

## **Longitudinal assessment of bone loss with chronic spinal cord injury**

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### **Project Summary/Abstract**

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*Principal Objective:* The purpose of this study is to evaluate the long-term changes in bone mineral density at the hip and midshaft femur in persons with established paralysis. We will also identify specific values (“cutpoints”) for factors underlying fracture risk in this population.

*Secondary Objectives:* As with any clinical condition, there may be contributing influences that alter the common or “normal” response. Therefore, we will investigate the potential influence on skeletal mass of factors such as overall health status, comorbidities, nutrition, physical activity, and functional mobility.

Continuity of care is a major goal of the VA health care system and is especially well practiced within the Spinal Cord Injury Centers. It is our mission to support the veteran patients with SCI to regain and maintain functional independence and achieve a high quality of life as well as treat them medically. Early and substantial bone loss has been well documented in this population, resulting in long bone skeletal mass approximately 25-50% below (non-SCI) reference values. It has also been demonstrated that this population is at increased risk of long bone fracture which can require hospitalization and limb immobilization and lead to reduction in independence and function. There have been no longitudinal studies of bone loss beyond the initial loss phase and no prospective studies to determine whether fractures can be predicted and potentially prevented. As there are now several agents available to reduce bone loss (eg, Fosamax or Forteo), it is essential to identify the natural history of bone loss in chronic paralysis in order to determine whether and when treatment with such agents may be beneficial.

The proposed study will involve a prospective follow-up of patients for whom prior bone mineral density studies have been performed and will include determination through chart review and interview of relevant clinical and lifestyle factors. Skeletal assessment will be performed by dual x-ray absorptiometry (DXA) at the standard measurement sites of proximal femur, spine, and whole body. Additional Bone mineral density (BMD) and external diameter measurements will be made at the midshaft femur as described in our laboratory. For each participant, we will perform two BMD studies: one upon recruitment into the current study as a follow-up of whatever time period since the initial study and a second study approximately one year later.

#### *Key Questions:*

Q1: What are the long-term effects on the skeleton of chronic paralysis due to spinal cord injury (SCI)?

Q2: Are there clinical or lifestyle factors that influence skeletal mass in chronic paralysis?

Q3: To what extent does low skeletal mass predispose to fracture and can fracture risk be predicted?

#### *Study Outcomes and Data Analysis:*

1. Primary outcome will be changes in bone mineral density at the various sites. Change will be calculated as percent of initial (%) and absolute ( $\text{g/cm}^2$ ) per year. This annualized change will be determined from the total change from initial study to final (third) study as well as from regression analysis.
2. Secondary outcomes will include relevant comorbidities, extended periods of bedrest or immobilization, change (positive/negative) in physical activity especially related to functional mobility, standing frame use, nutritional status, and fracture history. Regression and ANOVA will be used to determine the effect of clinical and lifestyle factors on change in skeletal mass.
3. Decision Tree (ROC) analysis will be used to estimate a cutpoint for BMD relative to fracture risk (Y/N).