CHI Institute for Research and Innovation

Title: Effects of using the Duracore Splinting Device on Patient Outcomes Related to Chest Trauma

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1) Investigators

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2) Funding Source

Financial funding was obtained by grants from local agencies through application processes, along with interviews and assessment of the medical device. The first grant was obtained through the Southern Colorado Society of Respiratory Care in hopes to obtain better choices for treatment for patients with rib fractures. Additional funding was provided by the Penrose Foundation as well.

3) Objectives and Hypothesis(es)

The purpose of this study is to use the Duracore patient operated torso splinting device for patients with chest trauma, including rib fractures, to improve deep breathing and help with reduced hospital length of stays (LOS). The hypothesis of this study is that the use of the Duracore splinting device will reduce hospital length of stays and improve patient lung capacities over the course of admission following chest trauma.

The study will use a randomized-experimental design and will be randomized via envelope randomization, with experimenters being blinded. A total of 104 patients, 26 in each group, will undergo initial incentive spirometry and force vital capacity (FVC) and FEV_1 tests. Groups will consist of a control versus experimental group, stratified into bilateral and unilateral rib fractures. Three days' worth of data will be collected for each of the tests and will also be collected 24 hours prior to discharge. Length of stays will be compared for experimental and control groups, as well as time to ambulation (collected from the first physical therapy assessment). Injury severity score will also be collected to determine any correlation by severity of injury. Patient satisfaction surveys for the device will also be collected to determine if the patients feel a difference with the device.

4) Background/Scientific Rationale and Significance

Little research as been conducted to determine the significance of a splinting device used in patients with chest trauma, and it is still uncertain whether these devices improve overall patient outcomes. Contradicting studies with similar experimental designs show either some significance (p-value) or insignificance in pulmonary function pre- and post-treatment. This gap in current knowledge leaves room for concern in whether the patient truly benefits from a splinting device in this type of injury. Changes in percent predicted FVC/FEV_1 ratio in this patient population are not readily demonstrated in most of these studies, as well as differing length of stays. This study will contribute to this base of knowledge by determining the effects of the Duracore splinting device on this patient population using the objectives.

5) Inclusion and Exclusion Criteria

Inclusion:

- Adult patient admitted to the trauma service at Penrose Hospital
- Willing and able to comply with all requirements of the study
- Active diagnosis of rib fractures
- Male or female ages 18 and older
- Able to provide written informed consent to participate in the study
- Must be physically able to don and use the splinting device independently without assistance

Exclusion:

- <18 years old
- History of pulmonary disease, lobectomy, or lung transplant
- Current smoker of tobacco products >5 years
- Diagnosis of flail chest

- Pregnant Women
- Prisoners
- Cognitively Impaired; must be alert and oriented x 3

6) Number of Subjects

Number of subjects was based on a power analysis using FVC/FEV_1 as the primary variable and stratified by unilateral versus bilateral diagnosis. Previous literature suggests a standard deviation of approximately 0.20-0.60 for FVC/FEV_1 values. SD was set at 0.40. Unilateral control was estimated to be 50% of predicted values (FVC/FEV_1) due to the nature of the injury, set at approximately 1.50L, with bilateral set at approximately 1.35L. Unilateral experimental group means were increased by 20% of predicted values to 1.80L, and bilateral to 1.50L. The required sample size to achieve 80% power to detect difference between splint and control groups is 104, with each group requiring 26 subjects each. Power calculations were performed in R version 4.0.0 with the pwr2ppl package, using the anova2x2 function.

Number of subjects to be used are 150 to account for withdrawals, incomplete data sets, extraneous results, etc. This is a single site study.

7) Recruitment Methods

Respiratory Therapy is part of the trauma multi-disciplinary team. and is involved with the care of every trauma patient admitted to Penrose Hospital. During trauma rounds in the ICU and floor patients that met criteria for the study will be identified. The investigators will approach those identified patients for potential enrollment in the study. Note they will not approach any patient for consent that is under their care that shift. There are no flyers or advertisements for this research or device.

8) Study Timelines

It is estimated that it will take at least one year to complete this study to include enrollment, subject completion, and all analysis. All primary variables and analyses should be completed by this time.

9) Study Endpoints

The primary endpoint of this study is to investigate the use of the Duracore splinting device in patients with chest trauma. Hospital length of stays, time to ambulation, a patient satisfaction survey, incentive spirometry, forced vital capacity measurements, and the injury severity score will be correlated to a control group to determine its' effectiveness. The quantitative data points will be collected over the first three days of hospital stay and 24 hours prior to discharge. The qualitative data will be collected prior to patient discharge. The hypothesis of this study is that the use of the Duracore splinting device will reduce hospital length of stays and improve patient lung capacities over the course of admission following chest trauma.

Variables to be collected are:

- Age (years)
- Gender
- Diagnosis

- Incentive Spirometry values for this admission
- FVC/FEV_1 values for this admission
- Height, Weight, and Ethnicity for FVC/FEV_1 % predicted calculation
- Averages from the patient satisfaction survey using a Likert Scale
- Length of Stays
- Time to Ambulation
- Injury Severity Score

10) Procedures Involved

The design of this study is a randomized experimental trial. The procedures involved in this study will first include obtaining the individual's consent to participate. Incentive spirometry is a standard of care that has been proven to improve deep breathing for patients. FVC/FEV_1 measurements are not always routinely done at this site but has been proven to be an indicator in respiratory deterioration in this population. Enrollment of each subject will be on a one to one basis for control and experimental groups. The trial will be randomized to reduce bias by randomly selecting patients between control and experimental groups by alternating every other patient receiving the treatment. Height, sex, ethnicity, and age will be accounted for as well to calculate the percent predicted FVC/FEV_1 to reduce statistical error. Enrollment will be based on patient consent. After enrollment into the study **after** admission to the hospital, baseline values of incentive spirometry (IS) and spirometry will be done. The patient will then be placed in the experimental or control group after being assigned a group via envelope randomization. If the patient is under experimental, they will receive a splinting device for treatment. Control groups will receive standard of care treatment without the splinting device. Continued analysis of IS and FVC/FEV_1 will occur over three days, and a final collection prior to discharge. Discharge planning will be coordinated with respiratory therapy, so the patient does not go home without completing the survey and final analysis. The patient satisfaction survey will be a paper survey administered to the patient. Patient identifying information will not be present on this form to maintain confidentiality. The patient will be asked if they would like to complete the form and that it is an anonymous short survey to help with identifying how the patient felt about the research. The subject will only be enrolled in the study for the duration of their hospital stay as an in-patient. There will be no follow-up after discharge, and any patients who are discharged without completing the final analysis will be omitted from the study.

11) Data Analysis Plan

Data analysis will include a two-tailed t-test to account for significance between control and experimental groups. This will be done with both incentive spirometry and FVC/FEV_1. Correlations will be made with time to ambulation and length of stays, as well as injury severity score. Graphic representation of trends will also be used to demonstrate differences between the groups. Qualitative analysis will include providing averages from the questionnaire using a Likert scale. These averages will be used to determine whether the population felt the device provided any help with their chest trauma. Number of subjects was based on a power analysis

using FVC/FEV_1 as the primary variable. Previous literature suggests a standard deviation of approximately 0.20-0.60 for FVC/FEV_1 values. SD was set at 0.40. Unilateral control was estimated to be 50% of predicted values (FVC/FEV_1) due to the nature of the injury, set at approximately 1.50L, with bilateral set at approximately 1.35L. Unilateral experimental group means were increased by 20% of predicted values to 1.80L, and bilateral to 1.50L. The required sample size to achieve 80% power to detect difference between splint and control groups is 104, with each group requiring 26 subjects each. Power calculations were performed in R version 4.0.0 with the pwr2ppl package, using the anova2x2 function. Number of subjects to be used are 150 to account for withdrawals, incomplete data sets, extraneous results, etc. This is a single site study.

Patient satisfaction surveys will use a numbered Likert Scale. The averages of each answer will be used to reinforce the efficacy of the device and correlate to primary data. Randomization will occur by experimenter-blinded envelope randomization.

12) Provisions to Monitor the Data to Ensure the Safety of Subjects

Subjects will be monitored for the duration of their stay by all staff members, and any adverse events related to the device itself will be reported accordingly. This device claims minimal risk to patients due to its unrestrictive and non-invasive nature but will be monitored by investigators for any adverse effects. **The Data Safety Monitoring staff will review all documentation accordingly at least quarterly.**

13) Withdrawal of Subjects

Subjects may voluntarily withdraw from the study at any time during their admission. Subjects may be withdrawn from the study if they are discharged prior to final analysis, deterioration of health rendering them incapable of participating in research, or verbal authorization to remove them from the study. Subjects may be removed in the case that the protocol needs to be revised due to an unforeseen adverse event that would exclude them from the study. All data will be retained unless specified by the subject up to the required date.

14) Risks to Subjects

The risk to subjects is extremely minimal. Chest trauma is consistently treated with incentive spirometry and monitored with FVC/FEV_1 percent predicted values. There is very little risk to the patient with these procedures, and only some discomfort and pain from the rib fractures may be associated. The difference is the addition of the splinting device. Splinting devices are routinely used in the hospital for open heart patients and produces no associated risk to those patients. It is unlikely that this splinting device will produce any adverse events. The device is unrestrictive and only splints the chest when the patient wants it to. The only

potential risks are some discomfort, and an unknown allergy to the urethane coated polyester fabric on the device.

15) Potential Benefits to Subjects

Potential benefits to the subjects are unknown currently.

16) Sharing of Results with Subjects

Specific study results will not be shared with subjects

17) Setting

Potential subjects will be recruited at Penrose Hospital in Colorado Springs, CO.

18) Resources Available

Research staff oversee enrollment and follow-up of subjects throughout their hospital stay. They are responsible for data collection and retention, as well as education of secondary hospital staff that will be seeing the device. The respiratory therapy department will perform the procedures because they are a standard of care. The department will not be directly involved in this research activity and will only be performing normal ordered procedures with the patients. All staff performing procedures are board certified and state-licensed respiratory therapists, and it is within their scope of practice to perform these procedures. This includes investigating staff. Nursing staff will also reinforce incentive spirometry use, which is a standard of care. Investigators will be the **only** people to be collecting relevant data from the chart. All relevant staff in the hospital will be educated on what the device is by investigators to better introduce the device into the work environment. Should it be necessary, the hospital is a place of availability for any medical or psychological need during the subjects' length of stay. This is the site in which all procedures and experimental data will be collected.

Penrose Hospital is a level I verified trauma center and receives patients with rib fractures and pulmonary contusions regularly. The sample size is justified statistically and is relevant to account for withdrawals. The actual sample size only needs to be 70% of the specified 150 to provide statistical significance.

19) Prior Approvals

The Duracore chest splint was presented at the trauma-research meeting May 2, 2019. Approval was granted for trial of the device pending modification of the device to include a removable shell for trial phase. Received financial assistance through approval of application process from the Southern Colorado Society of Respiratory Care for the Duracore chest splint for trial.

20) Confidentiality

Data will be protected by keeping it within the hospital system. All forms, online forms, EPIC data, etc. will be kept in the respiratory therapy department behind a locked door requiring a code. All other data will be kept in the hospital system's computer for security and HIPPA purposes and will not be removed from the site by personnel. Investigators will only have access to the data intended for interpretation, but all other data will be available on EPIC for viewing from relevant staff. Data will be retained within the system for at least three years. The protocol will follow all requirements as listed by CHI Research Data Security.

21) Provisions to Protect the Privacy Interests of Subjects

Should there be a desire to place a limit on whom the subject interacts with or provides personal information to, accommodations will be made to ensure they are comfortable. Subjects should always feel at ease and all questions regarding the research will be directed in a friendly, caring, and ethically sound manner. The research team is only permitted to have access to relevant information that pertains to the research, unless otherwise specified by the individual.

22) Compensation for Research-Related Injury

Subjects will not be compensated for participating in this study.

23) Economic Burden to Subjects

This study will not change the cost to the subjects. All tests are a part of a standard of care and will therefore be included in their hospital stay. The Duracore splinting device is not paid for by the hospital or subject, but by the sponsors. The splinting device is not sent home with the subject.

24) Consent Process

Written consent will be obtained from the subject prior to inclusion into the study. This study is minimal risk because it involves standards of care with the addition of a minimal risk device. Consent will take place when the patient is admitted to the hospital and in a room. The participant will be told of the research design, intended outcome, the role of the device, any associated risks, discomfort, or allergies. Any necessary amount of time will be dedicated to the consenting process so that the participant has reached a full and complete understanding. Inclusion specifics will be followed to ensure all coercion and undue influence is avoided. No potential subject unable to make their own decisions will be enrolled in the study.

Non-English-Speaking Subjects:

The primary non-English speaking subject will be Spanish in this region. The hospital has access to translators that can translate for a patient if this were to be necessary. A short form will be used to obtain consent if a non-English speaking patient is enrolled in the study.

Cognitively Impaired Adults/Temporary or Permanent Lack of Capacity to Provide Informed Consent

The process to determine whether an individual can give verbal consent will be conducted by determining if they are oriented to person, place, and time. If this changes after enrollment and the patient is unable to make decisions for themselves, the dedicated medical power of attorney for that patient will be consulted. The use of this device requires intact cognition and may cause them to be omitted from the study in this case.

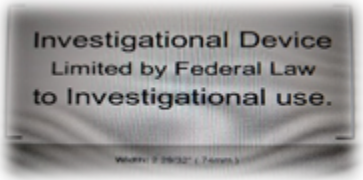
25) Process to Document Consent in Writing

Informed consent will be obtained in the patient room within the first 24 hours of admission. This will be a paper consent form and will be signed by the subject if the subject decides to be included in the study. All inclusion criteria must be met. The informed consent follows the CIRI template and outlines all procedures and risks associated with the study. Informed consent will be retained for the duration of the study and thereafter in accordance with regulations. Please see the informed consent for all information given to the patient.

26) Drugs or Devices

The splinting device will be primarily made of a urethane coated polyester fabric with anti-microbial additives which is soft, pliable, and stretchable. The device will be stored within the respiratory therapy equipment storage room at Penrose hospital and the research team will be notified by the Trauma team or respiratory therapy when a subject is admitted to the hospital who meets inclusion criteria for the study.
The FDA was contacted regarding the IDE Approval Process. Based on the response from the encounter with the FDA, that during the approval process with the IRB, the governing body of the IRB would deem the device as Significant or Non-Significant. The claim of the Duracore

splinting device is to be non-significant device. It is low risk and does not present potential for serious risk to the health, safety, or welfare of a subject. FDA recommendations are being followed to label the device accordingly. A nonsignificant risk device study requires only IRB approval prior to initiation of a clinical study. Sponsors of studies involving nonsignificant risk devices are not required to submit an IDE application to the FDA for approval per FDA regulations.
The plan is to comply with the abbreviated IDE requirements under §812.2 (b):
· The device will be labeled with "CAUTION – Investigational Device. Limited by Federal (or United States) law to investigational use."
· This is the current label for the device



· Will monitor for any adverse effects daily with subjects using the device

33) Other Requirements

REGULATORY, ETHICAL AND LEGAL OBLIGATIONS

Institutional Review Boards/Ethics Committees

- Before implementing this study, the protocol and all associated documents must be reviewed by a properly constituted committee or committees responsible for approving clinical studies. The IRB's written, signed approval letter must contain approval of the designated investigator(s) and the protocol (identifying protocol title, date and version number).

- Any change or addition to the protocol can only be made in a written protocol amendment that must be approved by the responsible party and the local IRB.

Patient Confidentiality and Disclosure

- Data on patients collected on eCRFs during the trial will be documented in an anonymous fashion and the patient will only be identified by the patient enrollment number, and by his/her initials. If, as an exception, it is necessary for regulatory reasons to identify the patient, all parties are bound to keep this information confidential.

- The investigator will guarantee that all persons involved will respect the confidentiality of any information concerning the study patients. All parties involved in the study will maintain strict confidentiality to assure that neither the person nor the family privacy of a patient participating in the trial is violated. Likewise, the appropriate measures shall be taken to prevent access of non-authorized persons to the study data.

Collection, Monitoring and Auditing Study Documentation, and Storage

Collection of Data and Monitoring Procedures

- This study will use an electronic data capture system (eDC). A paper case report form (CRF) is used for data recording. All data requested on the CRF must be entered and all missing data must be accounted for.

- The data will be checked for completeness and correctness as it is entered by the real-time online checks applied by the eDC system. Off-line checks will also be run to perform any additional data review required. Discrepancy reports will be generated accordingly and transferred to the study center for resolution by the investigator or his/her designee.

Auditing Procedure

- In addition to the routine monitoring procedures, the regulatory authority can conduct an audit or an inspection (during the study or after its completion) to evaluate compliance with the protocol and the principles of Good Clinical Practice. The investigator agrees that representatives of the Regulatory Authorities will have direct access, both during and after the course of this study, to audit and review all study-relevant medical records.

Retention of Documents

- The investigator must maintain source documents for each patient in the study, consisting of all demographic and medical information, including efficacy assessments. All information on case report forms must be traceable to these source documents in the patient's file. No data will be without a written or electronic record.

Disclosure of Information

- No disclosure shall be made except in accordance with a right of publication granted to the investigator. No information about this study or its progress will be provided to anyone not involved in the study other than Trauma Research, LLC or its authorized representatives, or in confidence to the IRB except if required by law.

Study Report, Publication Policy and Archiving of Study Documentation

Study Report and Publication Policy

- An integrated clinical and statistical report will be prepared upon completion of the study and data analysis. The results of the study will be published in a relevant peer-reviewed journal, with authorship status and ranking designated according to the acknowledged contributions of participating investigators, institutions.

Archiving of Documents

- Essential documents, as listed below, must be retained by the investigator for as long as needed to comply with national and international regulations. The investigator

agrees to adhere to the document retention procedures by signing the protocol. Essential documents include:

IRB/IEC/REB approvals for the study protocol and all amendments
All source documents
CRF copies
Any other pertinent study document.