

**Intramedullary Nailing of Tibia Shaft Fractures with Carbon
Fiber Implants versus Titanium Nails: A Randomized
Prospective Study**

Study Protocol & Statistical Analysis Plan

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**INTRAMEDULLARY NAILING OF TIBIA SHAFT FRACTURES WITH CARBON FIBER IMPLANTS
VERSUS TITANIUM NAILS: A RANDOMIZED COHORT STUDY**

TABLE OF CONTENT

LIST OF GENERAL ABBREVIATIONS/TERMINOLOGY

1. TITLE
2. SPONSOR
3. TYPE OF STUDY
4. STUDY HYPOTHESIS
5. STUDY OBJECTIVE
6. STUDY DESIGN
 - a. METHODOLOGY
 - b. STUDY DURATION
 - c. PATIENT POPULATION
 - i. Age
 - ii. Sex
 - iii. Ethnicity
 - iv. Health Status
 - v. Sample Size
 - d. INCLUSION CRITERIA
 - e. EXCLUSION CRITERIA
 - f. INFORMED CONSENT
7. DATA COLLECTION AND ANALYSIS
8. FUNCTION ASSESSMENT/OUTCOME MEASURES
9. BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE
10. POTENTIAL RISKS
11. BENEFITS
12. APPENDICES
 - APPENDIX A – STUDY CONTACT ROSTER
 - APPENDIX B - DATA COLLECTION SCHEDULE
 - APPENDIX C – INFORMED CONSENT DOCUMENT
 - APPENDIX D – INTERVIEWS

LIST OF GENERAL ABBREVIATIONS/TERMINOLOGY

AE – Adverse Events
BMI – Body Mass Index
BPI – Brief Pain Inventory
CRF – Case Report Form
CT – Computed Tomography
FDA – Food and Drug Administration
HIPPA – Health Insurance Portability and Accountability Act
ICH – International Conference on Harmonization
IRB – Institutional Review Board
MRI – Magnetic Resonance Image
MM – Medical Monitor
MRN – Medical Record Number
PI – Principal Investigator
PHQ – Patient Health Questionnaire
PTSD – Post-Traumatic Stress Disorder
OHRP – Office for Human Research Protections
OIRB – Office of the IRB
SMFA – Short Musculoskeletal Function Assessment

1. TITLE

Intramedullary Nailing of Tibia Shaft Fractures with Carbon Fiber Implants versus Titanium Nails:
A Randomized Prospective Cohort Study

2. SPONSOR

Carbo-Fix Orthopedics

3. TYPE OF STUDY

Randomized Prospective Cohort Study

4. STUDY HYPOTHESIS

We hypothesize that the Carbon fiber implant will decrease healing time with limited complications and allow better prognosis of concomitant injuries in a Level I trauma patient population.

5. STUDY OBJECTIVE

We will compare intramedullary nailing of open and closed tibia shaft fractures with Carbon fiber implant versus Titanium nail in a Level I trauma setting.

- **Primary Aim:** To compare the reduction accuracy, healing rate, functional outcome, and complications of tibia shaft fractures treated with a novel Carbon Fiber nail versus a standard Titanium nail.
 - **Primary Hypothesis:** Among patients with open or closed tibia shaft or metaphyseal fractures, the rate of healing, and ultimate return to function will be faster for patients treated with Carbon fiber implants than with Titanium nails.
 - **Secondary Hypothesis:** Measures of re-hospitalization for major limb complications, limb function, and patient-reported outcomes (such as pain) will be as good or better in patients treated with Carbon fiber compared with those treated with Titanium nail.
- **Secondary Aim #1:** To determine patient-reported levels of function and satisfaction with the fixation method and overall treatment, and to compare satisfaction between the two treatment groups.
- **Secondary Aim #2:** To determine the two-year treatment costs associated with fixation of tibia shaft fractures using novel Carbon fiber implants in comparison with standard intramedullary nailing using Titanium nails.

6. STUDY DESIGN

Level I trauma setting, randomized trial and prospective cohort study.

a. **METHODOLOGY**

All the patients will be managed by Specialist Orthopaedic Traumatologists. Scheduled follow-up would be per standard protocol of the University of Alabama at Birmingham Subdivision of Orthopaedic Trauma, and this includes 2-3 weeks, 6-8 weeks, 3 months, 6 months, and 12 months/1 year.

Patients would be randomized into two treatment groups.

Group 1: Definitive fixation with novel Carbon fiber implants.

Group 2: Definitive fixation with Titanium nails.

Randomization would be done using the Research and Electronic Data Capture software.

The randomization would help prevent bias that may arise due to certain identified significant risk factors for secondary surgery in tibia shaft fractures, which are:

1. High-energy trauma mechanisms
2. Fracture gaps due to bone loss

In addition, other possible risk factors for secondary surgery would be documented, namely:

1. Injury factors, such as injury severity score
2. Patient factors, such as BMI, tobacco use, illicit drug use, uncontrolled diabetes mellitus
3. Surgical factors, such as time to surgery, need for temporary fixation, and timing to definitive fixation

b. **STUDY DURATION**

Overall study duration – 2 years (Planning and database development – 3 months, Accrual – 12 months, Follow-up – 6 months, Data analysis, presentation in scientific conferences and publication – 3 months).

c. **PATIENT POPULATION**

- i. **Age** – 18 years and older
- ii. **Sex** – male and female
- iii. **Ethnicity** – all ethnicities
- iv. **Health status** – usual state of health prior to injury
- v. **Sample Size** – 50 in the Titanium treatment group and 50 in the Carbon fiber treatment group, making a total of 100.

d. **INCLUSION CRITERIA**

- i. Skeletal maturity (patients included will be 18 – 64 years, i.e. whose epiphyseal/growth plates are closed)
- ii. AO/OTA Fracture class 42; open and closed tibia shaft fracture (Gustilo-Anderson Types I and II; Tscherne closed types 0 and I)
- iii. Fractures amenable to intramedullary nailing
- iv. Fracture gaps less than 2cm due to bone loss
- v. Ipsilateral injuries would be counted as one, and in cases of bilateral injuries, the more severe one would be included in the study
- vi. Patient's informed consent or that of a legally acceptable representative

e. EXCLUSION CRITERIA

- i. Pregnancy
- ii. Subjects currently enrolled in one or more clinical studies
- iii. Skeletal immaturity (i.e. 17 years and younger)
- iv. Fractures planned for non-operative management
- v. Complex intra-articular involvement of tibia plateau or distal tibia
- vi. Pathologic fractures (fractures secondary to disease)
- vii. Concomitant ipsilateral tibia shaft fractures with complex pilon and/or plateau fractures requiring fixation
- viii. Patients already treated or in re-treatment
- ix. Tibia already infected as diagnosed by the attending physician
- x. Patients likely to be lost before completing adequate follow-up, such as prisoners or planned out-of-state (and other likely problems in the investigator's judgment, with maintaining follow-up visit schedule)
- xi. Patient is intellectually challenged or has a severe psychiatric condition
- xii. Patient is incompetent in the English Language
- xiii. Patient is non-ambulatory before injury or as a consequence of polytrauma
- xiv. Inability to obtain patient's informed consent and/or that of a legally acceptable representative

All inclusion/exclusion criteria would be satisfied for both treatment groups.

f. INFORMED CONSENT

After screening for eligibility, a detailed informed consent form would be provided to prospective participants, and questions which they may have would be succinctly answered by members of the research team.

In addition, a legally authorized representative who has reasonable knowledge of the potential participant would be acceptable to provide consent in cases whereby the patient is unable to provide consent, and whose cognitive level does not/is unlikely to improve before surgery (for example due to severity of their injury). This would be done with appropriate guidance.

7. DATA COLLECTION AND ANALYSIS

Baseline demographic information and injury characteristics data would be obtained. The reduction accuracy, callus formation and complications will be assessed and entered into the Research Electronic Data Capture (REDCap) software program hosted at the University of Alabama at Birmingham. Case report forms would be used to obtain information prior to transfer into REDCap. We will assess the patients' time to full weight bearing, return to work as well as conduct a musculoskeletal function assessment of our patients to observe any differences. This study will be performed over a 2-year period.

All data analysis would be performed using the SAS/STAT® software v 9.4. A significance test will be defined as one with a p-value <0.05 (i.e. 95% confidence level).

Source documents including CRF's, patient surveys, medical records, etc. will be kept on site and available for review by representatives of study sponsors and regulatory boards such as the IRB. Study records will be maintained according to current ICH guidelines and would be destroyed after 5 years. Any protocol deviations would be properly documented and duly reported to the IRB.

8. FUNCTION ASSESSMENT/OUTCOME MEASURES

Primary: The rate of fracture healing (radiographically and clinically determined), limb function/time to restoration of function, hospital re-admission for complications secondary to treatment of fracture, such as amputation, infection, non-union, mal-union, loss of reduction/poor final post-operative reduction accuracy, or hardware failure.

Secondary: Deep or superficial infection, intensity of pain, patient-reported functional outcome and quality of life. At the 6-month visit the patient will be assessed for pain, health and general well-being and will undergo a musculoskeletal function assessment in addition to their standard clinical evaluation.

Pain will be measured using the **Brief Pain Inventory (BPI)**, which would be administered to patients at 6, 12, and 24 months following injury. The BPI is a widely used, 15-item measure of pain intensity and interference with daily life. The questionnaire assesses three key pain domains: pain intensity, pain interference, and efficacy of pain treatments or medications.

Other functional assessment and outcome measures instruments to be utilized are the following:

- **The Short Form Musculoskeletal Assessment (SMFA)** will be administered to patients at 6, 12, 18, and 24 months following injury. The SMFA is a shorter version of the 101-item Musculoskeletal Function Assessment (MFA) questionnaire. The SMFA is a 46-item questionnaire consisting of the dysfunction and bother index. The Dysfunction Index includes 34 items for assessing patient function. Sub-scores for the following 4 domains can be calculated: Daily activities; Arm and Hand Function; Mobility and Emotional Status. The SMFA has been evaluated for reliability, validity and responsiveness in patient populations. This scale has been chosen because it is a short, reliable, patient reported assessment of functional status that has been specifically designed for and validated in patients with musculoskeletal conditions, including acute injury.
- **The Veterans RAND Health Survey (VR-12)**. The Veterans Rand 12-Item Health Survey is a multipurpose, self-administered generic measure of health status. It was developed to measure health-related quality of life, estimate disease burden and compare disease-specific benchmarks across populations. The VR-12 items measure eight health domains: general health perceptions, physical functioning and role limitations due to physical and emotional problems, bodily pain, energy-fatigue, social functioning and mental health. The instrument produces a physical health and mental health components.

- **Depression (PHQ)**

The presence of depressive symptoms will be measured using the nine item depression scale of the Patient Health Questionnaire (PHQ-9). The PHQ-9 is based directly on the diagnostic criteria for major depressive disorder in the Diagnostic and Statistical Manual Fourth Edition (DSM-IV). It is a well validated tool for assisting clinicians in diagnosing depression. There are two components of the PHQ-9: (1) assessing symptoms and functional impairment to make a tentative depression diagnosis, and (2) deriving the severity score.

- **Post Traumatic Stress (PTSD)**

This would be measured using the standard PTSD checklist (PCL), a 17-item measure that elicits responses for each of the DSM-IV disorders that comprise the diagnostic criteria for PTSD (intrusive, avoidant, and arousal symptoms). The civilian version, which is generally applied to any traumatic event, would be used.

- **Satisfaction with Care (PSQ-18)**

Patient satisfaction with treatment will be measured using the short form Patient Satisfaction Questionnaire (PSQ-18) at 12, and 24 months following injury. The PSQ-18 measures all the six sub-domains of technical quality, interpersonal manner, communication, financial aspects of care, time spent with doctor and accessibility.

- **Health Care Costs**

Healthcare costs associated with the following would be collected: length of hospital and ICU stay, number and types of surgeries performed during the initial acute hospitalization stage, hospital charges at the revenue center/cost department, and number of re-hospitalizations (including length of stay and charges). Costs would be calculated from charges at the revenue center/cost department line level using cost-to-charge ratios (CCRs).

9. BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

The tibia bears most of the body weight and is the most commonly fractured long bone in the body. According to the National Center for Health Statistics, tibia, fibula and ankle fractures account for an annual sum of 581,000 fractures and of all long bone fractures, the tibia are the most common site for nonunion. For many years, the standard practice in the treatment of fractures of the tibia shaft and other long bones has been intramedullary nailing using Titanium or stainless steel nails.

More recently however, orthopaedic surgeons have found an alternative in the novel composite Carbon fiber implants, especially in the prophylactic reinforcement of bones susceptible to pathological fractures following metastatic tumors as well as in the retreatment of tibia nonunion giving satisfactory outcomes. A clear advantage over metals is the implant's radiolucent property which allows for improved visualization of early callus formation and the

reduced fracture segments (i.e. cortical alignment), without the typical radiopaque density and artifact found with metals on X-ray, MRI or CT scans. The early visualization of callus formation may therefore serve as a good prognostic predictor of successful union.

Thus orthopaedic trauma patients, especially in cases of polytrauma may be able to heal faster, attain earlier weight bearing status, thereby affording more independence, decrease rehabilitation center stays and advance recovery with possibly quicker return to work. These benefits also have economic significance in reducing direct costs to patients and their families as well as to the healthcare system. Use of carbon fiber implants seems to hold the promise of a better functional outcome than with more rigid metals possibly due to factors like its modulus of elasticity which is approximate to that of bone, preventing it from stress shielding and consequent osteoporosis. Another is the possibility of reduced tendency for autodynamization that is important for a stable union of a nailed fracture, in which case the Carbon fiber implants may yield better results than Titanium nails.

10. POTENTIAL RISKS

Participants are not subject to any potential risk by being in either treatment group, except the potential adverse effects that are associated with the surgical management of tibia fractures. Most of these are to be examined as specific outcomes in the study (such as infection, amputation, nonunion, malunion, and loss of reduction or hardware failure).

Adverse Events: An adverse reaction, side effect, occurrence of toxicity, or sensitive reaction in excess of expectations. The study will monitor and report any untoward or unfavorable medical occurrence in the human subjects, including abnormal sign, symptom or any disease temporally associated with the subject's participation in the study whether or not considered related to the subject's participation. In addition, potential **severe adverse events** inherent in treatment of any tibia fractures are pulmonary embolism and death.

Unanticipated Problems: These are occurrences which present risks to participants or others (such as loss of study instruments), and would be reported to the IRB as well as to the study sponsor. The medical monitor (MM) would provide medical guidance and also oversee patient safety for this study.

11. BENEFITS

Participation in this study will benefit patients in that they will receive more intense follow-up than would be considered standard of care. At the 6 month visit the patient will be assessed for pain, health and general well-being and will undergo a musculoskeletal function assessment in addition to their standard clinical evaluation. In addition, further assessments will be conducted through the use of the Brief Pain Inventory (BPI), Short Form Musculoskeletal Assessment (SMFA), and the Veterans Rand 12 item Health Survey (VR12).

Findings from this study would help update the current body of knowledge concerning long bone fracture fixation, and facilitate an improved/evidence-based approach to the treatment planning process. Orthopaedic surgeons would thus be able to better avail their patients of care based on the most up-to-date and state-of-the-art in the field of Orthopaedic and Trauma Surgery.

12. APPENDICES

APPENDIX A: STUDY CONTACT ROSTER

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APPENDIX B: DATA COLLECTION SCHEDULE

Assessment/Procedure	Base-line	6 wks	3 mo	6 mo	12 mo	18 mo	24 mo
Patient Consent							
Patient Characteristics							
MRN, Encounter No., Name	X						
Age, Gender, Race/Ethnicity	X						
Height, Weight, BMI	X					X	
Educational level	X						
Disability and Employment History	X						
Medical History and Co-morbidities							
Insurance Status	X					X	
Current Medications	X						
Smoking, Alcohol, and Illegal Drug Use History	X					X	
Osteoporosis, Osteopenia, PVD, Cardiac Disease History	X						
General Injury Characteristics							
Date of Injury	X						
ED Visit	X						
Polytrauma	X						
General and Specific Injury Mechanism	X						
Abbreviated Injury Scale (AIS) Scores	X						
OTA, Tscherne, Gustilo-Anderson Classification	X						
Injury Severity Scores	X						
Compartment Syndrome	X						
Surgical Characteristics							
Damage Control Surgery	X						
Definitive Fixation: Titanium or Carbon-fiber	X						
Post-op. alignment, infection or wound dehiscence	X						
Final alignment			X	X	X	X	X
Pre-operative antibiotic prophylaxis	X						
Index Hospitalization							
Date of Hospital Admission	X						
Date of Hospital Discharge	X						
Length of Hospital Stay	X						
Transfer from Other Hospital	X						
Total ICU length of Stay	X						
Discharge Disposition	X						
UB-92 Billing Data	X						
Re-hospitalization							
Type (acute, rehabilitation, LTC/SNF)	X	X	X	X	X	X	X
Surgical Treatments Performed	X	X	X	X	X	X	X
Relation to study injury and/or complications	X	X	X	X	X	X	X

Admission and Discharge Dates	X	X	X	X	X	X	X
Total ICU length of Stay	X	X	X	X	X	X	X
Discharge Disposition	X	X	X	X	X	X	X
UB-92 Billing Data	X	X	X	X	X	X	X
Surgical Treatment							
Type and timing of all injury-related surgeries	X	X	X	X	X	X	X
Definitive Fixation Timing and Characteristics	X	X	X	X	X		
Complications							
Limb Complications	X	X	X	X	X	X	X
Systemic Complications	X	X	X	X	X	X	X
Limb Status and Limb Function							
Leg Length Discrepancy	X						
Rotational Alignment	X						
Presence of Callus		X	X	X	X	X	X
Weight bearing and Ambulatory status		X	X	X	X	X	X
Fracture Healing (Radiographic Alignment)					X	X	X
Sensation	X				X	X	X
Pain Intensity		X	X	X	X	X	X
Type and Dosage of Pain Medication		X	X	X	X	X	X
DVT Prophylaxis		X	X	X	X	X	X
Range of Motion			X	X	X	X	X
Self-Selected Walking Speed			X	X	X	X	X
Physical Therapy Need		X	X	X	X	X	X
Clinic Procedures Performed		X	X	X	X	X	X
Patient Reported Outcomes							
Brief Pain Inventory				X	X		X
Return to usual major activity		X	X	X	X	X	X
VR-12		X	X	X	X	X	X
Short Musculoskeletal Function Assessment				X	X	X	X
Workers' Compensation/litigation status					X		
Depression (PHQ)					X		X
PTSD (PCL)					X		X
Satisfaction with Care (PSQ-18)					X		X
Use of Health Care Resources (for cost)							
Ambulatory Care Visits (Number, Type)		X	X	X	X	X	X
Hours of Informal Care from Family/Friends		X	X	X	X	X	X
Billing Data							X

APPENDIX C: CONSENT FORM

[Will submit consent form and will attach separately]

APPENDIX D: INTERVIEWS

[Will submit BPI, SF12, SMFA, PSQ-18, and PTSD to IRB and will attach separately]

CARBOFIX

Short-Form Patient Satisfaction Questionnaire (PSQ-18)

Date: _____
Visit: _____

Subject Initials: _____
Subject ID: _____

Listed below are some things people say about health care. Please read each one carefully, keeping in mind the health care you are receiving now. (If you have not received care recently, think about what you would expect if you needed care today.) We are interested in your feelings, good and bad, about the health care you have received. The phrase "health care provider" includes physicians, physician assistants and nurse practitioners.

How strongly do you AGREE or DISAGREE with each of the following statements? (Circle One Number on Each Line)

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
1. Health care providers are good about explaining the reason for medical tests.	1	2	3	4	5
2. I think my health care provider's office has everything needed to provide complete medical care.	1	2	3	4	5
3. The health care I have been receiving is just about perfect.	1	2	3	4	5
4. Sometimes health care providers make me wonder if their diagnosis is correct.	1	2	3	4	5
5. I feel confident that I can get the health care I need without being set back financially.	1	2	3	4	5
6. When I go for health care, the provider is careful to check everything when treating and examining me.	1	2	3	4	5
7. I have to pay for more of my health care than I can afford.	1	2	3	4	5
8. I have easy access to the medical specialists I need.	1	2	3	4	5
9. Where I get health care, people have to wait too long for emergency treatment.	1	2	3	4	5
10. Health care providers act too businesslike and impersonal toward me.	1	2	3	4	5
11. My health care provider treats me in a very friendly and courteous manner.	1	2	3	4	5
12. Those who provide my health care sometimes hurry too much when they treat me.	1	2	3	4	5
13. Health care providers sometimes ignore what I tell them.	1	2	3	4	5
14. I have some doubts about the ability of the health care providers who treat me.	1	2	3	4	5
15. Health care providers usually spend plenty of time with me.	1	2	3	4	5
16. I find it hard to get an appointment for health care right away.	1	2	3	4	5
17. I am dissatisfied with some things about the health care I receive.	1	2	3	4	5
18. I am able to get health care whenever I need it.	1	2	3	4	5

CARBOFIX
THE VETERANS RAND 12-ITEM HEALTH SURVEY (VR-12)

Date: _____
Visit: _____

Subject Initials: _____
Subject ID: _____

The following questions ask for your views about your health—how you feel and how well you are able to do your usual activities. All kinds of people across the country are being asked these same questions. Their answers and yours will help to improve health care for everyone. There are no right or wrong answers; please choose the answer that best fits your life right now.

Q1. In general, would you say your health is:

- Excellent
- Very good
- Good
- Fair
- Poor

Q2. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

a. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf?

- Yes, limited a lot
- Yes, limited a little
- No, not limited at all

b. Climbing **several flights** of stairs?

- Yes, limited a lot
- Yes, limited a little
- No, not limited at all

Q3. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

a. Accomplished **less** than you would like.

- No, none of the time
- Yes, a little of the time
- Yes, some of the time
- Yes, most of the time
- Yes, all of the time

b. Were limited in the **kind** of work or other activities.

- No, none of the time
- Yes, a little of the time

- Yes, some of the time
- Yes, most of the time
- Yes, all of the time

Q4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

a. **Accomplished less** than you would like.

- No, none of the time
- Yes, a little of the time
- Yes, some of the time
- Yes, most of the time
- Yes, all of the time

b. Didn't do work or other activities **as carefully** as usual.

- No, none of the time
- Yes, a little of the time
- Yes, some of the time
- Yes, most of the time
- Yes, all of the time

Q5. During the past 4 weeks, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

- Not at all
- A little bit
- Moderately
- Quite a bit
- Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

Q6a. How much of the time during the past 4 weeks:

Have you felt calm and peaceful?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

Q6b. How much of the time during the past 4 weeks:
Did you have a lot of energy?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

Q6c. How much of the time during the past 4 weeks:

Have you felt downhearted and blue?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

Q7. During the past 4 weeks, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

- All of the time
- Most of the time
- Some of the time
- A little of the time
- None of the time

Now, we'd like to ask you some questions about how your health may have changed.

Q8. Compared to one year ago, how would you rate your **physical health** in general now?

- Much better
- Slightly better
- About the same
- Slightly worse
- Much worse

Q9. Compared to one year ago, how would you rate your **emotional problems** (such as feeling anxious, depressed or irritable) **now**?

- Much better
- Slightly better
- About the same
- Slightly worse
- Much worse

Your answers are important!

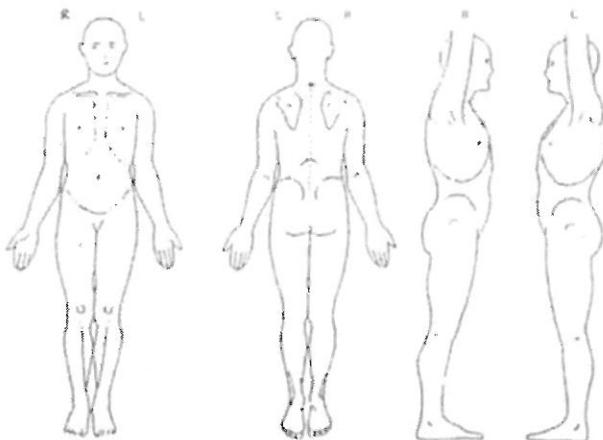
Thank you for completing this questionnaire!

CARBOFIX BRIEF PAIN INVENTORY

Date: _____
Visit: _____

Subject Initials: _____
Subject ID: _____

1. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts most.



2. Please rate your pain by circling the one number that best describes your pain at its worst in the last week.

0 1 2 3 4 5 6 7 8 9 10

No pain

Pain as bad as you can imagine

3. Please rate your pain by circling the one number that best describes your pain at its least in the last week.

A horizontal scale with numerical labels from 0 to 10. The label 'No pain' is positioned at the left end (0), and the label 'Pain as bad as you can imagine' is positioned at the right end (10).

4. Please rate your pain by circling the one number that best describes your pain on average.

A horizontal scale with numerical labels from 0 to 10. The label 'No pain' is positioned at the left end (0), and the label 'Pain as bad as you can imagine' is positioned at the right end (10).

5. Please rate your pain by circling the one number that tells how much pain you have right now.

6. What treatments or medications are you receiving for your pain?

7. In the last week, how much relief have pain treatments or medications provided? Please circle the one percentage that best shows how much relief you have received.

8. Circle the one number that describes how, during the past week, pain has interfered with your:

a. General activity

A horizontal scale from 0 to 10 with a midpoint at 5. The left side is labeled "Does not interfere" and the right side is labeled "Completely interferes".

h. Mood

0 1 2 3 4 5 6 7 8 9 10

c. Walking ability

0 1 2 3 4 5 6 7 8 9 10

d. Normal work (includes both outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10

e. Relations with other people

0 1 2 3 4 5 6 7 8 9 10

f. Sleep

0 1 2 3 4 5 6 7 8 9 10

a Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10

Does not interfere

Brief Pain Inventory Scoring Instructions

1. Pain Severity Score

This is calculated by adding the scores for questions 2, 3, 4 and 5 and then dividing by 4. This gives a severity score out of 10.

2. Pain Interference Score

This is calculated by adding the scores for questions 8a, b, c, d, e, f and g and then dividing by 7. This gives an interference score out of 10.

CARBOFIX
Patient Health Questionnaire (PHQ-9)

Date: _____
Visit: _____

Subject Initials: _____
Subject ID: _____

	Not at all	Several days	More than half the days	Nearly every day
1. Over the <u>last 2 weeks</u> , how often have you been bothered by any of the following problems?				
a. Little interest or pleasure in doing things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Feeling down, depressed, or hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Trouble falling/staying asleep, sleeping too much	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Feeling tired or having little energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Poor appetite or overeating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Feeling bad about yourself or that you are a failure or have let yourself or your family down	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Trouble concentrating on things, such as reading the newspaper or watching television.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Moving or speaking so slowly that other people could have noticed. Or the opposite; being so fidgety or restless that you have been moving around a lot more than usual.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Thoughts that you would be better off dead or of hurting yourself in some way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

PHQ-9* Questionnaire for Depression Scoring and Interpretation Guide

For physician use only

Scoring:

Count the number (#) of boxes checked in a column. Multiply that number by the value indicated below, then add the subtotal to produce a total score. The possible range is 0-27. Use the table below to interpret the PHQ-9 score.

Not at all (#) _____ x 0 = _____

Several days (#) _____ x 1 = _____

More than half the days (#) _____ x 2 = _____

Nearly every day (#) _____ x 3 = _____

Total score: _____

Interpreting PHQ-9 Scores

Score

Actions Based on PHQ Score

		Score	Action
Minimal depression	0-4	< 4	The score suggests the patient may not need depression treatment
Mild depression	5-9		
Moderate depression	10-14	> 5 - 14	Physician uses clinical judgment about treatment, based on patient's duration of symptoms and functional impairment
Moderately severe depression	15-19		
Severe depression	20-27	> 15	Warrants treatment for depression, using antidepressant, psychotherapy and/or a combination of treatment.

* PHQ-9 is described in more detail at the McArthur Institute on Depression & Primary Care website
www.depression-primarycare.org/clinicians/toolkits/materials/forms/phq9/

CARBOFIX

Short Musculoskeletal Function Assessment

Date: _____
Visit: _____

Subject Initials: _____
Subject ID: _____

Instructions: We are interested in finding out how you are managing with your injury or arthritis this week. We would like to know about any problems you may be having with your daily activities because of your injury or arthritis. Please answer each question by putting a check in the box corresponding to the choice that best describes you.

These questions are about how much difficulty you may be having this week with your daily activities because of your injury.

	Not at all Difficult A	A Little Difficult B	Moderately Difficult C	Very Difficult D	Unable to do E
1. How difficult is it for you to get in or out of a low chair?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. How difficult is it for you to open medicine bottles or jars?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. How difficult is it for you to shop for groceries or other things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. How difficult is it for you to climb stairs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. How difficult is it for you to make a tight fist?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. How difficult is it for you to get in or out of the bathtub or shower?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. How difficult is it for you to get comfortable to sleep?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. How difficult is it for you to bend or kneel down?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. How difficult is it for you to use buttons, snaps, hooks, or zippers?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. How difficult is it for you to cut your own fingernails?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. How difficult is it for you to dress yourself?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. How difficult is it for you to walk?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. How difficult is it for you to get moving after you have been sitting or lying down?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. How difficult is it for you to go out by yourself?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. How difficult is it for you to drive?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. How difficult is it for you to clean yourself after going to the bathroom?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. How difficult is it for you to turn knobs or levers (for example, to open doors or to roll down car windows)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. How difficult is it for you to write or type?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. How difficult is it for you to pivot?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. How difficult is it for you to do your usual physical recreational activities, such as bicycling, jogging, or walking?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. How difficult is it for you to do your usual leisure activities, such as hobbies, crafts, gardening, card-playing, or going out with friends?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. How much difficulty are you having with sexual activity?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. How difficult is it for you to do light housework or yard work, such as dusting, washing dishes, or watering plants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. How difficult is it for you to do heavy housework or yard work, such as washing floors, vacuuming, or mowing lawns?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. How difficult is it for you to do your usual work, such as a paid job, housework, or volunteer activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

These next questions ask how often you are experiencing problems this week because of your injury.

	None of the Time A	A Little of the Time B	Some of the Time C	Most of the Time D	All of the Time E
26. How often do you walk with a limp?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. How often do you avoid using your painful limb(s) or back?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. How often does your leg lock or give way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. How often do you have problems with concentrating?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. How often does doing too much in one way affect what you do the next day?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. How often do you act irritable toward those around you(for example, snap at people, give sharp answers, or criticize easily)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. How often are you tired?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. How often do you feel disabled?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. How often do you feel angry or frustrated that you have this injury or arthritis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

These questions are about how much you are bothered by problems you are having this week because of your injury.

	Not at All Bothered A	A Little Bothered B	Moderately Bothered C	Very Bothered D	Extremely Bothered E
35. How much are you bothered by problems using your hands, arms, or legs?	1	1 1	1	1	1 1
36. How much are you bothered by problems with your back?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. How much are you bothered by problems doing work around your home?	1	1 1	1	1	1 1
38. How much are you bothered by problems with bathing, dressing, toileting, or other personal care?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39. How much are you bothered by problems with sleep and rest?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40. How much are you bothered by problems with leisure or recreational activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
41. How much are you bothered by problems with your friends, family, or other important people in your life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
42. How much are you bothered by problems with thinking, concentrating, or remembering?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
43. How much are you bothered by problems adjusting or coping with your injury or arthritis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
44. How much are you bothered by problems doing your usual work?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
45. How much are you bothered with feeling dependent on others?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
46. How much are you bothered with stiffness and pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CARBOFIX
PTSD Checklist – Civilian Version (PCL-C)

Date: _____
Visit: _____

Subject Initials: _____
Subject ID: _____

Instruction to patient: Below is a list of problems and complaints that veterans sometimes have in response to stressful life experiences. Please read each one carefully, put an "X" in the box to indicate how much you have been bothered by that problem *in the last month*.

No.	Response	Not at all (1)	A little bit (2)	Moderately (3)	Quite a bit (4)	Extremely (5)
1.	Repeated, disturbing <i>memories, thoughts, or images</i> of a stressful experience from the past?					
2.	Repeated, disturbing <i>dreams</i> of a stressful experience from the past?					
3.	Suddenly <i>acting or feeling</i> as if a stressful experience					
4.	were <i>happening again</i> (as if you were reliving it)?					
5.	Feeling <i>very upset</i> when <i>something reminded</i> you of a stressful experience from the past?					
6.	Having <i>physical reactions</i> (e.g., heart pounding, trouble breathing, or sweating) when <i>something reminded</i> you of a stressful experience from the past?					
7.	Avoid <i>thinking about</i> or <i>talking about</i> a stressful experience from the past or avoid <i>having feelings</i> related to it?					
8.	Avoid <i>activities or situations</i> because they <i>remind</i> you of a stressful experience from the past?					
9.	Trouble <i>remembering important parts</i> of a stressful experience from the past?					
10.	Loss of <i>interest in things that you used to enjoy</i> ?					
11.	Feeling <i>distant</i> or <i>cut off</i> from other people?					
12.	Feeling <i>emotionally numb</i> or being unable to have loving feelings for those close to you?					
13.	Feeling as if your <i>future</i> will somehow be <i>cut short</i> ?					
14.	Trouble <i>falling or staying asleep</i> ?					
15.	Feeling <i>irritable</i> or having <i>angry outbursts</i> ?					
16.	Having <i>difficulty concentrating</i> ?					
17.	Being "super alert" or watchful on guard?					
	Feeling <i>jumpy</i> or easily startled?					

PTSD CheckList – Civilian Version (PCL-C)

The PCL is a standardized self-report rating scale for PTSD comprising 17 items that correspond to the key symptoms of PTSD. Two versions of the PCL exist: 1) PCL-M is specific to PTSD caused by military experiences and 2) PCL-C is applied generally to any traumatic event.

The PCL can be easily modified to fit specific time frames or events. For example, instead of asking about “the past month,” questions may ask about “the past week” or be modified to focus on events specific to a deployment.

How is the PCL completed?

The PCL is self-administered

Respondents indicate how much they have been bothered by a symptom over the past month using a 5-point (1–5) scale, circling their responses. Responses range from **1 Not at All – 5 Extremely**

How is the PCL Scored?

1) Add up all items for a total severity score

or

2) Treat response categories **3–5** (*Moderately* or above) as symptomatic and responses **1–2** (*Below Moderately*) as non-symptomatic, then use the following DSM criteria for a diagnosis:

- Symptomatic response to at least 1 “B” item (Questions 1–5),
- Symptomatic response to at least 3 “C” items (Questions 6–12), and -
- Symptomatic response to at least 2 “D” items (Questions 13–17)

Are Results Valid and Reliable?

Two studies of both Vietnam and Persian Gulf theater veterans show that the PCL is both valid and reliable (Additional references are available from the DHCC)

What Additional Follow-up is Available?

All military health system beneficiaries with health concerns they believe are deployment-related are encouraged to seek medical care

Patients should be asked, “**Is your health concern today related to a deployment?**” during all primary care visits.

- If the patient replies “**yes**,” the provider should follow the Post-Deployment Health Clinical Practice Guideline (PDH-CPG) and supporting guidelines available through the DHCC and www.PDHealth.mil