtained for clinical use and NOT solely or research purposes, however the images will undergo additional analysis by a blinded radiologist participating in the study. This will not incur any additional costs or radiation to the patient.

## DRUG AND DEVICE INFORMATION

*Investigators are encouraged to consult the UVM Medical Center Investigational Pharmacy Drug Service (847-4863) prior to finalizing study drug/substance procedures.*

***Drug (s)*** [x] ***Not applicable***

*Drug name – generic followed by brand name and common abbreviations. Availability – Source and pharmacology; vial or product sizes and supplier. If a placebo will be used, identify its contents and source. (attach investigational drug brochure)*

*N/A*

*Preparation: Reconstitution instructions; preparation of a sterile product, compounded dosage form; mixing guidelines, including fluid and volume required. Identify who will prepare.*

N/A

*Storage and stability – for both intact and mixed products.*

N/A

*Administration – Describe acceptable routes and methods of administration and any associated risks of administration.*

N/A

*Toxicity – Accurate but concise listings of major toxicities. Rare toxicities, which may be severe, should be included by indicated incidence. Also adverse interactions with other drugs used in the protocol regimen as well as specific foods should be noted. Address significant drug or drug/food interactions in the consent form as well. List all with above details.*

N/A

*Is it FDA approved: (include FDA IND Number)*

1. *in the dosage form specified? If no, provide justification for proposed use and source of the study drug in that form.*
   N/A
2. *for the route of administration specified? If no, provide justification for route and describe the method to accomplish.*
   N/A
3. *for the intended action?*
   N/A

***Device (s)*** ☐ ***Not applicable***

*Device name and indications (attach investigational device brochure)*

RibFx Rib Orthosis Belt (PelvicBinder,Inc.)

*Is it FDA approved: (include FDA IDE Number)*

1. *for indication specified? If no, provide justification for proposed use and source of the device.*

*The device is exempt from FDA approval as a Class I Medical Device*

*Risk assessment (non-significant/significant risk) - PI or sponsor needs to assess risk of a device based upon the use of the device with human subjects in a research environment.*

Non-significant risk to humans in a monitored research environment.

## SUBJECT CHARACTERISTICS, IDENTIFICATION AND RECRUITMENT

***Subject Selection:*** *Provide rationale for subject selection in terms of the scientific objectives and proposed study design.*

Subjects targeted for the study are those that would benefit most from the intervention (Rib belt)- patients with traumatic rib fractures. In order to determine if the belt has efficacy in this population, we must utilize the belt in this target population. Patients at the extremes of age (<18 or >80 years old) have been ruled out as they may create unreasonable confounding when measuring the relevant study outcomes, as well as potentially creating issues with autonomy and consent processes. There are also other exclusion criteria as dictated below.

***Vulnerable Populations:*** *Explain the rationale for involvement of special classes of subjects, if any. Discuss what procedures or practices will be used in the protocol to minimize their susceptibility to undue influences and unnecessary risk (physical, psychological, etc.).*

x ***Not applicable***

***Number of Subjects:*** *What is the anticipated number of subjects to be enrolled at UVM/UVM Medical Center and in the case of a multi-center study, with UVM/UVM Medical Center as the lead, the total number of subjects for the entire study.*

The current anticipated number of subjects is 35 patients in the intervention arm, and 15 in the control arm of the study, for a total of 50 patients. All these subjects with be enrolled at UVMMC.

***Inclusion/Exclusion Criteria:*** *Eligibility and ineligibility criteria should be specific. Describe how eligibility will be determined and by whom. Changes to the eligibility criteria at a later phase of the research have the potential to invalidate the research.*

Inclusion Criteria:
Adult person age 18-80 admitted with at least one acute traumatic closed rib fracture to the University of Vermont Medical Center

Exclusion Criteria:
Pediatric (<18 year old) and Geriatric (>80 year old) patients
Patients who are intubated on arrival or within first 24 hours of admission or with Glasgow Coma Scale (GCS) < 14 (altered or depressed consciousness)
Pregnant patients

Patients who undergo operative rib fixation for their rib fractures (such as open reduction internal fixation, or rib plating)
Patients with chest wall deformity, lacerations, burns, or soft tissue injuries that preclude placement of the RibFx belt
Patients with an additional mechanism of injury that would create severe distracting pain, as determine by the admitting team.
Isolated 1st rib or 2nd rib fractures

***Inclusion of Minorities and Women:*** *Describe efforts to include minorities and women. If either minorities or women are excluded, include a justification for the exclusion.*

The inclusion criteria make no specification for inclusion or exclusion from the study in regards to race, gender, religion, or sexual orientation. All groups will be included in the study if they wish to enroll and meet the otherwise laid out clinical criteria (see exclusion criteria above).

***Inclusion of Children:*** *Describe efforts to include children. Inclusion is required unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. If children are included, the description of the plan should include a rationale for selecting or excluding a specific age range of children. When included, the plan must also describe the expertise of the investigative team in working with children, the appropriateness of the available facilities to accommodate children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.* ***If children are excluded*** *then provide appropriate justification. Provide target accrual for this population.*

Due to concerns regarding potential size-match criteria for the RibFx medical device, as well as issues with the consent process, we have elected not to include children into the study population. As stated in the exclusion criteria, those less than 18 years of age will not be offered to participate in the trial.

*For protocols including the use of an investigational drug, indicate whether women of childbearing potential have been included and, if not, include appropriate justification.*

*N/A*

*If HIV testing is included specifically for research purposes explain how the test results will be protected against unauthorized disclosure. Include if the subjects are to be informed of the test results. If yes, include the process and provision for counseling. If no, a rationale for not informing the subjects should be included.*

[x] ***Not applicable***

***Recruitment:*** *Describe plans for identifying and recruitment of subjects. All recruitment materials (flyers, ads, letters, etc.) need to be IRB approved prior to use.*

Patients who are first identified by the clinical care team (The Acute Care Surgery/ACS/ Trauma Surgery team at UVMC) as meeting the desired inclusion criteria for the trial will be offered the opportunity to participate in the trial and appropriate clinical materials will be given by a member of the research team. There will be no advertisements, mailers, or other relevant recruitment materials other than an informational pamphlet, a device pamphlet, and the appropriate consent/authorization forms. These items are attached with the relevant research forms.

## FINANCIAL CONSIDERATIONS

***Expense to Subject:*** *If the investigation involves the possibility of added expense to the subject (longer hospitalization, extra studies, etc.) indicate in detail how this will be handled. In cases where the FDA has authorized the drug or device company to charge the patient for the experimental drug or device,* ***a copy of the authorization letter from the FDA or sponsor must accompany the application. Final approval will not be granted until the IRB receives this documentation.***
*There are very limited circumstances under which study participants may be responsible (either directly or via their insurance) for covering some study-related expenses. If the study participant or their insurer(s) will be billed for any portion of the research study, provide a justification as to why this is appropriate and acceptable. For example, if the study involves treatment that is documented standard of care and not investigational, state so. In these cases, the protocol and the consent should clearly define what is standard of care and what is research.*

The research team does not anticipate that participation in the trial will result in any additional hospital time or expense. The actual RibFx belt will be provided, free of charge to the patient (actual retail value $125 USD). All other interventions and modalities will be per the current standard of care for the treatment of rib fractures- patients will continue to be billed for the rest of their hospital care. In that (expectedly) extreme rare event that at any point during the trial it became apparent that the device has caused a medical complication necessitating additional treatment, this medical care will be provided without billing the patient for those services.

***Payment for participation:*** *Describe all plans to pay subjects, either in cash, a gift or gift certificate. Please note that all payments must be prorated throughout the life of the study. The IRB will not approve a study where there is only a lump sum payment at the end of the study because this can be considered coercive. The amount of payment must be justified. Clarify if subjects will be reimbursed for travel or other expenses.*

[x] ***Not applicable***

There will be no payment or financial incentive for the subjects to participate. The medical device RibFx belt will be provided to the intervention group free of charge, and they will be allowed to keep the medical device upon discharge (MSRP $125 USD).

***Collaborating Sites.*** *When research involving human subjects will take place at collaborating sites or other performance sites when UVM/UVM Medical Center is the lead site, the principal investigator must provide in this section a list of the collaborating sites and their Federalwide Assurance numbers when applicable. (agreements may be necessary)*

x ***Not applicable***

Single center study at the University of Vermont Medical Center main campus (Burlington, VT). No collaborating centers or satellite/off-site locations.

## INFORMED CONSENT

***Consent Procedures****: Describe the consent procedures to be followed, including the circumstances under which consent will be obtained, who will seek it, and the methods of documenting consent. Specify the form(s) that will be used e.g. consent (if multiple forms explain and place identifier on each form), assent form and/or HIPAA authorization (if PHI is included). These form(s) must accompany the protocol as an appendix or attachment.*

*Note: Only those individuals authorized to solicit consent may sign the consent form confirming that the prospective subject was provided the necessary information and that any questions asked were answered.*

Consent will be obtained at the time of enrollment (during the first 24 hours of the patient's inpatient admission/observation, on their initial encounter for acute traumatic rib fracture) and consent will be obtained at the bedside by one of the members of the research team.

All documentation of consent observation/supervision will be kept in the study regulatory binder.

After verbally explaining the rational, reasoning, risks, and potential benefits of the study, patients will have ample opportunity to decide whether or not to enroll without feeling pressured into enrolling (up to 24 hours will be permitted for deciding). Relevant written materials will be left for further review, including a written consent form, device pamphlet, and information pamphlet (All included in the IRB materials). Upon request of the patient, a member of the research team will always be available to answer further questions regarding the study via a "hot line" and also via the clinical care team.

***Information Withheld From Subjects:*** *Will any information about the research purpose and design be withheld from potential or participating subjects? If so, explain and justify the non-disclosure and describe plans for post-study debriefing.*

☐ ***Not applicable***

No information will be withheld from subjects. N/A

**Attach full grant application, including budget information and/or any contract or draft contract associated with this application.**

All materials must be submitted electronically to the IRB via InfoEd. Proper security access is needed to make electronic submissions. Visit the InfoEd Resource Materials page for more information.