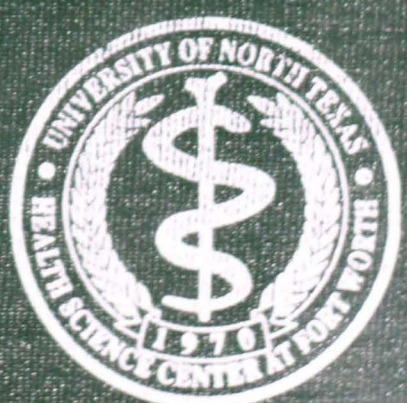
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The primary purpose of this study was to determine the efficacy of osteopathic manipulative treatment (OMT) in improving clinical outcomes in patients who had undergone a surgical procedure for either a hip fracture or osteoarthritis affecting the hip or knee. OMT treatment subjects were recruited from an inpatient rehabilitation unit housed within an osteopathic hospital. OMT subjects received a standard course of OMT throughout their stay in the rehabilitation unit. Clinical outcomes were assessed principally through the administration of the Functional Independence Measure (FIM), a standard disability measure, to study subjects on admission to and discharge from the rehabilitation unit. Mean FIM score changes were compared between the OMT and a control group of similar patients. Receipt of OMT was associated with shorter length-of-stay, higher total FIM score change, and greater improvement on FIM locomotion items. These findings suggest that OMT is a beneficial therapy for this population of patients.

EFFICACY OF OSTEOPATHIC MANIPULATIVE TREATMENT

IN IMPROVING CLINICAL OUTCOMES IN PATIENTS

WITH ORTHOPEDIC DIAGNOSES ADMITTED

TO A HOSPITAL-BASED REHABILITATION UNIT

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By

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Fort Worth, Texas

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CHAPTER 1

INTRODUCTION

Statement of the Problem and Purpose

Hip fractures and osteoarthritis are significant causes of morbidity and mortality among the elderly. Costs associated with these conditions due to increased levels of disability and loss of functional independence among individuals who suffer from these problems run into the billions annually. Many individuals who sustain a hip fracture or have hip/knee osteoarthritis are referred to an inpatient rehabilitation setting to undergo a course of therapies designed to decrease the level of disability and increase functional independence. Osteopathic manipulative treatment (OMT) is a therapy that has the potential to improve functional outcomes among a variety of patient populations, from acute, inpatient to outpatient. Our goal in this study was to examine the effectiveness of OMT in improving functional outcomes in patients admitted to an inpatient rehabilitation unit who had recently undergone a surgical procedure for either a hip fracture or osteoarthritis affecting the hip or knee.

The estimated incidence of hip fractures in the United States is 80 per 100,000 with 90% of these occurring in individuals over 50 years of age (Zuckerman, 1996). Almost a quarter of all individuals who experience a hip fracture die within a year thereafter and 10% of those who survive for more than a year become functionally dependent as a result of the hip fracture (Avioli, 1991). Among patients with a hip fracture, 40% to 60% experience a partial loss of ability to ambulate and 55% to 75% lose their ability to perform at least some activities of daily living (ADLs) (Kramer, et al., 1997).

Hip fracture incidence increases with age, doubling for each decade after 50 years (Zuckerman, 1996). It is not surprising, therefore, that osteoporosis, physical inactivity, residence in an institution, visual impairment, and other products of age are major risk factors for hip fracture. (Zuckerman, 1996). The rapidly growing elderly population, particularly in the United States as the baby-boomer generation approaches advanced years, coupled with the fact that hip fracture incidence increases exponentially with age sends a clear message that hip fractures will become a much greater geriatric public health burden into the next century (Gullberg, Duppe, and Nilsson, 1993).

Osteoarthritis is a progressive disease that causes the breakdown of cartilage in joints. As the cartilage breaks down, the joint inevitably loses its

normal shape (Arthritis Foundation, 1996). Bone ends thicken and form bony spurs where the ligaments and capsule attach to the bone (Arthritis Foundation, 1996). These anatomical changes produce pain when the joint is used. Osteoarthritis is more prevalent with age, especially in those over 50 (Arthritis Foundation, 1996). It commonly occurs in weight-bearing joints, as those present in the hips and knees (Arthritis Foundation, 1996). Risk factors for osteoarthritis include not only age, but also heredity, obesity, and overuse of certain joints. About 16 million individuals in the United States suffer from osteoarthritis (Arthritis Foundation, 1996).

Hip fractures and hip/knee osteoarthritis almost always require surgical intervention in the elderly. Hip fractures result in pronounced structural trauma to the hip joint, and hip/knee osteoarthritis typically triggers serious degenerative structural changes in the affected areas. Currently, arthroplasty or open-reduction-internal-fixation (ORIF) are the most effective treatments for hip fracture and total knee arthroplasty is the most effective surgical treatment for the debilitating pain associated with osteoarthritis of the knee. When individuals experiencing a hip fracture or advanced osteoarthritis have comorbid conditions that affect their ability to perform ADLs, they are commonly admitted to a rehabilitation unit for a course of

therapies designed to lessen the extent of total disability and to increase functional independence.

In the book *Rehabilitation Outcomes--Analysis and Measurement*, Hamilton, Granger, Sherwin, Zielezny, and Tashman (1987) state that "The purpose of medical rehabilitation is to decrease disability and handicap of physically impaired individuals and to minimize the extent of impairment." In its *International Classification of Impairments, Disabilities, and Handicaps*, the World Health Organization (WHO) defines "impairment" as any loss or abnormality of anatomical, physiological, or psychological *structure* or *function*. "Disability" is defined as any restriction or lack of ability, resulting from an impairment, to perform an everyday *activity* in the manner or within the range considered normal for a person of the same age, culture, and education. "Handicap" is a disadvantage for a given individual, resulting from an impairment or a disability that limits or prevents the fulfillment of a *role* that is normal, depending on age, sex, and social and cultural factors, for that individual. By virtue of their definitions, the terms "disability" and "handicap" have far-reaching psychological, psychosocial, and economic implications. A disability or handicap affects every area of an individual's life, from relationships to employment to the ability to perform basic ADLs such as eating or dressing. Given this, medical rehabilitation typically takes

a multidisciplinary approach, incorporating elements of physiatry, psychology, social work, occupational therapy, nursing, recreational therapy, speech therapy, and physical therapy to provide a comprehensive array of rehabilitative services to patients.

The growth of managed healthcare has led to a general trend toward lower healthcare costs and fewer days spent as an inpatient. Rehabilitation units are particularly affected by these trends since they deal primarily with an elderly population burdened by chronic and debilitating medical problems that generally require more lengthy hospital stays. Hence, the identification of therapies that provide the greatest improvement in functional independence in the least amount of time has become paramount in rehabilitation research.

The effects of healthcare provided in an osteopathic setting have been insufficiently studied. Research concerning the effects of osteopathic manipulative treatment (OMT) applied to patients undergoing medical rehabilitation is nonexistent. The primary purpose of this study was to determine the efficacy of OMT in improving clinical outcomes in patients who had undergone a surgical procedure for hip fracture or osteoarthritis affecting the hip or knee. Clinical outcomes were measured by Uniform Data System for Medical Rehabilitation's (UDS_{MR}) Functional Independence

Measure (FIM), as well as other standard outcome variables (Hamilton, et al., 1987). The FIM instrument is a well-established measure of disability that measures 18 areas in which a patient's degree of disability and burden of care are apparent.

Definitions of and Rationale for Using Osteopathic Medicine and OMT

Osteopathic medicine is rooted in the philosophy that the body's anatomic structure plays a central role in physiologic function. If the body's structure is optimal, then function will be optimal. However, if structure is altered, as with the burden of hip fractures or osteoarthritis, then efficiency of function decreases. The osteopathic philosophy encompasses four main principles:

The Body Is A Unit: Each body part works for the benefit of the others, and functioning of each part is necessary for optimal efficiency of the entire organism. Also, the physical component of each individual's body interacts with its mental and spiritual components. The health of each of these components affects the others;

The Body Has Self-Regulating Mechanisms: The body has mechanisms to protect, repair, and regulate itself. These allow the body to adjust to a wide variety of environmental stressors and still maintain homeostasis;

Structure and Function Are Reciprocally Interrelated: The structure of a person's body plays a significant role in that person's ability to perform daily activities. Conversely, functional demands initiate structural changes in the body to meet those demands; and

Rational Treatment Is Based On The Other Three Principles Of The Osteopathic Philosophy: In the words of Dr. William Kuchera (1993): "In every patient encounter, the D.O. filters the results obtained from the patient's history, physical examination (including osteopathic palpatory findings) and any other test results through the 'philosophic lens' formed by the four principles of osteopathy." Osteopathic physicians should use the osteopathic philosophy to integrate basic science information with clinical experience to provide true osteopathic evaluation and treatment to patients (Kuchera, 1993).

Osteopathic medicine also recognizes that 60% of the body is composed of muscles and bone, and holds that impaired or altered function of the neuromusculoskeletal system can produce stress leading to altered performance of many physiologic functions (Kuchera, 1993). According to osteopathic principles, a neuromusculoskeletal component is present in every disease or dysfunction (Kuchera, 1993).

OMT is a hands-on system of diagnosis and treatment used by osteopathic physicians to correct somatic dysfunction. Somatic dysfunction is defined as "the impaired or altered function of related components of the somatic (body framework) system: skeletal, arthroidal, and myofascial structures, and related vascular, lymphatic, and neural elements" (Kuchera, 1993). The changes that occur with a hip fracture or osteoarthritis, such as asymmetrical motor weakness, muscle contracture, peripheral edema, decreased joint mobility, and pain are diagnosed as somatic dysfunction.

Numerous published case studies cite the effectiveness of OMT in improving mobility and functioning in patients. However, to date, there exists only a handful of *controlled clinical trials* of OMT. Unfortunately, most information about the efficacy of OMT remains anecdotal, reinforcing the consensus among osteopathic physicians that controlled clinical trials are needed to help document and validate the effectiveness of OMT.

Statement of the Research Hypothesis

Patients who receive a standard course of OMT throughout their stay at an inpatient rehabilitation unit following a surgical procedure for either hip fracture or hip/knee osteoarthritis will attain a rehabilitation outcome superior to that of similar patients who receive no OMT.

CHAPTER 2

BACKGROUND & SIGNIFICANCE

Four areas of past research warranted examination in planning this study: 1.) studies of the effectiveness of OMT, in general; 2.) studies of the effectiveness of OMT in patients with a hip fracture or hip/knee osteoarthritis; 3.) studies of the effectiveness of *any* type of manual manipulation for hip fractures and hip/knee osteoarthritis, and 4.) studies of the validity and reliability of the Functional Independence Measure. The first three areas listed are discussed in this section. The Functional Independence Measure is discussed in the Methods section. Several searches were performed through the MEDLINE database covering the period from 1966 to April, 1997. Searches were performed by keywords, used individually and in combination. The keywords searched were: osteopathic, osteopathic manipulative treatment, OMT, osteopathy, manipulation, osteopathic manipulative medicine, manipulative medicine, manual medicine, hip, knee, osteoarthritis, rehabilitation, meta-analysis, functional independence measure, and FIM.

The bulk of osteopathic manipulative medicine (OMM) research is either never published or published in journals not included in the MEDLINE database. Furthermore, a database devoted exclusively to osteopathic literature does not exist currently. A MEDLINE search was performed for the single keyword "osteopathic" covering the entire MEDLINE coverage period from 1966 to April, 1997. A total of 532 titles and abstracts containing the term "osteopathic" was identified. Each of these was reviewed on-line to identify articles relevant to the study and to determine the types of material osteopathic healthcare providers are publishing, at least in journals included in the MEDLINE database. The vast majority of abstracts reviewed were either case studies of specific pathologies for which the author claimed OMT is beneficial or articles concerning ostepopathic education. Clinical studies of OMT effectiveness were an extremely rare find. To capture articles concerning osteopathic manipulative medicine not identified through MEDLINE, additional searches were performed, using many of the keywords listed, through two alternative databases-- The Alternative Medicine Database (AMED) and the Manual Alternative and Natural Therapy Index System (MANTIS). These databases include research published on numerous "alternative" therapies and were identified by the University of North Texas Health Science Center's (UNTHSC's) chief reference librarian as

the databases most likely to include osteopathic manipulative medicine research not cited in MEDLINE. Unfortunately, no OMT efficacy studies were identified in either of these alternative databases.

Based on case studies and the clinical experience of osteopathic manipulative medicine specialists, there is a strong consensus that OMT is effective in both hospitalized patients and outpatients for numerous conditions, especially musculoskeletal conditions. Hip fractures and hip/knee osteoarthritis therefore seemed well-suited as subjects of an OMT efficacy research project. The availability of an inpatient rehabilitation population for this study was important, given the lack of OMT research among this growing population. Unfortunately, no articles or case studies were identified from any of the three databases that research the efficacy of OMT in patients who are either in a rehabilitation unit or who have sustained a hip fracture or hip/knee osteoarthritis. To substantiate the rationale for studying OMT and manual medicine in general, two areas of past research are reviewed here: past research of OMT efficacy in patients with a musculoskeletal condition and past research of the efficacy of any type of manual technique for hip fractures or hip/knee osteoarthritis. These are presented in the next two sections.

Review of Past Research of OMT Efficacy

This review includes only original research articles of OMT efficacy for treatment of musculoskeletal conditions, since these are the most relevant to the current study. Case studies are excluded as they are of negligible validity. In the three databases searched, two clinical studies of OMT efficacy were identified as relevant to the present study, based on musculoskeletal involvement. The first was a clinical trial of OMT applied to 12 females complaining of a history of menstrual cramping with concommitant low back pain (between L-2 and S-1) (Boesler, Warner, Alpers, Finnerty, and Kilmore, 1993). The primary objective of this study was to determine if high-velocity-low-amplitude (HVLA) OMT could diminish low-back pain associated with menstrual cramping and if there were concomitant surface electromyographic (EMG) changes with OMT (Boesler, et al.). The twelve women, aged 22 to 36 years, were selected from the Osteopathic Manipulative Medicine Clinic of the University of Osteopathic Medicine and Health Sciences College of Osteopathic Medicine in Des Moines, Iowa. All subjects experienced dysmennorhea and associated low-back pain during the first day of menses. On that day, each subject received a physical examination and a lumbosacral surface EMG. After the initial recordings, subjects received OMT and a second EMG was performed. The

OMT technique used was HVLA applied to the lower limbs and spine. Subjects were divided into treatment and non-treatment groups. Eight of the subjects were used in both the treatment and non-treatment groups. These eight subjects went through an identical procedure for a second menstrual cycle when dysmennorhea with associated low-back pain occurred, except that a rest period was used in lieu of OMT. The remaining four subjects were divided equally between the treatment and non-treatment groups, but were evaluated only once. Subjects who received OMT reported immediate relief of low-back pain with OMT application. Additionally, these subjects reported an increased feeling of relaxation, ability to move with less resistance, and alleviation or significant reduction of menstrual cramping (Boesler, et al.). Subjects in the treatment group experienced a 25.60% decrease in EMG activity ($p = .006$) compared to no statistically significant EMG change occurring in the non-treatment group (Boesler, et al.).

In the second study, the goal was to determine whether evaluation of the effectiveness of OMT in treating low-back pain can be based upon surface EMG results (Ellestad, Nagle, Boesler, and Kilmore, 1988). 26 men and 14 women, aged 22 to 36 years, were selected from the Osteopathic Manipulative Medicine Clinic at the University of Osteopathic Medicine and Health Sciences College of Osteopathic Medicine and Surgery in Des

Moines, Iowa (Ellestad, et al.). Twenty of the 40 subjects complained of low-back pain (between L-2 and S-1) of between two weeks and six months duration (Ellestad, et al.). The other 20 subjects denied any history of low-back pain during the six months prior to the study (Ellestad, et al.). None of the 40 subjects had received OMT previously for a musculoskeletal condition (Ellestad, et al.). Ten subjects in each group were randomly assigned to receive OMT while the other subjects received no OMT (Ellestad, et al.). An initial physical examination was performed on every study subject followed by administration of a lumbosacral surface EMG (Ellestad, et al.). Next, subjects in the OMT group received a ten-minute treatment of OMT utilizing HVLA technique applied to the entire axial skeleton and pelvis. After receiving OMT, a second lumbosacral EMG was performed on these subjects. Subjects in the non-OMT group rested for ten minutes between EMG recordings. This same sequence of events was repeated for both the OMT and non-OMT groups seven days later. In the group who received OMT, a significant decrease in EMG activity was noted: -15.036 units for the back pain group and -5.383 units for the non-pain group ($p < .001$). In the group who did not receive any OMT, no statistically significant change was found between any of the EMG recordings (Ellestad, et al.). All subjects who received OMT reported "feeling better" following

treatment and improved range of motion was noted among subjects in this group (Ellestad, et al.).

There are clear limitations to both of these studies, the most obvious of which is sample size. Given the small sample sizes used in these studies and the lack of information about subject selection, the validity and reliability of the results are in question. The second problem with these studies is the lack of a more objective measure of OMT efficacy. Both studies used the reduction in EMG activity as a quantitative correlate of OMT efficacy. However, each study also relied on the subjective comments of the subjects as a measure of clinical efficacy. The use of a standardized pain scale or range-of-motion scale to measure clinical OMT efficacy would have provided needed quantitative strength to each of these studies. Finally, no information was provided regarding subject selection procedures for these studies. Was random selection used? How severe was the back pain in each of the subjects prior to receiving OMT? Was the level of back pain in treatrment and control groups comparable? Not having the answers to these questions seriously narrows interpretation of the results.

Review of Past Research of the Efficacy of Non-OMT Manual Techniques for Hip Fractures or Hip/Knee Osteoarthritis

From the three databases searched, no original research articles or

case studies were identified that examined efficacy of non-OMT manual techniques for treatment of hip fractures or hip/knee osteoarthritis. A number of articles were found which looked at the role of continuous passive motion (CPM) in treating patients who are post-operative for total knee arthroplasty. CPM involves the continuous movement of a joint through a specified range of flexion and extension over two to twelve hours per day (McInnes et al., 1992). CPM is typically performed by a machine into which the rate and specific arc of motion can be programmed (McInnes et al., 1992). CPM has proven beneficial in increasing range-of-motion and decreasing swelling among patients who have undergone a surgical procedure to the knee, as in arthroplasty (McInnes et al., 1992). Though CPM is distinct from manual techniques, it is the closest relative addressing the conditions of interest that could be found in the published literature.

CHAPTER 3

METHODS

Description of Study Population and Recruitment of Subjects

A total of 60 subjects comprised the study population. There were 20 treated and 40 control subjects to yield a 1:2 case-control ratio. The initial plan was to assign three control subjects to every treated subject in order to increase statistical power. However, this was not possible in the present study due to administrative difficulties in obtaining data from the hospitals on the control subjects.

All study subjects received the standard assessments, therapies, and treatments for their conditions during their stay in the rehabilitation unit. This included a FIM assessment on admission to and discharge from the unit.

All subjects in the treatment group were inpatients admitted to a 14-bed, acute, inpatient rehabilitation unit of the Osteopathic Medical Center of Texas (OMCT), known as the RehabCenter. Each of these subjects had a primary RehabCenter admitting diagnosis of either hip fracture or osteoarthritis affecting the knee or hip (either unilaterally or bilaterally).

Additionally, each subject had undergone a surgical procedure for repair of the hip or knee within two weeks prior to admission to the RehabCenter. A total of 20 subjects comprised the treatment group.

The RehabCenter is managed by RehabCare Group Incorporated under a contractual agreement with OMCT. RehabCare Group Inc. is a rehabilitation services management company in existence since 1983 that manages over 85 inpatient rehabilitation units across the United States. The RehabCenter has been under RehabCare's management since its opening on October 1, 1983. A search of RehabCare's national database was performed to identify inpatient rehabilitation units whose patients were similar to the treated subjects in terms of age, gender, ethnicity, rehabilitation setting, and rehabilitation unit admitting diagnosis. Factors such as humidity, temperature, and geographic physician practice variability may all influence an individual's physiological response to treatment in ways that are not currently recognized or appreciated. As such, the search was limited to those units located in Texas and Louisiana to minimize any bias due to climate or other environmental conditions. From this search, 16 hospitals were identified for recruitment of control subjects. In February, 1997, a joint letter from both the UNTHSC research team and RehabCare was sent to each of these 16 hospitals detailing the study and asking for their

participation. Of these, four were eliminated for administrative reasons and one elected not to participate. Of the remaining 12 hospitals, two were selected for control patient recruitment, one in Texas and one in Western Louisiana. These two hospitals were chosen based on the speed at which they could compile and send patient data to the UNTHSC research team. Each hospital was asked to identify 20 patients admitted to their rehabilitation unit between 12/1/96 and 4/21/97 who were at least 60 years of age and who fit study inclusion criteria. Each hospital was requested to send medical records abstracts and FIM reports for each identified patient in order to capture all study variables. Because the control hospitals did not send data on every study-appropriate patient admitted to the rehabilitation unit during the study period, it was important that the control subjects be selected randomly. This was accomplished by both hospitals. One hospital sent data on every third study-appropriate patient admitted during the study period. The second control hospital sent data for the first 20 study-appropriate patients admitted during the study period. As admissions from this second hospital were well-distributed over the study time-frame, no seasonal bias was introduced. No incentives of any kind were offered to subjects for study participation. Additionally, no advertising was used to recruit patients into the study.

Description of the Study Protocol

This study was based at the RehabCenter Rehabilitation Unit of the Osteopathic Medical Center of Texas (OMCT) and the Division of Healthcare Analysis and Management of the Office of Research and Biotechnology at UNTHSC. The study was presented to the Institutional Review Boards (IRBs) of both UNTHSC and OMCT in November, 1996 and was passed by both without any modification. A copy of the approved informed consent is provided in Appendix A.

All patients admitted to a RehabCare-managed, inpatient rehabilitation unit with a primary diagnosis of hip fracture or osteoarthritis affecting the knee or hip, either unilaterally or bilaterally, were eligible to participate as long as they had recently undergone (within one week prior to rehabilitation unit admission) a surgical procedure for either of these conditions. This surgical intervention had to be one of the following types: arthroplasty or open-reduction-internal-fixation (ORIF) for a hip fracture, arthroplasty for hip or knee osteoarthritis, or a revision for a previous hip or knee arthroplasty. The surgical procedure could have been performed unilaterally or bilaterally. In every case, diagnosis of hip fracture or osteoarthritis had been made by an orthopedic surgeon on that particular rehabilitation unit's treatment team, and surgical procedures were performed by these same orthopedic surgeons

in the rehabilitation unit's host hospital. After post-operative stabilization, subjects were transferred to the rehabilitation unit. Mean time from the date of surgery to the date of admission to the rehabilitation unit for the OMT group and control group, respectively, was 4.20 days (S.D., 1.88; Range, 2 - 9), and 5.30 days (S.D., 2.56; Range, 2 - 16).

All RehabCare-managed rehabilitation units employ similar therapies and treatments and have similar management policies and procedures. All personnel staffing these units, except nursing staff, are employed via contract with RehabCare Inc. Additionally, all of these units use the FIM as the primary measure of disability. Characteristics of the rehabilitation unit in which a patient receives treatment can potentially influence the response to therapy. Therefore, since the treatment population was seen through a RehabCare-managed unit, it was decided to use only those patients admitted to RehabCare-managed units as control subjects in order to minimize introducing bias due to treatment or management variations among different rehabilitation units.

Beginning on 12/1/96, the unit admissions administrator of the RehabCenter rehabilitation unit of OMCT began screening all incoming unit admissions for a primary diagnosis of hip fracture or hip/knee osteoarthritis. Once a potential study candidate was identified, the admissions

administrator notified one of the study physiatrists, who were both members of RehabCenter's treatment team. The study physiatrist verified the appropriateness of the patient for inclusion in the study and then contacted the study coordinator. The study coordinator had approximately five years experience in coordinating clinical trials of pharmaceuticals and was a student in the Epidemiology Track of the Public Health Program at UNTHSC. The study coordinator explained the study procedures and administered verbal and written informed consent to each of the subjects in the treatment group within the first few days of admission.

The study coordinator was responsible for alerting the OMT consultant to every potential study admission. The OMT consultant was an osteopathic physician and manipulative medicine specialist on the faculty of the Osteopathic Manipulative Medicine Department at UNTHSC and on the medical staff at OMCT. The consultant had 22 years of experience performing OMT. Each subject in the treatment group underwent a comprehensive osteopathic manipulative medicine assessment by the OMT consultant and a manipulative medicine resident. This consultation consisted of a complete medical history, physical and neurological exams, assessment of somatic dysfunction, and the development of OMT protocol specific to the subject's needs. The OMT protocol addressed the primary and

secondary diagnostic areas and was formulated according to the following parameters: a.) study patients were to receive three to five OMT treatments per week during the entire course of their stay in the RehabCenter with no more than two days between treatments; b.) OMT treatments were to last 10-30 minutes and be performed by a physician trained in OMT; and c.) osteopathic manipulative techniques could include one or a combination of the following: myofascial release, strain/counter-strain, muscle energy, soft tissue, high-velocity-low-amplitude (not at the surgical site), and cranial/sacral. These are all widely-accepted and highly-utilized osteopathic manipulative techniques. All areas of somatic dysfunction found in each study subject were treated. OMT was not limited just to the surgical site.

The OMT protocol guidelines utilized in this study were the product of several weeks discussion among members of the research team and numerous osteopathic manipulative medicine specialists. As discussed in chapter 2, there is insufficient information in the medical literature to answer even the most basic questions about OMT efficacy. How many OMT sessions should occur per week? What is the optimal length for each session? Which osteopathic manipulative techniques should be used, and in which areas? All of these questions spurred considerable debate among the OMM specialists, especially considering there is insufficient OMT research

evidence to provide direction in this area. One commonly voiced concern was that each proposed set of guidelines was too restricted, not allowing for customization of an OMT protocol to each subject's needs and limitations. Even though the research team finally agreed to a set of generally-written OMT guidelines, some team members felt even these were too restricted.

OMT sessions were performed on each treated subject by a 2nd-year manipulative medicine resident in accordance with the OMT protocol established with the OMT consultant. As the OMT protocol did not specify the length or frequency of OMT treatments to be performed, these elements were left to the judgement of the resident (within the parameters of the established OMT protocol guidelines). Due to occasional unavailability of the resident, 11 (18.30%) of the OMT treatments were performed by the principal investigator's nurse, who has over 20 years experience in administering OMT, and 12 (20.00%) of the OMT treatments were performed by third-year osteopathic medical students from UNTHSC who were on rotations in the Department of Osteopathic Manipulative Medicine during the study period. The remaining 37 (61.60%) treatments were given by the OMM resident.

All OMT performed at OMCT is recorded in the progress notes section

of the medical record. Progress notes of a hospital medical record usually vary considerably in the type and completeness of information recorded. For this study, a more systematic and standardized OMT recording mechanism was necessary to ensure complete and easily understood documentation of each OMT session. Therefore, an osteopathic manipulative treatment log was created for this purpose. A copy of this form is given in Appendix B. Every OMT session was recorded on OMT logs kept for each treated subject. Because all information recorded on the OMT logs would be essentially the same as would be recorded in the progress notes of the medical record, the research team proposed the OMT log be incorporated into the medical record in lieu of recording manipulative treatments in the progress notes. Approval to do this had to be granted by the Medical Records Review Committee of OMCT. The study coordinator submitted a written proposal to the committee and attended its monthly meeting in November, 1996. After considerable discussion, the committee approved usage of the form in the medical record on a 90-day trial basis. In February, 1997, the committee decided that use of the OMT log in the medical record would no longer be approved. The letter sent by the committee to the research team gave the following reason for discontinuation of approval: "The medical record must clearly communicate to a multitude of parties

including various health care disciplines..... The Medical Records Committee feels that the information is available in the medical record and the addition of a form will only serve to confuse communication in the future".

Each treated subject's progression through the study was monitored by the study coordinator. After each subject was discharged, specific demographic and diagnostic variables relating to that subject were collected by the study coordinator through the review of two reports. The RehabCenter Administrative Director generated a FIM score profile report from the RehabCare database. This report included admission and discharge FIM scores for all 18 items and summary totals. The Medical Records Supervisor for OMCT generated a medical abstract report for each discharged subject which provided the majority of the remaining needed information. The variables collected on all study subjects were: age, gender, ethnicity, patient's marital status, rehabilitation unit primary admitting diagnosis, date and type of surgical procedure performed for admitting diagnosis, rehabilitation unit admission and discharge dates, admission and discharge FIM score totals, admission and discharge FIM scale scores for all 18 items, listing of all comorbid conditions the subject was admitted to the rehabilitation unit with, type of insurance coverage the patient had, hospital admission origin and discharge destination and a

notation of whether the patient had been admitted to a hospital for a hip fracture of hip/knee osteoarthritis. The research team agreed that these were the main variables which could potentially influence a subject's response to treatment and should therefore be taken into consideration when performing the data analysis. For each subject, data from these two reports was transcribed onto customized "patient information forms" by the study coordinator. This was done to streamline the data entry process for analysis.

The Functional Independence Measure Instrument

The Functional Independence Measure Instrument (FIM) originated in the early 1980s with passage of the Social Security Amendments and subsequent creation of the diagnosis-related group (DRG) (Hamilton, et al., 1987). The DRG changed the way acute care hospitals were reimbursed for provided services by paying a predetermined amount for all patients with the same admitting diagnosis, based on the DRG, regardless of what the care actually cost (Hamilton, et al.). This was a significant change from reimbursement based on the fee-for-service system and created special problems for rehabilitation units, since their patients are treated not on the basis of *diagnosis*, but rather on the basis of *disability* (Hamilton, et al.).

Thus, length-of-stay on a rehabilitation unit is generally longer than length-of-stay on other acute care units. These reimbursement policy changes underscored the need for the creation of a uniform national data system for medical rehabilitation (Hamilton, et al.). The National Association of Rehabilitation Facilities (NARF) recommended: "A patient classification system, coding system, and uniform patient assessment instrument need to be developed for inpatients of rehabilitation hospitals so that the industry's 'products' can be defined accurately" (Hamilton, et.al.).

In October, 1983 a task force of members of the American Congress of Rehabilitation Medicine (ACRM) and the American Academy of Physical Medicine and Rehabilitation (AAPMR) was formed to develop a data set that would document the outcomes and real costs of medical rehabilitation (Hamilton, et al., 1987). Over the next year, this task force developed the FIM to be used as the functional assessment measure of a Uniform Data System for Medical Rehabilitation (UDS_{MR}), which is currently based at the State University of New York at Buffalo and has four components: a.) a data set that contains a minimum number of items used to determine the severity of disability of persons with impairments and the outcomes of medical rehabilitative care; b.) computer databank of patient information from subscribing hospitals; c.) a data management service that provides data

processing for subscribing facilities to collect and report individual facility, regional, and national data on a continuous basis, and d.) a training program designed to achieve and maintain national uniformity and reliability through credentialing of raters and review of facility reports (Granger and Brownscheidle, 1995).

The FIM was designed to measure the burden of care (type and amount of assistance) required for a disabled person to effectively perform basic life activities (Hamilton, et al., 1987). This burden of care should translate into consumption of social and economic resources and, thus, the FIM should ultimately reflect the cost of *disability* in social and economic terms (Hamilton, et al.). The FIM was not designed to measure *all* basic life activities, but rather a selected *minimum* number of key activities deemed to be necessary and sufficient indicators of the level or cost of disability (Hamilton, et al.). The task force reviewed several different disability rating instruments in developing the FIM (Hamilton, et al.). The goal was to develop a rating scale of common and useful functional assessment items that would be used by numerous rehabilitation facilities and which had the following characteristics: a.) quick to use, b.) easy to administer, c.) valid, d.) reliable, e.) discipline-free, and f.) acceptable to clinicians (Granger and Brownscheidle, 1995).

The FIM instrument is a minimal data set designed to assess functional independence (Hamilton, et al., 1987). The FIM includes 18 items covering independence level in self-care, sphincter control, mobility, locomotion, communication, and social cognition (McDowell and Newell, 1996). Each item is rated on an ordinal scale with a minimum possible score of 1 and a maximum possible score of 7 to give an overall FIM score total ranging from 18 to 126 (McDowell and Newell, 1996). Ratings are based on activities actually performed rather than on activities the patient is merely capable of doing (McDowell and Newell, 1996). The seven-point ratings represent different gradations of independence and reflect the amount of assistance the patient requires to perform a specific activity (McDowell and Newell, 1996). A complete description of the FIM seven-point rating scale is given in Table 1. A listing and description of the 18 scaled terms of the FIM is provided in Table 2. As can be seen from the rating scale information, there is a substantial amount of clinical judgement that must be employed when rating each activity.

FIM items are usually rated by different members of the rehabilitation unit treatment team: physicians, nurses, physical therapists, occupational therapists, recreational therapists, speech therapists, social workers, and psychologists. In the RehabCenter, there are two occupational therapists,

TABLE 1

Description of FIM Levels of Function and Their Scores

INDEPENDENT--Another person is not required for the activity (no helper).

7 **Complete Independence**--All of the tasks described as making up the activity are typically performed safely, without modification, assistive devices, or aids, and within a reasonable time.

6 **Modified Independence**--Activity requires any one or more of the following: an assistive device, more than reasonable time, or there are safety (risk) considerations.

DEPENDENT--Another person is required for either supervision or physical assistance in order for the activity to be performed, or it is not performed (requires helper).

Modified Independence--The subject expends half (50%) or more of the effort.The levels of assistance required are:

5 **Supervision or Setup**--Subject requires no more help than standby, cuing, or coaxing, without physical contact. Or, helper sets up needed items or applies orthoses.

4 **Minimal Contact Assistance**--With physical contact, the subject requires no more help than touching, and subject expends 75% or more of the effort.

3 **Moderate Assistance**--Subject requires more help than touching, or expends half (50%) or more (up to 75%) of the effort.

COMPLETE DEPENDENCE--The subject expends *less* than half (*less* than 50%) of the effort. Maximal or total assistance is required, or the activity is not performed. The levels of assistance required are:

2 **Maximal Assistance**--Subject expends less than 50% of the effort, but at east 25%.

1 **Total Assistance**--Subject expends less than 25% of the effort.

Note. From Measuring Health: A Guide to Rating Scales and Questionnaires (pp. 116-117), by Ian McDowell and Claire Newell, 1996, New York: Oxford University Press. Copyright 1996 by Oxford University Press.

TABLE 2

FIM Subscale Descriptions

SELF-CARE

Eating--Includes use of suitable utensils to bring food to mouth, chewing and swallowing, once meal is appropriately prepared.

Grooming--Includes oral care, hair grooming, washing hands and face, and either shaving or applying makeup.

Bathing--Includes bathing the body from the neck down (excluding the back), either tub, shower, or sponge/bed bath. Performs safely.

Dressing--Upper Body--Includes dressing above the waist as well as donning and removing prosthesis or orthosis when applicable.

Dressing--Lower Body--Includes dressing from the waist down as well as donning or removing prosthesis or orthosis when applicable.

Toileting--Includes maintaining perineal hygiene and adjusting clothing before and after toilet or bed pan use. Performs safely.

SPHINCTER CONTROL

Bladder Management--Includes complete intentional control of urinary bladder and use of equipment or agents necessary for bladder control.

Bowel Management--Includes complete intentional control of bowel movement and use of equipment or agents necessary for bowel control.

MOBILITY

Transfers: Bed, Chair, Wheelchair--Includes all aspects of transferring to and from bed, chair, and wheelchair, and coming to a standing position, if walking is the typical mode of locomotion.

Transfer: Toilet--Includes getting on and off a toilet.

Transfers: Tub or Shower--Includes getting into and out of a tub or shower stall.

TABLE 2
continued

LOCOMOTION

Walking or Using Wheelchair--Includes walking, once in a standing position, or using a wheelchair, once in a seated position, on a level surface.

Stairs--Goes up and down 12 to 14 stairs (one flight) indoors.

COMMUNICATION

Comprehension--Includes understanding of either auditory or visual communication (e.g. writing, sign language, gestures).

Expression--Includes clear vocal or non-vocal expression of language. This item includes both intelligible speech or clear expression of language using writing or a communication device.

SOCIAL COGNITION

Social Interaction--Includes skills related to getting along and participating with others in therapeutic and social situations. It represents how one deals with one's needs *together* with the needs of others.

Problem Solving--Includes skills related to solving problems of daily living. This means making reasonable, safe, and timely decisions regarding financial, social, and personal affairs and initiating, sequencing, and self-correcting tasks and activities to solve the problems.

Memory--Includes skills related to recognizing and remembering while performing daily activities in an institutional or community setting. It includes ability to store and retrieve information, particularly verbal and visual. A deficit in memory impairs learning as well as performance of tasks.

Note. From Measuring Health: A Guide to Rating Scales and Questionnaires (pp. 116-117), by Ian McDowell and Claire Newell, 1996, New York: Oxford University Press. Copyright 1996 by Oxford University Press.

one physical therapist, one psychologist, two social workers, one recreational therapist, and one speech therapist who are available Monday through Friday from 8:00 A.M. to 5:00 P.M., and as needed on Saturdays. In addition, the RehabCenter is run by two physicians trained in rehabilitative medicine and is staffed by at least two registered nurses, one licensed vocational nurse, and one nurse technician at all times. The type of therapist responsible for rating each FIM item is listed with the information provided in Table 3.

Validity and reliability of the FIM were initially assessed through a pilot study of the FIM that began in January, 1985 and ended in April 1986 (Hamilton, et al., 1987). During this study, 1,005 clinicians representing the various disciplines of rehabilitative medicine (i.e.- occupational therapy, psychology) at 36 rehabilitation facilities administered the FIM to a total of 360 patients (Hamilton, et al.). The average number of years of clinical rehabilitation experience among these clinicians was 5.80 (Hamilton, et al.). Face validity, the judgement that test items cover areas that are important to medical rehabilitation, was assessed by asking the clinicians who administered the FIM four questions:

TABLE 3

Types of Therapists Responsible for FIM Subscale Evaluations

FIM Subscale Category	Type of Therapist Who Evaluates
Eating	Speech Therapist
Grooming	Occupational Therapist
Bathing	Occupational Therapist
Upper Body Dressing	Occupational Therapist
Lower Body Dressing	Occupational Therapist
Toileting	Nurse
Bladder Management	Nurse
Bowel Management	Nurse
Bed, Chair Transfers	Physical Therapist
Tub, Shower Transfers	Occupational Therapist
Toilet Transfers	Occupational Therapist
Walking/Wheelchair Mobility	Physical Therapist
Stairs	Physical Therapist
Comprehension	Speech Therapist
Communication	Speech Therapist
Social Interaction	Speech Therapist
Problem Solving Skills	Speech Therapist
Memory	Speech Therapist

Note. From RehabCenter Staff, Personal Communication.

1. Were there items that were difficult to understand?
2. Were there items that were unnecessary?
3. Were there items that should be added?
4. How would you rate the FIM as a measure of severity of disability on a 1 to 5 scale, with 1 = poor, 3 = OK, and 5 = excellent? (Hamilton, et al).

The percentages of respondents who gave positive responses were: 12.00% for question 1, 3.00% for question 2, and 17.00% for question 3 (Hamilton et al.). Overall rating for question 4 was 3.44 (Hamilton et al.). Content validity, the judgement that test items represent medical rehabilitation domains well, was also assessed through asking these four questions (Dodds, Martin, Stolov, and Deyo, 1993). Based in part on this validity data, subcategories were added to the "Modified Dependence" and " Complete Dependence" categories after the pilot study (Hamilton, et al.). Other minor refinements in the FIM helped to improve both face and content validity after the pilot study (Hamilton, et al.).

Construct validity, the extent to which explanatory concepts account for test performance, has also been examined in the FIM (Dodds, et al., 1993). In a study of 11,102 rehabilitation inpatients, Dodds et al. posed several hypotheses about how FIM scores should vary with the presence of certain comorbid conditions in order to test FIM construct validity:

1. FIM scores should decrease with increasing age or comorbidity.

2. FIM scores should vary with patient discharge destination according to the level of care usually provided in a given setting.
3. FIM scores among amputee subjects should decrease with increased amputation severity.
4. FIM scores among persons with spinal cord injury should decrease with ascending injury level.
5. FIM scores of persons with right body-involved stroke should demonstrate lower communication subscale scores that left body-involved patients.

All of these hypotheses, with the exception of hypothesis number 3, were proved at a significance level of $p<.005$ (Dodds, et al.). The FIM appears to discriminate among patients on the basis of age, comorbidity, and discharge destination (Dodds, et al.). The FIM also demonstrates good internal consistency, Dodds et al. examined temporal changes between admission and discharge FIM scores by using paired t-tests, each of which was found to be significant at $p<.001$. Cronbach's α, which reflects the degree to which different items of a questionnaire correlate with all other items, was high on total and subscale FIM scores (overall admission FIM total $\alpha = 0.93$, overall discharge FIM total $\alpha = 0.95$) (Dodds, et al.). This indicates high internal consistency of the FIM.

In the pilot study of the FIM referenced above, test reliability was assessed through pairs of physicians, nurses, and therapists at 25 facilities rating a total of 263 patients on admission and discharge (Granger and Hamilton, 1987). Kappa (K) values, which measure the extent to which

agreement exists beyond that expected by chance alone, were calculated for subscale and total FIM scores (Granger and Hamilton, 1987). There is no consensus on most reliability coefficients as to cutoff values that determine acceptable reliability. However, one proposed set of rules for the K statistic gives the following parameters: 0.00 to <0.40, poor agreement; 0.40 to <0.75, fair to good agreement; >0.75, excellent agreement (Oleske, 1995). The mean K index of agreement between ratings for each item was found to be 0.71, indicating a fair to good reliability according to the described K limits (Granger and Hamilton, 1987). From this same study, intraclass correlation coefficients (ICC's) calculated for each of the 18 FIM items ranged from 0.93 to 0.96 (McDowell and Newell, 1996).

A subsequent study of FIM reliability examined data from 89 inpatient rehabilitation units, all of which subscribed to the UDS_{MR} (Hamilton, Laughlin, Fielder, and Granger, 1994). Pairs of clinicians, nurses, and therapists from these facilities evaluated 1,018 patients with the FIM (Hamilton, et al.). ICC and K coefficients were calculated yielding the following results: total FIM ICC, 0.96; FIM subscale score range, 0.89-0.94; FIM K range, 0.53-0.66 (Hamilton, et al.). These values indicate the FIM is reliable in acute, inpatient, medical rehabilitation facilities.

Data Entry and Analysis Strategy

Twenty subjects composed the OMT treatment group, and forty subjects composed the control group. Each group was analyzed separately according to the following variables: age, gender, ethnicity, marital status, insurance type, admission origin, discharge destination, history of previous hospital admission for hip fracture or hip/knee osteoarthritis, primary admitting diagnosis, number of comorbid conditions, length-of-stay in the rehabilitation unit, FIM score total on admission, FIM score total at discharge, and the total FIM score change from admission to discharge. The study team attempted to obtain total billed charges for each subject during their stay in the rehabilitation unit since this is an important outcome measure, especially under the umbrella of managed healthcare; however, no participating hospital was willing to release this data to the study team. Standard descriptive statistics (mean, standard deviation, frequency, and range of values) were calculated for these variables for each group. Additionally, mean FIM score changes from admission to discharge were calculated for both groups for each of the 18 FIM subscales.

To test for statistical significance of mean differences between the OMT and control groups, an independent samples t-test was performed for each of the variables listed above, as well as for each of the 18 FIM

subscales. Statistical significance was defined as $p < .05$ for each calculated t-value.

After descriptive statistics had been calculated, the data were reviewed not only to identify patterns and trends among the two study groups, but also to select those variables that were most likely to affect the two principal outcome measures: total FIM score change from admission to discharge and length-of-stay. Multiple linear regression models were used to examine the utility of specific, identified variables, particularly the receipt of OMT, in predicting the two outcome measures.

All analyses were performed using SPSS (version 6.1.2) statistical software. Each study variable was coded and appropriate data transformations were made prior to entry into SPSS. Coding values assigned to each variable are provided in Table 4. Note that many of the variables, such as ethnicity, type of insurance coverage, and marital status, were consolidated into two groups. The decision to do this was based on both the small sample size of the study population and the lack of significant diversity in these groups (i.e. only 10.00% of the OMT group and 12.50% of the control group were non-Caucasian). Creating multiple categories for these variables would probably not have added any additional value to the analyses performed, given their small numbers. Finally, the variable labeled

TABLE 4

Coding Rules Used for SPSS Data Entry

AGE Actual age in years entered

GROUP 0 = Control Group
1 = Treatment Group

GENDER 1 = Male
2 = Female

ETHNICITY 1 = Caucasian
2 = Other

ADMISSION FIM SCORE TOTAL Actual value entered

DISCHARGE FIM SCORE TOTAL Actual value entered

FIM SCORE TOTAL CHANGE (from admission to discharge) Actual value entered

FIM SUBSCALE SCORE CHANGES FROM ADMISSION TO DISCHARGE
-6 to 6 for 18 scales

TYPE OF INSURANCE COVERAGE 1 = Medicare
2 = Other

HX. OF PREVIOUS HOSPITAL ADMISSION FOR SURGICAL PROCEDURE FOR A HIP FX. OR HIP/KNEE OSTEOARTHRITIS
0 = No
1 = Yes

LENGTH OF STAY IN REHAB. UNIT Actual value entered (in days)

ADMISSION ORIGIN 1 = Home
2 = Other

DISCHARGE DESTINATION 1 = Home
2 = Other

MARITAL STATUS 1 = Married
2 = Other

MONTHS OF EXPERIENCE ADMINISTERING THE FIM INSTRUMENT
Actual value entered (in months)
NOTE: This was calculated as the mean for all individuals who administer the FIM Instrument at each unit.

NUMBER OF COMORBID CONDITIONS Actual number entered

TYPE OF COMORBID CONDITONS Neurological, Musculoskeletal, Endocrine, Pyschiatric, and Other. For each category, 0 = No, 1 = Yes. A "Yes" response means the patient has at least one diagnosis in the specified category.

ADMITTING DIAGNOSIS Hip Fracture (0 = No, 1 = Yes)
Hip Osteoarthritis (0 = No, 1 = Unilateral, 2 = Bilateral)
Knee Osteoarthritis (same as above)

SURGICAL CORRECTIVE PROCEDURE
ORIF to Hip (0 = No, 1 = Yes)
Arthroplasty to Hip (0 = No, 1 = Unilateral, 2 = Bilateral)
Arthroplasty to Knee (0 = No, 1 = Unilateral, 2 = Bilateral)
Revision to Knee (0 = No, 1 = Yes)
Revision to Hip (0 = No, 1 = Yes)

"months of experience using the FIM Instrument" was calculated as the mean for all individuals who administered the FIM Instrument at each unit. The rehabilitation unit program directors at each of the two control hospitals and the RehabCenter asked each member of the treatment team how many months experience administering the FIM he/she had. A listing of the months experience from each hospital was sent to the study coordinator who then calculated the mean for the control hospitals and for the RehabCenter. The mean months experience using the FIM Instrument among the rehabilitation unit staff was 32.20 for the RehabCenter and 32.40 for the control hospitals.

CHAPTER 4

RESULTS

Characteristics of the OMT and Control Groups

Characteristics of both the OMT and control populations are given in Tables 5 and 6, respectively. In general, subjects in both groups tended to be elderly, Caucasian females who live at home. All study subjects were discharged to the same place they were admitted from (i.e. if a subject was admitted from home, he was discharged back to home). The OMT group had a greater percentage of subjects admitted with hip fracture than the control group (45.00% vs. 22.50%). Conversely, the control group had a higher percentage of patients admitted with knee osteoarthritis (65.00% vs. 40.00%). Admissions for hip osteoarthritis were similar (OMT group, 15.00%; control group, 12.50%). Mean length-of-stay on the rehabilitation unit was 3.18 days shorter for the OMT group than for the control group (12.15 days vs. 15.33 days).

The three variables that demonstrated a statistically significant difference between the OMT and control groups were: insurance type ($p = .01$), history of previous admission for hip fracture or hip/knee

TABLE 5

OMT Group Characteristics (N = 20)

Trait Name	Frequency
Gender	Males 6 (30%) Females 14 (70%)
Ethnicity	Caucasian 18 (90%) Other 2 (10%)
Admission Origin	Home 19 (95%) Other 1 (5%)
Discharge Destination	Home 19 (95%) Other 1 (5%)
Insurance Type †	Medicare 11 (55%) Other 9 (45%)
Marital Status	Married 7 (35%) Other 13 (65%)
Hx. Prev. Admission † for Study Condition(s)	Yes 2 (10%) No 18 (90%)
Admitting Diagnosis	Hip Fx. 9 (45%) Unilateral Hip Osteo. 3 (15%) Unilateral Knee Osteo. 4 (20%) Bilateral Knee Osteo. 4 (20%)

Trait Name	Mean and S.D.	Range
Age	72.55 Years; S.D., 13.55	44 - 89 Years
Length-of-Stay in RehabCenter	12.15 Days; S.D., 6.58	5 - 28 Days
Number of Comorbid Conditions †	7.55; S.D., 3.83	1 - 15
FIM Total on Admission	83.85; S.D., 13.05	55 - 99
FIM Total at Discharge	109.80; S.D., 12.53	76 - 123
Total FIM Score Change	25.95; S.D., 9.50	3 - 45

† Independent samples t-test significant at $p < .05$ (compared to control group)

TABLE 6

Control Group Characteristics (N = 40)

Trait Name	Frequency
Gender	Males 7 (17.5%) Females 33 (82.5%)
Ethnicity	Caucasian 35 (87.5%) Other 5 (12.5%)
Admission Origin	Home 36 (90%) Other 4 (10%)
Discharge Destination	Home 36 (90%) Other 4 (10%)
Insurance Type †	Medicare 35 (87.5%) Other 5 (12.5%)
Marital Status	Married 21 (52.5%) Other 19 (47.5%)
Hx. Prev. Admission † for Study Condition(s)	Yes 13 (32.5%) No 27 (67.5%)
Admitting Diagnosis	Hip Fx. 9 (22.5%) Unilateral Hip Osteo. 5 (12.5%) Unilateral Knee Osteo. 26 (65%)

Trait Name	Mean and S.D.	Range
Age	74.12 Years; S.D., 8.80	60 - 93 Years
Length-of-Stay in RehabCenter	15.33 Days; S.D., 7.16	2 - 37 Days
Number of Comorbid Conditions †	2.53; S.D., 1.92	0 - 9
FIM Total on Admission	78.70; S.D., 14.35	44 - 101
FIM Total at Discharge	106.35; S.D., 13.40	72 - 119
Total FIM Score Change	27.65; S.D., 9.44	2 - 52

† Independent samples t-test significant at $p < .05$ (compared to OMT group)

osteoarthritis ($p = .03$), and number of comorbid conditions ($p < .001$). For insurance type, the percentage of subjects covered by Medicare versus private insurance or HMO coverage was lower for the OMT group than for the control group (55.00% vs. 87.50%). Fewer subjects in the OMT group had a history of prior admission for any of the study conditions (10.00% vs. 32.50%). Finally, subjects in the OMT group had more overall comorbid conditions present than the control group (7.55 vs. 2.53).

It is likely that the reported mean number of comorbid conditions among subjects in the control hospitals was an underestimate. For every OMT subject, the study coordinator reviewed both the physical medical record and the computer-generated medical records abstract to obtain all comorbid conditions present. This level of inquiry was probably not used at either of the control hospitals due to time constraints of the staff charged with extracting the data. Concerns about the length of time required for data extraction were voiced to the study coordinator numerous times by rehabilitation unit staff at the control hospitals. More objective evidence that the number of comorbid conditions was underestimated comes from the mean admission FIM score total and the mean time from surgery to admission to the rehabilitation unit. In chapter 3, it was noted that the mean time from the date of surgery to the date of admission to the rehabilitation

unit was longer for the control group than for the OMT group (5.30 days vs. 4.20 days). From tables 5 and 6, the FIM score total on admission was lower for subjects in the control group than in the OMT group (78.70 vs. 83.85). Both pieces of evidence appear to indicate that subjects in the control group experienced more post-operative complications and/or were more ill (i.e. had more comorbid conditions present). Given these results, it is difficult to understand how the control subjects, who had lower average admission FIM score totals and a longer length-of-stay, had an average of 5.02 comorbid conditions *less* than the "healthier" OMT subjects.

FIM Characteristics

As stated above, admission FIM score totals were lower for subjects in the control group than for subjects in the OMT group. All study subjects had increased FIM score totals compared to admission. Total FIM score changes from admission to discharge were similar for both the OMT and control groups (25.95 vs. 27.65).

Although there was no significant difference in total FIM score change between subjects in the two groups, there were differences seen in the individual FIM subscale items. Table 7 lists the mean FIM subscale score change experienced by subjects in both groups for each of the 18 FIM

items. Independent samples t-tests were performed for each item with the following statistically significant differences between the OMT and control group identified: bathing ($p < .001$), bowel management ($p = .002$), walking/wheelchair use ($p < .001$), and stairs ($p = .003$). t-tests performed on the other FIM items revealed no other statistically significant differences between the OMT and control groups. From Table 7, control subjects demonstrated more improvement in bathing and bowel management skills, but OMT subjects demonstrated greater increases in walking/wheelchair use ability and stair-climbing ability than control subjects. Both walking/wheelchair use and stair-climbing compose the locomotion construct of the FIM measure.

It is important to interpret the improvements seen in OMT subjects for these two locomotion items with caution. First, the OMT group was comprised of only 20 subjects. Second, no corrective procedure was applied when the t-tests were performed on this data. It is well-known that whenever multiple t-tests are performed to test hypotheses, the studywise type I error is inflated. To compensate for this, the Bonferroni Correction Procedure can be applied. This procedure divides the assigned type I error (.05 for this study) by the number of t-tests performed. If the Bonferroni Correction had been applied to the FIM subscale

TABLE 7

Mean FIM Subscale Score Changes--OMT vs. Control Group
[Mean ± S.D. (Range)]

FIM Item Description	OMT Group	Control Group
Eating	.15 ± .67 (0.0 - 3.0)	.58 ± 1.13 (0.0 - 5.0)
Grooming	.90 ± 1.25 (-2.0 - 3.0)	.90 ± .90 (0.0 - 3.0)
Bathing †	2.20 ± 1.15 (1.0 - 5.0)	3.65 ± 1.37 (0.0 - 6.0)
Upper Body Dressing	.95 ± 1.15 (-2.0 - 3.0)	.93 ± .94 (0.0 - 3.0)
Lower Body Dressing	2.45 ± 1.00 (0.0 - 4.0)	2.80 ± 1.20 (0.0 - 5.0)
Toileting	1.60 ± 1.14 (0.0 - 4.0)	2.12 ± 1.30 (0.0 - 5.0)
Bladder	1.95 ± 2.16 (0.0 - 6.0)	2.23 ± 2.38 (-3.0 - 6.0)
Bowel †	.40 ± .94 (0.0 - 4.0)	1.43 ± 1.41 (-2.0 - 4.0)
Bed, Chair Transfers	2.20 ± .89 (0.0 - 4.0)	1.88 ± 1.16 (0.0 - 5.0)
Toilet Transfers	2.05 ± 1.10 (0.0 - 4.0)	1.97 ± 1.19 (0.0 - 5.0)
Tub, Shower Transfers	2.65 ± 1.66 (0.0 - 6.0)	3.27 ± 1.54 (0.0 - 5.0)
Walking/Wheelchair Use †	4.00 ± 1.17 (1.0 - 5.0)	2.25 ± 1.39 (0.0 - 5.0)
Stairs †	3.80 ± 1.47 (0.0 - 5.0)	2.38 ± 1.93 (0.0 - 5.0)
Comprehension	.10 ± .31 (0.0 - 1.0)	.15 ± .53 (0.0 - 3.0)
Expression	.05 ± .22 (0.0 - 1.0)	.13 ± .52 (0.0 - 3.0)
Social Interaction	.25 ± .64 (-1.0 - 2.0)	.38 ± .67 (0.0 - 2.0)
Problem Solving	.20 ± .52 (0.0 - 2.0)	.35 ± .74 (0.0 - 4.0)
Memory	.05 ± .22 (0.0 - 1.0)	.28 ± .72 (0.0 - 4.0)

† Independent samples t-test significant at $p < .01$

data, the resulting p-value would have been lowered to .05/18 = .002. Because of the small N in this study, the study team felt that $p < .002$ was too stringent a p-value and would possibly eliminate any possibility of finding a statistically significant difference. Therefore, it was decided not to use Bonferroni's Correction and to accept this limitation in interpreting the data. As it turned out, most of the statistically significant differences were at $p < .002$, so not using the Bonferroni Correction was not a significant limitation. Finally, there were significant problems with the OMM resident who performed the OMT treatments. One consequence of these problems was that many of the OMT subjects were not treated according to the OMT treatment guidelines set forth in chapter 3. A complete discussion of these issues follows in the next section.

OMT Descriptive Patterns and Data Reconciliation

Without question, the most challenging aspect of this study was ensuring that each subject in the OMT group received manipulative treatments according to the OMT protocol guidelines outlined in chapter 3. Each subject in the OMT group did receive at least one manipulative treatment; however, several patients, unfortunately, were not provided OMT according to protocol. Table 8 lists the number of manipulative treatments

administered to each OMT subject. Note from this table that one subject dropped out of the study three days after admission to the RehabCenter claiming the OMT treatments were 'painful'. Also, no OMT consult was performed on one subject due to an administrative error. Both of these subjects were included in all analyses performed. The mean number of manipulative treatments provided to each subject was 3.00 (S.D., 1.97; Range, 1 - 9). A total of 60 manipulative treatments were administered to the 20 subjects in the OMT group. As stated in chapter 3, 11 (18.30%) of the treatments were provided by the principal investigator's nurse, 12 (20.00%) of the treatments were performed by third-year osteopathic medical students from UNTHSC who were on rotations in the Department of Osteopathic Manipulative Medicine during the study period, and the remaining 37 (61.60%) treatments were provided by the OMM resident.

A number of difficulties interfered with the administration of OMT according to the OMT protocol guidelines. First, the admissions coordinator was inconsistent in notifying the study physiatrists of potential study patient admissions to the RehabCenter. Because of this, the consult process was delayed for some of the OMT subjects. The mean time from the day of admission to the RehabCenter to the day of OMT consult was 2.00 days (range = 0 - 6 days). The delay of the OMT consult beyond the first 48 hours

OMT Group Manipulative Treatment Summary

Subject I.D.	Admission Date	Discharge Date	Consult Date	Treatment Dates
1	1/7/97	1/13/97	1/8/97	**1/8, 1/11, 1/12**
2	1/15/97	1/23/97	1/15/97	**1/16, 1/17, 1/20, 1/22**
3	1/19/97	2/14/97	1/23/97	**1/25, 1/28, 1/31, 2/3, 2/5, 2/7, 2/10, 2/13, 2/14**
4	1/28/97	2/7/97	1/29/97	**1/31, 2/3, 2/5**
5	1/28/97	2/2/97	1/28/97	**1/31**
6	2/11/97	2/28/97	Pt. dropped out on 2/14/97 *	**2/14**
7	2/12/97	3/4/97	No Consult Done	**2/14, 2/20, 2/22**
8	2/17/97	2/25/97	2/18/97	**2/20, 2/22**
9	2/25/97	3/4/97	2/27/97	**2/28**
10	2/26/97	3/11/97	2/27/97	**2/28, 3/4, 3/6, 3/9**
11	3/2/97	3/10/97	3/3/97	**3/6, 3/9**
12	3/4/97	3/14/97	3/7/97	**3/9, 3/13**
13	3/7/97	3/25/97	3/11/97	**3/14, 3/16, 3/17, 3/19, 3/24**
14	3/25/97	4/4/97	3/28/97	**3/31**
15	4/7/97	4/16/97	4/9/97	**4/10, *4/14*, 4/15**
16	4/8/97	4/16/97	4/10/97	**4/10, 4/15**
17	4/10/97	5/2/97	4/11/97	**4/15, *4/18, 4/21*, 4/24, 4/28**
18	4/13/97	4/23/97	4/14/97	***4/16, 4/17, 4/18***
19	4/14/97	4/23/97	4/16/97	***4/16, 4/17, 4/18, 4/21, 4/22***
20	4/18/97	4/29/97	4/24/97	**4/28**

* No consult done

Boldface type indicates treatments given by a third year medical student.
Italicized type indicates treatments given by a nurse with 20 years experience in administering OMT.

of admission meant lost potential OMT treatment time and fewer manipulative treatments provided to those subjects.

The second problem was rooted in the lack of specific OMT frequency and length instructions in the OMT consult note. Since the OMT consults were supposed to be done jointly by the OMT consultant and the OMM resident, allowing the resident to exercise personal judgement as to how long and how often to treat a patient would not normally have been a problem. However, because the resident in charge of performing the OMT treatments did not attend many of the study OMT consults, he was totally reliant on the written consult note. Therefore, specific instructions as to manipulative treatment length and frequency would have provided more structure and direction for the resident.

The most serious problem concerning the OMM resident was a general lack of compliance with the OMT protocol guidelines. This was, in part, the result of inadequate monitoring of the resident's activities to ensure the study protocol was followed. There were also interdepartmental issues between UNTHSC and OMCT that negatively affected the resident's performance in this study. An unfortunate consequence of the resident's behavior was that only 7 (35.00%) of subjects in the OMT group were treated according to the OMT protocol guidelines.

Thirteen (65.00%) subjects were treated suboptimally according to the protocol.

A final problem with the OMT component of this study was the inconsistent documentation of the length of provided OMT treatments. With much of this data missing, it was not possible to compute the average OMT treatment time for each subject in the OMT group. Given all of these difficulties, interpretation of significant findings is limited with respect to OMT.

Analysis of Outcome Variables

From the outset of the study, the two primary outcomes variables targeted for examination were the total FIM score change from admission to discharge and length-of-stay. After examination of the descriptive data from the study, it was decided to include the walking/wheelchair use and stair-climbing FIM score changes as outcome variables since subjects in the OMT group demonstrated statistically significant improvement on these two items compared to the control patients. Multiple linear regression models were performed to examine each of these four outcome variables. For each model, SPSS was programmed to enter all independent variables simultaneously for calculation.

Review of the descriptive data was performed to identify potential independent variables for the regression models. Selection of the independent variables was based on their epidemiologic significance (i.e.- age), their statistical significance determined by means comparison (i.e.- insurance type), or their potential contribution to the model (i.e.- using an outcome variable as an independent variable). Length-of-stay and the total FIM score change were used as both outcome and independent variables. The other independent variables selected for inclusion in every model were: age, insurance type, history of previous admission for hip fracture or hip/knee osteoarthritis, number of comorbid conditions present, and the receipt of OMT. The four regression models are presented below.

Regression Model 1; Outcome Variable = Length-of-Stay

The results of this model are presented in Table 9. Patient age and total FIM score change were both positively associated with length-of-stay at the 95% confidence level. These findings seem reasonable. Older patients may have more comorbid conditions or require a longer inpatient rehabilitation period to recover from surgery than younger patients. Though it was not statistically significant, receiving OMT had an inverse relationship with length-of-stay. Subjects who received OMT had a shorter length-of-

stay in the rehabilitation unit than the control subjects who received no OMT. This finding is underscored by the data in Tables 5 and 6--OMT subjects spent an average of 3.18 fewer days in the rehabilitation unit than the control subjects.

Regression Model 2; Outcome Variable = Total FIM Score Change

Table 10 provides the results of this model. The only statistically significant association here is between length-of-stay and total FIM score change. The more days spent in the rehabilitation unit, the greater the improvement in the overall FIM score. This finding implies that patients who have lower admission FIM scores may have more room for improvement, which is achieved through a longer rehabilitation unit stay. The receipt of OMT was positively associated with the total FIM score change, but was not statistically significant. This finding suggests that patients who receive OMT achieve higher total FIM score changes than patients who do not receive OMT. In this study, total FIM score change was equivalent between the OMT and control groups; however, this finding could have been due to the small sample sizes used in both groups.

Regression Model 3; Outcome Variable = FIM Walking/Wheelchair Use Change

The results of this model are listed in Table 11. A statistically significant inverse association was found between patient age and walking/wheelchair use change. Younger patients are more likely to attain greater improvement on this FIM item than older patients. Receiving OMT was positively associated with increases in walking/wheelchair use ability at the 95% confidence level. This finding is highlighted by the statistically significant difference found between the OMT and control group for this item (see Table 7). Other potential confounders were unable to explain the improvement seen among subjects who received OMT.

Regression Model 4; Outcome Variable = FIM Stair-Climbing Change

Table 12 presents the results for this final regression model. As with model 3, age was negatively associated with the stair-climbing item change, but was not statistically significant in this model. Receiving OMT was positively associated with stair-climbing ability at a statistically significant level.

The striking feature common to each of the four regression models pertains to subjects who received OMT. In each model, receiving OMT was

associated with a positive change, either an improvement in individual FIM items, overall FIM score total, or a shorter length-of-stay in the rehabilitation unit. Though not every association reached statistical significance, the pattern seen in the models appears to indicate that OMT is a beneficial therapy for an inpatient rehabilitation population with musculoskeletal diagnoses. Furthermore, the two FIM items that the OMT subjects achieved more improvement in, walking/wheelchair use and stair-climbing ability, are both elements of the same FIM construct, locomotion.

TABLE 9

Regression Model 1: Outcome Variable = Length-of-Stay

Variable Name	Beta Coefficient	95% Confidence Interval (β)
Age †	.25091	.095772 - .406031
Hx. Previous Admission	-1.477614	-5.100460 - 2.145231
Insurance Type	-1.741186	-5.747924 - 2.265551
No. Comorbid Conds.	.448490	-.122654 - 1.019634
Total FIM Change †	.276834	.114552 - .439117
Receive OMT	-4.329452	-8.771490 - .112586
(Constant)	-9.620902	-23.587774 - 4.345970

R^2 = .42770; † statistically significant association

TABLE 10

Regression Model 2: Outcome Variable = Total FIM Score Change

Variable Name	Beta Coefficient	95% Confidence Interval (β)
Age	-.051265	-.311830 - .209300
Hx. Previous Admission	4.569902	-.888248 - 10.028051
Insurance Type	1.655591	-4.527870 - 7.839051
No. Comorbid Conds.	-.638665	-1.519112 - .241781
Length-of-Stay †	.653547	.270432 - 1.036661
Receive OMT	3.993722	-2.987007 - 10.974452
(Constant)	19.699271	-1.458657 - 40.857199

R^2 = .23675; † statistically significant association

TABLE 11

Regression Model 3: Outcome Variable = FIM Walking/Wheelchair Use Change

Variable Name	Beta Coefficient	95% Confidence Interval (β)
Age †	-.039418	-.078342 - -4.98087E-04
Hx. Previous Admission	-.338609	-1.153973 - .476756
Insurance Type	-.021199	-.944914 - .902515
No. Comorbid Conds.	-.013208	-.144733 - .118317
Length-of-Stay	-.005483	-.062715 - .051748
Receive OMT †	1.667580	.624766 - 2.710395
(Constant)	5.423102	2.262430 - 8.583774

R^2 = .37431; † statistically significant association

TABLE 12

Regression Model 4: Outcome Variable = FIM Stair-Climbing Change

Variable Name	Beta Coefficient	95% Confidence Interval (β)
Age	-.035238	-.087865 - .017389
Hx. Previous Admission	.749786	-.352612 - 1.852183
Insurance Type	-.137114	-1.386004 - 1.111777
No. Comorbid Conds.	.004962	-.172864 - .182788
Length-of-Stay	-.038850	-.116228 - .038529
Receive OMT †	1.434483	.024565 - 2.844400
(Constant)	5.480437	1.207112 - 9.753762

R^2 = .23804; † statistically significant association

CHAPTER 5

DISCUSSION AND STUDY IMPLICATIONS

Limitations of the Study

This study had several limitations that affect interpretation of the results. Each of these limitations is discussed below.

Sample Size

One of the central truths of research is that the larger the sample size, the greater the power of the study. This study utilized 20 subjects in the treatment group and 40 subjects in the control group, yielding a 1:2 case-to- control ratio. Because of the time constraints of the rehabilitation unit staff members at the control hospitals, it was not possible to obtain data on more than 20 patients per unit. However, adequate random sampling strategies were employed by the control hospitals in the selection of subjects. Therefore, the study team was confident that the study population was representative of those individuals who are typically admitted to an inpatient rehabilitation unit with either a hip fracture or hip/knee osteoarthritis.

Probable Underreporting of Comorbid Conditions by Control Hospitals

As discussed in chapter 4, it is likely that the control hospitals did not provide a complete listing of comorbid conditions for every control patient. This introduced reporting bias into the study and affected the 'number of comorbid conditions' component of the regression models. The lack of consistent or statistically significant regression model results for this variable are probably a consequence of this underreporting.

Age Parameters Given to Control Hospitals for Selection of Control Subjects

In chapter 3, it was stated that the control hospitals were asked to select patients admitted to the rehabilitation unit who were at least 60 years of age at the time of admission. The age cut-off point of 60 years was used because this appeared to be the average age of subjects in the OMT group. Four subjects in the OMT group were younger than 60 years. Their ages were: 44, 48, 53, and 54 years. The inclusion of these subjects probably did not introduce any significant selection bias because 1.) the mean age of subjects in the OMT and control group were equivalent, and 2.) these four subjects were not substantially younger than 60.

Lack of Adherence to OMT Protocol Guidelines

This was the most serious problem and source of bias in this study. The combination of inadequate monitoring of the OMM resident's manipulative treatments and personnel difficulties with the resident led to most subjects in the OMT group being treated suboptimally, according to the established OMT protocol guidelines. Several weeks after initiating the study protocol, it was discovered that certain faculty mentors of the OMM resident had significant doubts about the OMT guidelines and, more specifically, about whether OMT would be beneficial to the study patients in the RehabCenter.The resident later admitted that he held the same opinions as his faculty mentors with respect to the effectiveness of OMT in the study population. It is unfortunate that the problems associated with the resident's performance of OMT negatively impacted such a crucial area of the study. Other problems faced by the study team pertaining to the OMT component of this study have already been thoroughly discussed in chapter 3.

Study Conclusions

Although most of the OMT subjects were not provided OMT treatments according to protocol, close examination of Table 8 reveals that most subjects who fell into this category fell short of meeting the protocol only by

one or two treatments. It is also important to remember that the OMT protocol guidelines do not represent the "gold standard" of how OMT should be performed. There is currently no consensus among osteopathic physicians as to how much and what kind of OMT is effective for any type of condition. Despite every OMT subject not receiving OMT according to protocol guidelines, the trend in the data analysis showed a positive association between the receipt of OMT and a beneficial outcome. Based on this finding, we conclude that more consistency in the administration of OMT might have demonstrated a more pronounced treatment effect.

The strength of the conclusion that OMT is a beneficial and effective treatment for this population of patients is grounded in the data presented in Table 7 and in the four regression models. Subjects in the OMT group demonstrated a statistically significant improvement in both items of the FIM locomotion construct (walking/wheelchair use, $p < .001$; stair-climbing, $p = .003$). Additionally, each of the four regression models showed a beneficial association between receipt of OMT and the outcome variable. Receiving OMT was associated with shorter length-of-stay in the rehabilitation unit, an increase in overall FIM score change, and more improvement on the FIM locomotion items. Even though these associations reached statistical significance only in the regression models performed on

the FIM walking/wheelchair use and stair-climbing items, the consistency of direction of the associations in all of these models illustrates a definite pattern.

Study Implications and Future Directions

The principal value of this study is rooted in its design of a ***controlled clinical trial*** of OMT efficacy. Studies employing this design are scarce in the osteopathic literature, so even one study contributes significantly. This paper presents the data for the first 20 subjects of the OMT group enrolled into the study. As discussed, major problems occurred in the implementation of this study and during the first months of data collection. Because of its potential contribution to osteopathic manipulative medicine research, the study team decided to continue the study beyond the original end date of April 25, 1997. Numerous procedural changes have been implemented to correct the problems encountered during the first phase of this study. First, the OMM resident who provided OMT treatments to the first 20 subjects has been replaced by another OMM resident. Second, vigilant monitoring of OMT treatments given by the resident is being performed by the principal investigator to ensure every OMT subject is treated according to protocol guidelines. Third, a reliable system of communication between the

RehabCenter and study personnel has been developed which has significantly shortened the length of time from admission to OMM consult for all potential study subjects. Finally, more frequent periodic review of study subject medical records by the study coordinator has led to more consistent and complete documentation of OMT treatments.

The changes instituted in this study have resulted in much tighter data collection procedures. As the study progresses, we will continue to refine the data collection process to ensure maximum utility of the data is achieved. While more studies are certainly needed to examine further the efficacy of OMT, this study represents a step in the right direction in terms of the type of study that will ultimately provide the greatest benefit to osteopathic manipulative treatment research.

APPENDIX A

Informed Consent Used for Study

INFORMED CONSENT AUTHORIZATION TO PARTICIPATE IN A RESEARCH PROJECT

TITLE: Efficacy of Osteopathic Manipulative Treatment in Improving Clinical Outcomes in Patients With Orthopedic Diagnoses Admitted To a Hospital-Based Rehabilitation Unit.

INSTITUTION: University of North Texas Health Science Center at Ft. Worth

SUBJECT NAME: _____

I. STUDY PURPOSE

The purpose of this research study is to evaluate the effectiveness of osteopathic manipulative treatment (OMT) in improving overall functioning (mobility, ability to dress yourself, ability to control urination, etc.) in patients who are admitted to a hospital rehabilitation unit after they have had a surgical operation for hip fractures or osteoarthritis. A hip fracture is a condition in which one of the areas of the hip joint breaks. This usually occurs as a result of a fall or other accident. Osteoarthritis is a condition in which the cartilage (tissue) between the joints breaks down. This causes excessive wear and strain on these joints and usually produces pain in the affected individual. Osteoarthritis commonly affects the knees and hips. OMT is a form of treatment that is performed by an osteopathic physician to reduce muscle contraction and to restore restricted mobility. We believe that OMT can be effective in improving your functioning and overall outcome and this is what this research study is designed to assess.

II. STUDY PROCEDURES

This clinical research study is being done at the RehabCenter Rehabilitation Unit of the Osteopathic Medical Center of Texas (OMCT) in cooperation with the University of North Texas Health Science Center at Ft. Worth. We will enroll approximately 40 patients. Your participation will begin upon your admission to the RehabCenter and last until you are discharged from the hospital. When you are admitted to the RehabCenter, you will be asked to

read and sign the informed consent. The doctor will ask you about your medical history and will give you a medical examination. The doctor and other members of the medical team at RehabCenter will also evaluate your current functional level by asking you to perform a series of tasks. Your performance on each of these tasks will be given a numerical score and all of the scores will be added together to give a grand total. This total is your initial functional level. This same data will be collected whether you enroll in this study or not.

If you meet all of the criteria for enrollment into the study, you will receive a series of osteopathic manipulative treatments during your stay at the RehabCenter. Early in your stay at the RehabCenter, you will be evaluated by a specialist in osteopathic manipulative medicine who will help design and coordinate an individualized OMT protocol for you. You will receive three to five manipulative treatments each week of your stay and each treatment will be anywhere from 10 to 30 minutes in length. Each treatment you receive will be given to you by a doctor who is trained in OMT. The exact type of treatment you receive and the number and length of the treatments will be determined by the doctor.

You will undergo repeated functional assessments throughout your hospital stay and at your discharge. OMT will be performed only while you are in the hospital. A member of the RehabCenter Treatment Team will contact you by telephone 90 days after your discharge for a follow-up assessment.

III. RISKS AND DISCOMFORTS OF THE STUDY

This is a noninvasive study with minimal risk. You may experience some increased pain during or after the manipulative treatment sessions. Every effort will be made to minimize pain.

IV. CONTACTS

If a study-related problem should occur, or if you have any questions at any time about the study, you may contact Dr. Scott Stoll's office at (817) 377-3422. If you have any questions about your rights as a participant in this study, you may contact Dr. Jerry McGill, Chairman, Institutional Review Board, University of North Texas Health Science Center at Ft. Worth at (817) 735-2561 for more information.

V. BENEFITS

By participating in this study, you will receive OMT after your surgery, which could potentially improve your functional status. If your functional status improves enough, there is a chance that you may be able to be discharged sooner and spend fewer days in the hospital. Finally, you could potentially experience a reduction in the pain associated with your condition by receiving manipulative treatments.

VI. ALTERNATIVE TREATMENTS

All standard treatments, such as medications, physical therapy, and occupational therapy, will be provided to you, regardless of whether or not you participate in the study. OMT is provided in addition to all other care.

VII. CONFIDENTIALITY

Your medical records will be kept as confidential as possible under current local, state, and federal laws. However, representatives of both the RehabCare Group, the company that manages the RehabCenter, and the Osteopathic Medical Center of Texas, as well as the Institutional Review Board and members of the research team may examine your medical records and the study data. In case the final study data should be prepared for publication, your name will not appear in any published material.

VIII. COMPENSATION FOR INJURY

If you are injured by the osteopathic manipulative treatments, and you have followed the directions of the study doctor or other study personnel, there is no compensation available to cover the medical expenses necessary to treat the injury. By signing this form, you have not waived any of the legal rights which you would otherwise have as a participant in a study of osteopathic manipulative therapy. Continuing medical care and/or hospitalization will not be provided free of charge to you. The University of North Texas Health Science Center at Ft. Worth, the Osteopathic Medical Center of Texas, and the RehabCare Group assume no responsibility for your participation in this study.

IX. LEAVING THE STUDY

You can choose not to be in the study or to leave it at any time without penalty or loss of benefits to which you are otherwise entitled. The doctor may take you out of the study for reasons of, but not limited to: (a) discovery of a contraindication for OMT, (b) occurrence of a serious side effect, or a severe worsening of the condition.

X. CONSENT

I voluntarily agree to participate in this study. I have had the chance to ask the doctor any questions I have regarding the study.

I HAVE RECEIVED A COPY OF THIS SIGNED INFORMED CONSENT AGREEMENT.

_____ _____

Signature of Subject or Legal Representative Date

_____

Relationship to Subject if Legal Representative

_____ _____

Signature of Investigator Date

_____ _____

Signature of Witness (Optional) Date

_____

Name of Witness (Print Name)

APPENDIX B

OMT Treatment Log

OSTEOPATHIC MEDICAL CENTER OF TEXAS

OSTEOPATHIC MANIPULATIVE TREATMENT LOG

DIAGNOSIS: _____

Date: Start:	Subjective & Objective Findings	Areas Treated & Techniques Used	Treater's Initials

References

Arthritis Foundation. (1996). Osteoarthritis [Brochure]. Atlanta, GA: Author.

Avioli, L.V. (1991). Significance of osteoporosis: a growing international health care problem. Calcified Tissue International, 49 (Suppl.), S5-7.

Boesler, D., Warner, M., Alpers, A., Finnerty, E.P., & Kilmore, M.A. (1993). Efficacy of high-velocity-low-amplitude manipulative technique in subjects with low-back pain during menstrual cramping. Journal of the American Osteopathic Association, 93, 203-214.

Dodds, T.A., Martin, D.P., Stolov, W.C., & Deyo, R.A. (1993). A validation of the functional independence measure and its performance among rehabilitation inpatients. Archives of Physical Medicine and Rehabilitation, 74, 531-536.

Ellestad, S.M., Nagle, R.V., Boesler, D.R., & Kilmore, M.A. (1988). Electromyographic and skin resistance responses to osteopathic manipulative treatment for low-back pain. Journal of the American Osteopathic Association, 88, 991-997.

Granger, C.V., & Brownscheidle, C.M. (1995). Outcome measurement in medical rehabilitation. International Journal of Technology Assessment in Health Care, 11, 262-268.

Gullberg, B., Duppe, H., & Nilsson, B. (1993). Incidence of hip fractures in Malmo, Sweden (1950-1991). Bone, 14 (Suppl. 1), S23-29.

Hamilton, B.B., Granger, C.V., Sherwin, F.S., Zielezny, M., & Tashman, J.S. (1987). A uniform national data system for medical rehabilitation. In M.J. Fuhrer (Ed.), Rehabilitation outcomes: Analysis and measurement (pp. 137-147). Baltimore, MD: Brookes.

Hamilton, B.B., Laughlin, J.A., Fielder, R.C., & Granger, C.V. (1994). Interrater reliability of the 7-level functional independence measure. Scandanavian Journal of Rehabilitation Medicine, 26, 115-119.

Kramer, A.M., Steiner, J.F., Schlenker, R.E., Eilertsen, T.B., Hrincevich, C.A., Tropea, D.A., Ahmad, L.A., & Eckhoff, D.G. (1997). Outcomes and costs after hip fracture and stroke: a comparison of rehabilitation settings. Journal of the American Medical Association, 277, 396-404.

Kuchera, W.A., & Kuchera, M.L. (1991). Osteopathic principles in practice. (2nd ed.). Kirksville, MO: KCOM.

McDowell, I., & Newell, C. (1996). Measuring health: A guide to rating scales and questionnaires. (2nd ed.). New York: Oxford.

McInnes, J., Larson, M.G., Daltroy, L.H., Brown, T., Fossel, A.H., Eaton, H.M., Kirwan, B., Steindorf, S., Poss, R., & Liang, M.H. (1992). A controlled evaluation of continuous passive motion in patients undergoing total knee arthroplasty. Journal of the American Medical Association, 268, 1423-1428.

Oleske, D.M. (1995). Measurement issues in the use of epidemiologic data. In D.M. Oleske (Ed.), Epidemiology and the delivery of health care services: Methods and applications (2nd ed.). (pp. 21-32). New York: Plenum.

World Health Organization. (1980). International classification of impairments, disabilities, and handicaps. Geneva: Author.

Zuckerman, J.D. (1996). Hip fracture. New England Journal of Medicine, 334, 1519-1525.